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 8, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On May 8, 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 ended March 31, 2017 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. First Quarter 2017 Financial Results Conference Call on May 8, 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: May 9, 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. First Quarter 2017 Financial Results Conference Call on May 8, 2017, at 4:30 p.m. ET.

Exhibit 99.1

Event ID:
Event Name: ACRX - AcelRx 1Q17 Financial Results
Event Date: 2017-05-08

Officers and Speakers
Tim Morris; AcelRx Pharmaceuticals, Inc.; CFO and Head of Business Development
Jane Wright-Mitchell; AcelRx Pharmaceuticals, Inc.; Chief Legal Officer
Vince Angotti; AcelRx Pharmaceuticals, Inc.; Chief Executive Officer
Pam 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
Sameer Singh, Piper Jaffray
Michael Higgins, ROTH Capital Partners

Presentation

Operator: Good day, everyone, and welcome to the AcelRx first quarter 2017 financial results conference call.

(Operator Instructions)

Please do note that this event is being recorded.

I would now like to turn the conference over to Tim Morris. Please go ahead.

Tim Morris: Thank you, Will. Good afternoon, everyone, and welcome to today's call. I'd like to welcome Vince Angotti, our Chief Executive Officer, to his first AcelRx conference call. We're also joined here today by Pam Palmer, our Co-Founder and Chief Medical Officer; Gina Ford, our Vice President, Commercial Strategy; and Jane Wright-Mitchell, our Chief Legal Officer.

Before we begin the call 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 of 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 and the anticipated joint advisory committee meeting; the potential approval of the DSUVIA NDA by the FDA; the European Medicines Agency, or EMA, scientific review of the ARX-04 Marketing Authorization Application, or MAA; 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 IAP312 clinical trial for ZALVISO; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for DSUVIA, ARX-04 and ZALVISO.

These forward-looking statements are based on AcelRx Pharmaceuticals' current expectation and inherently involve significant risk and uncertainty. 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; the anticipated joint advisory meeting for DSUVIA; and the EMA review of the ARX-04 MAA, including possibility that the FDA or EMA may dispute or interpret differently clinical results obtained from DSUVIA or ARX-04 Phase 2 and 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 products, including DSUVIA in the United States, ARX-04 in Europe, and ZALVISO in the United States; the uncertain clinical development process, including adverse events; the risk that planned clinical trials may not be effective clinical design -- excuse me, may not have an effective clinical design, enroll a sufficient number of patients or be completed on schedule, if at all; the success and timing of all development activities and clinical trials, including the additional clinical trial for ZALVISO, IAP312; 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 3, 2017. AcelRx undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

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

Vince Angotti: Thanks, Tim, and thanks, Jane, and thanks to everyone for dialing in for today's call.

In my short couple of months here at AcelRx I've not had an opportunity to meet many of you. Let me take a very brief moment and introduce myself.

My experience through the past 25-plus years has been across all business functions, with a primary focus toward sales, marketing and operations. I started out at Novartis, where I spent 10 years holding several different positions, including early in my career that of a sales rep and manager in the hospital and military accounts. This helped familiarize me with the unique challenges and opportunities in that segment.

From Novartis I moved to a commercial startup called Reliant Pharmaceuticals, where we built the commercial operation from scratch. After eight years we sold Reliant and I moved on to XenoPort, where I held roles as the chief commercialization officer, chief operating officer and CEO. While at XenoPort, relevant experiences included the reacquisition of Horizant and the successful rebranding and relaunch of that product in both restless leg syndrome and neuropathic pain.

Those experiences help me to appreciate AcelRx's commercial startup nature and its potential to have an impact on the current treatment paradigm of acute pain management, specifically in the emergency and ambulatory hospital settings, and as such we continue to develop the potential launch plan for DSUVIA in the US and have made a few select additions to the commercial team in the areas of market access, sales strategy and marketing. We continue to believe that AcelRx's portfolio is one that can be launched with a manageable commercial infrastructure and marketing spend.

