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 7, 2016

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 8.01. Other Events.

On March 7, 2016, AcelRx Pharmaceuticals, Inc., or the Company, conducted a conference call during which members of its senior management team provided a business update and discussed financial results for the quarter and twelve months ended December 31, 2015 and certain other information. A copy of the transcript of the conference call is attached as Exhibit 99.1 to this Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Transcript of AcelRx Pharmaceuticals, Inc. Annual 2015 Financial Results Conference Call on March 7, 2016, at 4:30 p.m. ET.

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 9, 2016

ACELRX PHARMACEUTICALS, INC.

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Transcript of AcelRx Pharmaceuticals, Inc. Annual 2015 Financial Results Conference Call on March 7, 2016, at 4:30 p.m. ET.

Exhibit 99.1

Event ID:
Event Name: AcelRx Pharmaceuticals Annual 2015 Financial Results
Event Date: 2016-03-07

Officers and Speakers
Tim Morris; AcelRx Pharmaceuticals, Inc.; CFO, Head of Business Development
Howie Rosen; AcelRx Pharmaceuticals, Inc.; Interim CEO
Pamela Palmer; AcelRx Pharmaceuticals, Inc.; Co-Founder & Chief Medical Officer
Gina Ford; AcelRx Pharmaceuticals, Inc.; VP, Commercial Operations

Analysts
Randall Stanicky, RBC Capital Markets
Michael Higgins, ROTH Capital Partners
Hugo Ong, Jefferies LLC

Presentation

Operator: Good day, and welcome to the AcelRx Pharmaceuticals annual 2015 financial results conference call and webcast.

(Operator Instructions)

Please note this event is being recorded.

I would now like to turn the conference call over to Mr. Timothy Morris, Chief Financial Officer. Mr. Morris, the floor is yours, sir.

Tim Morris: Thank you, Mike. Good afternoon, everyone, and welcome to today's call. On this call I'm joined by Howie Rosen, interim Chief Executive Officer; Pamela Palmer, a founder and our Chief Medical Officer; and Gina Ford, our VP of Commercial Strategy.

During the call today we will make forward-looking statements, including, but not limited to, statements relating to the process and timing of anticipated future development of AcelRx's product candidates, including the process and timing of anticipated future development of ARX-04 and Zalviso; anticipated results and completion of the SAP302 and SAP303 studies for ARX-04; timing for initiation and completion, along with anticipated results of IAP312 for Zalviso; launch timing and commercial availability for Zalviso in Europe; anticipated resubmission of the Zalviso NDA to the FDA, including the scope and timing of resubmission; and cash guidance for the year. 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 limitations, risk related to any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 and Zalviso; our ability to successfully design and complete the additional clinical study requested by the FDA to support the resubmission of the Zalviso NDA; our ability to timely resubmit the Zalviso NDA to the FDA and to receive regulatory approval for Zalviso; the success, cost and timing of all product development activities and clinical trials, including the SAP302 and SAP303 ARX-04 studies and the IAP312 Zalviso trial; the ability to manufacture a commercial supply of Zalviso; and other risks detailed in the Risk Factors and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Annual (sic - see press release, "Quarterly") Report on Form 10-Q filed with the SEC on November 3, 2015. AcelRx undertakes no duty or obligation to update any forward-looking statement contained in this announcement as a result of any new information, future events or changes in our expectations.

I will now turn the call over to Howie, interim Chief Executive Officer.

Howie Rosen: Thank you, Tim.

During today's call we'll provide business highlights and accomplishments for the fourth quarter, our corporate goals for 2016, updates on ARX-04 and Zalviso, and a review of the fourth quarter and year-end financial results.

Let me start with our recent accomplishments. In October we initiated an open-label Phase 3 study of ARX-04 called SAP302 for the treatment of adult patients who present in the emergency room with moderate-to-severe acute pain associated with trauma or injury. The first 40 patients have completed the study, and ARX-04 was found to be safe and effective in ER patients. Pam will share more results of this study with you in a moment.

