UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2021

Or

☐ **TRANSACTION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ___ to____

Commission File Number 1-10113

Acura Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

New York	**11-0853640**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
616 N. North Court, Suite 120, Palatine, Illinois	**60067**
(Address of Principal Executive Offices)	*(Zip Code)*

*(Registrant's telephone number, including area code: (***847) 705-7709**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:
Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this charter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files):
Yes ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company.

☐ Large accelerated filer ☐ Accelerated filer
þ Non-accelerated filer þ Smaller reporting company ☐ 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: ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):
Yes o No ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	ACUR	OTCQB Market

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practical date:
Common Stock, $0.01 par value Shares outstanding as of May 14, 2021: 22,104,668

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FORM 10-Q FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2021

Unless otherwise indicated or the context otherwise requires, references to the "Company", "registrant", "we", "us" and "our" refer to Acura Pharmaceuticals Inc. and its subsidiary. The Acura logo is our trademark and Acura Pharmaceuticals is our registered trademark. All other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this Quarterly Report on Form 10-Q, appear with the trade name, trademark or service mark notice and then throughout the remainder of this Quarterly Report on Form 10-Q without the trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense.

Item 1. Financial Statements

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited; in thousands except par value)

	March 31, 2021	December 31, 2020
Assets:		
Cash	$ 361	$ 413
Royalty receivable	30	30
Collaboration revenue receivable from related party	104	197
License fee revenue receivable from related party	800	400
Prepaid expenses and other current assets	84	139
Total current assets	1,379	1,179
Property, plant and equipment, net (Note 6)	473	484
Intangible asset, net (Note 3)	66	73
Total assets	$ 1,918	$ 1,736
Liabilities:		
Accounts payable	$ 65	$ 31
Accrued expenses (Note 7)	664	631
Loans under CARES Act	164	164
Other current liabilities (Note 11)	-	18
Convertible debt to related party, net of discounts (Note 8)	6,000	6,000
Accrued interest to related party (Note 8)	791	678
Total current liabilities	7,684	7,522
Loans under CARES Act – noncurrent	371	105
Total liabilities	$ 8,055	$ 7,627
Commitments and contingencies		
Stockholders' deficit:		
Common stock - $0.01 par value per share; 100,000 shares authorized, 22,105 and 21,650 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	221	216
Additional paid-in capital	383,105	383,097
Accumulated deficit	(389,463)	(389,204)
Total stockholders' deficit	(6,137)	(5,891)
Total liabilities and stockholders' deficit	$ 1,918	$ 1,736

See accompanying notes to unaudited consolidated financial statements.

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

	Three months Ended March 31,	
	2021	2020
Revenues:		
Royalties	$ 32	$ 33
Collaboration from related party	12	8
License fees from related party	600	1,050
Total revenues	644	1,091
Operating expenses:		
Research and development	405	387
General and administrative	385	1,187
Total operating expenses	790	1,574
Operating loss	(146)	(483)
Interest expense (Note 8)	(113)	(112)
Loss before provision for income taxes	(259)	(595)
Provision for income taxes	-	-
Net loss	$ (259)	$ (595)
Net loss per share (Note 13):		
Basic	$ (0.01)	$ (0.02)
Diluted	$ (0.01)	$ (0.02)
Weighted average number of shares outstanding:		
Basic	32,464	32,270
Diluted	32,464	32,270

See accompanying notes to unaudited consolidated financial statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENT OF CHANGES IN ACCUMULATED STOCKHOLDERS' DEFICIT
(Unaudited; in thousands)

	Common Stock		Additional		
	Number of Shares	$0.01 Par Value	Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2021	21,650	$ 216	$ 383,097	$ (389,204)	$ (5,891)
Net loss	-	-	-	(259)	(259)
Net distribution of common stock pursuant to restricted stock unit award plan	405	4	9	-	13
Exercise of stock options	50	1	(1)	-	-
Balance at March 31, 2021	22,105	221	383,105	$ (389,463)	$ (6,137)

	Common Stock		Additional		
	Number of Shares	$0.01 Par Value	Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2020	21,300	$ 213	$ 383,042	$ (387,996)	$ (4,741)
Net loss	-	-	-	(595)	(595)
Non-cash share-based compensation	-	-	9	-	9
Net distribution of common stock pursuant to restricted stock unit award plan	350	3	19	-	22
Balance at March 31, 2020	21,650	216	383,070	$ (388,591)	$ (5,305)

See accompanying notes to unaudited consolidated financial statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited; in thousands)

	Three months Ended March 31,	
	2021	2020
Cash Flows from Operating Activities:		
Net loss	$ (259)	$ (595)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	11	15
Non-cash share-based compensation	-	9
Amortization of intangible asset	7	51
Impairment charge on intangible asset	-	668
Changes in assets and liabilities:		
Royalty receivable	-	52
Collaboration revenue receivable from related party	93	73
License fee receivable from related party	(400)	-
Prepaid expenses and other current assets	55	47
Accounts payable	34	(129)
Accrued expenses	33	46
Accrued interest on related party loans	113	112
Other current liabilities	-	(2)
Net cash (used in) provided by operating activities	(313)	347
Cash Flows from Financing Activities:		
Proceeds from distribution of restricted stock units	3	3
Statutory minimum payroll withholding taxes paid on the distribution of shares pursuant to RSU award plan	(8)	(2)
Proceeds from loan under CARES Act	266	-
Net cash provided by financing activities	261	1
Net (decrease) increase in cash	(52)	348
Cash at beginning of period	413	862
Cash at end of end of period	$ 361	$ 1,210
Supplemental Disclosures of Cash Flow Information:		
Cash interest payments on loan	$ -	$ -

See accompanying notes to unaudited consolidated financial statements.

NOTE 1 – OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principal Operations

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the "Company", "Acura", "We", "Us" or "Our") We are 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. Our Limitx™ Technology is being developed to minimize the risk of overdose, our Aversion® Technology is intended to address methods of abuse associated with opioid analgesics while our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine, or PSE, into methamphetamine. Oxaydo Tablets (oxycodone HCl, CII), which utilizes the Aversion Technology, is the first approved immediate-release oxycodone product in the United States with abuse deterrent labeling. Nexafed brand products utilize our Impede Technology.

- Limitx, 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. The exclusive commercialization rights in the United States to LTX-03 as well as to LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam) are licensed to Abuse Deterrent Pharma, LLC (See Note 3).

- Our Aversion Technology has been licensed to Assertio Holdings Inc. for use in Oxaydo® Tablets (oxycodone HCl, CII), and is the first approved immediate-release oxycodone product in the United States with abuse deterrent labeling. Oxaydo is currently approved by the FDA for marketing in the United States in 5mg and 7.5mg strengths (See Note 3).

- Our Impede Technology is used in Nexafed® Tablets (30mg pseudoephedrine HCl) and Nexafed® Sinus Pressure + Pain Tablets (30/325mg pseudoephedrine HCl and acetaminophen). We have licensed to MainPointe Pharmaceuticals, LLC (MainPointe), our Impede Technology in the United States and Canada to commercialize these Nexafed products (See Note 3). MainPointe subsequently assigned its interest in the license to Abuse Deterrent Pharma, LLC but continues to market the products.

Basis of Presentation, Liquidity and Substantial Doubt in Going Concern

The accompanying consolidated financial statements of the Company have been prepared assuming the Company will continue as a going concern and in accordance with generally accepted accounting principles in the United States of America. The going concern basis of presentation assumes that we will continue in operation one year after the date these financial statements are issued and we will be able to realize our assets and discharge our liabilities and commitments in the normal course of business. As of March 31, 2021, we had cash of $361 thousand, working capital deficit of $6.3 million and an accumulated deficit of $389.5 million. We had a loss from operations of $146 thousand and a net loss of $259 thousand for the three months ended March 31, 2021, and had a loss from operations of $758 thousand and a net loss of $1.2 million for the year ended December 31, 2020. We have suffered recurring losses from operations and have not generated positive cash flows from operations. We anticipate operating losses to continue for the foreseeable future.

On June 28, 2019 we announced a License, Development and Commercialization Agreement, as amended in October 2020 (the "AD Pharma Amended Agreement"), with Abuse Deterrent Pharma, LLC ("AD Pharma"), Currently, 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 continues through the earlier of July 31, 2021 or FDA's acceptance of a New Drug Application for LTX-03, and reimburse all our outside development costs for LTX-03.

On May 12, 2021 we received from AD Pharma, the December 2020 license fee payment of $200 thousand. AD Pharma is delinquent in remitting monthly license payments for January, 2021 thru May, 2021 which aggregates to $1.0 million and approximately $100 thousand of reimbursable LTX-03 development expenses. Failure to make these payments is an event of default under the AD Pharma Amended Agreement.

The AD Pharma Amended Agreement, requires the NDA for LTX-03 be accepted by the FDA by July 31, 2021 or AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property. Failure to meet this date is an event of default under the Company's $6.0 million convertible debt to AD Pharma. The AD Pharma Amended Agreement allows AD Pharma to terminate the AD Pharma Amended Agreement "for convenience". Acura currently expects the submission and FDA acceptance of the NDA for LTX-03 to occur after July 31, 2021. Acura intends to renegotiate the NDA filing acceptance date for LTX-03, of which no assurance can be given. Pending resolution of this matter, the $6.0 million convertible debt is presented as a current liability in our financial statements. Whether or not AD Pharma exercises their right to terminate the AD Pharma Amended Agreement, we need to raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

In view of the matters described above, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date the financial statements are issued.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying balance sheets is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements on a continuous basis, to maintain existing financing and to succeed in its future operations. The Company's financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Our future sources of revenue, if any, will be derived from licensing fees, milestone payments and royalties under the AD Pharma Amended Agreement, the Assertio Agreement, the MainPointe Agreement and similar agreements which we may enter into for our LIMITx products in development with other pharmaceutical company partners, for which there can be no assurance.

The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our product candidates and the resources we devote to the development and commercialization of our product candidates.

COVID-19

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic ("coronavirus pandemic"), based on the rapid increase in exposure globally. The coronavirus pandemic is affecting the United States and global economies. If the outbreak continues to spread, it may affect the Company's operations and those of third parties on which the Company relies, including causing disruptions in the supply of the Company's product candidates and the conduct of current and planned preclinical and clinical studies and contract manufacturing operations. We may need to limit operations or implement limitations, and may experience limitations in employee resources. There are risks that it may be more difficult to contain if the outbreak reaches a larger population or broader geography, in which case the risks described herein could be elevated significantly.

The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. Additionally, while the potential economic impact brought by, and the duration of, the coronavirus pandemic is difficult to assess or predict, the impact of the coronavirus on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity and the Company's ability to complete its preclinical studies on a timely basis, or at all.

For example, we had an incident during 2020 where our contract manufacturer had delayed the installation of the auxiliary manufacturing equipment needed for LTX-03 development for several weeks due to COVID-19 risk mitigation strategies implemented in New Jersey, which equipment was needed to further our NDA application submission for LTX-03.

The ultimate impact of coronavirus is highly uncertain and subject to change. The Company does not yet know the full extent of further potential delays or impacts on its business, financing, preclinical and clinical trial activities, contract manufacturing operations or the global economy as a whole. However, these effects could have a material, adverse impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which we rely.

NOTE 2 – RECENT ANNOUNCING STANDARDS

New accounting standards which have been adopted

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes". This new guidance includes several provisions to simplify the accounting for income taxes. The standard removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation, and calculating income taxes in interim periods. This standard is effective for fiscal years beginning after December 15, 2020, including interim reporting periods within those years, with early adoption permitted. The Company's adoption of ASU No. 2019-12 did not have a impact on the financial statements and related footnote disclosures.

NOTE 3 – LICENSE AND COLLABORATION AGREEMENTS

The Company's revenues are comprised of amounts earned under its license and collaboration agreements and royalties. Revenue recognition occurs when a customer obtains control of promised services in an amount that reflects the consideration the Company expects to receive in exchange for those services based on a short-term credit arrangement.

AD Pharma Agreement covering LTX-03

On June 28, 2019 we entered into a License, Development and Commercialization Agreement which was amended on October 16, 2020 ("the AD Pharma Amended Agreement") with AD Pharma, for the development and license of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura's patented LIMITx™. Acura would receive a monthly license payment of $350 thousand by AD Pharma from inception through April 2020, at which time the monthly payments became $200 thousand thereafter until the earlier of July 31, 2021 or FDA's acceptance of a New Drug Application ("NDA") for LTX-03. The first license payment was received July 2, 2019. AD Pharma will reimburse all our outside development costs for LTX-03. If the NDA filing for LTX-03 is not accepted by the FDA by July 31, 2021, AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the Limitx intellectual property. Should AD Pharma choose not to exercise this option to terminate and the NDA for LTX-03 is subsequently accepted by the FDA, such option expires. AD Pharma does have the right to terminate the AD Pharma Amended Agreement anytime for "convenience on 30 days prior written notice". AD Pharma retains commercialization rights from which Acura will receive stepped royalties on sales and potential sales related milestones. AD Pharma also has a license to the Limitx patents for LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam) which are not subject to any development agreement or responsibilities by Acura.

