
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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)
December 17, 2008

Cadence Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-33103
(Commission File Number)

41-2142317
(IRS Employer
Identification No.)

12481 High Bluff Drive, Suite 200
San Diego, California 92130
(Address of principal executive offices, including zip code)

(858) 436-1400
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

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))
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Item 7.01 Regulation FD Disclosure

On December 17, 2008, at 5:00 p.m. Eastern time, Cadence Pharmaceuticals, Inc., hosted a conference call to provide an update regarding the announcement of topline results of its Phase III clinical trial of Acetavance™ (intravenous acetaminophen) in laparoscopic surgery, and announcing the completion of its adult clinical development program for Acetavance. The transcript of this conference call is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

A replay of the webcast of this conference call will be available on Cadence's website at www.cadencepharm.com for approximately sixty days.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

By filing this Current Report on Form 8-K and furnishing this information, Cadence makes no admission as to the materiality of any information in this report. The information contained in the transcript is summary information that is intended to be considered in the context of Cadence's other filings with the SEC and other public announcements that Cadence makes, by press release or otherwise, from time to time. Cadence undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

Cadence cautions you that statements included in the transcript attached hereto as Exhibit 99.1 that are not a description of historical facts are forward-looking statements. These forward-looking statements include statements regarding: Cadence's belief that it has completed the clinical development program for Acetavance, that its data will support two dosing regimens and that, if approved, Acetavance will provide important clinical and marketing benefits; the timeframes in which Cadence anticipates announcing the results of its final safety trial and filing an NDA for Acetavance, and the timeframe in which the company expects to complete its analysis and announce the full results of its other clinical trials of Acetavance; the company's belief that FDA will not require an advisory panel to review data regarding Acetavance as a part of the NDA review process; and, if approved, the anticipated pricing and marketing demand for Acetavance in the United States. The inclusion of forward-looking statements should not be regarded as a representation by Cadence that any of its plans will be achieved. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in the company's business, including, without limitation: the outcomes of final analyses of data from the company's clinical trials of Acetavance may produce negative or inconclusive results, may differ from the initial analyses, or may be inconsistent with previously conducted clinical trials, and the FDA may not agree with Cadence's interpretation of such results; the FDA may require Cadence to complete additional clinical, non-clinical or other requirements prior to the submission or the approval of NDAs for Acetavance; data from clinical trials of Acetavance may demonstrate inadequate therapeutic efficacy, and clinical trial data, as well as reports of adverse events from countries where intravenous acetaminophen is already approved and commercialized, may indicate that the prevalence or severity of adverse side effects is greater than anticipated; the company may experience delays in completing important pre-commercialization manufacturing development activities for Acetavance, and may be required to perform additional pre-clinical or clinical testing prior to submitting, or obtaining approval of, an NDA for this product candidate; the third parties on whom Cadence relies to assist with the development program for Acetavance, including clinical investigators, contract laboratories, clinical research organizations and manufacturing organizations, may not successfully carry out their contractual duties or obligations or meet expected deadlines, and the quality or accuracy of the nonclinical, clinical and manufacturing data generated by such third parties may be of insufficient quality to include in the company's regulatory submissions; the company expects intense competition and pricing pressure for Acetavance in the United States market, and new products may emerge that provide different or better therapeutic alternatives; Cadence may require substantial additional funding to complete its development

program for Acetavance and, if approved, to successfully launch this product candidate, and the company may not be able to raise sufficient capital when needed, or at all, particularly in light of the recent, unprecedented volatility in the overall capital markets; and other risks detailed in Cadence's prior press releases as well as in the company's periodic public filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Cadence undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Cadence Pharmaceuticals, Inc., conference call transcript, dated December 17, 2008

EXHIBIT INDEX

Exhibit No.

Description

99.1 Cadence Pharmaceuticals, Inc., conference call transcript, dated December 17, 2008

**Cadence Pharmaceuticals
Conference Call Script**

Results from Studies 304, 351, 102

December 17, 2008 at 2:00 p.m. Pacific Time

Operator: Good afternoon and welcome to the Cadence Pharmaceuticals conference call.

