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)
February 11, 2010

Cadence Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-33103**	**41-2142317**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 February 11, 2010, Cadence Pharmaceuticals, Inc. (the "Company," or "Cadence") hosted a conference call to discuss the Company's announcement that the U.S. Food and Drug Administration ("FDA") has issued a Complete Response letter to its New Drug Application ("NDA") for intravenous acetaminophen. In the Complete Response letter, the FDA only indicated that deficiencies were observed during the agency's facility inspection of the Company's third party manufacturer, which was completed on February 5, 2010. The FDA did not cite any safety or efficacy issues, nor did it request any additional studies to be conducted prior to approval. The script 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 contained in Exhibit 99.1 is being furnished pursuant to this Item 7.01 and 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, and it shall not 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 in such filing to such exhibit.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Script for conference call.

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: February 11, 2010

EXHIBIT INDEX

Exhibit No.	Description
99.1	Script for conference call.

Exhibit 99.1

Cadence Pharmaceuticals, Inc.
Conference Call
February 11, 2010

Operator: Good morning and welcome to the Cadence Pharmaceuticals conference call. At this time, I would like to inform you that this conference is being recorded and that the participants are in a listen-only mode at the request of the Company. We will open the conference up for questions and answers after management's presentation.

Our first speaker is Bill LaRue, Senior Vice President and Chief Financial Officer for Cadence Pharmaceuticals. Go ahead, sir.

Bill LaRue: Thank you for joining us today as we discuss the complete response letter we received from the FDA for our new drug application for IV acetaminophen product. On the call with me today is Ted Schroeder, our President and CEO, and Dr. Jim Breitmeyer, our Executive Vice President of Development and Chief Medical Officer.

Before we get started, I would like to remind everyone that statements included in this conference call that are not a description of historical facts are forward-looking statements and may be identified by the use of words such as believes, seeks and estimated and similar expressions. All forward-looking statements are based upon our current beliefs and expectations and should not be regarded as a representation that any of our plans will be achieved.

Our actual results may differ materially from those stated in this conference call due to the risks and uncertainties inherent in our business, including our reliance on our only product, OFIRMEV; the possibility that OFIRMEV may not be approved on a timely basis or at all; the possibility that we may not yet understand all of the corrective actions that will be required to resolve deficiencies identified during the inspection of our manufacturing facility for OFIRMEV and that we will experience significant delays and incur additional costs in order to fully resolve such deficiencies; the potential that further FDA scrutiny of the manufacturing site may raise additional issues that must be resolved prior to obtaining approval of the NDA, causing further delays and cost increases; intense competition from existing and new products, which could diminish the commercial potential for OFIRMEV; the possibility that patent rights covering OFIRMEV may not be sufficient to preclude other intravenous formulations

of acetaminophen from being developed by competitors; the potential that we will require substantial additional funding in order to complete the necessary corrective actions at the manufacturing site for OFIRMEV, obtain regulatory approval for and commercialize this product candidate, and the risk that we may not be able to raise sufficient capital when needed or at all; the impact of any such financing activity on our stock price; and other risks detailed in our Company's 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 hereof. All forward-looking statements are qualified in their entirety by this precautionary statement, and Cadence undertakes no obligation to revise or update statements made in this conference 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 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.

I will turn the call over to Ted.

Ted Schroeder: Thank you, Bill. Good morning, everyone, and thank you for joining us today. This morning, we will provide an update to the complete response letter we received from FDA for our IV acetaminophen NDA and then open the call for questions.

In the complete response letter, the FDA indicated that it has completed its review of the NDA and that the only reason for not approving the NDA at this time was due to deficiencies observed during the FDA's facility inspection of our third-party manufacturer completed last Friday, February 5. The letter did not cite any safety or efficacy issues, nor does it request any additional studies to be conducted prior to approval of our NDA.

We were very pleased with the progress of our label discussions and were in the final stages of label negotiation when we learned of the inspection observations. Additionally, the FDA did inform us that OFIRMEV has been determined to be an acceptable trade name for our IV acetaminophen product candidate, and we will use that name going forward.

Everyone at Cadence is committed to working closely with our third-party manufacturer and the FDA to ensure that the deficiencies observed during the facility inspection are addressed as quickly as possible to meet the requirements for NDA approval. Until we meet with the FDA, we will be unable to further characterize the inspection observations. We will provide you with an update when we can provide greater specificity around the expected timeline for the approval of OFIRMEV. We remain confident in our NDA, and our focus continues to be on making OFIRMEV available for the management of pain and reduction of fever as quickly as possible.

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

Operator: (Operator Instructions). Gary Nachman, Leerink.

