
**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)
November 2, 2010**

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 November 2, 2010, we hosted a conference call to discuss our announcement that the U.S. Food and Drug Administration, or FDA, granted marketing approval for OFIRMEV™ (acetaminophen) injection, the first and only intravenous, or IV, formulation of acetaminophen to be approved in the United States. OFIRMEV is indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics, and the reduction of fever. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript for conference call held November 2, 2010.

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: November 3, 2010

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript for conference call held November 2, 2010.

Cadence Pharmaceuticals, Inc.
OFIRMEV™ FDA Approval Call
November 2, 2010

MANAGEMENT DISCUSSION SECTION

Operator: Good afternoon. And welcome to the Cadence Pharmaceuticals Conference Call regarding the FDA's approval of Cadence's proprietary pharmaceutical product, OFIRMEV. On the call today are Ted Schroeder, President and CEO, Jim Breitmeyer, Executive Vice President and Chief Medical Officer, Scott Byrd, Senior Vice President and Chief Commercial Officer and Bill LaRue, Senior Vice President and Chief Financial Officer.

At this time, I would like to inform you that this conference call 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. [Operator Instructions]

Our first speaker is Bill LaRue. Please go ahead, sir.

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

Thank you and good afternoon everyone. Before we begin, 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 timing of the planned commercial launch of OFIRMEV, the market potential for OFIRMEV, OFIRMEV's ability to fulfill unmet medical needs in the treatment of pain and fever in the hospital setting and the timing of the post marketing efficacy study of OFIRMEV in infants and neonates.

Our actual results may differ materially from those discussed during this call due to the risks and uncertainties inherent in the our business, including without limitation; our dependence on the successful commercialization of OFIRMEV; the potential that we will require substantial additional funding in order to effectively commercialize OFIRMEV and the risk that we may not be able to raise sufficient capital when needed, or at all; the risk that delays in commercializing launching OFIRMEV would enable competitors to further entrench their existing products or develop and bring new products to market before OFIRMEV; our ability to ensure an adequate and continued supply of OFIRMEV successfully launch commercial sales or meet anticipated market demand; our ability to comply with the terms of our loan agreement and the potential for an event of default under our loan agreement; and the impact of healthcare reform legislation. These and other risks are detailed in our prior press releases in periodic public filings with the Securities and Exchange Commission.

You are cautioned not to unduly rely on these forward-looking statements, and we undertake no obligation to revise or update such statements. All forward-looking statements are qualified by this cautionary statement. 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 website at www.cadencepharm.com. Additionally, this conference call is being webcast through the company's website and will be archived there for future reference. Ted?

Ted Schroeder, President and Chief Executive Officer

Thanks Bill. Good afternoon everyone. Thank you for joining us today on short notice. We're obviously thrilled to announce that the U.S. Food and Drug Administration has granted marketing approval for OFIRMEV, the first and only intravenous formulation of acetaminophen to be approved in United States.

We firmly believe that OFIRMEV will benefit hospitalized patients by filling an unmet medical need for the treatment of pain and fever. I'd like to begin our discussion by asking Jim Breitmeyer to discuss our clinical development program and NDA, followed by Scott Byrd, who will briefly discuss our plans for launching OFIRMEV to the U.S. hospital market. Jim?

Jim Breitmeyer, Executive Vice President and Chief Medical Officer

Thank you, Ted. The approval of OFIRMEV offers physicians an important new non-opioid, non-NSAID treatment option for the management of pain and reduction of fever in hospitalized patients.

Our NDA for OFIRMEV included efficacy and safety data from clinical trials in over 1,000 adults and over 350 pediatric patients who received IV acetaminophen. The safety of OFIRMEV was supported by data from more than 60 million patients exposed to IV acetaminophen in countries outside the United States.

Our pivotal clinical trial in patients undergoing hip or knee replacement surgery demonstrated that, compared to placebo, OFIRMEV resulted in significantly decreased pain intensity with reduced opioid consumption, improved pain relief and improved patient satisfaction.

OFIRMEV has been shown to be safe and effective as a single agent in mild-to-moderate pain and when used as part of multi-modal regimen with opioids in moderate-to-severe pain. OFIRMEV was also demonstrated to be safe and effective in our randomized double-blind controlled clinical trial of induced fever in adults, significantly reducing temperature in comparison to placebo. In this study, fever reduction began within 15 minutes of completing administration of the drug, and then in another study it caused a more rapid decline in temperature than oral acetaminophen. OFIRMEV was shown to be safe and well tolerated in clinical trials in a range of patient and surgery types from newborns all the way to the elderly.