We had also previously granted authority to MainPointe Pharmaceuticals, LLC (MainPointe) to assign to AD Pharma the option and the right to add, as an Option Product to the Nexafed® Agreement, a Nexafed® 12-hour dosage (an extended-release pseudoephedrine hydrochloride product utilizing the IMPEDE® Technology in 120mg dosage strength, and the Option Product exercise price of $500 thousand was waived if the exercise of the option occurred by June 28, 2024 (five years from the effective date). Effective with the October 2020 amendment, this option and right was rescinded.

On June 28, 2019 Mr. John Schutte assigned and transferred to AD Pharma his $6.0 million convertible debt, the common stock purchase warrant for 10.0 million common shares, and the security agreement granting a security interest in all of the Company's assets. Mr. Schutte is our largest shareholder and directly owns approximately 45.7% of our common stock (after giving effect to the exercise of remaining common stock purchase warrants he holds). Mr. Schutte controls MainPointe and is the principal investor in AD Pharma.

Assertio Agreement covering Oxaydo

In April 2014, we terminated an agreement with Pfizer which resulted in the return to us of Aversion Oxycodone (formerly known as Oxecta®) and all Aversion product rights in exchange for a one-time termination payment of $2.0 million. Our termination payment of $2.0 million has been recorded in our financial statements as an intangible asset and is being amortized over the remaining useful life of the patent covering Aversion Oxycodone, which was 9.7 years as of the date the Pfizer agreement was terminated. As of March 31, 2021, the remaining useful life is 2.75 years. The recoverability of the Aversion intangible asset is contingent upon future Assertio royalty revenues to us. During the first quarter 2020 a triggering event occurred with the decline in royalty cash flows from Assertio, and we performed an impairment test which indicated that the carrying value of the intangible asset was greater than the fair value. The impairment test resulted in a $668 thousand impairment charge against the intangible asset, which was determined using our estimate of discounted royalty cash flows remaining under our license agreement with Assertio, and recorded a like amount to general and administrative expense. We have recorded amortization expense of $7 thousand and $51 thousand in each of the three months ending March 31, 2021 and 2020, respectively. Amortization of the patent for its remaining life is expected to approximate $6 thousand per quarter.

The Aversion intangible asset is summarized as follows (in thousands):

	March 31, 2021	December 31, 2020
Intangible asset – Aversion	2,000	2,000
Less: accumulated amortization	(1,266)	(1,259)
Less: reserve for impairment	(668)	(668)
Net	$ 66	$ 73

In January 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation (now known as Assertio Holdings Inc. and formerly known as Zyla Life Sciences), or collectively Assertio, entered into a Collaboration and License Agreement (the "Assertio Agreement") to commercialize Aversion Oxycodone under our tradename Oxaydo. Oxaydo is approved by the FDA for marketing in the United States in 5 mg and 7.5 mg strengths. Under the terms of the Assertio Agreement, we transferred the approved New Drug Application, or NDA, for Oxaydo to Assertio and Assertio is granted an exclusive license under our intellectual property rights for development and commercialization of Oxaydo worldwide (the "Territory") in all strengths, subject to our right to co-promote Oxaydo in the United States. Eaglet launched Oxaydo in the United States late in the third quarter of 2015.

In accordance with the Assertio Agreement Assertio is responsible for the fees and expenses relating to the product line extensions of Oxaydo, provided that Assertio will pay a substantial majority of the fees and expenses and we will pay for the remaining fees and expense relating to (i) annual NDA PDUFA product fees, (ii) expenses of the FDA required post-marketing study for Oxaydo and (iii) expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States. Assertio will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States. Assertio is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Assertio will have final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Assertio may develop Oxaydo for other countries and in additional strengths, in its discretion.

Assertio paid us a $5.0 million license fee upon signing of the Assertio Agreement and on October 9, 2015, paid us a $2.5 million milestone in connection with the first commercial sale of Oxaydo. We will be entitled to a one-time $12.5 million sales-based milestone payment when worldwide Oxaydo net sales reach $150 million in a calendar year. We are entitled to receive from Assertio a stepped royalty at percentage rates ranging from mid-single digits to double-digits based on Oxaydo net sales during each calendar year (excluding net sales resulting from our co-promotion efforts). In any calendar year of the agreement in which net sales exceed a specified threshold, we will receive a double digit royalty on all Oxaydo net sales in that year (excluding net sales resulting from our co-promotion efforts). If we exercise our co-promotion rights, we will receive a share of the gross margin attributable to incremental Oxaydo net sales from our co-promotion activities. Assertio's royalty payment obligations commenced on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA's Orange Book remains with respect to Oxaydo). Royalties will be reduced upon the entry of generic equivalents, as well as for payments required to be made by Assertio to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Assertio Agreement expires upon the expiration of Assertio's royalty payment obligations in all countries. Either party may terminate the Assertio Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Assertio Agreement, subject to applicable cure periods, or in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws. We also may terminate the Assertio Agreement with respect to the U.S. and other countries if Assertio materially breaches its commercialization obligations. Assertio may terminate the Assertio Agreement for convenience on 120 days prior written notice, which termination may not occur prior to the second anniversary of Assertio's launch of Oxaydo. Termination does not affect a party's rights accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations (but not expiration), the Assertio Agreement provides for the transition of development and marketing of Oxaydo from Assertio to us, including the conveyance by Assertio to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Assertio's supply of Oxaydo for a transition period.

MainPointe Agreement covering Nexafed Products and assignment thereof to AD Pharma

In March 2017, we and MainPointe entered into the MainPointe Agreement, pursuant to which we granted MainPointe an exclusive license to our Impede Technology to commercialize both of our Nexafed and Nexafed Sinus Pressure + Pain product ("Nexafed products") in the U.S. and Canada. We also conveyed to MainPointe our existing inventory and equipment relating to our Nexafed products. MainPointe is responsible for all development, manufacturing and commercialization activities with respect to products covered by the Agreement.

On signing the MainPointe Agreement, MainPointe paid us an upfront licensing fee of $2.5 million. The MainPointe Agreement also provides for our receipt of a 7.5% royalty on net sales of the licensed products. The royalty payment for each product will expire on a country-by-country basis when the Impede® patent rights for such country have expired or are no longer valid; provided that if no Impede patent right exists in a country, then the royalty term for that country will be the same as the royalty term for the United States. After the expiration of a royalty term for a country, MainPointe retains a royalty free license to our Impede® Technology for products covered by the Agreement in such country.

MainPointe has the option to expand the licensed territory beyond the United States and Canada to the European Union (and the United Kingdom), Japan and South Korea for payments of $1.0 million, $500 thousand and $250 thousand, respectively. In addition, MainPointe has the option to add to the MainPointe Agreement certain additional products, or Option Products, containing PSE and utilizing the Impede Technology for a fee of $500 thousand per product (for all product strengths). Such Option Products include the product candidate Loratadine with pseudoephedrine. If the territory has been expanded prior to the exercise of a product option, the option fee will be increased to $750 thousand per product. If the territory is expanded after the payment of the $500 thousand product option fee, a one-time $250 thousand fee will be due for each product. If a third party is interested in developing or licensing rights to an Option Product, MainPointe must exercise its option for that product or its option rights for such product will terminate.

On June 28, 2019, we granted authority to MainPointe to assign to AD Pharma the option and the right to add, as an Option Product to the Nexafed® Agreement, a Nexafed® 12-hour dosage (an extended-release pseudoephedrine hydrochloride product utilizing the IMPEDE® Technology in 120mg dosage strength and the Option Product exercise price of $500 thousand was waived if the exercise of the option occurred by June 28, 2024 (five years from the effective date of the AD Pharma Agreement). Effective with the October 2020 amendment, this option and right was rescinded.

The MainPointe Agreement may be terminated by either party for a material breach of the other party, or by Acura if MainPointe challenges certain of its patents. Upon early termination of the MainPointe Agreement, MainPointe's licenses to the Impede Technology and all products will terminate. Upon termination, at Acura's request the parties will use commercially reasonable efforts to transition the Nexafed® and Nexafed® Sinus Pressure + Pain products back to Acura.

On January 1, 2020, MainPointe assigned to AD Pharma, with Acura's consent, all of its right, title and interest in the MainPointe Agreement between MainPointe and Acura.

KemPharm Agreement Covering Certain Opioid Prodrugs

In October 2016, we and KemPharm Inc. ("KemPharm") entered into a worldwide License Agreement (the "KemPharm Agreement") pursuant to which we licensed our Aversion® Technology to KemPharm for its use in the development and commercialization of three products using 2 of KemPharm's prodrug candidates. KemPharm has also been granted an option to extend the KemPharm Agreement to cover two additional prodrug candidates. KemPharm is responsible for all development, manufacturing and commercialization activities.

Upon execution of the KemPharm Agreement, KemPharm paid us an upfront payment of $3.5 million. If KemPharm exercises its option to use our Aversion Technology with more than the two licensed prodrugs, then KemPharm will pay us up to $1.0 million for each additional prodrug license. In addition, we will receive from KemPharm a low single digit royalty on commercial sales by KemPharm of products developed using our Aversion Technology under the KemPharm Agreement. KemPharm's royalty payment obligations commence on the first commercial sale of a product using our Aversion Technology and expire, on a country-by-country basis, upon the expiration of the last to expire patent claim of the Aversion Technology covering a product in such country, at which time the license for the particular product and country becomes fully paid and royalty free.

The KemPharm Agreement expires upon the expiration of KemPharm's royalty payment obligations in all countries. Either party may terminate the KemPharm Agreement in its entirety if the other party materially breaches the KemPharm Agreement, subject to applicable cure periods. Acura or KemPharm may terminate the KemPharm Agreement with respect to the U.S. and other countries if the other party challenges the patents covering the licensed products. KemPharm may terminate the KemPharm Agreement for convenience on ninety (90) days prior written notice. Termination does not affect a party's rights accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations (but not expiration), the KemPharm Agreement provides for termination of our license grant to KemPharm.

NOTE 4 – REVENUE FROM CONTRACTS WITH CUSTOMERS

Revenue is recognized when, or as, performance obligations under terms of a contract are satisfied, which occurs when control of the promised service is transferred to a customer. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring services to a customer ("transaction price"). The Company will then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied. When determining the transaction price of the contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. None of the Company's licenses and collaboration agreements contained a significant financing component at either March 31, 2021 or December 31, 2020.

The Company's existing license and collaboration agreements may contain a single performance obligation or may contain multiple performance obligations. Those which contain multiple performance obligations will require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised services underlying each performance obligation.

The Company's existing license and collaboration agreements contain customer options for the license of additional products and territories. We determined the option's standalone selling prices based on the option product's potential market size in the option territory as compared to the currently licensed product and U.S. territory. Some of our existing license and collaboration agreements contain a license to the technology as well as licenses to tradenames or trademarks. The Company determined that the licenses to the tradenames or trademarks were immaterial in context of the contract. Price adjustments are accounted for as variable consideration. Provisions for variable consideration are based on current assumptions, executed contracts, and historical data and are provided for in the period the related revenues are recorded.

Sales-based Milestones and Royalty Revenues

The commercial sales-based milestones and sales royalties earned under the license and collaboration for Oxaydo and sales royalties earned under the license for the Nexafed products, are recorded in the period of the related sales by Assertio and MainPointe. Payments of sales-based milestones are generally due within 30 days after the end of a calendar year. Payments of royalties are generally due within 45 days after the end of a calendar quarter.

License and Collaboration Agreement Revenues

The achievement of milestones under the Company's license and collaboration agreements will be recorded as revenue during the period the milestone's achievement becomes probable, which may result in earlier recognition as compared to the previous accounting standards. The license fee of an option product or option territory under the Company's license and collaboration agreements will be recorded as revenue when the option is exercised and any obligations on behalf of the Company, such as to transfer know-how, has been fulfilled. The monthly license fee under the Company's LTX-03 license and collaboration agreement will be recorded as revenue upon the fulfillment of the monthly development activities. The out-of-pocket development expenses under the license and collaboration agreements will be recorded as revenue upon the performance of the service or delivery of the material during the month.

On June 28, 2019 we entered into an agreement with AD Pharma which was amended in October 2020 for the development and license of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura's patented LIMITx™ providing 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 became $200 thousand per month thereafter until the earlier of July 31, 2021 or FDA's acceptance of a New Drug Application ("NDA") for LTX-03. The Company provided a price adjustment to AD Pharma in September 2020 when it was probable that the monthly license payments were being reduced from $350 thousand to $200 thousand. AD Pharma is delinquent in remitting monthly license payments for January, 2021 thru May, 2021 which aggregates to $1.0 million and approximately $100 thousand of reimbursable LTX-03 development expenses. Failure to make these payments is an event of default under the AD Pharma Amended Agreement. AD Pharma will reimburse all our outside development costs for LTX-03.

Product Sales, net of allowance

Nexafed was launched in mid-December 2012 and Nexafed Sinus Pressure + Pain was launched in February 2015. Prior to entering into the MainPointe Agreement in March 2017, we sold our Nexafed products in the United States to wholesale pharmaceutical distributors as well as directly to chain drug stores. Our Nexafed products were sold subject to the right of return usually for a period of up to twelve months after the product expiration. During the second quarter 2020, we reviewed our product sales return allowance liability and recorded a $223 thousand favorable amount to product sales as we believe sufficient time has passed where the Nexafed product is no longer subject to right of return and we estimate no additional product will be returned and therefore, we no longer maintain a sales return allowance liability.

