

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 29, 2016

**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))
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**Item 8.01. Other Events.**

On March 29, 2016, AcetRx Pharmaceuticals, Inc., or the Company, conducted a conference call during which members of its senior management team provided a business update and discussed 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**

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99.1 Transcript of AcetRx Pharmaceuticals, Inc. Conference Call on March 29, 2016, at 4:30 p.m. ET.

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**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 31, 2016

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell \_\_\_\_\_

Jane Wright-Mitchell  
Chief Legal Officer

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## INDEX TO EXHIBITS

<b>Exhibit Number</b>	<b>Description</b>
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99.1	Transcript of AcelRx Pharmaceuticals, Inc. Conference Call on March 29, 2016, at 4:30 p.m. ET.
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Event ID:  
Event Name: [ACRX] - AcelRx Conference Call  
Event Date: 2016-03-29

Officers and Speakers

Tim Morris; AcelRx Pharmaceuticals, Inc.; CFO  
Howie Rosen; AcelRx Pharmaceuticals, Inc.; CEO  
Pamela Palmer; AcelRx Pharmaceuticals, Inc.; Founder and Chief Medical Officer  
Jane Wright-Mitchell; AcelRx Pharmaceuticals, Inc.; Chief Legal Officer

Analysts

Hugo Ong, Jefferies  
Michael Higgins, Roth Capital Partners  
Justin for Boris Peaker, Cowen & Company

Presentation

Operator: Good afternoon, everyone, and welcome to the AcelRx business update call.

(Operator Instructions)

Please also note today's event is being recorded.

At this time I'd like to turn the conference call over to Mr. Tim Morris, Chief Financial Officer. Sir, please go ahead.

Tim Morris: Thank you, Jamie. Good afternoon, everyone, and welcome to today's call.

On this call I'm joined by Howie Rosen, Chief Executive Officer; Pamela Palmer, Founder and our Chief Medical Officer; and Jane Wright-Mitchell, our Chief Legal Officer, who will read the forward-looking statements.

Jane Wright-Mitchell: 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 developments of AcelRx's product candidates, including the process of 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 the timing 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.

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These forward-looking statements are based on AcetRx's current expectations and inherently involve significant risks and uncertainties. AcetRx'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 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 for 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 AcetRx's U.S. Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-K filed with the SEC on March 7, 2016.

AcetRx 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.

Tim Morris: Thank you all for joining us today. The agenda is brief.

First we'd like to welcome Howie Rosen as our Chief Executive Officer. Second, we'll update you on our development priorities for 2016. And lastly we will take your questions.

As you know, Howie has served as the interim CEO for AcetRx since April 1, 2015. Howie is an experienced and technically trained executive with over 25 years of success growing startup and midsize biopharmaceutical companies. Howie previously held senior-level general management positions and functional roles in strategy, marketing, finance, business development, research and development at Gilead and ALZA Corporation.

The Nominating Governance Committee performed a full and complete search for qualified candidates with the help of an outside firm. In the meantime, FDA feedback took longer than expected. It had some influence on the development timeline for Zalviso.

The Board weighed all relevant factors prior to making the decision to ask Howie to consider taking this role. Over the past year Howie has been able to reduce his outside obligations, which helped to make it possible for him to take on this role. I'd like to be the first to welcome Howie in this new position. Pam would also like to say a few words.

Pamela Palmer: Thanks, Tim. I, too, would like to welcome Howie as our CEO. I have known Howie since he joined the Board of AcetRx in 2008. Over the past year he has spearheaded our efforts with the FDA to define the regulatory path for Zalviso in the U.S., he has overseen the approval of Zalviso in the EU and guided us through the scale-up and commercial production for Grunenthal.

He has also helped us revise our development and commercial priorities in support of the decision to focus on ARX-04. I look forward to continuing to work with Howie as we progress toward our goal of seeking approval for both of our products in the U.S. Howie will now give you an update on the development priorities for 2016.

Howie Rosen: Thank you, Pam, and Tim, also.

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First let me say that I've appreciated the support of the employees, the Board of Directors and our shareholders during the past year as interim CEO. I'm very pleased that the Board has offered me the ongoing CEO position and will continue to seek value for all of our stakeholders.

As we've just announced, we've revised our pipeline priorities for 2016 and have selected ARX-04 as our primary focus for clinical development and commercialization. We've also decided to postpone the start of the Zalviso Phase 3 trial, IAP312, originally planned for the first quarter of 2016.