At this time, I'd like to inform you that the conference is being recorded and that all participants are in a listen -only mode. At the request of the company, we will open the conference up for questions and answers after the management presentation. Should you have any problems during the call, press star/zero for a conference call operator. And now at this time, it's my pleasure to turn the conference over to Anna Gralinska, Director of Investor Relations of Cadence Pharmaceuticals.

Anna: Good afternoon everyone and thank you for joining us today to discuss the topline results from Acetavance Study 304 in laparoscopic surgery as well as our adult safety Study 351 and pediatric pharmacokinetic Study 102.

On the call with me today are Ted Schroeder, Cadence's President and CEO, and Dr. Jim Breitmeyer, the company's Executive VP and Chief Medical Officer.

Before we begin, I would like to remind everyone that statements made during this conference call that are not a description of historical facts are forward-looking statements. Words such as "plans," "expects," "anticipates," "believes," "should," and "will," and similar expressions, are intended to identify such statements, and are based on our current beliefs and expectations. Forward-looking statements include statements regarding: our belief that we have completed the clinical development program for Acetavance, that our data will support two dosing regimens, and that, if approved, Acetavance will provide important clinical and marketing benefits; as well as the timeframes in which we anticipate announcing topline results of our final safety trial and filing an NDA for Acetavance. The inclusion of forward-looking statements should not be regarded as a representation that any of our plans will be achieved, and our actual results may differ materially from those discussed during this call due to the risks and uncertainties inherent in our business, including, without limitation, the following:

The outcomes of final analyses of data from our clinical trials may produce negative or inconclusive results, may differ from our initial analyses, or may be inconsistent with previously conducted clinical trials, and FDA may not agree with our interpretation of these results. The FDA may require us to complete additional clinical, non-clinical or other requirements prior to the submission or approval of an NDA for Acetavance. Data from our clinical trials may demonstrate inadequate therapeutic efficacy and our clinical trial data, as well as reports of adverse events from countries where intravenous acetaminophen is already approved and commercialized, may indicate that the prevalence or severity of adverse side effects is greater than anticipated. We may experience delays in completing important pre-commercialization manufacturing development activities, and may be required to perform additional testing prior to submitting, or obtaining approval of, an NDA. The third parties on whom we rely, including clinical investigators, contract laboratories, clinical research organizations, and manufacturing organizations, may not successfully carry out their contractual duties or obligations or meet expected deadlines, and the quality or accuracy of the data generated by such third parties may be of insufficient quality to include in our regulatory submissions. We may require substantial additional funding to complete our development program for Acetavance and, if approved, to successfully launch this product candidate, and we may not be able to raise sufficient capital when needed, or at all. Other risks are detailed in our prior press releases as well as in our periodic public filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date made. All forward-looking statements are qualified in their entirety by this cautionary statement and we undertake no obligation to revise or update statements made during this call to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

If anyone has not seen our press release issued earlier today, you can access it on our web site at www.cadencepharm.com. Additionally, this conference call is being webcast through the company's web site and will be archived there for future reference.

With that, I'll turn the call over to Ted...

Ted:

Thank you, Anna.

Good afternoon everyone and thank you for joining us today.

We're very pleased to report positive topline results from Study 304, our Phase III clinical trial of Acetavance for the treatment of acute pain following abdominal laparoscopic surgery. The study successfully met its primary endpoint for the 1000mg dose, achieved a statistically significant positive result for the 650 mg dose, and the safety events reported from this study were similar for Acetavance and placebo treated patients.

We're also pleased to announce the completion of the adult portion of our clinical development program for Acetavance, and that we have enrolled the last patient in the final required clinical trial in pediatric patients. These developments represent the achievement of a significant milestone for our company in that we have now completed the clinical development program for Acetavance, including all clinical activities requested in the written guidance from the FDA that we received in July of this year.

