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): September 15, 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 September 15, 2016, AcelRx Pharmaceuticals, Inc., or the Company, conducted a conference call during which members of its senior management team discussed the results of its multicenter, open-label Phase 3 clinical study of ARX-04, known as SAP303, and discussed 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. Conference Call on September 15, 2016, at 9:00 a.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: September 19, 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. Conference Call on September 15, 2016, at 9:00 a.m. ET.

AcelRx Pharmaceuticals, Inc.
Positive Phase 3 Data Results
September-15-2016
Confirmation #13645416

Operator: Greetings, and welcome to the AcelRx Positive Phase 3 Data Results.

At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please, press star-zero on your telephone keypad.

I would now like to turn the conference over to your host, Mr. Timothy Morris, Chief Financial Officer.

Please go ahead.

Mr. Timothy Morris: Thank you, Michelle.

During the call today, we will make forward-looking statements, including, but not limited to, statements related to the process and timing of anticipated future development of AcelRx's product candidates: ARX-04 and Zalviso, including ARX-04 clinical trial results, anticipated submission of the new drug application, or NDA, for ARX-04 to the U.S. Food and Drug Administration, or FDA, AcelRx's pathway forward towards gaining approval of Zalviso in the United States and the therapeutic and commercial potential of AcelRx's product candidate, 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 includes without limitation risks related to AcelRx Pharmaceuticals ARX-04 development program, including anticipated submission of ARX-04 NDA and the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 studies of ARX-04, AcelRx's ability to successfully execute the pathway towards the resubmission of Zalviso--of the Zalviso NDA, including the successful initiation and completion of the IAP312 clinical study for Zalviso, uh, any delays or inability to obtain or maintain regulatory approval of its product candidates, including ARX-04 in the United States and Europe and the Zalviso in the United States, the uncertain clinical development process, including adverse events, the risk of planned clinical trials, including the IAP312 clinical study for Zalviso may not begin on time, have an effective clinical design, enroll a significant number of patients or be initiated or completed on schedule, if at all, and other risks detailed in the risk factors and elsewhere in AcelRx U.S. SEC filings and reports, including its quarterly reports on Form 10-Q filed with the SEC on July 29th, 2016. AcelRx undertakes no duty or obligation to update any forward-looking statement contained in this release as a result of new information, future events, changes, or changes in expectation.

Now, we'll turn the call over to Howie Rosen.

Mr. Howie Rosen: Thank you, Tim.

Good morning and thank you for joining our press briefing on the SAP303 clinical trial results for ARX-04, a late state investigational product candidate being developed by AcelRx Pharmaceuticals.

My name is Howie Rosen. I'm the Chief Executive Officer of AcelRx. I'm here today at the Emergency Nurses Association 2016 Conference with three members of my senior management team: Dr. Pamela Palmer, who is our Chief Medical Officer and a cofounder of AcelRx; Gina Ford, who serves as Vice President Commercial Strategy; and Tim Morris our Chief Financial Officer and Head of Business Development.

ARX-04 is being developed for the management of moderate-to-severe acute pain in medically-supervised settings. Also known as sufentanil sublingual tablet 30 micrograms, ARX-04 is a synthetic opioid analgesic with a novel, non-invasive route of administration. Designed to be delivered sublingually, ARX-04 consists of a very small 30-microgram sufentanil tablet that is administered under the patient's tongue by a healthcare professional using a disposable pre-filled single dose applicator, or SDA.

Today on behalf of AcelRx, my team and I are very pleased to announce positive safety and efficacy results for ARX-04 in the SAP303 trial, which is the third Phase 3 trial in the ARX-04 clinical development program.

I'll now turn it over to Pam, who will give you an overview of the SAP303 trial.

Dr. Pamela Palmer: Thanks, Howie.

The primary objective of SAP303 was to evaluate the safety of ARX-04 in postoperative patients, especially in higher risk patients, such as the elderly or those with comorbidities or impaired organ function.

