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

FORM 8-K

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

Date of Report (Date of earliest event reported): March 2, 2017

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**001-35068**	**41-2193603**
(State of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

351 Galveston Drive
Redwood City, CA 94063
(Address of principal executive offices and zip code)

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On March 2, 2017, 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 year ended December 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.

Exhibit Number	Description
99.1	Transcript of AcelRx Pharmaceuticals, Inc. Fourth Quarter 2016 Financial Results Conference Call on March 2, 2017, at 4:30 p.m. ET.

SIGNATURES

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

Date: March 6, 2017

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. Fourth Quarter 2016 Financial Results Conference Call on March 2, 2017, at 4:30 p.m. ET.

Exhibit 99.1

Event ID:
Event Name: ACRX - AcelRx 4Q16 and FY16 Financial Results
Event Date: 2017-03-02

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
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 fourth quarter fiscal year 2016 financial results conference call.

(Operator Instructions)

Please note this event is being recorded.

I would now like to turn the conference over to Tim Morris, Chief Financial Officer. Please go ahead.

Tim Morris: Thank you, Austin. Good afternoon, everyone, and welcome to today's 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 this call we will make forward-looking statements, and Jane will 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 the process and timing and anticipated future development of AcelRx's product candidates, DSUVIA, sufentanil sublingual tablet, 30 mcg, known as ARX-04 outside of the United States, and ZALVISO sufentanil sublingual tablet system, including US Food and Drug Administration, or FDA review of the new drug application, or NDA, for DSUVIA; the potential approval of the DSUVIA NDA by the FDA; the DSUVIA and ARX-04 clinical trial results; AcelRx's path forward towards gaining approval of ZALVISO in the United States, including successful completion of the IAP 312 clinical study for ZALVISO; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for DSUVIA, ARX-04 and ZALVISO; anticipated resubmission of the ZALVISO new drug application, or NDA, to the FDA, including the scope of the resubmission and the timing of the resubmission and FDA review time; and the status of the collaboration and license agreement with Grunenthal or any other future potential collaborations including 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 limitation, risks related to AcelRx Pharmaceuticals' DSUVIA and ARX-04 development programs, including the FDA review of the DSUVIA NDA; and the possibility that the FDA may dispute or interpret differently clinical results obtained from the DSUVIA Phase 3 studies; the ZALVISO development program, including successful 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 DSUVIA in the United States, ARX-04 in Europe, and ZALVISO in the United States; the uncertain clinical development process; the success, cost and timing of all development activities and clinical trials, including the clinical trial for ZALVISO, IAP312; AcelRx's ability to receive any milestone or royalty payments under the Grunenthal agreement and the timing thereof; ability to manufacture and supply sufficient quantities of ZALVISO to Grunenthal on a timely basis, the uncertain clinical development process, including adverse events; 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 Quarterly Report on Form 10-Q filed with the SEC on November 2, 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: Thanks, Jane.

While this announcement didn't take place in the fourth quarter, it's obviously going to be a topic of interest, so please allow me to take a moment to discuss our appointment of a new Chief Executive Officer.

You probably saw the recent press release announcing Vince Angotti, who's agreed to join AcelRx as CEO starting on Monday, March 6. We're very fortunate to have attracted someone with Vince's many years of successful commercial and management experience to lead the Company as we prepare for the potential approval and launch of DSUVIA in the US.

As many of you know, I stepped into the role of CEO for AcelRx in 2015 when the need arose. This transition to an externally recruited CEO is a key milestone in AcelRx becoming a commercial organization. I've served on the Board of Directors since 2008 and am looking forward to helping Vince and the AcelRx team in my continued role on the Board.

Now let's turn back to the fourth quarter achievements. The most important milestone we achieved in the fourth quarter was the submission of a new drug application, or NDA, with the US Food and Drug Administration for DSUVIA, our 30-mcg sublingual sufentanil tablet for the treatment of adult patients experiencing moderate-to-severe acute pain in a medically supervised setting.

