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): July 28, 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 July 28, 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 June 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. Second Quarter 2016 Financial Results Conference Call on July 28, 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: August 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. Second Quarter 2016 Financial Results Conference Call on July 28, 2016, at 4:30 p.m. ET.

Exhibit 99.1

Event ID:
Event Name: ACRX - AcelRx Second Quarter 2016 Financial Results
Event Date: 2016-07-28

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
Ashley Ryu, RBC Capital Markets
David Amsellem, Piper Jaffray
Boris Peaker, Cowen and Company
Ed Arce, H.C. Wainwright & Co., LLC
Michael Higgins, ROTH Capital Partners
Hugo Ong, Jefferies LLC

Presentation

Operator: Good afternoon, and welcome to the AcelRx second quarter 2016 financial results conference call.

(Operator Instructions)

Please note this event is being recorded.

I would now like to turn the conference over to Mr. Tim 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, sufentanil sublingual tablet system, including the ARX-04 clinical trial results; ability to fund the ARX-04 development from the contract with the Department of Defense; anticipated submission of the New Drug Application, or NDA, for ARX-04 to the United States Food and Drug Administration, or FDA; AcelRx's pathway forward towards gaining approval of Zalviso in the U.S.; the anticipated timing, design and results of the IAP312 clinical trial for Zalviso; anticipated resubmission of the Zalviso NDA to the FDA, including the scope of the resubmission and the timing of the resubmission and FDA review time; the status of the collaboration and license agreement with Grünenthal, a company organized under the laws of Germany, or Grünenthal or any other future potential collaborators, 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' ability to complete Phase 3 clinical development of ARX-04 and support ARX-04 development under the contract with the Department of Defense; AcelRx's ability to successfully execute the pathway forward toward the resubmission of the Zalviso NDA to the FDA, including the initiation and completion of the IAP312 clinical study for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 in the United States and Europe, and Zalviso in the United States; AcelRx's ability to receive any milestone or royalty payments under the Grünenthal agreement and 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 EU; the uncertain clinical development process, including adverse events; the risk that planned clinical trials may begin on time, have an effective clinical design, enroll a sufficient number of patients or be initiated or completed on schedule, if at all; the success, cost and timing of all development activities and clinical trials, including the Phase 3 ARX-04 SAP302 and SAP303 trials and the additional clinical trial for Zalviso IAP312; the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 SAP301 study of ARX-04; 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 United States Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-Q filed with the SEC on May 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 back over to Howie, Chief Executive Officer.

Howie Rosen: Thank you, Jane.

On today's call we'll provide business highlights and accomplishments since our last call, including an update on ARX-04 and Zalviso and review of the second quarter financial results.

Let me start with our recent accomplishments. This has been a productive quarter for the ARX-04 team. As you'll recall, we initiated two Phase 3 studies last quarter, an extension to SAP302 in emergency room patients and a new study, SAP303, in postoperative patients. Both of these trials have had their last patient visits, and data are currently being analyzed.

We are planning to present top-line results from the emergency room study at the upcoming Military Health System Research Symposium, or MHSRS, on August 15 during the plenary session of the conference. Results from the other study in postoperative patients are expected to be announced before the end of the third quarter. We've also begun preparation of the regulatory filing and expect to submit the NDA for ARX-04 by the end of the year.

Regarding Zalviso in the U.S., you'll recall from last quarter's conference call that we decided to switch to the commercial manufacture of the Zalviso systems and also incorporate software and hardware improvements based on our experience in Europe. We are finishing testing the updated Zalviso systems to be used in the Phase 3 IAP312 study.

We're coordinating with the manufacturing vendors for final study supplies and have moved forward with repairing the clinical sites, with the goal of being ready to initiate IAP312 by the end of September. Once final supplies have been received and successfully tested, we anticipate being ready to begin the study. Once we start and see how enrollment is progressing, we'll be able to provide an estimate of the timing to study completion and NDA resubmission.

In Europe, Grünenthal continues to make progress and has introduced Zalviso in Germany, France, the UK, Italy and Belgium. Zalviso has been used by several hundred patients in dozens of hospitals. Patients, nurses and doctors have provided positive qualitative feedback on their initial experience. Grünenthal plans to launch Zalviso in the Netherlands, Ireland and Portugal by the end of the year.

Finally, in June, AcelRx was added to the broad-market Russell 3000 and Russell 2000 Indexes. Membership in the Russell 3000 Index, as many of you know, will lead to automatic inclusion of AcelRx stock in certain growth and style indexes.