Now, I'd like to turn the call over to Jim for a more detailed overview of the topline results from Study 304, as well as our safety and PK studies 351 and 102. After that, I'll have some brief remarks and then open the call to your questions. Jim.

Jim:

Thanks, Ted.

Study 304 was a randomized, double-blind, multi-center study of 244 patients following laparoscopic surgery designed to evaluate the safety and efficacy of two dosing regimens of Acetavance, 1000 mg administered every six hours and 650 mg every four hours, each compared to placebo over a 24-hour period. The primary endpoint of the study was defined as the sum of pain intensity differences from baseline over 24 hours, that's known as the SPID24, of repeated doses of 1000 mg of Acetavance. We're pleased to report that the primary endpoint was successfully achieved with a p value of less than 0.01.

The study results also show a statistically significant reduction in SPID24 for the 650mg dose of Acetavance administered very four hours with a p value of 0.02.

Consistent with other placebo-controlled trials of intravenous acetaminophen, reported safety events from the Acetavance and placebo-treated patients were similar. Following the completion of all data analyses, we plan to communicate the study's full results in a peer-reviewed scientific venue.

We plan to include the data from Study 304 in our Acetavance NDA submission. With the completion of the study, we now have or may reference data from successful placebo-controlled trials for the treatment of fever and acute mild, moderate and severe pain following a range of surgical procedures including laparoscopic surgery, total joint replacement, open heart surgery, tonsillectomy, and third molar removal.

IMS data show that physicians commonly prescribe acetaminophen in the hospital in its oral form in dosages of both 1000mg and 650 mg. The data from Study 304 will support both of these dosage regimens. If the drug is approved by the FDA, we believe that this will provide flexibility of physicians prescribing Acetavance for the treatment of acute pain and fever.

Today we are also very pleased to report the successful completion of two studies of Acetavance that are required as part of our NDA submission – Study 351, evaluating the safety of repeated doses of Acetavance in adults, and Study 102, evaluating the pharmacokinetic profile of Acetavance in pediatric patients.

In the open label, multi-center adult study for safety, 351, 213 hospitalized adult patients were randomized to receive repeated doses of Acetavance, 1000 mg every six hours or 650 mg every four hours, and they were compared to a standard of care group for up to five days. Reported safety events from both groups of subjects receiving Acetavance were similar to those administered standard of care treatments, and the standard of care in most cases included oral acetaminophen. The proportions of subjects with elevated liver function tests were numerically lower in the two Acetavance groups compared to the standard of care group. With the successful completion of Study 351, our clinical development program for Acetavance in adult patients is now complete.

We have summarized hepatic safety data from a total of nine placebo-controlled single and repeated dose clinical trials conducted in more than 1,300 adults with acute post-operative pain or fever. These data demonstrate that intravenous acetaminophen has a hepatic safety profile comparable to placebo, with liver function test elevations reported as a treatment-emergent adverse event in five percent of subjects who received placebo, compared to only three percent of subjects who received intravenous acetaminophen.

With regard to the pediatric clinical program, Study 102 was a clinical trial designed to evaluate the pharmacokinetics of Acetavance in 75 pediatric patients. The study demonstrated the expected pharmacokinetic profile, which is generally comparable to adults, with an expected age-related reduction in clearance in newborns, which is also known to occur with oral acetaminophen. The drug was well tolerated for safety across all age groups, ranging from newborns to adolescents.

With the successful completion of our pediatric PK Study 102, the last clinical trial of Acetavance required to complete our NDA is Study 352. It is designed to evaluate safety in children receiving up to seven days of Acetavance at up to 15 mg/kg. As announced today, we have closed patient enrollment in this study and expect the results to be available in the first quarter of 2009.

With that, I'll turn the call back to Ted.

Ted: Thank you Jim. We are very pleased with the successful completion of Studies 304, 351, and 102, and with the completion of enrollment in Study 352 which is the final study required under the Acetavance clinical development program. We believe that if the drug is approved by the FDA, the results with the 650mg dosing regimen will provide an important clinical and marketing benefit allowing physicians the convenience and simplicity of prescribing acetaminophen intravenously at all the same doses and frequencies as they now prescribe the oral form.

