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 9, 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 March 9, 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 and year ended December 31, 2014 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 and Year Ended December 31, 2014 Earnings Conference Call on March 9, 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: March 12, 2015

ACELRX PHARMACEUTICALS, INC.

By: /s/ Timothy E. Morris
Timothy E. Morris
Chief Financial Officer

Exhibit 99.1

Event ID:
Event Name: [ACRX] - AcelRx Fourth Quarter and Annual Financial Results
Event Date: 2015-03-09

Officers and Speakers
Tim Morris; AcelRx Pharmaceuticals, Inc.; CFO
Richard King; AcelRx Pharmaceuticals, Inc.; President & CEO
Pam Palmer; AcelRx Pharmaceuticals, Inc.; Co-Founder & Chief Medical Officer

Analysts
Louise Chen, Guggenheim Securities
Oren Livnat, JMP Securities
David Amsellem, Piper Jaffray
Mario Corso, Mizuho Securities
Randall Stanicky, RBC Capital Markets
Boris Peaker, Cowen and Company
John Newman, Canaccord Genuity

Presentation

Operator: Good afternoon, and welcome to the AcelRx Pharmaceuticals fourth quarter and annual financial results conference call.

(Operator Instructions)

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 Richard King, Chief Executive Officer, and Pam Palmer, our Founder and Chief Medical Officer.

Today's call we will deviate from the standard agenda and focus our attention on the press release issued earlier today about the refiling timeline of Zalviso. The press release for the fourth quarter and full year 2014 financial results was also issued today, March 9, 2015. We refer you to the press release for more detailed information on our financial results, as we will only cover these in top line on this call.

During the call today we will make forward-looking statements, including, but not limited to, statements related to future financial results, including 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's product candidate, including Zalviso and ARX-04; the CRL issued by the FDA for Zalviso; the Type A meeting held with the FDA to discuss the CRL and the proposed Type A meeting to discuss the latest FDA requests; the tasks we have completed to address the issues raised in the CRL, and anticipated resubmission of the Zalviso NDA to the FDA, including the scope and potential timing of the resubmission and FDA review time; the impact, if any, of the FDA's review of the amendments to the Zalviso NDA that were not previously reviewed; a potential clinical trial for Zalviso; planned initiation of the Phase 3 clinical trial for ARX-04 and additional ARX-04 development activities; a potential contract with the DOD to receive development support for ARX-04; and the therapeutic and the 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 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 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; its ability to obtain sufficient financing; the success, cost and timing of all development activities and clinical trials, including the planned Phase 3 ARX-04 trial; the market potential for its product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and needs for financing; and other risks detailed in the Risk Factors and elsewhere in AcelRx Pharmaceuticals' US Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on November 10, 2014. 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 turn the call over to Richard, President and Chief Executive Officer.

Richard King: Thanks very much, Tim, and I'd like to thank everyone for joining us this afternoon for the year-end call.

As Tim mentioned and for obvious reasons we'll focus this call on the regulatory update to Zalviso announced by press release this morning.

Late last week we received correspondence from the FDA stating that, in addition to the bench testing and two human factor studies, an additional clinical study is needed to assess the risk of inadvertent dispensing and the overall risk of dispensing failures. There was no specific reference to a need for a clinical study in the CRL that we received for Zalviso in July 2014. Indeed, the only specific request for study conduct in the CRL related to the inadvertent dispensing issue and requested that the Company complete human factor studies to assess the mitigations implemented to address this issue.

As a reminder, the two key issues related to the Zalviso NDA review that the agency asked us to address in the CRL were to reduce the high-single digit rate of system errors observed in the Phase 3 program related to analgesic gaps and to mitigate the risk of inadvertent dispensing which was identified in 7 of the 768 patients treated with the Zalviso System in Phase 3, resulting in 15 doses out of a total of approximately 30,000 doses that were found in bedclothes or the system dosing cap. During our September meeting with the FDA we agreed to provide the agency with protocols for the bench testing of the design modifications made to address the system error issues identified in the CRL as well as human factors protocols requested in the CRL to assess the mitigations of the inadvertent dispensing issue.

