

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

**FORM 8-K**

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 2, 2016

**ACELRX PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State of incorporation)

**001-35068**

(Commission File No.)

**41-2193603**

(IRS Employer Identification No.)

**351 Galveston Drive  
Redwood City, CA 94063**

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(650) 216-3500**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01. Other Events.**

On May 2, 2016, AcetRx Pharmaceuticals, Inc., or the Company, conducted a conference call during which members of its senior management team provided a business update and discussed financial results for the quarter ended March 31, 2016 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	Transcript of AcetRx Pharmaceuticals, Inc. First Quarter 2016 Financial Results Conference Call on May 2, 2016, at 4:30 p.m. ET.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 4, 2016

ACELRX PHARMACEUTICALS, INC.

By: /s/ Jane Wright-Mitchell

Jane Wright-Mitchell  
Chief Legal Officer

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## INDEX TO EXHIBITS

<b>Exhibit Number</b>	<b>Description</b>
99.1	Transcript of AcetRx Pharmaceuticals, Inc. First Quarter 2016 Financial Results Conference Call on May 2, 2016, at 4:30 p.m. ET.

Event ID:  
Event Name: [ACRX] - AcelRx Q1 Results Call  
Event Date: 2016-05-02

Officers and Speakers

Timothy Morris; AcelRx Pharmaceuticals, Inc.; CFO and Head of Business Development  
Howie Rosen; AcelRx Pharmaceuticals, Inc.; CEO  
Pamela Palmer; AcelRx Pharmaceuticals, Inc.; Co-Founder and Chief Medical Officer

Analysts

Randall Stanicky, RBC Capital Markets  
Michael Higgins, ROTH Capital Partners  
Ed Arce, H.C. Wainwright & Co., LLC  
Hugo Ong, Jefferies LLC

Presentation

Operator: Good day, and welcome to the AcelRx Pharmaceuticals first quarter results conference call and webcast.

(Operator Instructions)

Please note this event is being recorded.

I would now like to turn the conference call over to Mr. Timothy Morris, Chief Financial Officer. Mr. Morris, the floor is yours, sir.

Timothy Morris: Thank you, Mike. Good afternoon, everyone, and welcome to today's call. On this call I'm joined by Howie Rosen, our 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 the process and timing of anticipated future development of AcelRx's product candidates, ARX-04, sufentanil sublingual tablet, 30 mcg, and Zalviso, sufentanil sublingual tablet system, including the anticipated timing of the completion of the Phase 3 SAP302 and SAP303 studies for ARX-04; ability to fund ARX-04 development from the contract with the Department of Defense; AcelRx's pathway forward towards gaining approval of Zalviso in the US; anticipated timing, design and results of the IAP312 clinical trial for Zalviso; anticipated resubmission of the Zalviso New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, including the scope of the resubmission and timing of the resubmission and FDA review time; anticipated submission of the NDA for ARX-04; the status of the collaboration and license agreement with Grünenthal or any other future potential collaborations, including potential milestones and royalty payments under the Grünenthal agreement; and the therapeutic and commercial potential of AcelRx's product candidates, including ARX-04 and Zalviso.

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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 as a result of these risks and uncertainties, which include, without limitations, risk related to AcelRx Pharmaceuticals' ability to complete Phase 3 development of ARX-04 and support ARX-04 development under the contract with the Department of Defense; AcelRx's ability to successfully execute the pathway towards the resubmission of the Zalviso NDA to the FDA, including the initiation and completion of the IAP312 clinical study for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 in the United States and Europe, and Zalviso in the United States; AcelRx's ability to receive any milestone or royalty payments under the Grünenthal agreement and timing thereof; ability to manufacture and supply sufficient quantities of Zalviso to Grünenthal on a timely basis; the uncertain clinical development process, including adverse events; the risk that planned clinical studies may not begin on time, have an effective clinical design, enroll a sufficient number of patients or be initiated or completed on schedule, if at all; the success, cost and timing of all development activities and clinical trials, including the additional clinical trial for Zalviso, IAP312, and the Phase 3 ARX-04 SAP302 and SAP303 trials; the fact that the FDA may dispute or interpret differently clinical results of pain to date from the Phase 3 SAP301 study of ARX-04; the market potential for AcelRx's clinical products; the accuracy of AcelRx's estimates regarding expenses, capital requirements and the need for financing; and other risks detailed in the Risk Factors and elsewhere in AcelRx's US Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-K filed with the SEC on March 7, 2016. AcelRx undertakes no duty or obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or changes in its expectations.

