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): October 29, 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 October 29, 2015, AcelRx Pharmaceuticals, Inc., or the Company, conducted a conference call during which members of its senior management team provided a business update and discussed financial results for the quarter and nine months ended September 30, 2015 and certain other information. A copy of the transcript of the conference call is attached as Exhibit 99.1 to this Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Transcript of AcelRx Pharmaceuticals, Inc. Quarter and Nine Months Ended September 30, 2015 Earnings Conference Call on October 29, 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: November 2, 2015

ACELRX PHARMACEUTICALS, INC.

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Transcript of AcelRx Pharmaceuticals, Inc. Quarter and Nine Months Ended September 30, 2015 Earnings Conference Call on October 29, 2015, at 4:30 p.m. ET.

Exhibit 99.1

Event ID:
Event Name: [ACRX] - AcelRx 3Q15 Financial Results
Event Date: 2015-10-29

Officers and Speakers
Tim Morris; AcelRx Pharmaceuticals, Inc.; CFO
Howie Rosen; AcelRx Pharmaceuticals, Inc.; Interim CEO
Pamela Palmer; AcelRx Pharmaceuticals, Inc.; Co-Founder & Chief Medical Officer

Analysts
James Chen, RBC Capital Markets
Boris Peaker, Cowen and Company
Michael Higgins, ROTH Capital Partners
Ed Arce, H.C. Wainwright & Co., LLC
Hugo Ong, Jefferies LLC

Presentation

Operator: Good afternoon, and welcome to the AcelRx third quarter 2015 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, sir.

Tim Morris: Thank you, Gary. Good afternoon, everyone, and welcome to today's call. On this call I am joined by Howie Rosen, Interim Chief Executive Officer, and Pamela Palmer, our Co-Founder and Chief Medical Officer.

During the call today we will make forward-looking statements, including, but not limited to, statements related to future financial results, including process and timing of anticipated future development of AcelRx's product candidates, including Zalviso and ARX-04; the timing and quality of data for ARX-04 and the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates, including Zalviso and ARX-04; anticipated results and the timing of the completion of the SAP302 study for ARX-04; AcelRx's plans to seek a pathway forward towards getting approval of Zalviso in the US; anticipated resubmission of the Zalviso NDA to the FDA, including the scope of the resubmission and the timing of the resubmission; statements related to the timing of the commercial launch of Zalviso in Europe; financial guidance and cash forecasts; and potential milestones and royalty payments under the Grunenthal agreement. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties.

AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements and as a result of these risks and uncertainties, which include, without limitations, risk related to any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso and ARX-04, its ability to successfully complete the additional clinical study requested by the FDA to support the resubmission of the Zalviso NDA; its ability to timely resubmit the Zalviso NDA to the FDA and to receive regulatory approvals for Zalviso; the fact that the FDA may dispute or interpret differently positive clinical results obtained to date from the pivotal Phase 3 SAP301 ambulatory surgery study of ARX-04; its ability to complete Phase 3 clinical development of ARX-04; inability to successfully manufacture Zalviso to meet the requirements of Grunenthal and potential delays in the timing of the European launch; the success, cost and timing of all product development activities and clinical trials, including the SAP302 ARX-04 trial; 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 and the timing related thereto; its ability to obtain sufficient financing; the accuracy of AcelRx's estimates regarding expenses, capital requirements and the needs for financing; and other risks detailed in the Risk Factors and elsewhere in AcelRx Pharmaceuticals' US Securities and Exchange filings and reports, including its Quarterly Report filed on Form 10-Q filed with the SEC on August 4, 2015. AcelRx Pharmaceuticals undertakes no duty or obligation to update any forward-looking statement contained in this presentation and as a result of new information, future events or changes in its expectations.

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

Howie Rosen: Thank you, Tim, and I'd like to thank everyone for joining us this afternoon for our third quarter call.

During today's call we'll cover the following: business highlights and accomplishments for the third quarter; an update on ARX-04; our plans for Zalviso in the US; and a brief review of the third quarter financial results.