In addition, the agency requested in the minutes to the meeting that we provide a risk assessment that analyzed the risks associated with inadvertent dosing and the rationale that bench testing and human factors studies are sufficient to address the specific items included in the CRL. We prepared and submitted the protocols and this rationale in November 2014. We received feedback on the bench testing protocol in January 2015. The agency requested some adjustments in the bench test protocol, mainly in the data analysis to be performed from the study results.

We have completed the bench test on 711 systems and have demonstrated a significant reduction in Zalviso System errors that might lead to an analgesic gap from the high-single digit rate seen in Phase 3 to a new rate of 1.55%. During this bench test we dispensed over 50,000 tablets, or over two-thirds more than we dispensed in the entire Zalviso Phase 3 program. And in addition to the substantial error rate reduction from Phase 3, the 1.55% error rate was below the target outlined in our protocols reviewed by the FDA and substantially lower than the 12% analgesic gap rate reported in the literature for current standard of care, IV PCA.

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 factors protocols. We completed the human factors studies in two populations, normal volunteers and postoperative patients. The defined acceptance criteria for each protocol were met, with HCPs and patients demonstrating ability to follow the refined set of instructions contained in the IFU.

While the design and results of the bench test and the HF work will be subject to review by the FDA, we believe that the results demonstrate that significant improvements to the system functionality have been accomplished, that these tests are relevant in completing this assessment and thereby are pertinent in addressing the associated items included in the CRL. At this time, we have not shared the results or had the opportunity to share the results of these tests with the agency.

We were diligently working with the agency and conducting the requested studies to resubmit the NDA, and preparations for that resubmission were on schedule. Last week's correspondence from the FDA was therefore unexpected. We plan to meet with the FDA to discuss and clarify the request for an additional clinical study and also to discuss the potential design and objectives of such a study. As a result of this FDA communication and a need for clarity with the FDA, we will not submit the Zalviso NDA resubmission this quarter. We will provide an update on the timing of the resubmission of the Zalviso NDA after our meeting with the FDA.

I'd like to turn attention briefly to progress with the MAA review for Zalviso in Europe. As you know, we are working with Grunenthal towards the submission of the response to the Day 120 questions. Grunenthal is working to complete the response and submit by the end of March 2015, and, assuming EMA accepts this filing, we would anticipate a CHMP opinion in the summer of 2015 and a final decision by the EMA in the fall of 2015.

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

Pam Palmer: Thank you, Richard.

ARX-04 is a noninvasive single-use 30-mcg sufentanil sublingual tablet in a disposable prefilled single-dose applicator, or SDA, which is administered by a healthcare professional. The proposed indication for this product is the treatment of moderate to severe acute pain in a medically supervised setting for durations of use that would typically be less than used for Zalviso, which is often over 30 days.

We previously completed and end-of-Phase 2 meeting with the FDA to identify a Phase 3 program pathway forward for evaluation of ARX-04. Key outcomes from the end-of-Phase 2 meeting include agreement on a 500-subject safety database, 100 patients of whom should be studied with multiple doses of ARX-04; agreement that the bunionectomy Phase 2 study was an adequate and well-controlled study and could be used as a pivotal study; agreement that a single additional Phase 3 pivotal efficacy and safety study in a model of visceral pain would be sufficient to support an NDA submission; and agreement that the primary endpoint in the remaining Phase 3 study could be the SPID-12, with a secondary endpoint following patients out to 48 hours.

In June of 2014 we completed a pharmacokinetic study in support of the ARX-04 development program. In this study in healthy volunteers it was shown that the pharmacokinetics of two sublingual administrations of a Zalviso 15-mcg sufentanil tablet dosed 20 minutes apart were comparable in terms of AUC exposure and peak plasma concentration to one sublingual administration of an ARX-04 30-mcg sufentanil tablet.