In addition to our achievement of these significant clinical development milestones, the other elements of our Acetavance development program remain on-track for submission of the NDA for this product candidate in the second quarter of 2009.

With that, I'd like to turn the call back to the operator and open the lines for questions.

Operator: Thank you, Mr. Schroeder. The question and answer session will begin at this time. If you're using a speakerphone, please pick up your handset before pressing any numbers and should you have a question, please press the star key followed by the digit one on your touchtone telephone. If you wish to withdraw your question, please press star/two. Just a moment for our first question.

Our first question will come from Juan Sanchez with Ladenburg Thalmann.

Q: Good afternoon, guys and congratulations.

Answer: Thank you Juan.

Q: I have a couple of questions in terms of, first of all, the level of pain that these patients had as baseline and what happened, I mean what's the mean number of hours or days that these patients were receiving IV APAP and if you measured the SPID at 48 hours as well?

Answer: Juan, this is Jim Breitmeyer, your question is regarding Study 304?

Q: Yes.

Answer: Okay, the baseline pain was in the moderate to severe range, right about the middle of the VAS pain score and they were on study for a total of 24 hours, starting their treatment the morning after surgery and finishing the study the following morning. We did not collect data on pain out to 48 hours, but we did collect follow up liver function tests a few days, several days after their Acetavance dosing.

Q: Got it. And a different question is if you can share with us the REM program that you want to provide to the FDA for approval, the risk management program.

Answer: Sure, again, this is Jim Breitmeyer. We believe that the drug will be found by the FDA to be safe. One known risk factor with the use of acetaminophen is to dose in higher than recommended doses, so a key element of a risk management strategy for this drug will be to ensure that hospitalized patients do not receive other acetaminophen-containing compounds at the same time that they're getting Acetavance. So we plan for example to have educational materials for the floor staff and one thing that we're discussing that we'll propose to FDA will be a large label hanging on the drug vial that reminds the staff not to administer other acetaminophen-containing drugs. Hepatic safety is the only substantial safety issue of concern that the FDA has expressed to us, and we believe that keeping the dose of the drug within recommended guidelines will provide a maximum level of hepatic safety.

Q: Thank you very much guys.

Answer: Thanks, Juan.

Operator: Our next question is from Ritu Baral with Canaccord.

Q: Hi, guys. Congratulations, again.

Answer: Thank you.

Q: So, I have two questions, the first of which is, could you go into a little bit how pediatric PK clearance and hepatic safety may differ from adults? And my second question surrounds your commercialization strategy and sales force plans given the current timing of Omigard and now Acetavance, as well.

Answer: Ritu, this is Jim, I'll take the pediatric question first. It's well-known among pediatricians that acetaminophen is metabolized a little bit more slowly in newborns than it is in older children, and so it is common in newborn and dosing of very young children to space out the doses and give doses less frequently than you would in older children or adults. We found confirmatory pharmacokinetics in our young children and believe that we'll be able to provide dosing guidelines that will overlap with the way that pediatricians dose oral acetaminophen now. As far as hepatic safety is concerned, in general, children metabolize acetaminophen in a way that is more safe than adults, because they have a higher ability to metabolize through the safest metabolic pathway, glucuronidation, and this is true in the youngest children through infants and other young children. So we have seen a good safety profile in our own studies of children and we expect that the FDA will agree with us that the drug can be given safely in children and newborns.

Q: Great, thanks. And the commercialization and current sales force plans?

Answer: The commercialization plans are to launch with a sales force of between 150 and 200 representatives. That's assuming both products. That will allow us to penetrate the top 2,000 hospitals that represent about 80 percent of the potential sales for Acetavance. So we'll have broad market penetration, which we anticipate will drive rapid adoption.

Q: And do you plan on concurrent launch of both products given the...?

