

ACURA PHARMACEUTICALS, INC

FORM 8-K (Current report filing)

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| Address | 616 N. NORTH COURT, SUITE 120 PALATINE, IL 60067 |
| Telephone | 847-705-7709 |
| CIK | 0000786947 |
| Symbol | ACUR |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Medical Research |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

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

March 31, 2017
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 (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition

On March 31, 2017 we issued a press release disclosing the financial results for our fourth quarter ended December 31, 2016 and our fiscal year ended December 31, 2016. 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> |
|-----------------------|--|
| 99.1 | Press Release dated March 31, 2017 announcing financial results for the fourth quarter ended December 31, 2016 and the fiscal year ended December 31, 2016 |

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: March 31, 2017

Exhibit Index

Exhibit Number

Description

99.1

Press Release dated March 31, 2017 announcing financial results for the fourth quarter ended December 31, 2016 and the fiscal year ended December 31, 2016



**Acura Pharmaceuticals Announces Fourth Quarter 2016
and Full Year 2016 Financial Results**

Palatine, IL – (March 31, 2017) - Acura Pharmaceuticals, Inc. (OTCQB: ACUR) , a specialty pharmaceutical company innovating abuse deterrent drugs, announced today financial results for the year and three months ended December 31, 2016.

The Company reported net income of \$1.5 million, or \$0.13 per diluted share, for the fourth quarter of 2016, compared to net loss of \$0.9 million or \$0.08 per diluted share for the same period in 2015. For 2016 the Company reported a net loss of \$7.4 million or \$0.62 per diluted share compared to a net loss of \$5.0 million or \$0.46 per diluted share for 2015.

For the twelve months ended December 31, 2016, the Company recorded \$3.5 million in license fee revenue derived from the October 13, 2016 License Agreement with KemPharm Inc. For the twelve months ended December 31, 2015, the Company recorded \$5.0 million and \$2.5 million in license fee revenue and milestone revenue, respectively, derived from the January 7, 2015 Collaboration and License Agreement with Egalet Corporation, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize OXAYDO® . We recorded collaboration revenue of \$0.4 million and \$0.2 million for the twelve months ended December 31, 2016 and 2015, respectively, some of which arises from the June 15, 2015 License and Development Agreement with Bayer Healthcare pursuant to which we granted Bayer an exclusive worldwide license to our IMPEDE® Technology for use in an undisclosed methamphetamine resistant pseudoephedrine – containing product and providing for the joint development of such product using our IMPEDE® Technology for the U.S. market. We also recorded \$0.4 million in NEXAFED® product line net sales as compared with \$0.7 million in NEXAFED® product line net sales in the same period in 2015.

Research and development expenses associated with product candidates utilizing the Company's LIMITX™, AVERSION® and IMPEDE® Technologies were \$4.0 million in the twelve months ended December 31, 2016, compared to \$2.6 million in the same period in 2015. These expenses were \$0.8 million in the fourth quarter 2016, compared to \$0.7 million for the same period in 2015.

Selling, marketing, general and administrative expenses were \$6.5 million in the twelve months ended December 31, 2016, versus \$9.0 million in the same period last year. These expenses were \$1.1 million in the fourth quarter 2015, versus \$2.6 million in the same period last year. The decrease in these expenses in 2016 were primarily associated with reductions in NEXAFED selling and marketing expenses as well as certain patent litigation costs.

At December 31, 2016, the Company had unrestricted cash and cash equivalents totaling \$2.7 million (after deducting the \$2.5 million compensating balance requirement required under the Oxford Loan Agreement) and \$5.5 million in term debt financing.

Conference Call Information

Acura Pharmaceuticals, Inc. will host a conference call on Monday, April 3, 2017 at 8:30 a.m. ET to discuss the results.

To participate in the live conference call, please dial 877-397-0286 (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is 3811250. A replay of the call will be available beginning April 3, 2017 and ending on April 13, 2017 by dialing 888-203-1112 (647-436-0148 in Canada). The replay participant code is 3811250.

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.