Before I get to the results, let me briefly give you some background on the trial and why it was conducted. At a pre-NDA meeting in December 2015, the FDA Review team agreed that the safety database requirements for the ARX-04 NDA could be supplemented with data for patients who received two 15-microgram doses of Zalviso within 20 to 25 minutes, which is another sublingual sufentanil product from AcelRx.

Zalviso is now approved in the EU and is in late stage development in the U.S. But, FDA agreement to supplement the ARX-04 safety database with these Zalviso patients came with two important requirements. The majority of the required safety data for the ARX-04 NDA should be comprised of patients exposed to ARX-04 and the remainder of the required safety database for 04 most also evaluate the potential risks to vulnerable populations, such as the elderly, patients with hepatic or renal impairment, or patients with American Society of Anesthesiologists, or ASA, physical status classification 2 or 3. Such patients may be a particular risk for anticipated adverse events, for example opioid related adverse events, such as life threatening CNS or respiratory depression or unanticipated adverse effects.

To satisfy these FDA requirements, AcelRx proposed running this Phase 3 SAP303 trial, an open label, single arm, 12-hour safety study that would seek to enroll elderly patients and patients with comorbidity. In SAP303, safety variables included the assessment of adverse events, vital signs, including blood pressure, heart rate, respiratory rate and oxygen saturation. Assessing efficacy was a secondary objective in the trial. The primary efficacy variable was a time weighted summed pain intensity difference over the 12-hour study period, or SPID12. And secondary efficacy variables included pain intensity and pain relief by evaluation time points.

The mean age for all patients in SAP303 was 54.7 years and 17 percent of patients were 65 years of age or older. More than one in four patients, or 29 percent, had some degree of baseline hepatic and/or renal impairment. Nearly seven in 10 patients, 69 percent, were ASA physical status class 2 or 3, which means mild or severe systemic disease.

Safety results showed that, overall there were no differences in adverse events between patients with normal and impaired liver function, or between patients with normal and impaired renal function. No clinically meaningful changes from baseline and vital signs or oxygen saturation were observed in the population and no opioid reversal agents were needed in the study. Regardless of age and organ function, approximately two in three patients had no adverse events during the study, 63 percent of all patients had no adverse events, 63 percent of those aged 65 years or older had no adverse events and 62 percent of those with hepatic impairment, and 70 percent of those with renal impairment had no adverse events. The most common adverse events were nausea and headache.

During the 12-hour study period the mean total number of ARX-04 doses administered was 3.3, which was similar for patients with normal and impaired liver function and for patients with normal and impaired renal function. The mean interdosing interval was more three hours at 193 minutes. The primary and secondary efficacy endpoint showed a reduction in pain intensity starting at 30 minutes after the first dose of ARX-04 followed by 27 percent, 49 percent and 57 percent reduction in mean pain intensity from baseline at one hour, two hours and 12 hours, respectively. The baseline pain score was 6.2 on average.

Finally, on a global assessment of ARX-04 as a method of pain control, 90 percent of healthcare professionals and 87 percent of patients responded good or excellent. Today's report of these data marks the completion of the ARX-04 Phase 3 clinical program, which comprises SAP303 and two earlier Phase 3 trials in patients with moderate-to-severe acute pain. SAP301, which was an ambulatory surgery pivotal study that reported positive results in 2015 at the American Society of Anesthesiologists Annual meeting, and SAP302, which was an emergency room study that reported positive results in 2016 at the Military Health System Research Symposium, or MHSRS. In addition, the pivotal Phase 2 SAP202 trial reported positive results in 2013 at the 67th Annual Post Graduate Assembly in Anesthesiology.

With data from all four trials and supplemental safety data from the Zalviso trial, AcelRx intends to submit an NDA for ARX-04 by the end of this year. The NDA will seek approval of ARX-04 in the management of moderate-to-severe acute pain in medically-supervised settings. Medically-supervised settings will include emergency medicine, outpatient or ambulatory surgery, non-surgical patients experiencing pain in the hospital or postoperative patients following short stay surgery who do not require more time--I'm sorry, more long-term analgesia. ARX-04 is intended to be administered only by a healthcare professional.

Gina will now talk about the commercial implications of the SAP303 results.

