# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 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 6, 2012**

# 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)**

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 6, 2012, Cadence Pharmaceuticals, Inc. ("Cadence") issued a press release regarding its voluntary recall of a single lot of OFIRMEV® (acetaminophen) injection. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

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 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, whether made before or after the date hereof, except as expressly set forth by specific reference to Items 7.01 and 9.01 to this Current Report on Form 8-K in such filing.

By filing this information, Cadence makes no admission as to the materiality of any information in this report. The information contained in the in this report and the exhibit hereto is intended to be considered in the context of Cadence's filings with the Securities and Exchange Commission 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 or the exhibit hereto, 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 Securities and Exchange Commission, through press releases or through other public disclosure.

**Item 8.01. Other Events.**

On February 6, 2012, Cadence announced a voluntary recall of a single lot of OFIRMEV® (acetaminophen) injection. The recall of OFIRMEV lot number V005710 was initiated due to the presence of an unidentified, visible particle in one vial of this lot during routine stability testing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description of Exhibit |
|---|---|
| 99.1 | Press Release, dated February 6, 2012 |

**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 6, 2012

## EXHIBIT INDEX

| Exhibit Number | Description of Exhibit |
| --- | --- |
| 99.1 | Press Release, dated February 6, 2012 |

**Exhibit 99.1**

**Cadence Pharmaceuticals Announces Voluntary Recall of One Lot of OFIRMEV® (acetaminophen) Injection**

**SAN DIEGO** – February 6, 2012 – Cadence Pharmaceuticals, Inc. (NASDAQ: CADX), a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary products principally for use in the hospital setting, announced today the voluntary recall of a single lot of OFIRMEV® (acetaminophen) injection. Cadence has notified the U.S. Food and Drug Administration of the recall.

The recall of OFIRMEV lot number V005710 was initiated due to the presence of an unidentified, visible particle in one vial of this lot during routine stability testing. Lot V005710 was distributed by Cadence to hospitals, wholesalers and distributors beginning in January 2011, and Cadence believes that fewer than 1,000 vials currently remain in the marketplace. Cadence has not received any reports of adverse patient events associated with particulate matter in the product, and has undertaken the recall as a precautionary measure.

“We regret that some of our customers experienced short-term supply delays due to our temporary suspension of shipments from the supplier of lot V005710,” said Scott Byrd, Chief Commercial Officer of Cadence. “Fortunately, we were successful in our efforts to accelerate shipments of OFIRMEV from another supplier, which allowed us to quickly resume normal shipments of the product. We do not anticipate any further supply delays.”

**Customer Recall Contact**

Customers with questions regarding this recall should call 1-866-338-4070.

**About OFIRMEV® (Acetaminophen) Injection**

OFIRMEV (acetaminophen) injection (1000 mg / 100 mL, 10 mg / mL; for intravenous use only), Cadence Pharmaceuticals’ proprietary intravenous formulation of acetaminophen, 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 FDA approval of OFIRMEV was based on data from clinical trials in approximately 1,020 adult and 355 pediatric patients. These trials included two studies evaluating the safety and effectiveness of OFIRMEV in the treatment of pain, and one study evaluating OFIRMEV in the treatment of fever. The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been studied in pediatric patients less than 2 years of age.

**Important Safety Information**

Do not exceed the maximum recommended daily dose of acetaminophen. Administration of acetaminophen by any route in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death. OFIRMEV is contraindicated in patients with severe hepatic impairment, severe active liver disease or with known hypersensitivity to acetaminophen or to any of the excipients in the formulation. Acetaminophen should be used with caution in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment. OFIRMEV should be administered only as a 15-minute intravenous infusion. Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur. Do not use in patients with acetaminophen allergy. The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients. The antipyretic effects of OFIRMEV may mask fever in patients treated for post-surgical pain.

For more information, please see the complete OFIRMEV Prescribing Information, available at www.OFIRMEV.com or www.cadencepharm.com.

**About Cadence Pharmaceuticals, Inc.**

Cadence Pharmaceuticals is a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. For more information about Cadence, please 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. Words such as “plans,” “believes,” “expects,” “anticipates,” and “will,” and similar expressions, are intended to identify forward-looking statements, and are based on Cadence’s current beliefs and expectations. Such statements include, without limitation, statements regarding: estimates of the number of vials of lot V005710 that currently remain in the marketplace and expectations regarding the supply of OFIRMEV. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Cadence’s actual future results may differ materially from the company’s current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: Cadence’s dependence on the successful commercialization of OFIRMEV, which is its only product; Cadence’s ability to ensure an adequate and continued supply of OFIRMEV to meet anticipated market demand; the risk that if Cadence’s contract manufacturers fail to meet its requirements for OFIRMEV, Cadence may be unable to meet market demand and may lose potential revenues; the potential that customers’ perception of OFIRMEV or Cadence’s relationships with its customers may be damaged by the recall; costs, re-stocking expenses and potential product liability claims that may be associated with the recall; the potential for additional recalls, supply disruptions, or manufacturing changes for OFIRMEV; and other risks detailed under “Risk Factors” and elsewhere in Cadence’s periodic reports and other filings made with the Securities and Exchange Commission from time to time. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, and Cadence undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.



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