ACURA PHARMACEUTICALS, INC
Form 8-K
March 11, 2016

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 11, 2016

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 Jones, President and Chief Executive Officer of Acura Pharmaceuticals, Inc. (the "Company"), will present at the 28th Annual ROTH Capital Conference on Monday, March 14, 2016 at 11:30 a.m. Pacific Time at the Ritz-Carlton Laguna Niguel in Dana Point, California. Slides from the presentation are attached hereto as Exhibit 99.1.

On March 11, 2016, it came to the Company's attention that it previously inadvertently disclosed to an analyst information not previously publicly disclosed by the Company, or disclosed in the same detail by the Company. The slides containing such information are attached as Exhibit 99.2. Each of these slides reflect one of several possible scenarios and were for illustrative purposes only. One of the slides contained information on one possible development timeline and possible costs associated with development activities through NDA submission for LimitX™. The Company believes the information contained therein was consistent with but more detailed than its previous disclosure. The Company intends to update the market with a more definitive development plan after a meeting the FDA assuming success from results from study AP-LTX-400. The other slide disclosed the potential market opportunity for a hydromorphone and hydrocodone/acetaminophen LimitX based product, based on an illustrated 10% market share and is not based on the Company's research or management's expectations. The information on this slide is not specific to the Company and is available from industry sources. The Company does not intend to update the information on these Extra Slides.

Information in this report furnished pursuant to Item 7.01 shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section. This report will not be deemed an admission as to the materiality or non-public nature of any information in the report that is required to be disclosed solely by Regulation FD.

Statements in the attached exhibits 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 Limitx™ and Impede® technologies;

- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;

- the projected timeline and development costs associated with our LimitX technology;

- the potential pricing, market size, market share or profitability of products or product categories utilizing our LimitX technology;

- the pricing and price discounting that may be offered by our licensee, Egalet for Oxaydo;

- whether we can successfully develop a product under our agreement with Bayer;
- 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, timing of commercial launch 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;
- our ability to develop and enter into additional license agreements for our 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," "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.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	**Description**
99.1	Slides from the Scheduled Presentation on March 14, 2016
99.2	Extra Slides

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 11, 2016

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