As a result of this study, we have proposed the inclusion of a number of patients from the Zalviso clinical program in the ARX-04 safety database to the FDA. We have confirmation from the FDA that some of the Zalviso patients can be included in the overall ARX-04 safety database. However, further discussion is needed to determine the exact number of such patients that can be used toward achieving the 500-patient minimum total safety exposure number required for ARX-04.

The single Phase 3 pivotal study requested by the FDA is Study SAP301, a multicenter, double-blind, placebo-controlled study 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 randomize up to 180 adult patients randomized two to one 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.

The primary endpoint of this study is to demonstrate a statistically significant difference in the time-weighted summed pain intensity difference, or SPID, of ARX-04 compared to placebo over a 12-hour dosing period, also known as a SPID-12. The study will be conducted at four sites in the United States. We anticipate that enrollment will take up to nine months. Pending the completion of enrollment in the study, we anticipate top-line results in the fourth quarter of 2015.

In 2015 we plan to initiate a second Phase 3 clinical trial of ARX-04. While this is not mandated to satisfy the regulatory requirements for ARX-04, it will be beneficial to understand how the application of ARX-04 treats trauma-related to moderate and 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 also wanted to provide an update on potential DOD funding. We have been notified by the DOD that they are preparing a contract to provide partial funding for the further development of ARX-04. We are engaged in the contracting process with the DOD to determine the nature, scope and timing of the contract.

As a reminder, in 2011 the DOD provided us a $5.6 million grant to support Phase 2 development of the program. The DOD continues to express keen interest in a potential product like ARX-04 to treat wounded soldiers in the battlefield. We will update the market as we finalize the contract with the DOD.

ARX-04 represents a promising new application of our sublingual tablet technology for delivery of sufentanil and has the potential to safely provide fast-acting analgesia for patients in moderate to severe pain. We believe ARX-04 may ultimately be used in a variety of medically supervised settings to manage moderate to severe pain, including in the emergency room or for postoperative patients who are transitioning from the operating room to recovery floor or who are recovering from either short stay or ambulatory surgery who do not require more long-term patient-controlled analgesia. Additional uses may also be for battlefield casualty treatment and by paramedics during patient transport.

The emergency room represents the single largest market segment, reflected by data from the National Emergency Department Sample, or NEDS, which reported more than 104 million adult emergency room visits during 2011, of which it is estimated that more than 48 million were associated with a moderate to severe acute pain. ARX-04 would obviate the need for the HCP to set up an IV in the ER to provide pain relief to the patient, which can be time-consuming in an environment that is always pressed for resources.

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

Tim Morris: Thank you, Pam.

Earlier today we reported our financial results for the quarter and year ended December 31, 2014. I refer you to that press release for details on the actual results.

As of December 31, 2014, AcelRx had cash, cash equivalents and investments of $75.4 million. This compares to $103.7 million at the end of December 2013. The decrease in cash during the year was driven mainly by cash used in operations and investing activities of $40.2 million, primarily offset by the $10 million drawdown of the second tranche of the loan agreement with Hercules and the receipt of $1.9 million from the exercise of stock options and the purchase of stock under Employee Stock Purchase Plan.

Given the recent update, it is difficult for us to give any financial guidance for the year at this present time. Cash burn in the fourth quarter was approximately $10 million. I would anticipate the burn in Q1 2015 to be approximately the same. Once we have determined the impact of the recent FDA request, we will adjust our planned spend and sources of cash accordingly.

Now we'll open the call to some questions and answers.

Questions & Answers

Operator: (Operator Instructions)

And our first question will come from Louise Chen, of Guggenheim.

Louise Chen: Hi. Thanks for taking my questions. I had a few questions here. First question I had was about your cash burn and time to market for Zalviso. I know you can't comment exactly what the change will be, but could you lay out some scenarios, likely scenarios, of how to think about that? And then secondly how surprised were you at the additional trial required by the FDA? And then lastly, just on the opportunity for ARX-04, do you plan to market this drug yourself? What is the peak sales potential here? And what is the cost of development for the product? Thank you.

