### **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) **January 18, 2011** 

## 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))

#### Item 7.01 Regulation FD Disclosure.

On January 18, 2011, Cadence Pharmaceuticals, Inc. hosted a conference call to discuss the U.S. launch and availability of OFIRMEV<sup>TM</sup> (acetaminophen) injection, the first and only intravenous formulation of acetaminophen to be approved in the United States. The transcript of management's presentation on the call is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2. of Form 8-K, the information under Items 7.01 and 9.01 of 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, or the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference to Items 7.01 and 9.01 in such filing to this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit
Number
Description of Exhibit

99.1 Transcript for conference call held January 18, 2011.

#### **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.

CADENCE PHARMACEUTICALS, INC.

By: /s/ WILLIAM R. LARUE

William R. LaRue Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary

Date: January 19, 2011

#### EXHIBIT INDEX

Exhibit Number <u>D</u>

Description of Exhibit

99.1 Transcript for conference call held January 18, 2011.

# Cadence Pharmaceuticals, Inc. OFIRMEV™ U.S. Launch Conference Call January 18, 2011

Operator:

Good afternoon and welcome to this Cadence Pharmaceuticals conference call. On the call today are Ted Schroeder, President and CEO, Bill LaRue, Senior Vice President and Chief Financial Officer, Jim Breitmeyer, Executive Vice President and Chief Medical Officer, and Scott Byrd, Senior Vice President and Chief Commercial Officer.

At this time, I would like to inform you that this 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, please press star zero for the conference call operator.

Our first speaker is Bill LaRue. Go ahead, sir.

Thank you. Good afternoon everyone. Before we get started today, I would like to remind you that statements included in this conference call that are not a description of historical facts are forward-looking statements. Such forward-looking statements include statements regarding the commercial launch of OFIRMEV, the anticipated U.S. market opportunity for IV acetaminophen, and our strategy for building a long term hospital pain franchise.

Our actual future results may differ materially from our current expectations due to the risks and uncertainties inherent in our business. These risks include our dependence on the successful commercialization of OFIRMEV; the risk that delays in commercially launching or achieving formulary acceptance for OFIRMEV at a substantial number of targeted accounts would enable competitors to further entrench their products and decrease the market opportunity for OFIRMEV; our ability to ensure an adequate and continued supply of OFIRMEV to successfully launch commercial sales or meet anticipated market demand; the fact that OFIRMEV

Bill LaRue:

remains subject to substantial ongoing regulatory requirements; our ability to comply with the terms of our loan agreement; the potential for an event of default under our loan agreement; the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen; our ability to successfully enforce our intellectual property rights and defend our patents; the impact of healthcare reform legislation; the potential that we will require additional funding in order to successfully commercialize OFIRMEV, and the risk that we may not be able to raise sufficient capital when needed, or at all; and other risks detailed under "Risk Factors" and elsewhere in our Quarterly Report on Form 10-Q for the period ended September 30, 2010 and our other filings made with the Securities and Exchange Commission from time to time. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and we undertake no obligation to revise or update the information discussed during this call to reflect events or circumstances after this call.

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.

I'll now turn the call over to Ted.

Thank you, Bill and good afternoon everyone. Thank you for joining us today. I'm excited to announce the national launch of OFIRMEV, the first and only intravenous formulation of acetaminophen to be approved in the United States. This event represents the culmination of years of hard work on the part of our partners in the medical community, including anesthesiologists, surgeons, pharmacists, nurses, and finally, our team at Cadence.

We have hit the ground running with our hospital sales team making calls on healthcare professionals. We are focused on making OFIRMEV available for use by physicians to safely and effectively manage pain in hospitalized

Ted Schroeder:

patients who are unable to use oral analgesics. We're also focused on turning OFIRMEV into what we believe will be a long term commercial success. I'll keep my remarks brief. Suffice it to say that I'm incredibly proud of the team that has made this possible.

I'd now like to turn the call over to Scott Byrd, our Chief Commercial Officer, to describe our launch activities and our expectations with regard to the hospital formulary process. Scott?

Thanks, Ted. As you know, OFIRMEV was approved in November, 2010 for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever.

