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

October 16, 2014
Date of Report (Date of earliest event reported)

ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

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-4(c))

Item 8.01 Other Events

On October 16, 2014 we issued a press release regarding the US Food and Drug Administration's (FDA) denial on procedural grounds of our appeal of the position taken by Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) of the FDA that abuse by snorting of hydrocodone with acetaminophen products lacks relevance.

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 October 16, 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: October 16, 2014

Exhibit Index

Exhibit Number	Description
99.1	Press Release dated October 16, 2014

Exhibit 99.1

Acura Pharmaceuticals Provides Update on its Hydrocodone Bitartrate with Acetaminophen Tablets Development

Palatine, IL - (October 16, 2014) - Acura Pharmaceuticals Inc. (NASDAQ: ACUR), announced today that the US Food and Drug Administration (FDA) has denied on procedural grounds Acura's appeal of the position taken by Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) that abuse by snorting of hydrocodone with acetaminophen products lacks relevance. Relevance is defined in FDA's January 2013 Draft Guidance on the evaluation and labeling of abuse deterrent opioids to be a "known or expected" route of abuse for that product.

In a letter decision from the Office of Drug Evaluation II, the FDA indicated that DAAAP's comments and correspondence to date with Acura, as well as the Draft Guidance on abuse deterrent opioids, should be viewed only as recommendations and opinions and do not preclude Acura from completing its clinical development and submitting a New Drug Application for its hydrocodone with acetaminophen product for consideration. FDA further noted that for issues such as abuse-deterrence an Advisory Committee meeting may greatly inform their considerations.

The FDA's letter also advised the Company that we may appeal this decision to the next level within the FDA. Acura is assessing its development strategy for its abuse deterrent hydrocodone with acetaminophen program, including the merits of appealing the FDA's decision.

Bob Jones, Acura's CEO, stated "We're frustrated that FDA chose not to make a decision on the fundamental question of whether nasal abuse of hydrocodone/acetaminophen products constitutes a "relevant" public health issue that should be addressed by the development of abuse-deterrent versions of this drug, even with all known information at its disposal. However, we are encouraged that FDA has demonstrated a willingness to seek advice on the issue of "relevance" from an Advisory Committee when such critical public health issues are at stake."

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. The Company has a development pipeline of additional AVERSION® Technology products containing other opioids.

In December 2012, the Company commenced commercialization of NEXAFED® (pseudoephedrine HCl), a 30 mg immediate-release abuse-deterrent decongestant. This next generation pseudoephedrine tablet combines effective nasal congestion relief with IMPEDE® Technology, a unique polymer matrix that disrupts the conversion of pseudoephedrine into the dangerous drug, methamphetamine.

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 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 results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to:

- the results of our dispute resolution request with the FDA, and any appeals therefrom, relating to our AVERSION® hydrocodone/acetaminophen product;
- the results of our development of our Limitx™ technology;
- our ability to fund, or obtain funding for, products developed utilizing our Limitx™ technology;
- our ability to enter into a license agreement for our FDA approved AVERSION® oxycodone product;
- our and our licensee's ability to successfully launch and commercialize our products and technologies including AVERSION® oxycodone and NEXAFED® Tablets;
- the results of our meetings or discussions with the FDA relating to our AVERSION® hydrocodone/acetaminophen product;
- whether we will conduct an additional intranasal abuse liability study on our AVERSION® hydrocodone/ acetaminophen product and, if conducted, whether the results of such study will support the filing of a New Drug Application and/or a claim of intranasal abuse deterrence;
- 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 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 AVERSION® Technology product candidates;
- 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 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;
- 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 our AVERSION® and Limitx™ 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,” “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. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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