Richard King: Tim, do you want to take --?

Tim Morris: Sure, Louise. As I mentioned momentarily ago, or briefly ago, the cash burn in the last quarter was about $10 million. I'd expect that to be fairly similar in the first quarter here. Obviously it's too early for me to speculate in terms of the duration of that. We do feel relatively comfortable that we can get with the existing resources clearly all the way through 2015 and into 2016, but it's difficult for me to comment as to the potential timing for commercialization of Zalviso until we've met with the agency.

Richard King: And then in terms of the question related to surprise, Louise, yes, we were surprised. The CRL was fairly specific in calling for human factors studies as the pathway to address the issues raised in the CRL, to address the inadvertent dispensing issue. And we were proceeding in accordance with that instruction from the FDA. So the recent request for a clinical trial wasn't expected, and we are now in the process of responding to that request.

Tim Morris: ARX-04.

Richard King: And just remind me what the question on ARX-04 was, sorry.

Louise Chen: Peak sales potential here, do you plan to market yourself, and then lastly just the cost of development for the product.

Richard King: Okay, so peak sales, we haven't identified a number out there, but we have talked about the market opportunity. Pam referenced the fact there's about 50 million, 40 million or so patients in the emergency room on an annual basis with moderate to severe acute pain. The majority of those get opioids.

And when we went and did some survey work of ER physicians talking about the product profile for ARX-04, they talked about the majority of those patients receiving ARX-04 in preference to what they would currently do, which is typically set up an IV and provide an opioid through an IV for that patient in moderate to severe acute pain. So that gives you some sense of the volume.

We would typically expect probably a couple of doses in that ER setting before the patient would be either admitted to the hospital for further follow-up, which is the less likely case, or more likely they would return home. We haven't talked about a price point at this stage for the product. But certainly at a volume level we're seeing robust interest in the ER setting that could translate into significant volume of doses at a price point that would be a reasonable price point.

In terms of the cost of the development program, Tim, the cost overall for the program? Have we about it publicly?

Tim Morris: Yes, no, we haven't provided any specific details there. We have said that the current planned Phase 3 study should be approximately $4 million to $5 million. I think once we've finalized our contract with the DOD we'll be able to give a much further report, so I would stay tuned for that.

Louise Chen: Okay, thanks a lot.

Operator: And the next question will come from Oren Livnat, of JMP Securities.

Oren Livnat: Thanks for taking the question, and sorry for your challenges. I guess the biggest question to me, given that I'm mostly baffled, as well, by their request or what their objective, is in Phase 3, did you in fact per your protocol account for all inadvertent dosing and/or optical errors in your efficacy data? In other words, if somebody had a jammed system and the nurse had to come in and deal with it and they missed their dose as a result of that, was that considered a fail, assuming their pain came back, and that was included in the data and carried forward and already baked into your superior data versus placebo and IV PCA?

Pam Palmer: Hi, yes, absolutely. I mean, certainly we collected any data that related to system failures. But you're absolutely right, I mean, regardless of what happened, whether there was a dropout due to an adverse event, whether there was inadequate analgesia, regardless of whether there happened to be a system error or not, all of that was assessed in the patients. And so the high-single digit analgesic gap here that we saw was, as you said, baked into the primary and secondary endpoints already. And since it was in fact lower than what has been published for IV PCA, which is the current standard of care, we were in fact a little surprised that it was even suggested to have it lowered. But as you can see from the data we presented today we've been able to do that. However, the agency has not had the time yet to look at that data.

Oren Livnat: Can you comment on, I guess, the language of their latest letter? When you've communicated to us that they want to have you further assess the risk of inadvertent dosing and overall system errors, do you read that to mean the risk of -- I mean, the rate of those occurrences, meaning just further characterizing the physical performance of this product, or do you read risk to mean the impact on the outcomes to a patient with regards to safety and efficacy?

