# **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** 

September 20, 2012

Date of Report (Date of earliest event reported)

# ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

State of New York (State of Other Jurisdiction of Incorporation)

#### 1-10113

(Commission File Number)

11-0853640

(I.R.S. Employer **Identification Number**)

616 N. North Court, Suite 120 Palatine, Illinois 60067

(Address of principal executive offices) (Zip Code)

(847) 705-7709

(Registrant's telephone number, including area code)

	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 ons (see General Instruction A.2. below):		
Notation (see General Instruction 7.1.2.1 sets w).			
	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 (17CFR 240.14a-12)		

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17CFR240.14d-2(b)) 

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-4(c))

## Item 8.01 Other Events

On September 20, 2012, we issued a press release announcing that we had received notice from a generic sponsor of a Paragraph IV Certification advising us of the filing of an abbreviated new drug application with the U.S. Food and Drug Administration ("FDA") listing Pfizer Inc's OXECTA® (oxycodone hydrochloride) Tablets CII as the reference listed drug and asserting that the generic sponsor believes that our patents listed in the FDA's Orange Book for OXECTA® are either invalid, unenforceable or not infringed thereby. A copy of our press release dated September 20, 2012, is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

#### Item 9.01 Financial Statements and Exhibits

Exhibit Number	Description
99.1	Press Release dated September 20, 2012 announcing filing of Paragraph IV Certification.

## **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 thereunto duly authorized.

## ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens

Peter A. Clemens Senior Vice President & Chief Financial Officer

Date: September 20, 2012

# **Exhibit Index**

Exhibit Number	Description
99.1	Press Release dated September 20, 2012 announcing filing of Paragraph IV Certification.



#### Acura Pharmaceuticals Announces Paragraph IV ANDA Filing for OXECTA®

Palatine, IL - (September 20, 2012) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, today announced that it has received notification from a generic sponsor of the filing of an Abbreviated New Drug Application (ANDA) for a generic drug listing Pfizer Inc.'s OXECTA (oxycodone HCl) Tablets CII as the reference listed drug. OXECTA is covered by U.S. patents issued to Acura and licensed to Pfizer. The notification includes a Paragraph IV certification indicating the generic sponsor believes Acura's patents are invalid, unenforceable or not infringed. Acura intends to take appropriate action to enforce its intellectual property.

#### **About Acura Pharmaceuticals**

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address medication abuse and misuse, utilizing its proprietary AVERSION<sup>®</sup> and IMPEDE<sup>TM</sup> technologies. In June 2011, the U.S. Food and Drug Administration approved OXECTA<sup>®</sup> which incorporates the AVERSION technology. The Company has a development pipeline of additional AVERSION technology products including other opioids and its IMPEDE technology for pseudoephedrine hydrochloride products.

The trademark OXECTA® is owned by Pfizer Inc.

#### **Forward-Looking Statements**

Certain statements in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to, our and our licensee's ability to successfully launch and commercialize our products and technologies including Oxecta® Tablets and Nexafed® Tablets, the price discounting that may be offered by Pfizer for Oxecta®, the ability of us or our licensee's to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, expectations regarding potential market share for our products and the timing of first sales, our ability to enter into additional license agreements for our other product candidates, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability of our patents to protect our products from generic competition, and the ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development to meet over-the-counter, or OTC, Monograph standards as applicable, the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates, changes in regulatory requirements, adverse safety findings relating to our product candidates, whether the FDA will agree with our analysis of our clinical and laboratory studies and how it may evaluate the results of these studies or whether further studies of our product candidates will be required to support FDA approval, whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and will be able to promote the features of our abuse discouraging technologies, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede technology will disrupt the processing of pseudoephedrine into methamphetamine. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our filings with the Securities and Exchange Commission.

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