With that said, the acceptance of the New Drug Application for DSUVIA by the FDA, the potential to resubmit the ZALVISO NDA in the US towards the end of the year, and notification from the European Medicines Agency that ARX-04's Marketing Authorization Application passed validation and consequently is under scientific review, has our immediate focus on the regulatory path for our portfolio.

Now I'll turn the call over to Pam to provide an update on these matters.

Pam Palmer: Thanks, Vince.

We had two significant regulatory milestones in the first quarter related to DSUVIA. First, as Vince mentioned, the US FDA notified us that they accepted our New Drug Application for DSUVIA, our 30 mcg sublingual sufentanil tablet product. We have also been informed that a joint meeting of the Anesthetic and Analgesic Drug Product Advisory Committee and the Drug Safety and Risk Management Advisory Committee will be convened, and we anticipate it will take place this summer.

Second, as Vince mentioned, the European Medicines Agency notified us that they have begun their scientific review of the Marketing Authorization Application for ARX-04, as DSUVIA is called outside of the US. We expect an opinion on the MAA from the Committee for Medicinal Products for Human Use in 2018.

The medical team has continued making presentations at medical meetings worldwide. We also published complete findings from the Phase 3 SAP301 trial comparing placebo to DSUVIA in patients who underwent ambulatory abdominal surgery. This publication is in the open access journal *Pain Practice* in an article titled, “Sufentanil Sublingual Tablet, 30 mcg, for the Management of Pain Following Abdominal Surgery: A Randomized, Placebo-controlled Phase 3 Study”. If you would like the link, please visit the Publication page on our website.

As you'll recall, patients in SAP301 who received DSUVIA experienced a greater reduction in pain from baseline over the study's 12-hour period, called SPID-12, than did patients administered a placebo, with a p-value less than 0.001. This pain reduction was observed as rapidly as 15 minutes after administration. On average, patients in the DSUVIA arm requested additional doses every three hours. DSUVIA was generally well tolerated by patients in SAP301, with mild to moderate nausea and headache being the most commonly reported side effects.

Our other two DSUVIA Phase 3 studies, SAP302 in emergency room patients with acute trauma or injury, and SAP303 in patients aged 40 years or older, have both been submitted for publication and hopefully will be available online later this year.

Regarding ZALVISO, our 15 mcg sublingual sufentanil tablet system, we just completed enrollment in the IAP312 study, which you'll recall is the Phase 3 study designed to capture information on device usability, such as failures to dispense medication or dropped tablets, as well as safety and efficacy. We expect to have top-line results for you this summer and would then look to present the full dataset at a medical congress later this year or early 2018. Based on the results of that trial, we would plan to resubmit the NDA for ZALVISO with the US FDA towards the end of 2017.

Now let me turn the call over to Tim, who can run through the first quarter financials with you.

Tim Morris: Thanks, Pam.

Earlier today we reported financial results for the first quarter ended March 31, 2017. I refer you to that press release for specific details on the actual results.

Net loss for the first quarter of 2017 was $15.6 million, or $0.34 basic and diluted net loss per share, compared to $11 million, or $0.24 basic net loss per share and $0.25 diluted net loss per share for the first quarter of 2016. The net loss from operations in the first quarter of 2017 was $12.1 million, compared to $8.5 million for the first quarter last year. The higher net loss was due to larger R&D expenses, specifically for the IAP312 study.

As of March 31, 2017, AcelRx had cash, cash equivalents and investments of $72.3 million. This compares to $80.3 million at December 31, 2016. The decrease was primarily attributable to cash used in operating activities.

With that, I believe we can open the call to questions. Operator?

Questions & Answers

Operator: Thank you.

(Operator Instructions)

And it looks like our first questioner today is Randall Stanicky, with RBC Capital Markets. Please go ahead with your question.