Disaggregation of Total Revenues

The Company has two license agreements for currently marketed products containing its technologies; the Oxaydo product containing the Aversion Technology has been licensed to Assertio and the Nexafed products containing the Impede Technology which have been licensed to MainPointe. The Company has a third license agreement having a product under development, LTX-03, containing its LIMITx™ technology to AD Pharma. We have recorded $0.6 million and $1.05 million of license fees for LTX-03 during the three months ended March 31, 2021 and 2020, respectively.

On January 1, 2020, MainPointe assigned to AD Pharma, with Acura's consent, all of its right, title and interest in the MainPointe Agreement between MainPointe and Acura. All of the Company's royalty revenues are earned from these two license agreements by the licensee's sale of products in the United States.

Royalty revenues by licensee are summarized below:

	For the Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Zyla (Oxaydo)	$ 30	$ 30
MainPointe (Nexafed)	2	3
Royalty revenues	$ 32	$ 33

Contract Balance and Performance Obligations

The Company had no contract assets and contract liability balances under the license and collaboration agreements at either March 31, 2021 or 2020. Contract assets may be reported in future periods under prepaid expenses or other current assets on the consolidated balance sheet. Contract liabilities may be reported in future periods consisting of deferred revenue as presented on the consolidated balance sheet.

NOTE 5 – RESEARCH AND DEVELOPMENT

Research and Development ("R&D") costs include internal R&D activities, external Contract Research Organization ("CRO") services and their clinical research and investigative sites, and other activities. Internal R&D activity costs can include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, formulation work, depreciation, salaries, benefits, insurance and share-based compensation expenses. CRO activity costs can include preclinical laboratory experiments and clinical trial studies. Other activity costs can include regulatory consulting, regulatory legal counsel, cost of acquiring, developing and manufacturing pre-clinical trial materials, costs of manufacturing scale-up, and cost sharing expenses under license agreements. Internal R&D costs and other activity costs are charged to expense as incurred. We make payments to the CRO's based on agreed upon terms and may include payments in advance of a study starting date. Payments in advance will be reflected in the consolidated financial statements as prepaid expenses. We review and charge to expense accrued CRO costs and clinical trial study costs based on services performed and rely on estimates of those costs applicable to the stage of completion of a study as provided by the CRO. Our accrued CRO costs are subject to revisions as such studies progress towards completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. We did not have prepaid CRO costs or prepaid clinical trial study expenses at March 31, 2021 and 2020.

In connection with our development and scale-up of LTX-03 under the AD Pharma Amended Agreement (See Note 3) we entered into obligations under non-cancelable arrangements at March 31, 2021 for which approximately $75 thousand has yet to be incurred.

NOTE 6 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment is summarized as follows (in thousands):

	March 31, 2021	December 31, 2020
	(in thousands)	
Building and improvements	$ 1,273	$ 1,273
Scientific equipment	597	597
Computer hardware and software	106	106
Machinery and equipment	274	274
Land and improvements	162	162
Other personal property	70	70
Office equipment	27	27
Total	2,509	2,509
Less: accumulated depreciation	(2,036)	(2,025)
Net property, plant and equipment	$ 473	$ 484

We do not have leasehold improvements nor do we have capitalized leases. Costs of betterments are capitalized while maintenance costs and repair costs are charged to operations as incurred. When a depreciable asset is retired from service, the cost and accumulated depreciation will be removed from the respective accounts.

Depreciation expense was $11 thousand and $15 thousand for each of the three month periods ended March 31, 2021 and 2020, respectively.

NOTE 7 – ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	March 31, 2021	December 31, 2020
	(in thousands)	
Cost sharing expenses under license agreements	$ 428	$ 428
Other fees and services	22	24
Payroll, payroll taxes and benefits	41	8
Professional services	124	117
Financed premiums on insurance policies	14	28
Property taxes	11	9
Franchise taxes	24	17
Total	$ 664	$ 631

NOTE 8 – DEBT

Related Party Convertible Loan

At December 31, 2018, we had borrowed an aggregate of $4.35 million from Mr. Schutte, a related-party. From January 1, 2019 and through June 27, 2019, we borrowed additional amounts from Mr. Schutte for $650 thousand and issued various promissory notes to him with the same terms and conditions from the previous loans (the Schutte Notes). On June 28, 2019 we restructured the $5.0 million loan to borrow an additional $725 thousand from Mr. Schutte bringing the aggregate principal of the loans and accrued interest to $6.0 million, and consolidated the loans into a single promissory note with a fixed interest rate of 7.5%, maturity date of July 1, 2023, granted principal and interest conversion rights into shares of our common stock at a price of $0.16 per share, issued a warrant for 10.0 million common shares having an exercise price of $0.01 per share, and granted a security interest in all of the Company's assets, which includes our intellectual property. The principal amount of the loan is convertible into 37.5 million shares of our common stock. The $6.0 million convertible debt, the common stock purchase warrant and the security agreement were all assigned and transferred by Mr. Schutte to AD Pharma on June 28, 2019. Interest expense was $113 thousand and $112 thousand for each of the three month periods ended March 31, 2021 and 2020, respectively. The accrued interest balance at March 31, 2021 and December 31, 2020 was $791 thousand and $678 thousand, respectively.

The events of default under the $6.0 million convertible debt are limited to bankruptcy defaults, failure to pay interest and principal when due on July 1, 2023 or upon failure to meet certain timelines in the AD Pharma Amended Agreement as defined in the loan agreement, including the date the FDA accepts our filing for LTX-03. The $6.0 million convertible debt may be prepaid at any time in whole or in part but only with the consent of the noteholder.

Included in the AD Pharma Amended Agreement entered into during October 2020, is the requirement that the NDA for LTX-03 now be accepted by the FDA by July 31, 2021, or AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property. Importantly, such failure to meet this date is an event of default under the Company's $6.0 million outstanding convertible debt to AD Pharma. Acura currently expects the submission and FDA acceptance of the NDA for LTX-03 to occur after July 31, 2021 and we have notified AD Pharma of this revised timeline for NDA submission. Acura intends to renegotiate the NDA filing acceptance date for LTX-03, of which no assurance can be given. Pending resolution of this matter, the $6.0 million convertible debt is presented as a current liability in our financial statements.

Paycheck Protection Program

1st PPP Loan

On April 13, 2020, the Company received a loan (the "1st Loan") from JP Morgan Chase Bank in the aggregate amount of $269 thousand, pursuant to the Paycheck Protection Program ("PPP") under Division A, Title I of the CARES Act, which was enacted March 27, 2020. The 1st Loan, in the form of a promissory note, matures on April 8, 2022. Under the terms of the PPP, certain amounts of the 1st Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. We have submitted a PPP loan forgiveness application to JP Morgan Chase Bank, who in turn submitted it to the Small Business Administration on or around April 20, 2021. We are awaiting the SBA's review of our forgiveness application and their decision, which we expect can take up to 90 days. To the extent that all or part of the 1st Loan is not forgiven, the Company will be required to make payments, including interest accruing at an annual rate of 1.0% beginning on the date of disbursement. The receipt of these funds, and the forgiveness of the loans attendant to these funds, is dependent on the Company having initially qualified for these loans and qualifying for the forgiveness of such loans is based on adherence to the forgiveness criteria. No assurance is provided that forgiveness for any portion of the 1st Loan will be obtained.

2nd PPP Loan

On March 16, 2021, the Company received a loan (the "2nd Loan") from JP Morgan Chase Bank in the aggregate amount of $266 thousand, pursuant to the PPP under Division A, Title I of the CARES Act. The 2nd Loan, in the form of a promissory note, matures after five years. Under the terms of the PPP, certain amounts of the 2nd Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. To the extent that all or part of the 2nd Loan is not forgiven, the Company will be required to make payments, including interest accruing at an annual rate of 1.0% beginning on the date of disbursement. The receipt of these funds, and the forgiveness of the loans attendant to these funds, is dependent on the Company having initially qualified for these loans and qualifying for the forgiveness of such loans is based on adherence to the forgiveness criteria. No assurance is provided that forgiveness for any portion of the 2nd Loan will be obtained.

NOTE 9 – RELATED PARTY TRANSACTIONS

In July 2017, we completed a $4.0 million private placement with Mr. Schutte, consisting of 8,912,655 units ("Units") of the Company, at a price of $0.4488 per Unit (the "Transaction"). Each Unit consists of one share of common stock and a warrant to purchase one fifth (0.2) of a share of common stock. The issue price of the Units was equal to 85% of the average last sale price of our common stock for the five trading days prior to completion of the Transaction. The warrants are immediately exercisable for 1,782,532 common shares at a price of $0.528 per share (which equals the average last sale price of the Company's common stock for the five trading days prior to completion of the Transaction) and expire five years after issuance (subject to earlier expiration in event of certain acquisitions). We have assigned a relative fair value of $495 thousand to the warrants out of the total $4.0 million proceeds from the private placement transaction and have accounted these warrants as equity.

As part of the closing of the Transaction, the Company and Essex Woodlands Health Ventures V, L.P. ("Essex") and Galen Partners III, L.P. ("Galen") amended and restated the existing Voting Agreement including such parties to provide for Mr. Schutte to join as a party (as so amended, the "Second Amended and Restated Voting Agreement"). The Second Amended and Restated Voting Agreement provides that our Board of Directors shall remain comprised of no more than seven members (subject to certain exceptions), (i) one of whom is the Company's Chief Executive Officer, (ii) three of whom are independent under Nasdaq standards, and (iii) one of whom shall be designated by each of Essex, Galen and Mr. Schutte, and the parties to such agreement would vote for such persons. The right of each of Essex, Galen and Mr. Schutte to designate one director to our Board will continue as long as he or it and their affiliates collectively hold at least 600,000 shares of our common stock (including warrants exercisable for such shares). Immanuel Thangaraj is the designee of Essex. Mr. Schutte has not designated a director as of the date of filing of this Report on Form 10-Q. Galen had not designated a director and lost that right in December 2017 when it disposed of its shares of common stock in the Company. Once such shareholder no longer holds such securities, the additional forfeited seat would become a seat for an independent director to thereafter be nominated to the Board of Directors from time to time by the then current directors and as applicable, to be elected by the directors to fill the vacancy created by the forfeited seat or submitted to the vote of shareholders at the Company's next annual meeting. An independent director has not been named to fill the seat forfeited by Galen.

MainPointe Pharmaceuticals LLC

Mr. Schutte is the principal owner of MainPointe Pharmaceuticals LLC, a Kentucky limited liability company (“MainPointe”). In March 2017, we granted MainPointe an exclusive license to our Impede Technology to commercialize our Nexafed® and Nexafed® Sinus Pressure + Pain Products in the United States and Canada for an upfront licensing fee of $2.5 million. The Company is receiving a 7.5% royalty on sales of licensed products. MainPointe also has options to expand the territory and products covered for additional sums. Included in the reported royalty revenue for the three months ended March 31, 2021 and 2020 is $2 thousand and $3 thousand, respectively of royalty revenue from MainPointe (See Note 3). On January 1, 2020, MainPointe assigned to AD Pharma, with Acura’s consent, all of its right, title and interest in the MainPointe Agreement between MainPointe and Acura.

Loans with Mr. John Schutte

At December 31, 2018, we had borrowed an aggregate of $4.35 million from Mr. Schutte, a related-party. During the period January 1, 2019 through June 27, 2019 we borrowed an aggregate of $650 thousand from Mr. Schutte. On June 28, 2019 we borrowed an additional $725 thousand from Mr. Schutte, bringing the aggregate principal of the loans and accrued interest to $6.0 million, and consolidated the loans into a single promissory note with a fixed interest rate of 7.5%, maturity date of July 1, 2023, granted conversion rights of principal and interest into shares of our common stock at a price of $0.16 per share, issued a warrant for 10.0 million common shares having an exercise price of $0.01 per share, and granted a security interest in all of the Company’s assets, which includes our intellectual property. The principal amount of the note is convertible into 37.5 million shares of our common stock. The $6.0 million convertible debt, the common stock purchase warrant and the security agreement were all assigned and transferred by Mr. Schutte to AD Pharma on June 28, 2019.

AD Pharma Agreement covering LTX-03

On June 28, 2019, we entered into a License, Development and Commercialization Agreement which was amended in October 2020 (the "AD Pharma Amended Agreement") with Abuse Deterrent Pharma, LLC (“AD Pharma”), a special purpose company representing a consortium of investors that will finance Acura’s operations and completion of development of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura’s patented LIMITx™ technology which addresses the consequences of excess oral administration of opioid tablets, the most prevalent route of opioid overdose and abuse. The AD Pharma Amended Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03 as well as LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam). Financial arrangements include:

- Monthly license payments to Acura by AD Pharma of $350 thousand from inception through April 2020 and $200 thousand thereafter until July 31, 2021 or FDA’s acceptance of a New Drug Application (“NDA”) for LTX-03;
- Reimbursement of Acura’s LTX-03 outside development expenses; and
- Upon commercialization of the licensed products, Acura receives stepped royalties on sales and is eligible for certain sales related milestones

AD Pharma is delinquent in remitting monthly license payments for January, 2021 thru May, 2021 which aggregates to $1.0 million and approximately $100 thousand of reimbursable LTX-03 development expenses. Failure to make these payments is an event of default under the AD Pharma Amended Agreement.