Ms. Gina Ford: Thanks, Pam.

Our clinical data defines some important features of ARX-04 that may help address unmet needs in managing moderate-to-severe acute pain in medically-supervised settings. As a result, we anticipate a large market opportunity for ARX-04. For example, we know that in ambulatory surgical centers: hospitals, emergency departments and ambulances, healthcare professionals need an opioid analgesic that is safe and effective across many patient types. ARX-04 is being developed with that need in mind, including higher risk patients. We also know that from a time and efficiency perspective healthcare professionals need an opioid analgesic that offers straightforward administration. ARX-04 offers non-invasive sublingual administration, and the SAP303 data show that the average re-dosing interval was more than three hours at 193 minutes.

As Howie mentioned, we're coming to you from the Emergency Nurses Association Annual Meeting, where there are approximately 4,000 nurses attending. Their annual meeting is a premium exchange for new technology and education. In speaking with these nurses here at ENA, one of their concerns is workflow. We believe a product like ARX-04 that is easy to administer may help patient flow.

And, finally, the SAP302 study, the data show that drug induced cognitive impairment was not seen with ARX-04, which could be beneficial to healthcare providers and their patients. We are developing ARX-04 to be a method of treating moderate-to-severe acute pain that is (1) safe and effective across many patients types, including higher risk patients; (2) non-invasive and easy to administer; and, (3) has a long duration of affect. The data from SAP303 will be an important part of the NDA we intend to submit later this year. Taken together, the clinical data from ARX-04 is positive, and we look forward to submitting the NDA for market approval.

According to the National Emergency Department Sample, or NEDS, there were more than 104 million adult emergency room visits in the United States during 2011, with more than 48 million involved in moderate-to-severe acute pain. In addition, there's evidence that patients who present to the ER with high levels of pain are often under treated, a treatment gap known as oligoanalgesia. Based on the National Survey of Ambulatory Surgery of 2006, an estimated 27 million adult patients underwent outpatient surgical procedures in the United States. Of these, it's estimated that more 11 million patients experience moderate-to-severe acute pain.

With the use of ARX-04 in medically-supervised settings, in addition to ER and ambulatory surgery, the market potential of ARX-04 in the United States is expected to be $1.3 billion. Between now and the end of the year, we will continue our presence at medical meetings. In addition to ENA, in September, we'll attend the American Society of Plastic Surgeons meeting, also here in Los Angeles, and in October and November we will attend the European Society for Emergency Medicine Congress in Vienna, Austria, the EMS World Expo in New Orleans, the American College of Emergency Physicians Scientific Assembly in Las Vegas, the International Society for Pharmacoeconomics and Outcomes Research European Congress in Vienna, Austria, the Obesity Society meeting in New Orleans, and the National Commission on Correctional Healthcare Conference in Las Vegas.

Thank you for your attention and your interest in ARX-04 and the SAP303 trial. Tim will now lead our Q&A session.

Mr. Timothy Morris: Uh, thank you, Gina.

So, for folks on the phone, we're happy to take your, uh, questions for, uh, Howie, Pam, uh, Gina or myself.

Operator: Thank you. At this time, we'll be conducting a question-and-answer session. If you would like to ask a question, please, press star-one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star-two if you'd like to remove your question from the queue. For participants using speaker equipment it may be necessary to pick up your handset before pressing the star keys. One moment, please, while we poll for questions.

Our first question comes from the line of Randall Stanicky with RBC Capital Markets. Please proceed with your question.

Ms. Ashley: Great. Thanks. Uh, good morning, guys. This is Ashley [sp] on for Randall. Uh, thanks for taking my questions.

Um, to start, I just wanted to start on, uh, the renal results. Can you talk a little bit more about them? And is there any claim that can be made around this label--on the label? Sorry.

Mr. Timothy Morris: Yeah, sorry, can you, um, repeat your question, Ashley, at the beginning?

Ms. Ashley: Yeah, sure. Um, if you can just touch a little bit more, um, on the renal results and if there's any claim that can be made around it on the label.

