

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

May 2, 2016
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 May 2, 2016 we issued a press release disclosing the financial results for our first quarter ended March 31, 2016. A copy of our press release is attached 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 May 2, 2016 announcing Financial Results for the First Quarter of 2016
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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

Date: May 2, 2016

Exhibit Index

Exhibit Number

Description

99.1	Press Release dated May 2, 2016 announcing Financial Results for the First Quarter of 2016
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Acura Pharmaceuticals Announces First Quarter 2016 Financial Results

Palatine, IL - (May 2, 2016) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), a specialty pharmaceutical company innovating abuse deterrent drugs, announced today financial results for the first quarter ended March 31, 2016.

The Company reported net loss of \$3.4 million for the first quarter 2016 or \$0.28 per diluted share, compared to net income of \$1.2 million or \$0.13 per diluted share for the same period in 2015. Revenues for the quarter were \$0.2 million compared to \$5.4 million in the first quarter of 2015 which included the \$5.0 million payment arising from licensing Oxaydo to Egalet Corporation entities.

Research and development expenses associated with product candidates utilizing the Company's LIMITX™, AVERSION® and IMPEDE® Technologies were \$1.0 million in each of the first quarters 2016 and 2015. Selling, marketing, general and administrative expenses were \$2.2 million in first quarter 2016 compared to \$2.3 million in the first quarter 2015. Selling expenses primarily consisted of advertising and marketing activities for NEXAFED® and NEXAFED® SINUS.

As of April 30, 2016, our cash, cash equivalents and marketable securities less our compensating balance requirement of \$2.5 million was \$7.7 million, and we had \$7.4 million in term debt financing.

Conference Call Information

Acura Pharmaceuticals is, Inc. will host a conference call on Tuesday, May 3, 2016 at 8:30 a.m. EDT to discuss the results.

To participate in the live conference call, please dial 888-339-3513 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 6043967. A digital replay of the call will be available beginning May 3, 2016 and ending on May 24, 2016 on the company's website, and by dialing 888-203-1112 (U.S. and Canada). The replay participant code is 6043967.

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.

OXAYDO® (oxycodone HCl immediate-release tablets) which incorporates the AVERSION Technology, is FDA approved and marketed in the U.S. by our partner Egalet Corporation.

Acura markets NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products that utilize the IMPEDE Technology.

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 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;
 - the expected results of clinical studies relating to LTX-04, the date by which such study results will be available and whether LTX-04 will ultimately receive FDA approval;
 - whether LIMITX will retard the release of opioid active ingredients as dose levels increase;
 - whether we will be able to reformulate LTX-04 to provide an efficacious level of drug when one or two tablets are taken;
 - whether our LIMITX technology can be expanded into extended-release formulations;
 - 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 pricing and price discounting that may be offered by 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;
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- 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 (“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 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,” “indicates”, “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.

Contact:
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ACURA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	(unaudited) March 31, 2016	(audited) December 31, 2015
Current assets	\$ 11,632	\$ 14,135
Property, plant and equipment, net	1,028	1,013
Other assets	1,761	1,813
Total assets	\$ 14,421	\$ 16,961
Other current liabilities	\$ 1,853	\$ 924
Debt - current	2,575	2,320
Debt - non-current portion, net of discount of \$167 and \$193, and debt issuance costs of \$83 and \$97	4,806	5,430
Accrued interest - non-current portion	433	387
Stockholders' equity	4,754	7,900
Total liabilities and stockholders' equity	\$ 14,421	\$ 16,961

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

	(unaudited)			
	Three Months Ended March 31,			
	2016		2015	
Revenues:				
License fee revenue	\$	-	\$	5,000
Collaboration revenue		100		-
Royalty revenue		17		-
Product sales, net		107		357
Total revenues, net		224		5,357
Operating expenses:				
Cost of sales (excluding inventory write-down)		102		324
Inventory write-down		-		260
Research and development		1,014		964
Selling, marketing, general and administrative		2,246		2,297
Total operating expenses		3,362		3,845
Operating (loss) income		(3,138)		1,512
Non-operating income (expense):				
Investment income		27		35
Interest expense		(249)		(308)
Other expense		(24)		-
Total other expense, net		(246)		(273)
(Loss) income before income taxes		(3,384)		1,239
Provision for income taxes		-		-
Net (loss) income	\$	(3,384)	\$	1,239
Other comprehensive income:				
Unrealized gains on securities		70		31
Comprehensive (loss) income	\$	(3,314)	\$	1,270
(Loss) income per share:				
Basic	\$	(0.28)	\$	0.13
Diluted	\$	(0.28)	\$	0.13
Weighted average shares outstanding:				
Basic		11,968		9,793
Diluted		11,968		9,869