Recently this application was accepted for filing, and a PDUFA date of October 12, 2017 was assigned. We continue to be excited about the potential for DSUVIA because of its simple single-dose applicator design that is administered to the patient by a healthcare professional. We're also grateful to our partners at the Department of Defense for bringing this unmet need to our attention and for their financial support.

The FDA has indicated to us that it plans to hold an advisory committee meeting to review the DSUVIA application. While the date of this meeting is yet to be determined, we're expecting to meet in a joint session with both the anesthetic and analgesic drug products advisory committee and a drug safety and risk management advisory committee during the summer.

We also anticipate instituting a REMS program to support the appropriate use of DSUVIA and to enhance proper administration.

While we started initial preparations for the advisory committee meeting, Gina and her commercial team continue to receive positive feedback from the market as they prepare for commercialization in the US should DSUVIA be approved. For Europe, we are on schedule to submit a marketing authorization application, or MAA, under the centralized procedure during the first half of this year.

We refined our expectations for DSUVIA's market potential in the US as well as in Europe, where the product is still called ARX-04, and we estimate peak revenues to be $1.1 billion and 700 million euros, respectively. We are seeing high interest from the medical community here about DSUVIA clinical results here and abroad.

I'll turn the call over to Pam now, who can give you an overview of what's been presented recently and what to look for in the coming months. Pam?

Pamela Palmer: Thanks, Howie.

Our efforts in the fourth quarter included presentations of results from the DSUVIA clinical program at the International Society for Burn Injuries, the Annual Meeting of the American Society of Plastic Surgeons, EMS World Expo, the European Congress on Emergency Medicine, the National Conference on Correctional Healthcare, and the Obesity Society Annual Meeting.

In addition, we made the first presentation of complete results from the DSUVIA Phase 3 SAP303 study at the Annual Pain Medicine Meeting of the American Society of Regional Anesthesia and Pain Medicine. SAP303, you will recall, was conducted in 140 patients, aged 40 years or older, who had undergone short-stay inpatient or outpatient surgery.

These results showed the patients administered DSUVIA experienced a 49% reduction in mean pain intensity from baseline during the first 2 hours and maintained that reduction for the duration of the 12-hour study period. The most frequently reported adverse events in the study population were nausea in 27% of participants and headache in 6%.

Another recent presentation we made at the ISPOR European Congress in Vienna is worth a mention, as well. That presentation outlined a European microcosting analysis of the direct and indirect costs associated with the administration of intravenous opioids. Direct cost of hydromorphone, morphine and other opioids are easy to find and tend to be relatively low, but materials and indirect costs such as IV setup equipment and nurse time to start an IV and to dose and monitor the patient, had not been clearly established.

Based on this analysis, we determined that an initial dose of an IV opioid can cost approximately EUR18 to EUR28 in emergency departments across the EU5. This finding was an important part or our market analysis and helped Gina and her team understand where the needs are in the marketplace.

Our earlier analysis of the cost of IV opioid administration in US emergency departments was presented at the US ISPOR meeting last year and is currently in press in the Journal of Health Economics and Outcomes Research. That analysis demonstrated a cost of over $140 for an IV setup and single-dose opioid administration in the emergency room.

Looking forward, we will continue to present our clinical data at medical conferences throughout the year, and two upcoming presentations are going to occur this month at the American Academy of Pain Medicine in Orlando and at the International Symposium on Intensive Care and Emergency Medicine in Brussels.

I will now turn the call over to Gina to talk more about commercial preparations.

Gina Ford: Thanks, Pam, and you're absolutely right. Conducting that pharmacoeconomic analysis was really eye-opening.

Since then we've learned a tremendous amount from KOLs about the impact that a product like DSUVIA might have in the emergency department. Not only is an initial dose of IV opioid surprisingly costly in both the US and Europe, as Pam mentioned, but it requires that a patient be assigned to a bed where they can be monitored.

