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): October 29, 2015

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**001-35068**	**41-2193603**
(State of incorporation)	(Commission File No.)	(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 October 29, 2015, AcelRx Pharmaceuticals, Inc., or the Company, issued a press release regarding its financial results for the third quarter ended September 30, 2015, a business update and certain other information. The full text of the press release concerning the foregoing is furnished herewith as Exhibit 99.1.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated October 29, 2015.

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: October 29, 2015

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell
Jane Wright-Mitchell
Chief Legal Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release dated October 29, 2015.

Exhibit 99.1

AcelRx Pharmaceuticals Provides Business Update and Reports Third Quarter and Nine Months 2015 Financial Results

REDWOOD CITY, Calif., October 29, 2015 – AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain, today provided a business update and reported financial results for the three and nine months ended September 30, 2015.

Business highlights include:

- On September 9, 2015, AcelRx announced that ARX-04 (sufentanil sublingual tablet, 30 mcg) met primary and secondary endpoints in a multi-center, double-blind, placebo-controlled Phase 3 trial (SAP301) in patients with moderate-to-severe acute pain following ambulatory abdominal surgery. Results demonstrated that patients receiving short-term treatment with ARX-04, administered via a disposable, pre-filled, single-dose applicator (SDA), experienced significantly greater pain reduction compared to placebo, as measured by the time-weighted summed pain intensity difference over the first 12 hours of treatment (SPID-12) ($p<0.001$).

- On September 22, 2015, AcelRx announced that the European Commission (EC) approved Zalviso™ (sufentanil sublingual tablet system) for the management of acute moderate-to-severe post-operative pain in adult patients in a hospital setting. The marketing authorization is granted for the 28 EU member states as well as for the European Economic Area (EEA) countries, Norway, Iceland and Liechtenstein. Grunenthal GmbH (Grunenthal), AcelRx's commercial partner in Europe and Australia, expects the product to be available to Western European patients in the first half of 2016. The approval triggered a $15.0 million milestone to AcelRx from Grunenthal which the company expects to receive in Q4 2015.

- On September 21, 2015, AcelRx announced the monetization of the expected royalty stream from the sales of Zalviso in the European Union by Grunenthal. AcelRx received $65.0 million from the royalty sale to PDL BioPharma, Inc. (NASDAQ: PDLI). PDL will receive 75% of the European royalties due under the Grunenthal Collaboration and License Agreement (CLA) as well as 80% of the first four commercial milestones, subject to a capped amount of $195 million. AcelRx will receive 25% of the royalties from product sales, 20% of the first four commercial milestones, and 100% of the remaining commercial and development milestones under the CLA with Grunenthal.

“The third quarter of 2015 was marked by considerable progress for AcelRx. The approval of Zalviso in Europe, positive Phase 3 results for ARX-04 and the monetization of a portion of the expected royalty stream from sales of Zalviso in Europe are tremendous accomplishments,” commented Howie Rosen, interim chief executive officer of AcelRx. “In the fourth quarter we are continuing to make progress, having started a study of ARX-04 in the emergency room. The study is designed to provide experience in this setting and to help add to the safety database requirements necessary to file the NDA for ARX-04. In addition, based on the teleconference we held with the FDA in early September regarding the regulatory path for Zalviso, we have submitted a protocol for an additional clinical study to address concerns raised by the FDA and to assess the overall performance of the device. Pending comments on the protocol from the FDA, we are preparing to initiate this study the first quarter of next year.”

Third Quarter Financial Results

Net income for the third quarter of 2015 was $5.1 million, or $0.11 basic and diluted net income per share, compared to net income of $0.7 million, or $0.02 basic net income per share, and $0.13 diluted net loss per share for the third quarter of 2014. The increase in net income and net income per share was primarily due to revenue recognized under AcelRx’s CLA with Grunenthal for Zalviso, and AcelRx’s contract with the Department of Defense (DoD) for ARX-04 development. In addition, general and administrative expenses decreased as a result of the cost reduction plan implemented at the end of March 2015, while other income decreased in the third quarter of 2015, as compared to the third quarter of 2014. Common shares used in calculating earnings per share were 44.4 million for basic EPS and 45.0 million for diluted EPS in the third quarter of 2015, compared to 43.5 million for basic EPS and 44.3 million for diluted EPS in the third quarter of 2014.

For the third quarter 2015, AcelRx recognized revenue under the Grunenthal CLA of $13.9 million. As mentioned above, we are entitled to receive a milestone payment of $15.0 million related to the approval of the Marketing Authorization Application (MAA), of which $13.2 million was recognized as revenue during the third quarter of 2015. In the third quarter of 2014, we received a milestone payment of $5.0 million related to the MAA submission, of which $4.6 million was recognized as revenue.