Let me start with our recent accomplishments. The third quarter of 2015 was marked by considerable progress for AcelRx. On September 9th we announced positive results from SAP301. In this study, ARX-04, a single 30-mcg sufentanil sublingual tablet in a prefilled single-dose applicator, met primary and secondary endpoints in a multicenter, double-blind, placebo-controlled Phase 3 trial in patients with moderate to severe acute pain following ambulatory abdominal surgery.

These results demonstrate that patients receiving short-term treatment with ARX-04 experienced significantly greater pain reduction compared to placebo as measured by the time-weighted summed pain intensity difference over the first 12 hours of treatment, or SPID-12. Pam will provide some additional information from SAP301 in a moment.

On September 22nd we and our commercial partner Grunenthal announced that the European Commission approved Zalviso sufentanil sublingual tablet system for the management of acute moderate to severe postoperative pain in adult patients in a hospital setting. The marketing authorization was granted for the 28 EU member states, as well as for European Economic Area countries. Grunenthal expects Zalviso to be available to Western European patients in the first half of 2016. The approval triggered a $15 million milestone to AcelRx from Grunenthal, which we expect to receive in the fourth quarter of 2015.

On September 21st we announced the monetization of the expected royalty stream from Grunenthal's sales of Zalviso in Europe. AcelRx received $65 million from the sale to PDL BioPharma, Inc. Tim will speak later about this transaction.

Finally, based on the teleconference we held with the FDA in early September regarding the regulatory path for Zalviso, we've submitted a protocol for an additional clinical study to address concerns raised by the FDA and to assess the overall performance of the device. Pending comments on the protocol from the FDA, we're preparing to initiate the study early next year. The protocol submitted includes a single-arm study with Zalviso in patients with moderate to severe acute pain following surgery.

Unlike the pivotal Phase 3 studies with Zalviso, we will include patients from multiple surgery types. We will allow multimodal pain treatment, only require a one-night stay, versus two nights that were required in the pivotal study, and we'll measure pain improvement using SPID-12. We'll measure the performance of the device, including error rates, on a patient basis, and will require study personnel to proactively look for dropped tablets. We expect to provide an update once we are prepared to proceed with the study. Zalviso remains a valuable asset in our portfolio, and the ultimate approval in the United States continues to be an important company objective.

I'd personally like to thank the employees of AcelRx, our contractors, consultants and investigators involved in the successful SAP301 Phase 3 clinical study of ARX-04. I also wish to thank and congratulate Grunenthal for their rigorous pursuit and ultimate approval of the MAA for Zalviso in the EU, and, lastly, our advisors, legal counsel and PDL for their completion of the royalty monetization that provided significant non-dilutive capital to AcelRx.

I'd now like to turn the call over to Pam, who will provide you with an update on ARX-04, including the recently announced results from SAP301.

Pamela Palmer: Thanks, Howie.

As previously announced, in the SAP301 trial ARX-04 met primary and secondary endpoints in a multicenter, double-blind, placebo-controlled Phase 3 trial designed to study the short-term treatment of patients with moderate to severe acute pain following ambulatory abdominal surgery. Results demonstrated that patients receiving ARX-04, a 30-mcg dose of sublingual sufentanil, experienced significantly greater pain reduction compared to placebo, as measured by the time-weighted summed pain intensity difference over the first 12 hours of treatment, or SPID-12.

The trial enrolled adult patients undergoing outpatient abdominal surgery procedures at four clinical sites in the United States. Following surgery, 163 patients were randomized to receive either ARX-04 or placebo in a two-to-one active to placebo ratio. ARX-04 or placebo was administered by site staff as requested by the patient, but no more than once per hour. The intent to treat, or ITT, population in this study averaged 40.9 years of age, with an average body mass index of 27.5, and had a higher percent of females to male, 68% to 32%. 89% of patients entering the study completed the 24-hour study period.

