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): **June 30, 2023**

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	OTC Market – OTC Expert 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 (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

Acura Pharmaceuticals, Inc. announces fourth quarter and full year 2021 financial results.

The Company reported an operating loss of $0.2 million for the fourth quarter 2021 compared to an operating loss of $0.1 million for the same period in 2020. For the twelve months ended December 31, 2021, the Company reported an operating loss of $1.2 million compared to an operating loss of $0.8 million for the same period in 2020. 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 income of $29 thousand or $0.00 per diluted share for the fourth quarter 2021 compared to net loss of $0.2 million or $0.01 per diluted share for the same period in 2020. For the twelve months ended December 31, 2021, the Company reported a net loss of $0.9 million or $0.02 per diluted share compared to a net loss of $1.2 million or $0.04 per diluted share for the same period in 2020.

The 2021 results were positively affected by the SBA forgiveness of both of our Loans under the Paycheck Protection Program. Our 1st Loan of $269 thousand was forgiven in July 2021 and our 2nd Loan of $266 thousand was forgiven in October 2021.

The Company recorded royalty revenue of $30 thousand for the fourth quarter of 2021. Revenue for the fourth quarter 2020 included $600 thousand in license fees derived from the license agreement with Abuse Deterrent Pharma, LLC (“AD Pharma”), and royalty revenue of $28 thousand. For the twelve months ended December 31, 2021, the Company recorded $1.4 million in license fees and $0.1 million in royalty revenue. In 2020 the Company recorded $3.0 million in license fees, $0.2 million in collaboration revenue and $0.1 million in royalty revenue. Both the license fee revenue and the collaboration revenue were derived from the license agreement with AD Pharma.

Research and development expense was $1.5 million for the twelve month period ended December 31, 2021, compared to $1.8 million for the same period in 2020. These expenses were $0.3 million for the fourth quarter 2021, compared to $0.4 million for the same period in 2020. The expenses for both years were primarily associated with various development activities of LTX-03 under the license agreement with AD Pharma.

General and administrative expense was $1.3 million for the twelve month period ended December 31, 2021, versus $2.5 million in the same period last year. These expenses were $0.1 million benefit for the fourth quarter 2021, compared to $0.4 million expense for the same period in 2020.

As of June 29, 2023, the Company had a cash balance of approximately $165 thousand.

On June 28, 2019, we entered into License, Development and Commercialization Agreement with AD Pharma, which has been amended several times, and recently for amendment #6 on June 15, 2023 to extend the FDA’s acceptance of a New Drug Application (“NDA”) for LTX-03 (hydrocodone bitartrate with acetaminophen immediate-release tablets utilizing Acura’s patented LIMITx™ technology) to November 30, 2023 (“Agreement”).

The Agreement includes, among other items, the granting to AD Pharma, the exclusive commercialization rights for our lead product candidate, 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 November 30, 2023, AD Pharma has the option of terminating the Agreement and taking ownership of the intellectual property. The Agreement is more fully described in our press releases as well as our SEC filings under our Form 8-Ks, Form 10-Qs, and Form 10-Ks.

The financial schedules are attached as Exhibit 99.1 to this report and incorporated herein by reference.

Forward-Looking Statements

Statements in this Current Report 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, currently November 30, 2023;
- 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 "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.

Item 9.01 - Financial Statements and Exhibits

Exhibit Number	**Description**
99.1	Financial Statements of the Registrant for Fourth Quarter and Full Year 2021
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

SIGNATURES

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.

ACURA PHARMACEUTICALS, INC.

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

Date: June 30, 2023

Exhibit 99.1

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

	(audited) December 31, 2021	(audited) December 31, 2020
Assets – current	$ 372	$ 1,179
Property, plant and equipment, net	438	484
Other assets	50	73
Total assets	$ 860	$ 1,736
Other liabilities - current	$ 515	$ 680
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
Promissory note to related party – non current	150	-
Other liabilities – non current	17	-
Stockholders' equity (deficit)	178	(5,891)
Total liabilities and stockholders' equity (deficit)	$ 860	$ 1,736

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,	
	2021	2020	2021	2020
Revenues:				
Royalties	$ 30	$ 28	$ 132	$ 109
Collaboration from related party	6	90	31	238
License fees from related party	-	600	1,400	3,000
Product sales	-	-	-	223
Total revenues	36	718	1,563	3,570
Operating expenses:				
Research and development	344	430	1,524	1,781
General and administrative	(71)	419	1,253	2,547
Total operating expenses	273	849	2,777	4,328
Operating loss	(237)	(131)	(1,214)	(758)
Gain on forgiveness of loans under CARES Act	266	-	535	-
Interest expense to related party	-	(112)	(200)	(450)
Income (loss) before provision for income taxes	29	(243)	(879)	(1,208)
Provision for income taxes	-	-	-	-
Net income (loss)	$ 29	$ (243)	$ (879)	$ (1,208)
Net loss per share:				
Basic	$ (0.00)	$ (0.01)	$ (0.02)	$ (0.04)
Diluted	$ (0.00)	$ (0.01)	$ (0.02)	$ (0.04)
Weighted average number of shares outstanding:				
Basic	75,604	32,319	56,801	32,320
Diluted	75,604	32,319	56,801	32,320