OFIRMEV is indicated for the management of mild-to-moderate pain, the management of moderate-to-severe pain with adjunctive opioid analgesics and the reduction of fever. The approval for pediatric patients older than two years of age was based on well- controlled studies in adults was additional pediatric safety data, and our demonstration that OFIRMEV pharmacokinetics are similar between adults and children. The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been in study in pediatric patients less than two years of age, and Cadence will conduct a post-marketing efficacy study of OFIRMEV in infants and newborns for this purpose. This study will also serve to satisfy our requirement under our written request that we expect will result in an extension of the patents.

Currently opioids and NSAIDs are the only two classes of IV medications available to treat pain, and their use is often limited by their significant side effects and risks. Since oral acetaminophen-opioid combination products have been prescribed for the treatment of acute pain for many years, and physicians are very familiar with them, the approval of OFIRMEV will allow physicians to use the same multi-modal treatment model in patients who are unable to take medication by mouth.

We are very excited that OFIRMEV is now available to address important unmet medical needs in the treatment of pain and fever.

Theodore R. Schroeder, President and Chief Executive Officer

Thanks again Jim. Scott, why don't you tell us about Cadence's commercial plans?

Scott A. Byrd, Senior Vice President and Chief Commercial Officer

Thanks Ted. This is an exciting time for the whole organization, as we begin our transition from launch planning to execution. As Jim described, OFIRMEV has an outstanding clinical data package and its introduction to the U.S. will give physicians and patients here a new option for improving pain management in the hospital.

IV acetaminophen has been widely adopted in the markets where it has been launched, such as the EU. Since its introduction to the European market by our licensor, Bristol-Myers Squibb, in 2002, more than 400 million doses of IV acetaminophen have been distributed. In 2008, approximately 90 million vials IV acetaminophen were sold in Europe, where it is the market-leading injectable pain medication. With 291 million IV analgesic units sold in U.S. during 2008 and approximately 50 million surgical procedures performed annually, we estimate that the U.S. market could be similar in size to that of the EU.

In addition to the significant penetration seen in Europe, we are encouraged by the extensive market research and customer profiling we have completed over the last year. Anesthesiologists and surgeons across the range of specialties have indicated in our market research that OFIRMEV could play a significant role in the treatment of post-operative pain in their practices. We believe that physicians will be attracted to the efficacy and safety profile of OFIRMEV, as demonstrated in the clinical studies, which to-date has been unavailable to them with other products. Our research indicates physicians believe that, as a non-opioid and non-NSAID IV analgesic, OFIRMEV will help address the significant unmet need in the management of pain in the hospital setting.

In addition to having outstanding product, we believe we are well positioned to maximize the launch and create value for hospitals through the efforts of a very experienced and well-prepared hospital sales, marketing and medical affairs team. Our front line sales management team averages 16 years of industry experience and over seven years in hospital sales management. They have recruited and are now in the process of hiring approximately 150 top performing sales specialists with an average of over nine years of hospital sales experience. Additionally, our medical affairs leadership is assembling a complementary team of highly experienced medical science liaisons to support the formulary review process and provide medical expertise. Most have advanced degrees in extensive hospital experience. I'm really quite proud of the team we've assembled and we all remain focused on executing an outstanding launch. We will utilize the coming weeks to complete the training of our sales and medical affairs teams and make final preparations for launch.

We expect that launch to occur early in the first quarter of 2011. We plan to provide more details regarding specific launch plans, pricing and our expectations regarding formulary adoption when we announce the commercial launch.

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

Ted Schroeder, President and Chief Executive Officer

Thanks, Scott. I think it would be a good point now for us to open the call for questions. Operator, would you open the lines please?

QUESTION AND ANSWER SECTION

Operator: Thank you Mr. Schroeder. The question-and-answer session will begin at this time. [Operator Instructions] Our first question comes from Eric Schmidt of Cowen and Company.

<Q – **Eric Schmidt**>: Good afternoon, congratulations on a wonderful milestone.

<A – **Ted Schroeder**>: Thank you.

<Q – **Eric Schmidt**>: You're welcome, I haven't seen the package insert; I don't know if there is one available yet, but in terms of some of the finer points in the label, Ted, can you speak to any warnings around liver toxicity or precautions or need for a REMs program to distribute the drug internally in hospitals, things like that?

