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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2020**

Or

☐ **TRANSITION 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 administrative office)	(Zip code)

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

Securities registered pursuant to section 12(b) of the Act:	**Name of each exchange on which registered:**
None	N/A

Securities registered pursuant to section 12(g) of the Act:
Common Stock, par value $0.01 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ☐No ☒

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 ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

☐ Large Accelerated Filer	☐ Accelerated Filer
☒ Non-Accelerated Filer	☒ 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 ☐ No ☒

Based on the last sale price on the OTCQB Market of the Common Stock of $0.35 on June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $2.6 million.

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

Title of each class	Ticker symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	ACUR	OTCQB Market

As of March 30, 2021, the registrant had 22,104,668 shares of Common Stock, par value $0.01, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Part III of this Annual Report on Form 10-K incorporates by reference portions of the registrant's Proxy Statement for its 2021 Annual Meeting of Stockholders, which Proxy Statement will be filed with the United States Securities and Exchange Commission within 120 days after the end of the registrant's 2020 fiscal year.

Acura Pharmaceuticals, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2020

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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 other 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 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.

PART I

ITEM 1. BUSINESS

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 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 us for development of LTX-03. The AD Pharma 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). At March 31, 2021 AD Pharma is delinquent in remitting monthly license payments for December, 2020 thru March, 2021 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.

Our Strategy

Our strategy is to focus on addressing the safe use of pharmaceuticals by developing a broad portfolio of technologies and products with enhanced safety features and benefits. Specifically, we intend to:

- *Capitalize on our experience and expertise in the research and development of innovative drug delivery technologies that address medication safety.* We have one FDA approved product containing our Aversion Technology commercially launched in the United States by our licensee, and two products commercially launched containing our Impede Technology. We are currently devoting our efforts to product candidates utilizing our LIMITx Technology, which we believe will offer a significant measure of safety to those who would intentionally or otherwise ingest excessive number of tablets.

- *Leverage our technologies by developing a full line of pharmaceutical products which utilize our proprietary technologies.* Medication abuse and misuse is not limited to single drugs but often pervades entire drug categories. We intend to develop or collaborate with strategically focused pharmaceutical companies to develop multiple products with our technologies, and are seeking licensing partners for products in development utilizing our LIMITx Technology.

- *Commercialize our products by licensing to strategically focused companies in the United States and other geographic territories. We have licensed our Oxaydo product to Assertio for commercialization, have licensed our Aversion Technology to KemPharm for use in certain of its prodrug products, have licensed our Nexafed products utilizing our Impede Technology to MainPointe/AD Pharma for commercialization (and granted MainPointe and AD Pharma options to other Impede products), and we entered into an agreement with AD Pharma that will finance Acura's operations, through July, 2021, provide for the completion of development of LTX-03 and grants them exclusive commercialization rights in the United States to LTX-03. Additionally, we are seeking other licensing partners for other product candidates utilizing our LIMITx, Aversion and Impede technologies.*

- *Maintain an efficient internal cost structure.* Our internal cost structure is focused on discovering new technologies and developing product formulations using those technologies. We outsource many high cost elements of development and commercialization, such as clinical trials and commercial manufacturing that minimize required fixed overhead and capital investment and thereby reduces our business risk.

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.

The CDC also identified rising overdose deaths resulting from “polysubstance” drug use. Polysubstance drug use occurs with exposure to more than one drug, with or without the person’s knowledge. This growing issue also means that an opioid-involved overdose often occurs in combination with exposure to other opioids and/or other non-opioid substances. Some examples of polysubstance exposures found in combination in overdose deaths include illicitly manufactured fentanyl (IMF) and heroin; illicitly manufactured fentanyl and cocaine; heroin and methamphetamine; and prescription or illicit opioids and benzodiazepines. Recent data indicate that the involvement of opioids in stimulant-involved deaths is increasing. Nearly three-quarters (72.7%) of cocaine-involved overdose deaths also involved an opioid in 2017. Although increases in psychostimulant-involved deaths have occurred Prescription opioids drugs, such as morphine and oxycodone, have a long history of use for the management of pain. Because they are highly effective, they are one of the largest prescribed drug categories in the U.S. However, a side effect of high doses of opioids is euphoria, or “a high”. For these reasons, opioids are the most misused or abused prescription drugs in the U.S. Opioids are offered in a variety of dosages including immediate-release tablets (or capsules), extended-release tablets (or capsules), patches and other formats. Those who misuse or abuse drugs will often do so in one of the following manners:

- Oral Excessive Tablet Abuse (ETA). Generally recognized as the most prevalent route of administration by abusers, the abuser simply orally ingests more tablets (or capsules) than is recommended for pain relief.
- Oral Manipulated Tablet Abuse (MTA). Extended-release tablets or patches are sometimes crushed, chewed or otherwise physically or chemically manipulated to defeat the extended-release mechanism and provide an immediate-release of the opioid for oral ingestion.
- Nasal snorting. Crushed tablets are insufflated for absorption of the drug through the nasal tissues.
- Injection. The opioid is physically or chemically removed from the dosage and injected into the vein using a syringe.
- Poly-substance. Opioids are sometimes used in conjunction with alcohol, methamphetamine, or other drugs to accentuate the high.
- Overdose. Drug abusers may accidentally introduce excessive quantities of drugs in their systems or combine drugs that may heighten the chance of adverse effects of drugs. Some patients may over ingest drugs accidentally or with the express intent of suicide.

Safe use technology formulations incorporate physical and/or chemical barriers or functionality in the products to prevent or discourage a user from inappropriately administering the product. The extent and manner in which any of the features of these formulations may be described in the FDA approved label for our development products will be dependent on the results of and the acceptance by the FDA of our and our licensees’ studies for each product.

Development of safe use products typically require one or more studies. These studies may include in vitro laboratory studies (which may include but not be limited to: syringeability of the formulation, extractability of the active ingredient, and particle size of the crushed product), animal studies (which may include but not be limited to: respiratory depression), and human clinical studies (which may include but not be limited to: human abuse liability, respiratory depression studies) comparing the benefits of our product candidates to currently marketed products.

Because our products use known active ingredients in approved dosage strengths, the safety and efficacy of the active ingredient(s) will need to be established by a series of pharmacokinetic studies demonstrating: (a) bioequivalence to an approved reference drug, (b) food effect of our formulations, (c) dose proportionality of our formulation, and (d) other external impacts to our unique formulations. A product candidate that does not achieve satisfactory pharmacokinetic results may require a phase III clinical efficacy study.

Further development 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 NDA phase of development. In accordance with the FDA's 2015 Guidance, we will likely have a post-approval requirement for each of our opioid products, if approved, to perform an epidemiology study to assess the in-market impact on abuse of our formulation and most approved opioid products are subject to an FDA approved risk evaluation and mitigations strategy (REMS).

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 (CO2) in the blood stream. Opioids also impact ancillary CO2 monitoring of the blood preventing the body from taking corrective action. The increased CO2 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 will be required 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 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 ≤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 "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 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 reimbursement by AD Pharma of Acura's LTX-03 outside development expenses. 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 December, 2020 thru March, 2021 and approximately $100 thousand of reimbursable LTX-03 development expenses. Failure to make these payments are an event of default under the Agreement, as amended. Based upon representations by AD Pharma, we anticipate receipt of these past due amounts by April 30, 2021 and payment obligations through July, 2021, for which no assurance can be given.

AD Pharma may terminate the 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 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 amend the Agreement. There can be no assurance that AD Pharma will agree to extend the NDA filing acceptance date or that they will not take ownership of the intellectual property.

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. 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 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 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 to the AD Pharma Agreement, 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 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 Intes Parties 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.

Research and Manufacturing

We conduct research, development, manufacture of laboratory clinical trial supplies, and warehousing activities at our operations facility in Culver, Indiana and lease an administrative office in Palatine, Illinois. The 25,000 square foot Culver facility is registered with the DEA to perform research, development and manufacture of certain DEA-scheduled active pharmaceutical ingredients and finished dosage form products. We have obtained quotas for supply of DEA-scheduled active pharmaceutical ingredients from the DEA and develop finished dosage forms in our Culver facility. We manufacture clinical trial supplies of drug products in our Culver facility. 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. Assertio is responsible for commercial manufacture of Oxaydo under the Assertio Agreement. We expect that future opioid product candidates developed and licensed by us will be commercially manufactured by our licensees or other qualified third party contract manufacturers.

Prior to our entering into the MainPointe Agreement, we relied on two contract manufacturers to manufacture, package and supply our commercial quantities of Nexafed and Nexafed Sinus Pressure + Pain products. We assigned our existing supply agreement to MainPointe in accordance with the terms of the MainPointe Agreement. Although we believe there are alternate sources of supply that can satisfy MainPointe's anticipated commercial requirements, replacing or adding a contract manufacturer may cause an interruption in supply and could adversely impact our royalties from MainPointe on the net sales of the Nexafed products.

Competition

Our products and technologies will, if marketed, compete to varying degrees against both brand and generic products offering similar therapeutic benefits and being developed and marketed by small and large pharmaceutical (for prescription products) and consumer packaged goods (for OTC products) companies. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us and our licensees in research, development and commercialization of their competitive technologies and products. Prescription generic products and OTC store brand products will offer cost savings to third party payers and/or consumers that will create pricing pressure on our or our licensed products. Also, these competitors may have a substantial sales volume advantage over our products, which may result in our costs of manufacturing being higher than our competitors' costs.

We believe potential competitors may be developing opioid abuse deterrent technologies and products. Such potential competitors include, but may not be limited to, Pfizer Inc., Purdue Pharma, Atlantic Pharmaceuticals, KemPharm, Shionogi, Pisgah Labs, Ensysce Biopharma, Inspirion Delivery Sciences and Collegium Pharmaceuticals.

