ACURA PHARMACEUTICALS, INC
Form 8-K
May 21, 2014

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	**1-10113**	**11-0853640**
(State of Other Jurisdiction of Incorporation)	(Commission File Number)	(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-J(b))

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

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 HCI 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.

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.

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

Exhibit Index

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