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): November 10, 2014

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 November 10, 2014, AcelRx Pharmaceuticals, Inc., or the Company, conducted a conference call during which the Chairman of the Board of Directors of the Company and members of its senior management team discussed a business update, financial results for the third quarter ended September 30, 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. Third Quarter Ended September 30, 2014 Earnings Conference Call on November 10, 2014, 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: November 13, 2014

ACELRX PHARMACEUTICALS, INC.

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Transcript of AcelRx Pharmaceuticals, Inc. Third Quarter Ended September 30, 2014 Earnings Conference Call on November 10, 2014, at 4:30 p.m. ET.

Exhibit 99.1

Event ID:
Event Name: [ACRX] - AcelRx Q3 Financial Results
Event Date: 2014-11-10

Officers and Speakers
Tim Morris; AcelRx Pharmaceuticals, Inc.; CFO
Adrian Adams; AcelRx Pharmaceuticals, Inc.; Chairman
Richard King; AcelRx Pharmaceuticals, Inc.; President & CEO

Analysts
Louise Chen, Guggenheim Securities LLC
Randall Stanicky, RBC Capital Markets
David Amsellem, Piper Jaffray & Co.
Boris Peaker, Cowen and Company
Ed Arce, Roth Capital Partners
Biren Amin, Jefferies & Company
Kevin Dai, Canaccord Genuity
Oren Livnat, JMP Securities

Presentation

Operator: Good afternoon, and welcome to the AcelRx Pharmaceuticals Q3 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. Please go ahead, sir.

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

On today's call I'm joined by Richard King, Chief Executive Officer, and Adrian Adams, the Chairman of the Board. In today's call we will provide an update on the activities since the receipt of the Complete Response Letter, or CRL, for Zalviso that we received on July 25, 2014. We will discuss the progress on the European regulatory approval of Zalviso. We'll provide an update on ARX-04. We'll review the financial results for the quarter and nine months ending September 30, 2014. We'll update our financial guidance for the remainder of 2014. And, lastly, we will take your questions.

During the call today we will make forward-looking statements, including, but not limited to, the Company's Zalviso NDA and the CRL; our plans to address the issues raised in the CRL; our anticipated resubmission of the Zalviso NDA to the FDA, including the scope of the resubmission, the timing of the resubmission and the FDA review time; planned initiation of the Phase 3 clinical trial for ARX-04; the therapeutic and commercial potential of AcelRx Pharmaceutical's product candidates, including Zalviso; statements related to future financial

results, including 2014 financial guidance and cash forecast; potential milestones and royalty payments out of the Grunenthal agreement; the process and timing of the submission of the marketing authorization application, or MMA (sic, see press release - MAA), and the CE registration in the EU; and the status of the collaboration agreement with Grunenthal or any other future potential collaborations.

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 Pharmaceuticals' 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; our ability to obtain sufficient funding to commercialize Zalviso and proceed with the clinical development of ARX-04; the success, cost and timing of all product development activities and clinical trials; and other risks detailed in the risk factors and elsewhere in AcelRx Pharmaceuticals' US Securities and Exchange Commission filings and reports, including our Quarterly Report on Form 10-Q filed with the SEC on August 11, 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 Adrian Adams, the Chairman of our Board of Directors.

Adrian Adams: Thank you, Tim, and good afternoon, everyone.

The Company has asked me to join the call today on behalf of the Board of Directors to comment on the announcement made last week of the departure of Richard King, the Company's President and Chief Executive Officer. The decision made by the Board of Directors was not made lightly, and it reflects our strong desire to seek a President and Chief Executive Officer with the proven experience and capabilities to take the Company into the next and most important phase of its evolution.

The Board of Directors has initiated a search for a new President and Chief Executive Officer, and we are pleased that Richard has agreed to remain with the Company as President and Chief Executive Officer while the search is ongoing and until the new CEO is in place. Speaking for the Board and the whole Company, we sincerely thank Richard for his significant contributions in leading the Company to this point, including its transition to a public company, multiple capital-raising transactions, an important partnering transaction with Grunenthal, and the Zalviso and ARX-04 clinical developments.

Finally, I and the Board would like to emphasize that we remain confident about the Zalviso and ARX-04 development programs, the work that is being done towards a timely resubmission of the Zalviso NDA in the first quarter of 2015, and last, but certainly not least, the potential for this company to create significant shareholder value.

With that, I will now turn the call over to Richard for a discussion of the business activities and to provide a regulatory update on Zalviso.

Richard King: Thank you very much, Adrian, and I'd like to thank everyone for joining us this afternoon for this call. I plan to address progress for Zalviso in the US and in Europe, progress on the patent front, and provide an update on status with ARX-04.