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

Howie Rosen: Thank you, Tim. On today's call we'll provide business highlights since our last call, including an update on ARX-04 and Zalviso, and a review of the first quarter financial results. Let me start with our recent activities.

As we previously announced, I accepted the full-time position of CEO after acting as Interim CEO for a year and as a Director since 2008. During my time with AcelRx, but especially this past year, I've become intimately familiar with the products and development strategy and helped further shape the culture of the Company. The products really resonate with me, since I've unfortunately been a patient in the emergency room and surgical suite.

A key factor in accepting the position, besides the technology and business opportunity, was the quality and dedication of the AcelRx employees. I look forward to working with everyone to continue to move ARX-04 and Zalviso forward.

Speaking of our product candidates, we made significant clinical progress on ARX-04 in the first quarter, initiating two Phase 3 studies. The first, an extension to the SAP302 study, may enroll up to an additional 60 patients who present to the emergency room, or ER, with moderate-to-severe acute pain associated with trauma or injury. The second study, SAP303, is an open-label trial targeted to enroll approximately 100 patients 40 years of age and older who have moderate-to-severe acute pain following a surgical procedure. The initial phase of SAP302 yielded positive results in February 2016. Pam will go into more detail about these findings in a few moments.

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Regarding Zalviso, we're excited to report that Grünenthal Group, our licensee in Europe, launched Zalviso in Germany the beginning of April. Regarding U.S. development of Zalviso, as we discussed in our late March conference call we made some important decisions that impact our clinical and regulatory guidance. In brief, we determined that our Zalviso commercial supplies provided the performance we would prefer to include in our NDA resubmission and, if approved, have available for an anticipated U.S. commercial launch.

In making these decisions we considered recent testing comparing Zalviso clinical and commercial supplies and determined that the commercial supplies may better optimize system functionalities for the conduct of IAP312, our planned Phase 3 usability study in postoperative patients.

Additionally, we have made some improvements to the Zalviso software and hardware in Europe that we were able to self-certify for the EU under our CE Mark. As part of this change in strategy we'll switch to using Plexus, the current commercial manufacturer of the EU Zalviso systems. It is our belief that making these changes now will ultimately make the launch of Zalviso in the U.S. smoother.

I'll let Pam provide you with some more background on this and an update on ARX-04. Pam?

Pamela Palmer: Thanks, Howie.

Let's start with ARX-04. We announced positive interim results in February from the single-dose phase of the SAP302 study, which enrolled 40 patients who present to the ER with moderate-to-severe acute pain from trauma or injury. The primary endpoint was the time-weighted, summed pain intensity difference to baseline over one hour, or SPID-1.

Study participants experienced a clinically meaningful drop in pain intensity of 1.3 points on a 0 to 10 scale within 20 minutes, and by 60 minutes the pain intensity had dropped 2.7 points below baseline. The usual opiate-induced adverse events were fairly low in frequency compared to the postoperative setting, with nausea and somnolence being the most frequent reported events, in only 5% of patients.

In March we initiated the extension phase of the SAP302 study, which will include the opportunity for patients to receive multiple doses of ARX-04 in the ER setting. This phase is enrolling up to an additional 60 patients who present to the ER with moderate-to-severe acute pain associated with trauma or injury. Patients in the extension phase may receive doses of ARX-04 hourly as needed for pain for up to four doses. The primary endpoint will still be the time-weighted, summed pain intensity difference to baseline over one hour, or SPID-1.

Also in March we initiated SAP303, a multicenter, open-label Phase 3 clinical study enrolling approximately 100 patients 40 years of age and older who have moderate-to-severe acute pain following a surgical procedure. Participants in SAP303 may receive doses of ARX-04 hourly as needed for pain for up to 12 hours. The primary efficacy endpoint is the summed pain intensity difference over the 12-hour study period, or SPID-12. Safety endpoints such as adverse events and vital signs will also be assessed.