Baseline demographics were evenly distributed between treatment arms, with approximately 50%, 30% and 20% of the patients undergoing abdominoplasty, laparoscopic surgery and hernia repair, respectively. The primary endpoint of the study was the difference in the SPID-12 score of patients receiving ARX-04 compared to those receiving placebo. SPID-12 scores were 25.8 for the ARX-04-treated patients and 13.1 for placebo-treated patients, the difference between the two groups being highly statistically significant. The baseline pain scores for ARX-04 and placebo patients were 5.6 and 5.5, respectively.

Statistical significance for ARX-04 over placebo was achieved as early as 15 minutes, the first interval in which pain relief was set. Patients were allowed either ARX-04 or placebo as requested for pain relief, but, as mentioned, no more often than once per hour. The median number of doses of ARX-04 was 4 tablets over the first 12 hours and 7 tablets over the total of the first 24 hours.

Patients were allowed 1 mg of IV morphine as rescue medication. 65% of placebo patients received rescue medication, as compared to 27% of ARX-04 patients, yet 5 times as many patients in the placebo cohort terminated early from the study due to lack of efficacy compared to the ARX-04 cohort, 18.5% versus 3.7%. Importantly, both patients and healthcare providers alike were impressed with the pain control afforded by ARX-04, rating the global satisfaction with pain control over the 24-hour study as either “good” or “excellent” in 80% of cases.

There were two serious adverse events, or SAEs, reported during the study period, both of which were in the placebo group and resulted in early termination of the affected patients. No patient in the ARX-04 group dropped out of the study prior to 24 hours due to an adverse event, and there were no statistical differences for any adverse event between the active and placebo groups.

These results bring AcelRx one step closer to commercializing a sublingual sufentanil product that we believe will have a meaningful impact by providing a noninvasive treatment of moderate to severe acute pain in medically supervised settings.

Also as previously announced, we've initiated a single-arm study with ARX-04 in the emergency room. This study, known as SAP302, is an open-label study in patients with moderate to severe pain. The study is intended to add to the safety database required for filing the NDA for ARX-04, and it's expected to enroll at least 40 patients across three clinical trial sites in the US. We intend to collect pain intensity and pain relief scores to assess pain relief over the first hour following treatment with ARX-04. We anticipate that the emergency room may be an initial market for ARX-04 and will serve as our gateway for utilization of ARX-04 across the hospital and other medically supervised settings.

We have a pre-NDA meeting scheduled with the FDA in December to review our plans for submitting the NDA for ARX-04, which we anticipate to occur in 2016. We have begun preparing the NDA and will provide an update on the timing following the pre-NDA meeting.

In Europe we held scientific advice meetings with the health authorities in Austria and the UK to discuss the clinical data package for ARX-04. Based on those meetings we believe we have sufficient information to proceed with the filing of an MAA under the centralized procedure. In summary, our meetings with the EU health authorities were very positive, and we are planning on filing an MAA for ARX-04 in 2016.

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

Tim Morris: Thank you, Pam.

Earlier today we reported financial results for the third quarter and the first nine months ended September 30, 2015. I refer you to the press release for specific details on the actual results.

Net income for the third quarter of 2015 was $5.1 million, or $0.11 basic and diluted net income per share. This compares to net income of $700,000, or $0.02 basic net income per share and $0.13 diluted net loss per share, for the third quarter of 2014. The net increase in net income and income per share was primarily due to revenue under AcelRx's Zalviso collaboration and license agreement with Grunenthal and AcelRx's contract with the Department of Defense for ARX-04 development. In general, G&A expenses decreased as a result of the cost reduction plan implemented at the end of March 2015, while other income decreased in the third quarter of 2015 as compared to the third quarter of 2014.

For the third quarter of 2015 AcelRx recognized revenue from the Grunenthal CLA of $13.9 million. As previously mentioned, we are entitled to receive a milestone payment of $15 million related to the approval of the MAA in Europe, which we expect to receive in the fourth quarter, of which $13.2 million was recognized as revenue during the third quarter of 2015. In the third quarter of 2014 we received a milestone payment of $5 million related to the MAA submission, of which $4.6 million was recognized as revenue.

Revenue attributed to the research and development work performed under the DOD contract was $1.6 million for the third quarter of 2015. There was no such revenue recognized for the third quarter of 2014.