Randall Stanicky: Great. Thanks, guys. Hey, Vince, can you maybe drill down a little bit further into the launches coming up for DSUVIA and ZALVISO. It's possible you could have two launches within roughly six months, and I assume there's an opportunity to leverage both of those. And maybe just go back to your comments on manageable commercial infrastructure and maybe help us understand how many reps and the timing for both DSUVIA relative to ZALVISO in terms of how those roll out.

Vince Angotti: Sure. Let me see if I can talk to that question, and thanks for that, Randall. So, when we talk about manageable cost structure, there's a couple different ways we look at it. First of all, from a sales team deployment standpoint, when we look at and do our research as it relates to institutional sales teams in the US, it comes out the data suggesting about an average of around 60 headcount in order to efficiently penetrate the markets.

Now, I can't tell you that's where we're going to be exactly. We would likely be on the lighter side of that as it relates to an adaptive approach where we would start small and as we begin to master the communications, understanding the timing of P&T committees, etc., and have success with a smaller sales team, look to replicate that as we move forward to give us more predictable return on our investment. And by doing so that allows us to really manage our cost structure to be sure it doesn't get too far ahead of revenue as we ramp up.

So that's as it relates to the structure. As you think about advertising promotional spend, the unique aspect of our particular product, and you would market it in institutions, is that where you typically might see many launches with a DTC spend in samples which often make up the predominant amount of investment in those launches outside of the sales team, those are two aspects we would not have in the launch of a DSUVIA or ZALVISO, keeping it much more manageable moving forward.

So we like the fact that you can penetrate the market with a relatively tight headcount and tight A&P spend moving forward, A&P being advertising and promotion. Beyond that, Randall, I think you mentioned a question as relates, is there overlap. And while we continue to evaluate the market and assess the accounts, and we'll have Gina talk to you a little about how we're segmenting accounts moving forward, there certainly would appear to be an overlap in accounts that are being targeted for both DSUVIA and ZALVISO, meaning you wouldn't have to start adding significant additional headcount for a ZALVISO launch thereafter DSUVIA.

What we're continuing to evaluate as it relates to those two particular launches is the time segment required for each of those particular launches, meaning that DSUVIA is really on a drug marketing communication, whereas ZALVISO is going to be heavier for the device aspect of the sale. And so we just want to be sure that we understand the opportunity cost of one versus the other as it relates to time spent in any particular area of the hospital which may affect the time spent on the alternative product.

So we're going to continue to focus early on for DSUVIA. Obviously we'll continue to analyze the overlap as it relates to time and messaging with ZALVISO. But we feel very good about a manageable cost structure moving forward where in the event we continue to move forward with the ZALVISO launch as well that you're going to have consolidated costs as it relates to the deployment of your resources.

I hope that helps answer most of your question. In addition, I'd ask just Gina to quickly comment on how we're looking at hospital segmentation.

Gina Ford: Sure. Randall, we're really studying or digging into hospitals that would be most receptive to DSUVIA during this initial adaptive launch. We believe those types of hospitals include hospitals with both high-volume emergency departments as well as those that conduct a high volume of surgeries or procedures that result in moderate to severe acute pain.

In addition to that, we're looking at hospitals that would be considered early adopters of new technologies or efficiency programs. And then, finally, we're looking at hospitals with emergency departments that are reporting providing pain relief in that first 30 to 45 minutes of a patient reporting moderate to severe acute pain.

Vince Angotti: So then you can see that there's clearly going to potentially be efficiency in account targeting, but as it relates to the departments within the account in this adaptive approach as Gina described it, we'll be going to the EMS setting first, with hopefully not long after expansion to other areas of the hospital that are appropriate for both products. Does that help, Randall?

Randall Stanicky: It does. And, Vince, if we looked at the other two buckets, the nonhospital setting buckets, I assume those are the later opportunity. But is there an opportunity to partner that aspect of the market and really focus on the hospital and the ER?