Let me turn the call over to Pam now for an update on ARX-04.

Pamela Palmer: Thanks, Howie.

Last quarter we announced positive results for ARX-04 from the first phase of the emergency room study, SAP302, in which 40 adults who presented to the ER with moderate-to-severe acute pain from trauma or injury received a single dose of ARX-04. The extension phase of SAP302, which enrolled an additional 36 patients, who received up to four doses of ARX-04 not more than hourly as needed, has now concluded.

ARX-04 efficacy will be assessed, as in the first cohort, based on a primary endpoint of time-weighted summed pain intensity difference to baseline over the first hour, or SPID1. We are currently analyzing these results and plan to present this data at the upcoming Military Health System Research Symposium, or MHSRS, on August 15 during the plenary session of the conference.

For those of you who are unfamiliar with the MHSRS meeting, it is the Department of Defense's premier scientific meeting and is the only military or civilian meeting that focuses specifically on the unique medical needs of our armed services. We felt this was an appropriate venue, since the Department of Defense funded the development of ARX-04. ARX-04, the sublingual formulation, avoids the time, effort, discomfort and infection rate of initiating an intravenous line.

Moving on to SAP303, which we initiated last quarter, this multicenter, open-label Phase 3 study completed enrollment of 140 patients who are 40 years or older on schedule. In this study, patients who reported moderate-to-severe acute pain following a surgical procedure were administered up to 12 doses of ARX-04 hourly as needed. The primary efficacy endpoint is the summed pain intensity difference over the 12-hour study period, or SPID12. We are analyzing these results and expect to present them by the end of the third quarter.

We have a whole slate of abstracts and presentations at medical meetings in the U.S. and Europe during the second half of the year that will feature ARX-04 results. These include the World Congress on Mountain & Wilderness Medicine August 2; the Military Health System Research Symposium, which I just mentioned, on August 15; the International Society for Burn Injuries, the European Society of Regional Anesthesia, the Emergency Nursing Association and Plastic Surgery meetings, all in September; the EMS World Expo, European Society of Emergency Medicine, the American College of Emergency Physicians, the International Commission for Alpine Rescue, and the National Conference of Corrections, all in October.

With our clinical development of ARX-04 concluding, many of us are taking a moment to reflect on the journey that got us here. ARX-04 was an idea borne a decade ago and funded by the Department of Defense for specific military need. Clinical and market research have expanded our understanding of the potential of ARX-04 to also include the treatment of acute moderate-to-severe pain in emergency medicine and for inpatient and outpatient surgeries.

We are approaching an important regulatory milestone, the filing of an NDA for ARX-04 by the end of 2016, and I would like to take a moment to thank our employees, whose dedication and hard work have brought us to this point. Our hard work is not done, of course, as we are beginning to make a number of commercial plans for ARX-04.

To discuss these in more detail, I'd like to turn the call over to Gina Ford, our Vice President of Commercial Strategy. Gina?

Gina Ford: Thanks, Pam.

As Pam mentioned, in anticipation of submitting the NDA for ARX-04 for the treatment of moderate-to-severe acute pain, we are ramping up our commercial preparation. Over the next several months we will initiate and complete several activities aimed at helping us understand the market opportunity for ARX-04.

These activities include validating the U.S. ARX-04 market forecast, initiating market access activities, understanding the landscape and buying process in the emergency department, surveying ER nurses and ER doctors, selecting our agency of record, and selecting a trade name and finalizing packaging and design, just to name a few.

Regarding the ARX-04 market forecast, I'd like to take a moment to review our process and expectations with you. We've analyzed the National Emergency Department Sample, the National Survey of Ambulatory Surgery and the National Inpatient Sample and have determined the approximate number of adult emergency room visits, the number of adult patients having undergone short-stay, inpatient and outpatient surgical procedures, the number of nonsurgical in-hospital acute pain patients, and the number of patients undergoing painful procedures.

An estimated 66 million of these individuals have moderate-to-severe acute pain annually, 48 million of whom appear in the emergency room. At peak sales, assuming a 2016 price of $20 per unit, taking into account standard price increases, we would expect this market to be approximately $1.3 billion.

We recently presented a study on the cost of administering IV opioid in the emergency department. Based on an analysis of over 7 million patients who received IV opioids in 614 U.S. emergency departments, it was found that doses ranged from $143 for morphine to $145 for fentanyl. We wouldn't set the price until closer to launch. We have plenty of room to set the price.