With this launch, we're now looking forward to making OFIRMEV a success in the marketplace.

Let me provide a short checklist of just some of the launch elements now in place. One hundred and forty-seven hospital sales specialists are currently promoting OFIRMEV. Our sales professionals have, on average, 10 years of hospital sales experience - many have launched successful hospital products and built brands - all in the face of formidable competition.

Leading our sales team is an outstanding sales management team. Each member of our sales leadership team has substantial experience in successfully managing hospital sales teams.

Together, we believe that we have assembled one of the most experienced and proven hospital sales teams in the industry.

We have 13 highly experienced field medical liaisons who will provide medical and scientific information to physicians interested in using OFIRMEV.

From January  $3^{rd}$  to the  $13^{th}$ , we ran a national launch meeting to educate, train, and prepare all of our sales and medical representatives. All three major wholesalers are now fully stocked and accepting orders from hospitals.

Scott Byrd:

Our focus now turns to working directly with physicians and hospitals to increase demand for OFIRMEV and ensure rapid formulary adoption. We have already profiled approximately 900 key institutions, which we believe represent approximately half of the target market opportunity for OFIRMEV, to identify the formulary process and the key decision makers.

Let me take a moment to outline how, in general, the process for adding a new medication, such as OFIRMEV, to hospital formularies works.

Typically, the institution's Pharmacy and Therapeutics Committee is the nucleus of the decision making process. P&T committees can consist of up to 10 to 20 professionals, including members of various hospital disciplines. They generally meet on a monthly or bimonthly basis to review drugs and medication guidelines.

On average, a company like Cadence will have several interactions with committee members and product champions prior to formulary acceptance, providing information and answering questions that may arise during the committee's deliberations.

Once a request is made to add OFIRMEV to a formulary, it can take anywhere between one and six months to calendar or schedule the meeting. Our expectation is that most formulary committee decisions will be made on the first pass.

As we have mentioned in the past, the primary tools that support our conversations with P&T committees are the clinical data that support our claims of significant pain relief, decreased opioid consumption and improved patient satisfaction.

Additionally, we can provide formulary committee members with published clinical studies of IV acetaminophen use in Europe, which may be useful to the committees in their evaluation of potential hospital cost savings.

As indicated in our press release, we anticipate that by the end of this year, OFIRMEV will be on formulary at approximately 800 to 1,000 hospitals nationwide, which we believe represents approximately half of the IV analgesic opportunity for the product.

Additionally, we have announced the pricing of OFIRMEV. The list price, or wholesale acquisition cost is \$10.75 per vial and the net realized price to the company, net of rebates, chargebacks, discounts, returns, et cetera, will be approximately \$10.05 per vial.

We have signed agreements with the five largest Group Purchase Organizations to provide services and discounted pricing to approximately 90 percent of hospital customers. We believe our pricing strategy will not only allow hospitals to access OFIRMEV at a fair price, but facilitate rapid formulary approvals at many institutions.

In a nutshell, our team is really excited to be launching the first and only IV formulation of acetaminophen approved in the U.S. that offers improved pain relief with reduced opioid consumption.

I'll now turn the call back over to Ted for his closing remarks.

Thank you, Scott. This is indeed an exciting time for Cadence as we take a significant step forward in achieving our goal to improve the lives of hospitalized patients. We are confident in the future of OFIRMEV and pleased with early feedback from customers.

In our first 24 hours of launch, at least 10 hospitals around the country have reported stocking OFIRMEV. Five institutions have already placed it on formulary and approximately 115 have scheduled it for formulary review during the first half of the year. Outstanding results. Most importantly, patients in the U.S. have begun receiving commercially available IV acetaminophen for the first time.

We'll now open the call to your questions. Operator?

Thank you, Mr. Schroeder. The question and answer session will begin at this time. If you're using a speaker phone, please pick up the handset before pressing any numbers. Should you have a question, please press star and the number one on your push button telephone. If you wish to withdraw your question, please press the pound key.

Ted Schroeder:

Operator:

Again, if you have a question, please press star and the number one on your push button telephone. Please stand by for your first question.

Our first question is from Eric Schmidt from Cowen and Company. Your line is open.

Eric Schmidt: Good afternoon. Congrats on the launch.

