
**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): **February 28, 2020**

ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as specified in its Charter)

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**

(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 February 28, 2020, Acura Pharmaceuticals, Inc. issued a press release announcing its financial results for its third quarter ended September 30, 2019. 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of the Registrant dated February 28, 2020

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: February 28, 2020

ACURA PHARMACEUTICALS, INC.

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



**Acura Pharmaceuticals Announces
Third Quarter 2019 Financial Results**

Palatine, IL – (February 28, 2020) - 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 nine months ended September 30, 2019.

The Company reported an operating income of \$0.3 million for the third quarter 2019 compared to an operating loss of \$1.0 million for the same period in 2018. For the nine months ended September 30, 2019, the Company reported an operating loss of \$1.0 million compared to an operating loss of \$3.7 million for the same period in 2018.

The Company reported net income of \$0.2 million or \$0.00 per diluted share for the third quarter 2019 compared to a net loss of \$1.1 million or \$0.05 per diluted share for the same period in 2018. Likewise, for the nine months ended September 30, 2019, the Company reported a net loss of \$3.9 million or \$0.16 per diluted share compared to a net loss of \$3.9 million or \$0.18 per diluted share for the same period in 2018. In the second quarter of 2019 the Company recorded a one-time expense of \$2.6 million due to the extinguishment of debt associated with a transaction with Abuse Deterrent Pharma, LLC.

For the nine months ended September 30, 2019, the Company recorded \$0.3 million in royalty revenue as compared to \$0.3 million for the same period in 2018. Under the license agreement with Abuse Deterrent Pharma, LLC, the Company recorded \$1.0 million in license fees and \$0.1 million in collaboration revenue for the nine month period ended September 30, 2019.

Research and development expense was \$1.0 million for the nine month period ended September 30, 2019, compared to \$1.7 million for the same period in 2018. These expenses were \$0.5 million for the third quarter 2019, compared to \$0.6 million for the same period in 2018.

General and administrative expense was \$1.4 million for the nine month period ended September 30, 2019, versus \$2.3 million in the same period last year. These expenses were \$0.6 million for the third quarter 2019, compared to \$0.5 million for the same period in 2018.

As of February 28, 2020, the Company had cash of approximately \$1.0 million. On June 28, 2019, we entered into a License, Development and Commercialization Agreement (the "Agreement") with Abuse Deterrent Pharma, LLC ("AD Pharma") for our lead product candidate, LTX-03 (hydrocodone bitartrate with acetaminophen immediate-release tablets utilizing Acura's patented LIMITx™ technology). The Agreement is described in our press release dated July 2, 2019 and our Form 8-K filed July 5, 2019. This 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 they will pay the Company for the outside development costs of LTX-03. We expect these amounts will fund our 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)

	(unaudited) September 30, 2019	December 31, 2018
Assets - current	\$ 1,015	\$ 461
Property, plant and equipment, net	555	606
Other assets	896	1,085
Total assets	<u>\$ 2,466</u>	<u>\$ 2,152</u>
Liabilities - current	\$ 1,267	\$ 1,435
Accrued interest to related party – non current	116	110
Debt to related party, net – non current	6,000	4,224
Stockholders' deficit	(4,917)	(3,617)
Total liabilities and stockholders' deficit	<u>\$ 2,466</u>	<u>\$ 2,152</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Royalties	\$ 172	\$ 73	\$ 285	\$ 347
Collaboration	102	-	102	-
License fees	1,050	-	1,050	-
Total revenues	<u>1,324</u>	<u>73</u>	<u>1,437</u>	<u>347</u>
Expenses:				
Research and development	465	549	1,040	1,676
General and administrative	548	543	1,391	2,332
Total expenses	<u>1,013</u>	<u>1,092</u>	<u>2,431</u>	<u>4,008</u>
Operating income (loss)	311	(1,019)	(994)	(3,661)
Loss on debt extinguishment	-	-	(2,600)	-
Interest expense, net	(111)	(76)	(335)	(189)
Income (loss) before provision for income taxes	200	(1,095)	(3,929)	(3,850)
Provision for income taxes	-	-	-	-
Net income (loss)	<u>\$ 200</u>	<u>\$ (1,095)</u>	<u>\$ (3,929)</u>	<u>\$ (3,850)</u>
Net income (loss) per share:				
Basic	\$ 0.00	\$ (0.05)	\$ (0.16)	\$ (0.18)
Diluted	\$ 0.00	\$ (0.05)	\$ (0.16)	\$ (0.18)
Weighted average number of shares outstanding:				
Basic	31,593	21,168	25,023	21,101
Diluted	<u>31,593</u>	<u>21,168</u>	<u>25,023</u>	<u>21,101</u>