In December we, along with representatives from our partner at the Department of Defense, held a pre-NDA meeting with the U.S. Food and Drug Administration to finalize the remaining plans for ARX-04. Based on those discussions, enrollment in the current SAP302 study will be expanded up to a total of 100 patients, and an additional study known as SAP303 is expected to enroll up to 100 postoperative patients with moderate-to-severe acute pain. Both the extension phase of SAP302 and SAP303 will allow for multiple doses of ARX-04 to be administered.

We've received approval from the Department of Defense to modify the SAP302 study protocol and to include the costs in our existing contract, as well as to include some of the costs associated with SAP303. The original contract amount, up to $17 million in funding, remains unchanged. The length of the contract was also extended, which does not reflect the change in our current thinking about NDA submission timing, but rather provides some flexibility to work on activities that may be requested by the DOD after submission.

Having received this approval, we've initiated the site, and, I'm happy to say, treated our first patient in SAP303 last week. The clinical sites for SAP302 are ready to proceed with the extension phase, and we anticipate beginning to enroll patients this month.

Switching now to Zalviso, based on the September 2015 meeting we held with the FDA, we've completed a protocol review with the FDA for an open-label clinical study of Zalviso called IAP312 in postoperative patients. Pam will provide you with a brief update on the study protocol in a few moments.

In Europe, Grunenthal Group, AcelRx's licensee, is continuing to work with the member states of the EU and EEA to ensure that Zalviso is made available to those patients who are suitable to treat their acute moderate-to-severe postsurgical pain. Grunenthal and we expect the product to be available to Western European patients in the first half of 2016.

On the commercial side, Gina Ford, who you will recall joined AcelRx full time at the beginning of October and who many of you had an opportunity to meet at our Analyst Day in October, has continued to help us hone our U.S. and ex-U.S. commercial strategies for both ARX-04 and Zalviso. As Tim mentioned, Gina has joined us on this call.

As always, I would personally like to thank the employees of AcelRx, our contractors, consultants and clinical investigators. The communications we have had with the FDA have been productive regarding both ARX-04 and Zalviso, and we are moving forward with final studies to support both candidates' NDAs.

As we outlined for you in early January, our corporate goals for 2016 remain: No. 1, to complete the open-label studies of ARX-04 and to file the NDA; No. 2, to complete the open-label study of Zalviso in postoperative patients and resubmit the NDA; and No. 3, to support the launch of Zalviso in Europe by Grunenthal. With the development pathway for both our products clarified, as you can see, our focus in 2016 will be on execution.

I'd now like to turn the call over to Pam, who will provide you with a more detailed update on ARX-04 and Zalviso.

Pamela Palmer: Thanks, Howie.

Let's start with ARX-04. Previously we reviewed results with you from SAP301, which is a Phase 3 study of ARX-04 for the short-term treatment of patients with moderate-to-severe acute pain following ambulatory abdominal surgery. ARX-04 met primary and secondary endpoints in this study, showing that patients who received ARX-04 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, or SPID-12.

Two weeks ago we reported encouraging interim efficacy and safety results from the single-dose phase of SAP302, an open-label single-arm Phase 3 study of ARX-04 in the emergency room. Pain intensity is measured using a 0 to 10 numeric rating pain scale, and in the ER setting, a drop in pain intensity of 1.3 on this scale has been demonstrated to be clinically meaningful. Of the 40 patients who have been enrolled and treated to date in this study, this mean drop of 1.3 points occurred approximately 20 minutes after dosing, and at one hour after dosing the pain intensity was 2.7 points below baseline.

The primary endpoint of this study is a time-weighted summed pain intensity difference to baseline over the first hour, or SPID-1. The mean SPID-1 value in these patients is similar to previous studies of sublingual sufentanil in postoperative patients. Adverse events were consistent with previous clinical studies, with the most frequent events, nausea and somnolence, each reported in 2 of the 40 patients. None of the participants to date have terminated the study early due to adverse events.