Thanks, Eric.

Eric Schmidt: Sure, Ted. My questions are about the goal of 800 to 1,000 formulary clearances by year end. Can you just talk a little bit more about, you know, how you've established that goal? Are these all hospitals that have been profiled already? So, you know, when formularies meet and what might be rate limiting and then what would be the goal for the other half of the

market that you can't reach by year end?

Hi, Eric. This is Scott. I'll give it a shot and Ted may have some comments as well. You know the profile of the accounts certainly are reflected by the accounts that we've profiled up until now with our district managers prior to launch, but they're not exclusively those accounts. Certainly, as our representatives get out and engage their accounts, I think there'll be not only formulary successes with those that we profiled in the previous year, but new accounts in which the hospital specialists had already established relationships in previous lives, if you will.

So it's reflective, if you will, of an average account across our 1,870 or so hospital targets. I wouldn't say that in this particular guidance there's a bias one direction or another. It's certainly our expectation that we'll be able to provide some additional guidance as we move forward, and of course get some more in depth insight into the customer interactions in the coming months.

Ted Schroeder:

Scott Byrd:

And then, beyond that, our expectation is that we'll be able to continue what would be a pretty strong push through the end of the year and early into next year to complete the hospital formulary process. So, you know, we haven't established any expectations beyond 2011, but as we move forward with our hospital formulary guidance in the future months, we can provide a little bit more color.

Yes, Eric, and to be clear, the 800 to 1,000 accounts are part of the targeted number that Scott referred to. We do expect that there'll be hospitals outside of those target accounts that will add OFIRMEV to formulary. But these are the accounts where we'll have visibility into the process and visibility of when a decision is made and those are the – it's against those numbers that we'll be updating the street.

OK, and then Ted, at the end of your prepared remarks, you said that 10 hospitals have stocked the product, only five have cleared formulary. So obviously purchases are not dependent on clearing formulary. How does that work and do you expect that to be a sizeable number of orders?

Yes, although I would say that five formularies in day one is pretty good.

Yes.

That's a pretty good start. So I'm pretty — I'm thrilled about that actually. Yes, you know one of the things that you'll see often in hospital products, particularly with a product like OFIRMEV that has such broad interest across hospital physicians, is that particular physicians will request that the product be ordered so they can trial it in the hospital while the formulary process is ongoing.

So, it does add to the sales line, but you really don't experience substantial sales until the – until the formulary decision is made and the product is available broadly to all physicians. So, you see initial stocking, you've seen that with other products. The real key here is to get on formulary so the representatives can encourage pull through sales across departments in the hospital.

Ted Schroeder:

Eric Schmidt:

Ted Schroeder:

Eric Schmidt:

Ted Schroeder:

Eric Schmidt: OK, then maybe last question for Bill LaRue, a revenue recognition question. When do you book sales?

Bill LaRue: Eric, we're going to book sales at the sale through to the hospital.

Eric Schmidt: So your wholesalers provide you with all that information?

Bill LaRue: That is correct, yes.

Eric Schmidt: Thanks a lot.

Bill LaRue: You bet.

Ted Schroeder: Thanks, Eric.

Operator: Thank you. Our next question is from Adam Cutler of Canaccord. Your line is open.

Adam Cutler: Hi, thanks for taking my question and congrats on the launch.

Ted Schroeder: Thank you.

Adam Cutler: Just to go into a little bit more detail there, I mean, you mentioned for instance that some of the hospitals who may have

ordered, but have not yet approved OFIRMEV on their formulary may be running trials. Is your expectation that that's how a lot of hospitals will work, and will some of them need to run trials of one form or another after formulary approval? Or is

it your assumption that once it's on the formulary the – that the doctors can just start using it as they see fit?

Ted Schroeder: Yes, Eric – not Eric – sorry, Adam. I'm sorry, excuse me. No, and I didn't mean actual trials. I mean trial usage in that they

were doing initial use of the product and evaluating it in their practice. Not a formal trial of any sort. We don't expect that that will be a requirement. But you will have early adopters that will want to have the product available for their use in the

institution before it's broadly available. Scott, did you have ...