Answer: They'll be spaced out a little bit, but they'll be nearly concurrent given the current timeline. Our plan for building the sales force is that we will begin hiring the management team toward the latter half of 2009 and then the management team will begin identifying the sales representatives in early 2010, with a goal of having the reps become active post-approval. We think in today's market — it's somewhat of a buyer's market for sales representatives — we think we'll be able to activate the reps post approval. The training on the product is straightforward, so we don't think it'll take a lot of time to get the reps fully trained and in the field making calls.

Q: Great, thanks.

Answer: Okay. Thank you.

Operator: Our next question is from Charles Duncan with JMP Securities.

Q: Hi guys. Let me add my congratulations on some pretty nice data and moving forward with Acetavance.

Answer: Thanks, Charles.

Q: I had a question regarding secondary endpoints and I know you haven't, or you plan to present this data in a peer-reviewed forum, but did you collect data on opiate-sparing in 304, and is it consistent with the thesis that you might be able to reduce the use of opiates?

Answer: Charles, this is Jim. We have hurried the primary data along to get it in your hands as fast as possible and performed intensive validation on the primary endpoint analyses and data. We are still working on all the secondary endpoints and so don't want to comment on them prematurely while they continue to be analyzed. We will make every effort to get them out in a timely manner.

Q: And when do you anticipate being able to submit – is that going to be abstracts to a meeting, or are you going to wrap up this data and submit to a journal?

Answer: We're looking at both possibilities and there are some meetings in the spring that we're looking at right now. But we'd also like to publish the data and get it out as well.

Q: If I may ask a question about 351, was there any elevation at any time points? I know that it looks pretty good across the primary endpoint but are you concerned at all about any elevation at any time?

Answer: In any elevation in liver function tests? Is that the question?

Q: Yeah.

Answer: The nice thing about this study design is that it includes this standard of care group, and so these are fairly ill hospitalized patients that were enrolled in the study and they were randomized to the two doses of Acetavance and to the standard of care. A lot of the patients had undergone quite complex surgery prior to enrollment, or had other conditions that indicated a need for five days of pain therapy, and so liver function tests come and go in that kind a population, but what we were happy to see was that they were very comparable between the standard of care and the Acetavance group, a pattern which we've observed now across several multi-dose studies. So our assessment at this point is indicating that the use of Acetavance doesn't add any significant level of elevated liver enzymes compared to what is already happening to these patients in the hospital.

Q: Okay. And if I could move onto another safety question, do you have access to the ex-U.S. safety reporting and, if so, what are you seeing in terms of background level of liver function testing coming out of Europe?

Answer: We do have access to the Bristol-Myers periodic safety update reporting system. There's no routine measurement of liver function tests in the post-marketing environment outside the U.S. There are occasional periodic safety reports, CIOMS and reportable events, in this enormous population of patients that have been treated with the drug with over 300 million doses distributed. We've examined on an ongoing basis hepatic-related events in that population. Our assessment is that the hepatic experience is consistent with the underlying diseases in that population and there's no indication that the drug is causing any substantial liver irritation on its own. In other words, the liver events that are reported almost always have another proximal cause.

Q: Okay, that makes sense. And a final question from a commercialization standpoint. Can you remind us of the obligations to Bristol-Myers Squibb in terms of milestone payments with development and then also the royalty? I think it's a tiered royalty, Can you give us some sense as to that level and the timing of that?

Answer: Yes, they're up to another \$40 million in milestone payments. The first and the largest of those payments are at NDA approval and then there are two smaller, backend commercialization milestones. Sorry to be a little vague, but our CDA with Bristol doesn't allow us to get much more detailed than this. The royalty, you're correct, it's a stacked, tiered royalty. It begins at dollar zero and resets each year. So it's based on sales tiers. The weighted average of those sales tiers at peak is a double-digit royalty below 20 percent.

Q: And this may seem bizarre, but the confusion, thank PDLI for the confusion, does the tiered royalty go up with increasing sales or does it go down with increasing sales?

Answer: It actually – each sales tier of royalty goes up and so it starts lower and weights up to be just below 20 percent.

Q: Okay. Thank you.