As we have previously discussed, in the US the FDA issued a Complete Response Letter, or CRL, for the Company's NDA for Zalviso. The CRL contains requests for additional information on the Zalviso system to ensure proper use of the device. The requests include submission of data demonstrating a reduction in the incidence of optical system errors; changes to the instructions for use for the device to address inadvertent dosing; and submission of additional data to support the shelf life of the product, among other things.

At the end of September we held a teleconference with the FDA to review our proposed response to the Zalviso CRL. Prior to the meeting we had provided a briefing document outlining plans for our response to the aforementioned issues in the CRL. During the teleconference with the FDA we confirmed that bench testing could be an acceptable approach to evaluate the reduction in optical system errors, subject to agency agreement with the test protocol and the target optical system error rate. We plan to submit the bench test protocol to the agency for review and comment shortly.

The protocol will clearly delineate all planned changes to reduce the optical system error rates, including addressing specific questions raised by the agency in its written response to the Company's proposal. To address the risk of inadvertent misplacement of tablets, we propose mitigations to the Zalviso system and IFU and to test these mitigations by way of a Human Factor Study. The protocol for the Human Factor Study is the final stage — is in the final stages of completion and will shortly be submitted to the FDA for review and comment.

In the CRL the FDA specified that the appropriate test mechanism to evaluate mitigations for the inadvertent dispensing of tablets is via a Human Factor Study. We believe that the protocol we are preparing for review by the agency to evaluate the mitigations that we propose for this issue should meet the requirements specified by the agency. At the same time as we submit the human factors protocol, and at the request of the agency, we will also provide a rationale for why clinical evaluation of these mitigations is inappropriate and unnecessary. We hope to receive feedback on both of the items in the response from the FDA.

The agency, of course, always preserves the right to decide on the adequacy of the design of a study to address any given question as well as the right to determine if the data from that study satisfactorily addresses the questions being asked. The FDA confirmed that the review of these responses will qualify as a Class 2 review, requiring a six-month review clock. The agency also confirmed that the adequacy of the bench test study and the Human Factor Study and the results of each study will be subject to final review and approval by the FDA.

We also proposed including additional stability data in the resubmission to support the proposed 24-month shelf life of the Zalviso system. The FDA has agreed with this approach, subject to review of the data previously submitted and to be submitted.

Based on the communications with the FDA and subject to the timing of the FDA review and comment on protocols to be submitted for the bench testing and Human Factor Study, we are targeting resubmission of the Zalviso NDA in the first quarter of 2015. However, depending on feedback from the FDA on the protocols and the materials to be submitted, the timing of filing of the NDA could be late in the first quarter of 2015.

Now let me turn attention to progress with Zalviso in Europe. As you are aware, we are progressing towards CE Marking the device components of the Zalviso system. There are two stages to securing a CE Mark. The first requires AcelRx's quality systems to be ISO 13485 certified, and the second requires a technical review of the Zalviso system.

Recently, an audit of our quality systems was completed by our notified body, the British Standards Institute, with no major or minor observations recorded. As we announced earlier today, AcelRx has now received ISO 13485 certification validating AcelRx's quality systems. This certification is the first step towards obtaining a CE Mark.

We are also pleased to confirm that BSI is in the process of reviewing the Zalviso technical file. Assuming BSI finds the technical file to be acceptable, we anticipate obtaining a CE Mark for the Zalviso device in the near future.

Continuing with Europe, the marketing authorization application, or MAA, review, continues in Europe through our marketing partner, Grunenthal, with 120-day questions from the EMA expected later this month. I'm also pleased to announce that Grunenthal has submitted an MAA to the Swiss Agency for Therapeutic Products, also known as Swissmedic, for Zalviso for the management of moderate to severe acute pain in adult patients in a medically supervised environment.

We are pleased with the regulatory progress Grunenthal has made with Zalviso in Europe, initially with the filing of the MAA with the EMA, and now the filing with Swissmedic. We look forward to Swissmedic's review of the application and to the potential approval of Zalviso in Switzerland.

In October of this year we provided an update on additions to our intellectual property portfolio. Since late last year we have received 11 issued patents, including both pharmaceutical and device patents, with a combination of composition and method claims, which expand the scope of protection for both Zalviso and our pipeline programs. Our growing patent estate now totals 30 issued patents worldwide.

These issued patents cover AcelRx's sufentanil Nanotab, medication delivery devices and platform technology, and include 13 issued US patents, four issued European patents and 13 issued patents in other international territories, including Japan and China. These issued patents are expected to provide coverage through 2027 to 2030.