Even the largest ERs have a limited number of beds, which they would prefer to reserve for critically ill patients. Unfortunately, if a patient in moderate-to-severe acute pain from a fracture, dislocation or other trauma comes in, they'll need to be assigned one of those beds in order to receive an IV opioid. So there's the increased indirect cost associated with IV opioids as well as increased utilization of hospital resources like beds that could be used to treat more critically ill patients if their moderate-to-severe acute pain patients could be treated elsewhere.

As it turns out, there may be alternatives. The same patient who came into the ER in moderate-to-severe acute pain from a fracture, instead of being assigned a bed, could be assigned to a chair, where they could receive DSUVIA. This process would save the patient from an intensive IV, would increase hospital throughput, decrease indirect costs and still allow the physician to treat and monitor their patient's pain so they can address the underlying trauma.

Given the size of the ER market -- an estimated 51 million adult Americans go to the ER for moderate-to-severe acute pain each year -- we decided to make this our initial launch target for DSUVIA. Once approved by the FDA we'll initiate our launch in a limited number of key institutions. We'll use the feedback during that initial launch to hone our strategy for a national rollout that we would expect to start in the first half of 2018.

When you factor in the markets outside of the ER -- ambulatory, short-stay and inpatient surgeries, certain other hospital procedures and certain painful procedures performed in offices -- we expect the peak sales in the US to be approximately $1.1 billion. As a reminder, we used an assumption of $45 to estimate the US market potential. However, that is not our expected price. We plan to do more analysis on the final price as we get closer to market launch.

Since our last call we have continued our commercial preparation, including completing DSUVIA brand identity, including finalization of the logo and packaging; hosting a face-to-face meeting of our product steering committee to review the ER positioning and to explore opportunities in other parts of the hospital and nonhospital surgical settings; analyzing the results of market access study in the EU to define standard of care in the emergency room in postoperative pain.

In the first quarter of 2017 we will continue our commercial planning, and our main activities will include: value proposition research; message testing; holding an advisory board with emergency department medical directors; and identifying target hospitals.

Tim, I'll turn the call to you to discuss our financial results.

Tim Morris: Thank you, Gina.

Earlier today we reported results for the fourth quarter and year ended December 31, 2016. You are encouraged to review that press release for specific details.

In summary, for the fourth quarter 2016 net loss was $9.7 million, or $0.21 basic and diluted net loss per share, as compared to net income[1] of $10.5 million, or $0.24 basic and diluted net income[2] per share for the fourth quarter of 2015. The decrease in net loss in the fourth quarter of 2016 as compared to the fourth quarter of 2015 was primarily due to an increase in revenue, partially offset by increased operating cost and expenses.

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[1] Correction: net loss
[2] Correction: net loss

For the full year ended December 31, 2016, we reported a net loss of $43.2 million, or $0.95 basic and diluted net loss per share, as compared to $24.4 million, or $0.55 basic net loss per share and $0.60 diluted net loss per share for the same period in 2015. For specific details on these results please refer to the press release and the Form 10-K.

As of December 31, 2016, AcelRx had cash, cash equivalents and investments of $80.3 million. This compares to $113.5 million at the end of 2015. The decrease was primarily attributable to cash used in operating activities.

As we discussed in last quarter's call, we amended the terms of the debt payable to Hercules Growth Technology, extending the interest-only period through to April 1, 2017. As a result of the FDA's acceptance of the DSUVIA NDA announced earlier, today we were able to refinance the loan in its entirety into a new 36-month term note with an initial 6-month interest-only period through October 2017. The scheduled maturity date is now March 2020.

In addition, under certain conditions we may be able to extend the repayment period up to 48 months, extend the interest-only period for a total of 18 months, as well as borrow an additional $10 million under the line. In the short term, the refinancing will give us the added flexibility to fund the commercial preparation for DSUVIA.

