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 1, 2016

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 1, 2016, 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 ended September 30, 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.

Exhibit Number	Description
99.1	Transcript of AcelRx Pharmaceuticals, Inc. Third Quarter 2016 Financial Results Conference Call on November 1, 2016, 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, 2016

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. Third Quarter 2016 Financial Results Conference Call on November 1, 2016, at 4:30 p.m. ET.

Exhibit 99.1

Event ID:
Event Name: ACRX - AcelRx 3Q16 Results Call
Event Date: 2016-11-01

Officers and Speakers
Tim Morris; AcelRx Pharmaceuticals, Inc.; CFO and Head of Business Development
Jane Wright-Mitchell; AcelRx Pharmaceuticals, Inc.; Chief Legal Officer.
Howie Rosen; AcelRx Pharmaceuticals, Inc.; CEO
Pamela Palmer; AcelRx Pharmaceuticals, Inc.; Co-Founder and Chief Medical Officer
Gina Ford; AcelRx Pharmaceuticals, Inc.; VP, Commercial Strategy

Analysts
Randall Stanicky, RBC Capital Markets
David Amsellem, Piper Jaffray
Michael Higgins, ROTH Capital Partners
Hugo Ong, Jefferies LLC
Justin Collinshaw, Cowan & Co.
Ed Arce, H.C. Wainwright & Co., LLC

Presentation

Operator: Hello, and welcome to the AcelRx third quarter 2016 results conference call.

(Operator Instructions)

Please note this event is being recorded.

I would now like to turn the conference over to Tim Morris. Mr. Morris, please go ahead.

Tim Morris: Thank you, operator. Good afternoon, everyone, and welcome to today's call. On this call I'm joined by Howie Rosen, our Chief Executive Officer; Pamela Palmer, our Co-Founder and Chief Medical Officer; Gina Ford, our Vice President of Commercial Strategy; and Jane Wright-Mitchell, our Chief Legal Officer.

During the call today we will make forward-looking statements, and Jane will now remind you of our Safe Harbor language.

Jane Wright-Mitchell: Thank you, Tim.

During the call today we will make forward-looking statements, including, but not limited to, statements related to financial results and trends; the process and timing of anticipated future development of AcelRx's product candidates, ARX-04, sufentanil sublingual tablet, 30 mcg, and Zalviso, the sufentanil sublingual tablet system, including the ARX-04 clinical trial results; anticipated submission of the new drug application, or NDA, for ARX-04 to the US Food and Drug Administration, or FDA; AcelRx's pathway forward towards gaining approval of Zalviso in the US, including the successful completion of the IAP 312 clinical study for Zalviso; anticipated resubmission of the Zalviso NDA to the FDA, including the scope and timing of the resubmission and the FDA review time; the status of the collaboration and license agreement with Grünenthal, a company organized under the laws of Germany, 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 potential market opportunities for ARX-04 and Zalviso.

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 limitation, risks related to AcelRx Pharmaceuticals' ARX-04 development program, including anticipated submission of the ARX-04 NDA and the possibility that the FDA may dispute or interpret differently clinical results obtained from the Phase 3 ARX-04 studies; the Zalviso development program, including completion of IAP312 and the resubmission of the Zalviso NDA to the FDA; 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 milestones or royalty payments under the Grünenthal agreement and the timing thereof; ability to manufacture and supply sufficient quantities of Zalviso to Grünenthal on a timely basis; the commercial success of Grünenthal's launch of Zalviso in the European Union, or the EU; the uncertain clinical development process, including adverse events; the success, cost and timing of all development activities and clinical trials; the market potential for AcelRx's product candidates; 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[1] Report on Form 10-Q filed with the SEC on July 29, 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 back over to Howie, our Chief Executive Officer.

Howie Rosen: Thank you, Jane.

On today's call we'll provide business highlights and accomplishments since last quarter, including an update on pipeline programs, ARX-04 and Zalviso, and a review of the third quarter financial results. Let me start with our recent accomplishments.