Vince Angotti: Yes, that's a great question. So I would communicate that they would be later segments as it relates to penetrating that market. And it's certainly something that we would entertain as it relates to penetrating those markets moving forward. Again, we want to stay focused as best as we can, at least today, in the accounts within which we'll be calling on at the start.

Randall Stanicky: Great. And, Tim, just really quick on cash, the $72 million, is that generally where you thought you'd be? And I think you threw out a $50 million target, midyear target previously. Maybe can you update that for us?

Tim Morris: Yes, we won't change that guidance. I mean, historically we've had about a $10 million per quarter burn rate, obviously a little bit under that in the first quarter. Some of that has to do with timing of working capitals. But for right now I think the prior guidance still stands.

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

Vince Angotti: Thank you.

Operator: And our next questioner today is Boris Peaker, with Cowen. Please go ahead with your question.

Boris Peaker: Great. Thanks for taking my questions. My first question is I'm just curious what you anticipate the advisory committee to focus on, since this is not really a new chemical entity.

Vince Angotti: Thanks, Boris. We'll have Pam answer that one.

Pam Palmer: Sure. I think, yes, you're right, it is pretty much new for them. Most of the opioids that have gone to the AdCom have really been around abuse-deterrent formulations. And so certainly that's not what we are. We're looking to be used in medically supervised settings.

So the majority of our REMS is really around making sure we have a restricted distribution specifically to medically supervised settings and not to retail pharmacies. So there could possibly be questions regarding the appropriateness and the details of our REMS. But we will see. Certainly we'll be learning more from the FDA when we get a chance to see the questions they're specifically interested in asking at the AdCom.

Boris Peaker: And also in the context of your regulatory process, I'm just curious, does the DEA get involved, or at which stage does it get involved, specifically?

Pam Palmer: No, the DEA is not specifically involved with us directly. They could be involved with the FDA, but we're not interacting with the DEA in this process.

Boris Peaker: Great. And lastly, maybe, on ZALVISO, with the study that's currently ongoing, I'm just curious, what pill handling error rate do you think is acceptable from the current study, or kind of where do you -- what do you anticipate to be good outcomes from the ongoing trial?

Pam Palmer: Well, we know that -- what the FDA has requested from us from a standpoint of powering the study, and that is we're looking for a device failure rate to be lower than 5% for the upper confidence interval. That is what we've agreed to with the FDA, and that's how we powered our Phase 3 clinical trial.

Boris Peaker: Great. Thank you very much for taking my questions.

Vince Angotti: Thank you.

Operator: And our next questioner today is going to be David Amsellem, with Piper Jaffray. Please go ahead with your question.

Sameer Singh: Hey, this is Sameer on for David, so just two quick ones here. How do you think the overall environment for opioids could impact your ability to gain traction with DSUVIA? Also you touched on this in the last question, but are you planning for potentially getting a more restrictive labeling or a restrictive REMS for the product, given all the scrutiny of this space? Thanks.

Vince Angotti: So, just as a general commentary, I just want to remind everyone that while it certainly isn't lost on us the concerns in the opioid market and epidemic in the US, and we clearly sympathize with that, our product is, as it relates to the indication and the studies we're moving towards, under medical supervision, typically in an institutional setting for the most part.

So this is not a product, I'll remind you, that you could get to take home with you, that you could get at your local Rite-Aid, your CVS, your Walgreens, etc. And just by the nature of that we feel that there is an opioid place in the acute pain setting and it would be restricted as it relates to the ability to receive that product in those institutional settings, for the most part.

Pam, do you have any additional commentary on that?

Pam Palmer: No, that's absolutely right. In fact, our label specifically will say for pain that cannot be managed, adequately managed any other way. And it is restricted to use in moderate to severe pain. Opioids have been around for many, many years, and they will continue to be around, and specifically in the acute setting in medically supervised settings no one's really questioning their appropriate use there.

Sameer Singh: Thanks.

