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): **August 16, 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 August 16, 2021, Acura Pharmaceuticals, Inc. issued a press release announcing its second quarter ended June 30, 2021 financial results. 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 August 16, 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: August 17, 2021

ACURA PHARMACEUTICALS, INC.

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

Exhibit 99.1

Acura Pharmaceuticals Announces
Second Quarter 2021 Financial Results

Palatine, IL – (August 16, 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 six months ended June 30, 2021.

The Company reported revenues of $613 thousand and an operating loss of $300 thousand for the second quarter 2021 compared to revenues of $1.4 million and an operating income of $421 thousand for the same period in 2020. For the six months ended June 30, 2021, the Company reported revenues of $1.3 million and an operating loss of $446 thousand compared to revenues of $2.4 million and an operating loss of $0.1 million for the same period in 2020.

The Company reported net loss of $387 thousand or $0.01 per diluted share for the second quarter 2021 compared to a net income of $308 thousand or $0.01 per diluted share for the same period in 2020. The Company reported net loss of $646 thousand or $0.02 per diluted share for the six months ended June 30, 2021 compared to a net loss of $0.3 million or $0.01 per diluted share for the same period in 2020.

Revenue for the second quarter 2021 and 2020 included $600 thousand and $1.05 million, respectively, in license fees derived from the license agreement with Abuse Deterrent Pharma, LLC ("AD Pharma") that was amended in July 2021. The Company also recorded royalty revenue of $3 thousand and $34 thousand, respectively, for the second quarter 2021 and 2020. Revenue for the six month period ended June 30, 2021 and 2020 included $1.2 million and $2.1 million, respectively, in license fees derived from the license agreement with AD Pharma. The Company also recorded royalty revenue of $35 thousand and $67 thousand, respectively, for the six month periods ended June 30, 2021 and 2020.

Research and development expense was $390 thousand for the second quarter 2021, compared to $445 thousand for the same period in 2020. Research and development expense was $0.8 million for each of the six month periods ended June 30, 2021 and 2020. The expenses reported for these periods were for our research facility, primarily associated with development of LTX-03.

General and administrative expense was $523 thousand for the second quarter 2021, versus $548 thousand for the same period in 2020. General and administrative expense was $0.9 million for the six month period ended June 30, 2021, versus $1.7 million for the same period in 2020. Included in the expense for 2020 was a one-time $668 thousand charge for an impairment of an intangible asset.

In June 2021, we received notice of conversion from AD Pharma for the $6.0 million Promissory Note and approximately $877 thousand of accrued but unpaid interest. The principal and interest were converted into 42,984,375 shares of the Company's common stock. Effective with this conversion, the Promissory Note is retired. AD Pharma directly owns approximately 66% of our common stock at June 30, 2021.

In July 2021, we were notified by our bank that our 1st Loan under the Paycheck Protection Program of $269 thousand has been forgiven in its entirety.

As of August 13, 2021, the Company had a cash balance of approximately $220 thousand. AD Pharma is delinquent in remitting monthly license payments for May, 2021 thru July, 2021 which aggregates to $0.6 million and approximately $97 thousand of reimbursable LTX-03 development expenses. Failure to make these payments is an event of default under the license agreement with AD Pharma.

In June 2019, we entered into License, Development and Commercialization Agreement with Abuse Deterrent Pharma, LLC, which was amended in October 2020 and July 2021 ("AD Pharma Amended Agreement"). The AD Pharma Amended 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) as well as to LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam). The AD Pharma Amended Agreement required AD Pharma to pay us a monthly license payment of $350,000 for a period from inception up to April 2020 at which time the payment became $200,000 per month and ended on July 31, 2021, and to reimburse all our outside development costs for LTX-03. 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 February 28, 2022, AD Pharma has the option of terminating the Agreement and taking ownership of the intellectual property.

The AD Pharma Amended Agreement is more fully described in our press releases dated July 2, 2020, October 28, 2020, and July 26, 2021 as well as in our Form 8-Ks filed July 5, 2020, October 29, 2020, and July 28, 2021 and our Form 10-Ks filed March 31, 2020 and March 31, 2021.

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 2020, we entered into License, Development and Commercialization Agreement, which was amended in October 2021, with Abuse Deterrent Pharma, LLC, a Kentucky limited liability company and 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 fund or 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 licensees will terminate the license prior to commercialization;
- the expected results of clinical studies relating to LTX-03 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 develop any additional products and utilize Acura for such development;
- 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 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 “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) June 30, 2021	(audited) December 31, 2020
Assets – current	$ 1,309	$ 1,179
Property, plant and equipment, net	461	484
Other assets	126	73
Total assets	$ 1,896	$ 1,736
Other liabilities - current	$ 946	$ 680
Loan under CARES Act - current	164	164
Accrued interest to related party – current	-	678
Convertible debt to related party – current	-	6,000
Other liabilities – non current	33	-
Loan under CARES Act – non current	371	105
Stockholders' equity (deficit)	382	(5,891)
Total liabilities and stockholders' equity (deficit)	$ 1,896	$ 1,736

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Royalties	$ 3	$ 34	$ 35	$ 67
Collaboration – related party	10	44	22	52
License fees – related party	600	1,050	1,200	2,100
Product sales, net of allowance	-	223	-	223
Total revenues	613	1,351	1,257	2,442
Expenses:				
Research and development	390	445	795	832
General and administrative	523	485	908	1,672
Total expenses	913	930	1,703	2,504
Operating income (loss)	(300)	421	(446)	(62)
Interest expense – related party	(87)	(113)	(200)	(225)
Income (loss) before provision for income taxes	(387)	308	(646)	(287)
Provision for income taxes	-	-	-	-
Net income (loss)	$ (387)	$ 308	$ (646)	$ (287)
Net income (loss) per share:				
Basic	$ (0.01)	$ 0.01	$ (0.02)	$ (0.01)
Diluted	$ (0.01)	$ 0.01	$ (0.02)	$ (0.01)
Weighted average number of shares outstanding:				
Basic	42,889	32,304	37,707	32,287
Diluted	42,889	32,482	37,707	32,287