Mr. Timothy Morris: Yeah, so, we'll ask Pam, um, about that. So, your question is, you know, comment more on the, uh, results in the renal patients, uh, and is there any specific label claim we could make with regards to, um, potential benefit or treatment with renal patients.

Ms. Ashley: Yep, exactly--.

Dr. Pamela Palmer: --Sure, sure. And in fact, uh, the advantage of sufentanil is there is no active metabolite. And, as you know, metabolites are cleared by the kidneys. Uh, the parent drug compound is metabolized by the liver. So, usually renal impairment is a concern in drugs that have active metabolites, because that's in fact how they're cleared, and that's the big issue with morphine and also an issue with hydromorphone as well.

Sufentanil has no active metabolites. And so, when we've looked in the past at studies of renal impairment versus normal, and including in the study, we actually see no difference in the plasma level of sufentanil in regular patients versus those with renal impairment. So, there just is not an impact.

Mr. Timothy Morris: But, I suspect, we won't be able to make any specific label claim in terms of, um, benefits for renal impaired patients. I mean, it will be in the clinical trial section, but, uh, I don't believe, Ashley, we'll be able to get anything specific in the label about, um, you know, for renal patients.

Dr. Pamela Palmer: It's possible. We have population PK results that takes all of the data from all the studies, and it's possible that that data might make into the label talking about the effective organ impairment on, uh, the pharmacokinetics, which, in fact, we haven't seen.

Ms. Ashley: Got it. And just one, uh, quick follow up, um, on Zalviso is the pivotal trial still expected to move forward by the end of this month?

Mr. Howie Rosen: Hi. Thanks. Uh, this is Howie. And we are still, uh, moving towards starting that by the end of the month, the Zalviso trial.

Ms. Ashley: Great. Thank you.

Operator: Thank you. Our next question comes from the line of Ed Arce with H.C. Wainwright. Please proceed with your question.

Mr. Ed Arce: Hi, everyone. Uh, congrats on the data. Um, I have a few questions. Uh, the first one is on, uh, the, uh, primary--or I guess the secondary, uh, endpoint, which is the--uh, the efficacy endpoint, the SPID12. What was the, uh, numerical value there and the p value if you could give that?

Dr. Pamela Palmer: Uh, sure. Uh, we didn't report it 'cause it doesn't really clinically mean anything. I mean the SPID12 in the study was 36. Um, there is no p value. It's just a single arm study, and there's nothing to compare it to.

Uh, what the FDA does do is they look at all of our trials in total when they look at the integrated summary of efficacy in the NDA filing. And, you know, as opposed to, for example, in our SAP301 study our SPID12 was 26 that we reported. So, we had great efficacy in the study, but it just numerically doesn't really mean anything in context by itself. You have to look at it in context with all the other studies we've run.

Mr. Ed Arce: Right. Great. Um, okay. And then--.

Dr. Pamela Palmer: --Some higher is better. I should say this, a greater SPID12 is--it means more efficacy.

Mr. Ed Arce: Right. Um, did you--have you, um, prepared the mean pain scores yet at one, two and 12 hours?

Dr. Pamela Palmer: We do have pain scores for individual time points, and we'll be, uh, reporting all of that data along with more detailed adverse event profiles, uh, later.

Mr. Ed Arce: Okay. Um, a couple more, if I may. Um, on the safety side, uh, you noted, uh, headache and nausea as the two primary AEs in this study. Uh, do you have the--um, the percentages? I know they're fairly low. Um, just wanted to know what the numbers were for those--.

Dr. Pamela Palmer: --Yeah, they were--.

Mr. Ed Arce: --Proportion--.

Dr. Pamela Palmer: --Very low. They were very low in this study, uh, which we're glad to see. The nausea was, uh, 27 percent and the headache was 6 percent. And so, you can imagine the other adverse events were very low.

Mr. Ed Arce: Right. Okay. Um, and I know that the army has been--for quite a while been funding development of ARX-04 actually since, uh, the very beginning and I know this is going to continue through at least NDA filing. I was wondering, um, how do you see your funding needs, uh, as you begin to ramp up, uh, commercial preparations?

