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 29, 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 September 29, 2014, we issued a press release announcing topline results from three clinical studies for AVERSION®, our hydrocodone bitartrate with acetaminophen development product. The press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	Description
99.1	Press Release dated September 29, 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: September 29, 2014

Exhibit Index

Exhibit Number	Description
99.1	Press Release dated September 29, 2014

Exhibit 99.1

Acura Pharmaceuticals Hydrocodone Bitartrate with Acetaminophen Tablets Meet Clinical Endpoints

Palatine, IL - (September 29, 2014) - Acura Pharmaceuticals Inc. (NASDAQ: ACUR), announced today preliminary results from three clinical studies for its abuse deterrent AVERSION® hydrocodone bitartrate with acetaminophen (AVERSION H/A) development product with the key study demonstrating that AVERSION H/A met the objective of conformance with the Food and Drug Administration's (FDA) standards for bioequivalence when compared to the reference drug NORCO®, when taken in the fasted state. A food effect was observed with the AVERSION H/A formulation with lower peak blood concentrations for both hydrocodone and acetaminophen than the comparator product.

Further, the studies demonstrated dose proportionality, or relatively consistent blood exposure, across all three dosage strengths of AVERSION H/A. Finally, Acura evaluated blood levels of hydrocodone compared to VICOPROFEN® and of acetaminophen compared to ULTRACET®, for additional safety. AVERSION H/A blood levels of hydrocodone were consistent with the comparator product while acetaminophen peak blood levels were higher than those observed for the comparator product.

AVERSION H/A was generally well tolerated in all the clinical studies with no serious adverse events observed. AVERSION H/A exhibited consistent exposure levels of hydrocodone and acetaminophen across all three studies. Acura continues to review the results from these studies.

The three Acura studies, Study AP-ADF-302, AP-ADF-303 and AP-ADF-304, conclude Acura's planned clinical studies to demonstrate the pain relief efficacy and safety of AVERSION H/A. Acura believes the level of food effect observed and the increased peak exposure to acetaminophen are not clinically relevant, but all these results will be subject to FDA review and concurrence. Acura has previously indicated the need to provide additional clinical data on the snorting abuse deterrent features of AVERSION H/A which is pending the successful completion of a dispute resolution proceeding Acura initiated with the FDA regarding FDA's determination that snorting is not a relevant route of abuse for hydrocodone combination products.

Study AP-ADF-302 is an open label, single dose, randomized, crossover study in 36 healthy adult subjects measuring blood concentration of hydrocodone and acetaminophen in fed and fasted states. In the fasted state, a single AVERSION H/A 10/325mg tablet was found to meet FDA's standards for bioequivalence compared to an equivalent dose of NORCO. A finding of bioequivalence compared to an FDA approved drug is typically sufficient to establish the safety and efficacy of a test formulation. AVERSION H/A 10/325mg was also tested in the fed state following a standardized meal, which demonstrated a 13.7% and 34.4% average reduction in peak blood concentration for hydrocodone and acetaminophen, respectively, compared to NORCO in the fasted state. These food effect results are consistent with the AVERSION technology and also the known effect of food on acetaminophen in general and the reduction is not expected to have a meaningful clinical impact.

Study AP-ADF-303 is an open label, single dose, randomized, crossover study in 24 healthy adult subjects measuring blood concentration of hydrocodone and acetaminophen in the fasted state across three different dose levels of AVERSION H/A. The blood exposure of hydrocodone and acetaminophen were proportionately the same across all three doses of AVERSION H/A successfully demonstrating dose consistency of the formulation.

Study AP-ADF-304 is an open label, single dose, randomized, crossover study in 24 healthy adult subjects measuring blood concentration of hydrocodone and acetaminophen in the fasted state to determine pharmacokinetics and safety of AVERSION H/A 7.5/325mg compared to equivalent doses of VICOPROFEN (for hydrocodone) and ULTRACET (for acetaminophen), for additional safety. Extent of exposure, measured by Area Under the Curve or AUC, is comparable for both hydrocodone and acetaminophen between AVERSION H/A and the respective comparator products. The peak exposure, measured by maximum plasma concentration or Cmax, is consistent for hydrocodone but AVERSION H/A was approximately 23% higher than the comparator based on the geometric mean. A large variability in acetaminophen results is observed in the study and is being further evaluated.

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. 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 hydrochloride (HCl)], a 30 mg immediate-release abuse-deterrent decongestant. The 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.

NORCO is a registered trademark of Watson Pharmaceuticals, Inc. VICOPROFEN is a registered trademark of Knoll Pharmaceutical Company. ULTRACET is registered trademark of Johnson & Johnson Corporation.

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 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 the results of studies AP-ADF-302, AP-ADF-303 and AP-ADF-304 will be acceptable to the FDA;
- 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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