# 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 9, 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

k 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 isions (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 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On August 9, 2012, AcelRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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.

Exhibit Number Description

99.1 Press Release dated August 9, 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: August 13, 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 August 9, 2012.



#### FOR IMMEDIATE RELEASE

#### AcelRx Pharmaceuticals Reports Second Quarter 2012 Financial Results

REDWOOD CITY, Calif., August 9, 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 three and six months ended June 30, 2012 and provided a development update.

Net loss for the second quarter of 2012 was \$7.2 million, or \$0.35 per share, compared with a net loss of \$4.8 million, or \$0.25 per share, for the second quarter of 2011. Common shares used in calculating basic and diluted earnings per share were 20,627,244 for the second quarter of 2012 compared to 19,374,909 common shares for the second quarter of 2011.

During the second quarter of 2012, AcelRx recognized revenue of \$224,000 resulting from reimbursement for work completed under a research grant from the U.S. Army Medical Research and Material Command, or USAMRMC, for development of its ARX-04 product candidate, a Sufentanil NanoTab ® for the treatment of moderate-to-severe acute pain.

Research and development expenses for the quarter ended June 30, 2012 totaled \$5.4 million, compared with \$3.0 million for the quarter ended June 30, 2011. The increase was primarily due to expenditures required to conduct two Phase 3 studies for ARX-01, the Sufentanil NanoTab PCA System, AcelRx's lead product candidate for the treatment of post-operative pain.

General and administrative expenses were \$1.8 million for the quarter ended June 30, 2012, compared with \$1.6 million for the quarter ended June 30, 2011. The increase of \$0.2 million resulted primarily from expenses associated with commercial market research and patent prosecution efforts.

For the six months ended June 30, 2012, AcelRx reported a net loss of \$14.3 million, or \$0.71 per share, compared with a net loss of \$8.0 million, or \$0.53 per share for the same period in 2011. Common shares used in calculating basic and diluted earnings per share were 20,114,608 for the six months ended June 30, 2012 compared to 15,058,546 common shares for the same period in the prior year.

As of June 30, 2012, AceIRx had cash, cash equivalents and investments of \$31.9 million, compared to \$27.7 million at March 31, 2012 and \$35.8 million at December 31, 2011.

"AcelRx continues to successfully execute its product development plans. We have initiated and are actively enrolling in two ARX-01 Phase 3 clinical trials, which are expected to report top-line data in the fourth quarter of 2012. We also expect to initiate our third Phase 3 study in the third quarter. We strengthened our intellectual property position with the recent issuance of three U.S. patents associated with our sufentanil NanoTabs, offering protection out to 2030," noted Richard King, President and CEO of AcelRx. "In June, we completed a \$10.0 million financing extending our cash horizon into the second quarter of 2013."

## **Development Update**

- In March 2012, AcelRx initiated the first of three planned Phase 3 clinical trials for ARX-01, a double-blind, placebo-controlled efficacy and safety trial of adult patients with post-operative pain following open-abdominal surgery. Patient recruitment for this study is ongoing and we expect top-line data for this study in the fourth quarter of 2012.
- In April 2012, AcelRx 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. Patient recruitment for this study is also ongoing, and we expect top-line data in the fourth quarter of 2012.
- In the third quarter, AcelRx 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 the first quarter of 2013.

#### Financial Outlook

AceIRx anticipates that research and development expenses for the remaining two quarters of 2012 and into 2013 will increase as AceIRx seeks to execute and complete three Phase 3 clinical trials with ARX-01. Development of ARX-04 through Phase 2 clinical work and Phase 3 preparatory work is expected to be funded by a grant from USAMRMC, contingent on approval of the proposed clinical protocol for the study by USAMRMC. The development of ARX-04 beyond Phase 2 and initial preparations for Phase 3 is dependent on the identification of sources of additional funding. Additionally, AceIRx 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.

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

#### **Conference Call**

AceIRx will conduct a conference call and webcast today, August 9, at 4:30 p.m. ET/1:30 p.m. PT, to discuss the company's financial results and development programs. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (800) 860-2442, 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 Investors section of the company's website at www.aceIrx.com.

A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investors section of the company's website at <a href="https://www.acelrx.com">www.acelrx.com</a>.

#### **Upcoming Corporate Presentations**

AcelRx is scheduled to present at the upcoming investor conference:

• Canaccord Genuity 32 nd Annual Growth Conference in Boston on August 15, 2012 at 8:00 a.m. ET/5:00 a.m. PT. Richard King, president and CEO of AcelRx Pharmaceuticals, will provide a corporate overview.

The presentation will be webcast through the "Investors" section of AcelRx's corporate website at <a href="www.acelrx.com">www.acelrx.com</a>, and a recording will be made available for 90 days following the event. To access the live webcast, please log on to the AcelRx website approximately fifteen minutes prior to the presentation to register and download any necessary audio software.

#### About AcelRx Pharmaceuticals, Inc.

AceIRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain. AceIRx'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. A fourth product candidate, ARX-04, is a sufentanil product for the treatment of moderate-to-severe acute pain, and AcelRx 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. For additional information about AcelRx's clinical programs please visit <a href="https://www.acelrx.com">www.acelrx.com</a>.

#### **Forward Looking Statements**

This press release contains forward-looking statements, including, but not limited to, statements related to AcelRx 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 AcelRx Pharmaceuticals' product candidates, including the anticipated timing for clinical trials, progress towards initiation of the remaining Phase 3 study for ARX-01 and the Phase 2 study for ARX-04, receipt of approval of ARX-04 Phase 2 clinical protocol from USAMRMC, strength of AcelRx Pharmaceuticals' intellectual property portfolio, 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; its ability to protect its intellectual property portfolio; 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 June 30.		Six Months Ended June 30.	
	2012	2011	2012	2011
Statement of Operations Data				
Research grant revenue	\$ 224	\$ 40	\$ 553	\$ 40
Operating expenses:				
Research and development (1)	5,394	3,029	10,165	4,975
General and administrative (1)	1,776	1,630	3,880	3,220
Total operating expenses	7,170	4,659	14,045	8,195
Loss from operations	(6,946)	(4,619)	(13,492)	(8,155)
Interest expense	(598)	(156)	(1,192)	(1,514)
Interest income and Other income (expense), net	350	12	425	1,702
Net loss	\$ (7,194)	\$ (4,763)	\$(14,259)	\$ (7,967)
Basic and diluted net loss per common share	\$ (0.35)	\$ (0.25)	\$ (0.71)	\$ (0.53)
Shares used in computing basic and diluted net loss per common share	20,627	19,375	20,115	15,059
(1) Includes the following non-cash, stock-based compensation expense:				
Research and development	\$ 254	\$ 204	\$ 505	\$ 325
General and administrative	276	262	566	464
Total non-cash, stock-based expense	\$ 530	\$ 466	\$ 1,071	\$ 789
	June 30, 2012	Decen	nber 31, 2011	
Selected Balance Sheet Data				
Cash, cash equivalents and investments	\$ 31,933	\$	35,785	
Total assets	36,644		40,835	
Total liabilities	29,016		23,367	
Total stockholders' equity	7,628		17,468	