Turning attention now to ARX-04, as previously announced in June 2014 we completed a pharmacokinetic study in support of the ARX-04 development program. In this study of healthy volunteers it was shown that two sublingual administrations of a Zalviso 15-mcg sufentanil tablet dosed 20 minutes apart were equivalent to one sublingual administration of an ARX-04 30-mcg sufentanil tablet.

As a reminder, the total ARX-04 safety database required by the FDA is 500 patients comprised of 100 patients receiving multiple doses of ARX-04 and 400 patients receiving a single dose. We have proposed the inclusion of approximately 300 patients from the Zalviso clinical program in the ARX-04 safety database to the FDA to partially address the 400-patient single-dose safety database requirement. We are seeking FDA agreement on this proposal, and we have designed the two Phase 3 ARX-04 trials accordingly.

In addition, I am pleased to announce that in response to a proposal submitted earlier this year we have been notified by the Department of Defense that AcelRx has been offered a contract to provide funding for the development of ARX-04, including funding for the proposed Phase 3 studies. We are in the process of completing the initial contracting process with the DOD, including negotiation of the amount and timing of the contract.

Currently we plan to defer the initiation of the ARX-04 Phase 3 trials until the contract is complete. We anticipate the contract negotiation process to conclude in the first quarter of 2015, allowing us to initiate the two Phase 3 studies shortly thereafter. However, if negotiations with the DOD become protracted, we may elect to initiate the first trial on our own rather than sustain additional delays. However, if current negotiations are successful, we believe the contract will provide significant funding for the development of ARX-04.

On the medical affairs front, we announced the results from the IAP310 study have been published in Regional Anesthesia and Pain Medicine, or RAPM, a peer-reviewed journal with broad, multidisciplinary readership. IAP310 was a randomized, placebo-controlled Phase 3 trial evaluating the safety and efficacy of Zalviso, also referred to as the sublingual sufentanil tablet system, or SSTS, for the treatment of postoperative pain in patients following open abdominal surgery.

With that summary of updates, I'd like to turn the call back over to Tim to provide an update on the financial and investor relations.

Tim Morris: Thank you, Richard.

For the third quarter of 2014, we had a net income of $671,000, or $0.02 basic net income per share, or $0.13 on a diluted net share. This compares to $11 million net loss, or $0.26 basic and diluted net loss per share for the third quarter last year.

Net income in the current quarter as compared to net loss in the prior-year quarter was primarily due to an increase in revenue from the receipt and recognition of the $5 million milestone payment for the MMA (sic, see press release - MAA) submission under the collaboration

agreement with Grunenthal, and noncash income from the reevaluation of the PIPE warrants issued in connection with the PIPE financing in June 2012, partially offset by an increase in operating expenses.

Changes in the valuation of PIPE warrants are recorded to the Other Income or Expense line item in the P&L. During the third quarter of 2014, the change in value of the PIPE warrants resulted in Other Income of $6.4 million for the quarter, whereas the change in fair value of the PIPE warrants in the third quarter of 2013 resulted in Other Expense of $2.4 million for the period, a positive swing of $8.8 million. As a reminder, this is a noncash charge.

Financial performance may be better measured by looking at the income or loss from operations. The loss from operations of $5.1 million decreased in the third quarter of 2013 (sic, see press release - 2014), compared to the loss of $8.3 million in the third quarter of 2013. The decrease in the operating loss was due to lower research and development expenses, primarily due to reduced development work to support the FDA's review of the Zalviso NDA, partially offset by higher general and administrative expenses, primarily related to precommercialization efforts for Zalviso.

For the nine months ended September 30, 2014, we reported a net loss of $19.5 million, or $0.45 per share basic net loss and $0.63 diluted net loss per share. This compares to $41.2 million net loss, or $1.07 basic and diluted net loss per share, for the same period in 2013.

The net loss from operations of $25.9 million decreased for the first nine months of 2014 compared to the loss of $26.7 million in the first nine months of 2013. The decrease in the operating loss was due to lower R&D expenses as the clinical trials for Zalviso ended in 2013, partially offset by higher G&A expenses, primarily related to the precommercialization efforts for Zalviso.

As of September 30, 2014, we had cash, cash equivalents and investments of $85.6 million, compared to $92.3 million at the end of June and $103.7 million at the end of December 2013. The decrease in cash during the year was driven by cash used in operations, partially offset by the $10 million drawdown of the second tranche from the loan and security agreement with Hercules in June of 2014. As mentioned above, we received a $5 million milestone payment from Grunenthal.

We have revised our financial guidance for 2014, with operating expenses anticipated to be in the range of $43 million to $47 million. Our estimated cash, cash equivalents and investment balances at December 31, 2014 should be at least $68 million. I refer you to the press release for more details on the third quarter financial results.