In addition to its analgesic efficacy, we assessed the cognitive impact of ARX-04 on patients in the study. We conducted this analysis at the request of the United States Department of Defense, since drug-induced cognitive impairment on the battlefield is a particular concern. Using a well-known cognitive test, the Six-Item Screener, patients demonstrated no change in mean test scores before and after dosing.

The SAP302 study will continue to enroll patients, with a goal of enrolling up to 100 patients in total. This extension arm of the study will allow for multiple doses of ARX-04 given hourly as needed for pain for up to four doses.

To further expand our experience with ARX-04 in various patient populations, we have also commenced SAP303, a Phase 3 study in postoperative patients with moderate-to-severe acute pain, focusing on patients greater than 40 years of age. In addition, the enrollment will be open to patients with comorbidities such as renal impairment or liver impairment. This study will also accommodate multiple doses of ARX-04, in this case allowing for administration for up to 12 hours. Both studies are expected to be completed by the third quarter of 2016.

Assuming successful completion of the SAP302 extension phase and the new SAP303 study, we anticipate submitting the NDA for ARX-04 in the fourth quarter of 2016 for the treatment of moderate-to-severe acute pain in a medically supervised setting.

Moving on to Zalviso, as Howie mentioned, based on our communications with the FDA we completed the protocol review and are planning to initiate an open-label clinical study called IAP312 of Zalviso in approximately 315 postoperative patients. This study will primarily measure the rate of device errors, including the failure to dispense medication, as well as the incidence of misplaced or dropped tablets. We will also collect additional efficacy and safety data in all patients.

To build on our previous Phase 3 studies, IAP312 will include all surgery types, require a minimum of only 24 hours in the study, and allow for multiple types of pain treatments before and during the study, known as multimodal analgesia. Pending successful and timely completion of this study, we expect to be in a position to resubmit the NDA for Zalviso by the end of 2016.

I will now turn the call over to Gina to provide an update on the commercial activities.

Gina Ford: Thank you, Pam.

Since I last spoke to you in October we have continued to further define specific market segments to refine our launch strategy for ARX-04. Specifically, we continue to review and research the potential use of ARX-04 in the prehospital setting that includes advanced lifesaving ambulance, paramedics and first responders, the emergency department, short-stay surgeries, ambulatory surgery centers, the U.S. government, DOD and NATO, and plastic surgery and burn patients.

We have completed preliminary interviews with payers to determine a market access process and price sensitivity in the U.S. and the EU. We are refining our estimates of the cost of current therapies, specifically the cost of IV opioids.

In the fall we completed a survey of emergency department professionals at a meeting of emergency medicine. From the survey[1]: 1) support the need for improvement in pain management; 2) suggest 80% of ER patients don't receive their first dose of IV opioid until 15 minutes or more; and 3) indicate that two-thirds of those surveyed would like to use a product like ARX-04 in their institution.

In 2016 we are continuing our commercial strategy activity, including preliminary launch planning for ARX-04 and Zalviso in the U.S.

I will now turn the call back over to Tim for the financial results.

Tim Morris: Thank you, Gina.

Earlier today we reported financial results for the fourth quarter and year ended December 31, 2015. I refer you to that press release for specific details on the actual results.

The net loss for the fourth quarter of 2015 was $10.5 million, or $0.24 basic and diluted net loss per share. This compares to $13.8 million, or $0.32 basic and net loss per share for the fourth quarter of 2014. The decrease in net loss in the fourth quarter of 2015 as compared to the fourth quarter of 2014 was primarily due to the reduction in costs related to the Zalviso development program, the cost reduction plan implemented at the end of March 2015, and the revenue attributed to the research and development work performed for ARX-04 under the DOD contract.

For the year ended December 31, 2015, AcelRx reported a net loss of $24.4 million, or $0.55 basic net loss per share. This compares to a net loss of $33.4 million, or $0.77 basic net loss per share for 2014.

