ACURA PHARMACEUTICALS, INC

FORM 8-K
(Current report filing)

Filed 05/12/17 for the Period Ending 05/12/17

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

May 12, 2017
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 (17 CFR 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On May 12, 2017 we issued a press release disclosing the financial results for our first quarter ended March 31, 2017. A copy of our press release is being furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	Description
99.1	Press Release dated May 12, 2017 announcing financial results for the first quarter ended March 31, 2017

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 12, 2017

Exhibit Index

Exhibit Number	Description
99.1	Press Release dated May 12, 2017 announcing financial results for the first quarter ended March 31, 2017

Exhibit 99.1

Acura Pharmaceuticals Announces
First Quarter 2017 Financial Results

Palatine, IL - (May 12, 2017) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR) , a specialty pharmaceutical company innovating abuse deterrent drugs, announced today financial results for the first quarter ended March 31, 2017.

The Company reported net income of $0.4 million for the first quarter 2017 or $0.03 per diluted share, compared to net loss of $3.4 million or $0.28 per diluted share for the same period in 2016. Revenues for the quarter were $2.7 million compared to $0.2 million in the first quarter of 2016 reflecting the $2.5 million payment arising from the NEXAFED® and NEXAFED® SINUS licensing agreement with MainPointe Pharmaceuticals LLC.

Research and development expenses associated with product candidates utilizing the Company's LIMITX™, AVERSION® and IMPEDE® Technologies were $0.7 million and $1.0 million in the first quarter 2017 and 2016, respectively. Selling, marketing, general and administrative expenses were $1.3 million in first quarter 2017 compared to $2.2 million in the first quarter 2016. Selling expenses primarily consisted of advertising and marketing activities for NEXAFED® and NEXAFED® SINUS. As of March 16, 2017, NEXAFED® and NEXAFED® SINUS are marketed and sold by MainPointe Pharmaceuticals LLC.

As of April 30, 2017, our outstanding secured term debt was $4.8 million and our cash and cash equivalents was $3.0 million (after deduction of our $2.5 million compensating balance requirement under our term debt financing). The Company expects that its unrestricted cash will be sufficient to fund the development of its products and related operating expenses only through mid-2017. The Company must raise additional funding or enter into a license or collaboration agreement with third parties providing payments to the Company in order to continue operations, of which no assurance can be given. Investors in the Company's common stock are encouraged to review the Company's Form 10-Q filing made with the Securities and Exchange Commission on May 12, 2017, including the discussion under the captions "Liquidity and Capital Resources" and "Risk Factors".

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, including the development of our products utilizing our LIMITX and IMPEDED Technologies;
- our ability to remain in compliance with our obligations under our term loan with Oxford Finance LLC, or to obtain a waiver from Oxford Finance LLC for our failure to comply with our covenants contained in such term loan agreement;
- 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 we will be able to reformulate LTX-04 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;
- 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 licensees’ 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;
- 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;
- whether the FDA will agree with or accept the results of our studies for our product candidates;
- 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," "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.

Contact:
Acura Investor Relations, investors@acurapharm.com , (847) 705-7709

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

	(unaudited) March 31, 2017	(audited) December 31, 2016
Assets		
Current assets - restricted	$ 2,500	$ 2,500
Current assets	4,238	3,410
Property, plant and equipment, net	739	867
Other assets	1,379	1,431
Total assets	$ 8,856	$ 8,208
Liabilities		
Current liabilities	$ 1,605	$ 1,111
Debt - current	2,798	2,376
Accrued interest – non-current portion	598	559
Debt - non-current portion, net of discounts	2,142	2,979
Total liabilities	$ 7,143	$ 7,025
Stockholders' equity	$ 1,713	$ 1,183
Total liabilities and stockholders' equity	$ 8,856	$ 8,208

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

	(unaudited) Three Months Ended March 31, 2017	2016
Revenues:		
License fee revenue	$ 2,500	$ -
Collaboration revenue	36	100
Royalty revenue	74	17
Product sales, net	107	107
Total revenues, net	2,717	224
Operating expenses:		
Cost of sales	128	102
Research and development	711	1,014
Selling, marketing, general and administrative	1,296	2,246
Total operating expenses	2,135	3,362
Operating income (loss)	582	(3,138)
Non-operating income (expense):		
Investment income	1	27
Interest expense	(178)	(249)
Other expense	-	(24)
Total other expense	(177)	(246)
Income (loss) before income taxes	405	(3,384)
Provision for income taxes	-	-
Net income (loss)	$ 405	$ (3,384)
Other comprehensive income:		
Unrealized gains on securities	-	70
Comprehensive income (loss)	$ 405	$ (3,314)
Income (loss) per share:		
Basic	$ 0.03	$ (0.28)
Diluted	$ 0.03	$ (0.28)
Weighted average shares outstanding:		
Basic	11,907	11,837
Diluted	12,083	11,837