Answer: And it's not cumulative, so in other words, it's weighted. You pay the first tier royalty and then the second tier. It goes up but it's on that next portion, it doesn't go all the way back to the beginning. Each tier has its own royalty structure.

Operator: Our next question is from David Steinberg with Deutsche Bank.

Q: Okay, thanks. A couple of questions. First, on commercialization, could you remind us of what you expect for your price for Acetavance on a per unit basis in the U.S., and then do you have any recent data on how the product is doing in Europe, either in sales or units? And, also, what's the current pricing structure in Europe? And then, finally, do you have a point of view as to whether you'll have an advisory panel given the FDA's interest in the hepatic toxicity issues?

Answer: I'll answer the first question last. We do not expect an advisory committee meeting on acetaminophen. We just don't think there's anything really controversial here and it's unlikely that there would be an advisory panel. There's no hepatotoxicity signal here. There's also been an advisory panel on acetaminophen in the last couple of years and doesn't seem like that's something the FDA would need to revisit. As far as commercialization, our anticipated price is between \$8 and \$10 per 1gram dose. That compares favorably with the price of Toradol[®] when it was branded 11 years ago which was \$7 a dose, both for four times a day, as you'll recall. The price in Europe ranges from a low of \$2.74 up to \$9.74. Those prices don't seem to have any impact on unit market share. In fact, the countries with the highest price have among the highest unit market shares in all of Europe. So it seems to be a function of the effort that was put behind the brand as opposed to price. The most recent data we have for unit sales out of Europe is for full-year 2007. That was 80 million doses in Europe and continuing to grow. That was up about 13 percent over 2006. We expect to get updated data for year-end 2008 in the first quarter of next year. But all indications are that the product continues to grow across Europe and some of the countries where market share is lagging behind continue to grow and to catch up, so it's been a pretty solid success. So we think we can at least match the Bristol performance. Keep in mind that they've achieved 80 million doses in five years with a staggered start, launching first in France, and then rolling it out one country at a time across Europe. That's certainly a suboptimal way to achieve peak sales. We'll have the advantage of launching with a fully dedicated sales force to the largest market in the world simultaneously and we think that will enable us to at least meet Bristol's performance, and our goal would be to exceed that.

Q: Great, thank you.

Answer: Okay. Thanks David.

Operator: Our next question is from John Newman with Oppenheimer.

Q: Hi, guys. Thanks for taking the question. Can you give us any idea as to the magnitude of pain score reduction between the treatment arms and the control arms, and could you also tell us when you might expect to present the full data in 2009? Thanks.

Answer: Yeah, John. The SPID24 is a particularly unintuitive pain scale to put into terms of magnitude and the difference between the two groups was – I can say that the difference between the groups was in the range that we had anticipated when we sized the study. It is – I’m trying to put it into qualitative terms — several millimeters of difference on the VAS scale over the 24 hour period of observation is probably a fair way of describing it. And the second question, I’m sorry, was...?

Q: Just wondering when you might present the full data, including the secondary endpoint in terms of the amount of morphine that was needed?

Answer: Yeah, we haven’t guided on that yet, but the first set of meetings would be in the spring, March/April timeframe, and we’re looking right now to see whether those would be suitable for abstract submission.

Q: Great. Thanks.

Operator: Our next question is then from Rachel McMinn with Cowen and Company.

Q: Okay. Thanks very much. Just to get back to the liver function test, so I understand this, when you’re quoting the five percent versus three percent, are you talking about any abnormal LFT that was reported over the course of that particular study?

Answer: Yes. It’s transaminase elevation specifically that we were focusing on. We haven’t seen, for example, there haven’t been any bilirubin elevations that occur separately from transaminases, so we focused on the transaminases and so these are treatment-emergent reports of transaminase elevations, which is the parameter that we’ve been able to analyze thoroughly first. We’re also looking at quantitative liver function, taking every liver function measured over the course of the placebo-controlled clinical trials. Those are being processed right now. The preliminary numbers that are coming out are reassuring and confirmatory to the reported transaminase elevations.