Mr. Timothy Morris: Yeah, Ed, this is the Tim. The contract for the, uh, DOD actually goes through the first quarter of next year 'cause they have agreed to pay for, um, you know, the filing fee and any additional studies. So, uh, from a funding standpoint we haven't given any guidance for 2017 spending. Uh, we still reiterate our guidance that we should end this year with a cash balance of between 70 and 75 million. Uh, I still think on kind of on a quarterly basis my burn's going to be around 10 million. The only trial we'll have ongoing in 2017 for now will be the, uh, IAP312 study. Uh, we do hope to invest into the commercial opportunity here. Uh, but we will give, um, some guidance, uh, I think on our third quarter call.

Mr. Ed Arce: Okay, great and congrats again, everyone.

Mr. Timothy Morris: Thank you, Ed.

Operator: Thank you. Our next question comes from the line of Michael Higgins with ROTH Capital. Please proceed with your question.

Mr. Michael Higgins: Congratulations, guys, uh, very good data. It looks like it's a little better than what you've seen in previous trials. Um, a couple of safety questions, a couple efficacy questions as well. In terms of safety, um, pardon me if you've given this already, but dropout rates and any reason for dropout rates, um, any color on that?

Dr. Pamela Palmer: Sure. We had a very high, uh, percentage of completers in this study. Out of 140 patients, we had 132 completers with only eight dropouts. Uh, half of those were due to adverse events and half were due to inadequate analgesia, which means the AE dropout rate was 2.9 percent and inadequate analgesia dropout rate was 2.9 percent and those are very, very low.

Mr. Michael Higgins: Um, let's jump to an efficacy question then. Um, what--uh, what were the rescue, uh, meds that were used and how often were those used?

Dr. Pamela Palmer: Sure. Rescue, uh, medication, as is typical with our studies, was IV morphine, and, uh, it was only used by 14 percent of the population, which again in these studies, um, of folks with an experimental pain medication is a very good result as well.

Mr. Michael Higgins: Yeah, I think that beats past trials. Um, back to the safety, um, did you collect cognition data in this trial?

Dr. Pamela Palmer: I'm sorry--.

Mr. Timothy Morris: --Cognition data, uh, no--.

Dr. Pamela Palmer: --No. No, we didn't. We specifically put that in for, uh, the Department of Defense in the emergency room study, but we did not, uh, perform any cognitive, uh, impairment studies in this trial.

Mr. Michael Higgins: Okay, understood. Um, in terms of efficacy at what point did you find the pain scores drop by 1.3 points? In 302 it was 17 minutes. But, how did it look here in 303?

Dr. Pamela Palmer: Uh, it was a little bit longer than that. Uh, we haven't gone through and calculated a lot of that data. Um, this data's pretty fresh off the press. And--uh, but we absolutely will be reporting all of that.

And just to back up on efficacy, you know, we calculate SPIDS and PRIDS and TOPARS and all the different, uh, things, but really what it boils down to and what we wanted to give a kernel of, uh, that data today is the global assessments. I mean that's really taking all of the data and asking the patient, "Hey, what did you think about this drug? How did it work for you?" And the fact that we had our highest patient global assessment and healthcare professional global assessment efficacy data that we've ever seen, I think really sums up the efficacy in general and it's just more meaningful than a SPID12, etc.

Mr. Michael Higgins: Yeah. No, overall the results are excellent. Um, I noticed you didn't provide the drop in pain scores at 30 minutes. Um, was there are drop that you can provide for us?

Dr. Pamela Palmer: Uh, actually right off the top of my head, I can't tell you exactly what it was at 30 minutes. We just gave you some ballpark estimate. All of this data will be presented in abstract and oral presentation form in upcoming meetings.

Mr. Michael Higgins: Okay. And then, one last one on efficacy, in the SAP study 202 patients on 30 microgram dose took five doses at 2.5 hour dosing interval. In 303 they took 3.3 doses at a 3.25 hour interval. Can you help us understand why there'd be a difference between the two?