Our Impede Technology products containing PSE will compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Some of our competitors will have multiple consumer product offerings both within and outside the cold, allergy and sinus category providing them with substantial leverage in dealing with a highly consolidated pharmacy distribution network. The competing products may have well established brand names and may be supported by national or regional advertising. Nexafed will compete primarily with Johnson & Johnson's Sudafed brand and Nexafed Sinus Pressure + Pain with Pfizer's Advil brand Cold and Sinus, as well as generic/store brand formulations of such products manufactured by Perrigo Company and others. A competing product from Perrigo is being marketed with claims of methamphetamine-resistance.

In addition to our license agreement with MainPointe/AD Pharma, we may consider licensing our Impede Technology or other products utilizing such technology for commercialization.

Government Regulation

All pharmaceutical firms, including us, are subject to extensive regulation by the federal government, principally by the FDA under the Federal Food, Drug and Cosmetic Act, or the FD&C Act, and, to a lesser extent, by state and local governments. Before our prescription products and some OTC products may be marketed in the U.S., they must be approved by the FDA for commercial distribution. Certain OTC products must comply with applicable FDA regulations, known as OTC Monographs, in order to be marketed, but do not require FDA review and approval before marketing. Additionally, we are subject to extensive regulation by the DEA under the Controlled Substances Act, the Combat Methamphetamine Act of 2005, and related laws and regulations for research, development, manufacturing, marketing and distribution of controlled substances and certain other pharmaceutical active ingredients that are regulated as Listed Chemicals. Extensive FDA, DEA, and state regulation of our products and commercial operations continues after drug product approvals, and the requirements for our continued marketing of our products may change even after initial approval. We are also subject to regulation under federal, state and local laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, state, federal and foreign regulations, including possible future regulations of the pharmaceutical industry. We cannot predict the extent to which we may be affected by legislative and other regulatory developments concerning our products and the healthcare industry in general.

The FD&C Act, the Controlled Substances Act and other federal statutes and regulations govern the testing, manufacture, quality control, export and import, labeling, storage, record keeping, approval, pricing, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements both before and after approval, can subject us, our third party manufacturers and other collaborative partners to administrative and judicial sanctions, such as, among other things, warning letters, fines and other monetary payments, recall or seizure of products, criminal proceedings, suspension or withdrawal of regulatory approvals, interruption or cessation of clinical trials, total or partial suspension of production or distribution, injunctions, limitations on or the limitation of claims we can make for our products, and refusal of the government to enter into supply contracts for distribution directly by governmental agencies, or delay in approving or refusal to approve new drug applications. The FDA also has the authority to revoke or withhold approvals of new drug applications.

FDA approval is required before any "new drug," can be marketed. A "new drug" is one not generally recognized, by experts qualified by scientific training and experience, as safe and effective for its intended use. Our products not subject to and in compliance with an OTC Monograph are new drugs and require prior FDA approval. Such approval must be based on extensive information and data submitted in a NDA, including but not limited to adequate and well controlled laboratory and clinical investigations to demonstrate the safety and effectiveness of the drug product for its intended use(s) as well as the manufacturing suitability of the product. In addition to providing required safety and effectiveness data for FDA approval, a drug manufacturer's practices and procedures must comply with current Good Manufacturing Practices ("cGMPs"), which apply to manufacturing, receiving, holding and shipping, and include, among other things, demonstration of product purity, consistent manufacturing and quality and at least six months of data supporting product expiration dating based on clinical registration batches. Accordingly, manufacturers must continue to expend time, money and effort in all applicable areas relating to quality assurance and regulatory compliance, including production and quality control to comply with cGMPs. Failure to so comply risks delays in approval of drug products and possible FDA enforcement actions, such as an injunction against shipment of products, the seizure of non-complying products, criminal prosecution and/or any of the other possible consequences described above. We are subject to periodic inspection by the FDA and DEA, which inspections may or may not be announced in advance.

The FDA Drug Approval Process

The process of drug development is complex and lengthy. The activities undertaken before a new pharmaceutical product may be marketed in the U.S. generally include, but are not limited to, preclinical studies; submission to the FDA of an Investigational New Drug application, or IND, which must become active before human clinical trials may commence; adequate and well-controlled human clinical trials to establish the safety and efficacy of the product; submission to the FDA of an NDA; acceptance for filing of the NDA by FDA; satisfactory completion of an FDA pre-approval inspection of the clinical trial sites and manufacturing facility or facilities at which both the active ingredients and finished drug product are produced to assess compliance with, among other things, patient informed consent requirements, the clinical trial protocols, current Good Clinical Practices, or GCP, and cGMPs; and FDA review and approval of the NDA prior to any commercial sale and distribution of the product in the U.S.

Preclinical studies include laboratory evaluation of product chemistry and formulation, and in some cases, animal studies and other studies to preliminarily assess the potential safety and efficacy of the product candidate. The results of preclinical studies together with manufacturing information, analytical data, and detailed information including protocols for proposed human clinical trials are then submitted to the FDA as a part of an IND. An IND must become effective, and approval must be obtained from an Institutional Review Board, or IRB, prior to the commencement of human clinical trials. The IND becomes effective 30 days following its receipt by the FDA unless the FDA objects to, or otherwise raises concerns or questions and imposes a clinical hold. We, the FDA or the IRB may suspend or terminate a clinical trial at any time after it has commenced due to safety or efficacy concerns or for commercial reasons. In the event that FDA objects to the IND and imposes a clinical hold, the IND sponsor must address any outstanding FDA concerns or questions to the satisfaction of the FDA before clinical trials can proceed or resume. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials.

Human clinical trials are typically conducted in three phases that may sometimes overlap or be combined:

Phase 1: This phase is typically the first involving human participants, and involves the smallest number of human participants (typically, 20-50). The investigational drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In addition, it is sometimes possible to gain a preliminary indication of efficacy.

Phase 2: Once the preliminary safety and tolerability of the drug in humans is confirmed during phase 1, phase 2 involves studies in a somewhat larger group of study subjects. Unlike phase 1 studies, which typically involve healthy subjects, participants in phase 2 studies may be affected by the disease or condition for which the product candidate is being developed. Phase 2 studies are intended to identify possible adverse effects and safety risks, to evaluate the efficacy of the product for specific targeted diseases, and to determine appropriate dosage and tolerance.

Phase 3: Phase 3 trials typically involve a large numbers of patients affected by the disease or condition for which the product candidate is being developed. Phase 3 clinical trials are undertaken to evaluate clinical efficacy and safety under conditions resembling those for which the product will be used in actual clinical practice after FDA approval of the NDA. Phase 3 trials are typically the most costly and time-consuming of the clinical phases.

Phase 4 or Post-Marketing Requirements: Phase 4 trials may be required by FDA after the approval of the NDA for the product, as a condition of the approval, or may be undertaken voluntarily by the sponsor of the trial. The purpose of phase 4 trials is to continue to evaluate the safety and efficacy of the drug on a long-term basis and in a much larger and more diverse patient population than was included in the prior phases of clinical investigation.

After clinical trials have been completed, and if they were considered successful, the sponsor may submit a NDA or Abbreviated New Drug Application, or ANDA, to the FDA including the results of the preclinical and clinical testing, together with, and among other things, detailed information on the chemistry, manufacturing, quality controls, and proposed product labeling. There are two types of NDAs; a 505(b)(1) NDA and a 505(b)(2) NDA. A 505(b)(1) NDA is also known as a “full NDA” and is described by section 505(b)(1) of the FD&C Act as an application containing full reports of investigations of safety and effectiveness, in addition to other information. The data in a full NDA is either owned by the applicant or are data for which the applicant has obtained a right of reference. A 505(b)(2) application is one described under section 505(b)(2) of the FD&C Act as an application for which information, or one or more of the investigations relied upon by the applicant for approval, “were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted”. This provision permits the FDA to rely for approval of an NDA on data not developed by the applicant, such as published literature or the FDA’s finding of safety and effectiveness of a previously approved drug. 505(b)(2) applications are submitted under section 505(b)(1) of the FD&C Act and are therefore subject to the same statutory provisions that govern 505(b)(1) applications that require among other things, “full reports” of safety and effectiveness.

The 505(b)(2) NDAs must include one of several different types of patent certifications to each patent that is listed in the FDA publication known as the Orange Book in connection with any previously approved drug, the approval of which is relied upon for approval of the 505(b)(2) NDA. Depending on the type of certification made, the approval of the 505(b)(2) NDA may be delayed until the relevant patent(s) expire, or in the case of a Paragraph IV Certification may lead to patent litigation against the applicant and a potential automatic approval delay of 30 months or more.

Under the Prescription Drug User Fee Amendments of 2017, PDUFA VI, the FDA collects two types of fees associated with NDAs – (i) a fee collected at the time applications are submitted, and (ii) prescription drug program fees (accounting for 80% of the total), which are collected annually for certain prescription drugs. Exceptions to the application fee include previously filed applications and applications for drugs designated as orphan drugs for a rare disease.

According to FDA’s fee schedule, posted on August 3, 2020, for the 2021 fiscal year, the user fee for an application fee requiring clinical data, such as an NDA is $2,875,842. The FDA adjusts PDUFA user fees on an annual basis. A written request can be submitted for a waiver of the application fee for the first human drug application that is filed by a small business. Where we are subject to these fees, they are significant expenditures that may be incurred in the future and must be paid at the time of submission of each application to FDA.