Gary Nachman: Ted, is there anyway you could characterize the manufacturing issues a little bit more than what you've told us so far? I know you don't know exactly how long it's going to take to resolve, but once you would resubmit, assuming that you do resolve all the issues, would it be a two- or a six-month turnaround at that point with the FDA?

Ted Schroeder: Well, Gary, we don't know the answer to that until the observations are responded to. So, much of that depends on kind of the response. The inspection was just completed last Friday the 5th. So we are still in the response window period for the contract manufacturer. And what I can say about the reasons is that they are related to manufacturing practices.

Gary Nachman: Okay. And this is Baxter, right?

Ted Schroeder: Yes.

Gary Nachman: Okay. So some of this may have had to do with the transfer over to Baxter in terms of trying to get those processes up and running?

Ted Schroeder: We don't really have any clarity on that, Gary. We just know that they are manufacturing practices.

Gary Nachman: Okay. Then when you say you were pleased with the labeling discussions as far as they had gone, was there any discussion of a black box in there?

Ted Schroeder: No.

Gary Nachman: Okay. Then lastly, would you guys need to raise more cash, you think, before approval, or you have enough in the bank, it seems?

Ted Schroeder: I'll let Bill answer that.

Bill LaRue: Yes, Gary, we believe that we have enough resources at this point in time that we would not need to raise cash before approval.

Gary Nachman: Okay. Thank you.

Operator: Adam Cutler, Canaccord Adams.

Adam Cutler: I guess a couple questions.

One is, I was a little surprised to read today that the inspection only occurred in February, given you originally had a November 13 PDUFA date on the delay at that point, at least as far as what the FDA seemed to tell you it was based on, of qualifying new data as a major amendment. So I'm wondering, was this the first inspection of that facility, or was this a second or more than second inspection of that facility?

And then if you can just also remind us what else Baxter may manufacture at this same facility in terms of other products that may be on the market in the US, if that's something you may be able to share?

Ted Schroeder: Sure, Adam. So it's our understanding this was part of a routine facility inspection and not an inspection for cause. So that is kind of the extent of what we know. You're correct. They do manufacture other products in this plant, other large-volume parenterals, some of which are Baxter's own multisource products, And they may manufacture on a contract basis for other manufacturers. I don't have real clarity on that. But it is their main plant.

With regard to other inspections as it relates to the IV acetaminophen product, this was the only inspection. There were none during the first six months of the review.

Adam Cutler: Okay. And then if I can just ask another question, is it possible, based on what you know about the FDA's comments about manufacturing from this inspection, that you may be able to address this without a re-inspection, or would you expect this to be another – to require another inspection?

And I guess on a related note, were the deficiencies that were observed specifically related to Acetavance, or is it related t all products manufactured at the facility, do you know?

Ted Schroeder: What we know, what has been shared with us are just the observations that are related to manufacturing processes that impact the acetaminophen manufacturing line. So we don't have any clarity beyond that when it relates to that. What was the other part of your question, Adam?

Adam Cutler: ... whether it's possible that you may be able to address this in writing or whether you expect that the FDA is going to want to come re-inspect the facility.

Ted Schroeder: Yes. I think the answer to that is that we truly don't know. The first step is for Baxter to respond to the 483 observations. And once that process is complete, we will then have a better view of if a re-inspection will be required or if this is able to be answered with a response from Baxter.

Adam Cutler: Okay. And then – sorry, just one last question.

In terms of financials, can you give us a sense of – I know that you have made a lot of conditional offers to sales reps, which obviously won't be triggered until the produce is approved. But in the interim can you give us a sense of what your quarterly burn looks like in advance of approval, just given that you have hired at least some people relayed to sales and marketing for the product?

Ted Schroeder: Adam, as typically is our case, we provide that when we provide fourth-quarter and full-year results. We will do the same this year and provide some additional clarity. And we should have that call within the next several weeks.

Adam Cutler: Okay. Thank you.

Operator: Eric Schmidt, Cowen and Company.

Eric Schmidt: In terms of the Baxter facility, are you aware as to whether it's still operating and producing these other products that Baxter sells for sale around the world?

Ted Schroeder: If the question is, is there a consent decree or the plant closed down, we are not aware of that, and it's our understanding that the facility continues to manufacture the other products.

Eric Schmidt: And Ted, was your fill/finish and everything else, the entire supply chain, inspected and signed off on other than the bulk manufacturing?

Ted Schroeder: So Baxter is the fill/finish. The bulk manufacturing, we actually purchase the API from Mallinckrodt. That comes from another manufacturer, and there were no comments regarding that. This is completely on the drug product that we are talking about.