Europe is also a significant market, and one that we believe is receptive to innovative treatment options for acute pain. We have recently completed extensive market research in Europe and have determined that there are an estimated 51 million patients in emergency medicine with moderate-to-severe acute pain and 16 million with moderate-to-severe acute pain following inpatient and outpatient surgery each year.

We believe ARX-04 could achieve a 15 euro price per unit. This is based on our analysis of the published price benchmarks of Penthrox, methoxyflurane, which is indicated for trauma pain, and branded fentanyl products, which are indicated for breakthrough cancer pain.

We are also conducting a micro-costing literature review to determine the total cost of administering IV opioids per patient in EU emergency departments. Based on this information, we believe peak sales in the emergency medicine and postoperative market segments across Europe could be approximately 700 million euro.

Unlike the United States, oligoanalgesia, or the undertreatment of pain, is a well-known phenomenon across Europe in emergency rooms. We believe the number of potential patients that can be treated for moderate-to-severe acute pain will actually grow with the introduction of new products in the ER. To support a European strategy we are actively seeking commercial partners and alternatives to commercialize ARX-04 in Europe and are moving forward on our own with planning and preparing for filing an MAA in the EU.

On a personal note, I want to add how exciting it is to be leading AcelRx's commercial efforts at this stage in the Company's evolution. I believe that ARX-04 has the potential to make an important impact on the treatment of moderate-to-severe acute pain for emergency medicine in the military and civilian settings. With the NDA planned by the end of the year, we will continue to make commercial preparations and share our progress in more detail later this year.

Pam, I'll return the call to you.

Pamela Palmer: Thanks, Gina.

Lastly, regarding Zalviso in the U.S., I wanted to comment on our protocol for IAP312. We will aim to enroll approximately 315 adult postoperative patients, and patients will self-administer 15 mcg of sublingual sufentanil as needed for 24 to 72 hours, to manage their moderate-to-severe acute pain.

The study will measure device usability, including the failure to dispense medication, as well as the incidence of misplaced or dropped tablets. Efficacy pain measurements and safety data will also be collected.

As Grünenthal's launch is progressing, we are receiving some valuable feedback. Grünenthal's customers are reporting that they appreciate the noninvasive nature of Zalviso, and they are experiencing good efficacy for pain control for sublingual sufentanil.

The launch, of course, is in its early days, so while these anecdotal reports are encouraging, we will wait a few more quarters before making a formal assessment. We will continue to support Grünenthal as they continue their European launch and will continue to learn from their experience so that we can apply their insights to an eventual Zalviso launch in the U.S.

Tim, I'll return the call back to you to discuss financial results.

Tim Morris: Thank you, Pam.

Earlier today we reported financial results for the second quarter ended June 30, 2016. You are encouraged to review that press release for specific details.

In summary, the net loss for the second quarter 2016 was $11.1 million, or $0.24 net loss per share, as compared to $8.9 million, or $0.20 net loss per share, for the second quarter of last year. During the second quarter of 2016 we recognized revenue of $1.3 million under the collaboration agreement with Grünenthal and $3.2 million related to work performed under the DOD contract for ARX-04.

This compares to $500,000 in revenue recognized under the collaboration agreement with Grünenthal and $1.4 million in revenue recognized related to the DOD contract for the second quarter of last year. We expect to begin to recognize royalty revenue from Grünenthal sales in Europe next quarter.

For the six months ended June 30, 2016, we reported net loss of $22.1 million, or $0.49 net loss per share. This compares to $18.9 million, or $0.43 basic net loss per share and $0.47 diluted net loss per share for the first six months of 2015.

During the six months ended June 30, 2016 we recognized revenue of $3.1 million under the collaboration agreement with Grünenthal and $4.4 million related to work performed under the DOD contract. This compares to $700,000 in revenue recognized for Grünenthal and $1.4 million in revenue under the DOD agreement for the first six months of 2015.

As of June 30, 2016 we had cash, cash equivalents and investments of $98.8 million. This compares to $113.5 million at the end of December 2015. The decrease was primarily attributed to cash used in operating activities. The net change in cash of $15 million was expected. We do anticipate quarterly burn in the second half will increase, as beginning in October this year we are scheduled to begin to repay amounts under the Hercules loan at a rate of $1.6 million per month.

On the investor relations front we presented earlier this month at the Cantor Fitzgerald conference and plan to present in September at the BioCentury Newsmaker Conference and the Annual Rodman & Renshaw Global Investment Conference sponsored by H.C. Wainwright.