<A>: Sure. I'll let Jim Breitmeyer address the label.

<A – **James Breitmeyer**>: Sure Eric. This is Jim. There is no REMS and, like oral acetaminophen, the drug is contraindicated in cases of allergy or in patients with severe hepatic impairment or severe active liver disease. And also like oral acetaminophen, OFIRMEV should be used with caution in patients who have active liver disease. There are warnings that in overdose, again like oral acetaminophen, severe hepatotoxicity or death can occur. But I think that, overall, we are very happy with the labeling and I think it will look very familiar to physicians who have been prescribing oral acetaminophen all these years.

<Q – **Eric Schmidt**>: That's helpful, Jim. Is it a maximum dose of four grams per day?

<A>: Yes. The maximum dose is four grams per day in adults and 75 milligrams per kilogram in children, again like oral acetaminophen.

<Q – **Eric Schmidt**>: In the language in the press release, it speaks to the reduction in opioids that you've observed with OFIRMEV. Is that also in the label?

<A>: It is in the label. It's in the clinical section of the label as part of the description of our orthopedic pain study.

<Q – **Eric Schmidt**>: Great. Thanks a lot. Congrats again.

<A>: Thanks, Eric.

Operator: Our next question comes from Charles Duncan of JMP Securities.

<Q – **Charles Duncan**>: Hi, guys. Let me add my congratulations on a great milestone for the company. My question is, I know that you're not willing to talk about pricing right now, but perhaps you could provide for us some color behind the way that you're thinking about that so we can get a handle on where to model?

<A>: Well, Charles, as we've previously disclosed, we are anticipating launching the product in the \$8 to \$10 price range. We haven't adjusted our thinking on that. We haven't landed on the final price yet and we'll announce that when we're ready to ship the product. But I think that range is probably the right range to be in for now.

<Q – **Charles Duncan**>: And with regard to the supply, are you set in terms of your early launch in 2011?

<A>: Yes, we'll be prepared to ship product before the commercial launch through the wholesale distribution channels. And we'll have product at the wholesalers, ready to ship the product before we launch to the market in the first quarter of 2011. So we're in good share there and we expect that product will ship with an 18 month shelf life.

<Q – **Charles Duncan**>: Okay. Very good. And then with regard to targeted hospitals, it sounds like you're going to be up and running with approximately 150 or so sales folks by the early part of the year. Can you give us any insights as to how you've decided to target certain accounts?

<A>: Sure, Charles, maybe Scott can jump in with some more color, but our approach with having 150 sales reps is that we would be able to address 80% of the market opportunity that means that we will be able to cover just over 1,800 hospitals. And our approach will be to use these reps to target those accounts. So over the last nine months, since the complete response letter, our district sales managers have been profiling accounts to understand those dynamics, so that they'll be able to work together with the representatives to create a business plan that appropriately addresses – that appropriately prioritizes accounts across the full target audience.

Equally, the other advantages our sales team will have is that most of them are employed at other companies, at least as of today, and they are hospital sales reps experienced in their territories. There is about a 75% overlap between the currently called-on universe and the accounts they will have at Cadence. So we believe that will be a significant driver of early penetration in the accounts.

<Q – **Charles Duncan**>: Okay. And then my final question is regarding the pediatric trial that you mentioned. Can you give us further insight on design - the timing and cost of that trial?

<A>: I'll let Jim answer that question, Charles.

<A – **James Breitmeyer**>: Hi, Charles. It will be a study of children under two, so, that encompasses infants and newborns. The that primary purpose of the study will be to show efficacy in the very youngest patients. We expect it to start within a year or so of launch and that gives us plenty of time to negotiate with the agency; so this study will fulfill the regulatory requirements for pediatric extension. And we haven't designed the study at this point, but we would expect it to be less expensive than our pivotal studies in adults.

<Q – **Charles Duncan**>: Okay. That's very helpful. Thanks again for taking my questions, and congratulations.

<A – **James Breitmeyer**>: Thanks, Charles.

Operator: Our next question comes from Joseph Schwartz of Leerink Swann.

<Q – **Joseph Schwartz**>: Hi, thanks. Let me also add my congratulations. This is fantastic. I was wondering if you could give us some more insight into what you've been learning as you've talked with some of the accounts about formulary placement, how they view this drug relative to the some of the other drugs that they have available, and it would seem like there is an unmet medical need and a pent up demand for non-opioid for certain segments of the market. Certainly other launches have been fairly slow in the field, so I am just wondering if you can help us with some of those issues?