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We anticipate both these studies to be completed by the third quarter of 2016. Based on our discussion with the FDA during our pre-NDA meeting in December, the combined enrollment goal in the SAP302 extension and the SAP303 study is approximately 160 patients.

The patient enrollment target did not result from any specific concerns from the FDA, rather the desire to explore different demographics and settings of use for ARX-04 from the previous studies. Pending enrollment activities we believe we are on track to submit the NDA for ARX-04 in the fourth quarter of 2016 for the treatment of moderate-to-severe acute pain in medically supervised settings.

As Howie mentioned earlier, we have made some improvements to the software and hardware of Zalviso in Europe that simplifies the initiation process the healthcare professional goes through during system setup. This revision doesn't affect patient safety or dosing but does represent the performance level that we would like to submit for U.S. regulatory approval.

Thus, it makes sense to move forward with this modified Zalviso system in the U.S., including using it in the planned IAP312 study. Considering recent testing and the desire to modify the Zalviso hardware and software now, we have postponed the initiation of IAP312 and reprioritized ARX-04 as our primary focus where we work with our vendors on securing Zalviso system supplies.

I would also like to comment on recently published treatment guidelines for opioids. In March the Centers for Disease Control published treatment guidelines for the use of opioids for chronic pain. Chronic opioid abuse is a serious problem, and we applaud the CDC for taking this step. It is important to note that the guidelines are specifically related to treatment of chronic pain present for more than three months and are aimed at primary care physicians.

Regarding treatment of acute surgical pain, the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine and American Society of Anesthesiologists Committee on Regional Anesthesia jointly published treatment guidelines for postoperative pain this February. Four of the recommendations relate specifically to opioids and include the use of opioids in a multimodal regimen, recommending oral instead of invasive routes of administration of opioids, suggesting patient-controlled modalities when appropriate, and avoiding the routine use of basal infusion of opioids. We believe these recommendations are in line with the envisioned use of our products in the clinical setting.

Opioids have been used for thousands of years, and we believe that opioids will continue to play a key role in the management of moderate-to-severe acute pain. The under-treatment of moderate-to-severe pain in the hospital setting has been well documented, and the resulting morbidity is substantial. We will continue to educate the public, healthcare professionals, regulators and elected officials on the benefits of sublingual sufentanil in medically supervised settings, and we appreciate the Department of Defense's support of the clinical development of sublingual sufentanil in the treatment of moderate-to-severe acute pain.

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

Timothy Morris: Thank you, Pam.

Earlier today we reported financial results for the first quarter ended March 31, 2016. I refer you to that press release for specific details on the actual financial results.

Net loss for the first quarter of 2016 was \$11 million, or \$0.24 basic net loss per share, as compared to \$10 million, or \$0.23 basic net loss per share, for the first quarter of 2015. The net loss from operations in the first quarter of 2016 was \$8.5 million. This compares to \$11.4 million for the first quarter last year. The net loss in the first quarter of 2016 includes \$2.2 million in noncash interest expense on the liability related to the sale of future royalties, whereas the net loss in the first quarter of 2015 included noncash income of \$2.2 million due to the change in the valuation of the outstanding PIPE warrants.

During the first quarter of 2016 AcclRx recognized revenue of \$1.8 million under the collaboration agreement with Grünenthal and \$1.2 million related to the work performed under the DOD contract. This compares to total revenue of \$181,000 from previously deferred revenue that was recognized in the first quarter of 2015 under the collaboration agreement with Grünenthal .

It's worth noting that ahead of the launch of Zalviso in Europe by our licensee, Grünenthal , we delivered \$1.4 million of commercial inventory. Delivered product consists of devices, drug product and related accessories. As the first commercial sale by Grünenthal happened in April 2016, we did not recognize any royalty revenue in the first quarter of 2016.

Beginning in the third quarter of 2016 we will receive quarterly royalty reports from Grünenthal for the prior quarter. As the royalty amounts are not currently reasonably estimatable without royalty reports, we will recognize royalty revenue and noncash royalty revenue quarterly in arrears beginning in the third quarter of 2016. In addition, this quarter we recognized \$400,000 in other revenue under the collaboration agreement with Grünenthal, primarily related to demonstration devices and research and development services.