After an NDA is submitted by an applicant, and if it is accepted for filing by the FDA, the FDA will then review the NDA and, if and when it determines that the data submitted are adequate to show that the product is safe and effective for its intended use, the FDA will approve the product for commercial distribution in the U.S. There can be no assurance that any of our products in development will receive FDA approval or that even if approved, they will be approved with labeling that includes descriptions of its abuse deterrent features. Moreover, even if our products in development are approved with labeling that includes descriptions of the abuse deterrent features of our products, advertising and promotion for the products will be limited to the specific claims and descriptions in the FDA approved product labeling.

In terms of program fees, subject to certain exceptions, each sponsor is required to pay the annual fee for each new prescription drug approved as of 1 October of each fiscal year (for 2021 such fee is $336,432 per product strength), but applicants may not be assessed more than five prescription drug program fees for a fiscal year, for prescription drugs identified in a single application. For example, an applicant that has 10 drug products identified in an approved NDA for 10 different strengths of tablet dosage form products is eligible for an assessment for a maximum of 5 program fees. PDUFA VI also eliminated fees for drug application supplements and establishment fees.

The FDA requires drug manufacturers to establish and maintain quality control procedures for manufacturing, processing and holding drugs and investigational products, and products must be manufactured in accordance with defined specifications. Before approving an NDA, the FDA usually will inspect the facility(ies) at which the active pharmaceutical ingredients and finished drug product is manufactured, and will not approve the product unless it finds that cGMP compliance at those facility(ies) are satisfactory. If the FDA determines the NDA is not acceptable, the FDA may outline the deficiencies in the NDA and often will request additional information, thus delaying the approval of a product. Notwithstanding the submission of any requested additional testing or information, the FDA ultimately may decide that the application does not satisfy the criteria for approval. After a product is approved, changes to the approved product, such as adding new indications, manufacturing changes, or changes in or additions to the approved labeling for the product, may require submission of a new NDA or, in some instances, an NDA amendment, for further FDA review. Post-approval marketing of products in larger or different patient populations than those that were studied during development can lead to new findings about the safety or efficacy of the products. This information can lead to a product sponsor’s requesting approval for and/or the FDA requiring changes in the labeling of the product or even the withdrawal of the product from the market.

The Best Pharmaceuticals for Children Act, or BPCA, became law in 2002 and was subsequently reauthorized and amended by FDAAA. The reauthorization of BPCA provides an additional six months of market exclusivity beyond the expiration date of existing market exclusivities or eligible patents to NDA applicants that conduct acceptable pediatric studies of new and currently-marketed drug products for which pediatric information would be beneficial, as identified by FDA in a Pediatric Written Request. The FD&C Act, as amended by the Pediatric Research Equity Act, or PREA, requires that most applications for drugs and biologics include a pediatric assessment (unless waived or deferred) to ensure the drugs’ and biologics’ safety and effectiveness in children. Such pediatric assessment must contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective. The pediatric assessments can only be deferred provided there is a timeline for the completion of such studies. FDA may waive (partially or fully) the pediatric assessment requirement for several reasons, including if the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed. The FDA has indicated our Oxaydo product is exempt from the pediatric studies requirement of the PREA.

The terms of approval of any NDA for our product candidates, including the indication and product labeling (and, consequently permissible advertising and promotional claims we can make) may be more restrictive than what is sought in the NDA or what is desired by us. Additionally, the FDA conditioned approval of our Oxaydo product on our commitment to conduct Phase 4 epidemiological studies to assess the actual abuse levels of Oxaydo in the market. The testing and FDA approval process for our product candidates requires substantial time, effort, and financial resources, and we cannot be sure that any approval will be granted on a timely basis, if at all.

Further, drug products approved by FDA may be subject to continuing obligations intended to assure safe use of the products. Specifically, under the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007, or FDAAA, FDA may require Risk Evaluation and Mitigation Strategies, or REMS, to manage known or potential serious risks associated with drugs or biological products. If FDA finds, at the time of approval or afterward, that a REMS is necessary to ensure that the benefits of our products outweigh the risks associated with the products, FDA will require a REMS and, consequently, that we take additional measures to ensure safe use of the product. Components of a REMS may include, but are not limited to, a Medication Guide and/or Patient Package Insert, a marketing and sales communication plan for patients or healthcare providers concerning the drug, Elements To Assure Safe Use, or ETASUs such as, but not limited to, patient, prescriber, and pharmacy registries, and restrictions on the extent or methods of distribution, a REMS implementation system, and a timetable for assessment of the effectiveness of the REMS. Currently, all extended-release or long-acting (ERLA) opioid products approved by the FDA are subject to a class-wide REMS program. The FDA has determined that a REMS is necessary for immediate release opioid analgesics and has begun the process of incorporating immediate-release opioids into this class-wide REMS program.

In addition, we, our suppliers and our licensees are required to comply with extensive FDA requirements both before and after approval. For example, we or our licensees are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning the advertising and promotion of our products, which, as discussed above, may significantly affect the extent to which we can include statements or claims referencing our technology in product labeling and advertising. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to avoid the product being rendered misbranded and/or adulterated under the FD&C Act as a result of manufacturing problems. In addition, discovery of any material safety issues may result in changes to product labeling or restrictions on a product manufacturer, potentially including removal of the product from the market.

Whether or not FDA NDA approval in the U.S. has been obtained, approvals from comparable governmental regulatory authorities in foreign countries must be obtained prior to the commencement of commercialization of our drug products in those countries. The approval procedure varies in complexity from country to country, and the time required may be longer or shorter than that required for FDA approval.

FDA's OTC Monograph Process

The FDA regulates certain non-prescription drugs using an OTC Monograph which, when final, is published in the Code of Federal Regulations at 21 C.F.R. Parts 330-358. For example, 21 C.F.R. Part 341 sets forth the products, such as pseudoephedrine hydrochloride, that may be marketed as an OTC cold, cough, allergy, bronchodilator, or antiasthmatic drug product in a form suitable for oral, inhalant, or topical administration and is generally recognized as safe and effective and is not misbranded. Such products that meet each of the conditions established in the OTC Monograph regulations and the other applicable regulations may be marketed without prior approval by the FDA.

The general conditions set forth for OTC Monograph products include, among other things:

- the product is manufactured at FDA registered establishments and in accordance with cGMPs;
- the product label meets applicable format and content requirements including permissible "Indications" and all required dosing instructions and limitations, warnings, precautions and contraindications that have been established in an applicable OTC Monograph;
- the product contains only permissible active ingredients in permissible strengths and dosage forms;
- the product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation; and
- the product container and container components meet FDA's requirements.

The advertising for OTC drug products is regulated by the Federal Trade Commission, or FTC, which generally requires that advertising claims be truthful, not misleading, and substantiated by adequate and reliable scientific evidence. False, misleading, or unsubstantiated OTC drug advertising may be subject to FTC enforcement action and may also be challenged in court by competitors or others under the federal Lanham Act or similar state laws. Penalties for false or misleading advertising may include monetary fines or judgments as well as injunctions against further dissemination of such advertising claims.

A product marketed pursuant to an OTC Monograph must be registered with the FDA and have a National Drug Code listing which is required for all marketed drug products. After marketing, the FDA may test the product or otherwise investigate the manufacturing and development of the product to ensure compliance with the OTC Monograph. Should the FDA determine that a product is not marketed in compliance with the OTC Monograph or is advertised outside of its regulations, the FDA may require corrective action up to and including market withdrawal and market recall.

DEA Regulation

Our Oxaydo product is, and several of our products in development, if approved and marketed, will be, regulated as "controlled substances" as defined in the CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the loss and diversion of potentially abused drugs into illicit channels of commerce and closely monitors and regulates handlers of controlled substances, and the equipment and raw materials used in their manufacture and packaging.

The DEA designates controlled substances as Schedule I, II, III, IV or V or as List I Chemicals. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. List I Chemicals are used to regulate potentially abused raw materials, such as pseudoephedrine HCl. We believe all of our products will receive DEA Scheduling consistent with current DEA Scheduling standards. For example, Oxaydo Tablets are listed as a Schedule II controlled substances under the CSA, the same as all other oxycodone HCl products. Consequently, their manufacture, shipment, storage, sale and use will be subject to a high degree of regulation. For example, generally, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Annual DEA registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance or List I Chemical. Except for certain DEA defined co-incidental activities, each registration is specific to a particular location and activity. For example, separate registrations are needed for import and manufacturing, and each registration must specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and, thereafter, on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include, among other things, background checks on employees and physical control of inventory through measures such as vaults, cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances and List I Chemicals, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or significant losses of any controlled substance and List I Chemicals, and to obtain authorization to destroy any controlled substance and List I Chemicals. In addition, special authorization, notification and permit requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II and List I Chemicals. Distributions of any Schedule I or II controlled substance must also be accomplished using special order forms, with copies provided to the DEA. Each entity distributing controlled substances is responsible for monitoring the use of such products to identify and control diversion and misuse. Because Oxaydo Tablets are Schedule II they are subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much oxycodone active ingredient may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of oxycodone that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We or our licensees must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance and List I Chemicals. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our or our licensees' quota of an active ingredient may not be sufficient to meet commercial demand or complete the manufacture or purchase of material required for clinical trials. Any delay or refusal by the DEA in establishing our or our licensees' quota for controlled substances or List I Chemicals could delay or stop our clinical trials or product launches, or interrupt commercial sales of our products which could have a material adverse effect on our business, financial position and results of operations.

