

**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 12, 2013

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))

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On March 12, 2013, AcetRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 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.

Exhibit Number	Description
99.1	Press Release dated March 12, 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 13, 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 12, 2013.



FOR IMMEDIATE RELEASE

1 AcelRx Pharmaceuticals Reports Fourth Quarter and Full-Year 2012 Financial Results

REDWOOD CITY, Calif., March 12, 2013—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 fourth quarter and year ended December 31, 2012, and provided a corporate update.

“We made important strides in the advancement of our sublingual Sufentanil NanoTab PCA System for the management of moderate to severe post-operative pain in 2012 and early 2013. We announced positive results from two completed Phase 3 clinical trials, and we expect the results from our third and final planned Phase 3 trial of the NanoTab System in the second quarter of 2013,” stated Richard King, President and CEO of AcelRx. Mr. King added, “In addition, in December 2012, we strengthened our balance sheet when we raised \$48 million in gross proceeds, \$44 million in net proceeds, through a public offering of our common stock. These funds will provide the capital needed to submit an NDA for the NanoTab System, expected in the third quarter of 2013, and to continue with commercial preparations for launch of the product in the U.S.”

Fourth Quarter and Full Year Financial Results

Net loss for the fourth quarter of 2012 was \$10.5 million, or \$0.41 per share, compared with a net loss of \$6.4 million, or \$0.33 per share, for the fourth quarter of 2011. Common shares used in calculating basic and diluted earnings per share were 25,587,614 for the fourth quarter of 2012 compared to 19,567,778 common shares for the fourth quarter of 2011.

During the fourth quarter of 2012, AcelRx recognized revenue of \$1.7 million, compared to \$624,000 for the same period in the previous year, related to a research grant from the U.S. Army Medical Research and Materiel 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, or R&D, expenses for the quarter ended December 31, 2012 totaled \$7.8 million, compared with \$4.7 million for the fourth quarter of 2011. The increase was primarily due to advancement of our clinical programs for the Sufentanil NanoTab PCA System, AcelRx’s lead product candidate for the treatment of post-operative pain and ARX-04. General and administrative expenses were \$1.9 million for the quarter ended December 31, 2012, compared with \$1.7 million for the quarter ended December 31, 2011, an increase primarily from higher legal costs related to intellectual property.

For the year ended December 31, 2012, AcelRx reported a net loss of \$33.4 million, or \$1.51 per share, compared with a net loss of \$20.1 million, or \$1.16 per share, for the same period in 2011. Common shares used in calculating basic and diluted earnings per share were 22,124,637 for the year ended December 31, 2012 compared to 17,344,727 for the year ended December 31, 2011.

As of December 31, 2012, AcelRx had cash, cash equivalents and investments of \$59.8 million, compared to \$35.8 million at December 31, 2011.

Review of Recent Accomplishments and Corporate Update

- On March 4, 2013, AcelRx announced positive top-line results from a pivotal Phase 3 double-blind, placebo-controlled efficacy and safety clinical trial for the NanoTab System. This trial involved 178 adult patients recruited at 13 U.S. sites following major open abdominal surgery, and focused on the management of acute pain for up to 72 hours after the first study dose was given shortly after completion of surgery. The primary endpoint for this trial was the time weighted summed pain intensity difference to baseline over 48 hours, or SPID-48. The top-line data 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, the SPID was significantly greater in the sufentanil-treated patients than in the placebo-treated patients (p<0.001 and p=0.004, respectively). Further, sufentanil NanoTab treatment in this study was well tolerated, with the rate of adverse events being similar in both the active and placebo groups, and adverse events were generally mild to moderate in nature.