Eric Schmidt: Got you. And then on the label, can you comment as to whether there might be any limitations on the maximum allowable dose per day or claims on reducing opiates, etc.?

Ted Schroeder: Well, the maximum allowable dose per day will be 4g, consistent with other acetaminophen-containing products. And as we've said in the past, we don't expect a specific indication for reduction of opioids, but we do expect the clinical data that show a reduction in opioids to be included in the clinical section of the label.

Eric Schmidt: And is there anything you can say about the risk management program that will be required?

Ted Schroeder: We do not expect a REMS to be required. As we've stated previously, we did submit a Risk MAP as part of the NDA detailing to the FDA the tactics that we would put in place to educate healthcare workers and patients about the need to stay below 4g a day in total acetaminophen consumption – really for any acetaminophen product, but particularly while they are receiving OFIRMEV.

Eric Schmidt: Great. Thanks a lot.

Operator: Charles Duncan, JMP Securities.

Charles Duncan: It sounds pretty clear that this is an issue that is more plant-related than product-related. But could you confirm that? Are there any specific steps that are required in the manufacture or final manufacture of Acetavance that caused this observation?

Ted Schroeder: No, you are correct. These are related to manufacturing practices. This is not related to the drug product itself and how you put the product together. Keep in mind that this is the same process that is used in Europe, where both Bristol and Baxter in Europe produce enough product to meet 90 million vials of annual sales demand. So that the mixing and all the components for the product itself are robust. This is related to manufacturing practices. And again, just to emphasize, it's Baxter – Baxter is responsible. And indeed, they are the only ones that can respond to these observations, to the inspector.

Charles Duncan: So that said, do you have any sense as to the timeline under which you expect them to or they've said to you that they will respond? And can you influence that in any way to speed it up?

Ted Schroeder: Well, typically, a manufacturer is required to respond to a 483 in 15 days.

Charles Duncan: So 15 days from the receipt of the 483. Will you be involved in processing following that, or are they simply involved in this and then the FDA is going to take action?

Ted Schroeder: We expect to work closely with our partner as they address these issues, but ultimately they are the ones that communicate with FDA, and the communication is confidential between the FDA and the third-party manufacturer.

Charles Duncan: Okay. And then if you had to ballpark, is this six-week or six-month kind of turnaround?

Ted Schroeder: Charles, we are not going to speculate on that, because, truly, until this issues are addressed and we have a chance to discuss it with FDA, we won't have good clarity on that.

Charles Duncan: Okay. Sounds good. Thanks for the added color.

Operator: Greg Fraser, Merrill Lynch.

Greg Fraser: I got a few minutes late, so I apologize if I ask something that has already been asked. But I guess based on your discussions with the agency and the content of the letter, can you now confirm that there are no outstanding issues preventing approval other than the manufacturing deficiencies?

Ted Schroeder: Yes.

Greg Fraser: Okay. And the contingent offers that you've extended to the sales reps, do those contemplate a lengthy delay of approval?

Ted Schroeder: Yes. And so the exact reason we made the contingent offers was because of the uncertainty surrounding any NDA and the delays that come into the process. So it is exactly the reason that we made contingent offers. We are reaching out to all those folks to answer their questions. I think the one thing that's in our favor is that most of the people who have offers are currently employed.

Greg Fraser: Okay. You mentioned being pleased with label discussions to date, which seems to imply that the label discussions have not been completed. Could you just clarify that comment? Am I reading too much into it?

Ted Schroeder: Well, they are not complete until you get an approval letter. So I think we were just trying to characterize that we were in the very final stages of discussing the label, and we are pleased with the direction of those discussions.

Greg Fraser: Okay. And it sounds like you probably won't know or won't have an answer to this until you meet with the agency and discuss it with your partner, but is this the type of letter that could require a complete response letter that would then trigger a two- or six-month review? Or is this totally different than that?

Ted Schroeder: Well, yes, I think it could. But we won't know the answer to that until the observations have been responded to. And then there's a disposition of those answers.

Greg Fraser: Okay. Thank you.

Operator: John Newman, Oppenheimer.

John Newman: I just wondered if you could give us any additional color on any feedback you've received from the FDA on the previous data that they requested, and if you could just talk a little bit more about what they wanted the last time you had a delay.

Ted Schroeder: So those data were related to clinical pharmacology, and there were no additional – there have been no additional questions on those data. And in the complete response, there were no requests for any additional data, not clinical, not preclinical, not pharmacology. – The only additional requirement is around the manufacturing practices.

John Newman: Okay. And did the FDA request any information on additional data analyses for the existing data that you already submitted?