As we enter the fourth quarter we will continue our investor relations activities and presence. We have a number of conference presentations planned in the next two months, including the Credit Suisse Healthcare Conference in Phoenix this week, the Jefferies Global Healthcare Conference in London on November 20, the Piper Jaffray Healthcare Conference in New York on December 2, RBC Corporate Access Day December 4 in Denver, and the Guggenheim One-on-One Conference December 16 in Boston.

With that I'd like to turn the call back to Richard.

Richard King: Thanks, Tim. I'd like to now open the call for questions, so, Chad, I'd like to turn it back to you so you can coordinate. I'd appreciate it.

Questions & Answers

Operator: Certainly.

(Operator Instructions)

Our first question comes today from Louise Chen, with Guggenheim. Please go ahead.

Louise Chen: I apologize in advance for the awkwardness of asking these, since, Richard, you're on the phone. But there has been a lot of controversy surrounding a potential replacement for you, and I was curious. First of all, myself and others have thought that you've done a great job with the Company, so curious specifically as to why the Board's decision to change the CEO now.

And then the timing obviously is controversial, given that you're ahead of resubmissions, and wondering why not do the resubmission and then look for somebody. And there hasn't been a replacement announced before they announced that there was going to be a change, so that's obviously drawn a lot of concern from people. And so maybe I'll stop there and see if you could answer any of these questions. Thanks.

Richard King: So, Louise, firstly, thank you for the comments. Why don't I turn that question over to Adrian to address it?

Adrian Adams: Yes, thanks, Richard, and thank you for the question. Clearly I think decisions like this are never easy. I think in taking this decision it's had nothing whatsoever to do with any concerns in relation to the operations of the business, and, very importantly, any concerns in relation to the work that was being done in anticipation of the resubmission of the Zalviso in the first quarter of next year.

It had everything to do with looking to make sure that as we move through the course of 2015 and beyond that we had a CEO in place with the proven experience and success and the capabilities to take this company to the next level. We are delighted, of course, as I mentioned, that Richard has agreed to stay on till we secure that new CEO, and we anticipate that to be in the, obviously, in the first half of next year.

With regard to the timing, obviously, as I mentioned, I think decisions like this are not made in a light fashion. I think most certainly, I think, there's been a tremendous amount of work that has been done to date and is being done as we speak to make sure that there are no kind of issues in relation to timing of the resubmission. So, and clearly I think one of the reasons we are very pleased that Richard has agreed to stay on until we get a new CEO is to ensure that things are done in a seamless fashion. So, and with that, I'll turn it back to Richard.

Richard King: Okay. Does that address your question, Louise?

Louise Chen: It does. Maybe if I could just push a little bit more. So, I mean, I was always under the impression that, Richard, you were experienced and have successfully launched products and run companies. So I guess maybe I'm curious as to specifically what the Board is looking for in a new CEO, that maybe if they could give more specifics around that.

Adrian Adams: I think you are — if one looks broadly at the management team at AcelRx, I think we have a very good quality management team and they're all kind of contributing in many different areas. And most certainly I think from the looks of the track record to date in relation to what has been done, as I've already commented on, I think most certainly the Company has moved to a very nice stage.

That said, I think it is our responsibility as a Board of Directors, given the very significant shareholder value creation here, is to make sure that as we move into the next very exciting phase of the Company that we have that skill set and proven successful experience to take us forward into the next phase. And most certainly I think this had nothing to do with any disagreements between Richard and the Company or indeed any matters related to the Company's operations.

So clearly I think we're in a good situation as we are at this particular point in time, and this had everything to do with making sure as a Board of Directors we had everything in place to put ourselves in a very strong position to increase shareholder value over the course of time.

Louise Chen: Thank you very much.

Adrian Adams: Thank you very much for the question.

Operator: The next question comes from Randall Stanicky, with RBC Capital.

Randall Stanicky: Let me ask this another way. As you move towards commercial approval, what else do you need from a management perspective? I'm just thinking about from a chief commercial officer or other people in that place. Thanks.

Adrian Adams: Clearly, I think, when one looks at the kind of broader aspects of capabilities and proven experience, I think we recognize that the commercialization of Zalviso, subject to FDA approval, is of fundamental importance. And clearly as it relates to the choice of a new CEO that particular capability and competence is a very strong component of that, as is the broad general management aspects in relation to building this company moving forward.

