
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 6, 2008

Cadence Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-33103
(Commission File Number)

41-2142317
(IRS Employer
Identification No.)

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

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition

On May 6, 2008, Cadence Pharmaceuticals, Inc. issued a press release and is holding a conference call announcing its financial results for the three months ended March 31, 2008. A copy of this press release is attached as Exhibit 99.1 to this Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the 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, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits**(d) Exhibits**

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release of Cadence Pharmaceuticals, Inc. dated May 6, 2008 |

EXHIBIT INDEX

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|--------------------|--|
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Cadence Pharmaceuticals Reports First Quarter 2008 Financial Results and Provides Clinical Program Update

Phase III Clinical Trial of Acetavance™ for the Treatment of Fever Achieves Primary Endpoint

Phase III Clinical Trial of Omigard™ Completes Patient Enrollment

SAN DIEGO, CA – May 6, 2008 – Cadence Pharmaceuticals, Inc. (NASDAQ: CADX), a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting, today reported financial results for the for the quarter ended March 31, 2008 and provided an update on the clinical development programs for its product candidates Acetavance™, an intravenous formulation of acetaminophen, and Omigard™, a topical antimicrobial gel.

The company announced that a Phase III clinical trial of Acetavance successfully met its primary endpoint of achieving a more rapid onset of action in the treatment of fever compared to oral acetaminophen. In addition, Cadence announced that it completed its goal of enrolling 1,850 patients in its Phase III clinical trial of Omigard for the prevention of catheter-related infections.

“We are very pleased with the outcome of our second Phase III clinical trial for the treatment of fever in adults. In addition to the positive data from our first Phase III clinical trial of Acetavance in fever announced earlier this year, we believe that the results of this study further strengthen the value proposition for Acetavance,” said Ted Schroeder, President and Chief Executive Officer of Cadence. “We believe that there is a significant unmet need among patients and physicians in the hospital setting for a safe and effective treatment for pain and fever, particularly in cases where patients cannot take oral medication or require a more rapid onset of action.”

“Reaching the patient enrollment target in our Phase III clinical trial of Omigard for the prevention of catheter-related infections is a major milestone in our clinical development program for this product candidate,” stated James Breitmeyer, M.D., Ph.D., Executive Vice President, Development and Chief Medical Officer of Cadence. “If approved, we believe that Omigard will address a rapidly growing need for more effective ways to lower hospital acquired infection rates, including the dangerous and costly complications from infections related to intravascular catheters.”

Cadence’s second clinical trial of Acetavance for the treatment of fever in adults, designated Study 303, was a Phase III, randomized, double-blind, double-dummy, single-dose study of intravenous acetaminophen (1 gram) compared to oral acetaminophen (1 gram) for the treatment of fever in 81 adult volunteers with experimentally-induced fever. In this study, a statistically significant difference in favor of Acetavance was observed compared to oral acetaminophen for the primary efficacy endpoint of WSTD2 (the weighted sum

of temperature differences over two hours) ($p < 0.01$). The mean temperature scores for patients in the Acetavance-treated group were significantly lower as early as 15 minutes after the study drug was administered. The peak temperature observed in the Acetavance group of patients was also significantly lower. Acetavance was very well tolerated, including no treatment-emergent serious adverse events or treatment-emergent hepatic adverse events.

Cadence's confirmatory Phase III clinical trial of Omigard (omigaran pentahydrochloride 1% gel), known as the Central Line Infection Reduction Study, or CLIRS, is a randomized, evaluator-blinded study in hospitalized patients whose medical condition requires a short-term central venous catheter. The primary objective of CLIRS is to evaluate the efficacy and safety of Omigard compared to 10% povidone-iodine in reducing local catheter site infections. The company achieved its goal of enrolling 1,850 patients at 58 clinical trial sites in the United States and Europe. CLIRS is being conducted under a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA).

First Quarter 2008 Financial Results

For the first quarter ended March 31, 2008, Cadence reported a net loss of \$13.7 million, or \$0.42 per share, compared to a net loss of \$9.6 million, or \$0.34 per share, for the same period in 2007.

As of March 31, 2008, Cadence held cash and cash equivalents of \$91.4 million, which included proceeds from the registered direct offering completed in February 2008, pursuant to which Cadence issued and sold approximately 9.2 million shares of common stock at a price of \$5.34 per share, and received net proceeds of approximately \$49.1 million.