In conjunction with the launch in the EU, we completed certain performance tests on the EU commercial systems. We determined that the Zalviso commercial supplies provided the performance quality we expect to provide with our NDA resubmission and that the commercial supplies may better optimize system functionalities for the conduct of the IAP312 study.

The use of commercial supplies may also reduce review time for any potential postapproval changes with supply manufacturers and software updates. We had planned to make the switch to commercial Zalviso supplies postapproval, but by doing it now we anticipate it will ultimately make the launch of Zalviso in the U.S. smoother. Zalviso remains an important product for AcelRx, and we look forward to updating you on its progress toward NDA submission.

Let me spend a few minutes now on ARX-04. With receipt of the necessary approvals from the Department of Defense and the initiation of the two remaining Phase 3 studies for ARX-04, we reviewed our resource needs and will focus our clinical, regulatory and commercial teams primarily on ARX-04. In addition, given the expected review time for the NDA resubmission of Zalviso is only six months, at this point our preference would be to launch ARX-04 ahead of Zalviso. The anticipated PDUFA date for Zalviso would have been before ARX-04's, so we have time to focus on ARX-04 and start the IAP312 study a bit later.

The Company confirms its corporate objective that, assuming successful completion of the ongoing ARX-04 Phase 3 studies, SAP302 and SAP303, by the third quarter of 2016, the Company anticipates submitting the NDA for ARX-04 in the fourth quarter of 2016.

We'll now open up the call to questions.

Questions & Answers

Operator: (Operator Instructions)

Our first question today comes from Hugo Ong, from Jefferies. Please go ahead with your question.

Hugo Ong: Hi, guys. Thanks for taking the question. And, Howie, just wanted to extend my congratulations. Really happy to see you onboard.

Howie Rosen: Thank you.

Hugo Ong: So, just a few questions. How does the decision today on Zalviso impact the EU launch, if at all?

Howie Rosen: Yes, we don't anticipate any impact on the EU launch.

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Hugo Ong: Okay. And do you anticipate any changes to the 312 design?

Howie Rosen: Not for the design, per se. It's really just the supplies that we'll use to actually do the study.

Hugo Ong: Okay, great. And just a final housekeeping question. Just how should we think about the R&D spend in 2016, and does this change your cash guidance for year-end 2016 at all?

Tim Morris: Yes, Hugo, this is Tim. We haven't changed the cash guidance yet, so I think what we gave you last time is still good.

Hugo Ong: Okay, great. Thanks for taking the questions.

Operator: Our next question comes from Michael Higgins, from Roth Capital Partners. Please go ahead with your question.

Michael Higgins: Thanks, operator. I also wanted to extend my congratulations to Howie for taking the full-time chair. Congrats, Howie.

Howie Rosen: Thanks, Michael.

Michael Higgins: Couple questions. I guess I had expected that you'd be manufacturing sufficient commercial quantities considering you've been making some changes to the Zalviso device, that you'd make those commercial quantities postapproval. So I've got a six to nine months from PDUFA to launch. But how much time do you think it will take before you get 312 up and going?

Howie Rosen: Yes, so specifically we're still working through things, so we're not giving guidance in terms of when we'll actually start. But it's not so much the launch quantities. It's the actual systems we're using.

So we have a different supplier for Europe than we have for the U.S. for controllers. And, as you know, the device in Europe is approved through the CE process, so we have a CE Mark. And that process allows us to make changes and self-certify.

In the U.S. any changes you make are part of the FDA review. So we had made some -- besides a different supplier we had made some changes to the software as well as the hardware just to refine the performance that currently aren't available in the U.S. systems.

Michael Higgins: So prior to today you were expecting to take the Zalviso device, including the cartridge, the controller, pretty much everything that was used in the previous three Phase 3s, make some adjustments to that, and then run 312. Now you're saying you're changing the manufacturer, as well?

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Howie Rosen: Well, yes, with the one thing that you will recall is that we had made changes. As part of the CRL, we had made changes to the system from what we had done with the Phase 3. So you'll recall that as part of the CRL we had made changes, and so we're making similar -- we're making additional, not similar, but we're making -- what we've decided at this point is that we want to make some additional changes before we do the study, again, things that we probably would've done after the product was approved, but sort of get ahead of the regulatory process rather than leave them out for afterward.