Our medical affairs team was busy in the third quarter making presentations of ARX-04 results at six medical meetings around the world. One such presentation at the Military Health System Research Symposium reported for the first time results of SAP302, the single-arm, open-label, Phase 3 trial of ARX-04 in patients who presented to the emergency room with moderate-to-severe acute pain associated with trauma or injury.

We also reported for the first time, results of SAP303, an open-label Phase 3 trial of ARX-04 in 140 patients who were at least 40 years old and included patients with baseline renal and/or hepatic impairment who underwent short-stay in-hospital surgeries associated with moderate to severe acute pain. Pam will discuss results from both of these studies in a moment.

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[1] Correction: Quarterly.

With SAP302 and 303 complete, we are now focusing on completing the new drug application, which we expect to submit before the end of the year. It goes without saying, but we're all extremely excited to have reached this milestone and look forward to bringing you further updates.

In the third quarter we also continued to make progress with Zalviso. In September we announced the initiation of IAP312, a Phase 3 trial of Zalviso in hospitalized postoperative patients. This study, as you'll recall, was designed with the FDA's input to measure device usability, including any incidence of Zalviso's failure to dispense medication as well as the incidence of misplaced or dropped tablets.

On the finance side during the quarter, we were able to make some favorable amendments to our debt agreement with Hercules Growth Technology that Tim will describe in more detail later in the call.

Let me turn the call over to Pam now for a more detailed update on our clinical program.

Pamela Palmer: Thanks, Howie.

I'll start with ARX-04. As you just heard, we had two significant announcements of ARX-04 results last quarter, the first from SAP302, our emergency department study, and the second from SAP303 in postoperative patients who were 40 years old or older.

Taking these one at a time, SAP302, if you'll recall, had two phases, one that treated 40 adults who presented to the ER with moderate-to-severe acute pain from trauma or injury with a single dose of ARX-04, and an extension phase that enrolled an additional 36 patients who were eligible to receive multiple doses of ARX-04.

Overall, the 76 study participants experienced a mean pain intensity difference, or PID, of 2.9, from a baseline of 8.1 on a 0 to 10 numeric rating scale at 60 minutes. This represents over a 35% decrease in pain intensity.

Interestingly, in the second cohort, even though patients were allowed multiple doses of ARX-04, only 7 of the 36 patients requested a second dose of ARX-04, and only 2 requested a third dose. Therefore, for 75% of patients in the second cohort a single dose of ARX-04 was sufficient for pain relief, and only 8% of patients overall received morphine in addition to ARX-04.

ARX-04 was well tolerated in the study, with 79% of patients having no adverse events. Among those with an AE, the most common was nausea, 9%; somnolence, 5%; and vomiting, 4%.

In addition to the PID, or pain intensity difference, and safety measures, we also included a cognitive assessment in the SAP302 protocol. This was not required by the FDA. Rather, we added it at the request of the Department of Defense, which is partially funding the development of ARX-04.

The Department of Defense is understandably concerned with cognitive side effects of pain medications given to wounded soldiers in the battlefield. In addition to presenting an issue on the battlefield, drug-induced cognitive effects can also be dangerous in civilian emergency rooms and can impede diagnosis and treatment.

So we used a validated test called the Six-Item Screener and found no instance of clinically meaningful cognitive impairment with ARX-04 in this study. No additional cognitive testing is planned or has been requested by the FDA or the Department of Defense.

Moving on to SAP303, this Phase 3 study was designed to study the effects of ARX-04 on moderate-to-severe acute pain in 140 patients 40 years of age or older who had undergone a short-stay inpatient procedure, or ambulatory surgery. The study included patients with renal and hepatic impairment.

Of note, 17% of study participants were 65 years of age or older and 29% had baseline renal or hepatic impairment. Patients in SAP303 were eligible to receive doses of ARX-04 every 60 minutes for up to 12 hours.

Results showed early pain reduction, and, more importantly, a sustained duration of pain relief over 12 hours. At 12 hours, patients had a mean reduction in pain intensity of 3.51, or a 57% drop from baseline.

