

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549

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FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act Of 1934

May 21, 2014  
Date of Report (Date of earliest event reported)

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**ACURA PHARMACEUTICALS, INC.**  
(Exact Name of Registrant as Specified in Charter)

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**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)

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 (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))
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## **Item 8.01            Other Events.**

### *Settlement of Patent Infringement Litigation with Sandoz Inc.*

On May 20, 2014, Acura Pharmaceuticals, Inc. (“Acura”) and Sandoz Inc. (“Sandoz”) entered into a License and Settlement Agreement dated the same date (the “Settlement Agreement”) to settle the parties patent infringement litigation concerning Acura’s AVERSION® oxycodone product, previously marketed by Pfizer Inc. under its brand name Oxecta® (oxycodone HCl tablets), pending in the United States District Court for the District of Delaware. In the suit, Acura alleges that a generic AVERSION® oxycodone product for which Sandoz is seeking approval to market in the U.S. pursuant to an Abbreviated New Drug Application (“ANDA”) filing with the U.S. Food and Drug Administration (“FDA”) infringes a U.S. patent owned by Acura (the “Acura Patent”).

The Settlement Agreement provides for a full settlement of all claims that were asserted in the suit. Under the terms of the Settlement Agreement, Acura will grant Sandoz a non-exclusive, royalty-bearing license to the Acura Patent and other current and future Orange Book listable patents to market, manufacture and sell a generic version of AVERSION® oxycodone in the United States (the “Licensed Patents”). Sandoz’ license becomes effective 180 days following the first sale of a generic AVERSION® oxycodone product in the United States by an entity that is entitled to the 180 day first-filer exclusivity provided in the Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the “Hatch-Waxman Act”) (or if no entity is entitled to the 180 day first-filer exclusivity provided in the Hatch-Waxman Act, the date on which a generic AVERSION® oxycodone product is first sold in the United States). The license granted to Sandoz would become effective earlier, if each of the Licensed Patents is held (1) invalid or unenforceable, or (2) not infringe with respect to a third-party’s generic version of AVERSION® oxycodone and that third party’s generic version of AVERSION® oxycodone receives tentative or final approval from the FDA, or (3) if a third party sells a generic version of AVERSION® oxycodone under a license or other authorization from Acura. Sandoz is not obligated to pay Acura a royalty if its current formulation of its generic to the AVERSION® oxycodone product is approved by the FDA. However, in the event Sandoz changes or modifies the structure of its generic AVERSION® oxycodone product, or materially changes or modifies the amounts or type of any excipient used in the Sandoz formulation disclosed in its ANDA filing with the FDA as of July 30, 2013, Sandoz is required to pay Acura royalties in the amount of seven percent (7%) of the Net Profits (as defined in the Settlement Agreement) derived from the net sales of such changed or modified Sandoz generic AVERSION® oxycodone product in the United States.

The Settlement Agreement will remain in effect until the expiration of the term of the license granted by Acura to Sandoz. The Settlement Agreement also contains customary confidentiality provisions and representations and warranties of the parties.

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Promptly following execution of the Settlement Agreement, the parties are required to file dismissals without prejudice with the United States District Court for the District of Delaware, which will conclude the suit. The Settlement Agreement also provide that the parties file the Settlement Agreement with both the U.S. Federal Trade Commission (“FTC”) and the Antitrust Division of the U.S. Department of Justice (“DOJ”) as required by the Medicare Prescription Drug Improvement and Modernization Act of 2003. There can be no assurance that the FTC and/or the DOJ will not raise objections to, or request modifications to, the Settlement Agreement; that any such modifications will be acceptable to the parties; or that the Settlement Agreement will continue to be effective.

The Settlement Agreement with Sandoz concludes our pending patent infringement litigation against those generic pharmaceutical companies that have filed ANDAs for generic AVERSION® oxycodone products.

### **Safe Harbor**

This filing contains forward-looking statement regarding the anticipated results of the settlement with Par. There are many important factors that could cause actual result to differ materially from those in these forward-looking statements. These factors include, among others, the following: that the U.S. District Court does not approve the stipulation of dismissal of the Acura/Sandoz Suit, that the FTC or DOJ challenge the enforceability of the Settlement Agreement, or that private plaintiffs challenge the Settlement Agreement, whether or not additional third parties may seek to market generic versions of AVERSION® oxycodone and the results of any litigation that we have filed or may file to defend and/or assert our patents against such companies; the possible occurrence of one of the specific events that would result in Sandoz marketing a generic AVERSION® oxycodone earlier than we anticipate; our ability to protect the proprietary technologies and intellectual property related to AVERSION® oxycodone and to secure and maintain additional intellectual property protection for AVERSION® oxycodone; and a variety of other risks common to our industry. Additional factors that could cause actual results to differ materially from those projected or suggested in any forward-looking statements are contained in Acura’s recent annual and quarterly reports filed with the Securities and Exchange Commission, including those factors discussed under the caption “Risk Factors” in such filings, which are incorporated in this filing by this reference.

Forward-looking statements speak only as of the date of this filing, and Acura undertakes no obligation to update or revise these statements.

A Press Release regarding the settlements is furnished as Exhibit 99.1.

