
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): **May 1, 2007**

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
(Address of Principal Executive Offices)

92130
(Zip Code)

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

(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.

Cadence Pharmaceuticals, Inc. hosted a conference call on May 1, 2007, at 8:30 a.m. Eastern time to discuss its plans to increase the number of patients to be enrolled in the ongoing Phase III clinical trial of its experimental product candidate, Omigard™ (omiganan pentahydrochloride 1% aqueous gel) for the prevention of local catheter site infections.

The conference call transcript is attached hereto as Exhibit 99.1 and is incorporated herein by reference. A webcast replay of the conference call will remain available on Cadence's website, www.cadencepharm.com, for fifteen days.

The information in this Current Report on Form 8-K, including the transcript attached hereto as 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 under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

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

Cadence cautions you that statements included in this report, including the transcript attached hereto as Exhibit 99.1, that are not a description of historical facts are forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Cadence that any of its plans will be achieved. Actual results may differ materially from those set forth in this report due to the risks and uncertainties inherent in Cadence's business, including, without limitation: Cadence's ability to enroll sufficient patients to complete the pending Phase III clinical trial of Omigard; anticipated timing to obtain the FDA's concurrence to increase patient enrollment and ultimately complete the trial; the potential that FDA may not agree with the company's proposal to increase patient enrollment, or may apply a statistical penalty to the clinical trial; the results of the company's continuing re-analysis of the data provided by Migenix and its former collaborator concerning the earlier Phase III clinical trial of Omigard; the adequacy of the trial design for the pending Phase III clinical trial of Omigard to generate data that are deemed sufficient by regulatory authorities to support potential regulatory filings, including an NDA, for Omigard; the potential for Omigard, or the company's other product candidate, IV APAP, to receive regulatory approval for one or more indications on a timely basis or at all; unexpected adverse side effects or inadequate therapeutic efficacy of IV APAP or Omigard that could delay or prevent regulatory approval or commercialization, or that could result in recalls or product liability claims; other difficulties or delays in development, testing, manufacturing and marketing of and obtaining regulatory approval for IV APAP or Omigard, including the ability to finalize a commercial supply agreement for IV APAP finished drug product; the market potential for pain, fever, local catheter site infections and other target markets, and the company's ability to compete; Cadence's ability to raise sufficient capital; and other risks detailed in Cadence's press releases as well as in Cadence's other filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Cadence undertakes no obligation to revise or update this report 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.

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Item 9.01. Financial Statements and Exhibits.

(c) *Exhibits.*

| <u>Exhibit Number</u> | <u>Description of Exhibit</u> |
|---------------------------|---|
| 99.1 | Conference Call Transcript, dated May 1, 2007 |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 1, 2007

CADENCE PHARMACEUTICALS, INC.

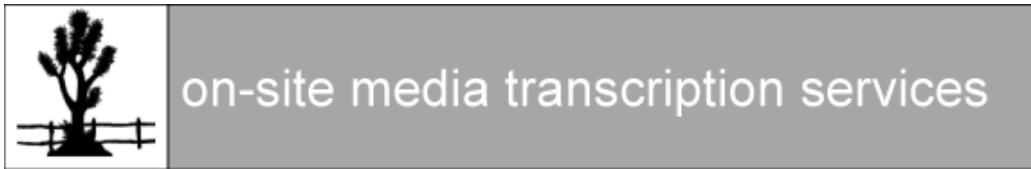
By: /s/ William R. LaRue

Name: William R. LaRue

Title: Senior Vice President, Chief Financial Officer,
Treasurer and Assistant Secretary

EXHIBIT INDEX

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CADENCE PHARMACEUTICALS, INC.

EVENT: CADENCE CONFERENCE CALL

DATE: TUESDAY, MAY 1, 2007

TIME: 5:30 A.M. PT

SPEAKERS: WILLIAM R. LARUE
SENIOR VICE PRESIDENT & CHIEF FINANCIAL OFFICER

THEODORE R. SCHROEDER
PRESIDENT & CHIEF EXECUTIVE OFFICER

JAMES B. BREITMEYER, M.D.
EXECUTIVE VICE PRESIDENT, DEVELOPMENT
& CHIEF MEDICAL OFFICER

SOURCE: WEBCAST

LENGTH: 20 MINUTES

MANAGEMENT DISCUSSION

OPERATOR: Good day, everyone. Welcome to the Cadence Conference Call.