AD Pharma may terminate the AD Pharma Amended Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by July 31, 2021, AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property. Importantly, such failure to meet this date is an event of default under the Company’s $6.0 million outstanding convertible debt to AD Pharma. Should AD Pharma choose not to exercise this option to terminate and the NDA for LTX-03 is subsequently accepted by the FDA, such option expires. Acura currently expects the submission and FDA acceptance of the NDA for LTX-03 to occur after July 31, 2021 and has notified AD Pharma of this revised timeline for NDA submission. Acura intends to renegotiate the NDA filing acceptance date for LTX-03, of which no assurance can be given.

We also granted authority to MainPointe Pharmaceuticals, LLC (MainPointe) to assign to AD Pharma the option and the right to add, as an Option Product to the Nexafed® Agreement, a Nexafed® 12-hour dosage (an extended-release pseudoephedrine hydrochloride product utilizing the IMPEDE® Technology in 120mg dosage strength), and the Option Product exercise price of $500 thousand was waived if the exercise of the option occurred by June 28, 2024 (five years from the effective date of the AD Pharma Agreement), however effective with the October 2020 amendment to the AD Pharma Agreement, this option and right was rescinded. In March 2017, we granted MainPointe an exclusive license to our IMPEDE ® Technology to commercialize our Nexafed® and Nexafed® Sinus Pressure + Pain Products in the United States and Canada. On January 1, 2020, MainPointe assigned to AD Pharma, with Acura’s consent, all of its right, title and interest in the MainPointe Agreement between MainPointe and Acura dated March 16, 2017.

NOTE 10 – COMMON STOCK PURCHASE WARRANTS

Our warrant activity during the three month periods ended March 31, 2021 and 2020 is shown below (in thousands except price data):

	March 31,			
	2021		2020	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, Jan. 1	11,782	$ 0.09	11,842	$ 0.10
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Modification	-	-	-	-
Outstanding, Mar. 31	11,782	$ 0.09	11,842	$ 0.10

As part of our July 2017 private placement transaction with Mr. Schutte, we issued warrants to purchase 1,782,531 shares of our common stock. The warrants are immediately exercisable at a price of $0.528 per share and expire five years after issuance in July 2022. (See Note 9). We have assigned a relative fair value of $495 thousand to the warrants out of the total $4.0 million proceeds from the private placement transaction and have accounted for these warrants as equity.

In June 2019 as part of the changes made to the loan agreements we had with Mr. Schutte, each having an original due date of January 2, 2020, we issued to him a warrant to purchase 10.0 million shares of our common stock exercisable at a price of $0.01 per share and expire five years after issuance in June 2024. We obtained a valuation of fair value on the warrant and $1.145 million was allocated to the warrant and accounted for as equity. (See Note 8 and Note 9). The warrant was assigned and transferred by Mr. Schutte to AD Pharma on June 28, 2019.

During December 2020, warrants expired that were exercisable for 60 thousand shares of our common stock and had an exercise price of $2.52 per share.

NOTE 11 – SHARE-BASED COMPENSATION EXPENSE

We have several share-based compensation plans covering stock options and RSUs for our employees and directors.

We measure our compensation cost related to share-based payment transactions based on fair value of the equity or liability classified instrument. For purposes of estimating the fair value of each stock option unit on the date of grant, we utilize the Black-Scholes option-pricing model. Option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of our common stock (as determined by reviewing our historical public market closing prices). Our accounting for share-based compensation for RSUs is based on the closing market price of our common stock on the date of grant.

Our total share-based compensation expense recognized in the Company's results of operations from non-cash and cash-portioned instruments issued to our employees and directors comprised the following (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development expense:		
Stock option awards	$ -	$ -
RSU awards	-	-
	$ -	$ -
General and administrative expense:		
Stock option awards	-	-
RSU awards	-	15
	$ -	$ 15
Total share-based compensation expense	$ -	$ 15

Stock Option Plans

We maintain various stock option plans. A summary of our stock option plans as of March 31, 2021 and 2020 and for the three months then ended consisted of the following (in thousands except exercise price):

	Three Months ended March 31,			
	2021		2020	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, Jan. 1	1,254	$ 3.46	1,356	$ 4.45
Granted	-	-	-	-
Exercised	(80)	0.15	-	-
Forfeited	-	-	-	-
Expired	(12)	17.30	(12)	27.35
Outstanding, Mar. 31	1,162	$ 3.55	1,344	$ 4.24
Exercisable, Mar. 31	1,162	$ 3.55	1,344	$ 4.24

We estimate the option's fair value on the date of grant using the Black-Scholes option-pricing model. Black-Scholes utilizes assumptions related to expected term, forfeitures, volatility, the risk-free interest rate, the dividend yield (which is assumed to be zero, as we have not paid any cash dividends) and employee exercise behavior. Expected volatilities utilized in the Black-Scholes model are based on the historical volatility of our common stock price. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected life of the grants is derived from historical exercise activity. Historically, the majority of our stock options have been held until their expiration date.

The intrinsic value contained in the stock option awards which are vested and outstanding at March 31, 2021 is approximately $25 thousand.

Restricted Stock Unit Award Plans

We have one Restricted Stock Unit Award Plan for our employees and non-employee directors, a 2017 Restricted Stock Unit Award Plan (the "2017 RSU Plan. Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. Our non-employee director awards allow for non-employee directors to receive payment in cash, instead of stock, for up to 40% of each RSU award. The portion of the RSU awards subject to cash settlement are recorded as a liability in the Company's consolidated balance sheet as they vest and being marked-to-market each reporting period until they are distributed. The liability was $6 thousand at December 31, 2020. There are no issued and outstanding non-employee director RSU awards at March 31, 2021.

The compensation cost to be incurred on a granted RSU without a cash settlement option is the RSU's fair value, which is the market price of our common stock on the date of grant, less its exercise cost. The compensation cost is amortized to expense and recorded to additional paid-in capital over the vesting period of the RSU award.

A summary of the grants under the RSU Plan as of March 31, 2021 and 2020, and for the three months then ended consisted of the following (in thousands):

	Three Months Ended March 31,			
	2021		2020	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, Jan. 1	839	839	1,017	1,017
Granted	-	-	219	-
Distributed	(447)	(447)	(397)	(397)
Vested	-	-	-	55
Forfeited	-	-	-	-
Outstanding, Mar. 31	392	392	839	675

2017 Restricted Stock Unit Award Plan

Our 2017 RSU Plan was approved by shareholders in November 2017 and permits the grant of up to 1.5 million shares of our common stock pursuant to awards under the 2017 RSU Plan. As of March 31, 2021, there are no shares which remain available for award under the 2017 RSU Plan.

Information about the award activity under the 2017 RSU Plan is as follows:

- In December 2017, we awarded 200 thousand RSUs to our employees. Such RSU awards vested 100% after one full year of service. Distributions of the vested RSU awards to the employees are being made in three equal installments on the first business day of each of January 2020, 2021, and 2022 or earlier upon a qualifying change of control.

- In December 2018, we awarded 488 thousand RSUs to our employees. Such RSU awards vested 100% after one full year of service. Distributions of the vested RSU awards to the employees are being made in three equal installments on the first business day of each of January 2021, 2022, and 2023 or earlier upon a qualifying change of control.

- In January 2019, we awarded approximately 83 thousand RSUs to each of our four non-employee directors which also allow for them to receive payment in cash, instead of stock, for up to 40% of each RSU award. Such awards vest 25% at the end of each calendar quarter in 2019. Settlement of this RSU award occurred on January 2, 2020, the first business day of the year after vesting. The portion of the RSU awards which were subject to cash settlement was also subject to marked-to market accounting having a liability recorded on the Company's consolidated balance sheet with quarterly adjustments which were recorded to stock compensation expense in the general and administration operating category of our income statement.

- In January 2020, we awarded approximately 55 thousand RSUs to each of our four non-employee directors which also allow for them to receive payment in cash, instead of stock, for up to 40% of each RSU award. Such awards vest 25% at the end of each calendar quarter in 2020. Settlement of this RSU award did occur on January 4, 2021, the first business day of the year after vesting. The portion of the RSU awards which are subject to cash settlement will also be subject to marked-to market accounting having a liability recorded on the Company's consolidated balance sheet with quarterly adjustments recorded to stock compensation expense in the general and administration operating category of our income statement.

Information about the distribution of share activity under the 2017 RSU Plan is as follows:

- In January 2019, 267 thousand RSUs were distributed to our non-employee directors from their January 2018 award and settled in common stock.
- In January 2020, 333 thousand RSUs were distributed to our non-employee directors from their January 2019 award with 296 thousand RSUs settled in common stock, 4 thousand RSUs used to settle the purchase price and 33 thousand RSUs settled in cash.
- In January 2020, 64 thousand RSUs were distributed to our current and former employees representing one third of their 2017 award with 54 thousand RSUs settled in common stock and 10 thousand RSUs used to settle the purchase price and employee withholding taxes.
- In January 2021, 219 thousand RSUs were distributed to our non-employee directors from their January 2020 award and settled in common stock.
- In January 2021, 228 thousand RSUs were distributed to our current and former employees representing one third of their December 2017 award and one third of their December 2018 award, with 185 thousand RSUs settled in common stock and 43 thousand RSUs used to settle the purchase price and employee withholding taxes.

NOTE 12 – INCOME TAXES

We account for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities and are accounted for using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse.

Deferred tax assets reflect the tax effects of net operating losses (“NOLs”), tax credit carryovers, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The most significant item of our deferred tax assets is derived from our Federal NOLs. We have approximately $138 million gross Federal NOLs at December 31, 2020 (of which approximately $132 million was generated prior to January 1, 2018). We believe the gross Federal NOL benefit we generated prior to January 1, 2018 available to offset taxable income is less than $150 thousand annually. As prescribed under Internal Revenue Code, any unused Federal NOL benefit from the annual limitation can be accumulated and carried forward to the subsequent year and will expire if not used in accordance with the NOL carried forward term of 20 years or 2037, if generated before 2018 while our Federal NOLs generated after 2017 can be carried forward indefinitely. Future common stock transactions, such as the exercise of common stock purchase warrants or the conversion of debt into common stock, may cause another qualifying event under IRC 382 which will most likely further limit our utilization of our NOLs.

The realization of deferred income tax assets is dependent upon future earnings, if any, and the timing and amount of which may be uncertain. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At March 31, 2021 and December 31, 2020, all our remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of NOL carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

NOTE 13 – BASIC AND DILUTED NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing net income or loss by the weighted average common shares outstanding during a period, including shares weighted related to both vested Restricted Stock Units ("RSUs") which settle in shares (See Note 11) and a stock warrant exercisable for 10.0 million shares having an exercise price of $0.01 per share (See Note 8). Diluted EPS is based on the treasury stock method and computed based on the same number of shares used in the basic share calculation and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and stock warrants, assuming the exercise of all in-the-money stock options and warrants. Common stock equivalents are excluded from the computation where their inclusion would be anti-dilutive. As the Company reported a net loss for the three month periods ending March 31, 2021 and 2020, the effects of common stock equivalents were excluded as the diluted net loss per share calculation would have been antidilutive. The weighted-average common share outstanding diluted computation is not impacted during any period where the exercise price of a stock option, common stock warrant or convertible loan is greater than the average market price of our common stock.

A reconciliation of the numerators and denominators of basic and diluted earnings (loss) per share ("EPS") consisted of the following (in thousands except per share data):

	Three Months Ended March 31,	
	2021	2020
Earnings (loss) per share – basic and diluted		
Numerator: net loss	$ (259)	$ (595)
Denominator (weighted):		
Common shares	22,072	21,650
RSUs - vested	392	620
Common stock purchase warrant	10,000	10,000
Basic and diluted weighted average shares outstanding	32,464	32,270
Loss per share – basic and diluted	$ (0.01)	$ (0.02)
Excluded securities (non-weighted):		
Common shares issuable:		
RSUs – nonvested	-	98
Stock options – vested and nonvested	1,162	1,344
Common stock purchase warrants	1,782	1,842
Convertible loan	37,500	37,500
Total excluded common shares	40,444	40,784

NOTE 14 – SUBSEQUENT EVENTS

On May 12, 2021 we received from AD Pharma, the December 2020 license fee payment of $200 thousand.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This discussion and analysis should be read in conjunction with the Company's financial statements and accompanying notes included elsewhere in this Report. Historical operating results are not necessarily indicative of results in future periods.

Forward-Looking Statements

Certain statements in this 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 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,” “should,” “suggest,” “target,” “will,” “would” 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 known and unknown 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 2020 Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission and in Item 1A of this Report. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Accordingly, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

Company Overview

We are 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. Our Limitx™ Technology is being developed to minimize the risk of overdose, our Aversion® Technology is intended to address methods of abuse associated with opioid analgesics while our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine, or PSE, into methamphetamine. Oxaydo Tablets (oxycodone HCl, CII), which utilizes the Aversion Technology, is the first approved immediate-release oxycodone product in the United States with abuse deterrent labeling. Nexafed brand products utilize our Impede Technology.