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- In November 2012, AcelRx announced positive top-line results for the NanoTab System in a Phase 3 open-label, active-comparator study evaluating the efficacy and safety of the Sufentanil NanoTab System versus IV PCA with morphine, a frequently used post-operative pain treatment in the hospital setting. The top-line data showed that the NanoTab System met its primary endpoint of non-inferiority in patient global assessment, or PGA, with method of pain control in comparison to IV PCA with morphine. Additional analyses also showed that the NanoTab System was statistically significantly superior to IV PCA morphine for the PGA measurement. In addition, using validated assessment tools, nurses managing patients in the study and the patients themselves reported that they had significantly greater Overall Satisfaction with the NanoTab System compared to IV PCA morphine and significantly greater Overall Ease of Care with the NanoTab System compared to IV PCA morphine.
 - A second placebo-controlled Phase 3 trial with the Sufentanil NanoTab PCA System continues to enroll patients following hip or knee replacement surgery with a target of enrolling approximately 400 patients. Dosing of the final subject in this study is expected in late March or early April 2013 and top-line results should be available during the second quarter of 2013. The primary endpoint for the orthopedic placebo-controlled Phase 3 study is the sum of pain intensity difference to baseline over 48 hours, or SPID-48.
 - 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 U.S. Army Medical Research and Materiel Command, or USAMRMC, and enrolled approximately 100 patients following bunionectomy surgery, randomizing them into one of three groups to receive one of two sufentanil NanoTab dosage amounts (20 mcg or 30 mcg) or placebo. Dosing has been completed and we expect to announce top-line results for this trial in the second quarter of 2013.
 - In October 2012, 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 December 2012, AcelRx completed a public offering of common stock resulting in gross proceeds of \$48 million, \$44 million in net proceeds after deducting commissions and offering expenses.
 - During 2012, the U.S. Patent and Trademark Office, or USPTO, issued five patents covering AcelRx's proprietary NanoTab technology and in early 2013, the USPTO issued the first NanoTab System device related patent. AcelRx has now received a total of six U.S. patents and two European patents underpinning its four product development programs, proprietary NanoTab technology and NanoTab System device.

Financial Outlook

AcelRx anticipates that quarterly R&D expenses for both the first and second quarters of 2013 will be in line with, or modestly higher than the R&D expenses experienced in fourth quarter of 2012 as AcelRx conducts and completes the Phase 3 clinical trials and prepares an NDA for the NanoTab System, and completes the ARX-04 Phase 2 clinical study. The development of ARX-04 beyond Phase 2 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 commercial preparations for launch of the NanoTab System in the US, and as AcelRx expands its corporate infrastructure to support development of its product candidates.

AcelRx believes its current cash, cash equivalents and investments are sufficient to fund operations into the third quarter of 2014.

Conference Call

AcelRx will conduct a conference call and webcast today, March 12, 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 Investors section of the company's website at www.acerlx.com and selecting the Webcast link for the Q4 2012 Financial results. 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 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 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. The NanoTab System 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 USAMRMC, 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.acerlx.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 the 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 Annual Report on Form 10-K filed with the SEC on March 12, 2013. 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)

	<u>Three Months Ended</u> <u>December 31,</u>		<u>Twelve Months Ended</u> <u>December 31,</u>	
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
Statement of Operations Data				
Research grant revenue	\$ 1,675	\$ 624	\$ 2,394	\$ 1,072
Operating expenses:				
Research and development ⁽¹⁾	7,795	4,702	24,908	13,624
General and administrative ⁽¹⁾	1,909	1,715	7,199	6,800
Total operating expenses	<u>9,704</u>	<u>6,417</u>	<u>32,107</u>	<u>20,424</u>
Loss from operations	(8,029)	(5,793)	(29,713)	(19,352)
Interest expense	(518)	(417)	(2,283)	(2,309)
Interest income and Other income (expense), net	(1,975)	(163)	(1,367)	1,560
Net loss	<u>\$ (10,522)</u>	<u>\$ (6,373)</u>	<u>\$ (33,363)</u>	<u>\$ (20,101)</u>
Basic and diluted net loss per common share	<u>\$ (0.41)</u>	<u>\$ (0.33)</u>	<u>\$ (1.51)</u>	<u>\$ (1.16)</u>
Shares used in computing basic and diluted net loss per common share	<u>25,588</u>	<u>19,568</u>	<u>22,125</u>	<u>17,345</u>

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

Research and development	\$ 236	\$ 207	\$ 998	\$ 785
General and administrative	281	280	1,152	1,048
Total non-cash, stock-based expense	<u>\$ 517</u>	<u>\$ 487</u>	<u>\$ 2,150</u>	<u>\$ 1,833</u>

	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Balance Sheet Data		
Cash, cash equivalents and investments	\$ 59,763	\$ 35,785
Total assets	64,520	40,835
Total liabilities	30,673	23,367
Total stockholders' equity	33,847	17,468