

**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): November 6, 2012**

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**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**

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 November 6, 2012, AcetRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 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.**

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release dated November 6, 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: November 6, 2012

ACELRX PHARMACEUTICALS, INC.

By: /s/ James H. Welch

James H. Welch  
Chief Financial Officer

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## INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release dated November 6, 2012.



FOR IMMEDIATE RELEASE

### AcelRx Pharmaceuticals Reports Third Quarter 2012 Financial Results

REDWOOD CITY, Calif., November 6, 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 reported financial results for the three and nine months ended September 30, 2012 and provided a corporate update.

Net loss for the third quarter of 2012 was \$8.6 million, or \$0.38 per share, compared with a net loss of \$5.8 million, or \$0.30 per share, for the third quarter of 2011. During the third quarter of 2012, AcelRx recognized revenue of \$166,000 resulting from reimbursement for work completed under a research grant from the U.S. Army Medical Research and Materiel Command, or USAMRMC, for development of its ARX-04 product candidate, a single dose Sufentanil NanoTab® for the treatment of moderate-to-severe acute pain.

Research and development expenses for the third quarter totaled \$6.9 million, compared with \$3.9 million for the quarter ended September 30, 2011. The increase was primarily due to expenditures associated with three ongoing 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 \$1.4 million for the quarter ended September 30, 2012, compared with \$1.9 million for the third quarter of 2011. This decrease resulted primarily from lower intellectual property and market research expenses.

For the nine months ended September 30, 2012, AcelRx reported a net loss of \$22.8 million, or \$1.09 per share, compared with a net loss of \$13.7 million, or \$0.83 per share, for the same period in 2011. As of September 30, 2012, AcelRx had cash, cash equivalents and investments of \$23.4 million, compared to \$31.9 million at June 30, 2012 and \$35.8 million at December 31, 2011.

“We continue to make progress in the execution of our Phase 3 program for ARX-01. During the third quarter, we initiated our third Phase 3 clinical trial, received four additional U.S. patents related to our sufentanil NanoTab technology and we were notified that ARX-01 was deemed sufficiently novel that we would be allowed to use the centralized filing procedure for ARX-01 in Europe,” stated Richard King, president and CEO of AcelRx. “In addition, we completed treatment of the final subject in our Phase 3 clinical trial comparing ARX-01 to IV PCA with morphine. We expect to announce top line data from this first trial later this month and results from our two other ARX-01 trials is expected in the first quarter of 2013.”

#### Review of Third Quarter Accomplishments and Corporate Update

- In August 2012, AcelRx initiated the third of three planned Phase 3 clinical trials for ARX-01, a double-blind, placebo-controlled efficacy and safety trial in adult patients with post-operative pain following hip or knee replacement surgery. This study is designed to enroll approximately 400 patients and is being conducted at approximately 45 academic and community hospitals in the U.S. The primary endpoint is the sum of the pain intensity difference to baseline, over the 48 hour study period, or SPID-48, which is the FDA standard for post-operative acute pain studies.
- Dosing of the last patient in the Phase 3 open label, active comparator study comparing efficacy and safety of the Sufentanil NanoTab System to the commonly used IV PCA with morphine is complete, and top line data are expected in November, 2012. Top line results from the two placebo-controlled Phase 3 clinical studies, one treating post-operative pain in patients following abdominal surgery and the other treating post-operative pain in patients following hip or knee replacement, are both expected during the first quarter of 2013.
- During the third quarter, the U.S. Patent and Trademark Office issued four additional patents covering AcelRx's proprietary NanoTab technology. AcelRx has now received a total of five U.S. patents underpinning its four product development programs and proprietary NanoTab technology.
- The European Medicines Agency, or EMA, notified AcelRx that it will permit registration of the Sufentanil NanoTab PCA System via the centralized procedure. This procedure will allow AcelRx to submit a single Marketing Authorization Application to the EMA for approval to market ARX-01 in all 27 EU member states, as well as in the 4 European Free Trade Association countries.
- In early November 2012, AcelRx dosed the first patient in a Phase 2 study for ARX-04, its single dose sufentanil NanoTab product candidate for the management of acute pain. The study is funded by a grant from the USAMRMC and will enroll approximately 100 patients following bunionectomy surgery, randomizing them into one of three groups to receive one of two sufentanil NanoTab dosage amounts (20 mcg and 30 mcg) or placebo.

#### Financial Outlook

AcelRx anticipates that research and development expenses for the fourth quarter of 2012 and the first half of 2013 will increase as AcelRx conducts and completes the Phase 3 clinical trials for ARX-01. Development of ARX-04 through Phase 2 clinical work and Phase 3 preparatory work is expected to be fully funded by a grant from USAMRMC. The development of ARX-04 beyond Phase 2 and initial preparations for Phase 3 is dependent on the identification of additional funding from USAMRMC or other sources. Additionally, AcelRx anticipates modest increases in general and administrative expenses due to costs associated with expansion of its corporate infrastructure to support ongoing development of its product candidates.

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## Conference Call

AcelRx will conduct a conference call and webcast today, November 6, at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) to discuss its financial results and program updates. 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.acerlx.com](http://www.acerlx.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.acerlx.com](http://www.acerlx.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 currently in Phase 3 clinical development and is designed to solve problems associated with post-operative intravenous patient-controlled analgesia, including side effects of morphine, 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 that 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 USAMRMC. For additional information about AcelRx's clinical programs please visit [www.acerlx.com](http://www.acerlx.com).

## 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, timing of interim and final results of its clinical trials, planned or 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 anticipated timing for remaining clinical trials, 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: AcelRx ability to raise additional funds to support its clinical trials and operations; the success, cost and timing of AcelRx Pharmaceuticals' product development activities and clinical trials, including timing, release and implications of interim or final results of the ARX-01 Phase 3 clinical trials; the uncertain clinical development process, including the risk that planned clinical trials may not 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; 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; sufficiency of its intellectual property portfolio; 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.

## Contact:

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
<b>Statement of Comprehensive Loss Data</b>				
Research grant revenue	\$ 166	\$ 408	\$ 719	\$ 448
Operating expenses:				
Research and development <sup>(1)</sup>	6,948	3,947	17,113	8,922
General and administrative <sup>(1)</sup>	1,410	1,866	5,290	5,086
Total operating expenses	<u>8,358</u>	<u>5,813</u>	<u>22,403</u>	<u>14,008</u>
Loss from operations	(8,192)	(5,405)	(21,684)	(13,560)
Interest expense	(573)	(377)	(1,765)	(1,891)
Interest income and Other income (expense), net	183	21	608	1,722
Net loss	<u>\$ (8,582)</u>	<u>\$ (5,761)</u>	<u>\$ (22,841)</u>	<u>\$ (13,729)</u>
Basic and diluted net loss per common share	<u>\$ (0.38)</u>	<u>\$ (0.30)</u>	<u>\$ (1.09)</u>	<u>\$ (0.83)</u>
Shares used in computing basic and diluted net loss per common share	<u>22,633</u>	<u>19,459</u>	<u>20,962</u>	<u>16,594</u>

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

Research and development	\$ 258	\$ 253	\$ 762	\$ 578
General and administrative	304	304	871	768
Total non-cash, stock-based expense	<u>\$ 562</u>	<u>\$ 557</u>	<u>\$ 1,633</u>	<u>\$ 1,346</u>

**Selected Balance Sheet Data**

	September 30, 2012	December 31, 2011
Cash, cash equivalents and investments	\$ 23,375	\$ 35,785
Total assets	28,151	40,835
Total liabilities	28,478	23,367
Total stockholders' equity (deficit)	(327)	17,468