Limitx, 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. We have completed four clinical studies of various product formulations utilizing the Limitx Technology which have demonstrated proof-of-concept for the Limitx Technology and will allow us to advance a product to development for a New Drug Application, or NDA. Studies AP-LTX-400, or Study 400, and Study AP-LTX-401, or Study 401, both utilizing our LTX-04 hydromorphone formulation demonstrated the mean maximum drug concentration in blood, or Cmax, was reduced in healthy adult fasted subjects by 50% to 65% when excessive buffer levels were ingested or a situation consistent with over-ingestion of tablets. Study AP-LTX-301, or Study 301 demonstrated drug Cmax from LTX-03, a Limitx hydrocodone bitartrate and acetaminophen combination product, in healthy adult fasted subjects trended toward bioequivalence in test formulations A through E and showed an increasing reduction in Cmax for formulations F through H; in which formulations A though H had increasing incremental amounts of buffer starting with no buffer in formulation A. We believe the results of Study 301 demonstrated that LTX-03 is a formulation that optimizes the balance between effective blood levels of drug for pain relief at a single tablet dose while retarding bioavailability of drug when multiple tablets are ingested. The FDA designated the development program for LTX-04 as Fast Track, which is designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. However, we intend to advance LTX-03, which combines the hydrocodone micro-particles, acetaminophen and buffer ingredients into a single tablet, as our lead Limitx product candidate due to its larger market size and its known prevalence of oral excessive tablet abuse and overdose, and we voluntarily placed the Investigational New Drug Application, or IND, for LTX-04 on inactive status. We submitted an IND for LTX-03 to the FDA in the first quarter of 2018 in order to advance to NDA development, which became effective in April 2018.

On June 28, 2019, we entered into License, Development and Commercialization Agreement, which was amended in October 2020, (“AD Pharma Amended Agreement”) with Abuse Deterrent Pharma, LLC, a Kentucky limited liability company (“AD Pharma”), a special purpose company representing a consortium of investors that will finance Acura’s operations through July 2021 and reimburse all our outside development costs for LTX-03. The AD Pharma Amended Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03 as well as to LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam). AD Pharma is delinquent in remitting monthly license payments for January, 2021 thru May, 2021 which aggregates to $1.0 million and approximately $100,000 of reimbursable LTX-03 development expenses.

In January 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation (now known as Assertio Holdings Inc. and formerly known as Assertio Life Sciences), or collectively Assertio, entered into a Collaboration and License Agreement (the “Assertio Agreement”) pursuant to which we exclusively licensed to Assertio worldwide rights to manufacture and commercialize our Aversion Technology product Oxaydo. Oxaydo is currently approved by the U. S. Food and Drug Administration, or FDA, for marketing in the United States in 5mg and 7.5mg strengths. Assertio launched Oxaydo in the United States late in the third quarter of 2015. We are not actively developing product candidates utilizing our Aversion Technology.

We launched our first Impede Technology product, Nexafed, into the United States market in December 2012 and launched our Nexafed Sinus Pressure + Pain product in the United States in February 2015. On March 16, 2017, we and MainPointe Pharmaceuticals, LLC, or MainPointe, entered into a License, Commercialization and Option Agreement, or the MainPointe Agreement, pursuant to which we granted MainPointe an exclusive license to our Impede technology in the U.S. and Canada to commercialize our Nexafed products. The MainPointe Agreement also grants MainPointe the option to expand the licensed territory to the European Union, Japan and South Korea and to add additional pseudoephedrine-containing products utilizing our Impede technology. MainPointe is controlled by Mr. John Schutte, who became our largest shareholder pursuant to a private placement completed in July 2017. On January 1, 2020, MainPointe assigned to AD Pharma, an entity controlled by Mr. Schutte, with Acura's consent, all of its right, title and interest in the Agreement between MainPointe and Acura.

We conduct research, development, laboratory, manufacturing, and warehousing activities at our operations facility in Culver, Indiana and lease an administrative office in Palatine, Illinois. In addition to internal capabilities and activities, we engage numerous clinical research organizations, or CROs, with expertise in regulatory affairs, clinical trial design and monitoring, clinical data management, biostatistics, medical writing, laboratory testing and related services. Our Supply agreements with two third-party pharmaceutical product manufacturers and packagers to supply our commercial requirements for our Nexafed and Nexafed Sinus Pressure + Pain products were assigned to MainPointe in accordance with the MainPointe Agreement.

Misuse or Abuse of Prescription Opioid Products and Development of Risk Mitigation Formulations

In 2018, there were 312,000 incidents of self-harm in the US. In 2019, suicides exceeded 47,000 with half the US states reporting a greater than 30% increase since 1999. For ages 15-24, suicide is the second leading cause of death and veterans die by suicide at a higher rate than the civilian population. Only 54% of suicide decedents had a prior diagnosis of a mental health issue and over 10% had chronic pain representing potential opioid patients. Suicide by poisoning, which would include overdose of prescription medications, make up over 10% of successful suicide attempts with those with prior diagnosed mental health issues twice as likely to die by poisoning.

Overdose is not limited to intentional acts of self-harm. In 2018, over 67,000 citizens died from accidental licit and illicit drug overdose, with the most prevalent licit drug classes being opioids, psychostimulants, benzodiazepines and antidepressants. The misuse and abuse of opioid analgesics continues to constitute a dynamic and challenging threat to the United States and in 2017, the US Government declared opioid abuse as an epidemic and national health emergency. In 2018, an estimated 9.9 million persons aged 12 years and older, reported opioid misuse in the past year. Overdoses involving opioids killed nearly 47,000 people in 2018 and 32% of those deaths involved prescription opioids.

Overdose Risk Mitigation - Products and Development

Any drug may initiate severe unwanted side effects when overdosed. For example, a known and FDA labelled side effect of the overdose of opioids is respiratory depression. High doses of opioids can affect the respiratory center of the brain resulting in a slowing and/or shallowing of the breathing which increases carbon dioxide (CO_2) in the blood stream. Opioids also impact ancillary CO_2 monitoring of the blood preventing the body from taking corrective action. The increased CO_2 and resulting decrease in oxygen in the blood systematically shuts down body systems and may result in death.

Abusers as well as legitimate pain patients are at risk of overdose. In some cases, overdose is accidental but anecdotal reports indicate suicide rates among pain patients are increasing presumably due to their inability to access the pain medications they need to manage their condition.

In June 2019, FDA issued a draft for public comment guidance on a Benefit-Risk Assessment Framework for Opioid Analgesic Drugs. The draft guidance indicates FDA will "consider the public health risks of the [opioid] drug related to misuse, abuse, opioid use disorder, accidental exposure, and overdose in both patients and nonpatients, as well as any properties of the drug that may mitigate such risks". We intend to develop our LIMITx Technology products consistent with this pending guidance and perform studies to demonstrate our drug candidates have properties to mitigate the risk of overdose. Further development of our LIMITx Technology products will likely also entail additional safety and/or efficacy assessment as may be identified by the FDA for each specific formulation during the Investigational New Drug application, or IND, or the NDA phase of development.

LIMITx™ Technology

LIMITx Technology is intended to address the accidental or intentional consumption of multiple tablets and provide a margin of safety against respiratory depression. We believe these benefits for opioids are consistent with FDA's proposed direction to require all newly approved opioid products to have features of benefits that provide safety or efficacy benefits over existing available opioid therapies.

LIMITx Technology Products in Development

We have the following products in development utilizing our LIMITx Technology:

LIMITx Technology Products	Status
Immediate-release hydrocodone bitartrate with acetaminophen (LTX-03)	FDA registration/clinical batches complete in Feb. 2021 – quality assurance testing is pending. IND updated Feb. 2021 with protocols for 3 human clinical studies.
Immediate-release oxycodone HCl (LTX-01) & (LTX-02)	Formulation development in process
Immediate-release non-opioid drug (LTX-09)	Formulation development in process
Immediate-release hydromorphone HCI (LTX-04)	Two Phase I exploratory pharmacokinetic studies completed. IND no longer active.

LTX-03 Development

Study 301

Study 301 was an open-label, parallel design pharmacokinetic study testing our LIMITx formulation LTX-03 in 72 fasted healthy adult subjects randomized into 9 groups (8 subjects per group). One group swallowed a single Norco® 10/325mg tablet, the marketed comparator or reference drug. The remaining 8 groups swallowed a single LTX-03 tablet with increasing buffering amounts starting with no buffer, LTX-03 formulations A through H, respectively. All 72 subjects completed the study and the doses were generally well tolerated with no serious adverse events. One subject in the Formulation E group was not analyzed due to emesis. LTX-03 is a combination of hydrocodone bitartrate and acetaminophen.

In Study 301 bioequivalence (BE) was examined to generate information for future registration studies. Results demonstrated a trend toward BE for both active ingredients in LTX-03 formulations A through E. Formulation E had BE ratios (log transformed) for hydrocodone of 0.89 and 0.97 for Cmax and Area Under the Curve (AUC), respectively. In this small sample size study both hydrocodone BE confidence intervals were below the acceptable lower BE range of 0.80 at 0.74 and 0.79 for Cmax and AUC, respectively. For acetaminophen, Formulation E's BE Ratios were 1.15 and 1.03 for Cmax and AUC, respectively. While the acetaminophen AUC's met the BE standards, the Cmax upper confidence interval of 1.61 was above the acceptable upper BE range of 1.25. We believe that bioequivalence of this formulation may be achieved by reducing data variability that can be achieved through an adequately powered crossover study design with sufficient numbers of subjects in the study. For LTX-03 Formulations F though H, the higher buffer level tablets, Study 301 demonstrated a progressively increasing reduction in hydrocodone Cmax culminating in a 34% Cmax reduction associated with Formulation H, the highest level evaluated. The Cmax for acetaminophen did not decline in Formulations F through H in Study 301.

We believe that Study 301 identified a formulation that optimizes the balance between providing therapeutic blood levels of drug for pain relief at a single tablet dose while retarding the bioavailability of drug when higher buffer levels are ingested.

Manufacturing

We have completed with AD Pharma, commercial scale-up of the LTX-03 manufacturing process at a contract manufacturing organization. In February 2021, we completed manufacturing three NDA required registration/clinical batches of the to-be-marketed LTX-03 formulation on the commercial scale manufacturing equipment with quality assurance testing of the product pending before these batches can be deemed successful and ready for use. We intend to complete a six month shelf life study on these tablets for submission in the NDA which will start once the tablets are deemed acceptable.

IND Update

We submitted an Investigational New Drug Application, or IND with respect to LTX-03, to the FDA in the first quarter of 2018, which became effective in April 2018. In February 2021, we submitted to the FDA an update to the LTX-03 IND with our proposed clinical protocols for further development of LTX-03. The clinical protocols includes:

· A one tablet, single dose pharmacokinetic study in fasted, healthy adult subjects;
· A 2, 5 and tablet single dose pharmacokinetic study in fasted, healthy adult subjects; and
· A one tablet, single dose pharmacokinetic study in fed, healthy adult subjects.

These studies also contains design components to evaluate certain pharmacologic data with respect to, among other things, acidic beverages and drug interactions. These design of these studies was based on advice letters received from the FDA but no guarantees can be made that these studies, even if successful, will be sufficient to warrant FDA approval. We have received no comments or suggested changes to our proposed clinical protocols from the FDA based on this IND update.

We intend to advance LTX-03 to clinical development for a New Drug Application (NDA).

Non-clinical Study APT-RDR-300

Study APT-RDR-300 was a non-clinical study of respiratory depression in which five groups of 11 Sprague-Dawley rats were orally administered doses of hydrocodone ranging from 100mg of drug per kg of body weight (mg/kg) up to 300 mg/kg and one group receiving placebo. 8 subjects in each group were measured for opioid induced respiratory depression (OIRD) assessing peripheral oxygen saturation (SpO2) of the blood over a 4 hour observation period. 36 subjects were analyzed as successfully completing the dosing. The additional 3 subjects in each group provided blood samples analyzed for hydrocodone at .5, 1, 2 and 4 hours post-dosing.

In Study APT-RDR-300 all doses above 100 mg/kg demonstrated with statistical significance ($p<.05$) SpO2 measured OIRD at all time points post-dosing. The 100 mg/kg dose was not statistically significant for OIRD at any time point post-dosing. The mortality rate was correlated with higher doses. In all animals exhibiting OIRD, OIRD was acutely evident within 30 minutes of dosing which was consistent with the Cmax of the hydrocodone dose. Increased Cmax was generally associated with an increased prevalence of acute OIRD (SpO2 $\leq$70%). Approximately 90% of animals reaching this acute OIRD level resulted in death. Due to a high variability in the pharmacokinetics and pharmacodynamics observed in the study, no further associations were possible. Acura believes the results of this study generally support the development of opioid products with a reduction in Cmax in overdose situations.

Non-clinical Study APT-RDR-301

Study APT-RDR-301 was a non-clinical study of respiratory depression in which five groups of 10 Sprague-Dawley rats were orally administered doses of hydrocodone ranging from 100mg of drug per kg of body weight (mg/kg) up to 300 mg/kg and one group receiving placebo. Subjects in each group were measured for OIRD assessing peripheral oxygen saturation (SpO2) of the blood at 30-miniutes post-dose. After the 30-minute SpO2 reading, a blood sample was taken from each subject.