<A>: Sure, Joseph, I will let Scott address that because we found a lot through market research; I will let Scott talk to the specifics.

<A – **Scott Byrd**>: The profiling exercise that Ted described has given us some really great insights into the processes that the hospitals are going to use, the specific individuals involved in the decision-making, the timelines within which the hospitals will be making decisions. So it structurally sets us up very well to know exactly how to move in and meet the needs of each individual account.

I think you are exactly right on your description of the interest. We, of course, in our hospital profiling haven't been talking about the product in that setting. However, through our research and engagement of physicians through consulting and advisory roles, we have learned an awful lot about how hospitals are looking at formularies and how they're going to be making decisions about formulary access.

You hit the nail on the head, being a non-opioid and non-NSAID product has given us quite a unique situation relative to some of the more recent product launches. We've got extensive data that has demonstrated improved pain relief and reduced opioid consumption across the range of surgical procedures.

This alone would be enough, I think, to warrant positive decisions on behalf of the hospitals. But the fact that acetaminophen is a new class, has a very well-understood safety profile that differentiates it from NSAIDs, in particular, we think that it's going to occupy a very separate and secure space on most hospital formularies.

I think the challenge with some of more recent product launches in the pain space with hospitals is that they have been challenged by really competing with established generic competitors, in doing so one needs to be able to differentiate the product and its characteristics. And I think they've struggled to do that and therefore be able to command the premium that would be necessary.

Certainly with the profile that OFIRMEV offers, we think that it will be highly valued by hospitals. And I think beyond the value of the product itself, we have assembled an extraordinarily experienced hospital commercial team, both on the sales front, the marketing front and our field medical support team. So we have spent the last year now very urgently preparing for this launch, understand our customers very well. And I think that also will set us up for quite a successful launch relative to some of the more recent product launches.

<Q – Joseph Schwartz>: Is there a difference in the way certain customers view the product versus others in terms of the way you think that they might be adopting the drug as early adopters or late adopters? Are there certain categories that you can provide, so we can envision how the launch curve might look?

<A>: Well, I think our plan is to provide a little bit more granularity in that direction as we get closer to commercial launch. I can tell you, very broadly, that certainly in the larger academic institutions, you have more structured and formal formulary review process that just by its very nature tends to take longer. The community-based hospitals often are able to, and do, act in a much more quick fashion.

So those are two very broad segments of hospitals. Within each one of those, there's a lot of variability. We've said before that we think that most hospitals will take up to six to nine months to make their formulary decision, and I think that still holds true, and again we'll be able to provide a little bit more clarity and guidance on our expectations for formulary adoption as we get closer to the commercial launch itself.

<Q – Joseph Schwartz>: That's very helpful. Thank you.

Operator: Our next question comes from Irina Rivkind of Duncan-Williams.

<Q – Irina Rivkind>: Hi, also my congratulations too; so I have questions on the manufacturing front. First, was there an inspection, did it or did it not happen?

<A>: Yes, there was. The Baxter plant was re-inspected.

<Q – **Irina Rivkind**>: Great. And what is manufacturing capacity for this product and the plant in 2011 and beyond? And I'm just wondering if that second manufacturing line that you were planning; are they up and running?

<A>: The second line is not up and running, but it will be in time to meet demand. We have substantial demand available in the Baxter plant and the facility is large enough to allow for expansion in the future. So we're very comfortable with the capacity – it's well in excess of our launch year needs and as we move into the following year, we'll be able to have a second line. It doesn't mean that we wouldn't pursue other geographic diversification for manufacturing, but we do believe that Baxter has the capacity and the expertise to meet our demands.

<Q – **Irina Rivkind**>: And then just one last question. I know that there was an additional \$25 million in milestones behind the \$15 million milestone to Bristol. Can you sort of provide a little clarity or remind us when these are due?

<A>: We have not described the exact milestones, but they are sales milestones and so they are backend loaded. They actually will occur, on the timeline of most people's projections, several years post launch.

<Q – **Irina Rivkind**>: Okay.

<A>: And it is two payments that add to the additional \$25 million.

<Q – **Irina Rivkind**>: Thank you. And again, congratulations.

<A>: Thanks.

Operator: Our next question comes from David Steinberg of Deutsche Bank.