Revenue attributable to the research and development work performed under the DoD contract, was $1.6 million for the third quarter of 2015. There was no such revenue recognized for the third quarter of 2014.

Research and development expenses for the third quarter of 2015 were $5.4 million, as compared to $5.2 million for the third quarter of 2014. Research and development expenses during the third quarter of 2015 included an increase of $0.4 million in ARX-04 costs primarily due to the initiation of the SAP302 study, and $0.7 million in research and development overhead expenses, compared to the third quarter of 2014. These increases were partially offset by a $0.9 million reduction in Zalviso development program expenses in the third quarter of 2015 as compared to the third quarter of 2014.

General and administrative expenses were $2.9 million for the third quarter of 2015, compared with $4.7 million for the third quarter of 2014. General and administrative expenses in the third quarter of 2014 included Zalviso-related market research and pre-commercialization costs of $1.5 million. There were no corresponding expenses in the third quarter of 2015.

Other income and expense included $0.3 million in non-cash income in the third quarter of 2015, as compared to $6.4 million in the third quarter of 2014, resulting from the accounting related to the PIPE warrants, which are considered a liability for accounting purposes and remeasured at the end of each reporting period utilizing the Black-Scholes valuation model. As of September 30, 2015, there were approximately 0.5 million PIPE warrants outstanding. In addition, other income and expense included $0.5 million in impairment charges related to leasehold improvements in our corporate offices and we recognized $0.3 million in non-cash interest expense related to the royalty monetization completed in the third quarter of 2015.

The royalty monetization results in a taxable gain of more than $60.0 million, the majority of which is expected to be offset with net operating loss carryforwards; however, AcelRx is expected to be subject to U.S. federal alternative minimum taxes in 2015, as reflected in our provision for income taxes in the third quarter of 2015.

Year-to-Date Financial Results

For the nine months ended September 30, 2015, AcelRx reported a net loss of $13.9 million, or $0.31 basic net loss per share and $0.37 diluted net loss per share, compared to a net loss of $19.5 million, or $0.45 basic net loss per share and $0.63 diluted net loss per share for the same period in 2014. Common shares used in calculating earnings per share were 44.2 million for basic EPS and 44.4 million for diluted EPS in the nine months ended September 30, 2015, compared to 43.3 million for basic EPS and 44.3 million for diluted EPS in the nine months ended September 30, 2014.

AcelRx recognized revenue of $14.5 million under the Grunenthal CLA in the nine months ended September 30, 2015, primarily related to the milestone for approval of the Zalviso MAA, while during the nine months ended September 30, 2014, AcelRx recognized revenue of $5.0 million under the Grunenthal CLA, primarily related to milestone payment for the Zalviso MAA submission. Revenue attributable to the research and development work performed under the DoD contract, was $3.0 million for the nine months ended September 30, 2015. There was no such revenue recognized for the nine months ended September 30, 2014.

Research and development expenses in the nine months ended September 30, 2015 were $19.0 million, compared to $17.2 million in the nine months ended September 30, 2014. The increase was primarily attributable to increases of $2.8 million for the ARX-04 development program, $1.2 million in manufacturing facilities expense, $1.3 million in personnel-related expenses, including stock-based compensation, partially offset by a $3.5 million decrease related to the Zalviso development program.

General and administrative expenses were $10.2 million in the nine months ended September 30, 2015, compared to $13.6 million in the nine months ended September 30, 2014. The decrease was the result of reduced market research and outside services of $4.4 million, primarily related to market research activities for Zalviso, partially offset by a $0.4 million increase in stock-based compensation, a $0.3 million increase in legal fees and a $0.2 million increase in ARX-04 market research costs.

Other income and expense includes $2.4 million and $8.2 million in non-cash income in the nine months ended September 30, 2015 and 2014, respectively, resulting from the liability accounting related to the PIPE warrants.

As of September 30, 2015, AcelRx had cash, cash equivalents and investments of $104.3 million, compared to $75.4 million at December 31, 2014. The net change in cash, cash equivalents and investments was $28.9 million for the nine months ended September 30, 2015. As mentioned above, the royalty monetization provided gross proceeds of $65.0 million in the third quarter of 2015.

“With the gross proceeds from the royalty monetization of $65.0 million, the $15.0 million approval milestone from Grunenthal and the support for ARX-04 under the DoD contract we anticipate we will end 2015 with over $100.0 million in cash,” stated Timothy E. Morris, chief financial officer of AcelRx Pharmaceuticals. “We anticipate this cash balance is sufficient to permit us to meet our capital and operational requirements through at least the first half of 2017.”