Richard King: I think we read it as the former, Oren. What we don't -- the terms that have been used, dispensing failures, for example, it's unclear what is to be included or not included in that term dispensing failures. It's a new term. We haven't used that term before. So we have a need to qualify what the agency is looking for in looking for the overall risk of dispensing failures. But we do believe it's a quantification and it's a rate that is specifically being asked for as opposed to, if you like, an assessment, a risk assessment.

Oren Livnat: But as far as you know, assuming that the caliber of your data to date in Phase 3 is what we all believe it to be, can you even fathom what an additional quote, unquote, clinical trial could teach us with regards to the inadvertent dosing or dispensing failures of this product? Or would -- are human factors studies essentially as close as you're going to get to a real-world performance?

Richard King: That's a great question, and I think that the difference clearly between a clinical study and a human factors study, clinical studies are designed to address clinical questions, human factors studies are often designed to address can instructions and can devices, tools be handled to provide support to a patient. We in our execution of our human factors studies certainly viewed the ability for the human factors study to assess the ability for a patient to follow the revised set of instructions that were designed as mitigations to the risk of an inadvertently dispensed tablet, felt that was an appropriate test vehicle. We felt quite comfortable with that test vehicle, and certainly that was the specified test vehicle in the CRL.

So it is difficult to -- for us at this stage. The agency probably has something in mind that they're thinking of. We'll need to explore that with them and understand in a bit more detail where they would like to explore from a clinical standpoint beyond the information that's already available from the studies that we've completed, both clinical and human factors and bench testing studies.

Oren Livnat: And at the risk of dragging on -- I apologize to anyone else in the queue -- is there any part of you guys and your lawyers telling you and different consultants that perhaps this -- you come out of this, whether it's in a friendly manner or dispute resolution fashion, with not having to do any quote, unquote, clinical study and going forward?

Richard King: I think that would be speculation at this stage. I think we need to get into that discussion with the FDA to -- and ideally for them to see the data available at hand that they haven't yet seen from our bench testing work as well as from our human factors work that would allow that question to even begin to be answered. But at this stage I don't think we'd be allowed to speculate on that.

Oren Livnat: Thanks so much.

Operator: And next we have a question from David Amsellem, of Piper Jaffray.

David Amsellem: Thanks. Just a couple. So first, Richard, what does this all mean in terms of the planned transition that you had discussed previously, and is the plan for you to see this all the way through to approval? And then, secondly, do you think that what's happening here in terms of this request for a trial has anything to do with the leadership changes in the division, and is there anything that we should read into those changes as it relates to the latest setback? Thanks.

Richard King: Okay, so on the first issue from a leadership change standpoint, I'm going to refer that back to the Board. The Board continues to pursue its planned transition for leadership of the Company and will address this in a timely fashion. I think it would be wrong of me to speculate on behalf of the Board as to that pathway.

On the second issue, yes, this division's seen quite a bit of change recently with the retirement of the former division director and the -- his replacement continuing to provide acting support for the division at this stage. I don't know, it'd be wrong to speculate that that had anything to do with this issue. It would be certainly wrong to speculate that. I think that we have to take it on its merits, on the request for additional information, and respond to that request based on the data that we have to hand and the provision of that data in a timely fashion to the agency. That's the right way to approach this and to manage it, I think.

David Amsellem: And if I may sneak in a quick follow-up, but clearly something has changed within the division in terms of what they think is necessary. I mean, what you're being asked to do is very, very different from what was in the CRL. So I guess the question here is can you speculate as to what did change?

Richard King: I could speculate till the cows come home, but I'm not sure we'd get it anywhere. One thing I can say, the information on the product, apart from some additional bench testing work now and some human factors work, has not changed. The product profile didn't change during that time to, I think, transition from a CRL to a human factors study. So something else did. I would hate to begin to speculate, David. It's difficult to go down that road, I think.

David Amsellem: Okay. Thank you.

Operator: And next we have a question from Mario Corso, of Mizuho.

