

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 9, 2015
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)

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

On September 9, 2015 we issued a press release disclosing the commercial launch of Oxaydo™ (oxycodone HCl) tablets in the United States by our licensing partner, Egalet Corporation. A copy of our press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated September 9, 2015 announcing the commercial launch of Oxaydo™ (oxycodone HCl) tablets in the United States by our licensing partner, Egalet Corporation.

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 9, 2015

Exhibit Index

Exhibit Number

Description

99.1

Press Release dated September 9, 2015 announcing the commercial launch of Oxaydo™ (oxycodone HCl) tablets in the United States by our licensing partner, Egalet Corporation.



Egalet Corporation Launches Acura Pharmaceuticals' OXAYDO™
First and only IR Oxycodone designed to discourage abuse via snorting

Palatine, IL (September 9, 2015) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), today announced that Egalet Corporation (NASDAQ: EGLT) has commercially launched in the United States OXAYDO (oxycodone HCl) tablets, a product Egalet licensed from Acura. OXAYDO, an immediate release oxycodone hydrochloride formulation that incorporates Acura's patented AVERSION® (abuse-deterrent) Technology, is indicated for the treatment of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. OXAYDO can be taken without regard to food, the way opioids generally are taken.

"We are excited that OXAYDO, for the first time, is being promoted to physicians by a pharmaceutical sales force", commented Bob Jones, President and CEO of Acura. "Our marketing partner, Egalet, has done a terrific job building their commercial infrastructure to make this launch happen."

Acura's AVERSION (abuse-deterrent) Technology is a patented mixture of gelling ingredients and nasal irritants designed to address common forms of opioid abuse.

Acura's license agreement with Egalet provides for a milestone payment of \$2.5 million upon the first commercial sale of OXAYDO in the U.S., which Acura currently expects to receive in the fourth quarter of 2015, and an additional one-time payment of \$12.5 million when annual world-wide net sales of OXAYDO first reach \$150 million in a calendar year. Acura is also to receive a stepped royalty at percentage rates from mid-single digits to double digits based on the level of OXAYDO world-wide net sales in a calendar year (including any product line extensions). Royalties are payable on the first commercial sale of OXAYDO and expire, on a country-by-country basis, upon the expiration of Acura's patent in such country.

Important Safety Information for OXAYDO™ (oxycodone HCl, USP) Tablets for oral use only – CII OXAYDO is an immediate-release oral formulation of oxycodone HCl indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate.

OXAYDO is contraindicated in patients with respiratory depression, paralytic ileus, acute or severe bronchial asthma or hypercarbia, or known hypersensitivity to oxycodone or any components of the product.

Respiratory depression is the primary risk of OXAYDO and it must be used with extreme caution in patients with chronic obstructive pulmonary disease or cor pulmonale, in patients with decreased respiratory reserve, hypoxia, hypercapnia or pre-existing respiratory depression.

OXAYDO™ contains oxycodone HCl, an opioid agonist and a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. OXAYDO can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing in situations where there is concern about an increased risk of misuse or abuse. OXAYDO may be abused by crushing, chewing, snorting or injecting the product and these practices pose a significant risk to the abuser that could result in overdose and death.

Patients receiving central nervous system depressants concomitantly with OXAYDO may exhibit an additive central nervous system depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced. Patients should not consume alcoholic beverages, or any medications containing alcohol while taking OXAYDO.

OXAYDO may cause severe hypotension in patients whose ability to maintain blood pressure has been compromised. OXAYDO may produce orthostatic hypotension in ambulatory patients. OXAYDO must be administered with caution in patients in circulatory shock.

Serious adverse reactions that may be associated with OXAYDO include: respiratory depression, respiratory arrest, circulatory depression, cardiac arrest, hypotension and/or shock. The most common adverse reactions are nausea, constipation, vomiting, headache, pruritus, insomnia, dizziness, asthenia and somnolence.

In opioid naïve patients, start dosing OXAYDO with five to 15 mg every four to six hours as needed for pain. OXAYDO should not be given to anyone other than the individual for whom it was prescribed. Keep OXAYDO in a locked cabinet, drawer or medicine safe so that it will not be stolen.

Please see full prescribing information for OXAYDO at oxaydo.com.

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 LIMITX™, AVERSION® and IMPEDE® Technologies. LIMITX contains ingredients that are intended to reduce or limit the rate or extent of opioid release when multiple tablets are ingested. AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages if the product is snorted. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet, pursuant to which we licensed to Egalet worldwide rights to manufacture and commercialize OXAYDO.

Acura also markets NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology.

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 results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to, our ability to raise capital, 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, our and our licensee’s ability to successfully launch and commercialize our products and technologies including OXAYDO Tablets and NEXAFED Tablets, the price discounting that may be offered by Egalet for OXAYDO, 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 pharmacies to stock our NEXAFED 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, our exposure to product liability and other lawsuits in connection with the commercialization of our products, the increased cost of insurance and the availability of product liability insurance coverage, 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 formulated with our Aversion or Limitx technologies 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,” “should,” “could,” “would,” “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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