<Q – **David Steinberg**>: Thanks and congratulations, guys. Just couple of commercial questions. I know you haven't indicated your pricing strategy, but given the size of the sales force, you indicated you're going to put together, could you help us with what sort of revenue levels will be necessary to attain breakeven? And then secondly, are you – now that you have an approved product, do you envision in-licensing or acquiring any other products to add to the bag for your reps?

<A – **William LaRue**>: Yeah. David, this is Bill. As you know we haven't given specific guidance in terms of where breakeven is. We think that we can get there relatively quickly if we are as successful as we think the product's going to be. We've had a walk through the margins in the past and think that the sales force is very leverageable. So I'll let Ted address the future strategies, but we definitely will look to bring other products in to leverage that, and use the positive cash flow to help support those activities.

<A – **Ted Schroeder**>: Yeah David, so our strategy has been, we do intend to grow the company by future acquisitions. And indeed we took the first step towards that in June when we took the option in Incline Therapeutics. As you may recall, Incline is developing IONSYS for the global market. So we're pleased with the progress that Incline has made to-date and we're looking forward to them continuing to progress. If they make sufficient progress, as you remember, there are two option periods in which we could exercise our option.

So that certainly gives us a first step toward growing a pipeline that is a strategic fit with our current sales organization. And then beyond that we will look for other late stage products to license or acquire. Over time, we may look at other opportunities to acquire hospital focused companies and certainly once we get passed the launch phase, we'll be looking to bring in co-marketing or co-promotion partnerships as well to fully leverage the sales force.

<Q – **David Steinberg**>: Okay. And one more question, now that you are going to launch the product, could you give us a quick reminder on your, on the protection surrounding OFIRMEV? Exclusivity that you have or about your Orange Book status? And then, any patents that you think you might be issued in the relatively near term which may add further protection?

<A>: Sure. So both the formulation and the process patents are Orange Book listable and we expect that to occur in the near period of time. Now as the product is approved, the formulation patent expires in late 2017. As Jim described, the pediatric post marketing commitment will also satisfy the pediatric written request. So we will receive a six month extension that would make the formulation patent expire in the first half of 2018. I recall that there is a process patent that expires in 2021 and that would also be eligible for this six month extension. So those two patents create really the basis for our pattern state. We are very confident in both patents but we are especially confident in the formulation pattern because this is the only formulation over decades of trying that ever revealed a stable, ready-to-use IV acetaminophen product. And so, at current time, there are no other pending applications in United States, but we will continue to explore those opportunities as we move forward.

<Q – **David Steinberg**>: Okay. Thanks.

<A>: Sure.

Operator: Our next question comes from Richard Lau of Wedbush.

<Q – **Richard Lau**>: Hi, guys. Thanks and again congratulations as well. My question is kind of regarding the formularies. In your market research, have you got any sense of hospitals having a greater sense of urgency to add it for the pediatric fever indication first, and then being able to use it for the pain indication once on formulary?

<A>: Sure. Scott, why don't you take that?

<A – **Scott Byrd**>: Yeah, absolutely. Now, I don't know that I can quantify for you at this point in time, the breadth of that interest. But we have heard a fair number of reports that there is some eagerness to move quickly from some institutions. In some situations, I think that's the pedantic indication, particularly in pediatric patients for fever, but not always. I think there are some institutions that are eager to move forward, because they think that, more broadly, the product is going to fill an important need in their hospital and on their formulary. So there will be a range of time lines, I think, across different segments of hospitals. Again, I think we'll be able to talk a little bit more about our expectations as we get closer to launch, but we do expect some hospitals to move fairly quickly.

<A>: Yeah, certainly, the treatment of pain and fever is a very large unmet medical need within hospitals, so there is a clear need for additional alternatives as Scott described. I would also say that the need to reduce narcotic use and to deliver better pain control, are also two big drivers in hospital decisions. These are measurable endpoints for JCAHO, CMS and really for patient satisfaction, as hospitals compete for patients among themselves. So we think in all those instances OFIRMEV has the opportunity to help patients and deliver better pain management – while at the same time reducing narcotic use. And it has broadly applications for the pediatric population, as previously described.

<Q – **Richard Lau**>: Okay, great. And then just a quick book-keeping question, in terms of the \$15 million milestone, does that get booked through your expense line? And then also, I'm assuming you guys plan on drawing down the \$10 million left on your loan facility?