On the investor relations front, we've already had a busy quarter, having presented at the BIO CEO Investor Conference February 14, the Source Capital Disruptive Growth & Healthcare Conference February 15, Small Cap Nation Family Office & Life Science Symposium on February 21, and the RBC Capital Markets Global Healthcare Conference on February 22. I'm currently scheduled to present at the Cowen Health Care Conference on March 8, the ROTH Annual Conference on March 12, the inaugural Trout CEO Investor West Coast Conference on March 23, and I will make a return trip to the Smallcap Event sponsored by Invest Securities April 18 in Europe.

We will now look forward -- I look forward to seeing you in person at one or more of these events.

I'll now turn the call back over to Howie for a few closing comments.

Howie Rosen: Thanks, Tim, and thank you to everyone for dialing in for our fourth quarter and year-end conference call.

As you've heard, it's been an excellent quarter. We filed an NDA for DSUVIA and have a PDUFA date of October 12. We also feel we have a good understanding of the market and are busily preparing for launch. We have plans underway to file an MAA in Europe and are considering our commercialization options in that region. In regards to ZALVISO, we are still enrolling patients in the IAP312 study, and based on an anticipated completion of the study around mid-year, we plan to resubmit that NDA by year-end.

So in summary, we began our transition to a commercial company in 2016 and look forward to Vince Angotti joining us as CEO next week to accelerate the transition in 2017.

On that positive note, let's open the call up to questions. Operator?

Questions & Answers

Operator: Thank you.

(Operator Instructions)

Operator: And our first question comes from Randall Stanicky, with RBC Capital Markets. Please go ahead.

Randall Stanicky: Great. Thanks, guys. Just on pricing to begin with, I know you're using $45 as a placeholder, and this question's probably for Gina, but what are the considerations that go into where that ultimately ends up, and how do you think about the difference in pricing in the US relative to Europe? And then I've got a couple of follow-ups, as well.

Gina Ford: So good question. We completed this very broad forecast on sublingual sufentanil back last fall, and part of that process was interviewing pharmacy directors and really kind of asking them where they expected the product to be priced, in addition, where they would seek to maybe limit use of the product in their hospital.

And that limitation sensitivity around pricing was around $50. And so that's why we had some comfort in putting in our model based on our study of the epidemiology of moderate-to-severe acute pain, physician preference, dosing in certain segments. We felt very confident including in $45 in that model.

Randall Stanicky: Okay, so it sounds like $45 is pretty close to where it's ultimately going to end up based on the work that you've done so far. And then the follow-up to that, how do you think about that relative to Europe? Because obviously you have a peak sales number for Europe. You've not submitted the filing yet, but it sounds like you're close in the first half.

And there's a partnering decision, I assume, that factors into that thinking, as well, in terms of pricing. Is that right?

Gina Ford: That's right. And I don't have any idea where our ultimate pricing will end up as we launch this product. We have some continued analysis to do, and very specific research on pricing in the US.

Regarding Europe, we've also done some extensive work there, as well, looking at the epidemiology, preference share, what potential analogs might be to ARX-04 in Europe. We looked at both the transmucosal fentanyl products as well as a product that's recently been launched in the UK called Penthrox that has a price in the $17, $18 --

Howie Rosen: Europe is pound.[3]

[3] Correction: Euro

Gina Ford: -- pound[4] range. So that's why we feel confident in that marketplace, in that geography, talking about a EUR15 dollar[5], again, put into our model to look at the peak potential for ARX-04 in those territories.

Randall Stanicky: Okay, that's helpful. Howie, can I ask you a big picture question? With Vince coming onboard and the strategic direction of AcelRx largely set, how much strategic variability could there be? And what I mean by that is it sounds like you've got a strategic or a commercial plan in place for DSUVIA. Could there be some change in thinking about how you're going to market or change in thinking about how you think about ZALVISO?