The DEA also regulates Listed Chemicals, which are chemicals that may be susceptible to abuse, diversion, and use in the illicit manufacture of controlled substances. Some Listed Chemicals, including pseudoephedrine, are used in various prescription and OTC drug products. DEA and state laws and regulations impose extensive recordkeeping, security, distribution, and reporting requirements for companies that handle, manufacture, or distribute Listed Chemicals, including lawful drug products containing Listed Chemicals. In particular, OTC drug products containing certain Listed Chemicals, including pseudoephedrine, are required to be secured behind the pharmacy counter and dispensed to customers directly by a pharmacist only in limited quantities. Pharmacists must obtain proof of identity from customers, and must keep detailed records and make reports to the DEA regarding sales of such products. Individual states may, and in some cases have, imposed stricter requirements on the sale of drug products containing Listed Chemicals, including requiring a doctor's prescription prior to dispensing such products to a customer.

The DEA conducts periodic inspections of registered establishments that handle controlled substances and Listed Chemicals. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Individual states also regulate controlled substances and List I Chemicals, and we or our licensees are subject to such regulation by several states with respect to the manufacture and future distribution of these products.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States, the commercial success of our product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payers at the federal, state and private levels. Government payer programs, including Medicare and Medicaid, private health care insurance companies and managed care plans may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy is not medically appropriate or necessary. Also, third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The United States Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among other cost containment measures, the Healthcare Reform Law establishes:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- A new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period (the "donut hole"); and
- A new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

Many of the Healthcare Reform Law's most significant reforms were implemented in 2014, with others thereafter, and their details will be shaped significantly by implementing regulations, some of which have yet to be finalized. If such reforms result in an increase in the proportion of uninsured patients who are prescribed products resulting from our proprietary or partnered programs, this could adversely impact future sales of our products and our business and results of operations. Where patients receive insurance coverage under any of the new options made available through the Healthcare Reform Law, the possibility exists that manufacturers may be required to pay Medicaid rebates on that resulting drug utilization, a decision that could impact manufacturer revenues. In addition, the Administration has also announced delays in the implementation of key provisions of the Healthcare Reform Law. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under government programs, and may also increase our or our licensees' regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payer interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. In addition to the Healthcare Reform Law, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to keep healthcare costs down while expanding individual healthcare benefits. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products. Certain of these changes could limit the prices that can be charged for drugs we develop or the amounts of reimbursement available for these products from governmental agencies or third-party payers, or may increase the tax obligations on pharmaceutical companies, or may facilitate the introduction of generic competition with respect to products we are able to commercialize. In short, our or our licensees' results of operations could be adversely affected by current and future healthcare reforms.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Healthcare Reform Law, and we expect there will be additional challenges and amendments to the Healthcare Reform Law in the future. The Trump administration and members of the U.S. Congress have indicated that they may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Healthcare Reform Law. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. It is uncertain the extent to which any such changes may impact our business or financial condition. In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget, or OMB, on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payers, that an adequate level of coverage or payment will be available so that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably.

Other Healthcare Laws and Compliance Requirements

We and our licensees that commercialize our products are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The reach of the Anti-Kickback Statute was broadened by the Health Care Reform Law, which, among other things, amends the intent requirement of the statute so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. The Healthcare Reform Law also provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. The civil False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The "qui tam" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. Violations of these laws or any other federal or state fraud and abuse laws may subject our licensees to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs, which could harm the commercial success of our products and materially affect our business, financial condition and results of operations.

Segment Reporting

We operate in one business segment; the research, development and commercialization of technologies and products intended to address safe use of medications.

Environmental Compliance

We are subject to regulation under federal, state and local environmental laws and believe we are in material compliance with such laws. We incur the usual waste disposal cost associated with a pharmaceutical research, development and manufacturing operation.

Human Capital Management

We have 12 full-time employees and 1 part-time employee, 9 of whom are engaged in the research, development and manufacture of product candidates utilizing our proprietary Aversion, Impede, and LIMITx Technologies. The remaining employees are engaged in administrative, legal, accounting, finance, market research, and business development activities. All of our senior management and most of our other employees have prior experience in pharmaceutical or biotechnology companies. We strive to maintain a safe, healthy and respectful workplace. We offer competitive compensation coupled with attractive health benefits. The average tenure of our employees is approximately 20 years. Since 2018, two employees have separated from the Company and neither were replaced. We believe engaging experienced pharmaceutical scientists in our Culver, IN facility could be difficult given its less populated geography and lack of other pharmaceutical companies in the immediate area.

The Compensation Committee of the Board of Directors has the primary responsibility of overseeing our human capital management activities (including assessing the effectiveness of employee programs and advising management with regard to the quality of the workforce to carry out our strategic goals and overall human resource strategies). Within management, our Human Resources function has management responsibility for advising and assisting the business on human resource matters and executing our overall human capital management strategies. We have had no turnover in our Board since 2018.

In response to the COVID-19 pandemic, we quickly implemented safety and health standards and protocols, including social distancing, limiting density, reporting and documenting exposures and providing for working from home as appropriate, all as recommended by the Centers for Disease Control or mandated by local regulations.

We have an ethics policy in place which is sent to all employees annually which encourages communication of any matter of concern to the Board of Directors through a process delineated in the ethics policy.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Before purchasing our common stock, you should carefully consider the following risk factors as well as all other information contained in this Report, including our consolidated financial statements and the related notes. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business and Industry

We have a history of operating losses and may not be able to generate a positive return on shareholders' investment; there is substantial doubt as to our ability to continue as a going concern: We had a net loss of $1.2 million, $3.8 million, and $5.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of March 30, 2021 we had approximately $350 thousand of cash. The Agreement with AD Pharma, as amended, provided us a monthly license payment of $350,000 from AD Pharma for a period from inception up to April 2020 at which time the payment became $200,000 per month through July 2021. However, AD Pharma has the right to terminate the Agreement at any time for convenience and such action would substantially and adversely affect our ability to fund continuing operations. Our future viability will depend on several factors, including:

- (i) the receipt of monthly license payments from AD Pharma for the entire period ending July 31, 2021; (ii) our receipt of milestone payments and royalties relating to our LIMITx Technology products in development from AD Pharma and future licensees, of which no assurance can be given; (iii) renegotiation of the AD Pharma Agreement to extend the FDA Filing Acceptance Date beyond July 2021; and (iv) the receipt of FDA approval and the successful commercialization by future licensees, yet to be identified and obtained, of products utilizing our LIMITx Technology and our ability to commercialize all our Impede and LIMITx Technology products without infringing the patents and other intellectual property rights of third parties, of which no assurance can be given.

We are currently focused primarily on the development of our lead LIMITx product candidate, LTX-03, as well as other LIMITx programs, which we believe will result in our continued incurrence of significant research, development and other expenses related to those programs. If preclinical studies or the clinical trials for any of our LIMITx drug candidates fail or produce unsuccessful results and those drug candidates do not gain regulatory approval, or if any of our LIMITx drug candidates, if approved, fail to achieve market acceptance, we may never become self-supporting resulting in significant doubt as to our ability to sustain operations.

Even if we and AD Pharma succeed in developing and commercializing one or more of our pipeline LIMITx Technology products, we expect to continue using cash reserves for the foreseeable future. Our expenses may increase in the foreseeable future as a result of continued research and development of these and other product candidates, maintaining and expanding the scope of our intellectual property, and hiring of additional research and development staff. We will need to generate revenues from royalties on sales to achieve and maintain liquidity. If we or AD Pharma cannot successfully develop, obtain regulatory approval and commercialize our LIMITx product candidates in development, specifically LTX-03, we will not be able to generate such royalty revenues or achieve future profitability. Our failure to achieve or maintain profitability would have a material adverse impact on our operations, financial condition and on the market price of our common stock.

We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us; if we fail to raise additional funding we will cease operations and/or seek protection under applicable bankruptcy laws: Our operations to date have consumed substantial amounts of cash. Negative cash flows from our operations are expected to continue until such time as royalties from AD Pharma's sale of LTX-03 occur which is not expected until 2023 at the earliest. Our cash utilization amount is highly dependent on the progress of our product development programs, particularly, the results of our preclinical and clinical studies and the cost, timing and outcomes of regulatory approval for our LIMITx product candidates. As of March 30, 2021 our cash balance was approximately $350 thousand. Additionally, the Agreement with AD Pharma, as amended, provided us a monthly license payment of $350,000 from AD Pharma for a period from inception up to April 2020 at which time the payment is $200,000 per month through July 2021 and as well as their payment of all outside development costs for LTX-03. AD Pharma is delinquent in remitting the required monthly license payments for December, 2020 thru March, 2021 as well as approximately $100,000 of reimbursable LTX-03 development expenses. Based upon representations by AD Pharma, we anticipate receipt of these past due amounts by April 30, 2021 and payment obligations through July, 2021, for which no assurance can be given. To fund further operations, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies.

We will require future additional capital infusions including public or private financing, strategic partnerships or other arrangements with organizations that have capabilities and/or products that are complementary to our own capabilities and/or products, in order to continue the development of our product candidates. However, there can be no assurances that we will complete any financings, strategic alliances or collaborative development agreements, and the terms of such arrangements may not be advantageous to us. Any additional equity financing will be dilutive to our current stockholders and debt financing, if available, may involve restrictive covenants or have other provisions, including possibly security interests in our assets that could be onerous. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates that we would otherwise seek to develop or commercialize. Our failure to raise capital when needed would materially harm our business, financial condition, results of operations and prospects. In the absence of the receipt of additional financing or payments under third-party license or collaborative agreements, we will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. This could result in a complete loss of shareholder value of the Company. Even assuming we are successful in securing additional sources of financing to fund continued operations, there can be no assurance that the proceeds of such financing will be sufficient to fund operations until such time, if at all, that we generate sufficient revenue from our products and product candidate to sustain and grow our operations.

