

**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): May 8, 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 May 8, 2013, AcetRx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2013. 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 May 8, 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: May 9, 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 May 8, 2013.



FOR IMMEDIATE RELEASE

AcelRx Pharmaceuticals Reports First Quarter 2013 Financial Results

REDWOOD CITY, Calif., May 8, 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 first quarter ended March 31, 2013.

“We continue to make progress in clinical development of our product candidates. We presented additional data at the recent American Society of Regional Anesthesia and Pain Medicine meeting from a head-to-head study of the Sufentanil NanoTab PCA System compared to intravenous morphine that showed rapid post-operative pain reduction and low rates of oxygen desaturation for the NanoTab system treated patients,” stated Richard King, president and CEO of AcelRx. “This highly encouraging data reinforces our selection of sufentanil, a fast-acting opioid with a high therapeutic index, to combine with our pre-programmed, non-invasive patient-controlled delivery technology. We also completed enrollment and look forward to announcing top-line results later this quarter from our third and final Phase 3 trial conducted with the NanoTab System in patients who have undergone hip or knee replacement surgery.” Mr. King added, “We were also very pleased to announce positive Phase 2 top-line results for ARX-04, a single-dose, sufentanil NanoTab product candidate administered by healthcare professionals for the management of moderate-to-severe acute pain, in which we successfully identified that a 30 mcg dose of sufentanil delivered no more frequently than hourly is an effective dose.”

First Quarter Financial Results

Net loss for the first quarter of 2013 was \$12.8 million, or \$0.34 per share, compared with a net loss of \$7.1 million, or \$0.36 per share for the first quarter of 2012. Common shares used in calculating basic and diluted earnings per share were 37,133,358 for the first quarter of 2013 compared to 19,607,483 for the first quarter of 2012.

During the first quarters of 2013 and 2012, AcelRx recognized revenue of \$940,000 and \$329,000, respectively, 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 ARX-04, a sufentanil NanoTab product candidate for the treatment of moderate-to-severe acute pain in a range of ambulatory environments.

Research and development, or R&D, expenses for the quarter ended March 31, 2013 totaled \$9.3 million, compared with \$4.8 million for the quarter ended March 31, 2012. The increase was primarily due to expense associated with Phase 3 clinical studies of the Sufentanil NanoTab PCA System, AcelRx’s lead product candidate for the treatment of post-operative pain, and Phase 2 study expenses for the single-dose sufentanil NanoTab product candidate, ARX-04.

General and administrative expenses were \$2.2 million for the first quarter of 2013, compared with \$2.1 million for the quarter ended March 31, 2012.

Other income and expense includes a \$1.8 million non-cash charge in the first quarter of 2013 resulting from the liability accounting related to the warrants issued in connection with the PIPE financing completed in June 2012. The primary determinant of this charge was an increase in stock price during the first quarter of 2013 and its resulting impact on the Black-Scholes valuation of these warrants.

As of March 31, 2013, AcclRx had cash, cash equivalents and investments of \$48.2 million, compared to \$59.8 million at December 31, 2012.

Review of Recent Accomplishments and Corporate Update

- On March 5, 2013, AcclRx announced positive top-line results from the first of two pivotal Phase 3 double-blind, placebo-controlled efficacy and safety clinical trials 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 (pain reduction) during the study period than placebo-treated patients ($p=0.001$). Secondary endpoint data also showed that 24 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). Sufentanil NanoTab treatment in this study was well tolerated, with the rate of adverse events being similar in both the active and placebo groups. Itching, a frequently observed side effect of opioids was the only adverse event that was significantly different between the two treatment arms, being seen more frequently in sufentanil-treated patients than placebo-treated patients. Adverse events were generally mild-to-moderate in nature.
- During the first week of April 2013, AcclRx completed enrollment in a second and final Sufentanil NanoTab PCA System pivotal Phase 3 trial, with approximately 420 patients randomized 3:1 (active:placebo) in a double-blind, placebo-controlled efficacy and safety clinical trial in adults immediately following major orthopedic surgery. Top-line results should be available in the second quarter 2013. The primary endpoint for the orthopedic Phase 3 study is SPID-48.
- On April 24, 2013, AcclRx announced positive top-line results in a Phase 2 double-blind, placebo-controlled, dose-finding trial for ARX-04, a single-dose, sufentanil NanoTab product candidate for the management of acute pain in ambulatory settings. The trial enrolled 101 patients following bunionectomy surgery, randomizing them into one of three groups (20 mcg or 30 mcg sufentanil NanoTab or placebo NanoTab), dosed no more frequently than once per hour. The study achieved its objective in identifying the 30 mcg dose as the effective dose for sufentanil NanoTabs when dosed once per hour. Patients treated with 30 mcg sufentanil NanoTabs administered by a healthcare professional had significantly greater pain reduction than patients treated with placebo NanoTabs as measured by the summed pain intensity difference to baseline during the 12-hour study period ($p=0.003$). Patients treated with 20 mcg sufentanil NanoTabs did not achieve statistically significant separation from placebo. Adverse events were generally mild-to-moderate in nature, with two serious adverse events occurring, both being judged unrelated to study drug. Two patients dropped out of the study due to adverse events, one deemed unrelated to study drug and the other considered probably related to study drug. The clinical study and associated research activities for ARX-04 are funded by a grant from USAMRMC.