Operating expenses for the first quarter ended March 31, 2008, were \$13.8 million, an increase of \$3.4 million from the \$10.4 million reported for the same period in 2007. This increase was primarily a result of \$1.7 million of additional research and development costs related to ongoing Phase III clinical trials and pre-commercialization manufacturing development activities for Acetavance and Omigard. Other supporting costs for research and development activities increased \$0.5 million, which included a \$0.2 million increase in stock-based compensation.

In addition, the increased operating expenses were due to a \$0.3 million increase in market research and personnel-related activities for Omigard, and an increase of \$0.8 million in general and administrative expenses, including a \$0.4 million increase in stock-based compensation charges.

Acetavance™ Clinical Program Update

- Following the announcement of results for Acetavance Studies 301 and 302 in January 2008, Cadence initiated discussions with the FDA to determine if the company may need to conduct additional trials or modify its ongoing trials of this product candidate. Cadence currently expects to receive guidance from the FDA in the second quarter of 2008.
- During the first quarter of 2008, Cadence also implemented several design enhancements to Study 304, a Phase III clinical trial of Acetavance for the treatment of acute pain in adults following abdominal laparoscopic surgery. The trial design modifications included tightening patient eligibility criteria, performing more frequent pain assessments and increasing control of opioid medications. Cadence currently expects to complete enrollment of this clinical trial in the third quarter of 2008 and announce top-line data in the second half of 2008.

- Also during the first quarter of 2008, Cadence initiated a multi-day safety study of Acetavance in adult patients and a multi-day safety study of Acetavance in pediatric patients.
- Assuming the successful outcome of Cadence's planned clinical trials for Acetavance, and FDA concurrence with its proposed clinical development plan, the company currently expects to submit a 505(b)(2) New Drug Application (NDA) for this product candidate to the FDA in the first half of 2009.

| <u>Acetavance Clinical Trials</u> | <u>Study</u> | <u>Phase</u> | <u>Enrollment Status</u> |
|--|------------------------|--------------|--------------------------|
| Treatment of pain following total knee & hip replacement | Sinatra ⁽¹⁾ | III | Completed |
| Treatment of pain following abdominal gynecologic surgery | 301 | III | Completed |
| Treatment of fever in adults (vs. placebo) | 302 | III | Completed |
| Treatment of fever in adults (onset of action) | 303 | III | Completed |
| Adult pharmacokinetics | 101 | I | Completed |
| Treatment of pain following abdominal laparoscopic surgery | 304 | III | Enrolling |
| Adult safety | 351 | III | Enrolling |
| Pediatric safety | 352 | III | Enrolling |
| Pediatric pharmacokinetics | 102 | I | Enrolling |

⁽¹⁾ Conducted by Bristol-Myers Squibb Company

Omigard™ Clinical Program Update

- Cadence currently expects to announce top-line data from CLIRS in the second half of 2008 and, if the results are positive, submit an NDA for Omigard to the FDA in the first half of 2009.

Conference Call and Webcast on May 6, 2008 at 5:30 a.m. Pacific Time (8:30 a.m. Eastern Time)

Cadence management will host a conference call on May 6, 2008 at 5:30 a.m. Pacific Time (8:30 a.m. Eastern Time) and interested investors may participate in the conference call by dialing 877-675-4750 (domestic) or 719-325-4865 (international). To access the webcast, please visit the company's website at www.cadencepharm.com and go to the Investor Relations page. A replay of the webcast will be available approximately two hours after the call and remain available on the company's website until the next quarterly financial results call.

About Cadence Pharmaceuticals, Inc.

Cadence Pharmaceuticals is a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. The company currently has two Phase III product candidates in development, Acetavance™ (intravenous acetaminophen) for the treatment of acute pain and fever, and Omigard™ (omigaman pentahydrochloride 1% topical gel) for the prevention of catheter-related infections. For more information about Cadence's pipeline, visit www.cadencepharm.com.