For the nine months ended September 30, 2015, AcelRx reported net loss of $13.9 million, or $0.31 basic net loss per share and $0.37 diluted net loss per share. This compares to a net loss of $19.5 million, or $0.45 basic net loss per share and $0.63 diluted net loss per share for the same period in 2014.

AcelRx recognized revenue of $14.5 million under the Grunenthal agreement in the nine months ended September 30, 2015, primarily related to the milestone for approval of the Zalviso MAA. During the nine months ended September 30, 2014, AcelRx recognized revenue of $5 million under the Grunenthal collaboration, primarily related to milestone payment for the Zalviso MAA submission.

Revenue attributed to the R&D work performed under the DOD contract was $3 million for the nine months ended September 30, 2015. There was no such revenue recognized for the nine months ended September 30, 2014.

As of September 30, 2015, AcelRx had cash, cash equivalents and investments of $104.3 million, compared to $75.4 million at December 31, 2014. The net change in cash, cash equivalents and investments was $28.9 million. As mentioned above, the royalty monetization gross proceeds of $65 million occurred in the third quarter of 2015.

With the gross proceeds from the royalty monetization of $65 million, the $15 million milestone from Grunenthal and support for ARX-04 under the DOD contract, we anticipate we will end 2015 with over $100 million of cash. We anticipate this cash balance is sufficient to permit us to meet our capital and operational requirements at least through the first half of 2017.

On the Investor Relations front, planned presentations and participation in upcoming conferences and meetings include: BIO-Europe 2015, November 2nd through the 4th in Munich Germany; the Credit Suisse Healthcare Conference, November 9th to the 11th in Phoenix, Arizona; the Jefferies Autumn 2015 Global Conference, November 18th and 19th in London; and the 27th Annual Piper Jaffray Health Care Conference, December 1st and 2nd in New York City.

Lastly, as we have previously announced, we have hired Gina Ford as our Vice President of Commercial Strategy. Gina has been a consultant to the Company for the last two years, helping lead the launch planning for Zalviso. As VP Commercial Strategy Gina will be responsible for developing the commercial plan for ARX-04 in US, Europe and other geographies.

As we advance ARX-04 into the final study, SAP301[1] in the emergency room, and prepare our regulatory filings in the US and the EU, we will be relying on Gina's expertise in market access, pricing, payer relations and branding to plan a successful launch. Gina represents our first commercial hire primarily focused on ARX-04. Her initial review of the potential market for ARX-04 was presented at our recent Analyst and Investor Event in New York City on October 2, 2015.

While we have much more work to do to better define the commercial opportunity for ARX-04, based on the preliminary estimates we believe peak sales for ARX-04 in the United States have the potential to be 2.5 times higher than that of Zalviso. We look forward to providing an update on the commercial potential for ARX-04 as we gain additional insights.

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

Howie Rosen: Thanks, Tim.

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[1] Mr. Morris intended to say SAP302

So far in the fourth quarter we are continuing to make good progress. To recap, based on the teleconference we held with the FDA in early September regarding the regulatory path for Zalviso, we've submitted our protocol for an additional clinical study to address concerns raised by the FDA and to assess the overall performance of the device. We're undertaking efforts to be ready to initiate the study early next year.

We also initiated a study of ARX-04 in the emergency room. The study is designed to provide experience in the setting and to add to the safety database. We're looking forward to the pre-NDA meeting with the FDA in December and discussing timing for submitting the ARX-04 NDA.

Approval of Zalviso in the EU was a great accomplishment, and we look forward to working with our supply chain partners to manufacture commercial product for Grunenthal's launch of Zalviso in Europe next year. After many years of dedicated work by our employees, it is exciting to anticipate seeing patients benefit from our first product.

We'll now open the call up to questions.

Questions & Answers

Operator: (Operator Instructions)

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

James Chen: Hi. This is James Chen on for Randall. For Zalviso rest of the world post the EU approval, has there been any interest that has stirred since then? And how do you see potentially balancing collecting royalties on additional ex-US region or potentially monetizing it helping the launch of Zalviso or ARX-04 in the US?