Howie Rosen: So, good question, and, as I mentioned and as you're probably aware, Vince's career comes from the commercial side before he got into general management, and so Gina and her team are looking forward to Vince's input on sort of more of the details. So, as we've mentioned, we feel like we have a good understanding of the market and where the products fit, but we still have a lot of work in terms of tactics and exactly how you enter the hospitals and what other opportunities there may be outside the hospital, as well.

So definitely we expect some fine-tuning, and especially as we work from the broader strategy to the tactics, but wouldn't necessarily expect big changes in the overall direction of wanting to commercialize these products ourselves in the US.

Randall Stanicky: Okay. That's great. Thanks, guys.

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

Boris Peaker: Great. Thanks for taking my question. Initially I just want to focus on the broader picture. And with all the discussion about reducing opioid use in general in the medical community, are there any initiatives that are being incorporated into the emergency room practice to also kind of reduce opioid use?

Howie Rosen: Pam, do you want to address that?

Pamela Palmer: Sure. The sensitivity around emergency room use of opioids really is in that outpatient prescription that's handed to the patient. Appropriate use in the emergency room when a patient's in there for just a few hours of opioids or any analgesic that's necessary to set a fracture or deal with severe low back strain or what have you has never really been challenged.

It's the idea of these folks coming in with low back strain and then walking out with 60 Percocet or OxyContin that's really the bigger problem. But our product is purely for use while they're in the hospital.

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[4] Correction: Euro
[5] Correction EUR15

Boris Peaker: Got you. Okay. And so my other question is on you said you want to do a kind of small trial launch of DSUVIA initially. What are the criteria that you're using in selecting these initial target hospitals?

Gina Ford: We're going through the process right now of really identifying from our ER strategy, really looking at where there is overutilization of resource, patients being delayed their treatment for an IV opioid while waiting on a bed. So we know or feel strongly that there are some hospitals that match that that we would really want to target first.

And so we're going through the analysis right now to really look at, as Howie mentioned, how we go from the overall strategy to identifying those hospitals that could really benefit from ARX-04 to begin with, help us learn, get some initial traction, and then we would plan to grow from there.

Boris Peaker: And how many of these hospitals do you anticipate? I just want to kind of get a sense of would it be any kind of material revenue from these hospitals that would provide a good readthrough to other hospitals, or is it going to be just too few of them to really make a conclusive kind of estimate?

Tim Morris: Yes, Boris, Tim here. The revenue won't be significant or even probably recordable. It's the learnings from the hospital, it's the establishment of best practices, the throughput, the data that we get from those early on. But the revenue numbers will be insignificant.

Boris Peaker: Okay, great. Thank you for taking my questions.

Tim Morris: Sure.

Operator: And our next question is from Michael Higgins, with ROTH Capital Partners. Please go ahead.

Michael Higgins: Hi, guys. Thanks for taking the questions. If we can go across the pond for a moment, just looking ahead to the potential DSUVIA European rights, how has the feedback been so far? What kind of companies are you talking to? Are they larger or smaller? Are you favoring a one-company approach versus several? Any color you can provide there would be helpful. Thanks.

Tim Morris: Sure. The potential market and potential partners in Europe take all forms and shapes, from multinationals to pan-European to regional. Even though we think sometimes of Europe as one nation, one country, or we'll be under a central procedure, each market is slightly different.

So we'll look at a variety. We won't lock ourselves in. Obviously for us it's about maximizing the value and the potential of the asset.

Michael Higgins: In terms of timing for that, is it something you want to do after approval, or would you consider that prior to approval?

Tim Morris: Yes, it's hard to put a timeline on BD activities. We'll continue to talk to folks, and if we have something we like we'll do it. If not, we'll cross that bridge when we come to it.

Howie Rosen: Michael, I'll just jump in and say one thing we did do with ARX-04 is we have put together the MAA ourselves and will be prosecuting that ourselves. So in the case of ZALVISO we felt as a company we weren't sort of comfortable with doing that, and we did wait until we had a partner.