Our ongoing capital requirements will depend on numerous factors, which likely will require that we continue to obtain capital infusions in the future. Our capital requirements, which cannot be predicted with certainty, include: the progress and results of preclinical testing and clinical trials of our LIMITx product candidates under development; the costs of complying with the FDA and other domestic regulatory agency requirements, the progress of our research and development programs and those of our partners; the time and costs expended and required to obtain any necessary or desired regulatory approvals; our ability to enter into licensing arrangements, including any unanticipated licensing arrangements that may be necessary to enable us to continue our development and clinical trial programs; the costs and expenses of filing, prosecuting and, if necessary, enforcing our patent claims, or defending against possible claims of infringement by third-party patent or other technology rights; the cost of commercialization activities and arrangements that we undertake; and the demand for our products, which demand depends in turn on circumstances and uncertainties that cannot be fully known, understood or quantified unless and until the time of approval, including the FDA approved label for any product.

COVID-19 may materially and adversely affect our business and financial results: Our business could be adversely affected by health epidemics in regions where third parties for which we rely, such a 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. On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of novel coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus spread globally beyond its point of origin. In March 2020, the WHO declared the COVID-19 outbreak a pandemic, which continues to spread throughout the world. The spread of this pandemic has caused significant volatility and uncertainty in U.S. and international markets. This could result in an economic downturn and may disrupt our business and delay our clinical programs and timelines. Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and manufacturing activities.

In addition, our clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of resources toward the pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 may adversely impact our clinical trial operations. The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

If we fail to comply with the covenants and other obligations under our loan with AD Pharma, LLC they may accelerate amounts owed and may foreclose upon the security interest in all of our assets securing our obligation: At June 28, 2019, we (including our wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc. ("APT")), entered into a Promissory Note and Security Agreement with John Schutte (Mr. Schutte) that consolidated existing promissory notes into a single Note for $6.0 million (after including accrued interest). Subsequently, Mr. Schutte assigned and transferred this Note to Abuse Deterrent Pharma, LLC ("AD Pharma") (an entity controlled by him). This Note includes a security interest in all of our assets. Our failure to comply with the terms of the loan agreement, if we file bankruptcy, failure to pay interest and principal when due on July 1, 2023, or upon failure to meet certain timelines as defined in the License, Development and Commercialization Agreement could result in the acceleration of payment of our loan, foreclosure on our assets, and other adverse results. Any declaration of an event of default by AD Pharma could result in the transfer of our business to AD Pharma without additional consideration and the loss by our shareholders of their entire interest.

Our failure to meet the development timelines in the AD Pharma License Agreement, as amended, including FDA acceptance of NDA submission for LTX-03 by July 31, 2021, will allow AD Pharma the option to terminate the Agreement and take ownership of the LIMITx intellectual property which will adversely impact our ability to develop, market and sell our LIMITx Technology products and our revenues and business will be materially adversely affected: The License Agreement with AD Pharma requires that the new drug application for LTX-03 be accepted by the FDA by July 31, 2021. Failure to do so gives AD Pharma the option to terminate this Agreement and take ownership of the LIMITx intellectual property. Acura expects the submission and FDA acceptance of the NDA for LTX-03 to now occur after July 31, 2021 and will need to be renegotiated with AD Pharma. Failure to amend the License Agreement would allow AD Pharma to seize the LIMITx IP which would have a material adverse impact our financial condition and results of operations.

We are largely dependent on our successful development of LIMITx product candidates which are unproven and may not be approved by the FDA: We expect that a substantial portion of our efforts and expenditures over the next few years, if we obtain additional funding, will be devoted to our lead LIMITx product candidate, LTX-03, and other LIMITx product candidates in development. Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approval and commercialization of our LIMITx product candidates, which may never occur. If our clinical studies for LTX-03 are not successful we may determine that further clinical development of LTX-03 or other LIMITx product candidates should be discontinued. Also, the failure of clinical studies for LTX-03 may cause AD Pharma to terminate the Agreement. We expect that any revenues from our LIMITx product candidates, specifically LTX-03 will be derived from upfront payments, milestone payments and royalties under license agreements with AD Pharma, of which no assurance can be given.

Our and our licensees' ability to market and promote LIMITx Technology products by describing the beneficial features of such products will be determined by the FDA approved label for such products: The commercial success of our LIMITx Technology products in development will depend upon our and our licensees' ability to obtain FDA approved labeling describing such products' benefits. Our or our licensees' failure to achieve FDA approval of product labeling containing such information will prevent or substantially limit our and our licensees' advertising and promotion of such beneficial features in order to differentiate our products from other immediate release opioid products containing the same active ingredients, and would have a material adverse impact on our business and results of operations.

Relying on third party contract research organizations, or CROs may result in delays in our pre-clinical, clinical or laboratory testing. If pre-clinical, clinical or laboratory testing for our product candidates are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines: To obtain FDA approval to commercially sell and distribute in the United States any of our prescription product candidates, we or our licensees must submit to the FDA a NDA demonstrating, among other things, that the product candidate is safe and effective for its intended use. As we do not possess the resources or employ all the personnel necessary to conduct such testing, we rely on CROs for the majority of this testing with our product candidates. As a result, we have less control over our development program than if we performed the testing entirely on our own. Third parties may not perform their responsibilities on our anticipated schedule. Delays in our development programs could significantly increase our product development costs and delay product commercialization.

The commencement of clinical trials with our product candidates may be delayed for several reasons, including, but not limited to, delays in demonstrating sufficient pre-clinical safety required to obtain regulatory approval to commence a clinical trial, reaching agreements on acceptable terms with prospective CROs, clinical trial sites and licensees, manufacturing and quality assurance release of a sufficient supply of a product candidate for use in our clinical trials and/or obtaining institutional review board approval to conduct a clinical trial at a prospective clinical site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or regulatory authorities due to several factors, including ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials, a determination by us or regulatory authorities that continuing a trial presents an unreasonable health risk to participants, failure to conduct clinical trials in accordance with regulatory requirements, lower than anticipated recruitment or retention rate of patients in clinical trials, inspection of the clinical trial operations or trial sites by regulatory authorities, the imposition of a clinical hold by FDA, lack of adequate funding to continue clinical trials, and/or negative or unanticipated results of clinical trials.

Clinical trials required by the FDA for commercial approval may not demonstrate safety or efficacy of our product candidates. Success in pre-clinical testing and early clinical trials does not assure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. Even if the results of our or our licensee's pivotal phase III clinical trials are positive, we and our licensees may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we or our licensees can submit NDAs or obtain regulatory approval for our product candidates.

Clinical trials are expensive and at times, difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, if participating subjects or patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we, our licensees or the FDA believes that participating patients are being exposed to unacceptable health risks, we or our licensees may suspend the clinical trials. Failure can occur at any stage of the trials, and we or our licensees could encounter problems causing the abandonment of clinical trials or the need to conduct additional clinical studies, relating to a product candidate. Even if our clinical trials and laboratory testing are completed as planned, their results may not support commercially viable product label claims or be interpreted by the FDA differently than our perspective. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their intended use. Such failure may cause us or our licensees to abandon a product candidate and may delay the development of other product candidates.

We have no commercial manufacturing capacity and rely on third-party contract manufacturers to produce commercial quantities of our products: We do not have the facilities, equipment or personnel to manufacture commercial quantities of our products and therefore must rely on our licensees or other qualified third-party contract manufactures with appropriate facilities and equipment to contract manufacture commercial quantities of products utilizing our technologies. These licensees and third- party contract manufacturers are also subject to cGMP regulations, which impose extensive procedural and documentation requirements. Any performance failure on the part of our licensees or contract manufacturers could delay commercialization of any approved products, depriving us of potential product revenue.

Our drug products require precise, high quality manufacturing. Failure by our contract manufacturers to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could materially adversely affect our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMP and other applicable government regulations; however, beyond contractual remedies that may be available to us, we do not have control over third-party manufacturers' compliance with these regulations and standards.

If for some reason our contract manufacturers cannot perform as agreed, or if we are unable to reach agreement with our contract manufacturers on the terms of continued supply of our products, we may be required to replace them. Although we believe there are a number of potential replacements, we will incur added costs and delays in identifying and qualifying any such replacements. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products or drug candidates, which could adversely impact the continued supply of our products or drug candidates.

We or our licensees may not obtain required FDA approval; the FDA approval process is time-consuming and expensive: The development, testing, manufacturing, marketing and sale of pharmaceutical products are subject to extensive federal, state and local regulation in the United States and other countries. Satisfaction of all regulatory requirements typically takes years, is dependent upon the type, complexity and novelty of the product candidate, and requires the expenditure of substantial resources for research, development and testing. Substantially all of our operations are subject to compliance with FDA regulations. Failure to adhere to applicable FDA regulations by us or our licensees would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time consuming and expensive. In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

We or our licensees may encounter delays or rejections during any stage of the regulatory review and approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the product candidates to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of a NDA, the FDA may refuse to file the application, deny approval of the application, require additional testing or data and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we or our licensees desire and could affect the marketability of our products.

We must maintain FDA approval to manufacture clinical supplies of our product candidates at our facility; failure to maintain compliance with FDA requirements may prevent or delay the manufacture of our product candidates and costs of manufacture may be higher than expected: We have equipment and procedures necessary to manufacture clinical trial supplies of our product candidates in tablet formulations at our Culver, Indiana facility. To be used in clinical trials, all of our product candidates must be manufactured, packaged, labeled and stored in conformity with cGMP regulations. Modifications, enhancements or changes in manufacturing sites of marketed products are, in many circumstances, subject to FDA approval, which may be subject to a lengthy application process or which we may be unable to obtain. Our Culver, Indiana facility, and those of any third-party manufacturers that we or our licensees may use, are periodically subject to inspection by the FDA and other governmental agencies, and operations at these facilities could be interrupted or halted if the FDA deems such inspections are unsatisfactory. Failure to comply with FDA or other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production or distribution, suspension of FDA review of our product candidates, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution.