Scott Byrd:

Yes, no. I think that that certainly represents a large portion of hospitals that will stock prior to the formulary decision. And then there's the other big group which is frankly, they recognize that there's a bureaucracy within their institutions to work through the formulary process and, you know, when physicians are clamoring for access to the product, they'll allow them to use it until that formulary decision is made. And so it's not even sometimes a formal review or assessment that's being made, but simply allowing the physician community to begin to get experience while they're going through the formulary process. And so I guess sometimes it can be a formal process and other times it's quite informal.

And often what you'll see is the community hospital centers tend to have a little less formality to their approach, and they tend to be the ones that are more willing to stock the product prior to the formal formulary decision.

Adam Cutler:

OK. So, in the case where there is a formulary approval, what is it that ultimately drives widespread use? Do individual hospitals then provide treatment guidelines to their own staff or is it really based on the clinicians' experience and a combination of the effectiveness of your sales force?

Scott Byrd:

Well, it's primarily the effectiveness of the sales force engaging and educating customers across the hospital. You know, there's clearly sometimes institution driven efforts to build standing orders or protocols for a product's use.

I think in the case of OFIRMEV, while we are expecting to be included on protocols and standing orders, the broad adoption really is going to be through the efforts of the representatives to engage anesthesiologists, surgeons, CRNAs and nurses in the PACUs and up on the floors. And, you know, that's a pretty standard selling model and process and, frankly, one that I think is going to reap some big rewards for us as our sales force gets through the formulary process.

Adam Cutler:

OK.

Ted Schroeder:

Yes, often Adam, those types of standing orders are physician or physician group specific and they're not necessarily adopted hospital wide.

Scott Byrd: That's right.

Ted Schroeder: So a particular surgery group, for example, may have a set of standing orders. That would be more typical than an

institution wide decision on a standing order.

The institution adopts it onto the approved list of drugs that can be used within the hospital, provides dosing guidances and maybe in some cases patient types and then the individual groups within the hospital will decide where in their treatment approach that drug would be used, in this case in the post operative setting mainly, but we'll see use broaden and into the

non-operative areas over time.

Adam Cutler: OK, thanks. And then just one last question is now that you've announced the price, you know, are you prepared to give

more detailed guidance on gross margins and what the gross margins are expected to be and whether there's certain –

whether that is expected to change dramatically with certain sales thresholds?

Bill LaRue: Adam, yes, we typically, you know, provide updated guidance during our year-end financial results conference call, and I

think we'll hold to that.

Adam Cutler: OK, thanks a lot.

Operator: Thank you. Our next question is from Charles Duncan of JMP Securities. Your line is open.

Charles Duncan: Hi, guys. Thanks for taking my call and let me add my congratulations on the launch and early success.

I had a question regarding communication on the launch activities. I'm kind of wondering how much granularity you're going to provide at least in the next couple of quarters? Are you going to talk about P&T committee meetings or formulary

acceptances, and will you continue to break out formulary acceptance from hospital stocking?

Ted Schroeder:

Yes, Charles, those are good questions. Our intent is to report actual formulary approvals as we move forward. In the early going, we go through stocking because it's relevant just to give a sense of the enthusiasm for the product, but I think the hard metrics are the – the actual formulary approvals. So our intent is to only report those when we can confirm that it's been officially added to the formulary. I don't expect to give guidance going forward of number of committee meetings scheduled, but really to focus on the actual approvals, which really are the gating item to sales.

Charles Duncan:

That said, I definitely appreciate the, I'll call it goal, that you set of 800 to 1,000 formulary clearances by year end.

That's significantly above what one of your mind share competitors is tracking to. Is that primarily a result, do you believe, of your better execution thus far or organization or is it really drug driven?

Ted Schroeder:

Charles, I think it's first and foremost drug driven. I think that IV acetaminophen being the only non-opioid, non-NSAID, IV analgesic available occupies a unique role in the hospital. It's also the only analgesic without a black box warning, and that's significant in the hospital setting as you know. There are many fragile patients in the hospital and picking the safest drug is often the best route to go. So we think those types of dynamics work in the favor of a broader and quicker adoption of IV acetaminophen. Of course, there's no generic competitor to OFIRMEV, and that also would bode well for broad formulary adoption.