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

Michael Higgins: Thanks, operator. Good afternoon, guys. A couple of questions, first on DSUVIA if I could. If you look at the European market dynamics how would you describe those in contrast with the US market?

Gina Ford: Hey, Michael, it's Gina. Thanks for the question. We still consider the European market a good opportunity for DSUVIA. Certainly, as Pam just mentioned, opioids in the treatment of acute pain is not restricted to the US. It's universal. So it certainly applies there, as well. We have looked at the size of that market and truly believe, again, the right place for an organization to target their opportunity would be in emergency medical services, and then also looking at post-op pain opportunities.

Michael Higgins: So given the learning that you've had from Europe so far with ZALVISO, how much clarity and insights can you gain from what Grunenthal's been doing to leverage the DSUVIA interactions?

Vince Angotti: I think what we can do is give you some insight as it relates to some recent performance related to ZALVISO in the European markets, and, Tim, if you can quickly touch base on that and some of the recent ramp or acceleration that we've seen.

Tim Morris: Sure. Through March ZALVISO has been used in about 4,800 patients and about 153 hospitals in nine countries across the EU. We have seen a nice growth in the first quarter of this year as compared to all the prior quarters. And so I think Grunenthal's shown that the product has a good uptake and people are looking forward to continuing to use the product.

Vince Angotti: Yes, I think some specifics as it relates to that, we've seen through the first quarter of this year close to 100% growth in the number of patients treated versus through the fourth quarter of last year. And we've seen the growth in actual accounts that have utilized ZALVISO up almost 40%, as well. So that translates into a couple different things.

Number one, the hospitals that were currently purchasing the product are beginning to expand their purchasing of the products. You're getting more adoption within those institutions. And secondly newer accounts are beginning to adopt ZALVISO, as well. So we're excited about how Grunenthal is continuing to move forward, again in a fairly stepwise approach as it relates to their targeting moving forward by country and by account, and the more recent growth or slope in the line as relates to adoption of the product.

Michael Higgins: That's great. Very helpful. Thanks. A question for you back in the States on DSUVIA, kind of an AdCom-related question, I suppose, is how many doses have patients received per patient in the DSUVIA studies? I guess I'm looking more so for the max number across those studies.

Pam Palmer: The maximum dose that has ever been dosed to a patient across those studies?

Michael Higgins: Right.

Pam Palmer: Well, it can be dosed hourly. On average the patients are dosing every two and a half to three hours depending on the study. It also depends on the length of the study. Most of our studies will run for 12 hours. One study did run out to 48 hours. But the most frequent dosing we've seen is about every hour and a half.

Of course, in our Phase 1 study we did dose every hour to get a multiple-dose exposure, but those patients were naltrexone blocked. So if you're looking at it from a safety standpoint it's going to be limited safety data given that naltrexone block.

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

Vince Angotti: Thank you.

Operator: There look to be no further questions, so this will conclude our question-and-answer session. I would like to turn the conference back over to Vince Angotti for any closing remarks.

Vince Angotti: Great. Thank you, operator.

As you heard, we had two important milestones in the first quarter. The FDA accepted our New Drug Application for DSUVIA and the EMA notified us that their scientific review of the Marketing Authorization Application for ARX-04 has commenced.

Over the next few months we expect to be able to provide you with more information about a date for the joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee for DSUVIA, efforts to build a commercial infrastructure to support a DSUVIA launch, and, finally, top-line results and the presentation of complete results from the ZALVISO IAP312 study, which recently concluded enrollment.

We're working to prepare for the DSUVIA AdCom meeting, which we will expect to be taking place in the summer. And with the conclusion of IAP312 we're also preparing for the resubmission of the New Drug Application for ZALVISO, which we expect to be submitted by the end of the year. So, needless to say, the second half of 2017 holds a significant number of milestones for AcelRx, and we'll continue to keep you informed as we move forward with commercialization plans, and we appreciate your continued support.

So thanks again for tuning in to our first quarter call. Have a great evening.

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