Revenue for 2015 was $19.3 million, which included $14.9 million recognized under our collaboration agreement with Grunenthal and $4.4 million in revenue recognized under the DOD contract. Revenue for the year ended December 31, 2014, was $5.2 million, related to our collaboration agreement with Grunenthal.

At the end of 2015 AcelRx had cash, cash equivalents and investments of $113.5 million. This compares to $75.4 million we had at the end of December 2014.

The increase in cash balance was primarily attributable to the $61.2 million in net proceeds from the royalty monetization, offset by the cash required to fund our continuing operations. Excluding the net cash received from the royalty monetization and the milestone payment of $15 million from Grunenthal for the EU approval of Zalviso, the decrease in cash, cash equivalents and investments would have been $38.1 million for 2015.

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[1] Ms. Ford intended to say “Findings from the survey”

Assuming the timely completion of clinical studies and accomplishments of the 2016 corporate objectives that Howie mentioned above, we anticipate cash, cash equivalents and investments to be between $70 million and $75 million at December 31, 2016.

On the IR front, planned presentations and participation in the upcoming conferences and meetings include this week the Cowen and Company 36th Annual Health Care Conference, specifically March 9 in Boston; the 28th Annual ROTH Conference on March 15 in Laguna Niguel; and the BIO-Europe Spring 2016 on April 5 in Stockholm, Sweden.

I will now turn the call back over to Howie for some closing comments.

Howie Rosen: Thank you, Tim.

We've made significant progress in both ARX-04 and Zalviso in the fourth quarter, receiving important input from the FDA on both products' regulatory paths. Based on FDA discussions, we expanded the ARX-04 SAP302 study and initiated SAP303 to provide broader experience with various patient populations and treatment settings.

For Zalviso, we completed the protocol review with the FDA and plan to initiate IAP312, which is designed to assess the overall performance of the device. We expect a number of clinical and regulatory announcements during the year and look forward to keeping you informed of our progress.

Thank you for being on the call today. We'll now open up the call to questions.

Questions & Answers

Operator: Thank you, sir.

(Operator Instructions)

The first question we have comes from Randall Stanicky, from RBC Capital Markets. Please go ahead.

Randall Stanicky: Great. Thanks, guys, for the questions. I just have a couple. On the first it sounds like you made some changes to the pricing model internally, but can you just talk a little bit more about how you're thinking about pricing ARX-04? Has anything evolved on that front?

And then secondly just as we look at the NDA submissions and resubmission timelines for ARX-04 and Zalviso, as we think about next year, they could be coming to market roughly around the same time. Can you just talk about how we should think about the rollout, which is going to come out first, and any additional color on the commercial ramp you can help us with would be great. Thanks.

Tim Morris: Sure, Randall. This is Tim. I'll turn it back to Pam. On the pricing front for ARX-04 we still have a lot of work to do there before we figure that out. But I think what we have done is a fair amount of work as it relates to the current cost of IV opiate use. And so, Pam, what are the specific elements that you're looking at and that have been included in your submission for the abstract?

Pamela Palmer: Sure. So, yes, we'll be presenting at the ISPOR Pharmacoeconomic Meeting in May in Washington, D.C. And we've looked at the price of what it costs an emergency room basically to start an IV and give one dose of an IV opioid, whether it's morphine, hydromorphone or fentanyl. We looked at all three. And it's substantial enough that we feel very comfortable with we have quite a broad margin for pricing of ARX-04.

Randall Stanicky: Has that changed from the -- I know you're talking about $20 per unit on the DOD commitment, but is there any range that you could provide us at this point just in terms of how we should model that high to low opportunity?

Tim Morris: Yes, I mean, I think we've always felt that the price that we have with the DOD represents a floor price. And so, given some of the information I think that will come out in terms of the current cost, we do believe that there should be a significant amount of room above that between that $20 and then what the actual current cost of the standard of care is today.

