ACURA PHARMACEUTICALS, INC
Form 8-K
March 10, 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**

**March 10, 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-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.**

Robert B. Jones, our Chief Executive Officer, is scheduled to make a presentation about Acura Pharmaceuticals, Inc. at the 26th Annual ROTH Capital Conference on Tuesday, March 11, 2014 at 4:00 p.m. Pacific Time at the Ritz-Carlton Laguna Niguel in Dana Point, California. Slides from the presentation are attached hereto as Exhibit 99.1.

Statements in the investor 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, 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, whether private plaintiffs will challenge the Settlement Agreements we entered into with each of Par Pharmaceutical and Impax Laboratories relating to our Oxecta® patent infringement litigation, 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 Pharmaceutical or Impax Laboratories marketing a generic Oxecta® earlier than we anticipate, the possible approval by the U.S. Food and Drug Administration (“FDA”) of Sandoz Inc.’s or Ranbaxy Inc.’s generic Oxecta product prior to the expiry of our patents covering Oxecta, our and our licensee's ability to successfully launch and commercialize our products and technologies including Oxecta® Tablets and Nexafed® Tablets, the price discounting that may be offered by Pfizer for Oxecta, 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 wholesalers and pharmacies to stock Nexafed® Tablets, 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, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, 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 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," "will," "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 and beliefs with respect to future events and are based on assumptions and subject to significant risks and uncertainties. Given these uncertainties, you should not place undue

reliance on these forward-looking statements.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in the slides may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Forward-looking statements speak only as of the date of this Report, and Acura undertakes no obligation to update or revise these statements.

**Item 9.01 Financial Statements and Exhibits.**

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Slides from the Scheduled Presentation on March 10, 2014 |

**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 10, 2014

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Slides from the Scheduled Presentation on March 10, 2014 |