Total cost of goods was \$3.6 million for the first quarter 2016, related to commercial production of Zalviso. Cost of goods sold includes internal indirect cost plus the actual cost to manufacture at our contract manufacturers. Under our agreement with Grünenthal we will sell Zalviso components and drug to Grünenthal at a predetermined transfer price that approximates the direct cost to manufacture at our contract manufacturers. We will not recover indirect costs consisting of internal overhead costs as part of the transfer price.

Research and development and general and administrative expenses for the first quarter were \$4.2 million and \$3.8 million, respectively. These compare to \$6.3 million of R&D and \$4.5 million of G&A in the first quarter last year.

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The decrease in G&A expenses was primarily due to reduction in personnel-related expenses, predominantly as a result of the cost reduction plan implemented in March 2015. The decrease in R&D expenses was primarily related to lower personnel expenses of \$1.4 million due to the reclassification of production-related personnel expenses to cost of goods sold and a reduction in the headcount due to the March 2015 cost reduction plan. In addition, Zalviso-related R&D spending decreased by \$700,000 due to the slowing of development activities.

At March 31, 2016 AcelRx had cash, cash equivalents and investments of \$107.2 million, as compared to \$113.5 million at December 31, 2015. The decrease of \$6.3 million was primarily attributed to cash used in operating activities.

On the investor relations front, planned presentations and participation in upcoming meetings and conferences include BioEquity Europe in Copenhagen on May 11, Bank of America Merrill Lynch Health Care Conference in Las Vegas on May 12, the Jefferies Healthcare Conference in New York on June 9, and the ROTH Healthcare Day in London on June 22.

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

Howie Rosen: Thank you, Tim.

We made significant progress in ARX-04 in the first quarter. Although our timelines for Zalviso are pushed back, we anticipate that the decision to use commercial vendors for IAP312 will ultimately make the launch of Zalviso in the U.S. smoother.

We believe ARX-04 will be a simpler product to explain to the medical community, so potential launch ahead of Zalviso could benefit both products. We appreciate your support and will continue to update you as we progress ARX-04 and Zalviso through their clinical programs and prepare the regulatory submissions.

Thank you for being on the call today. Operator, let's open up the call to questions.

Questions & Answers

Operator: Thank you, sir.

(Operator Instructions)

The first question we have comes from Randall Stanicky, of RBC Capital Markets. Please go ahead.

Randall Stanicky: Great. Thanks, guys. Any early feedback from the Grünenthal launch that you can share? And in conjunction with that any early observations from Ionsys? And then, secondly, understanding that we still don't have a lot of visibility around timing, but what are the factors in determining the timing for the path forward for Zalviso? Thanks.

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Timothy Morris: Sure, Randall, hi. It's Tim here. Obviously Grünenthal is very excited for the first launch. They will kind of roll this out in systematic nature across Germany. You can imagine they have good relationships there. But, I mean, the early feedback has been positive, but it's probably too early to tell, obviously, as it relates to other trends. So overall I think the first pilot programs have been going well, and we'll anticipate hopefully another update as we have our second quarter call.

From Ionsys' standpoint, actually, they've been relatively silent. We haven't seen much in the way of commercial and/or medical affairs. I don't know, Pam, if you have any comments based on your attendance at medical meetings. But it's been relatively silent. So it's really hard to say much, if anything, on that product and how it's doing and what the read-through is back to Zalviso.

And then in terms of IAP312, we'll let Howie comment on that.

Howie Rosen: Yes, and thanks for your question on that. And really, as we've mentioned, it's a matter of lining up the suppliers we've been using for commercial, getting the right software that we can use in the U.S. put in those controllers, and working through the testing of those. And so things are going along. We just want to make sure we have everything done and know exactly where we are before we give guidance on that.

And, again, part of what made us, as I mentioned, part of what makes us feel comfortable about this is that we were heading down a path where we potentially are going to have a Zalviso approval significantly before ARX-04. And, as we've learned more about the marketplace, as I mentioned, we feel like starting out with ARX-04 is the better place to go. And so that made us feel a little more comfortable about taking the time now to switch to the commercial vendors rather than trying to do that postapproval.

Randall Stanicky: Got it. So, just to be clear, is this something -- should Zalviso start moving forward in the back half, or is this something we should think about as a 2017 event?

Howie Rosen: Don't know at this point. So we will definitely give you guidance when we're more comfortable.