And then on your question as to relates to the timing of the launch and the various approvals, we'll let Howie comment.

Howie Rosen: Yes, thanks for your question. So at this point we're still working through exactly how we'd sequence launches. And, as I mentioned, the focus really is on the clinical and regulatory side.

The nice thing when we look at these two products is that there's some overlap in terms of the call points, so with the emergency rooms and the hospitals. There's obviously opportunities for ARX-04 outside the hospital setting, as well. So we're still sort of working through how we would actually launch the products, in what sequence and timing.

Randall Stanicky: Got it. Thanks, guys.

Operator: Next we have Michael Higgins, ROTH Capital Partners.

Michael Higgins: Hi, guys. Thanks. A couple of questions, if I could, the first being your cash situation looks good. Your guidance is in line. Q4 seemed to be a bit higher on the expense side than we had expected. So if you could help us with the quarters going forward, how we should look at the R&D line with three Phase 3s ongoing and data coming up in Q3. Thanks.

Tim Morris: Sure. I think as relates to kind of the fourth quarter, I mean, clearly some of the prep work for these clinical studies that are now moving forward and some of the work that we had done with the FDA was probably driving that a little bit. In terms of the actual cash and the cash burn next year, I think you guys have -- we tried to give some guidance on that.

But I would also say that I believe R&D will be slightly higher next year, sorry, in 2016 than it was in 2015, mainly because we'll have now three studies ongoing, even though those are open-label studies. But the offset on that is going to be the additional revenue that's going to come from the remainder of the DOD contract in 2016 as compared to 2015.

Michael Higgins: Okay. That's helpful. Help us out with the timing for filing 04 in Europe. Might that come late this year, or is that more likely in 2017?

Tim Morris: Yes, most likely that's a 2017 event. We'd want to use the same exact database that we've used in the U.S. for Europe. We're also going to get some clarifying -- initial clarifying meetings with some scientific -- from scientific advice in Europe in the next couple of months, as well.

So there also is just a natural timeline between the filing of the NDA and the MAA. So that will follow on fairly quickly, but from a timing standpoint most likely it looks like the filing for the MAA will be a 2017 event.

Michael Higgins: Okay. Now that it seems like the clinically events seem to be fairly straightforward, things have kind of come to a calm here, I suppose, any updates for us on the outlook for filling the CEO spot and who and what you're looking for for that position?

Howie Rosen: Thanks for that question. As I mentioned before, we have been screening and interviewing candidates, and I've told the Board that I'm here for as long as need be. So that'll give us the opportunity to be thoughtful about that. But we'll definitely update you on progress there.

Michael Higgins: Fair enough. Thanks, guys.

Operator: Next we have Hugo Ong, of Jefferies.

Hugo Ong: Hi, guys. Thanks for taking the question. Just quickly on SAP303, you mentioned that you'll be enrolling patients that are 40 years or older. Is there an upper limit at all in terms of the age of the patients you'll be enrolling?

Pamela Palmer: No. We've actually never had an upper limit in any study that we've ever conducted.

Hugo Ong: Okay. Great. And in 302 will you also investigate ARX-04 in patients with pain due to severe burns?

Pamela Palmer: Sure, if they come in to the emergency room. We're looking at any acute trauma to a patient, so whether it's due to severe burns or a car accident or a fall, what have you.

Hugo Ong: Okay, got it. Thank you.

Operator: At this time we're showing no further questions. We'll go ahead and conclude our question-and-answer session. I would now like to turn the conference call back over to Mr. Howard Rosen, interim Chief Executive Officer, for any closing remarks. Sir?

Howie Rosen: Thank you, Michael.

Thank you again for joining us for our fourth quarter and year-end call. We'll be participating at several investment conferences, as we mentioned, in the coming months, so we look forward to keeping you updated on our progress.

Operator: And we thank you, sir, to the rest of the management team, for your time also today. The conference call has now concluded. At this time you may disconnect your lines. Thank you, take care, and have a great day, everyone.