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): March 4, 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.)

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 March 4, 2013, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing top-line data show primary endpoint achieved in pivotal phase 3 study of Sufentanil NanoTab PCA System for post-operative pain in major open abdominal surgery patients. 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 March 4, 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: March 6, 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 March 4, 2013

Exhibit 99.1

FOR IMMEDIATE RELEASE

AcelRx Top-line Data Show Primary Endpoint Achieved in Pivotal Phase 3 Study of Sufentanil NanoTab PCA System For Post-Operative Pain in Major Open Abdominal Surgery Patients

- Patients experienced significantly greater reduction in pain as measured by SPID-48 vs. placebo (p=0.001) -

- Adverse events in sufentanil-treated patients similar to placebo -

- AcelRx to conduct conference call and webcast tomorrow, March 5, at 8:30 a.m. EST (5:30 a.m. PST) to discuss top-line results –

REDWOOD CITY, Calif., March 4, 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 top-line data results demonstrating that the first of two pivotal placebo-controlled Phase 3 studies for its investigational sublingual Sufentanil NanoTab PCA (patient-controlled analgesia) System met its primary endpoint. Adverse events reported in the study were generally mild or moderate in nature and similar in both placebo and treatment groups.

The primary endpoint evaluated pain intensity over the 48-hour study period compared to baseline, or Summed Pain Intensity Difference (SPID-48), in patients following major open abdominal surgery. Results demonstrated that patients receiving sufentanil NanoTabs realized a significantly greater SPID-48 during the study period than placebo-treated patients (p=0.001). Secondary endpoint data also showed that 24 hours and 72 hours after first dose, SPID was significantly greater in the sufentanil-treated patients than in the placebo-treated patients ($p<0.001$ and p=0.004 respectively).

“These favorable results enable AcelRx to continue moving forward towards submission of a New Drug Application (NDA) for the Sufentanil NanoTab PCA System in the third quarter of this year,” said Richard King, president and CEO of AcelRx. “In the weeks ahead, our team will work with the FDA to complete a pre-NDA meeting in support of this goal.”

Phase 3 Study Results

Utilizing a randomized, double-blind, placebo-controlled design, this pivotal Phase 3 study enrolled 178 adult patients at 13 U.S. sites for the treatment of acute post-operative pain immediately following major abdominal surgery. Patients were treated for post-operative pain for a minimum of 48 hours, and up to 72 hours. Patients were randomized 2:1, with 119 patients randomized to sufentanil and 59 to placebo treatment. Both treatments were delivered by the patient, as needed, using the NanoTab System with a 20-minute lock-out period. Patients in both groups could receive up to 2 mg morphine intravenously per hour as a rescue medication, the primary purpose of this rescue medication being to provide placebo-treated patients access to pain medication to enable them to stay in the study as long as possible. Pre-rescue pain scores were imputed to minimize the impact of this rescue opioid on efficacy evaluations.

Eighty, or 70.2% of the sufentanil NanoTab-treated patients completed the 48-hour study period, compared to 30 (51.7%) placebo-treated patients. Reasons for drop-out in the sufentanil- and placebo-treated groups were adverse events (5.3% and 6.9% respectively), lack of efficacy (16.7% and 31.0% respectively) and other (7.9% and 10.3% respectively). The primary endpoint measure, SPID-48, was 105.6 for sufentanil-treated patients and 55.6 for placebo-treated patients (p=0.001).

Treatment-emergent adverse events occurred in 64.0% of sufentanil-treated patients and 67.2% of placebo-treated patients. Adverse events with an occurrence greater than 5% in either the sufentanil group or the placebo group were nausea (30.7% and 41.4% respectively), fever (14.9% and 8.6% respectively), vomiting (8.8% and 6.9% respectively), itching (8.8% and 0.0% respectively), oxygen saturation decrease (6.1% and 1.7% respectively), and hypertension (2.6% and 5.2% respectively). Itching, a frequently observed side effect of opioids, was the only adverse event that was significantly different between the groups (p=0.017). All reported cases of itching in the study were mild in nature. Only one patient (in the sufentanil group) experienced a serious adverse event, which was determined to be unrelated to the study drug by the investigator.

“These efficacy and safety results underscore the impact of the Sufentanil NanoTab PCA System by potentially providing medical professionals a non-invasive method to help relieve moderate-to-severe post-operative pain in patients undergoing major surgical procedures, such as open abdominal surgery,” commented Pamela Palmer M.D., Ph.D., chief medical officer and AcelRx co-founder. “We look forward to completing the full analysis of these data and working with the FDA on the NDA for this important post-operative pain advancement.”

“The positive results to date for this, non-invasive approach for the management of moderate-to-severe post-operative pain are intriguing and I look forward to the complete study results for the entirety of this Phase 3 program,” stated study investigator Dr. Tong-Joo Gan, Vice-Chair of the Department of Anesthesiology at Duke University School of Medicine, Durham, N.C.

One additional pivotal Phase 3 double-blind, placebo-controlled study of the Sufentanil NanoTab PCA System is underway. The study began in August 2012, and is designed to enroll approximately 400 patients in a 3:1 randomization following hip or knee replacement surgery at up to 35 sites. The primary endpoint, SPID-48, is identical to the primary endpoint for the abdominal surgery trial. We expect top-line results for this trial to be available in the second quarter of 2013. Additional information can be found by visiting www.ClinicalTrials.gov and using the identifier NCT01660763.

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 U.S. and EU, with an additional 27 million procedures occurring in countries with moderate to high per capita healthcare expenditures. The U.S., 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 the Sufentanil NanoTab PCA System

The NanoTab System 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 NanoTab System is designed to address the limitations of IV PCA by offering:

- A high therapeutic index opioid: The NanoTab System 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 of analgesia: The sublingual route of delivery used by the NanoTab System provides rapid onset of analgesia, therefore eliminating the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections, associated with IV PCA delivery. In addition, because patients are not tethered to IV tubing and a pump for pain relief, the NanoTab System allows for ease of patient mobility.
- A simple, pre-programmed PCA solution: The NanoTab System is pre-programmed, and thereby eliminates the risk of pump programming errors by healthcare providers.

Conference Call

AcelRx will conduct a conference call and webcast tomorrow morning, March 5, 2013, at 8:30 a.m. Eastern time (5:30 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.

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, 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. ARX-01 has successfully completed two of its three planned Phase 3 clinical trials and a New Drug Application submission is planned for the third quarter of 2013. AcelRx recently completed enrollment in a Phase 2 study for ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from U.S. Army Medical Research and Materiel Command, and top-line results are expected in the second quarter of 2013. 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 process and timing of anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the release of sufentanil NanoTab PCA System top-line clinical trial data, the release and anticipated timing of additional NanoTab System clinical trial data, the potential submission of an NDA for NanoTab System and the timing thereof, therapeutic and commercial potential of NanoTab System 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 the sufentanil NanoTab System, that fact that subsequent analyses of the top-line data 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 and maintain 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 registration 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 Current Report on Form 8-K filed with the SEC on December 7, 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.

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