During the 12-hour study period the mean total number of ARX-04 doses administered was 3.3, which was similar for patients with normal or impaired liver or renal function. Overall, there were no differences in adverse events between patients with normal and impaired liver or renal function, with nausea and headache being the two most commonly reported AEs. Sixty-three percent of patients in the study experienced no adverse events.

As Howie mentioned at the beginning, the medical affairs team has been very active over the last couple of months, with presentations at various medical meetings, and this is continuing this quarter. We'll be presenting a number of abstracts and presentations at medical meetings in the US featuring ARX-04 and Zalviso results.

These include the Obesity Society Meeting, which is taking place this week in New Orleans, and the Annual American Society of Regional Anesthesia and Pain Medicine Meeting in San Diego November 17 through 19, and the International Society for Pharmacoeconomics and Outcomes Research Meeting, which is taking place in Vienna this week.

I will now turn the call over to Gina to discuss the commercial preparations for ARX-04.

Gina Ford: Thank you, Pam.

In order to better understand the market for ARX-04, AcelRx has also attended a number of important medical conferences in September and October, including the Emergency Nurses Association Conference in Los Angeles; the American Society of Plastic Surgeons Meeting in Los Angeles; the European Society for Emergency Medicine Congress in Vienna, Austria; the National Conference on Correctional Healthcare in Las Vegas; the EMS World Expo in New Orleans; and the American College of Emergency Physicians Scientific Assembly in Las Vegas.

Information from a year's worth of market research and insight from these meetings is helping us shape the commercial strategy for ARX-04. Currently, that strategy is to launch ARX-04 ourselves with an internal sales force. The initial target will be emergency medicine.

We've developed our positioning and are finalizing our strategy so that as the NDA is submitted we can move into launch planning. Most of our thinking on the commercial strategy for ARX-04 in the US will be completed in the next month. We decided to hold an Analyst Meeting in December where we will review these plans with you and provide a fresh perspective of the market potential for ARX-04 in the US.

I would therefore like to formally announce that AcelRx will hold its second Analyst Meeting in New York City on the morning of December 1 at the Benjamin Hotel. This meeting will feature a presentation from Harold S. Minkowitz, MD, from Memorial Hermann Memorial City Medical Center, a principal investigator for ARX-04, of the integrated safety and efficacy databases for ARX-04 to be included in the NDA.

I will host a panel discussion with several emergency room physicians who can share with you their real-world trauma experience, both military and civilian, and their impressions of the various treatments for acute pain. The panel will consist of James R. Miner, MD, Chief, Emergency Medicine, Hennepin County Medical Center; Colonel John Holcomb, MD, Vice Chair, Professor and Chief of the Division of Acute Care Surgery at the University of Texas Health Science Center at Houston. Colonel Holcomb served in the Army for 23 years and created comprehensive trauma systems for DoD. Michael Ritter, MD, Chief of Emergency Medicine at Mission Hospital in Mission Viejo, California. The Trout Group will be sending invitations for the event, but for now please save the date and I will see you in New York City on the morning of December 1.

Tim, I'll turn the call back to you to discuss the ISPOR presentation and the Q3 financial results.

Tim Morris: Thank you, Gina.

The presentation we are giving at the International Society for Pharmacoeconomics and Outcomes Research, or ISPOR, Annual Meeting contains some interesting findings which will inform our European commercial strategy for ARX-04. The team is presenting an analysis of the cost of delivering IV opiates in the European emergency departments.

Specifically, it was determined that the cost of IV administration of morphine ranges from 18 to 28 Pounds[2] in the EU5 countries of Germany, Spain, France, Italy and the United Kingdom. Most of this cost is associated with nursing time, specifically for drug administration and patient monitoring.

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[2] Mr. Morris intended to say Euros.

However, when the cost of treating adverse events, or AEs, and complications commonly associated with IV morphine, such as nausea, vomiting, phlebitis are factored into the equation, this range now increases to 121 to 132 Euros per patient. Thus, while drug costs themselves may be relatively low, the economic burden of treatment with IV morphine is rather high due to the costs associated with staffing and complications of IV administration.

