

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

March 23, 2015  
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**

On March 23, 2015 we issued a press release announcing preliminary topline results from a pilot clinical study which demonstrated bioequivalence of one formulation of NEXAFED® (pseudoephedrine HCl) extended-release tablets to Sudafed® 12-Hour Tablets. The press release is attached hereto and filed as Exhibit 99.1.

**Item 9.01        Financial Statements and Exhibits****Exhibit Number   Description**

99.1	Press Release dated March 23, 2015
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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: March 23, 2015

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## Exhibit Index

<u>Exhibit Number</u>	<u>Description</u>
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99.1 Press Release dated March 23, 2015



**Acura Pharmaceuticals Reports Successful  
Topline Results from Nexafed® Extended-Release Clinical Study**

**Palatine, IL** (March 23, 2015) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), today announced preliminary topline results from a pilot clinical study which demonstrated bioequivalence of one formulation of NEXAFED (pseudoephedrine HCl) extended-release tablets to Sudafed® 12-Hour Tablets. NEXAFED extended-release tablets utilize Acura's IMPEDE 2.0 enhanced methamphetamine-resistant technology. Acura intends to request a pre-IND meeting with the US Food and Drug Administration (FDA) to review this data and discuss a complete development program.

"These study results validate our ability to move our IMPEDE technology into extended-release formulations", said Dr. Al Brzezczko, Acura's Vice President of Technical Affairs. "Demonstrating bioequivalence with one formulation this early in our development process allows us to more rapidly advance to discussions with FDA to determine our full development program for this product".

The study was conducted in 12 fasted, healthy subjects and measured the systemic absorption of the active ingredient, pseudoephedrine, from a single dose each of two experimental NEXAFED extended-release formulations compared to Sudafed® 12-Hour tablets. NEXAFED formulation B met FDA's standards for bioequivalence for maximum plasma concentration (C<sub>max</sub>) and extent of absorption (AUC). NEXAFED formulation A met the bioequivalence criteria for extent of absorption but was low for maximum plasma concentration.

***About NEXAFED and IMPEDE***

NEXAFED is Acura's line of next generation pseudoephedrine products built around IMPEDE technology, that uses a unique polymer matrix to disrupt the conversion of pseudoephedrine into the dangerous drug, methamphetamine. Specifically, IMPEDE tablets forms a thick gel when the tablets are dissolved in solvents typically used in the pseudoephedrine extraction or methamphetamine production processes, trapping the pseudoephedrine or converted methamphetamine to prevent its isolation or purification. Acura commercially launched NEXAFED (pseudoephedrine HCl) 30mg tablets in December 2012 and the only commercially available meth-resistant combination pseudoephedrine product, NEXAFED Sinus Pressure + Pain (pseudoephedrine HCl/acetaminophen) 30/325mg tablets in February 2015. The NEXAFED line is available at national and regional drug, grocery and mass merchandiser pharmacies. NEXAFED delivers the same efficacy and is priced comparably to similar branded pseudoephedrine products. For more information about NEXAFED, please visit [www.nexafed.com](http://www.nexafed.com).

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## 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.

In June 2011, the U.S. Food and Drug Administration approved our oxycodone HCl immediate-release tablets which incorporate the AVERSION Technology. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialized Oxaydo. The Company has a development pipeline of additional AVERSION Technology products containing other opioids.

## 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. Forwarding-looking statements may include, but are not limited to, the meth resistant benefits of our IMPEDE 2.0 technology, the results of our pre-IND meeting with the FDA, whether our formulation of NEXAFED extended-release tablets will lead to commercial products, whether or when we are able to obtain FDA approval of this product candidate, whether we will be able to promote the features of our meth-resistant technology, whether our product candidates utilizing our IMPEDE 2.0 technology will disrupt the processing of pseudoephedrine into methamphetamine, and whether competitors will develop and commercialize products using alternative meth-resistant technologies that are more effective than our IMPEDE 2.0 technology. Such forwarding-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.

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Sudafed is a registered trademark of Johnson and Johnson Corp.

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