ACURA PHARMACEUTICALS, INC
Form 8-K
October 09, 2013

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

October 9, 2013

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.

A. Settlement of Patent Infringement Litigation with Par Pharmaceutical

On October 4, 2013, Acura Pharmaceuticals, Inc. ("Acura") and Par Pharmaceutical, Inc. ("Par") entered into each of a License Agreement dated September 27, 2013 (the "Par Agreement") to settle the parties patent infringement litigation concerning Oxecta® (oxycodone HCI tablets) pending in the United States District Court for the District of Delaware (the "Acura/Par Suit"). In the suit, Acura alleges that a generic Oxecta® product for which Par 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"). Par is the first ANDA filer for a generic Oxecta® product and is entitled to the 180-day first-filer exclusivity period provided in the Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the "Hatch-Waxman Act").

The Par Agreement provides for a full settlement of all claims that were asserted in Acura/Par Suit. Under the terms of the Par Agreement, Acura will grant Par a non-exclusive, royalty-bearing future license to the Acura Patent and other current and future Orange Book listable patents to market, manufacture and sell a generic version of Oxecta® in the United States (the "Licensed Patents"). Par's license becomes effective January 1, 2022, approximately 23 months prior to the expected expiration of the Acura Patent in November, 2023. The license granted to Par would become effective earlier if each of the Licensed Patents is held invalid or unenforceable, or not infringed with respect to a third party's generic version of Oxecta®, or if a third party sells a generic version of Oxecta® under a license or other authorization from Acura. In consideration for the license grant, Par is required to pay Acura royalties in an amount ranging from 10% to 15% of Par's net profits from the sale of its generic Oxecta® product.

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

Promptly following execution of the Par 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 Acura/Par Suit. The Par Agreement also provide that the parties file the License 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 Par Agreement; that any such modifications will be acceptable to the parties; or that the Par Agreement will continue to be effective.

B. Settlement of Patent Infringement Litigation with Impax Laboratories

On October 7, 2013, Acura and Impax Laboratories, Inc. ("*Impax*") entered into a License and Settlement Agreement, dated September 27, 2013 (the "Impax Agreement") to settle the parties' patent infringement litigation concerning Oxecta® pending in the United States District Court for the District of Delaware (the "Acura/Impax Suit"). In the suit, Acura alleges that a generic Oxecta® product for which Impax is seeking approval to market in the U.S. pursuant to ANDA filing with the FDA infringes the Acura Patent.

The Impax Agreement provides for a full settlement of all claims in the Acura/Impax Suit. Under the terms of the Impax Agreement, Acura will grant Impax a non-exclusive, royalty free, future license to the current and future Orange Book listable patents to market, manufacture and sell a generic version of Oxecta® in the U.S. (the "Licensed Patents"). Impax's license becomes effective 180 days following the first sale of a generic Oxecta® product in the United States by an entity that is entitled to the 180 day first-filer exclusivity provided in 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 Oxecta® product is first sold in the United States or November 27, 2021, whichever date occurs first). The license granted to Impax 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 Oxecta® if that third party's generic version of Oxecta® received final approval from the FDA, or (3) if a third party sells a generic version of Oxecta under a license or other authorization from Acura.

The Impax Agreement will remain in effect until the expiration of the Licensed Patents. The Impax Agreement also contains customary confidentiality provisions and representations and warranties of the parties.

Promptly following execution of the Impax Agreement, the parties are required to file the Impax Agreement with both the FTC and the 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 Impax Agreement; that any such modifications will be acceptable to the parties; or that the Impax Agreement will continue to be effective. The Impax agreement also requires the parties to file dismissals without prejudice with the United States District Court for the District of Delaware forty-five days after submission of the Impax Agreement to the FTC and DOJ. The dismissal will conclude the Acura/Impax Suit.

The Par Agreement and the Impax Agreement do not affect the status of Acura's separate Oxecta® patent litigations against Sandoz and Ranbaxy pending in the United States District Court for the District of Delaware.

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 each of the Acura/Par Suit and the Acura/Impax Suit, that the FTC or DOJ challenge the enforceability of the Par Agreement or the Impax Agreement, or that private plaintiffs challenge the Par Agreement or the Impax Agreement, whether or not additional third parties may seek to market generic versions of Oxecta® 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 Par or Impax marketing a generic Oxecta® earlier than we anticipate; our ability to protect the proprietary technologies and intellectual property related to Oxecta® and to secure and maintain additional intellectual property protection for Oxecta®; 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 October 9, 2013 Regarding Settlements With Par Pharmaceutical, Inc. and Impax Laboratories, 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: October 9, 2013

Exhibit Index

Exhibit Number	Description
99.1	Press Release dated October 9, 2013 Regarding Settlements With Par Pharmaceutical, Inc. and Impax Laboratories, Inc.