A product such as ARX-04, which is a fixed-dose sublingual tablet, has the potential to have a lower healthcare burden. You could find this and our other posters we presented on our website under the Publications tab.

Now, on to our financials. Earlier today we reported the results for the third quarter ended September 30, 2016. You are encouraged to review that press release for specific details.

In summary, the net loss for the third quarter of 2016 was $11.4 million, or $0.25 basic and diluted net loss per share. This compares to a net income last year of $5.1 million, or $0.11 basic and diluted net income per share.

The net loss from operations in the third quarter this year was $8 million, as compared to net income of $7.1 million for the third quarter last year. As you'll recall, we recognized a milestone payment from Grünenthal for the approval of Zalviso in Europe in the third quarter of 2015, which resulted in positive net income for the quarter.

For the nine months ended September 30, 2016 we reported a net loss of $33.5 million, or $0.74 basic and diluted net loss per share. This compares to $13.9 million, or $0.31 and $0.37, respectively, diluted net loss per share for the same period in 2015.

At the end of September we had cash, cash equivalents and investments of $92.5 million. This compares to $113.5 million we had at the end of the year in 2015. This decrease was primarily attributable to cash used in operating activities.

Total cash used to date through the nine months ended September 30 was $21 million. We anticipate our cash balance will be approximately $75 million at the end of 2016.

Now for an update on Grünenthal. Grünenthal continues to roll out additional hospitals in countries in Europe. Germany, France and the UK are now in full launch mode. Belgium, Italy, the Netherlands and Ireland are still in pilot mode.

To date, Zalviso has been used in 83 hospitals over 7 countries. Informal feedback from patients and healthcare providers has been positive. We anticipate royalty revenue from Grünenthal will continue to be modest in 2016 and into 2017 as they continue their pilot programs and commercial expansion in various countries.

One item that investors may have missed is that we amended the terms of the debt payable to the Hercules Growth Technology. This happened at the end of the quarter.

We extended the interest-only period through April 1, 2017. If we are able to obtain FDA acceptance of the NDA for ARX-04 prior to April 1, 2016[3], Hercules has agreed to refinance the loan into a 36-month term note with an additional 6-month interest-only period.

In addition, subject to the achievement of certain milestones, AcelRx may be able to extend the repayment period up to 48 months and extend the interest-only period up to a total of 18 months. Also under certain conditions we may be able to borrow an additional $10 million over the amount outstanding.

In the short term, the additional interest-only period will reduce cash burn over the next six months. In the long term, the potential to refinance the debt and obtain an additional $10 million will give us added flexibility to fund the anticipated launch of ARX-04.

On the investor relations front, we will present at several investor meetings in Q4, including the Global Mizuho Investor Conference on November 14 in New York City; the Jefferies Healthcare Conference on November 15 and 17 in London; and the Piper Jaffray Health Care Conference November 29 in New York City.

Now I'll turn it back to Howie for a quick update on Zalviso and a few closing comments.

Howie Rosen: Thanks, Tim.

One last update regarding Zalviso. As I mentioned earlier, we initiated IAP312, a Phase 3 trial on hospitalized postoperative patients. IAP312 is an open-label study that will enroll approximately 315 patients who will use the Zalviso system to self-administer sublingual sufentanil tablets as often as once every 20 minutes for 24 to 72 hours to manage their moderate-to-severe acute pain.

The types of surgeries being included are abdominal, orthopedic and other surgeries. Multimodal pain therapy is also allowed.

The materials for IAP312 were manufactured by our commercial supply chain partners, and, based on our experience in previous clinical trials and in Europe, we incorporated certain software and hardware revisions to improve device usability and optimize system functionalities. We anticipate the enrollment and treatment period for IAP312 will continue through the middle of next year.

As Gina discussed, ARX-04 is advancing on schedule. With SAP302 and 303 completed now, we are working on the final sections of the new drug application, which we expect to submit to the FDA before the end of the year.

