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 4, 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 8.01. Other Events.

On May 4, 2015, AcelRx Pharmaceuticals, Inc., or the Company, conducted a conference call during which members of its senior management team discussed a regulatory update for Zalviso, other program updates, financial results for the quarter ended March 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. Quarter Ended March 31, 2015 Earnings Conference Call on May 4, 2015, 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: May 6, 2015

ACELRX PHARMACEUTICALS, INC.

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

Exhibit 99.1

AcelRx Pharmaceuticals
First Quarter 2015 Financial Results
May 4, 2015 @ 4:30 pm Eastern

CORPORATE PARTICIPANTS
Tim Morris – *Chief Financial Officer*
Howie Rosen – *interim Chief Executive Officer*
Pamela Palmer –*Co-Founder and Chief Medical Officer*

PRESENTATION

Operator
Good afternoon and welcome to the AcelRx Pharmaceuticals First Quarter 2015 Financial Results conference call. All participants will be in listen-only mode. Should you need assistance, please signal a conference specialist by pressing the star key followed by zero. After today's presentation, there will be an opportunity to ask questions. To ask a question, you may press star, then one on your touch-tone phone. To withdraw your question, please press star, then two. Please note, this event is being recorded.

I would now like to turn the conference over to Tim Morris, Chief Financial Officer. Please go ahead.

Tim Morris
Thank you, Laura. Good afternoon everyone and welcome to today's call. On this call I'm joined by Howie Rosen, interim Chief Executive Officer, and Pamela Palmer, our Founder and Chief Medical Officer.

During the call today, we will make forward-looking statements including, but not limited to, statements related to future financial results including AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the U.S.; including meeting with outside advisors for consultation; potential additional clinical studies; additional Human Factor studies; additional data analysis or one of the dispute resolution processes provided for by the FDA; AcelRx believes that additional clinical studies should not be required to demonstrate the safety and efficacy of the Zalviso system beyond what has already been established in the Phase III clinical studies, anticipated resubmission of the Zalviso NDA to the FDA including the scope of the resubmission and the timing of the resubmission, and FDA review time, financial guidance and cash forecast; potential milestones and royalty payments under the Grunenthal agreement; the process and timing of submissions on the Zalviso MAA, including timing for potential approval of the MAA by the EMA; the status of the collaboration agreement with Grunenthal or any other future potential collaborations; the process and timing of anticipated future development of AcelRx product candidates including Zalviso and ARX-04; a potential contract with the Department of Defense to receive partial development support for ARX-04; and the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates including Zalviso and ARX-04. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitations, risk related to AcelRx Pharmaceuticals' ability to finalize the pathway towards timely resubmission of the Zalviso NDA to the FDA, including its ability to use dispute resolution processes provided for by the FDA; potential additional clinical studies; Human Factor studies and/or additional data analysis necessary in order to resubmit the Zalviso NDA; AcelRx's ability to receive regulatory approval for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso in the United States and Europe; its ability to receive any milestones or royalty payments under the Grunenthal agreement; it's ability to obtain sufficient financing; the success, cost and timing of all development activities and clinical trials including the Phase III ARX-04 trial; the market potential for its product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and the 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 13, 2015.

AcelRx Pharmaceuticals undertakes no duty or obligation to update any forward-looking statement contained in this release as a result of new information, future events or changes in its expectations.

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

Howie Rosen
Thank you very much, Tim, and I'd like to thank everyone for joining us this afternoon for the First Quarter call. During today's call we'll provide the following: a regulatory update on Zalviso in the U.S.; a brief update on our progress towards Zalviso approval in Europe, with our partner Grunenthal; a clinical update on ARX-04 which is currently enrolling a Phase III trial; and a brief review of the first quarter financial results. So let me start with the Zalviso regulatory update.

On April 21, 2015, we submitted a request to the Division of Anesthesia, Analgesia and Addiction Products—which I'll also refer to as the Division—of the Food and Drug Administration for a Type B meeting. This past Friday, the Division notified the Company that the request for a meeting was denied. In their response, the Division restated their view that a clinical study is required for the approval of Zalviso. We disagree with this response and are consulting with our regulatory, legal and clinical advisors to determine our next steps. We'll be considering all options to determine a pathway forward for Zalviso, including the possibility of dispute resolution through one of the FDA prescribed pathways, as well as conducting additional clinical or Human Factor studies.

