

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): May 8, 2012**

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**ACELRX PHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**

**DELAWARE**  
**(State of incorporation)**

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**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**

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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))

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**ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.**

On May 8, 2012, AcelRx Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2012. A copy of the press release is furnished as Exhibit 99.1 to this report.

The information in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this current report shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this current report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.****(d) Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release dated May 8, 2012.

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**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: May 8, 2012

ACELRX PHARMACEUTICALS, INC.

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

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**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release dated May 8, 2012.



FOR IMMEDIATE RELEASE

### **AcelRx Pharmaceuticals Reports First Quarter 2012 Financial Results**

REDWOOD CITY, Calif., May 8, 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 financial results for the first quarter ended March 31, 2012.

Net loss for the first quarter of 2012 was \$7.1 million, or \$0.36 per share, compared with a net loss of \$3.2 million, or \$0.30 per share, for the first quarter of 2011. Common shares used in calculating basic and diluted earnings per share were 19,607,483 for the first quarter of 2012 compared to 10,742,182 common shares for the first quarter of 2011.

During the first quarter of 2012, AcelRx recognized revenue of \$329,000 resulting from reimbursement for work completed under a research grant from the US Army Medical Research and Material Command, or USAMRMC, for development of its ARX-04 product candidate, a Sufentanil NanoTab<sup>®</sup> for the treatment of moderate-to-severe acute pain.

Research and development expenses for the quarter ended March 31, 2012 totaled \$4.8 million, compared with \$1.9 million for the quarter ended March 31, 2011. The increase was primarily due to development expenses for ARX-01, the Sufentanil NanoTab PCA System, AcelRx’s lead product candidate for the treatment of post-operative pain. During the first quarter, AcelRx prepared for and initiated the first of three planned Phase 3 clinical trials, a randomized, double-blind, placebo-controlled efficacy and safety trial in adults with post-operative pain, following open-abdominal surgery. In April 2012, AcelRx initiated the second ARX-01 Phase 3 study, a randomized, open-label, parallel-group comparison of 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 in adults immediately following major abdominal or orthopedic surgery.

General and administrative expenses were \$2.1 million for the quarter ended March 31, 2012, compared with \$1.6 million for the quarter ended March 31, 2011. This increase resulted primarily from expenses associated with market research and patent prosecution efforts as well as personnel related expenses, including stock-based compensation, and expenses associated with being a public company.

As of March 31, 2012, AcelRx had cash, cash equivalents and investments of \$27.6 million, compared to \$35.8 million at December 31, 2011.

“With two of our three planned Phase 3 clinical studies actively enrolling, and with the initiation of the third Phase 3 clinical study planned for the third quarter of 2012, we are looking forward to seeing top-line data from all three Phase 3 clinical trials by late 2012 or early 2013,” said Richard King, President and CEO of AcelRx. Mr. King added, “Based on our dialog with FDA, data from these studies should support an NDA filing, expected in the middle of 2013.”

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## Development Update

- In March 2012, AcetRx initiated the first of three planned Phase 3 clinical trials, a double-blind, placebo-controlled efficacy and safety trial of adult patients with post-operative pain following open-abdominal surgery. We expect top-line data for this trial in the second half of 2012.
- In April 2012, AcetRx initiated a second Phase 3 clinical trial, an open-label active-comparator study comparing ARX-01 to the current standard of care, IV PCA with morphine, in patients with post-operative pain following open-abdominal surgery or major orthopedic surgery. We expect top-line data for this trial in the second half of 2012.
- In the third quarter of 2012, AcetRx plans to initiate our third planned Phase 3 clinical trial, a double-blind, placebo-controlled efficacy and safety study of patients with post-operative pain following hip and knee replacement surgeries, with top-line data expected in late 2012 or early 2013.

## Financial Outlook

AcetRx anticipates that research and development expenses for the remainder of 2012 and into 2013 will increase significantly as AcetRx seeks to execute and complete the Phase 3 clinical development program of ARX-01. Development of ARX-04 through Phase 2 clinical work and Phase 3 preparatory work is fully funded by a grant from USAMRMC. The development of ARX-04 beyond Phase 2 and initial preparations for Phase 3 is dependent on identification of sources of additional funding. Additionally, AcetRx anticipates modest increases in general and administrative expenses due to costs associated with operating as a public company and expansion of its corporate infrastructure to support ongoing development of its product candidates.

AcetRx believes its current cash, cash equivalents and investments are sufficient to fund operations into the first quarter of 2013.

## About AcetRx Pharmaceuticals, Inc.

Based in Redwood City, CA, AcetRx 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. AcetRx'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. AcetRx 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. A fourth product candidate, ARX-04, is a sufentanil product for the treatment of moderate-to-severe acute pain, and AcetRx plans to initiate a Phase 2 study funded by a grant from USAMRMC, contingent on approval of the proposed clinical protocol for the study by USAMRMC.

## Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to AcetRx Pharmaceuticals' financial viability, anticipated increases in research and development and general and administrative expenses, the sufficiency of funds to support its clinical trials and operations, planned or anticipated future clinical development of AcetRx Pharmaceuticals' product candidates, including the anticipated timing for clinical trials, progress

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towards initiation of the remaining Phase 3 study for ARX-01 and the Phase 2 study for ARX-04, 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; AcelRx Pharmaceuticals' ability to repay a portion of the principal under the loan and security agreement with Hercules with common stock; 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 and the Quarterly Report on Form 10-Q for the three months ended March 31, 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.

**Contact:**

Jim Welch  
Chief Financial Officer  
650.216.3511  
jwelch@acelrx.com

**SELECTED FINANCIAL DATA**  
(in thousands, except per share data)  
(unaudited)

	Three Months Ended March 31,	
	2012	2011
<b>Statement of Operations Data</b>		
Research grant revenue	\$ 329	\$ —
Operating expenses:		
Research and development <sup>(1)</sup>	4,771	1,946
General and administrative <sup>(1)</sup>	2,104	1,589
Total operating expenses	<u>6,875</u>	<u>3,535</u>
Loss from operations	(6,546)	(3,535)
Interest expense	(594)	(1,359)
Interest income and Other income (expense), net	75	1,690
Net loss	<u>\$ (7,065)</u>	<u>\$ (3,204)</u>
Basic and diluted net loss per common share	<u>\$ (0.36)</u>	<u>\$ (0.30)</u>
Shares used in computing basic and diluted net loss per common share	<u>19,607</u>	<u>10,742</u>

(1) Includes the following noncash, stock-based compensation expense:

Research and development	\$251	\$120
General and administrative	<u>291</u>	<u>203</u>
Total non-cash, stock-based expense	<u>\$ 542</u>	<u>\$ 323</u>

	<u>March 31, 2012</u>	<u>December 31, 2011</u>
<b>Selected Balance Sheet Data</b>		
Cash, cash equivalents and investments	\$ 27,571	\$ 35,785
Total assets	33,990	40,835
Total liabilities	22,959	23,367
Total stockholders' equity	11,031	17,468