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 presentation. Should you have any problems during the call, please press “star 0” for the conference call operator.

Our first speaker is Bill LaRue, Senior Vice President and Chief Financial Officer of Cadence Pharmaceuticals. Please go ahead, sir.

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

Good morning. Before we get started, I would like to remind everyone that statements made during this conference call that are not a description of historical facts are forward-looking statements. For example, statements about our expectations, beliefs, plans, objectives, assumptions, or future events or performance are not historical facts and are forward-looking statements. Such forward-looking statements, which may be identified by the use of words or phrases such as “believe,” “may,” “anticipate,” or “expect,” and other risks are based upon our current expectations, but do not represent historical fact. You can also find detailed risk factors in our Securities and Exchange Commission filings. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today’s date. All forward-looking statements are

qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update the information presented in this conference call to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Yesterday we issued a press release that announced our plans to modify the Omigard™ Phase III clinical trial. If anyone has not seen that news release, 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.

On the call with me today is Ted Schroeder, Cadence's President and CEO. Dr. Jim Breitmeyer, our Executive Vice President of Development and Chief Medical Officer, is also here and available to answer questions later in the call. I will now turn the call over to Ted.

Theodore R. Schroeder, President and Chief Executive Officer

Thank you, Bill. And good morning and welcome. Thank you for joining us today to discuss Cadence's clinical trial of Omigard for the prevention of catheter-related infections.

During today's call I will summarize the ongoing Phase III Omigard trial; discuss our initial findings of the re-analysis of data from a previous Phase III clinical trial; and discuss our preliminary plan to increase the number of patients in our ongoing Phase III trial of Omigard. Then we'll open the call so that Bill, Jim, and I can respond to your questions.

Yesterday we announced our intention to discuss with the U.S. Food and Drug Administration a proposal to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of our experimental drug candidate Omigard for the prevention of local catheter site infections associated with central venous catheters. Omigard is a topical antimicrobial that has shown to be rapidly bactericidal and fungicidal with prolonged duration of activity against microorganisms commonly found on the skin's surface, including multi-drug resistant strains. Our Phase III study is a superiority trial of Omigard versus the topical antiseptic povidone-iodine that was initiated in August 2005. We call it the Central Line Infection Reduction Study, or CLIRS. We've been pleased with patient enrollment, and the current pace indicates that we'll be

able to enroll approximately 1,250 patients by the second half of this year.

The plan to increase the number of patients in the CLIRS trial is intended to maintain the statistical power of the trial and was prompted primarily by our planned re-analysis of data from the initial Phase III clinical trial of Omigard. As you may recall, in a large Phase III trial completed by our licensor, Omigard demonstrated statistically significant outcomes for the reduction of local catheter site infections and catheter colonization. These were two secondary efficacy endpoints in a study of over 1,400 patients where the primary efficacy endpoint was the prevention of catheter-related bloodstream infections.

Our extensive re-analysis is being performed as part of the standard procedure for analyzing data to prepare a final report of the study for a New Drug Application or other applications for marketing authorization. This includes a thorough reconciliation of electronic data files against case report forms summarizing information obtained from the clinical trial sites. This has been a very substantial effort that has taken us several months as it involved a

team of six to ten statisticians and data managers at our CRO, as well as Cadence internal staff.

Our re-analysis, which uses a slightly different, stricter definition of local catheter site infection, indicates a statistically significant reduction of local catheter site infections of approximately 42 percent in the Omigard treatment arm, as compared to the povidone-iodine treatment arm, as well as a reduction in the overall local catheter site infection rate. The previous analysis indicated an approximately 49 percent reduction.

Because the target sample size for the CLIRS clinical trial was based in part upon this local catheter site infection rate and treatment effect, we now believe that adding patients is prudent in order to maintain the statistical power of the study. As you may recall, the current protocol requires 1,250 patients. Also, the CLIRS trial is currently designed to have 80 percent power to detect significance at the 0.05 level. Additionally, improvements to hospital infection prevention practices since the CLIRS trial began may reduce catheter-related infection rates, further supporting our decision to increase the number of patients.

The CLIRS clinical trial is being conducted under a Special Protocol Assessment with the FDA, so we must obtain the FDA's concurrence with the proposal to increase enrollment in this trial. We have already notified the FDA that we will be requesting a meeting to discuss our plan, and we intend to initiate discussions immediately.