As part of the Type B meeting, we had intended to share with the Division the results of the bench testing and the Human Factor studies we performed to address items included in the Complete Response Letter, or CRL, that they had sent us, and as we also discussed at the Type A meeting we held with the Division. We also wanted to further discuss their desire for additional clinical work. We continue to believe that an additional clinical study should not be required to demonstrate the safety and efficacy of the Zalviso system beyond what has already been established in the Phase III clinical studies and the additional studies performed since receipt of the CRL.

As we've just received the response from the Division, we need some time to finalize a course of action. We are committed to the approval of Zalviso, and will provide a further update as to our next steps once we finalize our plan for moving forward.

As a reminder, the two key issues related to the Zalviso NDA review, that the FDA asked us to address in the CRL, were to reduce the rate of system errors observed in the Phase III program, and to mitigate the risk of inadvertent dispensing, also referred to as dropped tablets. We've completed bench testing on 711 systems and have demonstrated a significant reduction in Zalviso system errors that might lead to an analgesic gap. During this bench test we dispensed over 50,000 tablets, or over two-thirds more than we dispensed in the entire Zalviso Phase III program. The 1.55% error rate seen in the bench testing was below the target outlined in our protocols reviewed by the FDA.

Turning now to the second CRL issue, we received written communication from the FDA in February of this year that they had no comment on our proposed Human Factor protocols, which were designed to test the mitigations we put in place to address dropped tablets. We completed the Human Factor studies in two populations: normal volunteers and post-operative patients. The defined acceptance criteria for each protocol were met, with healthcare professionals and patients demonstrating the ability to follow the refined set of instructions contained in the Instructions for Use, or IFU. While the results of the bench test and the Human Factors work will be subject to review by the FDA, we believe that the results demonstrate that significant improvements to the system functionality have been made and should address the associated items identified in the CRL.

It's important to remember why we developed Zalviso in the first place. Zalviso utilizes a pre-programmed non-invasive solution to deliver sublingual sufentanil in a patient-controlled setting and, we believe, overcomes the limitations of the current standard of care IV PCA. Zalviso successfully met its primary endpoints in three Phase III studies, including an open-label study against IV PCA morphine. Despite the regulatory hurdles, we will continue our pursuit to provide patients and healthcare providers with a non-invasive route for pain relief that uses sufentanil, a proven analgesic with a wide therapeutic index and established onset of action. We'll provide an update on our regulatory path forward for the Zalviso NDA as details are known.

For Zalviso in Europe, we have confirmed that Grunenthal submitted the response of the Day 120 questions and that the EMA has accepted the filing. Under the current timeline, we anticipate receiving the Day 180 questions this quarter, a CHMP opinion in the summer of 2015, and a final decision by the EMA in the fall of this year.

I'd now like to turn the call over to Pam who will provide you with an update on ARX-04.

Pamela Palmer
Thank you, Howie. As we mentioned last time, we have initiated a pivotal Phase III trial for ARX-04. As a reminder, ARX-04 is a single-use, 30 microgram sufentanil sublingual tablet, in a disposable, pre-filled, single-dose applicator, that is administered to the patient by a healthcare professional. The proposed indication for this product is the treatment of moderate to severe acute pain in a medically supervised setting. This Phase III study, SAP301, is a multi-center, double-blind, placebo-controlled trial that will evaluate the efficacy and safety of ARX-04 versus placebo for the treatment of moderate to severe acute pain, following ambulatory abdominal surgery. SAP301 is expected to enroll up to 160 adult patients randomized 2-to-1 active-to-placebo to be treated for up to 48 hours. ARX-04 or placebo will be administered by site staff, as requested by the patient, but no more than once per hour. Enrollment is on-track and pending the completion of enrollment in the study, we anticipate top-line results in the fourth quarter of 2015.

The primary endpoint of this study is to demonstrate a statistically significant difference in the time-weighted summed pain intensity difference to baseline, or SPID, of ARX-04 compared to placebo over a 12-hour dosing period, also known as SPID-12. The study is being conducted at four sites in the United States.

As you will recall, we are also working with the Department of Defense, or DoD, on a contract to partially support our development of ARX-04. After completion of the DoD contract, we plan to initiate a second Phase III clinical trial of ARX-04. This study will add to the safety database for ARX-04 and will help us understand how the application of ARX-04 treats trauma-related, moderate to severe pain in the emergency room, one of the large target markets for the product. This study is therefore an open-label safety study in patients who present to the emergency room with moderate to severe pain due to trauma or injury. Approximately 40 patients are planned to be enrolled in this study. We anticipate the contract will be completed this quarter. The DoD continues to express interest in a potential product like ARX-04 to treat wounded soldiers in the battlefield.

