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

Date of Report (Date of earliest event reported): **September 16, 2019**

ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as specified in its Charter)

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

(847) 705-7709
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value	ACUR	OTC – PINK

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):

☐ 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 September 16, 2019, Acura Pharmaceuticals, Inc. issued a press release announcing its financial results for its fourth quarter ended December 31, 2018. A copy of that press release and the attached financial schedules are attached as Exhibit 99.1 to this report and incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits

Exhibit Number	Description
99.1	Press Release of the Registrant dated September 16, 2019

SIGNATURE

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.

Date: September 16, 2019 .

ACURA PHARMACEUTICALS, INC

By: /s/ Peter A. Clemens
Peter A. Clemens
Senior Vice President & Chief Financial Officer

Exhibit 99.1

Acura Pharmaceuticals Announces Fourth Quarter 2018 and Full Year 2018 Financial Results

Palatine, IL – (September 16, 2019) - Acura Pharmaceuticals, Inc., a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and product candidates intended to mitigate the risk of outcomes associated with product misuse announced today financial results for the three and twelve months ended December 31, 2018.

The Company reported a net loss of $3.8 million or ($0.18) per diluted share for 2018 compared to a net loss of $5.7 million or ($0.36) per diluted share for 2017. For the fourth quarter 2018 the Company reported net income of $8 thousand or $0.00 per diluted share, compared to a net loss of $1.7 million or (0.08) per diluted share for the same period in 2017.

The Company recorded royalty revenue of $0.4 million and $0.3 million for the twelve month periods ended December 31, 2018 and 2017, respectively, and $0.1 million and $0.1 million in royalty revenue for the three months ended December 31, 2018 and 2017, respectively.

Research and development costs and expenses from our development facility and product candidates were $1.8 million for the twelve month period ended December 31, 2018, compared to $3.7 million for the same period in 2017. These expenses were $0.1 million for the fourth quarter 2018, compared to $0.9 million for the same period in 2017.

General and administrative expenses were $2.6 million for the twelve month period ended December 31, 2018, versus $4.3 million in the same period last year which includes selling and marketing expenses we incurred with respect to the Nexafed product line during the first half of 2017. We out-licensed this product line in March of 2017 and discontinued selling efforts at that time. General and administrative expenses were $0.2 million for the fourth quarter 2018, compared to $0.9 million for the same period in 2017.

The Company delayed filing the Form 10-K for 2018 pending the completion of the License, Development and Commercialization Agreement (the "Agreement") with Abuse Deterrent Pharmaceuticals, LLC ("AD Pharma") for our lead product candidate, LTX-03 (hydrocodone bitartrate with acetaminophen immediate-release tablets utilizing Acura's patented LIMITx™ technology). We entered into the Agreement at June 28, 2019. The Agreement is described in our press release dated July 2, 2019 and our Form 8-K filed July 5, 2019. This Agreement provided the capital necessary to fund ongoing operations, including the expense associated with our annual audit and quarterly SEC filings. The Company plans to file the first and second quarter 2019 Form 10-Qs as quickly as possible and then return to timely submission of our required SEC filings.

As of September 12, 2019, the Company had cash of $0.75 million. Additionally, the Agreement provides that AD Pharma will pay the Company monthly license payments of $350,000 from July 2019 through November 2020, subject to AD Pharma's right to terminate such payments, and pay all outside development costs for LTX-03. We expect these amounts will fund operations through 2020.

About Acura Pharmaceuticals

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and product candidates intended to mitigate the risk of outcomes associated with product misuse. The Company has three proprietary technologies: LIMITx™ Technology, AVERSION® Technology and IMPEDE® Technology.

LIMITx™ Technology utilizes acid neutralizing ingredients to precisely control gastric acidity, which limits the release of drug from tablets and its subsequent systemic absorption when multiple tablets are ingested. LIMITx™ Technology is useful with products whose side effect risks can be mitigated by limiting exposure to a drug in overdose situations.

AVERSION® Technology, used in the FDA approved drug OXAYDO® (oxycodone HCl) marketed by Zyla Life Sciences, utilizes polymers designed to limit the abuse of the product by nasal snorting and injection. AVERSION® Technology is also licensed to KemPharm for use in certain of their products.

IMPEDE® Technology, used in NEXAFED® (pseudoephedrine HCl) and NEXAFED® Sinus (pseudoephedrine HCl/acetaminophen) marketed by MainPointe Pharmaceuticals, utilizes polymers and other ingredients to disrupt the extraction and processing of pseudoephedrine from the tablets into 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 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;
- whether our licensees will terminate licenses prior to commercialization;
- the expected results of clinical studies relating to LTX-03, IMPEDE® or any successor product candidate, the date by which such studies will complete and the results will be available and whether any product candidate will ultimately receive FDA approval;
- the ability of LTX-03 single tablets to achieve bioequivalence or to demonstrate efficacy in a clinical study;
- whether our licensing partners will exercise their options to additional products;
- whether LIMITx™ Technology will retard the release of opioid active ingredients as dose levels increase;
- whether the extent to which products formulated with the LIMITx™ Technology mitigate respiratory depression risk will be determined sufficient by the FDA;
- our and our licensee's ability to successfully launch and commercialize our products and technologies;
- 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;
- 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 adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support an NDA and FDA approval of our product candidates;
- changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;
- 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 technologies; and
- whether our product candidates will ultimately perform as intended in commercial settings.

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)

	(audited) December 31, 2018	(audited) December 31, 2017
Assets - current	$ 461	$ 2,566
Property, plant and equipment, net	606	679
Other assets	1,085	1,359
Total assets	$ 2,152	$ 4,604
Liabilities - current	$ 1,435	$ 1,237
Accrued interest - current portion	-	700
Debt – current, net	-	2,694
Accrued interest to related party, non-current portion	110	-
Debt to related party - non-current portion, net	4,224	-
Stockholders' deficit	(3,617)	(27)
Total liabilities and stockholders' deficit	$ 2,152	$ 4,604

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

	(audited) Twelve Months Ended December 31,		(unaudited) Three Months Ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenues:				
License fee revenue	$ -	$ 2,500	$ -	$ -
Collaboration revenue	-	59	-	-
Royalty revenue	410	300	63	74
Total revenues, net	410	2,966	63	74
Cost and expenses:				
Cost of sales (excluding inventory provisions)	-	128	-	-
Research and development	1,759	3,721	83	913
Selling, marketing, general and administrative	2,566	4,342	234	915
Total cost and expenses	4,325	8,191	317	1,828
Operating (loss) income	(3,915)	(5,225)	(254)	(1,754)
Non-operating income (expense):				
Interest expense, net	(223)	(592)	(34)	(119)
Other income	296	-	296	-
Total other income (expense), net	73	(592)	262	(119)
(Loss) income before income taxes	(3,842)	(5,817)	8	(1,873)
Provision for income taxes	-	(135)	-	(135)
Net (loss) income	$ (3,842)	$ (5,682)	8	$ (1,738)
Loss per share:				
Basic	$ (0.18)	$ (0.36)	$ (0.00)	$ (0.08)
Diluted	$ (0.18)	$ (0.36)	$ (0.00)	$ (0.08)
Weighted average number of shares outstanding:				
Basic	21,146	15,903	21,280	20,998
Diluted	21,146	15,903	21,280	20,998