We are taking these measures because we believe they will enhance the statistical power of this study and allow us a better opportunity to achieve a positive result in the CLIRS trial. Clearly, our efforts will be focused on accelerating enrollment in order to offset the longer duration of the trial.

After we have completed our discussions with the FDA, we expect to announce the number of patients to be added to the trial, the anticipated financial impact, and other potential implications on the Omigard development program. However, we currently anticipate that adding patients to the CLIRS clinical trial will move the completion of enrollment in this study from the second half of 2007, as we previously expected, to mid-2008.

We believe the market for the prevention of local catheter site infections is substantial and will continue to grow as hospitals look for new ways to prevent hospital-acquired infections. With approximately 325,000 catheter-related bloodstream infections in hospitals annually, which contribute to an alarming 40,000 to 80,000 deaths and millions of dollars in extra costs to hospitals, there is an urgent need to improve on the current standard of care for this persistent problem. Even after our re-analysis of the previous Phase III trial, treatment with Omigard was statistically better than a two-minute scrub with povidone-iodine at each dressing change, decreasing infections by more than 40 percent. We believe, and we have heard consistently from physicians, that the only acceptable rate of catheter-related infection is zero. Ultimately, Omigard could play an important role in reducing infections associated with central lines, as well as the costs associated with these infections.

The focus of our call today is on one of our late-stage drug programs. Before we open the call to take your questions, I'll take a moment to say that our second late-stage program, the Phase III trials evaluating intravenous acetaminophen for the treatment of acute pain in adults and

children, as well as for the reduction of fever in adults and children, continues to enroll patients, and we are pleased with its progress.

I will now ask our operator to open up the call to questions from the participants.

QUESTION AND ANSWER

OPERATOR: Thank you. The question-and-answer session will begin at this time. If you are using a speakerphone, we ask that you please pick up your handset before pressing any numbers. Should you have a question, please press "star" and the number "1" on your pushbutton telephone. If you wish to withdraw your question, please press "star" and the number "2." Your questions will be taken in the order they are received. Please stand by, and we will take your first question in just a moment.

We will go first to Matthew Jacobsen with BDR Research.

MATTHEW JACOBSEN: Hi, thanks for taking my question. I was wondering if you could tell us how many patients were recharacterized by this re-analysis?

THEODORE SCHROEDER: Sure. Jim, probably best for you to handle that question.

JAMES BREITMEYER: Matt, we haven't disclosed the exact numbers. But it's a very small number of subjects in each of the two arms of the study. As you know, LCSI occur relatively infrequently. And so very small changes in the numbers of subjects in the two groups can cause a swing in the percentage difference between the two.

MATTHEW JACOBSEN: Okay. And if I recall from the original analysis, the p-value was 0.004?

JAMES BREITMEYER: Yes.

MATTHEW JACOBSEN: Can you tell us what the p-value looks like on the re-analysis?

JAMES BREITMEYER: We're not disclosing that. It still remains solidly significant – clinically significant and solidly statistically significant.

MATTHEW JACOBSEN: Okay, great. Thanks so much.

OPERATOR: Once again, that is “star 1” for questions at this time. We’ll go next to Adam Cutler with JMP Securities.

ADAM CUTLER: Hi, thanks for taking the question. In your assumption that adding patients will push out the completion of enrollment from the second half of ’07 to mid-’08, how many additional patients do you expect you’ll need that lead to that time shift?

THEODORE SCHROEDER: Again, I’ll let Jim answer that question.

JAMES BREITMEYER: Adam, we’ve got – we have an approximate number in mind that we need to confirm with the FDA. But taking – and so we’re using that reasonable estimate to give you some idea about the timeframe. But we need to confirm with FDA that the way that we’re looking at this statistically is in accord with their thinking since we’re under this Special Protocol Assessment. So we expect to have clarity about the numbers and then timing and details as soon as we complete discussions with FDA.

ADAM CUTLER: Okay. Is it fair to assume maybe that the additional time is proportionate to the additional patients, in terms of how enrollment has gone so far?

JAMES BREITMEYER: Yes. Yes, that's right. I mean, enrollment is good. But yes, the time is proportional to the number of added subjects.