So we are being more proactive with ARX-04 so that we can keep building value. And we have the flexibility now to be able to wait for the right kind of deal, because we are moving the product ahead in the regulatory process.

Michael Higgins: Sure. And from a value standpoint it makes more sense to hold onto it. So point taken. And then back here in the US, what are your thoughts on potential timing for an AdComm? With an October 12 PDUFA you could fall into that August trap. So wondering what kind of timing you're looking for there.

Howie Rosen: We're planning sort of the July-August time frame. So I'm not quite sure what you mean by the August trap. They actually, if you look back the past few years, this division has had meetings in August, I know last year and I think the year before, and you could probably go back past years. So if you're referring to everyone going away in August and nothing happening, they do have a history of actually having AdComms in the early part of August.

Michael Higgins: Okay. Understood. And if I can move to ZALVISO, any stocking that we saw in Q4 numbers, any updates you can provide for us there in the country-by-country launches?

Tim Morris: No, I wouldn't -- I mean, there obviously is a little bit of inventory, but not enough to point out. We don't have any breakdown of the country-by-country revenues. We do know that Grunenthal is now engaged in nine countries across Europe for the commercial launch of the product.

Michael Higgins: Okay. That's helpful. And should we see a few more here in the first half of the year?

Tim Morris: Yes, they do continue to plan to roll out. They have the rights to all of Europe, which includes 40 territories. But they are being methodical, and they are rolling it out across all of these different countries and territories.

Howie Rosen: And they are continuing to make the transition from what they are doing in terms of their pilot rollouts to a broader commercial effort in the countries. And they're doing that this year.

Michael Higgins: And then one final one financially. Operationally it looks like you've got some programs that are winding down. The marketing spend will gradually increase later in the year, more so in 2018 it seems like. If, Tim, you can provide us some sense as to how the quarters may look looking into 2017?

Tim Morris: Sure. I think I'll just reiterate the guidance that we had given previously. The historical burn is around $10 million a quarter. I would expect that trend to continue at least for the first half. I've given guidance that we would expect to end Q2 at around $50 million in cash.

Beyond that, assuming there's a positive decision at advisory committee, you would expect the commercial spend to increase. But I haven't given much if any guidance on that.

Michael Higgins: Very helpful. Thanks, guys.

Operator: And our next question is from Ed Arce, with H.C. Wainwright. Please go ahead.

Ed Arce: Great. Thanks for taking my questions. So, first one just focused on DSUVIA and your upcoming AdComm, just wanted to get a little more details around some of the key aspects that you're thinking of, that you're preparing for, in particular things where you think the FDA and the panel could focus on, and how you're thinking through that. And then I have a couple of follow-ups.

Howie Rosen: Yes, so it's a little -- I guess this division's a little bit different than what you typically see is usually you think of AdComms being called because there's some major question or issue around the drug. And, as you know, with this division they really have sort of put in place just the practice of with a new opioid having an AdComm.

And so I just mentioned that because it's not like there's something in particular about our product that says, oh, we need to have an AdComm. It's more just that we fall into -- it's the sort of thing you would call class labeling if you were talking about the product label.

But as typical with these products, it's joint between the division as well as the safety panel, and so, I don't know, Pam, if you want to comment on the types of things that often come up in terms of REMS and those types of things.

Pamela Palmer: Sure. I mean, recently it's been around the abuse-deterrent nature of opioids and the outpatient use of them. And our product's so different, being in a medically supervised setting and not being an extended release product, that we're not even sure what they would utilize at AdComm for what would be the question posed them, and we've not definitively actually heard, but we stated that we were going to have one and what date it would be on. So we're just assuming that we are having one and we're going forward and preparing for it as best we can for -- assuming it'll be in the July-August time frame.