It's been a very busy time for AcelRx, with a presentation of clinical results, participation at the various medical meetings, preparations of the ARX-04 NDA and supporting Grünenthal's launch. I want to personally thank Pam and Gina and their respective teams as well as their other employees for all their long hours and dedication on behalf of patients and their shareholders.

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[3] Mr. Morris intended to say April 1, 2017.

Operator, let's open the call up to questions.

Questions & Answers

Operator: Thank you.

(Operator Instructions)

And the first question comes from Randall Stanicky with RBC Capital Markets.

Randall Stanicky: Great. Thanks, guys. I just have a couple. The first one is as you think about the launch of ARX-04 yourself inside the next year, when do you start ramping commercially? How big of a sales force do you think you'll need? And then lastly I guess this is probably for Tim, where can we expect that to take your quarterly burn rate to? And then I have a follow-up, as well.

Howie Rosen: Thanks, Randall. This is Howie. In terms of sort of our launch plans and ramp and things, those are things we're going to -- we'll go into a little bit more at our Analyst Day. But we are in general thinking about starting with some sort of pilot program to get to know the intricacies of the hospitals and other places where ARX-04 might be used, and then ramp from there.

As you're probably familiar with getting through the formularies and P&T committees and things, takes some time. So we want to make sure we do a good job of that and don't get ahead of ourselves in terms of putting resources in place.

Randall Stanicky: Well, let me follow up on that one. Tim, I mean, right now you're going to end the year at $75 million. You're burning about $10 million a quarter. Do you have the ability to self-fund that launch, either with partnering OUS or other opportunities? How should we think about that for 2017?

Tim Morris: Yes, I mean, clearly with the addition of commercial and support personnel the burn rate will go up. We haven't given any guidance on that yet. With the monies we have on hand right now, well, clearly, we have enough money to get through to the approval, but I probably don't have enough money or resources to get through the full launch.

Randall Stanicky: Okay. One last question for me. Howie, this is probably for you. Should we expect an AdComm just given what we've seen with opioids in general? And then if the answer to that is yes, which I suspect it is, how do you start preparing for that? Where do you think the focus will be?

Howie Rosen: Randall, thanks. That's a good question. So we won't know for sure until after we've submitted the NDA and we get feedback from the FDA. But we are anticipating there will be one, and as a result we are planning for that.

And so we already have contracted with an outside group to help us with the preparation. And also, rather than wait until three or four months before to get going, they've actually been helping us as we finish off preparing the NDA to just give us advice and input into what's in the NDA and also thinking ahead to if we do have an AdComm making sure we've covered key topics in what we have in our filing.

Randall Stanicky: Okay. Okay, great. Thanks, guys.

Operator: Thank you. And the next question comes from David Amsellem, with Piper Jaffray.

David Amsellem: Thanks. Just a couple. So first on 04, can you provide a little color on how you're thinking about pricing? And perhaps you'll probably address that at the Analyst Day, but maybe give us a window into your thinking and how you're thinking about comparators that inform your thinking on pricing.

And then, secondly, on Zalviso, are you confident that there are no more changes you actually need to make to the device? Is it safe to assume that the tweaking of the device is something that's a thing of the past and that there's nothing you need to do? I just wanted to make sure I'm not missing anything there. Thank you.

Howie Rosen: Yes, thanks for both those questions. So, in terms of pricing, we have not done our formal pricing study yet, so that's one of the things Gina and her team will do in 2017. But there's two things that we look at from the price.

We have said that as part of the funding we're getting from the Department of Defense, as part of that contract you have to agree to an initial potential purchase and a price, and the price we set with them was $20. So we really think of that as the floor.

And part of what's guiding our thinking is the ISPOR presentation we did earlier this year, the work that Pam did going into the claims databases and looking at actual costs in the -- it was like 6 million[4] patients in about 600 or more emergency departments over a couple-year period, is what we saw was that the cost to administer -- we were very surprised by this -- the cost to administer an IV opioid is over $140.

So we see that as representative of the overall impact in the emergency room of giving someone an IV. So if we can avoid that for a lot of patients we think there's a reasonable value there.