In Study APT-RDR-301 all drug doses demonstrated with statistical significance (p<.05) SpO2 measured OIRD at 30-minutes post-dosing. The mortality rate was correlated with higher doses with a lethal dose in 50% of the animals (LD50) consistent with study APT-RDR-300. A regression analysis of individual subjects demonstrated a statistically significant association between Cmax and SpO2 at the 30-minute timepoint.

Since our non-clinical studies are to characterize the pharmacology of our tablet formulation and not the toxicologic safety of the active ingredients, these studies were not run in compliance with FDA's current good laboratory practices.

AD Pharma Agreement covering LTX-03

On June 28, 2019 we announced a License, Development and Commercialization Agreement, as amended in October 2020 (the "AD Pharma Amended Agreement"), with Abuse Deterrent Pharma, LLC ("AD Pharma"), a special purpose company representing a consortium of investors that will finance Acura's operations through July, 2021, and completion of development of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura's patented LIMITx™ technology which addresses the consequences of excess oral administration of opioid tablets, the most prevalent route of opioid overdose and abuse. AD Pharma retains commercialization rights from which Acura will be entitled to receive royalties and potential sales related milestones. AD Pharma also has licensed commercialization rights to LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam).

The AD Pharma Amended Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03. Financial arrangements include monthly license payments by AD Pharma of $350,000 up to April 2020 and $200,000 thereafter until the earlier of July 31, 2021 or FDA's acceptance of a New Drug Application ("NDA") for LTX-03 and reimburse all our outside development costs for LTX-03. Upon commercialization of LTX-03, Acura receives stepped royalties on sales and is eligible for certain sales related milestones. AD Pharma is delinquent in remitting monthly license payments for January, 2021 thru May, 2021 which aggregates to $1.0 million and approximately $100,000 of reimbursable LTX-03 development expenses. Failure to make these payments is an event of default under the AD Pharma Amended Agreement, as amended.

AD Pharma may terminate the AD Pharma Amended Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by July 31, 2021, AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property. Should AD Pharma choose not to exercise this option to terminate and the NDA for LTX-03 is subsequently accepted by the FDA, such option expires. Acura expects the submission and FDA acceptance of the NDA for LTX-03 to now occur after July 31, 2021. Acura is currently in discussions with AD Pharma to further amend the AD Pharma Amended 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.

We also granted authority to MainPointe Pharmaceuticals, LLC (MainPointe) to assign to AD Pharma the option and the right to add, as an Option Product to the Nexafed® Agreement, a Nexafed® 12-hour dosage (an extended-release pseudoephedrine hydrochloride product utilizing the IMPEDE® Technology in 120mg dosage strength) and the Option Product exercise price of $500 thousand was waived if the exercise of the option occurred by June 28, 2024 (five years from the effective date), however effective with the October 2020 amendment, this option and right was rescinded. In March 2017, we granted MainPointe an exclusive license to our IMPEDE ® Technology to commercialize our Nexafed® and Nexafed® Sinus Pressure + Pain Products in the United States and Canada. On January 1, 2020, MainPointe assigned to AD Pharma, with Acura's consent, all of its right, title and interest in the MainPointe Agreement between MainPointe and Acura dated March 16, 2017. We understand that MainPointe continues to market the Nexafed products.

Mr. Schutte is our largest shareholder and directly owns approximately 44.8% of our common stock (after giving effect to the exercise of warrants he holds) as of February 15, 2021. Mr. Schutte also controls MainPointe and is an investor in AD Pharma.

Aversion Technology

Aversion Technology incorporates gelling ingredients and irritants into tablets to discourage abuse by snorting and provide barriers to abuse by injection. Our Aversion Technology and related opioid products, like Oxaydo, are covered by claims in six issued U.S. patents, which expire between November 2023 and March 2025. Our Aversion Technology products are intended to provide the same therapeutic benefits of the active drug ingredient as currently marketed products containing the same active pharmaceutical ingredient.

Oxaydo Tablets

Oxaydo (oxycodone HCI tablets) is a Schedule II narcotic indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. On January 7, 2015, we entered into a Collaboration and License Agreement with Assertio pursuant to which we exclusively licensed to Assertio worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is approved in 5mg and 7.5mg strengths. Assertio commenced shipping Oxaydo in the United States in October 2015.

The safety and efficacy of Oxaydo 5mg and 7.5mg tablets was established by demonstrating bioequivalence to commercially available oxycodone immediate-release tablets in the fasted state. Oxaydo differs from oxycodone tablets when taken with a high fat meal though these differences are not considered clinically relevant, and Oxaydo can be taken without regard to food. The FDA-approved label for Oxaydo describes elements unique to our Aversion Technology, which differs from current commercially available oxycodone immediate-release tablets. The label for Oxaydo includes the results from a clinical study that evaluated the effects of nasally snorting crushed Oxaydo and commercially available oxycodone tablets, and limitations on exposing Oxaydo Tablets to water and other solvents and administration through feeding tubes. The clinical study evaluated 40 non-dependent recreational opioid users, who self-administered the equivalent of 15mg of oxycodone. After accounting for a first sequence effect, the study demonstrated:

- 30% of subjects exposed to Oxaydo responded that they would not take the drug again compared to 5% of subjects exposed to immediate-release oxycodone;
- subjects taking Oxaydo reported a higher incidence of nasopharyngeal and facial adverse events compared to immediate-release oxycodone;
- a decreased ability to completely insufflate two crushed Oxaydo Tablets within a fixed time period (21 of 40 subjects), while all subjects were able to completely insufflate the entire dose of immediate-release oxycodone; and
- small numeric differences in the median and mean drug liking scores, which were lower in response to Oxaydo than immediate-release oxycodone.

We and Assertio have a post-approval commitment with the FDA to perform an epidemiology study to assess the actual impact on abuse of Oxaydo Tablets.

Further, the Oxaydo product label guides patients not to crush and dissolve the tablets or pre-soak, lick or otherwise wet the tablets prior to administration. Similarly, caregivers are advised not to crush and dissolve the tablets or otherwise use Oxaydo for administration via nasogastric, gastric or other feeding tubes as it may cause an obstruction. We believe that Assertio has shifted focus to marketing other products in their portfolio and deemphasized the marketing Oxaydo.

Assertio Agreement Covering Oxaydo

On January 7, 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, (now known as Assertio Holdings Inc.), entered into a Collaboration and License Agreement, or the Assertio Agreement, to commercialize Oxaydo Tablets containing our Aversion® Technology. Oxaydo is approved by the FDA for marketing in the United States in 5 mg and 7.5 mg strengths. Under the terms of the Assertio Agreement, we transferred the approved NDA for Oxaydo to Assertio and Assertio is granted an exclusive license under our intellectual property rights for development and commercialization of Oxaydo worldwide, or the Territory, in all strengths, subject to our right to co-promote Oxaydo in the United States.

In accordance with the Assertio Agreement, we and Assertio formed a joint steering committee to oversee commercialization strategies and the development of product line extensions. Assertio pays a significant portion of the expenses relating to (i) annual NDA PDUFA program fees, (ii) expenses of the FDA required post-marketing study for Oxaydo and (iii) expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States and pays all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States. Assertio is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Assertio has final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Assertio may develop Oxaydo for other countries and in additional strengths, in its discretion.

Assertio paid us an upfront payment of $5.0 million upon signing of the Assertio Agreement and a $2.5 million milestone in October 2015 in connection with the launch of Oxaydo. In addition, we will be entitled to a one-time $12.5 million milestone payment when worldwide Oxaydo net sales reach $150.0 million in a calendar year. In addition, we are entitled to receive from Assertio a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on Oxaydo net sales during such year (excluding net sales resulting from our co-promotion efforts). In any calendar year in which net sales exceed a specified threshold, we will receive a double digit royalty on all Oxaydo net sales in that year (excluding net sales resulting from our co-promotion efforts). If we exercise our co-promotion rights, we will receive a share of the gross margin attributable to incremental Oxaydo net sales from our co-promotion activities. Assertio's royalty payment obligations commenced on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA's Orange Book remains with respect to the Product). Royalties will be reduced upon the entry of generic equivalents, as well as for payments required to be made by Assertio to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Assertio Agreement expires upon the expiration of Assertio's royalty payment obligations in all countries. Either party may terminate the Assertio Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Assertio Agreement, subject to applicable cure periods, or in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws. We also may terminate the Assertio Agreement with respect to the U.S. and other countries if Assertio materially breaches its commercialization obligations. Assertio may terminate the Assertio Agreement for convenience on 120 days prior written notice. Termination does not affect a party's rights accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations (but not expiration), the Assertio Agreement provides for the transition of development and marketing of Oxaydo from Assertio to us, including the conveyance by Assertio to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Assertio's supply of Oxaydo for a transition period.

As part of a 2020 restructuring by Assertio, it is our understanding that they have decided to reduce selling efforts pertaining to Oxaydo and as such, we expect royalties to decline over the remainder of the Agreement.

KemPharm Agreement Covering Opioid Prodrugs

On October 13, 2016, we and KemPharm Inc., or KemPharm, entered into a worldwide License Agreement, or the KemPharm Agreement, pursuant to which we licensed our Aversion® Technology to KemPharm for its use in the development and commercialization of three products using 2 of KemPharm's prodrug candidates. KemPharm has also been granted an option to extend the KemPharm Agreement to cover two additional prodrug candidates. KemPharm is responsible for all development, manufacturing and commercialization activities, although we may provide initial technical assistance.

Upon execution of the KemPharm Agreement, KemPharm paid us an upfront payment of $3.5 million. If KemPharm exercises its option to use our Aversion Technology with more than the 2 prodrugs licensed, then KemPharm will pay us up to $1.0 million for each additional prodrug license. In addition, we will receive from KemPharm a low single digit royalty on commercial sales by KemPharm of products developed using our Aversion Technology under the KemPharm Agreement. KemPharm's royalty payment obligations commence on the first commercial sale of a product using our Aversion Technology and expire, on a country-by-country basis, upon the expiration of the last to expire patent claim of the Aversion Technology covering a product in such country, at which time the license for the particular product and country becomes fully paid and royalty free. As of December 31, 2020 we are unaware of KemPharm's use of our Aversion technology under the KemPharm Agreement.

The KemPharm Agreement expires upon the expiration of KemPharm's royalty payment obligations in all countries. Either party may terminate the KemPharm Agreement in its entirety if the other party materially breaches the KemPharm Agreement, subject to applicable cure periods. Acura or KemPharm may terminate the KemPharm Agreement with respect to the U.S. and other countries if the other party challenges the patents covering the licensed products. KemPharm may terminate the KemPharm Agreement for convenience on ninety (90) days prior written notice. Termination does not affect a party's rights accrued prior thereto, but there are no stated payments in connection with termination other than payments of obligations previously accrued. For all terminations (but not expiration), the KemPharm Agreement provides for termination of our license grant to KemPharm.

Aversion Technology Development Opioid Products

We have suspended further development of our Aversion hydrocodone/APAP product candidate, in order to focus our time and available resources on the development of our LIMITx Technology product candidates. We currently have 6 additional opioids at various stages of formulation development using the Aversion Technology which are not being actively developed.

Abuse of Pseudoephedrine Products

The 2019 CDC Drug Surveillance Report reported two million Americans aged 12 or older having used methamphetamine in the past year. From 2015-2018, an estimated 1.6 million U.S. adults aged ≥18 years, on average, reported past-year methamphetamine use. A 2018 study by researchers at Washington University in St. Louis found that methamphetamine use has increased significantly among people with an existing opioid use disorder (OUD). People with OUD in their study reported substituting methamphetamine for opioids when the latter are hard to obtain or are perceived as unsafe, or that they sought a synergistic high by combining them. People who purposefully combine heroin and cocaine or methamphetamine report that the stimulant helps to balance out the sedative effect of opioids, enabling them to function "normally." However, the combination can enhance the drugs' toxicity and lethality, by exacerbating their individual cardiovascular and respiratory effects.

The chemical structure of pseudoephedrine, or PSE, is very similar to methamphetamine, facilitating a straight-forward chemical conversion to methamphetamine. OTC PSE products are sometimes purchased and used for this conversion. There are multiple known processes to convert PSE to methamphetamine, all of which are not complex and do not require specialized equipment; however, many do require readily available but uncommon ingredients. Two of the three most popular processes follow two general processing steps: (1) dissolving the PSE tablets in a solvent to isolate, by filtration, purified PSE and (2) a chemical reduction of the PSE into methamphetamine for drying into crystals. The third method, or the "one-pot" method, involves the direct chemical reduction of the PSE to methamphetamine in the presence of the tablet's inactive ingredients. All the solvents used are ultimately dried off or otherwise removed, so a wide range of solvents are amenable to the process.

Impede Technology Products

Our initial Impede 1.0 Technology being used in Nexafed Sinus Pressure + Pain contains a proprietary mixture of inactive ingredients, prevents the extraction of PSE from tablets using known extraction methods and disrupts the direct conversion of PSE from tablets into methamphetamine.

We have developed a next generation Impede 2.0 Technology with additional inactive ingredients to improve the meth-resistance of our technology which is currently used in Nexafed Tablets. One-pot, direct conversion meth testing performed by our CRO on the following commercially available products resulted in:

Product/Formulation	Meth Resistant Technology	Meth Recovery[1]	Purity[2]
Sudafed® 30mg Tablets	None	67%	62%
Nexafed 30mg Technology	Impede® 1.0	38%	65%
Zephrex-D® 30mg Pills	Tarex®	28%	51%
Nexafed 120mg Extended-release tablets	Impede® 2.0	17%	34%

[1] Total methamphetamine HCl recovered from the equivalent of 100 PSE 30mg tablets divided by the maximum theoretical yield of 2.7 grams.