And we feel that now is the right time for us to look at the next phase of evolution of the Company, and there's a lot of different components that will come into the choice of a new CEO. And very importantly, and again stepping back to what I mentioned earlier, we are very pleased

that Richard has agreed to stay on until that new CEO is in place. And we will make sure that the decisionmaking and the qualities that we are looking for in a CEO drive the timelines of that. We want to make sure that we choose the right CEO to take us into the next stage of development.

Randall Stanicky: Got it. And then let me just ask a question on where we are with the process. Have we submitted the protocol to FDA? If not, when would you expect to do that? And then how long do you think it's going to be for the FDA to come back to you? And where I'm going with this is I'm trying to understand if the timing's been pushed back a little bit if we're thinking about now early 2015 before we understand what else we need to do for submission. Thanks.

Richard King: Good question. Obviously these protocols are critical documents, and we want to get them exactly right, so we're taking every opportunity to review them, both via very careful internal review and also by external expert review, as well. But the protocol submissions for both bench testing and also for human factors are imminent.

Randall Stanicky: Thanks.

Operator: The next question comes from David Amsellem, with Piper Jaffray.

David Amsellem: Thanks. So I guess at the risk of beating a dead horse maybe I'll try to ask the question a different way, Adrian. Maybe you can provide specifics on what are the ideal qualities in a new CEO. Maybe if you can give us some more color on that. And what exactly would that CEO do that would, to be frank, be better or different than from what Richard could do? Thanks.

Adrian Adams: I mean, thank you again for the question. I think I'm going to reiterate a number of points. And most certainly I think I don't want to get into comparisons of any profile of a new CEO that we will recruit versus Richard. I think that is not appropriate. I think Richard has done a very good job of getting the Company to where it is at this particular point in time.

I think just to reiterate, I think the Company is in very good shape, and I think most certainly we think is a very attractive proposition for a potential new CEO, I think. And most certainly I think given the potential to unlock significant shareholder value over the course of time we're pretty confident that the identification and introduction of a new CEO will be of great benefit to the Company.

I think when one references a deep track record of success and in terms of deep commercial experiences, the broader aspects of those attributes and capabilities that we think are important as we move into the next phase, I think. And this has nothing to do in relation to any challenges we've had to date in terms of where we are at this particular point in time. As I have referenced in my earlier comments, I think we're very pleased with what Richard has done to get the Company to the next level.

This is all about putting in place a CEO that has the proven deep experience and success and capabilities not just commercially, although that is very important, but broadly to take the Company to the next stage. And I think that is the sufficient comment at this particular point in time.

David Amsellem: Okay, let me ask a follow-up, so maybe switching gears. How would you comment on the relationship with Grunenthal? I mean, there's obviously been — you obviously have the CRL and response pending. Now you have the management change. So is there anything that's changed in your relationship with Grunenthal given the upheaval? Thanks.

Richard King: So let me comment first off, David. The answer is we've had a very, very good working relationship with Grunenthal ever since, well, right up to signature on the agreement and then ever since that time, as well. We work hand in glove with them from a regulatory standpoint as we prosecute the Marketing Authorization Application in Europe and also as we prosecute the CE Marking process for the Zalviso device.

I'd like to go one space further. We have a joint steering committee. Tim, you're on that joint steering committee between ourselves and Grunenthal. Maybe you could comment from the inside of that side of things, as well.

Tim Morris: Sure. I actually think that Grunenthal is pleased with the progress we've made on the filing and the application in Europe. As we've mentioned before, we got our ISO 13485 certification. The next step will be the CE Mark. And we're basically on time to have a decision by CHMP in the third quarter of next year.

So, while the — obviously the CRL was a setback in the US and the change in CEO will be something we'll have to deal with internally here, I think for the most part Grunenthal still sees the extreme value in the product. They still are preparing their commercial prep. And the MA process kind of remains on schedule. So I think they're very satisfied.

Richard King: Just one — and I'll just add one other thing to that, as well, which is that today or tomorrow, I'm not sure which of the two, but there is an expanded board meeting in Germany at Grunenthal, and Pam is actually there presenting to the board to give them full insight to the Zalviso opportunity, to continue to cement that relationship going forward. So I think that it's a solid one and it's one which is active and dynamic.

David Amsellem: Thank you.

Richard King: Pleasure.

Operator: Our next question comes from Boris Peaker, with Cowen.

Boris Peaker: Good evening, gentlemen. So I just want to probe a little farther into the FDA discussions. What exactly is the FDA looking in the bench protocol as well as the Human Factor Study protocol? I mean, I'm just trying to get a sense of how standardized are those and make sure that — understand if there's going to be a lot more back and forth on something like this, or is there a clear template to follow?