So I'll turn to Zalviso. In the case of Zalviso, part of the reason we've taken a little time to get the trial going is that we had been in mode of not really wanting to change things, and we realized since we were going to do another trial we should take the opportunity to change things that were on our list, so, for example, switching to our commercial suppliers for the controllers. So we have made what we think were the things that made sense at this point.

[4] Correction: it was over 7 million patients.

Having said that, in the world of -- this is a combination product. It's regulated by the drug side of the FDA, but there is a device component. And in the device world you actually have to have a process in place where you continue to collect information from the marketplace and evaluate it and, where appropriate, make changes.

So my expectation is that, yes, we will make changes in the future. But we feel good about the systems we're using in this study. And I would expect things we do in the future would be relatively minor would be what I would expect.

David Amsellem: Good. Thank you.

Tim Morris: Thank you, David.

Operator: Thank you. And the next question comes from Michael Higgins, with ROTH Capital Partners.

Michael Higgins: Thanks, operator. Afternoon, guys. A couple of questions for you, first on 04, your leading asset. Should we look for a filing in Europe in the first half of next year? And when do you look to seek a partnership for 04 in Europe?

Tim Morris: Yes, Michael, this is Tim. That is our plan, to file for the MAA the first half of next year. We've done a little bit of market research there and have some sense of what the market access will take. And so, yes, we will begin in earnest to talk with potential European partners about 04 in Europe.

Michael Higgins: Could you expand on that a bit? Are you looking for a regional, country-by-country? How do you approach that?

Tim Morris: It will be centralized filing, and so perhaps would be somebody who has pan-European presence, somebody that has some ability to promote to a hospital and also somebody that's experienced with either pain or opiates is helpful. So it could be multinational, but since the territory is limited to Europe or EU or the Continent or however you want to phrase it, most likely it'll be somebody who's fairly strong there but may not have a presence outside of that geography.

Michael Higgins: Okay. That's helpful. And then on your follow-on, Zalviso, I think from your comments you're looking for results possibly in Q3 of next year, just to clarify that for us, please.

Tim Morris: I'm sorry, you're looking for the end of the study, Michael, was it? What's your question?

Michael Higgins: Yes, for results on Zalviso, yes.

Tim Morris: Yes, that -- our guidance is that we think it's about nine months in life, and so that puts us sometime in the third quarter of next year for data.

Michael Higgins: Okay. And then it's hard to look and not see some studies being done with ketamine over the last few years. Just curious if in the 04 studies if patients who were allowed to have background ketamine use, I know they've had some rescue meds, if there's any data there around how you would expect that to work with both drugs onboard.

Pamela Palmer: Well, I mean, with any opioid we always have label warnings to be careful with other CNS depressants. So doctors, for the most part, wouldn't combine a ketamine with an opioid. They'd choose one or they'd choose the other.

You know, it's funny. People give a lot of lip service to ketamine, and they think it's kind of an interesting drug, but if you really go into most ERs, it's not a super commonly used drug the way that opioids are.

So, no, our patients -- we've had a couple of patients exposed to ketamine. They've used it in the operating room before they've started the patient on our ARX-04 or Zalviso in the postoperative period. And we've not noticed any particular issues. But, like I say, it's not a super commonly used drug at this point.

Michael Higgins: Maybe more so in the PCA setting, there's an article in August Pain Journal, 19 meta-analysis study with ketamine added to PCA with good results. Any impact at all that you've seen with your NanoTab with ketamine?

Pamela Palmer: So, are you saying -- so are you saying is there an adverse event issue of combining them? I guess I'm not sure of the question.

Michael Higgins: A little bit of both, I guess. Just trying to look to see how the two would interact. I don't -- I haven't found sufentanil IV being used in conjunction with ketamine, but it has been used with opioids. So just curious to see how -- if it has data in your studies, how it's worked.

Pamela Palmer: Yes, I mean, the thing about -- people don't use IV sufentanil because it's too short-acting when given IV, and that's the whole point of our company is that we're (multiple speakers) by giving it sublingually we're enabling it to have a pharmacokinetic profile that's usable in a postoperative setting.