We develop our products, and manufacture clinical and commercial supplies, at a single location. Any disruption at these facilities could adversely affect our business and results of operations: We rely on our Culver, Indiana facility for developing our product candidates and the manufacture of clinical supplies of our product candidates. Our marketed products are manufactured at a single contract manufacturing organization. If any of these facilities are damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to repair or replace. If our Culver facility were affected by a disaster, we would be forced to rely entirely on CROs and third-party contract manufacturers for an indefinite period of time. Although we believe we possess adequate insurance for damage to our property and for the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. Any disruptions or delays to our clinical or commercial supplies could impair our ability to develop our product candidates, which could adversely affect our business and results of operations.

Our operations are subject to environmental, health and safety, and other laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance: Our business, properties and product candidates are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage and disposal of hazardous substances, waste and other regulated materials. Because we own and operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or may be altered in the future, could adversely affect our financial condition and results of operations.

Our failure to successfully establish new license agreements with pharmaceutical companies for the development and commercialization of our other products in development may adversely impair our ability to develop, market and sell such products: The AD Pharma Agreement grants AD Pharma an exclusive license to develop and commercialize LTX-03 in the US. The Assertio Agreement grants Assertio an exclusive worldwide license to develop and commercialize Oxaydo. Our license agreement with KemPharm Inc., or the KemPharm Agreement, grants exclusive worldwide rights to KemPharm to utilize our Aversion technology in certain of KemPharm's prodrug products. Our license agreement with MainPointe grants exclusive rights in the U.S. and Canada (with option rights to expand the licensed territory) to our Nexafed products with option rights to certain other pseudoephedrine-containing products utilizing our Impede technology. We believe that opportunities exist to enter into license agreements similar to the AD Pharma Agreement, Assertio Agreement, the KemPharm Agreement and the MainPointe Agreement with other pharmaceutical company partners for the development and commercialization of our LIMITx, Impede and Aversion Technologies in the United States and worldwide. However, there can be no assurance that we will be successful in entering into such license agreements in the future. If we are unable to enter into such agreements, our ability to develop and commercialize our product candidates, and our financial condition and results of operations, would be materially adversely affected.

If our licensees do not satisfy their obligations, we will be unable to develop our licensed product candidates: If a licensee fails to fulfill its obligations under an agreement with us, we may be unable to assume the development and/or commercialization of the product covered by that agreement or to enter into alternative arrangements with another third party. In addition, we may encounter delays in the commercialization of the products that are the subject of a license agreement. Accordingly, our ability to receive any revenue from the products covered by such agreements will be dependent on the efforts of our licensees. We could be involved in disputes with a licensee, which could lead to delays in or termination of, our development and/or commercialization programs and result in time consuming and expensive litigation or arbitration. In addition, any such dispute could diminish our licensee's commitment to us and reduce the resources they devote to developing and/or commercializing our products. If any licensee terminates or breaches its agreement, or otherwise fails to complete its obligations in a timely manner, our chances of successfully developing and/or commercializing our product candidates would be materially adversely effected. Additionally, it may be necessary for us to license a significant portion of our product candidates for a single technology to a single company, thereby eliminating our opportunity to commercialize other product candidates with other licensees.

The market may not be receptive to products incorporating our LIMITx Technology: The commercial success of our products will depend on acceptance by health care providers and others that such products are clinically useful, cost-effective and safe. There can be no assurance given that our products utilizing the LIMITx Technology will be accepted by health care providers and others. Factors that may materially affect market acceptance of our product candidates include but are not limited to:

- the relative advantages and disadvantages of our products compared to competitive products;
- the relative timing to commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products
- the product's ability to perform as tested under real world conditions;;
- the perception of health care providers of unique benefits of our products and their willingness to prescribe our products and their willingness to undertake administrative processes that may be invoked by third party payers; the willingness of third party payers to reimburse for our prescription products;
- the willingness of pharmacy chains and wholesalers to stock our products;
- the willingness of pharmacists to recommend our Nexafed products to their customers; and
- the willingness of consumers to utilize and pay for our products.

If we, our licensees or others identify serious adverse events or deaths relating to any of our products once on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues: We or our licensees are required to report to relevant regulatory authorities all adverse events or deaths involving our product candidates or approved products. If we, our licensees, or others identify such events, regulatory authorities may withdraw their approvals of such products; we or our licensees may be required to reformulate our products; we or our licensees may have to recall the affected products from the market and may not be able to reintroduce them onto the market; our reputation in the marketplace may suffer; and we may become the target of lawsuits, including class actions suits. Any of these events could harm or prevent sales of the affected products and could materially adversely affect our business and financial condition.

Our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers: The ability of our licensees to successfully commercialize our products may depend in part on the availability of reimbursement for our prescription products from government health administration authorities, private health insurers, and other third-party payers and administrators, including Medicaid and Medicare. We cannot predict the availability of reimbursement for newly-approved products utilizing our technologies. Third party payers and administrators, including state Medicaid programs and Medicare, are challenging the prices charged for pharmaceutical products. Government and other third-party payers may limit coverage, reduce reimbursement, and/or impose administrative processes for our products. Third-party insurance coverage may not be available to patients for any of our product candidates. The continuing efforts of government and third-party payers to contain or reduce the costs of health care may limit our commercial opportunity. If government and other third party payers do not provide adequate coverage and reimbursement for any product utilizing our technologies or impose burdensome administrative processes, health care providers may not prescribe them or patients may ask their health care providers to prescribe competing products with more favorable reimbursement. In some foreign markets, pricing and profitability of pharmaceutical products are subject to government control. In the United States, we expect there may be federal and state proposals for similar controls. In addition, we expect that increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or our licensees charge for any of our products in the future. Further, cost control initiatives could impair our ability or the ability of our licensees to commercialize our products and our ability to earn revenues from commercialization

Federal and foreign legislation may be enacted that may seriously impact the commercial viability and acceptance of the products we have licensed and are developing: In both the United States and certain foreign jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory changes to the health care system that could impact our or our licensees' ability to sell our products profitably. In particular, in 2010, the Patient Protection Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Law, was enacted. The Healthcare Reform Law substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the Healthcare Reform Law of greatest importance to the pharmaceutical industry are the following:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- An increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- A new Medicare Part D coverage gap discount program, under which manufacturers must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- Extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research;
- A revision to the definition of "average manufacturer price" for reporting purposes; and
- Encouragement for the development of comparative effectiveness research, which may reduce the extent of reimbursement for our products if such research results in any adverse findings.

At this time, it remains uncertain what the full impact of these provisions will be on the pharmaceutical industry generally or our business in particular. The full effects of these provisions will become apparent as these laws are implemented and the Centers for Medicare & Medicaid Services and other agencies issue applicable regulations or guidance as required by the Healthcare Reform Law. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. In addition, since its enactment, there have been judicial and Congressional challenges to certain aspects of the Healthcare Reform Law, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. It is uncertain the extent to which any such changes may impact our business or financial condition.

Consolidation in the healthcare industry could lead to demands for price concessions or for the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations: Because healthcare costs have risen significantly, numerous initiatives and reforms by legislatures, regulators and third-party payers to curb these cost increases have resulted in a trend in the healthcare industry to consolidate product suppliers and purchasers. As the healthcare industry consolidates, competition among suppliers to provide products to purchasers has become more intense. This in turn has resulted, and will likely continue to result, in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, and large single accounts continue to use their market power to influence product pricing and purchasing decisions. We expect that market demand, government regulation, third party reimbursement policies and societal pressures will continue to influence the worldwide healthcare industry, resulting in further business consolidations, which may exert further downward pressure on the prices of our anticipated products. This downward pricing pressure may adversely impact our business, financial condition or results of operations. Under each of the Assertio Agreement, the KemPharm Agreement, the MainPointe Agreement and AD Pharma Agreement, our licensees control (or will control in the case of AD Pharma for LTLX-03) the price of the licensed products, and we expect that our licensees, if any, of our products in development, will control the price of such products and may provide price discounts and price reductions in its discretion. Such price discounts and reductions will reduce the net sales of our licensed products and, correspondingly, our royalty payments under such license agreements. In addition, if any of our large customers is acquired or merged with another provider of similar products, we may lose that customer's business

Our success depends on our ability to protect our intellectual property: Our success depends on our ability to obtain and maintain patent protection for products developed utilizing our technologies, in the United States and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual questions. Notwithstanding our receipt of U.S. patents covering our Aversion, Impede and LIMITx Technologies, there is no assurance that any of our patent claims in our other pending non-provisional and provisional patent applications relating to our technologies will issue or if issued, that any of our existing and future patent claims will be held valid and enforceable against third-party infringement or that our products will not infringe any third-party patent or intellectual property. Moreover, any patent claims relating to our technologies may not be sufficiently broad to protect our products. In addition, issued patent claims may be challenged, potentially invalidated or potentially circumvented. Our patent claims may not afford us protection against competitors with similar technology or permit the commercialization of our products without infringing third-party patents or other intellectual property rights.