Forward-Looking Statements

Statements included in this press release that are not a description of historical facts are forward-looking statements. Forward-looking statements include statements regarding: the timeframes in which Cadence expects to complete enrollment in, and announce the results of, clinical trials of its product candidates; the timeframes in which Cadence anticipates filing submissions with regulatory authorities seeking marketing authorizations for its product candidates; the expected impact of clinical trial results on the market and clinical value of Cadence's product candidates; and the potential for Cadence's product candidates to address unmet medical needs. The inclusion of forward-looking statements should not be regarded as a representation by Cadence that any of its plans will be achieved. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in Cadence's business, including, without limitation: the outcomes of final analyses of data from Cadence's clinical trials of its product candidates may vary from the company's initial analyses, and the FDA may not agree with Cadence's interpretation of such results; the company's clinical trials may produce negative or inconclusive results, or may be inconsistent with previously conducted clinical trials; Cadence may experience delays in completing its clinical trials or achieving its product development goals, or experience problems with the designs or execution of its clinical trials; the company may decide, or be required by FDA, to expand or modify its ongoing clinical trials or conduct additional clinical trials in order to support applications for market approval of its product candidates; the market demand for Cadence's product candidates, and their ability to compete with new or existing products, may be less than anticipated; the company's product candidates may have unanticipated adverse side effects or inadequate therapeutic efficacy; Cadence may experience delays and increased costs with respect to completion of pre-commercialization manufacturing development activities, and may be required to perform additional pre-clinical or clinical testing as a result of changes to manufacturing processes for its product candidates; the company may require substantial additional funding to complete its clinical development programs and successfully launch its products, and it may not be able to raise sufficient capital when needed, or at all; and other risks detailed in Cadence's prior press releases as well as in Cadence's periodic public filings with the Securities and Exchange Commission.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Cadence undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Cadence™, Acetavance™ and Omigard™ are trademarks of Cadence Pharmaceuticals, Inc.

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CADENCE PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED STATEMENTS OF OPERATIONS
(unaudited)

| | Three Months Ended March 31, | |
|--|---------------------------------|------------------------------|
| | 2008 | 2007 |
| Operating expenses: | | |
| Research and development | \$ 10,478,047 | \$ 8,241,804 |
| Marketing | 583,702 | 302,183 |
| General and administrative | 2,667,038 | 1,827,592 |
| Other | 28,257 | — |
| Total operating expenses | <u>13,757,044</u> | <u>10,371,579</u> |
| Loss from operations | (13,757,044) | (10,371,579) |
| Other income (expense): | | |
| Interest income | 550,380 | 1,031,890 |
| Interest expense | (506,856) | (220,009) |
| Other expense | (3,395) | — |
| Total other income, net | <u>40,129</u> | <u>811,881</u> |
| Net loss | <u><u>\$(13,716,915)</u></u> | <u><u>\$ (9,559,698)</u></u> |
| Basic and diluted net loss per share ⁽¹⁾ | <u><u>\$ (0.42)</u></u> | <u><u>\$ (0.34)</u></u> |
| Shares used to compute basic and diluted net loss per share ⁽¹⁾ | <u><u>32,921,093</u></u> | <u><u>28,402,352</u></u> |

⁽¹⁾ As a result of the issuance of 9,240,307 shares of common stock pursuant to an effective shelf registration in the first quarter of 2008, there is a lack of comparability in the per share amounts between the 2008 and 2007 periods presented.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED BALANCE SHEETS

| | <u>March 31,</u> <u>2008</u> | <u>December 31,</u> <u>2007</u> |
|---|---------------------------------|------------------------------------|
| | <u>(unaudited)</u> | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 91,443,447 | \$ 55,392,921 |
| Restricted cash | 1,981,848 | 1,981,848 |
| Prepaid expenses and other current assets | 1,211,887 | 959,321 |
| Total current assets | 94,637,182 | 58,334,090 |
| Property and equipment, net | 5,280,094 | 5,139,538 |
| Restricted cash | 885,434 | 885,434 |
| Other assets | 242,743 | 252,963 |
| Total assets | <u>\$ 101,045,453</u> | <u>\$ 64,612,025</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,943,002 | \$ 1,974,991 |
| Accrued liabilities | 13,306,016 | 13,901,770 |
| Current portion of long-term debt | 7,127,222 | 5,617,928 |
| Total current liabilities | 23,376,240 | 21,494,689 |
| Deferred rent | 1,159,187 | 1,224,869 |
| Long-term debt, less current portion and discount | 11,308,814 | 13,412,349 |
| Other long-term liabilities | 22,048 | 22,048 |
| Total stockholders' equity | 65,179,164 | 28,458,070 |
| Total liabilities and stockholders' equity | <u>\$ 101,045,453</u> | <u>\$ 64,612,025</u> |