Tim Morris: Sure, James. Yes, there is definitely interest outside of the US and Europe for Zalviso. We'll continue to carry on those discussions and have actually added new parties to the mix. That's part of the focus for our meeting next week at the BIO conference in Munich.

It's difficult to say exactly what the potential for those territories are. I would say that South America or Latin America is of interest, Asia is of interest. China is a little of a challenge just because of the timeline. So, and then potential parts of Eastern Europe and then the Middle Eastern with Africa region is another one.

So we'll continue those discussions. Clearly with the approval in Europe it's a little bit easier in those territories to get partners and to seek approval, so we'll continue those out.

Now, historically those haven't been as lucrative as Europe or the US, but they should provide some proceeds. We haven't gotten far enough along in those discussions to really determine whether to weigh the monetization of those royalties or just collect the royalties ourselves, and obviously that's probably more of a clinical question than not. So we will continue to look at that, because having some cash flows, as you suggest, to help launch ARX-04 in the timeline would be nice. But we'll clearly weigh all those options and move all those discussions forward.

James Chen: Okay, thanks. And perhaps just one more. For ARX-04 I believe before you guys had mentioned peak sales potentially $1.3 billion, potentially around a 65-person sales force. I just want to confirm everything's on schedule starting in September, I believe, anticipated results first quarter. And can you talk about the biggest differences between targeting the ER and the ambulatory surgery care market and what might be some of the challenges there? Thanks.

Tim Morris: Sure, and I'll ask Howie to comment, as well. The information that Gina presented at our Analyst Day did have potential peak sales of about $1.3 billion, but clearly you would need more than a 65-person sales force to get there. So I think the 65-person was something from a launch standpoint in terms of targeting the initial market of both the emergency room and the ambulatory surgery centers. They each have slightly unique characteristics. But it's felt that you could launch with a relatively sufficient sales force of probably 65 into both of those areas.

So I think for us when we think about the ER, obviously there's about 5,000 ERs there. A lot of this work is very similar to some of the profiling work we had done with Zalviso. You can look at it geographically and size it the right way. In this case, the ER, there is a reimbursement component to it which actually might help the uptake from that standpoint. So obviously a lot more work to be done, but for right now that's kind of where we're comfortable.

The ambulatory surgery centers, while there's a fair amount of those, at least from a corporate standpoint there is some concentration of ownership. To the extent you can take advantage of a corporate formulary or corporate purchasing or a procurement process we could do that with a relatively smaller, efficient team. Clearly, the pull-through would have to happen at the local level in geographies where we already have reps, so we believe there's some efficiency there.

So at least initially we think that's kind of the target and how we would plan to launch. And obviously we've got a lot more work to be done there.

James Chen: Okay, Tim, thanks.

Howie Rosen: Yes, Tim pretty much covered the key things. That's fine.

Operator: The next question comes from Boris Peaker, with Cowen. Please go ahead.

Boris Peaker: Great. Thanks for taking my questions. So the first one is on ARX-04. I'm just curious, is there any patient or physician training required with this drug specifically, and how and when would this training occur?

Pamela Palmer: Hi, it's Pam. No, there isn't. This is a standard nurse-administered drug, so there's very simple instructions on how to use the single-dose applicator, which is just a two-step procedure. So it's almost like just giving a syringe to a patient, but obviously it's noninvasive and sublingual.

Boris Peaker: I see. And in terms of getting such a drug approved on a hospital formulary, have you had discussion with KOLs or experts on that field? I'm just curious, what are they specifically looking at and how sensitive would they be to pricing in that setting?

Tim Morris: Yes, we have had some discussions around that, and at least the early response is they like the profile of the drug. They like some things about the onset. They like the PK level and also a more predictable offset.

From a pricing standpoint, you've got to remember the emergency room is a little different animal than your standard hospital procedure, where it's included as part of the DRG. So at least the preliminary feedback to date has been very positive.