Mario Corso: Good evening. Thanks for taking my questions. Not to beat a dead horse, obviously, but in terms of your future interactions with the FDA, I think it was a teleconference last time, and do you expect a face-to-face meeting this time? And I would imagine that you'll go into that meeting prepared to not only present a summary of the human factors and bench testing but also preparing potential designs of a clinical trial. So I'm wondering what you think the timeline to that meeting might be. And is there anything analogous, any analogous situations you can find in the industry that you think may help you? And then, finally, in terms of the EU review, were any of these issues, dispensing errors and system errors, have they been highlighted at all in the 120-day questions? Thanks.

Richard King: All right, so let me try and deal with the first element. Certainly a face-to-face meeting with the agency would be helpful, I think, to ensure that they have some familiarity with the data that we've generated in the course of preparing to respond to the CRL and then to have a broader dialog, I think, in the face of that data around what the clinical profile and clinical expectations might be coming out of a clinical study that the agency has identified as needed here. So that would be, I think, beneficial. We don't control that. That'll be -- the agency will decide on that format for that meeting. But certainly it would be helpful.

I don't have any analogous situations that I can think on. I don't know whether anybody else does around the table. But I would struggle.

And then the last question related to --

Tim Morris: EU, the impact of the 120-day questions.

Richard King: Yes, so, Pam, you'll probably have some more familiarity with those questions than anybody else. What would you comment on in relation to? Is there anything in those 120-day questions that kind of identifies the same set of issues or focuses heavily on those?

Pam Palmer: Well, the EMA, I mean, handles drug/device combination products quite differently. The device really is through the CE Mark, and the functionality of the device and meeting its specifications are really governed through that pathway. So, no, the vast majority, in fact every single one of the questions relating to the 120-day questions were about the drug in very, very detail, about the different populations, about adverse events, about efficacy, etc. They really do distinguish between the dispensing and the device aspects of the drug and the actual drug itself, which is different than the FDA. And that's the issue with the FDA is CDRH versus CDER and the interactions between them and how that plays out I think makes it a bit more difficult, maybe, than you would find with the EMA.

Richard King: And, just as a reminder, on the European front we did receive a CE Mark associated with the device toward the end of last year. So this device is effectively approved for use in Europe. It's pending the approval of the drug going through the EMA.

Mario, was there any other question that you had that we didn't address?

Mario Corso: No, I guess the other piece of that was just in terms of will you be prepared or are you preparing potential trial designs to bring to the FDA, or in fact do you argue -- I guess you would have to argue, at least in part, that another trial might not be needed, correct?

Richard King: Yes, we've got to go explore, I think, all the different options and do so in a Type A meeting format, and that would certainly be our plan.

Mario Corso: Thank you.

Richard King: Thanks, Mario.

Operator: And the next question will come from Randall Stanicky, of RBC Capital Markets. Mr. Stanicky, your line is open.

Randall Stanicky: Sorry, can you hear me, guys?

Richard King: Yes.

Randall Stanicky: Thanks. Are you guys comfortable or confident that this is specific to your device, there's not a broader drug/device opioid in the hospital setting read here? And then the follow-up would be, Richard, can you just talk about the competitive dynamics as you see this marketplace? I mean, if you're delayed -- I don't know, it's hard to put a time frame on it, but if you're delayed 6 to 12 months and we're looking at next year or mid-next year in terms of a launch, how do you see the market forming? Obviously you're not the only one coming to market. Thanks.

Richard King: Okay, maybe, Pam, you might speak to the is this a device-specific issue or does it have some rollover play into the opioid device delivery vehicle based on comments from the agency?

Pam Palmer: Well, I mean, it wouldn't be a surprise to anybody if I said that it's a trying time for opioids in general. The Zohydro uproar, etc., that came down the agency, I mean, who knows really how that is playing out? It's surprising, though, to me, because opioids in a home environment, if you think about how little they are regulated once they sort of leave the pharmacy and go home, I mean, they're sitting in medicine cabinets, they're sitting out on sinks, they're in a little amber twist-off bottle if you're lucky, otherwise they're in a Monday-Tuesday-Wednesday-Thursday-Friday pill container with no security or locks whatsoever.

