

ACURA PHARMACEUTICALS, INC

Form 8-K

December 12, 2014

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

December 10, 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-J(b))

--Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17CFR 240.13e-L(c))

Item 8.01 Other Events

In August 2014, Purdue Pharma L.P. (“Purdue”) announced that it has submitted a New Drug Application (“NDA”), presumably under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) for an immediate-release (“IR”) oxycodone hydrochloride formulation designed with the intent to deter intranasal and intravenous abuse of the medication.

On December 10, 2014 we filed a Citizen Petition with the United States Food and Drug Administration (“FDA”) requesting that the FDA require that Purdue file its drug application in a manner citing our Aversion® oxycodone hydrochloride product (formerly known as OXECTA) as a reference listed drug with certifications to the patents related to our Aversion oxycodone hydrochloride product listed in the FDA’s Orange Book.

If the FDA grants the relief we are seeking in the Citizen Petition and Purdue is required to provide the certifications required under 21 U.S.C §355(b)(2)(A) or §355(j)(2)(A)(vii), as applicable, of the FD&C Act, with respect to our patents listed in the FDA’s Orange Book for our Aversion oxycodone hydrochloride product, Purdue must certify that it will not market its product before the expiry of our patents, or that our patents are invalid or will not be infringed by Purdue’s product (a “Paragraph IV Certification”). If Purdue were to submit such a Paragraph IV Certification it must promptly give us notice. A Paragraph IV Certification would vest in us important statutory rights, including the right to bring an infringement action against Purdue within 45 days of receiving notice of the Paragraph IV Certification, and the FDA is statutorily prohibited from approving Purdue’s application until 30 months have passed, our patents have expired, or a court has found our patents invalid or not infringed. There can be no assurance that the FDA will grant the relief we are seeking in the Citizen Petition.

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: December 12, 2014