Charles Duncan:

So now, Ted, turning from, you know, what it could look like in the first year to what it - how big it could be, what about use outside of the post op setting. Do you have any plans to pursue some additional clinical data outside of the post op setting?

Ted Schroeder:

I'll let – I'll let Scott comment on that.

Scott Byrd:

Outside of the clinical trial work, and maybe Jim can kind of clean that part up Charles, but we absolutely see significant opportunity in the non operative pain space. In addition, frankly, pediatric utilization we think is going to be as strategically important for us. We're going to stay true to our focus here on launch and really hone in on peri-operative pain management and establishing OFIRMEV as the foundation for IV analgesia in that patient population.

Having said that, we're expecting there to be use outside of that setting, certainly in this first year. And as we reach our goals in hospitals establishing OFIRMEV in peri-operative pain, we will then begin to expand our promotional efforts out beyond the post op setting into the other areas of the hospital where there's still a significant amount of unmet need.

In terms of the clinical work, you know we're not planning specific studies in those models, of course outside of the commitments we have with the agency in pediatrics.

OK, and then my last question is on intellectual property. I'm wondering if you could remind us what are the dates for the patent coming off, and then whether or not you expect a possible first paragraph IV filing any time soon?

So the formulation patent has an expiration date late in the year in 2017. We expect to get the six month extension for pediatrics, so that would make it a first half 2018 exclusivity period. And as you know, we've always talked about that as being the primary patent.

The process patent runs until 2021. Again, we would also have the six month extension available to us and those are the two key patents. And we have great confidence in those patents. You know it took four decades for someone to figure out how to put IV acetaminophen into a stable commercially reasonable formulation and we think the patents are broad enough to protect that invention.

As to a paragraph IV, that's less of a Cadence risk and more of an industry risk. Every company has the risk of a paragraph IV and, indeed, with a 505(b)(2) filing, we could have had a paragraph IV the day after the drug was approved. But of course, there is a solid patent estate and we will rely on the intellectual property that protects the product.

Both patents are orange book listable by the way, so that gives us the – gives us the opportunity to access remedies available through that pathway, as well.

Charles Duncan:

Ted Schroeder:

Charles Duncan: OK, thanks for the added color and good luck on the launch activities.

Ted Schroeder: Thanks.

Operator: Thank you. Our next question is from Joseph Schwartz of Leerink Swann. Your line is open.

Joseph Schwartz: Thanks, and congratulations.

Ted Schroeder: Thank you.

Joseph Schwartz: I was wondering if you could just give us a sense of your expectations in terms of the surgical settings and where do you

expect most OFIRMEV sales to be generated in at first and where do you see this evolving over time?

Scott Byrd: Well, I would say that there is not any obvious surgical specialties where we think OFIRMEV wouldn't apply. It's really more driven by the numbers of the surgeries and the different specialties. So general surgery certainly will be a setting of significant use, particularly with physicians that are doing surgeries in the abdomen. We think there's a particularly strong clinical value in those procedures.

Obviously, our pivotal study was in orthopedic procedures, which tend to be very, very painful procedures with strong desires to get these patients up and moving and ambulated very quickly. So that's another big market opportunity for us.

We've got additional data in OB/GYN patients, in that there's a tremendous number of patients undergoing procedures within that specialty.

Those would be the big three, but certainly we're not counting out use in cardiothoracic procedures, neurosurgery, ENT and others.

So, you know, I know I've listed all of the surgical specialties, but that's pretty much because we think the clinical application is consistent across them. Our focus at launch is of course going to vary hospital to hospital based on the types of procedures and the physician champions, but focused on the areas of greatest opportunity, which were the first three specialties that I mentioned.

Joseph Schwartz:

Scott Byrd:

OK, and what distinguishes the accounts that you expect to adopt OFIRMEV this year, versus those that won't? Is it primarily timing or are there other factors and how do you address anything in the latter camp?

I think there's a range of factors that play into it. Certainly, and we spoke about this before, there are many of the larger academic institutions that tend to have quite – not rigorous, which is fine – but slow moving processes to move product through a series of subcommittees ultimately up to P&T and the medical executive committees for their final approvals, and that process just takes quite a long time.