[2] Total methamphetamine HCl recovered from the equivalent of 100 PSE 30mg tablets divided by the total weight of powder recovered.

We have previously demonstrated in a pilot clinical study the bioequivalence of a formulation of our Nexafed extended release tablets utilizing our Impede 2.0 Technology to Sudafed® 12-hour Tablets.

Nexafed Products and the MainPointe Agreement

Nexafed and Nexafed Sinus Pressure + Pain, consist of immediate release tablets. Nexafed is a 30mg pseudoephedrine tablet which until the third quarter of 2017 incorporated our patented Impede 1.0 Technology and commencing in such quarter incorporated our Impede 2.0 Technology. Nexafed Sinus Pressure + Pain is a 30/325mg pseudoephedrine and acetaminophen tablet which incorporates our Nexafed 1.0 Technology. PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products. While the 30mg PSE tablet is not the largest selling PSE product on the market, we believe it is the most often used product to make meth due to: (a) its relatively low selling price and (b) its simpler formulation provides better meth yields.

We have demonstrated that our Nexafed 30mg tablets are bioequivalent to Johnson & Johnson's Sudafed 30mg Tablets when a single 2 tablet dose is administered. Commencing in 2006, the CMEA, required all non-prescription PSE products to be held securely behind the pharmacy counter, has set monthly consumer purchase volume limits, and has necessitated consumer interaction with pharmacy personnel to purchase PSE-containing products.

On March 16, 2017, we and MainPointe entered into a License, Commercialization and Option Agreement, or the MainPointe Agreement, pursuant to which we granted MainPointe an exclusive license to our Impede Technology to commercialize our Nexafed products in the U.S. and Canada. We also conveyed to MainPointe our existing inventory and equipment relating to our Nexafed products. MainPointe is responsible for all development, manufacturing and commercialization activities with respect to products covered by the MainPointe Agreement and controls the marketing and sale of our Nexafed products.

On signing the MainPointe Agreement, MainPointe paid us an upfront licensing fee of $2.5 million plus approximately $425 thousand for inventory and equipment being transferred. The MainPointe Agreement also provides for our receipt of a 7.5% royalty on net sales of licensed products. The royalty payment for each product will expire on a country-by-country basis when the Impede® patent rights for such country have expired or are no longer valid; provided that if no Impede patent right exists in a country, then the royalty term for that country will be the same as the royalty term for the United States. After the expiration of a royalty term for a country, MainPointe retains a royalty free license to our Impede® Technology for products covered by the MainPointe Agreement in such country.

MainPointe has the option to expand the licensed territory beyond the United States and Canada to the European Union (and the United Kingdom), Japan and South Korea for payments of $1.0 million, $500 thousand and $250 thousand, respectively. In addition, MainPointe has the option to add to the MainPointe Agreement certain additional products, or Option Products, containing PSE and utilizing the Impede Technology for a fee of $500 thousand per product (for all product strengths), including the product candidate Loratadine with pseudoephedrine. MainPointe has assigned and transferred its option rights to a Nexafed 12-hour formulation to AD Pharma. If the territory has been expanded prior to the exercise of a product option, the option fee will be increased to $750 thousand per product. If the territory is expanded after the payment of the $500 thousand product option fee, a one-time $250 thousand fee will be due for each product. If a third party is interested in developing or licensing rights to an Option Product, MainPointe must exercise its option for that product or its option rights for such product will terminate. On June 28, 2019, we granted authority to MainPointe to assign to AD Pharma the option and the right to add, as an Option Product to the Nexafed® Agreement, a Nexafed® 12-hour dosage (an extended-release pseudoephedrine hydrochloride product utilizing the IMPEDE® Technology in 120mg dosage strength) and waived the $500 thousand option fee, however effective with the October 2020 amendment, this option and right was rescinded.

The MainPointe Agreement may be terminated by either party for a material breach of the other party, or by Acura if MainPointe challenges certain of its patents. Upon early termination of the MainPointe Agreement, MainPointe's licenses to the Impede Technology and all products will terminate. Upon termination, at Acura's request the parties will use commercially reasonable efforts to transition the Nexafed® and Nexafed® Sinus Pressure + Pain products back to Acura.

On January 1, 2020, MainPointe assigned to AD Pharma, with Acura's consent, all of its right, title and interest in the MainPointe Agreement between MainPointe and Acura dated March 16, 2017.

Other Impede Technology Products

Given the fragmented nature of the PSE market with products containing multiple active ingredients, we have developed additional products for our Nexafed franchise:

Impede Technology Products	Status
Extended-release formulation utilizing Impede 2.0 Technology	Pilot pharmacokinetic testing demonstrated bioequivalence to Sudafed® 12-hour Tablets. Pre-IND meeting held with the FDA No imminent development planned
Extended-release combination products	No imminent development planned
Loratadine with pseudoephedrine	No imminent development planned

In July 2015, we had a pre-IND meeting with the FDA to discuss the results from our pharmacokinetic and meth-resistance testing studies to determine the development path for our extended-release development product. The FDA acknowledged the potential value of the development of risk-mitigating strategies for new formulations of pseudoephedrine products while also recognizing an approved "meth-deterrent" extended release pseudoephedrine product would be novel in the over-the-counter (OTC) setting. The FDA did not make a formal determination whether "meth-resistant" claims would be appropriate but is open to consider such an appropriately worded, evidence-based claim directed to the consumer and/or retailer. As recommended by the FDA, we have submitted additional "meth-resistant" testing information to the FDA for review prior to submitting an IND. In October 2016, we received FDA recommendations on our meth-resistant testing protocols for our Nexafed extended release tablets. We can now scale-up our manufacture batch size at a contract manufacturer which allows us to submit an IND to the FDA for our Nexafed extended release tablets, however, we have not yet committed to that level of development.

In March 2017, we completed a pilot pharmacokinetic study for the PSE and Loratadine combination product using our Impede 1.0 Technology. The study in 24 healthy adult subjects demonstrated sufficient, but not bioequivalent blood levels of PSE to the comparator while the second active ingredient achieved bioequivalence. Based on the product profile, we believe this formulation can be moved into final development for a 505(b)(2) NDA submission. The Company has upgraded a portion of this formulation with its Impede 2.0 Technology.

U.S. Market Opportunity for Impede PSE Products

PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products. PSE is sold in products as the only active ingredient in both immediate and extended-release products. In addition, PSE is combined with other cold, sinus and allergy ingredients such as pain relievers, cough suppressants and antihistamines. PSE also competes against phenylephrine, an alternate nasal decongestant available in non-prescription products. The top retail selling PSE OTC cold/allergy products are:

Reference Brand[1]	Brand Company	Active Ingredient(s)
Claritin-D	Bayer	PSE & Loraditine[2]
Allegra-D	Chattem	PSE & Fexofenadine[2]
Zyrtec-D	Pfizer	PSE & Ceterizine[2]
Advil Sinus	Pfizer	PSE & Ibuprofen
Sudafed 12 Hour	J&J	PSE[2]
Sudafed 30mg	J&J	PSE

[1] Branded product only. Does not include store brand sales.

[2] Extended release PSE formulations

MainPointe controls the price of Nexafed and Nexafed Sinus under the terms of the MainPointe Agreement. The market for cold, sinus and allergy products is highly competitive and many products have strong consumer brand recognition and, in some cases, prescription drug heritage. Category leading brands are often supported by national mass marketing and promotional efforts. Consumers often have a choice to purchase a less expensive store brand. Store brands contain the same active ingredients as the more popular national brands but are not supported by large marketing campaigns and are offered at a lower price. Non-prescription products are typically distributed through retail outlets including drug store chains, food store chains, independent pharmacies and mass merchandisers.

Product Labeling for Impede Technology Products

Nexafed and Nexafed Sinus Pressure + Pain products are marketed pursuant to the FDA's OTC Monograph regulations, which require that our products have labeling as specified in the regulations. Marketing for the Nexafed products includes advertising the extraction characteristics and methamphetamine-resistant benefits of these products which is supported by our published research studies.

We expect that any of our other Impede Technology products that are marketed pursuant to an NDA or ANDA will be subject to a label approved by the FDA. We expect that such a label will require submission of our scientifically derived abuse liability data and we intend to seek descriptions of our abuse liability studies in the FDA approved product label, although there can be no assurance that this will be the case.

U.S. Market Opportunity for Opioid Analgesic Products

According to the Centers for Drug Control's 2019 Drug Surveillance Report, opioid analgesics are one of the largest prescription drug markets in the United States with 153 million prescriptions dispensed in 2019 comprised of approximately 139 million and 14 million, immediate and extended release prescriptions, respectively. Further, it is estimated in 2018 that nationally, approximately 49.5 million people, across all age groups, received at least one opioid prescription. CDC data for 2016 identified hydrocodone and oxycodone as the most widely prescribed opioids with 6.2 billion hydrocodone pills/tablets and 5 billion oxycodone pills/tablets distributed in the US.

We expect our LIMITx Technology and Aversion opioid products, to compete primarily in the IR segment of the United States opioid analgesic market. Because IR opioid products are used for both acute and chronic pain, a prescription, on average, contains 66 tablets or capsules. According to IMS Health, in 2016, sales in the IR opioid product segment were approximately $2.7 billion, of which ~98% was attributable to generic products. Due to fewer identified competitors and the significantly larger market for dispensed prescriptions for IR opioid products compared to ER opioid products, we have initially focused on developing IR opioid products utilizing our Aversion and LIMITx Technologies.

Product Labeling for Products Using Our Technologies

We or our licensee may seek to include descriptions of studies that characterize the safety features of our technologies in the label for our products in development. Assertio has committed to undertake FDA required epidemiological studies to assess the actual consequences of abuse of Oxaydo in the market for which we share a minority portion of appropriate fees and expenses. The extent to which a description of the results of epidemiological or other studies will be added to or included in the FDA approved product label for our products in development will be the subject of our discussions with the FDA as part of the NDA review process. Further, because the FDA closely regulates promotional materials, even if FDA initially approves labeling that includes a description of the properties of the product, the FDA's Office of Prescription Drug Promotion, or OPDP, will continue to review the acceptability of promotional labeling claims and product advertising campaigns for our marketed products.

In April 2015, the FDA published guidance for industry on the evaluation and labeling of abuse-deterrent opioids and in June 2019, FDA issued a draft for public comment guidance on a Benefit-Risk Assessment Framework for Opioid Analgesic Drugs which may be beneficial to use in the development and labeling of our product candidates.

Patents and Patent Applications

We have the following issued patents covering, among other things, our LIMITx Technology:

Patent No. (Jurisdiction)	Subject matter	Issued	Expires
9,101,636 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Aug. 2015	Nov. 2033
9,320,796 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Apr. 2016	Nov. 2033
9,662,393 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	May 2017	Nov. 2033
10,441,657 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Sept. 2019	Nov. 2033
10,688,184	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Jun. 2020	Nov. 2033
2,892,908 (CAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Apr. 2016	Nov. 2033
5,922,851 (JAPAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Apr. 2016	Nov. 2033
ZL201380062421.0 (CHN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Jul. 2018	Nov. 2033
201711090908.6 (CHN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Oct.2020	Nov. 2033
2,925,304 (EUR)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Sept. 2018	Nov. 2033
2015124694 (RUS)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Nov. 2018	Nov. 2033
2013352162 (AUS)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Dec. 2018	Nov. 2033
366159 (MEX)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Jul. 2019	Nov. 2033
238713 (ISR)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Jul. 2019	Nov. 2033

We have the following issued patents covering, among other things, Oxaydo and our Aversion Technology:

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
7,201,920 (US)	Pharmaceutical compositions including a mixture of functional inactive ingredients and specific opioid analgesics	Apr. 2007	Mar. 2025
7,510,726 (US)	A wider range of compositions than those described in the 7,201,920 Patent	Mar. 2009	Nov. 2023
7,981,439 (US)	Pharmaceutical compositions including any water soluble drug susceptible to abuse	Jul. 2011	Aug. 2024
8,409,616 (US)	Pharmaceutical compositions of immediate-release abuse deterrent dosage forms	Apr. 2013	Nov. 2023
8,637,540 (US)	Pharmaceutical compositions of immediate-release abuse deterrent opioid products	Jan. 2014	Nov. 2023
9,492,443 (US)	Pharmaceutical compositions of immediate-release abuse deterrent opioid products	Nov. 2016	Nov. 2023

We have the following additional issued patents relating to our Aversion Technology:

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
8,822,489 (US)	Pharmaceutical compositions of certain abuse deterrent products that contain polymers, surfactant and polysorb 80	Jul. 2014	Nov. 2023
2,004,294,953 (AUS)	Abuse deterrent pharmaceuticals	Apr. 2010	Nov. 2024
2,010,200,979 (AUS)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,547,334 (CAN)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,647,360 (CAN)	Abuse deterrent pharmaceuticals	May 2012	Apr. 2027
175,863 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
221,018 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
1694260 (EUR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024

We have the following issued patents covering, among other things, our Nexafed product line and Impede 1.0 and 2.0 technologies:

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
8,901,113 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Dec. 2014	Feb. 2032
9,757,466 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Sept. 2017	Feb. 2032
10,004,699 (US)	Methods and compositions for interfering with extraction or conversion of a drug susceptible to abuse	Jun. 2018	Dec. 2035
10,155,044 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Dec. 2018	Feb. 2032
2010300641 (AUS)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sept. 2030
2,775,890 (CAN)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sept. 2030
2,488,029 (EUR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Mar. 2016	Sept. 2030
218533 (ISR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jan. 2016	Sept. 2030
2015274936 (AUS)	Methods and compositions for interfering with extraction or conversion of a drug susceptible to abuse	Sept. 2018	Jun. 2035
13102020.5 (HK)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Oct. 2016	Sept. 2030

In addition to our issued patents listed above and additional unlisted issued patents, we have filed multiple U.S. patent applications and international patent applications relating to compositions containing abusable active pharmaceutical ingredients as well as applications covering our Impede 1.0 and 2.0 Technologies and filed U.S. patent applications for our LIMITx Technology. Except for the rights granted in the Assertio Agreement, the KemPharm Agreement, the MainPointe Agreement, and the AD Pharma Amended Agreement and in the patent infringement settlement agreements described below, we have retained all intellectual property rights to our Aversion Technology, Impede Technology, LIMITx Technology and related product candidates.