Conference Call

AcelRx will conduct a conference call and webcast today, October 29, 2015 at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) to discuss its financial results and business updates. To listen to the conference call, dial in approximately ten minutes before the scheduled call 1-866-361-2335 for domestic callers, 1-855-669-9657 for Canadian callers, or 1-412-902-4204 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.acelrx.com and selecting the Webcast link for the Q3 2015 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.acelrx.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 pain. The company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg) for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso™ (sufentanil sublingual tablet system) for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

ARX-04 delivers 30 mcg sufentanil, a high therapeutic index opioid, sublingually through a disposable, pre-filled, single-dose applicator. AcelRx has reported positive results from the pivotal Phase 3 SAP301 ambulatory surgery study, and has advanced ARX-04 into a study (SAP302) in emergency room patients. Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. Zalviso is approved in the EU as well as Norway, Iceland and Liechtenstein and is in late-stage development in the U.S. AcelRx submitted a New Drug Application (NDA) for Zalviso and received a Complete Response Letter (CRL) from the FDA on July 25, 2014. The FDA subsequently requested an additional clinical study to evaluate the effectiveness of product changes made in response to the CRL, and the company is working with the FDA regarding the resubmission of the Zalviso NDA and initiation of a clinical study to support resubmission.

For additional information about AcelRx's, please visit www.acelrx.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 development of AcelRx's product candidates, including Zalviso and ARX-04; anticipated results and timing of the completion of the SAP302 study for ARX-04; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the United States, including the anticipated timing, design and results of the additional clinical trial for Zalviso; the anticipated resubmission of the Zalviso NDA to the FDA; statements related to the timing and success of commercial launch of Zalviso in Europe; ability to fund ARX-04 development from the contract with the Department of Defense; the status of the Collaboration and License Agreement with Grunenthal, including potential milestones and royalty payments under the Grunenthal CLA; anticipated cash balance at year-end 2015 and cash forecasts. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and uncertainties. AcelRx's 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: any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso and ARX-04; its ability to timely and successfully design and complete the additional clinical study requested by the FDA to support resubmission of the Zalviso NDA; its ability to timely resubmit the Zalviso NDA to the FDA and to receive regulatory approval for Zalviso; the fact that the FDA may dispute or interpret differently positive clinical results obtained to date from the pivotal Phase 3 SAP301 ambulatory surgery study of ARX-04; its ability to complete Phase 3 clinical development of ARX-04; inability to successfully manufacture Zalviso to meet the requirements of Grunenthal and potential delays in the timing of the European launch; the success, cost and timing of all product development activities and clinical trials, including the SAP302 ARX-04 trial; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on August 4, 2015. AcelRx 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.

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Selected Financial Data
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Statement of Comprehensive Loss Data				
Collaboration agreement revenue	$ 13,863	$ 4,825	$ 14,530	$ 4,991
Contract revenue	1,565	-	3,003	-
Total revenue	15,428	4,825	17,533	4,991
Operating expenses:				
Research and development (1)	5,393	5,244	19,009	17,239
General and administrative (1)	2,930	4,650	10,186	13,622
Restructuring costs	-	-	756	-
Total operating expenses	8,323	9,894	29,951	30,861
Income (loss) from operations	7,105	(5,069)	(12,418)	(25,870)
Other (expense) income:				
Interest expense	(713)	(816)	(2,296)	(1,818)
Interest income and other income (expense), net(2)	(269)	6,556	1,915	8,153
Non-cash interest expense on liability related to sale of future royalties to PDL	(282)	-	(282)	-
Total other (expense) income	(1,264)	5,740	(663)	6,335
Provision for income taxes	(772)	-	(772)	
Net income (loss)	$ 5,069	$ 671	$ (13,853)	$ (19,535)
Basic net income (loss) per common share	$ 0.11	$ 0.02	$ (0.31)	$ (0.45)
Shares used in computing basic net income (loss) per common share	44,407	43,469	44,210	43,332
Diluted net income (loss) per common share	$ 0.11	$ (0.13)	$ (0.37)	$ (0.63)
Shares used in computing diluted net income (loss) per common share	45,049	44,263	44,400	44,288

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

Research and development	$ 636	$ 568	$ 1,967	$ 1,607
General and administrative	535	631	1,853	1,461
Total	$ 1,171	$ 1,199	$ 3,820	$ 3,068

(2) Interest income and other income (expense) includes $0.3 million and $2.4 million in non-cash income for the three and nine months ended September 30, 2015 as compared to $6.4 million and $8.2 million in non-cash income for the three and nine months ended September 30, 2014, respectively, related to warrants issued in connection with a private placement equity financing, completed in June 2012.

	September 30, 2015	December 31, 2014
Selected Balance Sheet Data		
Cash, cash equivalents and investments	$ 104,333	$ 75,350
Total assets	131,560	86,416
Total liabilities	91,594	39,760
Total stockholders' equity	39,966	46,656