

**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 8, 2011

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.)

575 Chesapeake 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 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On November 8, 2011, AcelRx Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2011. A copy of the press release is furnished as Exhibit 99.1 to this current 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 November 8, 2011.

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 8, 2011

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 8, 2011.



FOR IMMEDIATE RELEASE

AcelRx Pharmaceuticals Reports Third Quarter 2011 Financial Results

REDWOOD CITY, Calif., November 8, 2011—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, reported financial results today for the third quarter and nine months ended September 30, 2011.

Net loss for the third quarter of 2011 was \$5.8 million, or \$0.30 per share, compared with a net loss of \$3.6 million, or \$5.38 per share, for the third quarter of 2010. Common shares used in calculating basic and diluted earnings per share were 19,459,000 in the third quarter of 2011 compared to 669,000 common shares in the third quarter of 2010.

During the third quarter of 2011, AcelRx recognized revenue of \$408,000 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. Research and development expenses for the three months ended September 30, 2011 totaled \$3.9 million, compared with \$1.5 million for the three months ended September 30, 2010. The increase was primarily due to development expenses for ARX-01 as AcelRx prepared for planned Phase 3 trials. General and administrative expenses were \$1.9 million for the quarter ended September 30, 2011, compared with \$1.1 million for the quarter ended September 30, 2010. The increase results primarily from expenses associated with operation as a public company.

For the nine months ended September 30, 2011, AcelRx reported a net loss of \$13.7 million, or \$0.83 per share, compared with a net loss of \$10.8 million, or \$16.63 per share for the same period in 2010. Common shares used in calculating basic and diluted earnings per share were 16,594,000 for the nine months ended September 30, 2011 compared to 651,000 common shares for the same period in the prior year.

As of September 30, 2011, AcelRx had cash, cash equivalents and investments of \$32.0 million, compared with \$37.8 million as of June 30, 2011 and \$3.7 million as of December 31, 2010. In February 2011, AcelRx completed its initial public offering, resulting in net proceeds to AcelRx of \$34.9 million. In June 2011, AcelRx entered into a \$20.0 million secured loan agreement with Hercules Technology Growth Capital, or Hercules. Upon execution of the agreement, AcelRx received \$10.0 million in the first tranche of the loan, \$2.8M of which was used to pay down existing debt.

“During the third quarter of 2011, we continued to move towards initiation of our Phase 3 studies for ARX-01, our lead product candidate for acute post-operative pain, and also towards initiation of a Phase 2 study for ARX-04, our product candidate for moderate-to-severe acute pain” said Richard King, President and CEO of AcelRx. “We have made progress on the ARX-01 device related activities that must be completed prior to initiation of Phase 3 clinical studies. We anticipate feedback from FDA on the submitted software verification and validation protocols, and a device reprocessing protocol, and currently expect that we will be in a position to dose the first patient in the Phase 3 clinical program in late 2011 or early 2012, with an expectation to complete all Phase 3 clinical studies by the end of 2012,” said Mr. King.

Development Updates

- The contract research organization, or CRO, PharmaNet, has been engaged to conduct the first two ARX-01 Phase 3 studies. Clinical sites have been engaged for the abdominal surgery study and a majority of the sites for the head-to-head comparator study have been identified.
- We recently received correspondence from the FDA stating that a final planned Human Factor study, though required for final product approval, is not a prerequisite to initiating ARX-01 Phase 3 studies. There are, however, three additional device assessments focused on software verification, software validation and device reprocessing, originally planned as precursors to, or associated with, the final Human Factor Study, which remain as requirements from FDA prior to the start of Phase 3. Protocols for these assessments have been submitted to the FDA for review, and we await the agency's feedback. We plan to conduct the software verification and validation and device reprocessing studies prior to initiation of the Phase 3 clinical program. We currently expect that we will be in a position to dose the first patient in a Phase 3 placebo-controlled post-operative pain study following major abdominal surgery in late 2011 or early 2012. The remaining Phase 3 studies, an active comparator study comparing the sufentanil NanoTab PCA System to intravenous morphine patient-controlled analgesia in post-operative patients, and a placebo-controlled study in patients after major orthopedic surgery, are expected to be initiated and completed in 2012. We plan to complete the final Human Factor study alongside the Phase 3 clinical program.
- The NanoTab commercial manufacturing facility at AcelRx's contract manufacturer, Patheon, Inc., has been built, tested and qualified as a Good Manufacturing Practices, or GMP, facility. AcelRx will manufacture clinical and commercial supplies at this facility.
- In early October 2011, AcelRx filed an Investigational New Drug application for ARX-04, its product candidate for management of moderate-to-severe acute pain, with the FDA, and plans to initiate the Phase 2 study later this year with top line results available in the first half of 2012. AcelRx has retained a CRO to conduct the Phase 2 ARX-04 study and the clinical sites for this study have been selected and retained.