Ted Schroeder: In this response, no.

John Newman: Okay. Just wondered if you had any sort of feel or idea as to the number of 483 citations that Baxter received?

Ted Schroeder: It's confidential to Baxter, so we don't know.

John Newman: Okay. And I guess you've been asked this question already, so I apologize, but is this something that you guys would consider like a Class I type response or more of a Class II? And what type of timeline do you anticipate in terms of meeting with the FDA? Also, could you tell us where the facility is located for Baxter? Is this outside the United States or –

Ted Schroeder: No, it's in Cleveland, Mississippi, which is their large-volume parenteral facility. And at this time, we are not going to speculate on timing or type of response, because, truly, the first step is for the manufacturer to respond to the 483 observations. That has to occur first before there will be any clarity beyond that.

John Newman: Okay, great. Thanks, guys.

Operator: Eric Schmidt, Cowen and Company.

Eric Schmidt: It's unclear to me, Ted, as to whether you've spoken yet to Baxter or whether you just got this response directly from the FDA and you haven't yet communicated with your partner.

Ted Schroeder: No, we've been communicating with our partner.

Eric Schmidt: Okay. And you just – based on those communications, you don't yet have any sense of timelines? It's just too early?

Ted Schroeder: Too early, but our expectation is that they will respond in the required period of time.

Eric Schmidt: And then assuming they respond, why wouldn't you be able to resubmit very shortly after?

Ted Schroeder: It depends on the disposition of those responses.

Eric Schmidt: Well, can you help me out there? I'm not sure I understood that.

Ted Schroeder: So the way the process works there, in general, for any observation like this, the manufacturer has the opportunity to respond to the inspector's findings. That goes through the inspection office. And then, like every other communication with FDA, then they weigh the merits of those responses.

There may be things that the inspector didn't review that were pertinent, and they will supply whatever supporting documentation that they feel is important to support their point of view. And then there is a determination made by the Office of Inspection. That is then communicated to the review division. The FDA cannot discuss with us those issues because they are confidential to Baxter, and they will not discuss them with the sponsor.

Eric Schmidt: Okay. So how do –

Ted Schroeder: Until after the process makes its way through the normal process.

Eric Schmidt: So what has to happen before you need to resubmit, I guess, on your side of the equation? Do you need to get final sign-off that the 483s have been satisfactorily answered and responded to?

Ted Schroeder: Yes. And in fact, that would be – any discussion we will have with the FDA, whether it's a meeting or another type of a discussion, the goal would be to be certain that those issues have been addressed so we can resubmit.

Eric Schmidt: And the resubmission, I assume, on the Cadence side is going to be essentially, here's the same – I mean, what are you going to resubmit? Baxter and the FDA have all of the manufacturing data, and that has been reviewed between those two parties. The resubmission, I guess, is just a piece of paper saying we want to be back on file?

Jim Breitmeyer: This is Jim, Eric. That is the key piece of information. But any time a resubmission of this type is done, the FDA also requests an interim safety update. And since the product is on the market in Europe, we would summarize any additional safety information that is in our possession in the interim.

Eric Schmidt: Okay. Thanks a lot.

Ted Schroeder: Again, we've been doing that on a routine basis anyway, so it isn't – this isn't out of course for us to submit the –

Jim Breitmeyer: Yes, exactly. That should be routine. There were no safety concerns expressed in the complete response letter.

Eric Schmidt: So really limited requirements on your side after Baxter responds successfully.

Jim Breitmeyer: Yes, statutory requirements on our side, nothing for cause.

Eric Schmidt : Okay. Thank you.

Operator: As a final reminder that is star one to ask a question. Our next question is from Juan Sanchez, Ladenburg.

Juan Sanchez: The first question is, how many deficiencies were found in the plant?

And the second question is, if you give us an update of the stability work you're doing and whether or not these issues could affect the stability work you have been –

Ted Schroeder: One, we are not privy to the extent of any findings in the plant. That is confidential to Baxter. So we are unable to comment on that. And again, at this point, what we are aware of relate to manufacturing practices that relate to the IV acetaminophen manufacturing. So we're not going to speculate beyond that until we have more clarity as we move forward.

Juan Sanchez: Got it. Thank you.

Operator: Thank you. So I'll join the conference back to Mr. Schroeder, as there are no further questions in the queue at this time.

Ted Schroeder: So thank you, everyone, for participating in the call today. We look forward to speaking with each of you over the coming weeks and months. And we will update as – if there's any significant information as we move forward. Thank you.

Operator: Thank you, ladies and gentlemen, for your participation in today's conference. This does conclude the program. You may now disconnect. Good day.

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