I think the pricing at least that we have with the US government is at $20 per application. Most of the folks that we've talked to, and Pam has been out at some of her medical meetings, I think the response has been that is clearly not a barrier. Obviously there's more work to be done on the pricing and with payers, and we're doing that. But to date I think the KOLs have been very responsive at least to that as a floor price.

Howie Rosen: And one other thing that is important that we've learned in the emergency room, as well, is that there's -- if you're giving someone, for example, an IV, have to put in an IV in order to give them their pain medicine, that there's costs associated with that in terms of the nursing time and the items that are needed to do the IV, as well as it takes longer to actually get all that in place and provide pain relief to the patient. So there's more than just -- there's more of a pharmacoeconomic story than -- and also benefit to the patient than just substituting one pain medication for another.

Boris Peaker: Got you. And my last question is on Zalviso. If you end up starting the pivotal study, I guess, in that timeline that you estimate, which is in the first quarter of 2016, do you have a sense of how long it would take to actually complete it?

Howie Rosen: Well, the short answer is not yet, because we did propose a certain size trial to the FDA, and one of the things we are looking for feedback from them is on the size of the trial. So obviously that will influence how long it'll take. But Pam can comment more if she wants to. We've designed it to be quickly enrolling, and, as I mentioned, will be multiple types of surgery and allow multimodal pain relief, as well.

Pamela Palmer: Yes, we're really going to be using the same clinical sites we've used for the Phase 2 and Phase 3 studies for Zalviso. These folks love the device, love the drug and are very eager to work with us and start enrolling.

Boris Peaker: Got you. All right. Well, thank you very much for taking my questions.

Tim Morris: Thanks, Boris.

Operator: The next question comes from Michael Higgins, with ROTH Capital Partners. Please go ahead.

Michael Higgins: Thanks, operator. Good afternoon, guys. How are you?

Tim Morris: Very good.

Michael Higgins: A couple of questions on Zalviso and then two on 04. First on Zalviso, regarding inadvertent dosing, in your discussions with the FDA have they given you any sense for whether it's more important to have error rates on a patient basis or more important to have error rates on the overall dosing basis?

Howie Rosen: Yes, so they've focused on the -- well, they focus on the per-patient basis.

Michael Higgins: Okay. And then also on Zalviso, regarding the device failures, I believe the FDA is asking to rule out an error rate with the device. Do you know if they're looking for something, if they're looking for results on a point estimate or an upper bound, and then was that something that you're waiting until the end of the year to find out?

Howie Rosen: Yes, that's -- we proposed a statistical plan along with our protocol, and that's one of the things we expect them to comment on, as well.

Michael Higgins: Okay. Okay. And then on 04, should we look in Q4 to see contract revenue pick up versus what we saw in Q3? If you can give us any near-term guidance on that it would be appreciated.

Tim Morris: Yes, I mean, obviously the reimbursement will happen for the SAP302 study. So at what rate? I mean, that's a relatively small study, so as compared to Q3 my guess it's probably going to be roughly the same. We would expect it to -- there will be a blip in 2016 with the filing fee, which is a couple of million dollars that is included in DOD. So from a contract standpoint if you assume about the same level that you saw in the third quarter I think that's a safe assumption.

Michael Higgins: Okay. Regarding the entire $17 million, should we look for all of that to hit your P&L at some point, or is it up to the $17 million?

Tim Morris: The contract is up to. It's subject to calculation of overhead rates and fringe rates, which can vary. And so we're still comfortable that we should be able to realize a majority if not nearly all of the $17 million. As we go through our year end and true up those amounts for the two rates I mentioned before, if we think there's an adjustment we'd be happy to kind of let you guys know at that time.

Michael Higgins: Okay. Pam, you've done some work on Zalviso's pharmacoeconomics. Might you do the same for 04, and if so when might we see the results of that work?

Pamela Palmer: Great question. I'm working on that now. What we did for Zalviso was we presented a poster at the Spring ISPOR meeting, and then we used that data for the publication, and I believe that's going to be our plan for ARX-04, as well.

