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): **March 31, 2021**

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 March 31, 2021, Acura Pharmaceuticals, Inc. issued a press release announcing its financial results for its three and twelve months ended December 31, 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 March 31, 2021

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: April 1, 2021

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 and Full Year 2020 Financial Results

Palatine, IL – (March 31, 2021) - Acura Pharmaceuticals, Inc. (OTCQB: ACUR), an innovative drug delivery company engaged in the research, development and commercialization of technologies and products intended to address safe use of medications, announced today financial results for the three and twelve months ended December 31, 2020.

The Company reported an operating loss of $0.1 million for the fourth quarter 2020 compared to an operating income of $0.3 million for the same period in 2019. For the twelve months ended December 31, 2020, the Company reported an operating loss of $0.8 million compared to an operating loss of $0.7 million for the same period in 2019. Included in expenses for the results for 2020 was a one-time charge of $668 thousand to recognize an impairment in our Aversion intangible asset.

The Company reported net loss of $0.1 million or $0.01 per diluted share for the fourth quarter 2020 compared to net income of $0.2 million or $0.00 per diluted share for the same period in 2019. For the twelve months ended December 31, 2020, the Company reported a net loss of $1.2 million or $0.04 per diluted share compared to a net loss of $3.8 million or $0.14 per diluted share for the same period in 2019. Included in the results for 2019 is a one-time expense of $2.6 million due to the extinguishment of debt associated with the June 2019 transaction with Abuse Deterrent Pharma, LLC.

For the twelve months ended December 31, 2020, the Company recorded $3.0 million in license fees, $0.2 million in collaboration revenue and $0.1 million in royalty revenue. In 2019 the Company recorded $2.1 million in license fees, $0.2 million in collaboration revenue and $0.4 million in royalty revenue. Both the license fee revenue and the collaboration revenue are derived from the license agreement with Abuse Deterrent Pharma executed in June 2019 and amended in October 2020.

Research and development expense was $1.8 million for the twelve month period ended December 31, 2020, compared to $1.5 million for the same period in 2019. These expenses were $0.4 million for the fourth quarter 2020, compared to $0.5 million for the same period in 2019. The expenses for both years were primarily associated with development of LTX-03 under the license agreement with Abuse Deterrent Pharma.

General and administrative expense was $2.5 million for the twelve month period ended December 31, 2020, versus $1.9 million in the same period last year. These expenses were $0.4 million for the fourth quarter 2020, compared to $0.5 million for the same period in 2019.

As of March 30, 2021, the Company had a cash balance of approximately $350 thousand. AD Pharma is delinquent in the remittance of the required $200 thousand monthly license payments for December, 2020 thru March, 2021 as well as approximately $100 thousand of reimbursable LTX-03 development expenses. Failure to make these payments are an event of default under the Agreement, as amended. Based upon representations by AD Pharma, we anticipate receipt of these past due amounts by April 30, 2021 and payment obligations through July, 2021, although no assurance can be given.

On June 28, 2019, we entered into License, Development and Commercialization Agreement with Abuse Deterrent Pharma, LLC, which was amended in October 2020 (the "Agreement"). The Agreement grants AD Pharma exclusive commercialization rights for our lead product candidate, LTX-03 (hydrocodone bitartrate with acetaminophen immediate-release tablets utilizing Acura's patented LIMITx™ technology). Financial arrangements include monthly license payments to Acura by AD Pharma of $350,000 from inception through April 2020 and $200,000 thereafter until July 31, 2021 or FDA's acceptance of a New Drug Application ("NDA") for LTX-03 and reimbursement by AD Pharma of Acura's LTX-03 outside development expenses. Upon commercialization of LTX-03, Acura will be entitled to stepped royalties on sales and is eligible for certain sales related milestones. However, if the NDA application for LTX-03 is not accepted by the FDA by July 31, 2021, AD Pharma has the option of terminating the Agreement and taking ownership of the intellectual property. Acura currently expects the submission and FDA acceptance of the NDA to occur after July 31, 2021 and has notified AD Pharma of this revised timeline. Acura is currently in discussions with AD Pharma to amend the Agreement. There can be no assurance that AD Pharma will agree to extend the NDA filing acceptance date or that they will not take ownership of the intellectual property. The Agreement is 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. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products: LIMITx™ Technology, AVERSION® Technology and IMPEDE® Technology.

LIMITx™ Technology a development stage technology, is designed to retard the release of active drug ingredients when too many tablets are accidentally or purposefully ingested by neutralizing stomach acid with buffer ingredients but deliver efficacious amounts of drug when taken as a single tablet with a nominal buffer dose. In June 2019, we entered into License, Development and Commercialization Agreement, which was amended in October 2020 with Abuse Deterrent Pharma, LLC, a Kentucky limited liability company, a special purpose company representing a consortium of investors that will finance Acura's operations through July 2021 and reimburse us for development of LTX-03. AD Pharma has exclusive commercialization rights in the United States to LTX-03 as well as to LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam).

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 can renegotiate the date by which we are required to obtain FDA acceptance, currently July 31, 2021, for an NDA for LTX-03 by our Agreement with AD Pharma on which we depend to finance operations;
- 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 reduce respiratory depression will be determined sufficient by the FDA to support approval or labelling describing safety 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:
Acura Investor Relations
investors@acurapharm.com
847-705-7709

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

	(audited) December 31, 2020	(audited) December 31, 2019
Assets – current	$ 1,179	$ 1,178
Property, plant and equipment, net	484	540
Other assets	73	844
Total assets	$ 1,736	$ 2,562
Other liabilities - current	$ 680	$ 1,074
Loan under CARES Act - current	164	-
Accrued interest to related party – current	678	-
Convertible debt to related party – current	6,000	-
Loan under CARES Act – non current	105	-
Accrued interest to related party – non current	-	229
Convertible debt to related party – non current	-	6,000
Stockholders' deficit	(5,891)	(4,741)
Total liabilities and stockholders' deficit	$ 1,736	$ 2,562

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

	(unaudited) Three Months Ended December 31,		(audited) Twelve Months Ended December 31,	
	2020	2019	2020	2019
Revenues:				
Royalties	$ 28	$ 87	$ 109	$ 372
Collaboration – related party	90	83	238	185
License fees – related party	600	1,050	3,000	2,100
Product sales	-	-	223	-
Total revenues	718	1,220	3,570	2,657
Operating expenses:				
Research and development	430	465	1,781	1,505
General and administrative	419	486	2,547	1,877
Total operating expenses	849	951	4,328	3,382
Operating (loss) income	(131)	269	(758)	(725)
Loss on debt extinguishment	-	-	-	(2,600)
Interest expense	(112)	(114)	(450)	(449)
(Loss) income before provision for income taxes	(243)	155	(1,208)	(3,774)
Provision for income taxes	-	-	-	-
Net (loss) income	$ (243)	$ 155	$ (1,208)	$ (3,774)
Net (loss) income per share:				
Basic	$ (0.01)	$ 0.00	$ (0.04)	$ (0.14)
Diluted	$ (0.01)	$ 0.00	$ (0.04)	$ (0.14)
Weighted average number of shares outstanding:				
Basic	32,319	31,755	32,320	26,720
Diluted	32,319	31,755	32,320	26,720