So I think that outpatient use of opioids is a dicey issue, does -- is fraught with concerns. However, I see the inpatient monitored setting of extremely short-duration use drugs for one or two days as a highly differentiated environment. And so, while the uproar over opioids could spill into that environment, I think it's inappropriate if it does. And so that's the way that I'm sort of looking at this and moving forward.

Richard King: And then on your second question, what's the delay imply for the competitive dynamics and environment, it has to imply something. Ionsys has a PDUFA date later this year. So would a lag of let's -- I think you said a year be impactful? The answer has to be yes.

But, having said yes, I would give, firstly, the profile of Zalviso is particularly strong, particularly relative to Ionsys. Secondly, we believe that we can more closely match the needs of the institution, its buying process, etc., with Zalviso. And thirdly I would add that we have a long pathway to run from a commercial opportunity standpoint. Our IP is out through 2027 to 2031, giving us a lot of time to go and make commercial headway with Zalviso. That doesn't change how we think about Zalviso internally, and it doesn't change how we perceive the opportunity for Zalviso to create a new standard of care in this postoperative acute to severe, moderate to severe pain management environment.

Randall Stanicky: And, Richard, if I missed it, did you -- do you guys have a date or a time frame in mind of when you're going to meet with FDA?

Richard King: As soon as possible.

Randall Stanicky: Okay. And how will you let us know what comes of that meeting? Will you release that?

Richard King: Traditionally -- Tim has to remind me. Have we released the outcome on these?

Tim Morris: We'll try to provide updates as they happen in some format, whether it's a quarterly call or conference or even an 8-K. So we will try to give you a current update on the timeline once the meeting has transpired.

Randall Stanicky: Okay. Thanks, guys.

Operator: And the next question comes from Boris Peaker, of Cowen.

Boris Peaker: Good evening. I guess I just want to probe a little bit into the bench test that you've conducted. I'm just curious, how would the use of the device be different in that test versus from what was actually happening in the clinic? And also in the bench testing, what was the -- what kind of subjects were you using, maybe age or any demographic elements, compared to the actual clinical studies?

Richard King: Okay, so in a bench test what we're doing is setting up devices on a mechanical jig, and instead of a patient's thumb pushing the dosing button it's actually a mechanical device pushing the dosing button with a thumb tag on that push [mod] that's basically pushing the dosing button. That's really the only difference. The angle at which the systems are set up to dose is typically what we would expect to see the angle of dispensing in the clinic. And I guess we set up banks of these things to do them rapidly rather than waiting for establishing those actually in the hospital environment. But the mechanics of what the device is doing are exactly identical.

Boris Peaker: Okay. And when you spoke to the FDA, I guess, regarding this study, did they want actual human testing, or did they say just purely mechanical, automated testing would be adequate?

Richard King: So certainly when we presented the protocols for bench testing to the agency they reviewed those protocols. The commentary back was your protocols are fine subject to a couple of ways in which you analyze the data. But fundamentally the work associated with the protocols was validated and supported by the FDA commentary. That's the reason why we're surprised with the request now for a clinical study.

Boris Peaker: Got you. And this is my last question. I guess since your last communication -- or how many communications have you had with the FDA since the CRL, and was there something that's submitted that you think that could've kind of triggered their thought process on bringing in a new study as part of that communication?

Richard King: Obviously the primary communication was the Type A meeting that we held in September. Other than that, we have had backwards and forwards on protocols, mostly for ARX-04, actually, but I'm not sure we've had any other formal meetings with the agency other than that Type A meeting.

Boris Peaker: Great. Well, thank you very much for taking my questions.

Richard King: Thanks, Boris.

Operator: And next we have a question from John Newman, of Canaccord.

