## 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): August 18, 2011

## 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

 $(Registrant's\ telephone\ number,\ including\ area\ code)$ 

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 8.01. Other Events.

On August 18, 2011, Cadence Pharmaceuticals, Inc. ("Cadence") and SCR Pharmatop ("Pharmatop") filed suit in the United States District Court for the District of Delaware against Paddock Laboratories, Inc., Perrigo Company and Paddock Laboratories, LLC (collectively, "Paddock") and Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc. (collectively, "Exela").

As previously reported, on July 8, 2011, Cadence received a notice from Paddock concerning its filing of an Abbreviated New Drug Application ("ANDA") containing a "Paragraph IV" patent certification with the U.S. Food and Drug Administration (the "FDA") for a generic version of Cadence's drug, OFIRMEV® (acetaminophen) injection (1000 mg/100 mL, 10 mg/mL). On July 13, 2011, Cadence received a notice from Exela concerning its filing of an ANDA containing a "Paragraph IV" patent certification with the FDA for a generic version of OFIRMEV®. The FDA will determine which, if any, of these ANDA filers may be eligible for the 180-day exclusivity period described in 21 U.S.C. § 355(j)(5)(B)(iy).

The lawsuit filed by Cadence alleges that Paddock and Exela have each infringed U.S. Patent Nos. 6,028,222 (the "'222 patent") and 6,992,218 (the "'218 patent") by filing their respective ANDAs seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The '222 and the '218 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the '222 and '218 patents, the entry of a settlement order or consent decree stating that the '222 and '218 patents are invalid or not infringed, a decision in the infringement case that is favorable to Paddock or Exela, or such shorter or longer period as the court may order.

Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. Specifically, the FDA has granted OFIRMEV three years of regulatory exclusivity, which expires November 2, 2013 (or May 2, 2014 if Cadence completes certain pediatric studies and the FDA grants a pediatric extension).

Cadence intends to vigorously enforce its intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of its patents. The '222 patent expires August 5, 2017 (or February 5, 2018 if pediatric exclusivity is granted) and the '218 patent expires June 6, 2021 (or December 21, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, Cadence cannot predict the outcome of this matter or guarantee the outcome of any litigation.

For a discussion of risks related to the ANDA filings by Paddock and Exela, see the discussion of "Intellectual Property" under the "Business" section of Cadence's Annual Report on Form 10-K for the year ended December 31, 2010 filed with the Securities and Exchange Commission (the "SEC") on March 4, 2011 and the "Risk Factors" section of Cadence's Quarterly Report on Form 10-Q for the period ended June 30, 2011 filed with the SEC on August 4, 2011, including the risks described under the headings "We expect intense competition for OFIRMEV, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications," "If the government or third-party payors fail to provide coverage and adequate coverage and payment rates for OFIRMEV or any future products we may license or acquire, if any, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited" and "The patent rights that we have in-licensed covering OFIRMEV are limited to a specific intravenous formulation of acetaminophen, and our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient itself and other formulations that may be developed by competitors," as well as any updates to such sections contained in Cadence's subsequent reports filed with the SEC.

Statements included in this report 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 Cadence's intention to vigorously enforce its intellectual property rights. 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 Cadence's current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: Cadence's ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend the patents covering OFIRMEV; the substantial costs associated with these lawsuits; the potential introduction of generic competition to OFIRMEV; Cadence's dependence on its licensors for the maintenance and enforcement of its intellectual property rights; Cadence's dependence on the successful commercialization of OFIRMEV, which is its only product; the potential that delays in achieving formulary acceptance for OFIRMEV at a substantial number of targeted accounts may enable competitors to further entrench their products and decrease the market potential for OFIRMEV; Cadence's ability to ensure an adequate and continued supply of OFIRMEV to meet anticipated market demand; the risk that Cadence may not be able to raise sufficient capital when needed, or at all; and other risks detailed under "Risk Factors" and elsewhere in Cadence's periodic reports and other filings made with the SEC 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 the company undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof.

## **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: August 19, 2011