We're very excited to work on that pharmacoeconomic story. I think it almost writes itself after having talked to many ER docs about the cost of the nursing time and effort to place an IV in an ER is quite expensive, and then you add to that the drug cost of the IV opioids, and then of course the time for morphine to kick in, which of course takes a while. Having a noninvasive route of administration for ARX-04, it's just really helpful, not only for paramedics and medics in the Army, but for ER docs. And I think that's going to be a relatively easy paper to write.

Michael Higgins: I've got $20 for a dose. I'm thinking it may be a little light. Can you give us some feedback that you've heard from docs regarding the cost of the drug, nursing time, the bag, the lines, that kind of a thing in aggregate? Have they given you any kind of feedback?

Howie Rosen: We really just -- at this point we really just have anecdotes. And so, as Tim mentioned, we'll at some point do a more typical quantitative pricing study, and as Pam works through the pharmacoeconomic story we'll have some more solid data on that.

Michael Higgins: Okay. Great. And thanks, guys.

Operator: The next question comes from Ed Arce, with H.C. Wainright & Co. Please go ahead.

Ed Arce: Hey, guys. Thanks for taking my questions. I have a couple. First, on your upcoming study which you've submitted or are working on proposed protocol, can you give us a little more detail around some of the specific things that you are looking for, specific details around the error rates, like if it's patient based or procedure based on the device?

Pamela Palmer: Sure. Well, our endpoint that we're looking at is we're -- the FDA has suggested to us a primary endpoint around dispensing errors. And so we have written that up as a primary endpoint for the study that we've submitted as a protocol to the FDA.

And we're -- our bench testing clearly met that endpoint, and we believe that we'll be able to show that in clinical testing, as well. But, again, until we have the feedback from the FDA -- we submit the protocol in line with what they have recommended, so we're not expecting a huge pushback, but we don't definitively know yet.

Ed Arce: Okay. And perhaps you could give us an update, as well, on Grunenthal's progress with their launch in Europe?

Tim Morris: Actually they're moving ahead at full speed. We've taken a look at their launch plan and their commercial strategy there. Actually I've put a fair amount of work into this. Pam actually was at a meeting earlier in September, a big pain meeting in the US, where Zalviso was unveiled, literally, to the medical community there. And so Grunenthal will continue those efforts, both kind of at the trade level.

They also have and are beginning an awareness campaign, or might refer to that as an unbranded campaign, which they call Change Pain. They were very effective with this type of campaign in the chronic setting, so they're adapting those principles and the philosophy to the acute setting. They'll begin to roll that out. They kind of have a full strategy to look at both, both traditional PR and press release to roll that out.

So they are ramping up. They have a lot of folks involved. It's very significant to them. We don't know exactly when they're going to launch, but it looks like clearly in the first half of 2016. And they're going full speed ahead.

Ed Arce: Okay. And then just one last housekeeping question, this noncash liability expense for the PDL royalties that you now have on your income statement, is that something we can expect on an ongoing basis?

Tim Morris: Yes. Unfortunately, how you have to account for the sale is more debt-like under GAAP, and so what you see there is an amount that we will take as royalties that are actually collected from Grunenthal and disbursed both to AcelRx and to PDL, who will essentially take an interest charge. And at some point that will come off the books, but unfortunately it's around for 15 years until they reach the capped amount. So we're happy to talk a little bit more about the accounting for that, but it does represent a noncash charge, and unfortunately it is in accordance with GAAP.

Ed Arce: All right. Great. Thanks.

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

Unidentified Participant: Hey, this is Michael on for David. Just a couple of quick ones. For the Zalviso study you mentioned that you'd be including other surgery types. I was wondering if you could maybe just give a little bit of color on what types of surgery specifically. And just a housekeeping one, I was just wondering if you guys had any color on maybe how we should think about R&D spend moving through the end of this year and through 2016, given that you'll have these additional programs running. Thanks.

Pamela Palmer: Sure, David. So I'll take the first question. This is not an efficacy study. We've clearly beaten placebo many, many times in our trials. So we can be a little less careful as far as selecting very specific types of surgeries. Before we've allowed major abdominal, hip and knee replacement surgeries, which is fairly broad for Zalviso.