Randall Stanicky: Got it. And then final one for Tim, can you just remind us, I think you have \$107 million in cash. Can you just walk through the funding pathway, talk about cash burn, and then also the opportunity to continue to license either ARX-04 or Zalviso to other regions, and is that a source of capital raising for you? Thanks.

Timothy Morris: Sure, Randall. The guidance that we had given on the earlier call this year, so we then -- and this year with \$70 million to \$75 million I can confirm that guidance. So I think from a cash burn standpoint, I mean, we only used \$6 million this quarter. Obviously that will ramp up a little bit as some of these other studies come in, but also offset by some of the monies we get from DOD.

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So we still feel fairly comfortable with the cash balance ending this year, and the cash burn in 2017, while we haven't given guidance on, shouldn't change a whole lot from where we are. The one thing I will point you to is that we should be getting principal payments of our debt facility under Hercules in the fourth quarter this year, so that will take some cash, as well.

In terms of the ability to use out-licensing business development activities to help fund, that clearly does exist. We do have discussions for both Zalviso and ARX-04 in other parts of the world outside of the U.S. And so that would clearly offset and provide some potential non-dilutive funding for our operations as we move forward.

Randall Stanicky: Great. Thanks, guys.

Howie Rosen: Thank you, Randall.

Operator: Next we have Michael Higgins, with ROTH Capital Partners.

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

Howie Rosen: Good.

Pamela Palmer: Good.

Michael Higgins: Just a couple of follow-ups, if I could, from Europe, from Grünenthal. Any help for us on the pricing? I think that the pricing's been set in Germany. If you could provide that for us, as well as how it looks across Europe.

Timothy Morris: Yes, Michael, Tim here. We do believe that they've gotten the price that they were looking for from a publish standpoint, and I think on average they anticipate that being around 99 euros per patient across all the countries. Obviously, those are going to vary a little bit by country. And that is for the drug.

They will also charge for the disposal pieces, and the controllers have a variety of different methods for them to seek reimbursement for. But we feel relatively comfortable that at least from a published pricing standpoint that they have gotten the price that they were looking for.

Michael Higgins: Okay. That's helpful. And then regarding Zalviso's manufacturing in Europe for 312, I understand there's a few steps along the way before you can provide some guidance on the start of 312. Is it possible or is it reasonable to look to Q2's earnings call for some guidance as to the next steps, or when might you think we will have some guidance on Zalviso's 312 start?

Howie Rosen: So, good question, and we hope to have an update by the Q2 call. So, I mean, we definitely will update you on the Q2 call in terms of where we are, and ideally we would have something more definitive we could say by then.

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Michael Higgins: Okay. And then, lastly, on 04 you've been helpful with an Analyst Day last fall. You have another Analyst Day in February. When the interim ER results came out, might we see more of the same coming into this fall as you continue to flesh out the opportunity for 04?

Timothy Morris: The simple answer is yes, Michael. In terms of timing it's hard to exactly predict. But in terms of the studies reading out probably sometime in the third quarter, I think that's still appropriate, although there's probably a little bit higher production value out of these results. And so to the extent we need to preserve the quality of them for medical meetings we'll coordinate the timing of the release to the general public, keeping in mind some of the embargo concepts of the upcoming medical meetings.

But, yes, we will, as we get more information both on the clinical setting and this current ongoing study results, and also the commercial opportunities. We'll learn more about that. So I would envision that at some point we will have another, more complete Analyst Day. But also we'll release top-line results when appropriate in coordination with some of the medical meetings.

Michael Higgins: Okay. Very good. I'll jump back in. Thanks, guys.

Operator: Ed Arce, of H.C. Wainwright.

Ed Arce: Hi, guys. Thanks for taking my questions.

Timothy Morris: No problem.

Ed Arce: I just wanted to follow up again on the opportunity unfolding now in Europe with the pilot studies or the pilot programs underway in Germany. I'm wondering if you could help us in understanding what's the likely path and timeline for rolling out the product across Europe and specifically across the EU5 and what that looks like.

Timothy Morris: Sure. They definitely have plans to do the EU5 this year. I think, as we've mentioned before, as a private family-owned German company they don't have the same pressures that us small public biotechs have in the States in terms of launch in terms of reporting results. They are very methodic about it.