Dr. Pamela Palmer: Yes, actually this was the first trial--I'm glad you asked that. This was the first trial where we allowed adjuvant analgesics to be more real world. Uh, up until this point you know when you're trying to challenge yourself against beating placebo, the placebo response is very difficult to beat. Surprisingly, 35 percent of patients will survive postoperatively with nothing but the placebo response.

So, you really cannot cloud the waters with adjuvant analgesics, meaning you're also allowing non-steroidals or nerve block, etc. So, what we told our investigators was the patient still has to have greater than a four pain score, but you can use, you know, adjuvant analgesics, as you do in the real world. And so, I believe that's why we're seeing a little bit longer interdosing interval in this study compared to the SAP202 study.

Mr. Michael Higgins: Gotcha makes sense. Um, and this is a safety study. So, uh, [unintelligible] real world, I suppose.

Mr. Howie Rosen: Mike, I was just going to add in terms of the range, and we'll have more data on this at some point, um, you know, there were patients that used update doses. So, um--.

Mr. Michael Higgins: --Right. Okay--.

Mr. Howie Rosen: --Yeah, there still were, um, you know, patients at the longer end as well.

Mr. Michael Higgins: Okay. Uh, and then, lastly, um, uh, any device errors, any human errors, any changes to the device since you started SAP202?

Dr. Pamela Palmer: Uh, no, no. Uh, the, uh, device is just very simple, very straightforward and it's not posing a problem for healthcare providers or patients.

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

Dr. Pamela Palmer: Sure.

Operator: Thank you. Our next question comes from the line of Boris Peaker with Cowen. Please proceed with your question.

Mr. Boris Peaker: Uh, good morning and congratulations on the progress. I guess, uh, my first question, uh, just curious have you had any discussions with the FDA regarding drug liking or abuse potential studies or just in general abuse potential for this drug?

Dr. Pamela Palmer: You know, in our work with, uh, the FDA, they have not asked for specific studies relating to that. We are not--uh, the reason why is we're not trying to be an opioid, uh, or abuse diversion type of, uh, formulation. We are straightforward, immediate relief, used in the hospital only and we're a C2.

So, we're not looking to be at a lower, uh, classification in the scheduled drug standpoint. We're not trying to claim we're abuse deterrent or we're looking for that type of liability for our tablets. So, there really isn't anything about our product that we're looking for in the label. Um, it's used in a medically-supervised setting in the place of IV liquid opioids. So, there's, um, really nothing to be learned from abuse liability studies. It will be a C2 drug.

Mr. Boris Peaker: Gotcha. Okay. And so, I'm just curious also, uh, you mentioned the label. Um, as you discuss, uh, the NDA or you file the NDA and you discus the filing with the FDA on ARX-04 are there specific label attributes that you think is important to get into the label to really make this product to add significant commercial value to it, whether it'd be on the safety or the efficacy side?

Mr. Timothy Morris: I think for the most part we're going to end up getting, um, class label. I mean, obviously, we'll--you know, we're looking for a relatively, uh, broader label with moderate to--um, treatment for moderate–to-severe pain, acute pain. Um, we will be limited to administration by healthcare professionals, and we do believe that medically-supervised setting will be helpful. Um, but in terms of anything specific for, um, safety or onset it's--um, we really expect it to be, uh, essentially a class label there for--um, for a C2.

Mr. Boris Peaker: Gotcha. And my last question is so if you get approved for ARX-04 and then, you know, you restart this Zalviso study in a few weeks and then file Zalviso afterwards, would the Zalviso filing be a new standalone NDA or it'd really be just a supplementary NDA because essentially it's the same product just formulated and have a different device?

Mr. Howie Rosen: Yeah, so, it's--this is Howie. Uh, so it would be a supplemental NDA but actually off the original Zalviso NDA.

Mr. Timothy Morris: Six-month review.

Mr. Howie Rosen: Yeah, so--and it would be a six month review, um--.

Mr. Boris Peaker: --Gotcha. Okay. All right, well, thank you very much for taking my questions.

Operator: Thank you. Our next question comes from the line of Hugo Ong with Jefferies. Please proceed with your question.