We're now opening it up to other types of surgeries. They could have spine surgery, they could have different types of surgeries, just so long as they will be requiring systemic opioids for at least 24 hours after surgery and obviously that they have a qualifying pain score that's going to be a moderate to severe pain score in order to enter into the study. So we're just trying to increase the enrollment, but we're also trying to be more real world.

I think the data from this study, even though it's open label and single arm, will still be very valuable to show the use of Zalviso in other patient populations than we've done before, and to look at the efficacy of Zalviso and the use of Zalviso in a multimodal environment, which we also couldn't really do in a placebo-controlled study. So I'm actually excited about this study for many reasons.

Tim Morris: And then on the R&D spend, I mean, the current trend is somewhere between $5 million and $5.5 million. I really don't expect that trend to be any different, at least in the fourth quarter, and then obviously depending on where we come out with the study with the FDA most likely it won't be dramatically different next year.

Unidentified Participant: All right. Thanks, guys.

Operator: The next question comes from Hugo Ong, with Jefferies. Please go ahead.

Hugo Ong: Hi, guys. Thanks for taking the question. This is Hugo Ong speaking in for Biren Amin. Just wanted to get your latest thoughts on the developing competitive landscape in postop pain. How do you look at, say, Medicine Company's Ionsys, which recently got approved? Cara's going into Phase 2 for their kappa opioid receptor agonist, and I know Trevena has presented some good Phase 2 data. Maybe you just could share your thoughts. Thanks.

Pamela Palmer: Sure. Wow, that's a lot to cover. I'll be glad to take them on individually. So Ionsys, we were thrilled when they were approved. I'm still thrilled. Two companies beating up on IV PCA is a good thing. We think that from an efficacy standpoint and onset standpoint, a pricing standpoint, we probably will look more competitive than Ionsys does. But we'll see. We'll see when we get to the market.

I think that, again, the issue with Ionsys, it is a one-day patch. It has some dermatological issues with it. And it has really no onset of action, so they -- you have to titrate a patient to comfort, you have to maintain them with comfort for three hours before you can really let them loose on their own with the patch. And so, and that's how we ran our clinical trials. And there's advantages to the product, but there's disadvantages, as well.

Regarding the kappa agonist story, kappa agonists have been around for a while, and they're not the most profound analgesics. The play there really is that you'll have some level of analgesia that hopefully has a better, safer side effect profile than a pure mu agonist. That's always the claim of kappa agonists. But they're just not usually that strong of a powerful opioid that when you're talking about sufentanil or fentanyl and those sorts of drugs. So I do look at it as sort of a different patient population than what we're talking about for our product.

Regarding the TRV130 drug that you're referring to, I think it's interesting. The biased ligand story is an interesting one. Their data is a little confusing to me in Phase 2. They have a side effect profile for their drug which looks very much like our drug. But it's their morphine side effect profile that's exquisitely high, extremely high for any opioid after surgery. So I think that's interesting.

But I'm looking forward to their data. They're injectable, they're IV, so I don't really see them as competing with us at all. We're noninvasive, and our whole point is to avoid IV PCA. Our whole point is to avoid the IV route of administration. It's invasive. It's not at all the trend where people are going to oral multimodal therapies. They're going to enhanced recovery after surgery programs. The whole push is to be noninvasive.

So as far as an IV opioid goes, I think it's an interesting story. But we're noninvasive. We in fact have a side effect profile that's equal to placebo. Beating morphine to me is a very low bar. I'm -- that's the way we look at it. We beat morphine as it relates to oxygen saturation occurrences in our Zalviso program, and we have an ARX-04 side effect profile that's equal to placebo. So as far as side effects, we love our sufentanil product, and it's a noninvasive product. We really think we'll win the day.

Hugo Ong: Got it. Very helpful. Thank you.

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

Howie Rosen: I just want to thank everyone again for participating in our third quarter call. We'll be presenting at several investment conferences, as we mentioned, next month. So we look forward to providing you updates as they come along.

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