And so I think those will be hospitals that will be on the outer reaches of time to formulary approval.

There are other situations that might accelerate the formulary approval either because they are physicians with experience with IV acetaminophen either outside of the U.S. or in clinical studies and they tend to be fairly aggressive and supportive, and that of course helps to accelerate the formulary review process.

And those even that don't have necessarily previous experience with the product, physicians that have a lot of influence and a lot of interest in the application of OFIRMEV with their patients will be strong advocates in the process. And particularly in the outlying community hospital settings where the process is somewhat less formal than it might be in a major academic center if you have the cross section between really strong advocacy across a range of physician specialties like anesthesia and surgery without a significant bureaucracy, that will be a setting for fairly rapid formulary review.

I hope that gives you a sense of the cross section and who might move earlier rather than later. But the simple answer is that we think that the moderate sized community based hospitals will probably move somewhat faster than the very large academic institutions.

That's very helpful. Thank you. Joseph Schwartz:

Operator: Thank you. Our next question is from Richard Lau of Wedbush Securities. Your line is open.

Richard Lau: Thanks guys and congrats on a timely launch. Quick question about the pediatrics trial. Is that still scheduled to start kind

of in the second half of this year? And can you remind us what that trial might look like and how much it might cost? Hi, Rich, this is Jim Breitmeyer. We have two different things to do in pediatrics – two different goals to reach. One is to

extend our patent with a pediatric written request study and in a separate regulatory process we have a post approval

commitment to generate efficacy data and pharmacodynamic - PK correlations in children under two.

We are negotiating with the FDA right now to determine whether or not those two different goals can be best served with a single study or with two studies.

In any case, I think we are – the timing is as we've discussed previously, the second half of this year. And, overall, the magnitude of these studies is relatively modest compared to some of the other therapeutic areas that you work in and will probably involve a couple hundred patients or less. And so, you know costs are in the range of a – you know single digit

million dollars. Probably on the low end there.

So, overall we don't think that our planned pediatric studies will have a major effect on our burn rate.

Richard Lau: OK, thank you.

Jim Breitmeyer:

Ted Schroeder: And, Richard, just to make sure everyone's clear that we don't have to complete the study by the second half of this year. Really, we need to have an agreed upon protocol with the FDA and we anticipate starting the study. We'll complete it

sometime, you know, after that. But it's probably not – we don't expect data to read out from those studies this year.

Jim Breitmeyer: Certainly not.

Richard Lau: OK. Great. All right, thanks.

Thank you. Our next question is from Irina Rivkin of Duncan Williams. Your line is open.

Congratulations. I just had two quick questions. One is, you've previously said - or talked about, the 90 million vials that are used in Europe on an annual basis, and I was just wondering if you'd be willing to provide an estimate or a target for

how many vials you think you could sell, you know, this year?

And the second question is, is regarding commercial initiatives. I was just wondering what types of impactful or noisy type

programs you've started already and what else you have planned for the end of the year? Thanks.

Ted Schroeder: I'll take the first part of that question. I think we're going to shy away from specific vial projections for this year, because really its – the work of this year is getting on the formularies so that we have the access open to us. And so it's very much

> access dependant. So we will continue to update on formularies, but don't anticipate updating on vials. Although, I think from a broad opportunity, looking toward Europe and how the product ramped up in Europe is certainly a useful exercise.

And I'll let Scott answer the second part of that question on the commercial initiatives.

Yes, happy to do it. And I think that – by far the – to use your term, the noisiness – that you might see will be coming primarily from our field sales organization. I don't think there's any question that's our primary mode for promotion of the

However, to provide a little bit more color around some of the other activities that are definitely going to be important to get the word out and continue to generate interest, we have probably, I don't know, 15 or so medical meetings that we'll be having a presence at across the surgical and anesthesia space

Operator:

Irina Rivkin:

Scott Byrd:

over the course of the year. These can be very, very productive, particularly for a product like OFIRMEV, in which the molecule is well understood, but the availability of the IV formulation might be news to folks.

