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): **November 16, 2020**

ACURA PHARMACEUTICALS, INC.

(Exact Name of Registrant as specified in its Charter)

New York	**1-10113**	**11-0853640**
(State or other jurisdiction of incorporation or organization)	(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)

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 per share	ACUR	OTCQB Market

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 (17CFR 240.14d-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 November 16, 2020, Acura Pharmaceuticals, Inc. issued a press release announcing its financial results for the three and nine months ended September 30, 2020. 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 November 16, 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: November 16, 2020

ACURA PHARMACEUTICALS, INC.

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

Exhibit 99.1

Acura Pharmaceuticals Announces
Third Quarter 2020 Financial Results

Palatine, IL – (November 16, 2020) - Acura Pharmaceuticals, Inc. (OTCQB: ACUR), 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, 2020.

The Company reported revenues of $410 thousand and an operating loss of $565 thousand for the third quarter 2020 compared to revenues of $1.3 million and an operating income of $311 thousand for the same period in 2019. For the nine months ended September 30, 2020, the Company reported revenues of $2.9 million and an operating loss of $627 thousand compared to revenues of $1.4 million and an operating loss of $1.0 million for the same period in 2019. Included in expenses for the nine months ended September 30, 2020 was a one-time charge of $668 thousand to recognize an impairment in our Aversion intangible asset.

The Company reported net loss of $678 thousand or $0.02 per diluted share for the third quarter 2020 compared to a net income of $200 thousand or $0.00 per diluted share for the same period in 2019. The Company reported net loss of $965 thousand or $0.03 per diluted share for the nine months ended September 30, 2020 compared to a net loss of $3.9 million or $0.16 per diluted share for the same period in 2019.

Revenue for the third quarter 2020 included $300 thousand in license fees derived from the license agreement with Abuse Deterrent Pharma, LLC (“AD Pharma”) that was amended in October 2020. The Company also recorded royalty revenue of $14 thousand and $172 thousand, respectively, for the third quarter 2020 and 2019. Revenue for the nine month period ended September 30, 2020 included $2.4 million in license fees derived from the license agreement with AD Pharma. The Company also recorded royalty revenue of $81 thousand and $285 thousand, respectively, for the nine month periods ended September 30, 2020 and 2019.

Research and development expense was $519 thousand for the third quarter 2020, compared to $465 thousand for the same period in 2019. Research and development expense was $1.4 million for the nine month period ended September 30, 2020, compared to $1.0 million for the same period in 2019. The expenses reported for these periods were for our research facility, primarily associated with development of LTX-03.

General and administrative expense was $456 thousand for the third quarter 2020, versus $548 thousand in the same period last year. General and administrative expense was $1.5 million (excluding the one-time $668 thousand charge for the impairment of the intangible asset) for the nine month period ended September 30, 2020, versus $1.4 million in the same period last year.

As of November 12, 2020, the Company had a cash balance of approximately $1.0 million.

On June 28, 2019, the Company entered into a License, Development and Commercialization Agreement (the “Agreement”) with AD Pharma for our lead product candidate, LTX-03 (hydrocodone bitartrate with acetaminophen immediate-release tablets utilizing Acura’s patented LIMITx™ technology). The Agreement was amended in October 2020. Included in the amended Agreement is the requirement that the NDA for LTX-03 be accepted by the FDA by July 31, 2021 or AD Pharma has the option to terminate the amended Agreement and take ownership of the LIMITx intellectual property. Importantly, such failure to meet this date will be an event of default under their $6.0 million note to Acura. The amended Agreement provides a monthly license payment of $350 thousand from AD Pharma to us for a period from inception up to April 2020 at which time the payment is $200 thousand per month through July 2021. AD Pharma will pay directly for or reimburse Acura to the extent Acura pay’s for, all out-of-pocket development expenses. We have received the required monthly license payments for June thru October 2020 from AD Pharma. The Agreements are more fully described in our press releases dated July 2, 2019 and October 28, 2020 as well as in our Form 8-Ks filed July 5, 2019 and October 29, 2020.

About Acura Pharmaceuticals

Acura Pharmaceuticals is an innovative drug delivery company engaged in the research, development and commercialization of technologies and products intended to address safe use of medications. 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 Assertio Holdings Inc., 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 obtain funding for our continuing operations, including the development of our products utilizing our LIMITx™ and Impede® technologies;
- whether we will receive FDA acceptance for an NDA for LTX-03 by the target date;
- whether our licensing partners will develop any additional products and utilize Acura for such development;
- the expected results of clinical studies relating to LTX-03, a LIMITx hydrocodone bitartrate and acetaminophen combination product, 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;
- our business could be adversely affected by health epidemics in regions where third parties for which we rely, as in CROs or CMOs, have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely;
- whether LIMITx will retard the release of opioid active ingredients as dose levels increase;
- whether the extent to which products formulated with the LIMITx Technology deter abuse or overdose will be determined sufficient by the FDA to support approval or labelling describing safety and/or 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 results and timing of our development of our LIMITx Technology, including, but not limited to, the submission of a New Drug Application and/or FDA filing acceptance;
- 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;
- 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 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 “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “indicate,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “seek”, “should,” “suggest,” “target,” “will,” “would” and similar expressions that convey the uncertainty of future events or outcomes are used to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to known and unknown risks and uncertainties. Such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, some of which are beyond the control of Acura. Given these uncertainties, you should not place undue reliance on these forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We discuss many of these risks in greater detail in our filings with the Securities and Exchange Commission. While Acura may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to update or revise any forward-looking statements contained in this press release whether as a result of new information or future events, except as may be required by applicable law.

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

	(unaudited) September 30, 2020	(audited) December 31, 2019
Assets – current	$ 1,623	$ 1,178
Property, plant and equipment, net	498	540
Other assets	78	844
Total assets	$ 2,199	$ 2,562
Other liabilities - current	$ 1,021	$ 1,074
Loan under CARES Act - current	164	-
Loan under CARES Act - noncurrent	105	-
Accrued interest to related party – noncurrent	566	229
Debt to related party – noncurrent	6,000	6,000
Stockholders' deficit	(5,657)	(4,741)
Total liabilities and stockholders' deficit	$ 2,199	$ 2,562

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Royalties	$ 14	$ 172	$ 81	$ 285
Collaboration	96	102	148	102
License fees	300	1,050	2,400	1,050
Product sales, net of allowance		-	223	-
Total revenues	410	1,324	2,852	1,437
Operating expenses:				
Research and development	519	465	1,351	1,040
General and administrative	456	548	2,128	1,391
Total operating expenses	975	1,013	3,479	2,431
Operating income (loss)	(565)	311	(627)	(994)
Loss on debt extinguishment	-	-	-	(2,600)
Interest expense – related party	(113)	(111)	(338)	(335)
Income (loss) before provision for income taxes	(678)	200	(965)	(3,929)
Provision for income taxes	-	-	-	-
Net income (loss)	$ (678)	$ 200	$ (965)	$ (3,929)
Net income (loss) per share:				
Basic	$ (0.02)	$ 0.00	$ (0.03)	$ (0.16)
Diluted	$ (0.02)	$ 0.00	$ (0.03)	$ (0.16)
Weighted average number of shares outstanding:				
Basic	32,336	31,593	32,304	25,023
Diluted	32,336	31,593	32,304	25,023