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

Howie Rosen: It's hard to believe that the year is over half over, but when I think back we've made great progress with ARX-04 during the first two quarters of the year. We basically completed two Phase 3 studies and began work on the NDA filing, as well.

So I'd like to thank the entire team for all the work they've been doing. As I mentioned earlier, we're on track to submit the NDA for ARX-04 to the FDA this year, and we're working toward submitting the MAA in Europe in the first half of 2017.

Over the next few months we'll be presenting results from SAP302 and 303 and preparing our regulatory filing for ARX-04. We'll keep you updated as we meet these milestones, and thank you for your continued interest in AcelRx.

Now we'd like to open it up to calls, or to questions, sorry.

Questions and Answers

Operator: (Operator Instructions)

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

Ashley Ryu: Hey, great, thanks. This is Ashley Ryu on for Randall. I've just got a few. So, first, with Zalviso it looks like we can now expect a late September start. How does the new trial date for Zalviso affect your cash burn expectations? And also if you could just touch upon the feedback from Grünenthal around Zalviso progress now that the pilot launch has begun to rollout in key regions, and is the launch progressing as expected? Thank you.

Tim Morris: Sure. Hi. This is Tim. I'll take the first one. The cash burn -- we've assumed that in cash burn in the guidance we have previously given essentially that spending for the 312 study will replace some of the spending that was ongoing for the 302 and the 303 study, so it really shouldn't have much, if any, dramatic impact on a quarter-to-quarter basis.

In terms of feedback from Zalviso in Europe, Pam, would you like to comment on that?

Pamela Palmer: Sure. In fact, the launch is going exactly as they laid it out, and Grünenthal is very detailed with us in what they were planning to do, and they've accomplished country by country and hospital by hospital exactly what they planned. So, they're marching forward and expanding as predicted and as laid out.

Ashley Ryu: Great. Thanks.

Operator: Our next question comes from David Amsellem, of Piper Jaffray. Please go ahead.

David Amsellem: So, just wanted to drill down a bit on how you think about the opportunity for 04, so a couple of questions on that front. First, do you think that you could be running into a paradigm where the opportunity is diminished just because of all of the public health concern surrounding the use of opioid and the CDC guideline (inaudible) that's going to come out earlier this year? So I'm wondering how you think that the public health exigencies affect the opportunity around opioid diversion and abuses could affect the opportunity for 04.

And then secondly, it's no secret that you've got cheaper opioid options in the hospital that are available, generically available, so I guess the question is how do you get P&T committees onboard with what presumably will be a premium-priced product? Thanks.

Tim Morris: Sure, David, Pam will address your first question, then Gina can follow up.

Pamela Palmer: Yes, the vast majority of the concern on opioids, which is a legitimate concern, is around the outpatient prescribing. As it relates to the emergency room setting, the concern is around the dispensing and prescribing of opioids for the patients to go home and use at home.

Currently, the most recent guidelines, in fact, that just came out from three different organizations in February around treating acute pain in the hospital in a postoperative setting still strongly recommend the use of opioids. Of course, they do caution that a multidisciplinary approach should be used, but that's been consistent with guidelines over the past 10 years, and we completely agree with those guidelines, as well.

So in the medically supervised setting, certainly in acute moderate-to-severe situations, no one is dialing back the use of opioids or recommending dialing back the use of opioids. It's the prescribing in the outpatient setting, and also for chronic use in the outpatient setting that is problematic.

Gina Ford: Hi, David. This is Gina. I just want to address your question regarding P&T committees. We do have a very robust health economic story to tell. Pam has already presented that data in poster format at ISPOR recently. So I believe really based on our pharmacoeconomic story the pharmacodynamic, pharmacokinetic profile of sublingual sufentanil for use in acute pain in emergency room will be very appealing for hospital pharmacists to review.

David Amsellem: Thank you.

Operator: Our next question comes from Boris Peaker, of Cowen and Company. Please go ahead.

Boris Peaker: Great. Thank you for taking my question. My question first on ARX-04. I'm just surprised why you would use a Department of Defense meeting to present the data where the ultimate goal is to really promote it to emergency room physicians. Aren't there ER-related conferences where you think that that would make sense to profile this drug?

Pamela Palmer: We will be extensively -- I think I listed many of them in that long list of meetings that I mentioned, but we're going to many, many emergency room meetings. The data is quite robust. We'll be looking at safety. We'll be looking at efficacy. There are so many different ways to present that data and look at that data and do subgroup analysis of that data that we will be presenting ARX-04 at many of these different meetings.