Michael Higgins: And just to clarify on the manufacturing, it will now be the same manufacturer as in Europe, or simply a third manufacturer?

Howie Rosen: Yes, and so we're -- the point is we're switching to the commercial manufacturer. So you had done things at higher volumes, more robust, and the things that we would just feel more comfortable in terms of using those supplies now rather than waiting till afterwards. And part of what we're benefiting from is the fact that we've now had the experience of ramping up and launching for Grunenthal in the EU. So we decided we might as well take advantage of that, having had the opportunity to learn from that and go through that process.

Michael Higgins: Okay, and then last question, Howie, what had made the change for you, or what drove the decision to make the change and to take that permanent CEO role?

Howie Rosen: That's a personal question? For me, I'll tell you the same thing I told the employees just a few minutes ago, is that after working with everyone -- I've been on the Board since 2008, as Pam mentioned, but after working with everyone more closely for a year, and just seeing the excitement and enthusiasm, I just really want to be part of it going forward.

And as you've also heard me say I've, unfortunately, been a patient for both these -- both the potential uses of this in the ER as well as postsurgical, and so what we're trying to do really resonates with me on a personal level, as well. So I decided that I could make it work. With the other things I've done, I've cut back on a lot of those, and I'm excited about being here and getting us all the way to the end.

Michael Higgins: Understood. Congrats again. Thanks, guys.

Operator: And our next question comes from Boris Peaker, from Cowen and Company. Please go ahead with your question.

Justin for Boris Peaker: Hi. This is Justin on for Boris. Thank you for taking our questions, and, Howie, congratulations on your new role.

Howie Rosen: Thanks, Justin.

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Justin for Boris Peaker: One of the questions was in regards to Zalviso, what was the trigger for the decisions? Was there any new FDA feedback? And I know you had talked about a new manufacturer, but does anything have to be reengineered based on additional feedback from the FDA?

Howie Rosen: Yes, nothing was FDA driven. It's just as I said, that we were going through the process of doing the commercial supplies for Grunenthal and then we also did do testing on the clinical supplies, and that's what -- which we just completed just very, very recently, and that's what, when we just looked at everything all together and thought about the regulatory process and also our priorities in terms of launching the products that it just made sense to make these -- do these switches now.

And so in terms of launch priorities, the current view of the market is that we're really bringing two things new into the hospital setting. One is the sublingual sufentanil and the second is the device part of Zalviso. And our current thinking is that we'd like to lead with the sublingual sufentanil and get people familiar with that. And so that's an easier story to tell with ARX-04.

And so the thought is to -- our current thought is to, given the approvals, that we would launch with ARX-04 first. And so Zalviso is ahead of that, especially given it only has -- we were told we would have a six-month review. So also that was another reason we felt we just had some time to do the switch to the commercial supplies now rather than waiting.

Justin for Boris Peaker: Okay. All right. Great. And then just one question on the ARX-04 front. We hear a lot about opioids and abuse potential. I was just wondering if there's any discussions with the FDA in which there were abuse-potential concerns. And then also do you know how many repeat dose patients you will need for approval in these new trials?

Pamela Palmer: Yes, so there's not an issue with opioids in hospitals to date. I mean, I think the vast majority of issues, and they've been ongoing for quite a while, they're just reaching a peak now, have been outpatient non-cancer-related patients.

Currently we are not using opioids in any new setting. We're talking about using ARX-04 where opioids have been used forever. In fact, usually IV doses of opioids have been used there. So there's been nothing from the FDA regarding ARX-04 and any problem as far as we can see with issues relating to opioids and diversion, etc.

The multiple dose, they've been very clear about how many single and multiple dose. We've easily met the number of multiple-dose exposures already for this program. And what we're doing now is just filling out the safety database for the total number of patients they'd like to see exposed to ARX-04 overall.

Justin for Boris Peaker: Okay. All right. Great. Thank you for taking the questions.

Operator: And, ladies and gentlemen, at this time I'm showing no additional questions. I'd like to turn the conference call back over to Howie Rosen for any closing comments.

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Howie Rosen: I just would like to thank everyone for taking time to join us this afternoon on short notice. Thank you again.

Operator: Ladies and gentlemen, that does conclude today's conference call. We do thank you for attending today's presentation. You may now disconnect your lines.