### **Item 9.01 Financial Statements and Exhibits**

#### **Exhibit Number**

#### **Description**

99.1	Press Release dated May 21, 2014 Regarding Settlement Agreement with Sandoz Inc.
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## **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: May 21, 2014

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## Exhibit Index

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press Release dated May 21, 2014 Regarding Settlement Agreement with Sandoz Inc.
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**Acura Pharmaceuticals  
Announces Settlement of Patent Litigation  
with Sandoz Inc.**

Palatine, IL - (May 21 2014) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today that it has entered into a Settlement Agreement with Sandoz Inc. to settle Acura's patent infringement action pending against Sandoz in the United States District Court for the District of Delaware. In the suit, Acura alleges that a generic of Acura's AVERSION® oxycodone product, previously marketed by Pfizer Inc. under its brand name OXECTA®, for which Sandoz is seeking approval to market in the United States pursuant to an Abbreviated New Drug Application (ANDA) filing with the U.S. Food and Drug Administration (FDA) infringes a U.S. patent owned by Acura.

Under the Sandoz Settlement Agreement, Sandoz may launch its generic to the AVERSION® oxycodone product in the U.S., through the grant of a non-exclusive license from Acura to Sandoz that would trigger 180 days following the first sale of a generic to the AVERSION® oxycodone product in the U.S. by an entity that is entitled to the 180 day first-filer exclusivity under applicable law and FDA regulations (or if no entity is entitled to such 180 day exclusivity period, the date on which a generic to the AVERSION® oxycodone product is first sold in the U.S). In certain circumstances, Acura's license to Sandoz would become effective prior to such time. Sandoz is not obligated to pay Acura a royalty if its current formulation of its generic to the AVERSION® oxycodone product is approved by the FDA. However, in the event Sandoz changes or modifies the structure of its generic AVERSION® oxycodone product, or materially changes or modifies the amounts or type of any excipient used in the Sandoz formulation disclosed in its ANDA filing with the FDA as of July 30, 2013, Sandoz is required to pay us royalties in the amount of seven percent (7%) of the Net Profits (as defined in the Settlement Agreement) derived from the net sales of such changed or modified Sandoz generic AVERSION® oxycodone product in the United States.

Acura's President and CEO, Bob Jones said, "We are very pleased to have now concluded all our patent infringement suits concerning AVERSION oxycodone. We still await FDA's guidance on what these generic ANDA filers must do to gain approval on a product considered to be equivalent to our AVERSION oxycodone in terms of both efficacy and safety."

The Settlement Agreement provides for a full settlement of all claims that were asserted in the Sandoz suit, subject to the Court's acceptance of the stipulation of dismissal. As required by law, the Settlement Agreement with Sandoz will be submitted to the U.S. Federal Trade Commission and US. Department of Justice.

The Settlement Agreement with Sandoz concludes all of our pending patent infringement litigation against those generic pharmaceutical companies that have filed ANDAs for generic AVERSION® oxycodone products.

### **Background on the litigations settled**

On September 20, 2012, we announced that we had received a Paragraph IV Certification notice from a generic sponsor of an ANDA for a generic OXECTA® product. Since such date, we have received similar Paragraph IV Certification notices from four other generic pharmaceutical companies that have filed ANDAs for generic AVERSION® oxycodone products. As a result, on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. – Florida (Watson), Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc. in the United States District Court for the District of Delaware. On April 29, 2013, we initiated suit against Ranbaxy Pharmaceuticals in the United States District Court for the District of Delaware. In each such litigation, we have alleged infringement of our U.S. Patent No. 7,510,726 listed in the FDA's Orange Book, and having an expiration date in November 2023.

On January 2, 2013, our motion to dismiss the litigation against Watson on the grounds that Watson had amended its ANDA from a Paragraph IV Certification to a Paragraph III Certification, which indicated its intent not to market its generic AVERSION® oxycodone product in advance of our patent expiring, was accepted by the Court. On October 9, 2013 we announced Settlement Agreements with each of Par Pharmaceutical and Impax Laboratories. On May 8, 2014, we announced our Settlement Agreement with Ranbaxy Pharmaceuticals.

### **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® and IMPEDE® Technologies. AVERSION® contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages. IMPEDE® is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

In June 2011, the U.S. Food and Drug Administration approved OXECTA® (oxycodone HC1 tablets) which incorporates the AVERSION® technology. The Company has a development pipeline of additional AVERSION® technology products containing other opioids.

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, that the U.S. District Court does not approve the Stipulation of Dismissal of the litigation with Sandoz, that the U.S. Federal Trade Commission or the U.S. Department of Justice challenge the enforceability of the Settlement Agreement or that private plaintiffs challenge the Settlement Agreement, whether or not additional third parties may seek to market generic versions of our AVERSION® oxycodone product and the results of our pending litigation or future litigation we may file to defend and/or assert our patents against such companies, the possible occurrence of one of the events that would result in Sandoz marketing a generic AVERSION® oxycodone product earlier than we anticipate, our ability to enter into a license agreement for our Aversion oxycodone product, our and our licensee’s ability to successfully launch and commercialize our products and technologies including our Aversion oxycodone and NEXAFED® Tablets, the price discounting that may be offered by our licensee for Aversion oxycodone, our or our licensee’s ability to obtain commercial supplies of Aversion oxycodone from a third party contract manufacturer, our and our licensee’s ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, the willingness of wholesalers and pharmacies to stock NEXAFED® Tablets, expectations regarding the terms and payments under any license agreement for 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 AVERSION® Technology product candidates, our exposure to product liability and other lawsuits in connection with the commercialization of our products, the increasing cost of insurance and the availability of product liability insurance coverage, 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, our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation, 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 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,” “would,” “expects,” “plans,” “anticipates,” “believes,” “indicates,” “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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