Q: And in terms of the severity of liver function by quantitative, is there a prescribed time period either in Study 304 or in other studies where it's like a few hours after the dose is given or how do you standardize that in the trial?

Answer: It's standardized by pre-specified time points that the liver functions are drawn, at least once a day during dosing and then once several days after the last dose. For example, in the 304 study we obtained the sample on the seventh day which would be six days after the last dose.

Q: And then, in terms of the quality of the data, so at this point, do you feel like you don't have a lot of missing data? If there was a hole to kind of pick apart, do you feel comfortable with the quality of the data coming out of the trials?

Answer: Very happy with the quality of the data.

Q: Okay, great. And then, just going back to your comment, the commercialization comment on the 150 to 200 sales reps, if Omigard ends up not being commercialized unexpectedly and you're just left with Acetavance, what would that sales force look like? Have you run those numbers?

Answer: It would certainly be smaller. We haven't done a sizing exercise, but I would anticipate it would be closer to the 150 number than the 200 number.

Q: Okay. And then on the Bristol-Myers obligation, so you're saying that a large portion of the \$40, I don't know if you can quantify it further, but if not, if we just assume it's in the tens of millions of dollars to Bristol, is due on NDA approval? Are there any, I guess any arrangements that you can make with Bristol to defer some of those payments?

Answer: Well, we can't be more granular because of our CDA. They're a little sensitive about it. The – deferring the payments, I guess we could go back and try to negotiate that. You know, there's no payment on submission, which is a typical type of structure. I would, you know, I guess it probably wouldn't be wise to comment on any kind of negotiating strategy, but it's certainly not a discussion that we've had.

Q: Okay. That's helpful. Thanks very much.

Operator: And as a reminder, for an initial or follow-up question is by pressing star /one. We'll next go to Vincent Xiang at Franklin Advisors.

Q: Hi. Regarding this SPID24, I just wonder, when you design a trial, what is the power and then what's the intended difference between the two arms that you intend?

Answer: We haven't disclosed at that level of granularity, Vincent, and we would expect all of that to be included in the peer-reviewed publication.

Q: Right. That's fine. And then another question is that if you reengineer the definition or endpoint to be more close to what you did at the 301 trial, namely not look at the SPID, but the same window of observation for 24 hours but rather look at the difference versus baseline, you look at the total area under curve for the total sum of the pain severity and if you do that, what's the p value? Is that still less than .05?

Answer: If I'm understanding your question correctly, the primary endpoint for 301 was a SPI24. This is a SPID24, so the only difference between the two is subtracting the baseline before you do your calculations and so...

Q: Actually, you also shifted the window of observation by 10 hours.

Answer: What we did in this study, this design... I see what you're saying, yes, so, you mean because we started the patients the next morning?

Q: That's right.

Answer: But we don't have any data between the time they woke up from surgery and when they enrolled the following morning.

Q: Yeah, no, that's fine, so what I want you to do is look at the total area on the curve between hour 10 and hour 34, and then you measure, you measure the sum of the total severity between your treatment arms...

Answer: Oh, in 301.

Q: Whether you will hit the P value 0.05.?

Answer: The reason you can't do that with the 301 data is that everybody was on rescue medication by hour 10, and so the pain scores were simply a reflection of how much morphine they were getting at any given time. So it's not – the data from 10 to 34 in 301 is not clinically comparable to the data that we have in 304.

Q: But if you're looking at the trial 304 and then you look at the just the area rather than looking to the difference in deltas, you look at the total area of the curve, would you hit the p values then?

Answer: I haven't seen that analysis yet.

Q: Okay. Thank you.

Operator: And with that, there are no further questions in the queue. I'd like to turn the call to Ted Schroeder for any additional or closing comments.

Ted: Well, thank you everyone. Appreciate your participation today and your interest and your insightful questions, and we look forward to seeing you in person as we move into the New Year. And thanks again, and Happy Holidays to all.

Operator: Ladies and gentlemen, this concludes our conference call. All parties may now disconnect.

END