Financial Outlook

AcelRx anticipates that research and development expenses will increase over the next several quarters as it seeks to complete Phase 3 development of ARX-01. The development of ARX-02, a product candidate for the treatment of cancer breakthrough pain, and ARX-03, a product candidate for mild sedation and pain relief in procedures conducted in a physician's office, will not advance until additional funding or the identification of a partner to support these efforts is secured. The development of ARX-04 beyond Phase 2 and initial preparations for Phase 3 is dependent on the identification of sources of additional funding or the identification of a partner to support these efforts. Additionally, AcelRx anticipates 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.

AcelRx believes its current cash, cash equivalents and investments, including the drawing, at AcelRx's option, of the second \$10.0 million tranche pursuant to the \$20.0 million Hercules loan facility are sufficient to fund operations into the first quarter of 2013.

About AcelRx Pharmaceuticals, Inc.

Based in Redwood City, CA, AcelRx 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. AcelRx's lead product candidate, the ARX-01 Sufentanil NanoTab PCA System, which is in preparation for 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 providing 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 that is expected to enter Phase 2 clinical development in the fourth quarter of 2011 under a grant from USAMRMC.

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 the clinical trials, progress towards initiation of its Phase 3 studies for ARX-01 and Phase 2 study for ARX-04, the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates, anticipated feedback from the FDA related to its Human Factor studies and software validation, and statements related to future events under the loan and security agreement with Hercules, including its ability to access the second tranche funds under such agreement. 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 satisfy the conditions required to access the second tranche funds under the loan and security agreement with Hercules or repay a portion of the principal thereunder 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, 2010 and its Quarterly Reports on Form 10-Q. 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,	
	2011	2010	2011	2010
Statement of Operations Data				
Research grant revenue	\$ 408	\$ —	\$ 448	\$ —
Operating expenses:				
Research and development (1)	3,947	1,515	8,922	6,309
General and administrative (1)	1,866	1,090	5,086	3,033
Total operating expenses	<u>5,813</u>	<u>2,605</u>	<u>14,008</u>	<u>9,342</u>
Loss from operations	(5,405)	(2,605)	(13,560)	(9,342)
Interest expense	(377)	(197)	(1,891)	(656)
Interest income and Other income (expense), net	21	(799)	1,722	(823)
Net loss	<u>\$ (5,761)</u>	<u>\$ (3,601)</u>	<u>\$ (13,729)</u>	<u>\$ (10,821)</u>
Basic and diluted net loss per common share	\$ (0.30)	\$ (5.38)	\$ (0.83)	\$ (16.63)
Shares used in computing basic and diluted net loss per common share	<u>19,459</u>	<u>669</u>	<u>16,594</u>	<u>651</u>

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

Research and development	\$ 253	\$ 92	\$ 578	\$ 638
General and administrative	304	148	768	469
Total non-cash, stock-based expense	<u>\$ 557</u>	<u>\$ 240</u>	<u>\$ 1,346</u>	<u>\$ 1,107</u>

Selected Balance Sheet Data

	September 30, 2011	December 31, 2010
Cash, cash equivalents and investments	\$ 32,020	\$ 3,682
Total assets	36,703	6,830
Total liabilities	13,348	16,781
Total stockholders' equity (deficit)	23,355	(9,951)