Just the timing of the MHSRS came about right when we were getting top-line SAP302 data, and because of all their $25 million reasons for us to present -- that's how much money they gave us -- to present data at their conference, we really felt honored, and they selected us. I think it was 17 abstracts were selected for plenary sessions out of 1,400, and we were chosen for one of those. So we're very honored, in fact, to present at that meeting.

Boris Peaker: Got you. Okay. Now, in terms of from the regulatory perspective, staying with ARX-04, in the emergency room study, are there any unique safety endpoints or things that the FDA requested to look at maybe in terms of pill handling, misuse, loss, abuse or anything like that that would -- maybe we wouldn't think of as investors?

Pamela Palmer: You know what? Actually, with -- because it's a C2 drug, every single study that we run that is exactly what we have to do. We have to reconcile down to the pill on every single one of our studies. So that's something we've done all along. We're currently -- we continue to do it for these studies. We've never seen a problem with that.

I will say that one of the requests for special measurements in the emergency room study was in fact by the Department of Defense. They requested a cognitive impairment analysis. And, as you know from our release of the first 40 patients, that first cohort, we in fact found no impact on cognitive functioning with sublingual sufentanil, which is very different than what has been published in the literature regarding ketamine.

Boris Peaker: Got you. Okay. And my last question on 04 is what commercial investments are you making right now? When do you plan to actually start hiring maybe the head of the sales force or specifically sales force leaders for various geographies and making further investments commercially into the drug?

Howie Rosen: Yes, this is Howie. I'll answer that for you. So, as Gina mentioned during the call we're really focused on the commercial strategy, understanding the markets, market research. We've had some ad boards and have more coming up where we can sit face to face with people in the various hospitals in the various specialties.

And so our plan in terms of building out the infrastructure would be next year. So we feel like we still have plenty of time with the submission in the fourth quarter and a 10-month PDUFA review that next year is the right time to be putting the plans in place and the things in place to be building out the sales force and the other infrastructure we need.

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

Operator: Our next question comes from Ed Arce, of H.C. Wainwright & Co., LLC. Please go ahead.

Ed Arce: Hi, guys. Thanks for taking my questions. I guess the first one is for Gina. I was wondering as you described about ramping up your commercial prep for ARX-04 and some of the survey work and other things that you're looking at if you could give us a little more detail around the activities related to validating your market forecast, specifically with the market opportunities that you quoted for the U.S. and EU markets.

Gina Ford: Yes, good question, Ed. We are in the process of evaluating potential partners to do a validated forecast for us. We'll go out, resurvey emergency room physicians. We'll survey anesthesiologists. We'll survey surgeons so we get a good feel for exactly what's going on in the market. We'll use the newest epidemiology information that we can find, and then we hope to have that pulled together later this fall.

Ed Arce: Could we expect any further details around that later this year, perhaps?

Tim Morris: Yes, Ed, hi, this is Tim. Yes, we do hope to hold another analyst day later in the fall where we're happy to kind of share with you the results that we've learned in terms of revalidation of the forecast, in terms of some of the information that Gina is able to obtain through some of these surveys and the like. So, yes, we'd be happy to kind of share more details with it with you guys once they're available.

Ed Arce: Okay, great. And then switching gears to Zalviso, as you've noted you are working through a number of software and hardware improvements. I was just wondering how, when you go about making those corrections and improvements, on the one hand, while making sure that you don't at the same time create new potential issues with the issue?

Howie Rosen: Issues in terms of modifications that would require some testing?

Ed Arce: Right. I mean, as you work on correcting or improving the process of dispensing the drug with the device, catching any potential new problems that could some up with changes to the existing device.

Howie Rosen: Yes, this is Howie. Two things, one to keep in mind is that the drug part hasn't changed at all. And in terms of the device the changes are not significant. Some of the changes are to the software, which are relatively easy to do, and then there's a part here or there where we've made changes just to improve the reliability/usability.

And basically, as we have previously, we have a pretty extensive process for doing bench testing and other validations of the system as we go along. And that's what we've been doing and the reason we've taken some time before we actually start up the study.

Ed Arce: Okay. And then one last one, if I may, just in terms of funding. Could you expect or expect to receive any potential additional funding from the DOD between now and submission on ARX-04? And are there any potential near-term milestones from your partner in Europe, Grünenthal?

