

ACURA PHARMACEUTICALS, INC
Form 8-K
September 28, 2015

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 28, 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)
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616 N. North Court, Suite 120

Palatine, Illinois 60067

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(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-L(c))

Item 7.01 Regulation FD Disclosure.

Commencing in October 2015, Robert B. Jones, our Chief Executive Officer, and Peter A. Clemens, our Senior Vice President and Chief Financial Officer, are scheduled to make presentations about Acura Pharmaceuticals, Inc. at meetings with institutional and retail brokers at various locations in the U.S. and Canada. Slides to be used in such presentations are attached hereto as Exhibit 99.1.

Statements in the slide presentation that are not strictly historical may be “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:

- our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our Aversion®, Impede® and Limitx™ technologies;
- our and our licensee’s ability to successfully launch and commercialize our products and technologies, including Oxaydo Tablets and our NEXAFED products;
 - the pricing and price discounting that may be offered by Egalet for OXAYDO;
- whether we can successfully develop a product under our IMPEDE license agreement with a multi-national pharmaceutical company;
 - the results of our development of our LIMITX technology;
- our and our licensee’s ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
 - 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 develop and enter into additional license agreements for our AVERSION Technology product candidates using our technologies;
- 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;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- 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 process to meet over-the-counter 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 commercialized products or product candidates in development;
- whether the FDA will agree with our analysis of our clinical and laboratory studies;
- 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; and
- whether OXAYDO or our AVERSION and LIMITX product candidates will ultimately deter abuse in commercial settings and whether our NEXAFED products and Impede technology product candidates 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,” “expect,” “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. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments.

Item 9.01 Financial Statements and Exhibits.

Exhibit

Number Description

99.1 Slides to be used in Acura Presentations

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 28, 2015

Exhibit

Number Description

99.1 Slides to be used in Acura Presentations