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- On May 2, 2013 AcelRx presented five posters on the Sufentanil NanoTab PCA System at the American Society of Regional Anesthesia and Pain Medicine (ASRA) annual meeting in Boston. In one of these posters, new analyses from the Phase 3 trial comparing the NanoTab System to intravenous patient-controlled analgesia (IV PCA) with morphine demonstrated the NanoTab System had a significantly faster reduction in pain intensity compared to IV PCA morphine ($p < 0.01$). In addition, fewer patients experienced oxygen desaturation events below 95% in the NanoTab System-treated group than in the IV PCA morphine-treated group ($p = 0.028$). Overall adverse events were similar between groups, and most were mild-to-moderate in nature in both groups.

Financial Outlook

AcelRx records as revenue the reimbursement received pursuant to the \$5.6 million USAMRMC grant received in 2011. To date, revenue from this grant has been the only source of revenue recognized by AcelRx and we have recorded revenues of \$4.4 million through March 31, 2013. We expect the remaining \$1.2 million to be recorded as revenue over the remaining life of the grant, which terminates on January 31, 2014.

We anticipate that research and development expenses for the remaining quarters of 2013 will be substantially lower than the \$9.3 million reported for the first quarter of 2013 due to lower clinical development expenses associated with our NanoTab System and ARX-04 programs. These decreases in R&D will be partially offset by the work involved in the preparation of a New Drug Application for the Sufentanil NanoTab PCA System, expected to be submitted to the FDA in third quarter of 2013. Additionally, AcelRx anticipates modest increases in 2013 in general and administrative expense due to costs associated with commercial preparations for the launch of the NanoTab System in the U.S. and expansion of its corporate infrastructure to support a commercial launch. Total operating expenses for 2013 are anticipated to be modestly higher than they were in 2012.

Other income and expense in future periods is expected to include non-cash charges that result from the liability accounting related to the warrants we issued in connection with the PIPE financing completed in the second quarter of 2012. The primary determinant of this charge is stock price change over each quarter and its impact on the Black-Scholes valuation of these warrants. For this reason the impact in future periods is very difficult to predict and is not included in the Company's guidance.

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, May 8, 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.ancelrx.com and selecting the Webcast link for the Q1 2013 earnings conference call. 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.ancelrx.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, or NanoTab 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. AcelRx has announced results from two Phase 3 clinical trials for the NanoTab System, and a third Phase 3 study has completed enrollment, with data expected in the second quarter of 2013. A New Drug Application submission is planned for the third quarter of 2013. AcelRx recently announced positive top-line results for a Phase 2 trial for ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from USAMRMC. 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.acelrx.com.

Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to future financial results, including 2013 financial guidance, 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: that fact that subsequent analyses of the 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 uncertain clinical development process, including the risk that clinical trials, have an effective design, or have expected data available on schedule; any delays or inability to obtain and maintain regulatory approval of its product candidates in the United States and Europe; 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 Quarterly Report on Form 10-Q filed with the SEC today on May 8, 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)

	Three Months Ended March 31,	
	2013	2012
Statement of Operations Data		
Research grant revenue	\$ 940	\$ 329
Operating expenses:		
Research and development ⁽¹⁾	9,318	4,771
General and administrative ⁽¹⁾	2,191	2,104
Total operating expenses	<u>11,509</u>	<u>6,875</u>
Loss from operations	(10,569)	(6,546)
Interest expense	(454)	(594)
Other income (expense), net ⁽²⁾	(1,739)	75
Net loss	<u>\$ (12,762)</u>	<u>\$ (7,065)</u>
Basic and diluted net loss per common share	<u>\$ (0.34)</u>	<u>\$ (0.36)</u>
Shares used in computing basic and diluted net loss per common share	<u>37,133</u>	<u>19,607</u>

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

Research and development	\$ 355	\$ 251
General and administrative	402	291
Total non-cash, stock-based expense	<u>\$ 757</u>	<u>\$ 542</u>

(2) Other income and expense includes a \$1.8 million non-cash charge in the first quarter of 2013 related to warrants issued in connection with a PIPE financing, completed in June 2012.

	<u>March 31, 2013</u>	<u>December 31, 2012</u>
Selected Balance Sheet Data		
Cash, cash equivalents and investments	\$ 48,198	\$ 59,763
Total assets	52,985	64,520
Total liabilities	31,062	30,673
Total stockholders' equity	21,923	33,847