Richard King: Okay. Well, there's never a template when you've got a very specific and very unique product, which is what Zalviso starts off as. Bench testing, though, is, as it's described, we basically take systems, we put them through a test protocol on the bench and we look for the rate at which the system produces unexpected optical errors.

And that's a fairly standard sort of a process in relation to the work that we've done to evolve the Zalviso system to address those optical system errors. So, whilst the Zalviso system itself is unique, the process of bench testing is fairly standard, and we think that we're following all the right and necessary elements to support that bench testing.

Similarly, as well, for the mitigations that have been developed to avert the inadvertent dosing of Zalviso tablets, that 15 tablets in the 30,000 overall that were identified in Phase 3, when you evaluate mitigations that involve instructions for use, instructions for patients, instructions for healthcare providers, you do that through human factors testing as the appropriate test vehicle.

And, again, the human factors test, while it's specific to Zalviso, is fairly standardized from a device standpoint. So we're following those standardized procedures, and obviously the specific areas of how effective are these mitigations that have been developed is the subject of very specific elements of the human factors test that are unique to Zalviso.

Boris Peaker: I see. And have they testified exactly what the — how will they determine if the Human Factor Study is a success or failure, like what frequency of failure is acceptable?

Richard King: So, that's part and parcel of the protocol review. We will propose that in the protocol review for the bench test. Human factors is a little more imprecise than that. You're looking for the effectiveness of the training solutions that you proposed as mitigations to the issues that you're trying to address.

If those prove to be ineffective, then you go and reevaluate those mitigations and try and make them effective so that healthcare professionals and patients can follow them reliably. But that's — we believe that the mitigations that we have developed and proposed to test the human factors are going to prove effective and that they will prove to be straightforward for both patients and healthcare professionals to follow and can be validated through the human factors test.

Boris Peaker: Got you. And my last question is on the sales force. With kind of the delay in the NDA, what is your strategy on the sales force? Are you making contingent offers? Would you delay hiring? Where do you stand?

Richard King: Yes, so on the sales side of things we have four out of seven of our regional business director positions filled. We did not recruit any of our sales — those are the sales managers, right, so they're the guys that manage the sales team, right, 65 sales representatives. We did not recruit any of our 65 sales representatives. We're waiting for the approval to go ahead and do that.

What we'll do now as we look towards the resubmission of the NDA and then the six-month review clock is that we will prepare contingency offers such that at the time of the approval the ability to go and move forward to recruit quickly a sales organization is in place. And that will happen, obviously, in the latter part of next year.

So that's how we propose to do it. But at this stage we will retain and continue to leverage the experience of our four in situ regional business directors, who are evaluating institutional sales targets to make sure we understand which of those we go to first so that we can maximize the ramp for the Zalviso introduction.

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

Richard King: Thanks Boris.

Operator: Our next question comes from Ed Arce, with Roth Capital Partners.

Ed Arce: Thanks for taking my questions. Actually most of them have been asked, but I do have one further. I was curious about your mention that in addition to submitting new protocols for both the bench testing and Human Factor Studies you will be also providing some evidence that clinical evaluations of either of these two is unnecessary. And I'm wondering to what degree do you think that is a likely scenario, and why do you think that that's really necessary as part of the submission. Thanks.

Richard King: That's a great question. Thanks, Ed. And again I'm going to just go back to the CRL for a minute. In the CRL that we received, the FDA was very specific in that in order to evaluate the mitigations for inadvertent dispensing of tablets they identified that human factors testing – and they specified human factors testing as being the appropriate test mechanism in the Complete Response Letter. And we concur with that. We think that is exactly the right response.

At the same time, they've also invited us to provide for them a rationale as to why clinical evaluation of these mitigations is inappropriate and unnecessary. We'll do that alongside the protocols. And obviously we'll want to see what comes of that dialog. But at this stage that's how we propose to handle things with the Agency, to respond to their request for a human factors protocol and also to their request for why clinical evaluation is inappropriate.

Ed Arce: Thank you.

Operator: Our next question comes from Biren Amin, with Jefferies.

Biren Amin: Thanks for taking my questions. I guess a couple of questions on Zalviso. Once you submit the bench test and human factor protocols, is it typical for FDA to respond in 30 days? And I'm wondering whether it's company submit that it would start the two tests this quarter. Thanks.

Richard King: Okay, so, unfortunately, typical is — I don't think typical is available to us. I think that — we think certainly, and based on historical elements associated with the Zalviso development program, that 30 to 60 days is not at all unusual, or it's the norm. But we're in the situation of a CRL, which is why the commentary about the expectation that the FDA will get back to us in a timely fashion but without a specific guarantee that they will do so. So we're — that's the reason for the hesitancy on saying definitively Q1 for the response to go into the agency.