They do have a pilot program in place whereas they put the units in the hospital, they dose patients, they study, they make adjustments as needed, and then will multiply that out in a series of hospitals and institutions in a given country. And then at some point they will go to kind of what we might consider full launch status.

They do intend to do this in a similar fashion across the EU5. I think they are confirming the exact timeline of that. They are a little bit more sensitive about summers and holidays and the like there. But we do believe that their plans are still to roll it out through the EU5 through the rest of this year.

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It will be a little bit challenging until we're kind of up to full speed to report a lot of details around that other than just some incremental progress. They do recognize the importance of us discussing that progress, and I think they'll be cooperative. And to date they've been great partners, and so we're looking forward to more information as they continue to roll out across Germany and the rest of the EU.

Ed Arce: Okay, great. Then a couple of questions on the P&L just to clarify. Quarterly royalty reports that you're expecting to get from Grünenthal beginning in the third quarter, that will be the sort of reporting or recognition event for you to start recognizing those royalties, and I just wanted to understand how the mechanics of that flow through. And also the predetermined transfer price for the COGS, if you could just explain that again, as well. Thanks.

Timothy Morris: Sure, so two things. I think on the quarterly royalty reports, they will come to us essentially and we'll report one quarter in arrears. And so, as I mentioned, obviously in the first quarter there were no royalties due. In the second quarter there will be. We will receive that report in the third quarter. And so in the third quarter we'll report the Q2 royalties.

And we'll continue along that path until we have a better history and are able to better predict the royalty. So the way to think about it is essentially the royalty reports and the royalty revenue recognition will happen one quarter in arrears.

As it relates to your question on transfer price, as part of our agreements with Grünenthal we do have fixed transfer prices for all of the Zalviso components, including the disposable drug product, and the controller is essentially reusable. Those essentially equal our cost to manufacture but does not include any of our internal cost, or historically known as period cost, in that transfer price. So what you'll see from a cost of goods sold standpoint is the actual cost of the direct materials, per se, from our contract manufacturers.

Ed Arce: Okay, great. Thanks again.

Timothy Morris: Sure. Thank you, Ed.

And next we have Hugo Ong, of Jefferies.

Hugo Ong: Hey, guys. Thanks for taking the questions. Most of my questions have been answered already, so let me just ask a couple. One is on SAP302. You mentioned that you were enrolling up to an additional 60 patients, which would be on top of the 40 patients that you had data for at interim. Has there been a small change there, because I was under the impression that the total enrollment would be 120 patients?

Pamela Palmer: Yes, hi, it's Pam. We say 120 just because we are running SAP302 and SAP303 concurrently. And so we have to in the protocol have a bit of a fudge factor in case one of the studies ends up enrolling a little bit faster.

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We need to collect 160 patients between the two studies. And so that was just an upper limit, but it's looking like we're probably going to have more of the numbers we just reported now, which is 60 additional in the ER and 100 in the SAP302 study, or 303 study, sorry.

Hugo Ong: Okay, got it. And are you guys still active in trying to license ARX-04 in Europe, and do you think Grünenthal would be interested?

Timothy Morris: Yes, we are active for ARX-04 in Europe. Hard to comment to the interest level of Grünenthal, but obviously they have a lot of experience with sublingual sufentanil, so clearly they could or should be some point. But for right now obviously we'll focus on all the potential partners out there.

We think this is a big opportunity in Europe, and as we progress with these studies here in the States we've also had some additional health authority meetings in Europe and have gotten some feedback there, and we also try to refine that opportunity. It looks very promising. So we are continuing to work on that, and that's clearly one of our objectives for this year.

Hugo Ong: Okay, great. Thanks, guys.

Timothy Morris: Thanks, Hugo.

Operator: At this time we have no further questions. We'll go ahead and conclude today's presentation. At this time I'd like to turn the conference back over to management for any closing remarks.

Howie Rosen: Thanks, Mike, and I'd like to thank everyone again for participating in our first quarter call. We look forward to seeing you at investor events over the next few months and to keeping you apprised of our progress. Thanks again.

Operator: And we thank you, sir, and to the rest of the management team for your time also today. The conference call has now concluded. At this time you may disconnect your lines. Thank you, take care and have a great day, everyone.