Mr. Hugo Ong: Hey, guys, thanks for taking my questions and congrats on the data.

Um, most of my questions have been, uh, answered, but maybe just a couple of follow-ups. Um, so, one, were, um, any obese patients with a BMI greater than 30 included in the study?

Dr. Pamela Palmer: Oh, yes, yes, uh, you know, absolutely. All of our studies, uh, have obese patients in them.

Mr. Hugo Ong: Okay, great. And, Gina, maybe you could remind us, uh, you know, in your market research about how many patients, uh, you know, coming through the hospital, including the ER, um, you know, have renal and hepatic impairment that would make them good candidates for ARX-04 but not morphine?

Ms. Gina Ford: You know, Hugo, uh, thanks for the question. We've not segmented, um, either the market that low. We really are looking at the total market of moderate-to-severe acute pain patients that are, um, presenting to ERs, uh, for trauma pain or those patients that are having surgery on an annual basis. So, we're not cutting the market at this point.

Mr. Hugo Ong: Okay, got it. All right, thanks, guys.

Operator: Thank you. Our next question comes from the line of Ed Arce with H.C. Wainwright. Please proceed with your question.

Mr. Ed Arce: Hi, again. Thanks for taking the follow-up. Uh, just wanted to ask about, um, the broader scope of your commercial opportunity. This is probably mostly for Gina. Uh, I know, uh, the primary target here is the ER, and with 11 million moderate-to-severe patients annually, that's a big enough target already. But, I know you're looking at quite a few ancillary, um, uh, market opportunities, uh, for example, burn units, uh, interventional procedures, prisons, uh, ASCs and the like. And I was thinking how--I was wondering if you could just, um, describe to us how you're thinking about, uh, approaching, uh, those varied markets. Thanks.

Ms. Gina Ford: Sure, Ed. Thanks for the question. You know, the annual number of patients, um, that we're looking at that, uh, present to an emergency department with moderate-to-severe acute pain annually is 48 million. So, that is--um, that is a large market for us to consider. But, we're taking into consideration really, um, what our data points to, first and foremost of where ARX-04 will be, um, appropriate for treatment. So, yes, in our emergency room study we saw burns patients. We saw fracture patients. We saw sprains and strains, uh, dislocations. Um, and then in our post surgical data, um, anything from abdominoplasty, um, which is extremely painful. Um, in the last SAP303 study, we've seen some orthopedic procedures as well.

So, looking purely at the data and our marketplace of hospital and post-op pain, um, you know, we have this very large market to approach. I think as we look further in the context of AcelRx considering itself an opportunity within hospitals, we'll continue to look there for patients experiencing acute pain, um, in the burn units, um, in situations where, um, there's a very painful procedure that's performed in the hospital outpatient department. So, there are multiple ways for us to continue to look at this, um, market opportunity even really beyond sort of where we see our clinical data and those results, um, netting out.

Howie?

Mr. Howie Rosen: And I just add, it's, um--you're personally adding--asking about sort of sales force size and deployment. It's, um, one of the things that we like about ARX-04 and Zalviso is that, you know, they both are anchored in the hospital, Zalviso completely and, uh, you know, with ARX-04 obviously in the emergency rooms. And then, um, things like burn--you know, special burn units there's only, you know, about 150 of those in the U.S. So, those are very easy to target. And then, um, you know, as we look at the ambulatory surgery centers, um, you know, at least geographically, they typically are, you know, near hospitals and things. And so, that probably--that may require, you know, a little bit of extra sales force, um, size in terms of covering all those as well. Overall, we sort of like the fact that it's a pretty--you know, pretty focused, uh, set of call points.

Mr. Ed Arce: Great. Thanks again. That's helpful.

Operator: Thank you. There are no further questions. At this time, I would like to turn the call back over to Mr. Howie Rosen for closing comments.

Mr. Howie Rosen: I'd just like to thank everyone again for participating in our call today, and we look forward to updating you as we move forward towards NDA submission for ARX-04.

Operator: Ladies and gentlemen, this concludes today's conference. Thank you for your participation. You may disconnect your lines at this time and have a wonderful day.