In terms of the protocols themselves, since we have the protocols in hand, we will actually execute those protocols ahead of feedback from the agency. If the agency comes back with comments that modify those elements, then obviously we'll modify and repeat accordingly. But that's why we're spending the time, to make sure that we've covered every aspect that we can do associated with these protocols. So the answer to your question is we will initiate the work this year, but obviously the issue as to whether that satisfies the agency's needs will depend on the agency feedback to the protocols themselves.

Biren Amin: Thanks. And, Richard, how long do you anticipate it would take to finish those tests?

Richard King: They're relatively short tests. So the bench test is in the sort of four- to six-week range. The human factors test is in the — similar, actually, four to six weeks, closer to four than six weeks. But that's the sort of scale of our work.

Biren Amin: Got it. And then maybe another question on Zalviso. Given the Ionsys PDUFA and potential for Ionsys to launch in Q2 of next year, would that at all influence how the Company thinks about pricing for Zalviso?

Richard King: That's a good question. So, the — I'll go back historically a little bit. So Ionsys has priced once before in Europe, where they priced at around about $120 or so per patch, i.e., per day of treatment. That's certainly a robust price point. As you know, it's at the top end of where we've described the IV PCA-related costs on a per-day basis based on analysis of the Premier data set. But that was seven, eight years ago, and that device has evolved somewhat since then. So quite where the Ionsys product will price is obviously up to anybody to guess.

Our valuation for Zalviso will be based primarily on the market, the market opportunity, how we want to approach the marketplace and the ability of us to leverage the Zalviso value against the expectations for pricing the product in the marketplace. Obviously our first and foremost intent is to see Zalviso used as broadly as possible in the institutional setting. We believe it has a significant value to offer to patients, to healthcare providers and to institutions, and pricing of Zalviso will be reflective of that opportunity first and foremost, and secondarily we'll look at what Ionsys does.

Biren Amin: Got it. And then maybe a question on ARX-04. What are the key issues that the Company needs to complete in order to finalize the DOD contract?

Richard King: So, we have — we have been notified that we have been awarded a grant. There are basically two elements that need to be completed. The first is an agreement with our clinical approach that the — there's a human office of approval for protocols that are conducted under DOD grants that has to review our protocols and be comfortable with them.

And secondly there is a negotiation around the actual final value of the contract reflective of the work that's to be planned. We applied for this grant some time ago, and of course in the intervening time we've continued to evaluate the scale and cost of the ARX-04 program, and that discussion is to be held with the DOD to finalize the terms of that contract.

So those are basically the two elements, clinical review and then contract review and agreement.

Biren Amin: Okay. And then just a final question. I guess this one's probably for Adrian. On the CEO search, does the Board have any candidates on deck, and, I guess, in terms of the process, will it be a particular person on the Board that's spearheading the search, or is this a decision by committee?

Adrian Adams: I think as it relates to the search we've just initiated the search. I don't think it would've been appropriate for the Board to initiate a search without having the discussion with Richard.

As it relates to, obviously, moving forward with the search, I think this will be a search that will be done by the Nominating and Governance Committee that is chaired by Mark Wan. I'm a member of that, and Steve Hoffman, as well. So it'll be done by Nominating and Governance Committee, and then we'll make recommendations to the Board.

Biren Amin: Great. Thank you.

Operator: Our next question comes from John Newman, with Canaccord Genuity.

Kevin Dai: This is Kevin Dai in for John Newman. Just playing devil's advocate here, in case the FDA does come back to you requiring additional clinical studies, are you prepared for this type of resubmission currently, and how fast can you guys respond to the FDA with this resubmission?

Richard King: At this stage, as I say, the agency has requested a rationale for why clinical evaluation of the mitigations that we propose to test in human factors is inappropriate and unnecessary. So let's assume, because, again, there's no guarantees in this life, let's assume that they came back and said, okay, we've decided that human factors work isn't appropriate. There's a number of things that one could do.

Firstly, there's a kind of mix of human factors and clinical work that could be done. You could actually evaluate human factors work in clinically disposed patients. So that's one kind of halfway house. The clinical study work itself we haven't contemplated, and so I don't think it would be appropriate to talk about how long it would take to do that work. Certainly given the rate at which we had dropped tablets, which is 15 tablets in 30,000, clinically proving that you've reduced that rate would be not an insignificant amount of work if it was at all possible. So that's something which we would need to evaluate, but it's not part of our evaluation at this stage.

Kevin Dai: Okay. Thank you.

Richard King: Pleasure.

Operator: The next question is from Oren Livnat, with JMP Securities.