Tim Morris: Yes, Ed, this is Tim. The DOD contract essentially is a fixed amount, so we do anticipate we should be able to kind of continue to bill and collect all of our activities under that, including the PDUFA fee that we'll have to pay. So that's -- we don't expect additional funding above and beyond the contractual amount, but we do expect to be able to collect the entire amount, the contract, this particular portion.

And then in terms of Grünenthal, while there are some milestones and the like out there we don't anticipate, this year at least, obtaining any of those additional development and/or sales milestones.

Ed Arce: Okay, great. Thanks.

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

Michael Higgins: Thanks, operator. Hi, guys. Thanks for taking my questions. Questions on SAP302. It looks you've got data in hand from that short study from just over a month ago and you've got a presentation coming up in about two weeks out. Hoping to get some insights from you as to how that data looks, and specifically any information you can share by age based on those over and under 40.

Pamela Palmer: Yes, we're still under review. Our statistician's working to get us the top-line data on that. So we had 40 patients in the first cohort, which was a single-dose cohort, hit 36 in the multiple-dose cohort, and we're -- they're all still -- there's three sites. We're looking at folks who come into the emergency room with injury, etc., so there is -- there's not a huge difference in general between the last 36 and the first 40, but we'll have all that data sown up just in time, in fact, for the August 15 presentation. So we're kind of cutting it down to the wire.

Michael Higgins: Understood. Okay. Thanks. Then a quick question on IAP312, if I could. Any additional instructions to the nurses and the patients before starting Zalviso or anything materially different, or is it mostly changes in the device that you're banking on?

Pamela Palmer: Yes, no, we're expecting the device, obviously, to function very well. The engineers have been doing a great job just fine-tuning that. The one key thing for 312, remember, is that we're actively having as an endpoint looking for the dropped tablets. We never had that as an endpoint in the previous Phase 3s. It was just when they were noted it was documented.

That's why the slight difference there is we're actively having nurses look for that. And the FDA just wants to make sure that it's not just an accidental finding, that it was an overt endpoint that was measured, and they just want to feel comfortable. And so that's really the only difference with the 312 study versus our other study.

Michael Higgins: Do you think if you repeated the same error rate of dropped tablets the FDA would be okay with the NDA acceptance?

Pamela Palmer: Yes, I mean, well, the error rate isn't -- error rate is not a dropped tablet, so it's two things. An error rate specifically relates to the device actually not dispensing versus a dropped tablet is actually a user interface issue where the patient's just not using it correctly.

To me it wasn't the actual -- our number was extremely low, if you remember, from how many thousands of actual tablets were dispensed that were observed. I think they just want to make sure that that wasn't some sort of tip of an iceberg, because, again, it was not a measured endpoint. We know our clinical sites. We're very happy to do that study for them again because we know, in fact, that it was not a problem.

Michael Higgins: Understood. That was very helpful. Thank you, guys.

Operator: Our next question comes from Hugo Ong, of Jefferies LLC. Please go ahead.

Hugo Ong: Hey, guys. Thanks for taking my questions, and congrats on all the progress. Just a question on ARX-04, on your pharmacoeconomic analysis I notice that you didn't include infection risk and other complications like you did with Zalviso. Any intentions to do that kind of analysis, and does it suggest maybe that the cost of IV opioids might be higher?

Pamela Palmer: Absolutely great question. So what we did was for Zalviso is we actually -- the fact that we were doing it for ARX-04, our ISPOR abstract was purely around the hard cost of setting up and using, well, in the case of Zalviso, an IV-to-opioid PCA. We then layered on later for the actual pharmacoeconomic publication the soft cost, around avoiding infections, things like that.

That's exactly what we're planning on here. The ISPOR abstract was around the hard cost advantages of ARX-04, and we're planning on a publication that will come out with both hard and soft costs.

Hugo Ong: Okay, great. And when can we expect that publication?

Pamela Palmer: Well, we're in the process of working on it. So journal, you can't predict with journals. I mean, they may accept it and then take three, four months to actually get it. But we usually do all of ours open access. So hopefully sooner than later, but we're still working on writing that up right now.

Hugo Ong: Got it. Understood. And I believe you mentioned that a similar analysis would be done for European emergency departments, and will infection risk be evaluated there, as well?

Pamela Palmer: Yes, absolutely.

Hugo Ong: Okay, great. Thanks a lot, guys.

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

Howie Rosen: Thank you. We look forward to keeping everyone updated on our progress and meeting you, possibly, on some of our upcoming road shows and investor conferences. I want to thank you again for joining us for our second quarter call, and I hope everyone has a good afternoon.

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