<A>: **Bill LaRue** >: In terms of the accounting, it actually will be capitalized and then amortized. So it will not flow through, well, it will be amortized through expense. But a big cash hit, actually, you won't see it, as I said it would be a capitalized asset. And we're evaluating all types of equity structures and debt structures and we have that availability upon approval and so we'll be making that decision shortly.

<Q – **Richard Lau**>: Okay. Thanks guys.

Operator: [Operator Instruction] Our next question comes from Greg Fraser.

<Q – **Greg Fraser**>: Thanks. Let me follow along with congratulations getting the approval.

<A>: Thanks, Greg.

<A>: Thank, Greg.

<Q – **Greg Fraser**>: Can you discuss some of the market activities that you're planning between now and launch, are there some things that you can do in the field to further prepare now that you have the label in hand?

<A>: **Scott Byrd**: Sure. We – our primary focus over the coming weeks is going to be preparing our sales team and our medical affairs team to launch the product early next year. There are some things that we'll be doing, more non-personal promotion activities in the meantime.

Certainly, we are expecting that hospitals will want to begin the process of making formulary decisions possibly before when we've launched the product.

And one of the most frequent ways to initiate that process is to request information from our medical affairs department through dossiers that will be available. So that's not promotional activity, of course, but it's certainly a capability that Jim and his team are preparing for and will help support our customers as we get closer to the launch period and then certainly afterwards.

<Q – **Greg Fraser**>: Okay.

<A>: **Scott Byrd**: And we have a series of medical meetings coming up in November and December, as well. So you'll see a presence of OFIRMEV at those meetings. We, of course, have been present at many of the meetings, but have been limited by being in a pre-approval status. So we'll be engaging customers much more rigorously in those environments.

And we think that's going to – we've certainly created a lot of interest with our "coming soon" activity as we led up to approval. So we're expecting there to be much more interest and certainly we'll have an ability to have some interesting conversations with customers now at those meetings, as well.

<A>: **Ted Schroeder** >: And Greg, in addition as a robust publication plan, as you may be aware, to date there have been 62 randomized controlled trials studying IV acetaminophen in a broad range of applications. That activity continues, and you can expect to see publications in journals, as well as abstracts at meeting as we move through the next few months.

<Q – **Greg Fraser**>: Okay. And when will you bring the sales reps on board? And how should we think about fully burden costs for your sale reps?

<A>: Sale reps will be coming on board quickly. So, we will be contacting the contingent hires almost immediately, and assessing how quickly they can come on board. We'd expect the majority to be on board over the next two to three weeks. And from a fully loaded cost basis, I think, because we only have a single product and the lack of allocation, most people are picking a number around \$300,000 per rep, fully loaded, which includes all the various components of sales force support.

<Q – **Greg Fraser**>: Okay. That's helpful. And that post marketing study, it sounded like it may not start until the end of next year, I hear that correctly?

<A – James Breitmeyer>: This is Jim. It could, we'll start it as soon as we finish negotiating the study design and the regulatory details with the FDA. It was clear — it's clear that the FDA wants to have a discussion about the design, before we launch which we think is helpful.

<Q – Greg Fraser>: Are there any other areas that you're planning on spending R&D dollars, I guess, near-term for the next few quarters?

<A>: There are no other required post approval studies, and we are considering our Phase IV program carefully. We were waiting to see the final label, until we made those decisions, and so we're huddling right now to make the final line up for post-approval studies.

But I would say this, Greg, that there is a significant amount of interest from investigators to study the drug, and of course we won't be able to fund every request, but there are some interesting ideas that I think we have an obligation as a company to fund to advance the science.

<Q – Greg Fraser>: Okay. Thank you.

Operator: At this time, there are no further questions. So I'll turn the conference back to Mr. Schroeder.

Ted Schroeder, President and Chief Executive Officer

Well, thank you and thanks, all, for joining us. We really appreciate your continuing interest in the company. The approval of OFIRMEV is a significant achievement for Cadence and represents the first step in our ongoing efforts to improve the lives of hospitalized patients. It also represents the culmination of several years of hard work by our employees and would not have been possible without the assistance of the clinicians who have advised us and participated in our clinical trials. On behalf of Cadence's entire management team and Board of Directors, I would like to thank them for their dedicated and generous support.

I'll close today's call by reminding you that we're planning to issue our quarterly financial results this Friday, November, 5 and invite you to join us for our conference call to discuss these results at 8.30 AM Eastern Time on that day. Thanks everyone, and now you can spend the evening watching election results.

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