Our success also depends on our not infringing patents issued to others. We may become aware of patents belonging to competitors and others that could require us to obtain licenses to such patents or alter our technologies. Obtaining such licenses or altering our technology could be time consuming and costly. We may not be able to obtain a license to any technology owned by or licensed to a third party that we or our licensees require to manufacture or market one or more of our products. Even if we can obtain a license, the financial and other terms may be disadvantageous.

Our success also depends on maintaining the confidentiality of our trade secrets and know-how. We seek to protect such information by entering into confidentiality agreements with employees, potential licensees, raw material suppliers, contract research organizations, contract manufacturers, consultants and other parties. These agreements may be breached by such parties. We may not be able to obtain an adequate, or perhaps any, remedy to such a breach. In addition, our trade secrets may otherwise become known or be independently developed by our competitors. Our inability to protect our intellectual property or to commercialize our products without infringing third-party patents or other intellectual property rights would have a material adverse effect on our operations and financial condition.

We may become involved in patent litigation or other intellectual property proceedings relating to our Aversion, Impede or LIMITx Technologies or product candidates, which could result in liability for damages or delay or stop our development and commercialization efforts: The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include:

- litigation or other proceedings we or our licensee(s) may initiate against third parties to enforce our patent rights or other intellectual property rights, including the submission of drug applications to the FDA certifying a challenge to our patents (Paragraph IV Proceedings);
- litigation or other proceedings we or our licensee(s) may initiate against third parties seeking to invalidate the patents held by such third parties or to obtain a judgment that our products do not infringe such third parties' patents;
- litigation or other proceedings third parties may initiate against us or our licensee(s) to seek to invalidate our patents or to obtain a judgment that third party products do not infringe our patents;
- if our competitors file patent applications that claim technology also claimed by us, we may be forced to participate in interference, inter partes or opposition proceedings to determine the priority of invention and whether we are entitled to patent rights on such invention; and
- if third parties initiate litigation claiming that our products infringe their patent or other intellectual property rights, we will need to defend against such proceedings.

The costs of resolving any patent litigation, including the Paragraph IV Proceedings, or other intellectual property proceedings, even if resolved in our favor, could be substantial. Many of our potential competitors will be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation, including the Paragraph IV Proceedings, and other intellectual property proceedings may also consume significant management time.

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it would harm our business. In certain circumstances, we expect that our licensees will have first right to control the enforcement of certain of our patents against third party infringers. Our licensees may not put adequate resources or effort into such enforcement actions or otherwise fail to restrain infringing products. In addition, in an infringement proceeding, including the Paragraph IV Proceedings, a court may decide that a patent of ours is invalid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation, including the Paragraph IV Proceedings, or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Our technologies or products may be found to infringe claims of patents owned by others. If we determine that we are, or if we are found to be infringing a patent held by another party, we, our suppliers or our licensees might have to seek a license to make, use, and sell the patented technologies and products. In that case, we, our suppliers or our licensees might not be able to obtain such license on acceptable terms, or at all. The failure to obtain a license to any third party technology that we may require would materially harm our business, financial condition and results of operations. If a legal action is brought against us or our licensees, we could incur substantial defense costs, and any such action might not be resolved in our favor. If such a dispute is resolved against us, we may have to pay the other party large sums of money and use of our technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited. Even prior to resolution of such a dispute, use of our technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited. We cannot assure you that our technologies, products and/or actions in developing our products will not infringe third party patents. Our failure to avoid infringing third-party patents and intellectual property rights in the development and commercialization of our products would have a material adverse effect on our operations and financial condition.

We may be exposed to product liability claims and claims regarding marketing of products and may not be able to obtain or maintain adequate product liability insurance and some claims may not be covered by insurance: Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products, and in particular opioid products. Manufacturers and distributors of prescription opioid medications, are the subject of lawsuits and have received subpoenas and other requests for information from various state and local government agencies regarding the sales and marketing of opioid medications. Product liability claims or marketing related claims might be made by patients, health care providers or others that sell or consume our products or insurance companies that insure those affected by our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale. We currently have clinical trial product liability insurance on a claims-made basis for our subject clinical trials and have product liability insurance for the Nexafed and Oxaydo products. Our product liability insurance may not cover claims against products sold by our predecessor company, Halsey Drug Co., which were discontinued over 20 years ago. This coverage may not be adequate to cover any product liability claims. Product liability coverage and other insurance is expensive. In the future, we may not be able to maintain such product liability insurance or other insurance at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims or other claims. In addition our insurance may not cover certain marketing related claims and excludes certain products from product liability coverage. Any claims that are not covered by product liability insurance or other insurance could have a material adverse effect on our business, financial condition and results of operations.

We face significant competition, which may result in others developing or commercializing products before or more successfully than we do: Our products and technologies compete to varying degrees against both brand and generic products offering similar therapeutic benefits and being developed and marketed by small and large pharmaceutical (for prescription products) and consumer packaged goods (for OTC products) companies. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us and our licensees in research, development and commercialization of their competitive technologies and products. Prescription generic products and OTC store brand products will offer cost savings to third party payers and/or consumers that will create pricing pressure on our products. Also, these competitors may have a substantial sales volume advantage over our products, which may result in our licensee's costs of manufacturing being higher than our competitors' costs. If our products are unable to capture and maintain market share, we or our licensees may not achieve significant product revenues and our financial condition and results of operations will be materially adversely affected.

Our Impede Technology products containing PSE, including our licensed Nexafed products, will compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Some of our competitors will have multiple consumer product offerings both within and outside the cold, allergy and sinus category providing them with substantial leverage in dealing with a highly consolidated pharmacy distribution network. The competing products may have well established brand names and may be supported by national or regional advertising. Our Nexafed products compete directly with Johnson & Johnson's Sudafed® brand as well as generic formulations manufactured by Perrigo Company and others.

We are concentrating a substantial majority of our efforts and resources on developing product candidates utilizing our LIMITx Technologies. The commercial success of products utilizing such technology will depend, in large part, on the intensity of competition, FDA approved product labeling for our products compared to competitive products, and the relative timing and sequence for commercial launch of new products by other companies developing, marketing, selling and distributing products that compete with the products utilizing our LIMITx Technology. Alternative technologies and non-opioid products are being developed to improve or replace the use of opioid analgesics. In the event that such alternatives to opioid analgesics are widely adopted, then the market for products utilizing our LIMITx Technology may be substantially decreased, thus reducing our ability to generate future revenues and adversely affecting our ability to generate a profit.

Key personnel are critical to our business and our success depends on our ability to retain them: We are dependent on our management and scientific team, including Robert Jones, our President and Chief Executive Officer, Peter A. Clemens, our Chief Financial Officer, and Albert W. Brzeczko, Ph.D., our Vice President of Pharmaceutical Sciences. We may not be able to retain the services of key personnel or attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. While we have employment agreements with our CEO and CFO, all of our other employees are at-will employees who may terminate their employment at any time. We do not have key personnel insurance on any of our officers or employees. The loss of any of our key personnel, or the inability to attract and retain such personnel, may significantly delay or prevent the achievement of our product and technology development and business objectives and could materially adversely affect our business, financial condition and results of operations.

Our products are subject to regulation by the U.S. Drug Enforcement Administration, or DEA, and such regulation may affect the development and sale of our products: The DEA regulates certain finished drug products and active pharmaceutical ingredients, including certain opioid active pharmaceutical ingredients and pseudoephedrine HCl that are contained in our products. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of regulation. Furthermore, the amount of active ingredients we can obtain for our clinical trials is limited by the DEA and our quota may not be sufficient to complete clinical trials. There is a risk that DEA regulations may interfere with the supply of the products used in our clinical trials.

In addition, we and our licensees and contract manufacturers are subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be a rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain FDA approval and adverse scheduling could have a material adverse effect on the attractiveness of such product. We or our licensees must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law. Further, many of our raw ingredients and manufacturing equipment comes from international sources. Trade agreements and/or disagreements or other unforeseen disruptions to international supply chains may have an adverse impact on our business.

Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioid and regulatory efforts to combat abuse, could decrease the potential market for our LIMITx product candidates: Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are commonplace. Law enforcement and regulatory agencies may apply policies that seek to limit the availability of opioids. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs, the limitations of abuse resistant formulations, public inquiries and investigations into prescription drug abuse, litigation or regulatory activity, sales, marketing, distribution or storage of our drug products could harm our reputation. Such negative publicity could reduce the potential size of the market for our product candidates and decrease the revenues and royalties we are able to generate from their sale.

In addition, efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for our product candidates. For example, in February 2016, as part of a broader initiative led by U.S. Department of Health and Human Services to address opioid-related overdose, death and dependence, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid medications. The plan identifies the FDA's focus on implementing policies to reverse the opioid abuse epidemic, while maintaining access to effective treatments. The actions set forth in the FDA's plan include strengthening post marketing study requirements to evaluate the benefit of long-term opioid use, changing the REMS requirements to provide additional funding for physician education courses, releasing a draft guidance setting forth approval standards for generic abuse-deterrent opioid formulations, and seeking input from the FDA's Scientific Board to broaden the understanding of the public risks of opioid abuse. Many of these changes could require our licensing partner and us to expend additional resources in developing and commercializing Oxaydo and our product candidates to meet additional requirements. In October 2017, the acting director of HHS under the directive of the President, declared the opioid crisis a national health emergency and initiated a five point plan including (i) improving access to prevention, treatment, and recovery support services; (ii) targeting the availability and distribution of overdose-reversing drugs; (iii) strengthening public health data reporting and collection; (iv) supporting cutting-edge research on addiction and pain; and (v) advancing the practice of pain management. The impact that this five point plan will have on us and our licensing partners is unclear at this time.