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

Tim Morris
Thank you, Pam. Earlier today we reported financial results for the first quarter ended March 31, 2015. I refer you to that press release for specific details on the actual results.

Net loss for the first quarter of 2015 was $10 million, or $0.23 basic net loss per share, and $0.27 diluted net loss per share. This compares to a net loss of $9.6 million, or $0.22 basic and diluted net loss per share, for the first quarter last year. The increase in net loss and net loss per share was due primarily to higher headcount related expenses in the first quarter of 2015, as compared to the first quarter of 2014. At the end of March, we implemented a cost reduction plan and reduced our workforce by approximately 36%. The associated termination and related costs are reflected as restructuring costs in the Statement of Comprehensive Loss.

For the first quarter we recognized $181,000 of previously deferred revenue under the collaboration agreement with Grunenthal, as compared to $95,000 for the first quarter last year. R&D expenses for the quarter were at $6.3 million; this compared with $4.7 million for the first quarter last year. The increase was primarily due to increased Medical Affairs personnel and the initiation of SAP301, a pivotal Phase III clinical study for ARX-04. G&A expenses were $4.5 million for the first quarter compared with $3.9 million for the first quarter of 2014. Again, the increase was primarily due to increased commercial personnel in anticipation of the potential approval of Zalviso last year. These positions again have subsequently been eliminated as part of the cost reduction plan that we implemented in March 2015.

Other income and expense includes $2.2 million in non-cash income in the first quarter of 2015, and $700,000 in non-cash expense in the first quarter last year, respectively, resulting from the liability accounting related to the warrants issued in connection with the PIPE financing completed in June 2012. These PIPE warrants are considered a liability for accounting purposes and they are re-measured at the end of each reporting period, utilizing the Black-Scholes valuation model. As of March 31, 2015, there were approximately 500,000 PIPE warrants outstanding.

At the end of March 2015, AcelRx had cash, cash equivalents and investments of $64.4 million, compared with $75.4 million at December 31, 2014. The net decrease in cash, cash equivalents and investment was $11 million for the first quarter.

We'll now open the call up to questions.

QUESTIONS AND ANSWERS

Operator
At this time, if you would like to ask a question, you may press star, then one on your telephone keypad. If you are using a speaker phone, please pick up your handset before pressing the keys. To withdraw your question, please press star, then two. At this time we will pause momentarily to assemble our roster.

Our first question will come from David Amsellen of Piper Jaffray.

David Amsellen
Thanks. Just a couple. So you had referenced potentially exploring dispute resolution with the FDA. I guess the question on that is at what point do you go that route? Howard, maybe a little more clarity on how you're thinking about it and when you play that card. Then secondly, what are your thoughts on the wisdom of dispute resolution in the first place given that you presumably are going to eventually file on 04 and want to presumably maintain a constructive relationship with the Division. So how are you thinking about dispute resolution from that context? Thanks.

Tim Morris
Sure, David. Hi. This is Tim. Let me take the first one and we'll let Howie take the second one.

I guess in terms of how we're going to come to that decision, obviously we just found out about this on Friday. So as you know, the FDA has a number of pathways forward and one of them does include kind of a formal dispute resolution process. One of them does include kind of an informal pathway. I think once we have input from all of our legal and our regulatory advisors, plus a little bit of internal conversation, we will decide on a path forward. At such point when we have a little bit more of a definitive plan we'll obviously let the market know.

So, it's still a little bit fresh to us. We obviously have to weigh all of the potential options here, both, you know, probability of success and also keeping a good relationship with the Agency. There might be some benefits of one route versus another but it's probably too early to tell. So, from the wisdom of that, Howie?

Howie Rosen
Further to your question about ARX-04 and, you know, everything is particular to the specific facts around specific products and so oftentimes these things are just around interpretation of data or miscommunications and those types of things, and so again as Tim said, we'll focus on what makes sense for Zalviso but we'll obviously keep the bigger picture in mind as well.

David Amsellen
Thank you.

Operator
Again, if you would like to ask a question, please press star, then one at this time.

Showing no further questions, I would like to turn the conference back over to Management for closing remarks.

CONCLUSION

Howie Rosen
Thank you, Laura. So I'd like to thank everyone for attending today's call, and also we look forward to continuing to provide you with updates on our progress with Zalviso in Europe and the U.S. and the ARX-04 Phase III program. Thank you again.

Operator
The conference is now concluded. Thank you for attending today's presentation. You may now disconnect.