

ACURA PHARMACEUTICALS, INC

FORM 8-K (Current report filing)

Filed 11/13/17 for the Period Ending 11/13/17

Address	616 N. NORTH COURT, SUITE 120 PALATINE, IL, 60067
Telephone	847-705-7709
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SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
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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 13, 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))

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 November 13, 2017 we issued a press release disclosing the financial results for our third quarter ended September 30, 2017. A copy of our press release is being furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

<u>ExhibitNumber</u>	<u>Description</u>
99.1	Press Release announcing financial results for the third quarter ended September 30, 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

Palatine, Illinois
Date: November 13, 2017

Exhibit Index

Exhibit Number

Description

[99.1](#)

[Press Release announcing financial results for the third quarter ended September 30, 2017](#)



Acura Pharmaceuticals Announces Third Quarter 2017 Financial Results

Palatine, IL – (November 13, 2017) - Acura Pharmaceuticals, Inc. (OTCQB: ACUR) , a specialty pharmaceutical company innovating abuse deterrent drugs, announced today financial results for the three and nine months ended September 30, 2017.

The Company reported a net loss of \$2.2 million or \$0.12 per diluted share for quarter ended September 30, 2017 compared to a net loss of \$2.3 million or \$0.19 per diluted share for the same period in 2016. For the nine months ended September 30, 2017 the Company reported net loss of \$3.9 million or \$0.27 per diluted share, compared to net loss of \$8.9 million or \$0.75 per diluted share for the same period in 2016.

For the nine months ended September 30, 2017, the Company recorded \$2.5 million in license fee revenue 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 \$1.1 million in the third quarter 2017 compared to \$0.8 million in the same period in 2016. These expenses were \$2.8 million for the nine months ended 2017 compared to \$3.3 million for the same period in 2016.

Selling, marketing, general and administrative expenses were \$1.1 million in the third quarter 2017 compared to \$1.3 million in the same period in 2016. These expenses were \$3.4 million for the nine months ended 2017 compared to \$5.4 million in the same period in 2016. The decrease in these expenses in 2017 were primarily associated with reductions in NEXAFED product line selling and marketing expenses as well as in patent litigation costs.

At November 10, 2017, the Company had \$3.5 million in cash and cash equivalents and \$3.2 million in term debt financing.

About Acura Pharmaceuticals

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research and development of technologies and products intended to address medication abuse and misuse, utilizing its proprietary LIMITx™, AVERSION® and IMPEDE® Technologies. Our LIMITx™ and AVERSION® Technologies are intended to address methods of product tampering associated with opioid abuse while our IMPEDE® Technology is directed at minimizing the extraction and conversion of pseudoephedrine 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 that utilize the IMPEDE Technology, are marketed in the U.S. by our partner MainPointe Pharmaceuticals LLC.

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;
 - 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-03 or any successor product candidate, the date by which such studies will be complete and the results will be available and whether LTX-03 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-03 or any successor product candidate, to provide an efficacious level of drug when one or two tablets are taken;
 - whether a reformulated Limitx formulation that achieves an efficacious level of drug will continue to demonstrate acceptable abuse deterrent performance;
 - whether we will be able to reformulate LTX-03 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;
 - the pricing and price discounting that may be offered by Egalet for OXAYDO;
 - the results of our development of our LIMITx Technology;
 - our or 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;
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- 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,” “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)

	(unaudited) September 30, 2017	(audited) December 31, 2016
Assets – current	\$ 4,787	\$ 3,410
Assets – restricted	-	2,500
Property, plant and equipment, net	699	867
Other assets	1,783	1,431
Total assets	\$ 7,269	\$ 8,208
Liabilities – current	\$ 1,382	\$ 1,111
Debt – current	2,917	2,376
Debt – non-current portion, net of discounts	702	2,979
Accrued interest – non-current portion	668	559
Stockholders' equity	1,600	1,183
Total liabilities and stockholders' equity	\$ 7,269	\$ 8,208

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

	(unaudited) Three Months Ended September 30,		(unaudited) Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
License fee revenue	\$ -	\$ -	\$ 2,500	\$ -
Collaboration revenue	-	74	59	307
Royalty revenue	83	39	226	86
Product sales, net	-	105	107	306
Total revenues, net	83	218	2,892	699
Cost and expenses:				
Cost of sales (excluding inventory provisions)	-	108	128	309
Inventory provisions	-	-	-	26
Research and development	1,077	841	2,808	3,258
Selling, marketing, general and administrative	1,068	1,338	3,427	5,392
Total cost and expenses	2,145	2,287	6,363	8,985
Operating loss	(2,062)	(2,069)	(3,471)	(8,286)
Non-operating income (expense):				
Interest and investment income	1	11	3	59
Interest expense	(139)	(215)	(476)	(697)
Other income	-	23	-	2
Total other expense, net	(138)	(181)	(473)	(636)
Loss before provision for income taxes	(2,200)	(2,250)	(3,944)	(8,922)
Provision for income taxes	-	-	-	-
Net loss	\$ (2,200)	\$ (2,250)	\$ (3,944)	\$ (8,922)
Other comprehensive income:				
Unrealized (losses) gains on marketable securities	-	(26)	-	65
Comprehensive loss	\$ (2,200)	\$ (2,276)	\$ (3,944)	\$ (8,857)
Loss per share:				
Basic	\$ (0.12)	\$ (0.19)	\$ (0.27)	\$ (0.75)
Diluted	\$ (0.12)	\$ (0.19)	\$ (0.27)	\$ (0.75)
Weighted average number of shares outstanding:				
Basic	16,686	11,880	14,147	11,858
Diluted	16,686	11,880	14,147	11,858