Opioids in general, there's no specific contraindication to combine them with ketamine. They are both seen as depressants, and so you always have to use a lower dose of the two when you're using them.

And I think ketamine's been around for many, many years, and it's become a little bit more popular in its use, and, yes, you will have a number of small studies where people have tried using it, and, like I say, we've had a couple of patients being given ketamine in the operating room as part of their general anesthetic.

But it's not something that people commonly use with an opioid. They sometimes use it in place of an opioid.

Michael Higgins: Yes, it may be something that they're being proactive on rather than in the real world, so to speak, patient setting. And then, just finally, my last question, the Q3 cost of goods sold, should we look for that to continue going forward? Does it settle out over time?

Tim Morris: Yes, we would -- I'm sorry, could you repeat your question, Michael?

Michael Higgins: Sure. The cost of goods sold in Q3, is that a level that we should look forward to continuing, or is there some upfront costs there that level off over time?

Tim Morris: No, there are some fixed costs that will continue, so I would expect that particular line item to probably grow. It obviously is a function of ordering and the like from Grünenthal. But there are some fixed costs that get included in cost of goods sold. So I do not expect that numbered line item to go down over time.

Michael Higgins: Okay. Very good. Thanks, guys.

Tim Morris: Sure.

Operator: Thank you. And the next question comes from Hugo Ong, with Jefferies.

Hugo Ong: Hey, guys. Thanks for taking the question. I understand that you'll be presenting an analysis on obese patients from the 301 trial later this week. Any plan to do a similar analysis from the 302 and 303 trials in the future, and if not is there any reason to expect anything different from 301?

Pamela Palmer: No. You know, the 302 study was only 76 patients, so we're sort of limited in our ability to start cutting up that data and getting anything meaningful out of that analysis. But certainly with 140 patients in the 303 study, we'll probably do some analysis of that.

But the fun thing about -- one of the many fun things about writing up an NDA is that you get this integrated safety database where you really can look across all of your studies. And we're including some Zalviso patients into our ARX-04 database, as we've previously stated.

And so we can get so many different cross-sections of analyses, whether it’s looking at age, it’s looking at in BMI, it's looking at a whole different race, etc. You can look at a lot of different demographics.

So I'm excited about presenting much of that data from that NDA cross-sectional ISS, integrated safety analysis, in the meetings to come in 2017.

Hugo Ong: Okay, great. And maybe a question for you, Gina. Can you talk about how you see the plastic surgery market for ARX-04, and is this included in your peak estimate?

Gina Ford: Hi, Hugo. How are you doing? We are including that. We do think plastic surgery in a couple of areas, in our core market of hospitals, particularly around burn, so burn patients typically come in through the ER if they're admitted, and oftentimes have to have skin procedures. Plastic surgeons are typically involved in their care.

The other really exciting area, though, for ARX-04 is in plastic surgeons who have an affiliated surgical suite with their office. So they're actually performing a couple of procedures on a daily basis, and their goal is similar, in that they want to make sure that patients come out of surgery successfully, their pain is treated rapidly and they can be sent home as quickly as possible.

Plastic surgeons, that's their goal. If they can't manage pain today, and in fact I saw one of these patients at a recent surgeon that I visited, they actually had to send the patient to a step-down unit. So we are excited about that segment for ARX-04, and it will be included in our peak sales numbers.

Hugo Ong: Okay, great. Thanks for taking the questions, and looking forward to your Analyst Day in December.

Tim Morris: Thanks, Hugo.

Operator: Thank you. And the next question comes from Boris Peaker, with Cowen and Company.

Justin Collinshaw: Hi. This is Justin on for Boris. Thanks for taking my questions. I had a couple around the December Analyst Day. Do you think we'll get a Zalviso accrual update? And I was also wondering do you think you'll be able to share any lessons learned from your partner in EU, Grünenthal, with their launch and anything you could extrapolate towards the US market?