Between October, 2013 and May, 2014 we settled on an individual basis, patent infringement suits we brought against generic manufacturers Par Pharmaceuticals, Inc., Impax Laboratories, Inc., Sandoz Inc. and Ranbaxy Inc. initiated by their seeking to market generic versions of Oxaydo. Principally, the settlements grant to Par a royalty bearing license to use our Aversion Technology patents in an immediate-release oxycodone product starting in January 2022, or sooner depending on other generic competition. None of such settlements impacted the validity or enforceability of our Patents.

On May 20, 2016, we, Purdue Pharma L.P. and Assertio settled patent infringement actions initiated by Purdue against Oxaydo and an Inter Partes Review initiated by us against a Purdue patent. The parties dismissed or withdrew the actions, requested that the USPTO terminate the IPR Review and exchanged mutual releases. No payments were made by the parties under the settlement agreement. The settlement provides that Acura will not, in the future, assert certain Acura U.S. Aversion Technology patents against selected Purdue immediate and extended-release products. In addition, Purdue has certain rights to negotiate to exclusively distribute an authorized generic version of certain Assertio products, including, in some circumstances, Oxaydo® and other products using Acura's Aversion® Technology if licensed to Assertio.

Reference is made to the Risk Factors contained in this Report on Form 10-K for the year ended December 31, 2020 for a discussion, among other things, of patent applications and patents owned by third parties, including claims that may encompass our Aversion Technology and Oxaydo Tablets, and the risk of infringement, interference or opposition proceedings that we may be subject to arising from such patents and patent applications.

Company's Present Financial Condition

As of March 31, 2020, we had cash of $361 thousand million, working capital deficit of $6.3 million and an accumulated deficit of $389.5 million. We had a loss from operations of $146 thousand and a net loss of $259 thousand for the three months ended March 31, 2021, and had a loss from operations of $758 thousand and a net loss of $1.2 million for the year ended December 31, 2020. We have suffered recurring losses from operations and have not generated positive cash flows from operations. We anticipate operating losses to continue for the foreseeable future. As of May 14, 2021 our cash balance was approximately $200 thousand.

Currently, the License, Development and Commercialization Agreement dated June 28, 2019 as amended ("AD Pharma Amended Agreement"), requires 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 continues through the earlier of July 31, 2021 or FDA's acceptance of a New Drug Application for LTX-03, and reimburse all our outside development costs for LTX-03.

AD Pharma is delinquent in remitting monthly license payments for January, 2021 thru May, 2021 which aggregates to $1.0 million and approximately $100,000 of reimbursable LTX-03 development expenses. Failure to make these payments is an event of default under the AD Pharma Amended Agreement.

The AD Pharma Amended Agreement, requires that the NDA for LTX-03 be accepted by the FDA by July 31, 2021 or AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property. Failure to meet this date is an event of default under the Company's $6.0 million convertible debt to AD Pharma. The AD Pharma Amended Agreement allows AD Pharma to terminate the AD Pharma Amended Agreement "for convenience". Acura currently expects the submission and FDA acceptance of the NDA for LTX-03 to occur after July 31, 2021 and has notified AD Pharma of this revised timeline. Acura intends to renegotiate the NDA filing acceptance date for LTX-03, of which no assurance can be given. Pending resolution of this matter, the $6.0 million convertible debt is presented as a current liability in our financial statements. Whether or not AD Pharma exercises their right to terminate the AD Pharma Amended Agreement, we need to raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

In view of the matters described above, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date the financial statements are issued.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying balance sheets is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements on a continuous basis, to maintain existing financing and to succeed in its future operations. The Company's financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Our future sources of revenue, if any, will be derived from licensing fees, milestone payments and royalties under the AD Pharma Amended Agreement, the Assertio Agreement, the KemPharm Agreement, the MainPointe Agreement and similar agreements which we may enter into for our LIMITx products in development with other pharmaceutical company partners, for which there can be no assurance.

The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our product candidates and the resources we devote to the development and commercialization of our product candidates.

Three months Ended March 31, 2021 Compared to Three months Ended March 31, 2020

	March 31			
	2021	2020	Increase (decrease)	
Revenues:		$000's		Percent
Royalties	$ 32	$ 33	$ (1)	(3)%
Collaboration from related party	12	8	4	50
License fees from related party	600	1,050	(450)	(43)
Total revenues	644	1,091	1,024	(41)
Expenses:				
Research and development	405	387	18	5
General and administrative	385	1,187	(802)	(68)
Total operating expenses	790	1,574	(784)	(50)
Operating loss	(146)	(483)	(337)	(70)
Interest expense – related party	(113)	(112)	1	1
Loss before income taxes	(259)	(595)	(336)	(56)
Provision for income taxes	-	-	-	-
Net loss	$ (259)	$ (595)	$ (336)	(56)%

Revenues

License Fees

We recognize license fees under the license and development agreement with AD Pharma for LTX-03 dated June 2019 and as amended in October 2020. We recognized $0.6 million and $1.05 million of license fees revenue during the three months ended March 31, 2021 and 2020, respectively.

Collaboration Revenue

Collaboration revenue is derived from research and development services we perform under the license and development agreement with AD Pharma for LTX-03. We recognized $12 thousand and $8 thousand of collaboration revenue during the three months ended March 31, 2021 and 2020, respectively.

Royalty Revenue

In connection with our license agreement with Assertio for Oxaydo Tablets, we earn a royalty based on product net sales. We recognized $30 thousand of royalty revenue for Oxaydo during each of the three months ended March 31, 2021 and 2020. We expect future lower royalties from lower product net sales of Oxaydo Tablets as Assertio has indicated they have ceased promoting this product.

In connection with our license agreement with MainPointe for our Nexafed product line, we earn a royalty based on product net sales. We recognized $2 thousand and $3 thousand of royalty revenue on Nexafed during the three months ended March 31, 2021 and 2020, respectively.

Operating Expenses

Research and Development

Research and development expenses ("R&D") primarily consisted of our activities with respect to our LIMITx Technology development under license with AD Pharma and can include, among other items, costs of preclinical and non-clinical internal and external activities, clinical study trials, clinical supplies and its related formulation and design costs, salaries and other personnel related expenses of our employees, consultants and our facility costs. Our R&D expenses remained relatively unchanged with having only a $18 thousand increase between reporting periods, all expenses relate to the LTX-03 development activities.

General and Administrative

Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Excluding the share-based compensation expense of $15 thousand included in the three months ended March 31, 2020, our general and administrative expenses decreased by approximately $0.8 million between reporting periods. The decrease is primarily due from a nonrecurring impairment charge taken in 2020 of $668 thousand on an intangible asset as well as a reduction in its associated amortization expense of $46 thousand and a reduction in legal expenses of $66 thousand.

Non-Operating Expense

Interest Expense

For the three month period ending March 31, 2021 and 2020, we incurred interest expense of $113 thousand and $112 thousand, respectively, on our $6.0 million convertible debt.

Income Taxes

Our results for the three month period ended March 31, 2021 and 2020 include no federal or state income tax benefit provisions due to 100% allowances placed against our deferred tax assets for the uncertainty of their future utilization.

Liquidity and Capital Resources

At March 31, 2021 we had cash of cash of $361 thousand and working capital deficit of $6.3 million. At December 31, 2020 we had cash of $413 thousand. We had a loss from operations of $146 thousand and a net loss of $259 thousand for the three months ended March 31, 2021, and had a loss from operations of $758 thousand and a net loss of $1.2 million for the year ended December 31, 2020. We have suffered recurring losses from operations and have not generated positive cash flows from operations. We anticipate operating losses to continue for the foreseeable future. At May 14, 2021 our cash balance was approximately $200 thousand.

The License, Development and Commercialization Agreement with AD Pharma dated June 28, 2019, as amended in October 2020, requires AD Pharma to pay to us for a period from inception up to April 2020 at which time the payment became $200,000 per month and continues through the earlier of July 31, 2021 or FDA's acceptance of a New Drug Application for LTX-03, and to pay all outside development costs for LTX-03 (the "AD Pharma Amended Agreement").

AD Pharma is delinquent in remitting monthly license payments for January, 2021 thru May, 2021 which aggregates to $1.0 million and approximately $100 thousand of reimbursable LTX-03 development expenses. Failure to make these payments is an event of default under the AD Pharma Amended Agreement.

The AD Pharma Amended Agreement, requires the NDA for LTX-03 be accepted by the FDA by July 31, 2021 or AD Pharma has the option to terminate the AD Pharma Agreement and take ownership of the LIMITx intellectual property. Failure to meet this date is an event of default under the Company's $6.0 million outstanding convertible debt to AD Pharma. The Agreement allows AD Pharma to terminate the Agreement "for convenience". Acura currently expects the submission and FDA acceptance of the NDA for LTX-03 to occur after July 31, 2021 and has notified AD Pharma of this revised timeline. Acura plans to renegotiate the LTX-03 NDA filing acceptance date, of which no assurance can be given. Pending resolution of this matter, we have presented the $6.0 million convertible debt as a current liability in our financial statements. Whether or not AD Pharma exercises their right to terminate the AD Pharma Amended Agreement, we need to raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

In view of the matters described above, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date the financial statements are issued and our independent registered public accounting firm have included in their report relating to our 2020 financial statements a "going concern" explanatory paragraph as to substantial doubt of our ability to continue as a going concern.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying balance sheets is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements on a continuous basis, to maintain existing financing and to succeed in its future operations. The Company's financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Our future sources of revenue, if any, will be derived from licensing fees, milestone payments and royalties under the AD Pharma Amended Agreement, the Assertio Agreement, the KemPharm Agreement, the MainPointe Agreement and similar agreements which we may enter into for our LIMITx products in development with other pharmaceutical company partners, for which there can be no assurance.

The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our product candidates and the resources we devote to the development and commercialization of our product candidates.

Critical Accounting Policies

Note 1 of the Notes to Consolidated Financial Statements, in the Company's 2020 Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company's critical accounting policies described in the 2020 Annual Report are also applicable to 2021.

Item 4. Controls and Procedures

(a) *Disclosure Controls and Procedures*. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined on Rules 13a – 13(e) and 15(d) – 15(e) under the Exchange Act) as of the end of the period covered by this Report. The Company's disclosure controls and procedures are designed to provide reasonable assurance that information is recorded, processed, summarized and reported accurately and on a timely basis in the Company's periodic reports filed with the SEC. Based upon such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures are effective to provide reasonable assurance. Notwithstanding the foregoing, a control system, no matter how well designed and operated, can provide only reasonable, not absolute assurance that it will detect or uncover failures within the Company to disclose material information otherwise require to be set forth in the Company's periodic reports.

(b) *Changes in Internal Controls over Financial Reporting*. There were no changes in our internal controls over financial reporting during the first fiscal quarter of 2021 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

The information required by this Item is incorporated by reference Commitments and Contingencies, in Part I, Item 1, "Financial Statements".

Item 6. Exhibits

The exhibits required by this Item are listed below.

31.1	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
31.2	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
32.1	Certification of Periodic Report by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase

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.

May 14, 2021

ACURA PHARMACEUTICALS, INC.

/s/ Robert B. Jones
Robert B. Jones
Chief Executive Officer

/s/ Peter A. Clemens
Peter A. Clemens
Senior VP & Chief Financial Officer

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Robert B. Jones, the President & Chief Executive Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d – 15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with general accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrants most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

May 14, 2021

/s/ Robert B. Jones
Robert B. Jones
President & Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Peter A. Clemens, the Chief Financial Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrants most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

May 14, 2021

/s/ Peter A. Clemens
Peter A. Clemens
Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS OF THE CHIEF EXEUTIVE OFFICER AND THE CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Acura Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert B. Jones, the Chief Executive Officer of the Company, and Peter A. Clemens, Chief Financial Officer certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 14, 2021

/s/ Robert B. Jones
Robert B. Jones
Chief Executive Officer

/s/ Peter A. Clemens
Peter A. Clemens
Chief Financial Officer