Additionally, we've already initiated some direct marketing campaigns inclusive of journal advertising and some very targeted journals, high impact journals for anesthesia and surgery. And e-pharma alerts, which is basically an e-communication out to several thousand pharmacists making them aware of the availability of the product has been initiated. And we're on the front end of beginning to execute a speaker training for peer to peer promotional programs where physicians can educate one another and we're expecting to launch that program a little later this quarter. So we've got pretty much the full gamut of our promotional resources in full swing.

As you might know, if you've already clicked on ofirmev.com as of this morning, that Web site has been expanded from the initial launch flash page where we had the package insert available to have more information available about the efficacy and safety of the product and lots more.

So that, in a nutshell, are the primary promotional programs we've got ongoing at this point in time.

I would also add, that although this is not a promotional activity, to date there have been 65 randomized control trials published on IV acetaminophen. We anticipate another 10 or 11 will be published and those are the ones we know about. There are actually multiple publications that come from around the world that are initiated by investigators that we don't have good sense of. So there is an enormous amount of data supporting the use of IV acetaminophen in a number of – across a wide gamut of surgical uses as well as non operative uses, pediatrics, special populations, et cetera. So that growing repertoire of literature is really an important support for the product adoption.

Thanks very much.

Ted Schroeder: Welcome.

Ted Schroeder:

Irina Rivkin:

Operator: Thank you. And again, if you have a question or comment, please press star and the number one button on your push

button telephone. Again, please press star then one on your push button telephone.

Our next question is from Greg Frazier of Bank of America. Your line is open.

Greg Frazier: Thank you. First, on the detail aids that the sales force is using. Can you describe what the main selling points are that are

highlighted in the materials and how would you characterize your level of conservatism that you took when designing the

materials?

Scott Byrd: I'm sorry, what was the second part of your question, Greg?

Greg Frazier: How would you characterize the level of conservatism that you took when designing the materials?

Scott Byrd: Well, I'll start with that one. It's pretty straight forward. We frankly only include messages in our promotional materials

that are fully compliant and of course we've had rigorous internal reviews to ensure that's the case.

The content is very straight forward. You know, there are four primary communication elements to the story around OFIRMEV. The first is that it provides significant pain relief. Secondly, it reduces opioid consumption and third, it improves patient satisfaction. And fourth, it's got a very well established safety profile. So those are the primary communication elements of our promotional efforts and of course, depending upon the tool that we're using, we have

varying amounts of supportive but certainly substantial on all four of those communication elements.

Ted Schroeder: Yes, and Greg, you can get a good sense of those communication elements by logging onto ofirmev.com where you'll be

able to see them graphically represented much the same way the physicians would see them.

Scott Byrd: Exactly.

Greg Frazier:

OK, you mentioned discussing guidance on the year end call. Can you give us a preview of which line items you're planning to guide on?

Bill LaRue:

You know, Greg, not at this point. We'll just go ahead and do our update at that point in time.

Greg Frazier:

OK, and can you comment even just generally on the size of the orders that you've gotten from the hospitals that have added OFIRMEV to their formularies?

Ted Schroeder:

You know what, I actually don't have visibility into what the size of the orders have been. I – you know, at a minimum, they have to order a case. So that would be the smallest order and I know that there are probably some that have ordered multiple cases, but I don't expect that there are anything in the dozens or hundreds of cases at this point.

Greg Frazier:

OK, thank you.

Operator:

Thank you. I'm showing no further questions or comments at this time. I'd like to turn the call over to Ted Schroeder for any closing remarks.

Ted Schroeder:

Well, thank you. And thank you everyone for joining us on the call today. With the launch of OFIRMEV, the first and only IV formulation of acetaminophen approved in the U.S., we have delivered on a promise to patients to provide an analgesic that offers significant improved pain relief, reduced opioid consumption and improved patient satisfaction. We expect the benefits of OFIRMEV will be evident to hospitals in the coming year. We look forward to providing updates on our commercial progress as well as feedback from the surgeons and anesthesiologists who have direct experience with OFIRMEV in the weeks to come.

Thanks very much for joining us on the call, and your continued support of Cadence.

We're scheduled to be at a number of conferences during the coming weeks where we hope to see many of you.

Thanks again.

Operator:

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the program. You may now disconnect. Have a wonderful day.

END