John Newman: Hey, guys. Thanks for taking my question. Actually I have two questions. So when you met to discuss the concerns with FDA, first meeting after the Complete Response Letter, did you specifically ask the agency if a clinical study would be required to address them? And also has the FDA ever made any comments or raised any questions pertaining to the changes that have been made to the device in relation to what type of data would be required?

Richard King: We did not specifically ask the agency if a clinical study was needed. The CRL was fairly specific in that the -- I'll take the inadvertent dispensing example. The CRL called for modifications to the system or to the instructions that would be tested in human factors, and it was very explicit in that regard. So we did not ask that question. And then the second part of your question, John, just repeat it again for me.

John Newman: I just wondered if the FDA ever made any comments or raised any questions regarding changes to the device in a way that suggested concern that might warrant other studies.

Richard King: No, the agency -- again, let's take that inadvertent dispensing issue, requested us to modify the system or the instructions such that the risk of inadvertent dispensing could be mitigated and test that through human factors. They don't tend to specify or get involved in what changes might be relevant. They leave that up to the sponsor. And we've been diligently going through the process of looking at root causes, understanding what might be those root causes, and then addressing those root causes through our instructions in the case of the inadvertent dispensing, for example, which we then tested in human factors.

John Newman: Okay. And the last question is just in terms of the plan to go forward with ARX-04 in terms of the Phase 3 trial that's planned and the second that's contemplated, I'm just wondering, do you think that might be affected based on what you learn from the FDA when you meet with them on Zalviso? Just it seems like the spending is -- well, it's manageable, but I'm just curious if that might be altered depending on what you learn when you meet with FDA.

Pam Palmer: We're currently going forward with the SAP301 study. It's a relatively small study, total of, as I mentioned before, about 150 patients all in, with a cost of under $4 million. We are expecting a significant amount of money from the Department of Defense to complete the rest of the work that we need to do, and, again, we will have that information hopefully sooner than later. But we are moving forward with ARX-04, and I don't see it at all affected by the current issues with Zalviso.

Richard King: Yes, remember, it's quite a – (inaudible) uses the same pill. It's a very simple applicator that we use and the healthcare professional uses to place the pill under the tongue. And there's nothing that we see as, if you like, a clinical data read through, more of a device-related set of questions that the agency continues to raise on Zalviso. But that is not the case with ARX-04. It's a simple applicator that the healthcare professional uses to place the NanoTab onto the patient's tongue. So we don't particularly see any read through, I think, from that sector.

John Newman: Okay. Great. Thank you very much.

Richard King: Thanks, John.

Operator: And next we have a follow-up question from Oren Livnat, of JMP Securities.

Oren Livnat: Thanks. If I could just quickly follow up on the bench testing issue, you saw high-single digit in Phase 3, and you are now at a 1.55% error rate. Are those numbers apples to apples -- i.e., before your device changes were you seeing yourself in bench testing high-single digit error rates so that one can assume whatever rate you're now getting on the bench should carry across into the real world?

Richard King: Yes, and that's a great question, Oren. So there was a bench test that was completed with the Zalviso System. I can't remember the exact dating on it, but the Phase 3 Zalviso System. And not exact correlation, but very close correlation was seen between that bench test and the experience in the Phase 3 program. So we -- I mean, that was part of the response to the FDA was identifying that that correlation did exist and therefore we felt that bench testing was appropriate as a vehicle to test the revised system changes that we put in to offset this set of errors that we were seeing in the clinical environment.

Oren Livnat: All right, thanks.

Richard King: So, are there any more questions, or are we clear at this stage?

Operator: No, there are no further questions. I was just going to turn it back to you for closing remarks.

Richard King: Thank you. So, with that I'd like to thank everybody for attending today's call. We appreciate it. Obviously it's been a fairly busy couple of days here as we've begun to prepare our response to the agency's request for additional work. We feel that we're headed down that pathway towards better clarification with the agency through a meeting and in the meantime moving forward with both ARX-04 in Phase 3 as well as with the European work to approve Zalviso for Europe.

Thank you again for your attention, and we'll look forward to catching up on our next call.

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