NEXAFED® and NEXAFED® Sinus, which are pseudoephedrine containing products, 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;
 - the expected results of clinical studies relating to LTX-04 or any successor product candidate, the date by which such study results will be available and whether LTX-04 or any successor product candidate 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 or any successor product candidate to provide an efficacious level of drug when one or two tablets are taken;
 - whether we will be able to reformulate LTX-04 or any successor product candidate to improve its abuse deterrent performance;
 - whether the extent to which products formulated with the LIMITX technology deter abuse will be determined sufficient by the FDA to support approval or labelling describing abuse deterrent features;
 - whether our LIMITX technology can be expanded into extended-release formulations;
 - our and our licensee’s ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
 - our and our licensee’s ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
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- the market acceptance of, timing of commercial launch and competitive environment for any of our 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;
- 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 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 whether we 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:

Acura Investor Relations, investors@acurapharm.com, 847-705-7709

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

| | (audited) December 31, 2016 | (audited) December 31, 2015 |
|---|-----------------------------------|-----------------------------------|
| Assets, current | \$ 5,910 | \$ 14,135 |
| Property, plant and equipment, net | 867 | 1,013 |
| Other assets | 1,431 | 1,813 |
| Total assets | \$ 8,208 | \$ 16,961 |
| Liabilities, current | \$ 1,111 | \$ 924 |
| Debt, current | 2,376 | 2,320 |
| Debt, non-current portion - net of discount of \$98 and \$193 and debt issuance costs of \$47 and \$97 at 2016 and 2015 | 2,979 | 5,430 |
| Accrued interest, non-current portion | 559 | 387 |
| Stockholders' equity | 1,183 | 7,900 |
| Total liabilities and stockholders' equity | \$ 8,208 | \$ 16,961 |

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

| | (audited) | | (unaudited) | |
|---|----------------------------------|------------|---------------------------------|-----------|
| | Twelve Months Ended December 31, | | Three Months Ended December 31, | |
| | 2016 | 2015 | 2016 | 2015 |
| Revenues: | | | | |
| License fee revenue | \$ 3,500 | \$ 5,250 | \$ 3,500 | \$ - |
| Milestone revenue | - | 2,500 | - | 2,500 |
| Collaboration revenue | 392 | 170 | 85 | 75 |
| Royalty revenue | 149 | 5 | 63 | 5 |
| Product sales, net | 423 | 662 | 117 | 99 |
| Total revenues, net | 4,464 | 8,587 | 3,765 | 2,679 |
| Cost and expenses: | | | | |
| Cost of sales (excluding inventory reserves) | 451 | 656 | 142 | 102 |
| Inventory reserve expense for write-downs (write-ups) | 26 | 330 | - | (4) |
| Research and development | 4,028 | 2,608 | 770 | 701 |
| Selling, marketing, general and administrative | 6,516 | 8,994 | 1,124 | 2,590 |
| Total cost and expenses | 11,021 | 12,588 | 2,036 | 3,389 |
| Operating (loss) income | (6,557) | (4,001) | 1,729 | (710) |
| Non-operating income (expense): | | | | |
| Investment income | 60 | 166 | 1 | 56 |
| Interest expense | (893) | (1,157) | (196) | (265) |
| Other income | 2 | 3 | - | 3 |
| Total other expense, net | (831) | (988) | (195) | (206) |
| (Loss) income before provision for income taxes | (7,388) | (4,989) | 1,534 | (916) |
| Provision for income taxes | - | - | - | - |
| Net (loss) income | \$ (7,388) | \$ (4,989) | \$ 1,534 | \$ (916) |
| Other comprehensive income (loss): | | | | |
| Unrealized gains (losses) on marketable securities | 65 | (52) | - | (54) |
| Comprehensive (loss) income | \$ (7,323) | \$ (5,041) | \$ 1,534 | \$ (970) |
| (Loss) income per share: | | | | |
| Basic | \$ (0.62) | \$ (0.46) | \$ 0.13 | \$ (0.08) |
| Diluted | \$ (0.62) | \$ (0.46) | \$ 0.13 | \$ (0.08) |
| Weighted average number of shares outstanding: | | | | |
| Basic | 11,870 | 10,796 | 11,902 | 11,836 |
| Diluted | 11,870 | 10,796 | 11,902 | 11,836 |