

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

November 3, 2014
Date of Report (Date of earliest event reported)

ACURA PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Charter)

State of New York
(State of Other Jurisdiction
of Incorporation)

1-10113
(Commission File Number)

11-0853640
(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))
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Item 2.02 Results of Operations and Financial Condition

On November 3, 2014 we issued a press release disclosing the financial results for our third quarter ended September 30, 2014. A copy of our press release is being furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press Release dated November 3, 2014 announcing financial results for the third quarter ended September 30, 2014
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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

Palatine, Illinois
Date: November 3, 2014

Exhibit Index

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press Release dated November 3, 2014 announcing financial results for the third quarter ended September 30, 2014
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**Acura Pharmaceuticals Announces
Third Quarter 2014 Financial Results**

Palatine, IL - (November 3, 2014) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company developing products intended to address medication abuse and misuse, announced today financial results for the three and nine months ended September 30, 2014.

The Company reported a net loss of \$2.9 million for the third quarter 2014 or \$0.06 per diluted share, compared to net loss of \$3.2 million or \$0.07 per diluted share for the same period in 2013. Research and development expenses associated with product candidates utilizing the Company's AVERSION® and IMPEDE® Technologies were \$1.0 million in the third quarter 2014, compared to \$1.3 million for the same period in 2013. Selling, marketing, general and administrative expenses were \$1.7 million in the third quarter 2014, versus \$1.9 million in the same period last year. Selling and marketing expenses primarily consist of advertising and marketing activities for NEXAFED®.

The Company reported net losses of \$10.5 million and \$0.22 per diluted share for each of the nine months ended 2014 and 2013. Research and development expenses associated with product candidates utilizing the Company's AVERSION® and IMPEDE® Technologies were \$3.7 million in the nine months ended 2014, compared to \$4.1 million for the same period in 2013. Selling, marketing, general and administrative expenses were \$5.9 million in the nine months ended 2014, versus \$6.1 million in the same period last year. Selling and marketing expenses primarily consisted of advertising and marketing activities for NEXAFED®.

As of October 30, 2014, the Company had cash, cash equivalents and marketable securities of \$14.0 million and had \$10.0 million in term debt financing.

We launched NEXAFED® commercially in mid-December 2012. Given the limited sales history of NEXAFED®, we could not reliably estimate expected returns of the product at the time of shipment. Accordingly, we have deferred recognition of revenue and the related cost of sales on selected product shipments of NEXAFED® until the right of return no longer exists or adequate history and information is available to estimate product returns. At September 30, 2014 we have deferred \$228 thousand of revenue from shipments of NEXAFED®. During the third quarter 2014 we shipped \$68 thousand of NEXAFED® and we recognized revenue of \$145 thousand for shipments to customers where the right of return no longer existed either because a pricing allowance was accepted in exchange for forfeiting the right of return or because information became available on pharmacy's reorder activity with their drug wholesaler. We will continue to analyze information to assess the recognition of our revenue but also expect to continue the deferral of some revenue from NEXAFED® in the foreseeable future.

Conference Call Information

Acura Pharmaceuticals, Inc. will host a conference call to discuss the results on Tuesday, November 4, 2014 at 8:30 a.m. ET.

To participate in the live conference call, please dial 1-888-428-9473 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 9602172. A replay of the call will be available beginning November 6, 2014 at 11:30 a.m. ET and ending on November 22, 2014 on the company's website.

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, including 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 the results of studies AP-ADF-302, AP-ADF-303, and AP-ADF-304 relating to our Aversion hydrocodone/acetaminophen product 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;
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- 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.
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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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ACURA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	(unaudited) September 30, 2014	(audited) December 31, 2013
Current assets	\$ 16,143	\$ 27,453
Property, plant and equipment, net	957	941
Other assets	180	236
Intangible asset	2,000	-
Total assets	<u>\$ 19,280</u>	<u>\$ 28,630</u>
Current liabilities	\$ 1,644	\$ 820
Deferred revenue - current	228	287
Current maturities of long-term debt	1,160	-
Long-term portion of accrued interest	140	-
Long-term debt, net of debt discount of \$311 and \$400	8,529	9,600
Stockholders' equity	7,579	17,923
Total liabilities and stockholders' equity	<u>\$ 19,280</u>	<u>\$ 28,630</u>

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands, except per share data)

	Unaudited Three Months Ended September 30,		Unaudited Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Royalty revenue	\$ -	\$ 3	\$ 4	\$ 8
Product sales, net	145	80	218	80
Total revenues, net	145	83	222	88
Operating expenses:				
Cost of sales (excluding inventory write-down)	108	78	188	78
Inventory write-down	-	-	201	361
Research and development	955	1,289	3,674	4,120
Selling, marketing, general and administrative	1,728	1,941	5,903	6,138
Total operating expenses	2,791	3,308	9,966	10,697
Operating loss	(2,646)	(3,225)	(9,744)	(10,609)
Non-operating income (expense):				
Investment income	46	55	143	136
Loss on sales of marketable securities	-	(20)	(5)	(11)
Interest expense	(304)	-	(907)	-
Total other income (expense)	(258)	35	(769)	125
Loss before income taxes	(2,904)	(3,190)	(10,513)	(10,484)
Provision for income taxes	-	-	-	-
Net loss	\$ (2,904)	\$ (3,190)	\$ (10,513)	\$ (10,484)
Other comprehensive income:				
Unrealized gains (losses) on securities	(44)	114	6	35
Total other comprehensive income (expense)	(44)	114	6	35
Comprehensive loss	\$ (2,948)	\$ (3,076)	\$ (10,507)	\$ (10,449)
Loss per share:				
Basic	\$ (0.06)	\$ (0.07)	\$ (0.22)	\$ (0.22)
Diluted	\$ (0.06)	\$ (0.07)	\$ (0.22)	\$ (0.22)
Weighted average shares outstanding:				
Basic	48,922	47,458	48,871	47,297
Diluted	48,922	47,458	48,871	47,297