Oren Livnat: Thanks, Rich. So you just teed me up for my question with that extremely low, 0.05% tablet misplacement rate, and I think it was less than 1% of patients that that happened in. Given that those rates are extremely low, can you just help us understand, is the FDA asking you to show some reduction in the actual rate based on updated interface and instructions, or is the point just to show that people understand that that could happen and what to do if it does?

Richard King: Yes, it's the latter. Again, I'll refer back to the CRL. FDA is very specific. They talk about mitigations to the inadvertent dispensing of tablets and that the appropriate test vehicle, which we agree with, being human factors to evaluate that. So you're talking about mitigations to reduce it as far as you can, and then also what to do in the event that it does occur.

And we all acknowledge that if you're asking individuals to take something from A to B there's always the possibility of a misstep between A and B, and so to instruct both patient and healthcare provider as to what to do in the event that something goes wrong between picking up the device and then putting it under your tongue to dispense a tablet. So it's very much the latter, that the mitigations that we have proposed would be appropriate if the agency suggests to test through a Human Factors Study.

Oren Livnat: Just to follow up again, so obviously the second part of that, what to do if it does occur, I get. But, again, since we're talking about small numbers of people and very rare occurrences, presumably there's not going to be any data you can point to to show that you've in fact mitigated their actual occurrence, because the rate is going to be so low. So is it just intuitive, like asking a patient a question, do you understand that you need to be aware of this, so that implies that they would be less likely to make that error? Do you know what I mean?

Richard King: So that's — human factors doesn't quite work that way. What human factors does, it — you give a patient or a healthcare provider an instruction and you evaluate their ability to follow the instruction, in the basic sense that if they can follow the instruction then you can mitigate whatever it is that you're trying to assess.

So I'll give you a concrete example. With Zalviso we have a thumbtag which the patient wears on their thumb. It has to be close to the dose button to get a dose, correct?

Oren Livnat: Yes.

Richard King: So if the patient picks up the device with the hand that has the thumbtag on it, there's a risk that they could press the dose button somewhere between picking up the device and putting it in their mouth. If you instruct the patient to pick it up not with the hand with the thumbtag but with the other hand, and they can follow that instruction repeatedly, there's no way that you can actually dose a tablet until you bring the thumb with the dose — with the thumbtag up to the dose button to press it, which presumably you can instruct them to make sure it's in their mouth beforehand.

That's part of what we've already submitted to the agency as one of the mitigations to evaluate — to demonstrate the mitigations against the inadvertent dispensing of tablets. That's part of — that's one of the elements that they haven't reviewed yet. And so we've done a number of mitigations already and presented those to the agency against this particular issue. And what we're doing now and what we're proposing to evaluate is continuance of that, particularly as it relates to what to do in the event of a dropped tablet for either the patient or the nurse.

Oren Livnat: I hate to just harp on this, but, again, since these rates are so low, yes, you can see that someone used the other hand and what percentage did that. But obviously the rate was so low and well — if you look at guidance for device Human Factor Studies, obviously nothing is set in stone with the FDA, but they do talk about acceptably low error rates when it comes to devices, and I would think that a 0.05% error rate that you saw in clinical trials would not alarm anybody, especially in the setting of a — in the healthcare setting, not at home.

So I'm just wondering if there's any chance that you can't show statistically or hard data proving quote, unquote, mitigation, is there any reason to think that they can say, well, you did it. You improved your instructions. You at least addressed the issue. But the rate is so low anyways it's not a deal breaker for us.

Richard King: Difficult to comment on that, because, again, the registered body has obviously requested that we look at this issue and that we do put in as many mitigations as we can to what is already, as you've already discussed, events at a low rate of occurrence. We've done that partly in the material that's been submitted. We continue to do that.

I think the core here is — and it's the responsibility of the sponsor to put in as many mitigations as possible to reduce that error rate down to as low as possible. Again, I don't think anybody's expectation is to get to a zero rate or to get to no dropped tablets. Humans are humans. And we'll continue to move forward to evaluate the mitigations that we are describing to the agency and that will be part of the protocol that we present to the agency for them to review and comment on.

Oren Livnat: All right. Thanks, Rich, and thanks for everything.

Operator: This concludes our question-and-answer session. I would like to turn the conference back over to Richard King for any closing remarks.

Richard King: Thanks, Chad. I just want to thank Tim and Adrian for their joining the conference call today, and obviously also to thank everyone for your time and questions on this call and, indeed, on previous calls, as we kind of move forward.

Just one other comment. I think Dave Amsellem referred to beating a dead horse. I don't like to be called a dead horse, but that's a time and place for another discussion later on. Anyway, with that thought, I'll leave you, and have a good rest of the day.

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