ADAM CUTLER: Okay. So if I'm looking at this right, it looks like you're looking at about a third more time, so is that right?

JAMES BREITMEYER: Yeah, approximately. I mean, remember studies start enrolling slowly, and then they get up to a, you know, their peak levels of enrollment. And we think we're at or near peak enrollment right now.

ADAM CUTLER: Okay, fair enough. And then one other question is, in your press release you note that, in addition to the re-analysis of the previous Phase III, you note that there have been improvements in hospital infection prevention practices since this study began. I'm wondering if you can kind of go over what some of those are, given

that there don't seem to be too many new options like Omigard available.

JAMES BREITMEYER: Yes, absolutely. And there are no options like Omigard available. And so we are addressing an unmet medical need. What the hospitals are doing are hygiene-based measures. And that is, for example, at the time that they insert the catheter, even if it's done in the hospital bed or the intensive care unit, they try to create a micro environment around the catheter insertion site that's like the operating room. So they will put surgical drapes over the patient from head to toe. They'll have the catheter inserter put on full surgical scrubs as though they were in the operating room. They do a more extensive antiseptic cleansing of the site. And they try to stay away from insertion sites in the body where there's a higher microbial count than others, like the groin, for example, is discouraged.

And so these are called "the bundle" in the vernacular of hospital infection control. And what we've noticed is that, when all of these measures are performed, up to and including having a third party standing and watching the operator to make sure they're using strict sterile

technique, then infection rates go down. But they're burdensome, and they're particularly difficult to put in place when patients are critically ill. And so in several cases we've noticed that hospitals have a dip in their infection rate. But then, when they get tired of the measures, the infection rates creep up again.

ADAM CUTLER: Okay. That's helpful. And then, I guess, in your assumptions about the discussion with the FDA about adding patients, do you expect that they will assume that there will be some statistical hit to the study in adding patients part of the way through?

JAMES BREITMEYER: Well, we can't predict what FDA will say. But our strategy for approaching the FDA is one that would typically not add a statistical hit to the study.

ADAM CUTLER: Okay. Thanks a lot.

OPERATOR: And as a reminder, ladies and gentlemen, if you do have a question, please press "star 1" on your pushbutton telephone at this time.

We'll go next to Michael Higgins with Rodman & Renshaw.

MICHAEL HIGGINS: Right, thanks for taking my question. On that last point, Jim, what approach can you take to not increase the statistical hit?

JAMES BREITMEYER: Yeah, good question, Michael. The usual circumstance in which you take a statistical hit is if you analyze your data midway through in an interim analysis, and the FDA considers then that you're analyzing your study twice, and so you have two chances to get a positive result randomly. So they make you take off some statistical power for that. In this case we're not using any study-related data. And the company is fully blinded to any outcome results in the study. And so we're not asking for the increase in sample size based on study data, but rather based on a refinement in our understanding of the assumptions going into the sample size.

MICHAEL HIGGINS: Okay. Of the roughly 7 percent difference with this new statistical trial design, let's say, for example, there's 400 more patients that you'll need to complete the study. I guess what I'm trying to get to is what percentage of those are related to the change in the

trial design and what percent are related to the change in infection rates that you're seeing?

JAMES BREITMEYER: The trigger for the increase in sample size is the re-analyzed information in the treatment effect. And so the driver is the refined understanding of the presumed infection rate based on our re-analysis of data using the stricter LCSII criteria.

MICHAEL HIGGINS: And not having to do with the change in infection rates.

JAMES BREITMEYER: Correct.

MICHAEL HIGGINS: Okay. Thank you.

OPERATOR: At this time we have no further questions. I'd like to turn the conference back over to Mr. Schroeder for any additional or closing remarks.

Theodore R. Schroeder, President and Chief Executive Officer

Thank you, Operator. And thank you to each of you for participating in the call. And I think at this time we will look forward to updating you as soon as we can communicate specific changes as we continue with our discussions with

the FDA. Thanks again for your participation, and we'll be in touch as soon as we can. Thank you.

OPERATOR: Ladies and gentlemen, this does conclude today's teleconference. We do appreciate your participation. You may disconnect at this time.

PRESS RELEASE:

http://files.shareholder.com/downloads/CADX/120771172x0x93972/a23a7a86-3123-4744-98dc-4dfebe2c70d1/CADX_News_2007_4_30_General_Releases.pdf

END AUDIO



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