Tim Morris: Yes, hi, Justin, this is Tim. Really the purpose of the Analyst Day is to really present more about the opportunity for ARX-04, and that's the way the panel today is designed around that. I'm sure if we have something that we can share, since the program will be webcast and the Q&A will be webcast that we could probably give a brief update if there has been anything substantial in terms of either accrual or progress in Europe, but that's --

Justin Collinshaw: Okay. And then just one final question, is your current partner, Grünenthal, have they shown any interest in partnering for 04, or have you been able to rule them out as a partner?

Tim Morris: Well, we won't go into any specifics about certain discussions, but clearly they have Zalviso there. They understand the molecule. They understand the market. So from the outside looking in they look like they would be a good candidate.

Justin Collinshaw: All right. Thank you very much for taking my questions.

Tim Morris: Sure.

Operator: Thank you. And the next question comes from Ed Arce, with H.C. Wainwright & Co.

Ed Arce: Hi, everyone. Thanks for taking my questions. The first one is probably for Gina. As you start to look forward to the commercial launch and a targeted launch plan across the many hospitals, I understand some of these will be early adopters and will probably bring the molecule onboard within two or three months, others will probably take close to a year that are probably larger, more bureaucratic institutions. I'm just wondering how you think about rolling out pilots across the various different types of facilities like that.

Gina Ford: Thanks, Ed. We are really having a very focused look at our pilot and want to consider specific hospital types along with their prehospital ambulance agencies. We're looking in particular for those hospitals where there is a single formulary, so those hospitals that make a formulary decision for use in the hospital as well as use in the ambulance.

Those can be hospitals that are for-profit hospitals with county-fire EMS. They could be a not-for-profit hospital with a private EMS association.

So we're looking for very specific hospital types that will give us good insight to their formulary decisionmaking, how they will stock and maintain par levels of the product. Do they have nurse-initiated opioid administration protocols? And how can we go about getting ARX-04 onto those protocols quickly? That learning then will help us take this opportunity of running a pilot into a larger set of hospitals.

But we will continue to look for opportunity to walk before we run. We'd like to streamline that formulary process as much as we can. But we also know there's much more to implementing a product in a hospital, and we're going to learn as much as we can in our pilot program.

Ed Arce: Okay. Another question I had around the launch is just while there are some facilities that are more like an ACA, facilities that are looking at costs more holistically within the facility, I know there's a small subset of hospitals where the hospital pharmacist really only cares about the actual price of the opioid and not the all-in cost as you mentioned with your ISPOR data. Wondering how you might approach those facilities. And I would imagine those are probably a little bit later on in the roll-out.

Gina Ford: Actually, it's one of our first initiatives in the coming year, Ed, is to really evaluate integrated delivery networks, the IDNs, the ACA affiliations, where a patient is really monitored from the first point of care until they're actually discharged from whatever facility that could be. So we are interested in that type of model as a potential to bring the product into full use in those types of facilities, but we're certainly going to evaluate that before we just take on IDNs headstrong to begin with.

Ed Arce: Okay. A couple more questions, if I may. Is there any updated timeline with regard to filing for Australia? And since Pam had mentioned the NDA, I was just wondering if perhaps you could give us a number, a total number of patient count that's going to be submitted in that filing. Thanks.

Tim Morris: Sure, Ed, this is Tim. I don't have an update for you on the filing for Australia. That's actually the territory of Grünenthal. We'll look to get an update here in the next couple of weeks.

And in terms of patient numbers that will be included in the NDA, Pam?

Pamela Palmer: Sure. Yes, it's a total of 904 patients, including all active and placebo groups.

Ed Arce: All right. Great. Thank you so much.

Tim Morris: Thanks, Ed.

Operator: Thank you. And as there no more questions at the present time, I would like to return the call to Howie Rosen for any closing remarks.

Howie Rosen: Thank you. We look forward to keeping you updated on our progress and meeting you on December 1 at our Analyst Meeting.

Thank you again for joining us for our third quarter call, and if you're a baseball fan enjoy the World Series.

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