Ed Arce: Right. Well, I mean, I guess that's what I was really driving to is that given the compound is so well-known and understood, and this is an oral that is given in the hospital and all those other abuse issues are almost -- they don't apply, but their -- I think the practice has been, as you mentioned, with all opioids to have one. So I'm not really sure what they're going to fill the half-day or day with in terms of questions.

Howie Rosen: Yes, but we will prepare and we will eventually find out.

Ed Arce: Okay. And in terms of your ongoing discussions with potential partners in Europe and perhaps in other areas, one question I was wondering is in your agreement with Grunenthal is there any sort of a legal structure in there, some sort of a right of first refusal around the compound that would apply to DSUVIA, as well, or is that -- is there -- there no such agreement?

Tim Morris: Correct, yes. There's no rights to ARX-04 in the agreement with Grunenthal, and their agreement is exclusive to EA40[6] for ZALVISO.

Ed Arce: Okay. And then just one last question, Tim, I just wanted to, if you could, go over again the refinancing terms that you mentioned earlier just to get that clear.

Tim Morris: Sure. So the debt that you'll see on the balance sheet at the end of 2013, the $21-some-odd million, is now -- starting at the end of 2016 -- is now going to be reset on a 36-month amortization beginning today with a six-month interest-only period that will go through October of 2017.

Also included in the refinancing or the new note is the ability to earn two additional six-month interest-only periods following the initial six-month period that have to do, essentially, with the approval of DSUVIA in the US and the collection of an additional $40 million of either partner or new equity in the same time frame. We also have the ability to, if we've reached those last two requirements, to get an additional year of amortization, so that would push the term out an additional 12 months, as well.

Ed Arce: Okay. Great. Thanks for taking the questions.

Tim Morris: Certainly, thanks Ed.

Operator: Our next question is from Hugo Ong, with Jefferies. Please go ahead.

Hugo Ong: Hey, guys. Thanks for taking the question. Most of mine have been asked, but let me follow up with just one question on DSUVIA. In the past you've hinted at running a head-to-head trial of DSUVIA versus IV morphine. Can you talk a little more about the design and kind of what you hope to show with that trial?

Pamela Palmer: Sure. Our plan is to start that trial at the end of this year, following our PDUFA date with DSUVIA here in the US. And it's really to help support both DSUVIA here in the US as well as ARX-04 in Europe.

And the idea is looking at sort of the first hour of efficacy, and that hour would start with randomization. So the idea is that you would randomize someone to receive DSUVIA. All the nurse has to do is go to the Pyxis, take out the drug and dose the patient. But if they get randomized to the IV morphine arm they actually have to go and collect the materials, start the IV, then go to the Pyxis, get the drug, dose the morphine, bring it to the patient, dose the patient, etc.

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[6] Countries of the European Union, the European Economic Area, Switzerland and Australia.

And so we're really trying to show that when someone is walking through a door without an IV that it's actually faster for sublingual DSUVIA than having to start an IV and dose them with an IV opioid. And, in fact, we've already shown in our ZALVISO studies that sublingual sufentanil is more rapid than IV morphine when they're started at the same time.

So when we actually have a head start with having to start the IV, we think that that SPID1, the SPID over the first 60 minutes, will in fact be pretty easy to show both the noninferiority as well as probably superiority.

Hugo Ong: Okay. And when would you expect this trial to finish?

Pamela Palmer: Well, we'll probably run about six months in life with that.

Hugo Ong: Okay. Okay. And would the DOD pay for this trial?

Pamela Palmer: No. This is something we'd be using probably for commercialization purposes here in the US. Europe often likes to see active comparator studies, and our MAA will be in process at the time. So it's just almost belt and suspenders in case they want to see a little extra data possibly there.

Hugo Ong: Got it. Okay. Thanks for taking the questions.

Pamela Palmer: Sure.

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: Thank you. We look forward to keeping you apprised of our progress, and thank you again for joining us for our call today, and have a good afternoon and evening.

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