We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data storage risks: Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit confidential information, and it is critical that we do so in a secure manner in order to maintain the confidentiality and integrity of such confidential information. Our information technology systems are potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners, vendors, or from attacks by malicious third parties. Maintaining the secrecy of this confidential, proprietary, and/or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful access or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination or misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material effect on our business, financial position, results of operations and/or cash flow.

Prior ownership changes have limited our ability to use our tax net operating loss carryforwards as part of a corporate restructure or reorganization: Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of Net Operating Loss ("NOL"), carryforwards and other tax attributes. In addition, under the Tax Cuts and Jobs Act of 2017, NOL usage in any given year will be limited to 80% of taxable income, without regard to the NOL deduction, and losses incurred in 2018 and forward may not be carried back but can be carried forward indefinitely, but losses incurred prior to 2018 can only be carried forward for 20 years. We have determined that we have undergone ownership changes in both 2004 and 2017 (as defined by Section 382 of the Internal Revenue Code) and as a result, our use of NOL carryforwards on an annual basis will be very limited. As such, an entity that may seek to acquire the Company would likely be limited in the amount of NOLs they may be able to utilize. Neither the amount of our NOL carryforwards nor the amount of limitation of such carryforwards claimed by us have been audited or otherwise validated by the Internal Revenue Service, which could challenge the amount we have calculated. The recognition and measurement of our tax benefit includes estimates and judgment by our management, which includes subjectivity. Changes in estimates may create volatility in our tax rate in future periods based on new information about particular tax positions that may cause management to change its estimates.

Risks Relating to our Common Stock

Our results of operations will fluctuate, and these fluctuations could cause our stock price to decline: Our quarterly and annual operating results are likely to fluctuate in the future. These fluctuations could cause our stock price to decline. The nature of our business involves variable factors, such as the timing of any license agreement, the timing of launch and market acceptance of our products, and the timing of the research, development and regulatory submissions of our products in development that could cause our operating results to fluctuate. The forecasting of the timing and amount of sales of our products is difficult due to market uncertainty and the uncertainty inherent in seeking FDA and other necessary approvals for our product candidates. As a result, in some periods, our clinical, financial or operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of our stock.

Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline: During 2020, our stock traded as high as $0.43 per share and as low as $0.14 per share. The trading price of our common stock is likely to continue to exhibit wide fluctuations in response to various factors, some of which are beyond our control. These factors could include:

- results from our pre-clinical and clinical development programs, including our LIMITx product candidates;
- FDA actions related to our products in development;
- FDA actions related to any of our potential products;
- announcements regarding the progress of our preclinical and clinical programs;
- announcements regarding the execution of license agreements with third parties for our products or product candidates;
- failure of any of our products in development, if approved, to achieve commercial success;
- quarterly variations in our results of operations or those of our competitors;
- our ability to develop and market new and enhanced products on a timely basis;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies;
- additions or departures of key personnel;
- commencement of, or our involvement in, litigation;
- the inability of our contract manufacturers to provide us with adequate commercial supplies of our products;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board or management;
- general economic conditions and slow or negative growth of our market; and
- political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of our products and potential products may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

We do not have a history of paying dividends on our common stock: Historically, we have not declared and paid any cash dividends on our common stock. We intend to retain all of our earnings for the foreseeable future to finance the operation and expansion of our business. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases.

Any future sale of a substantial number of shares in a capital raising transaction could depress the trading price of our stock: In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the then current trading price of our common stock. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the then current trading price of our common stock. As of February 15, 2021, our two largest shareholders own an aggregate of 12,651,582 shares (including 1,782,531 shares underlying warrants) (representing approximately 53.0% of our outstanding shares, including shares issuable upon exercise of these warrants but not including any other warrants, options or convertible debt outstanding to other entities). If some or all of such shares are sold by such stockholders, it may have the effect of depressing the trading price of our common stock and could make it more difficult for us to raise capital if needed in the future.

As of February 15, 2021, approximately 44.8% of our common stock, after giving effect to exercise of a warrant, is owned by a single individual, who is also a principal of AD Pharma LLC and MainPointe Pharmaceuticals LLC, and that individual has right to designate a director: A significant amount of our common stock is owned by a single individual, Mr. Schutte. On July 24, 2017, we completed a $4.0 million private placement with him for the sale of 8,912,655 shares and warrants to purchase 1,782,531 shares at an exercise price of $0.528 and expiring on July 24, 2022. Mr. Schutte is a principal of 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. MainPointe also has options to expand the territory and products covered for additional sums. Further, Mr. Schutte has the right to designate a director (he has not done so). During 2018 and through June 28, 2019, Mr. Schutte had lent us an aggregate of $6.0 million (including accrued interest) on a secured basis with a security interest in all of our assets, including our intellectual property.

At June 28, 2019, we entered into a Promissory Note with Mr. Schutte that consolidated existing promissory notes into a single Note with a principal amount of $6.0 million (after including accrued and unpaid interest through that date). To secure our performance of our obligations under the Note, we granted Mr. Schutte a security interest in all of our assets. Terms of the consolidated Note provide for a July 1, 2023 maturity date rather than the previous maturity date of January 2, 2020, interest at fixed rate of 7.5% per annum with all payments of principal and interest deferred to maturity. The Note is convertible into Acura common stock at $0.16 per share. As additional consideration, Mr. Schutte received a warrant to purchase 10 million shares of the Company's common stock at a price of $0.01 per share. With our consent, Mr. Schutte assigned and transferred to AD Pharma, effective June 28, 2019, all of his right, title and interest in this Note, its associated Security Agreement and the Warrant to purchase 10 million common shares of our stock. Mr. Schutte is an investor in AD Pharma.

The combination of Mr. Schutte's direct share ownership, control of one of our key licensing partners, the right to designate a director to oversee the long-term affairs of our company, his ownership interest in AD Pharma LLC and the security interest AD Pharma has in all of our assets gives him considerable influence over our business and affairs. As a result, Mr. Schutte, as a practical matter, is able to control all matters requiring approval by our shareholders, including the approval or rejection of mergers, sales or licenses of all or substantially all of our assets, or other business combination transactions. The interests of Mr. Schutte as a shareholder and creditor may not always coincide with the interests of our other shareholders and as such he may and cause the Company to take action to advance his interests to the detriment of our other shareholders. Accordingly, you may not be able to influence any action we take or consider taking, even if it requires a shareholder vote.

Our common stock is deemed a "penny stock," which would make it more difficult for our investors to sell their shares: Our common stock is subject to the "penny stock" rules adopted under the Exchange Act. The penny stock rules generally apply to companies whose common stock is not listed on the NASDAQ Stock Market or other national securities exchange and trades at less than $5.00 per share, other than companies that have had average revenue of at least $6,000,000 for the last three years or that have net tangible assets of at least $5,000,000 ($2,000,000 if the company (such as Acura) has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than "established customers" complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. If our securities are subject to the penny stock rules, investors will find it more difficult to dispose of our securities.

Our shares of common stock have been thinly traded, so you may be unable to sell at or near ask prices or even at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares: Our common stock is quoted on the OTCQB Market. Our common stock experiences periods when it could be considered "thinly-traded." This situation may be attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. In addition, certain institutions are prohibited or limited from trading in shares priced at less than specified levels, including the prices at which our shares currently trade. As a consequence, there may be periods of several days, weeks or months when trading activity in our shares is minimal, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common stock will be sustained, or that current trading levels will be sustained or not diminish.

We are a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors: We are currently a "smaller reporting company," meaning that we are not an investment company, an asset- backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than $250 million. "Smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports and in certain registration statements. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" may make it harder for investors to analyze our results of operations and financial prospects.

ITEM 1B. UNRESOLVED STAFF COMMENTS

The Company has received no written comments regarding periodic or current reports from the staff of the SEC that were issued 180 days or more preceding the end of its 2020 fiscal year that remain unresolved.

ITEM 2. PROPERTIES

We rent from an unaffiliated Lessor, approximately 1,600 square feet of administrative office space at 616 N. North Court, Suite 120, Palatine, Illinois 60067 on a month-to-month basis. The lease agreement provides for rent, property taxes, common area maintenance, and janitorial services of approximately $2 thousand per month. We utilize this lease space for our administrative and business development functions.

We conduct research, development, laboratory, development scale manufacturing and other activities relating to developing product candidates using Aversion, Impede and LIMITx Technologies at the facility we own (through a wholly owned subsidiary) located at 16235 State Road 17, Culver, Indiana. At this location is a 25,000 square foot facility with 7,000 square feet of warehouse, 8,000 square feet of manufacturing space, 4,000 square feet of research and development labs and 6,000 square feet of administrative and storage space. The facility is located on 28 acres of land.

ITEM 3. LEGAL PROCEEDINGS

Not Applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market and Market Prices of Common Stock

During 2018 fiscal year and through May 20, 2019 our common stock was quoted on the OTCQB under the symbol "ACUR". However, commencing May 20, 2019 as a result of late filing of our 2018 Annual Report on Form 10-K our common stock was relegated to the OTC Markets OTC Pink tier. The Company regained compliance with the OTCQB in March, 2020 and effective March 23, 2020 it was quoted on the OTCQB.

Set forth below for the period indicated are the high and low sales prices for our common stock in the OTC Market of OTCQB and Pink tier.

	Sales Prices	
Period	**High**	**Low**
2020 Fiscal Year		
First Quarter	$ 0.43	$ 0.22
Second Quarter	$ 0.40	$ 0.14
Third Quarter	$ 0.35	$ 0.22
Fourth Quarter	$ 0.30	$ 0.18
2021 Fiscal Year		
First Quarter thru March 15, 2021	$ 0.50	$ 0.15

On March 15, 2021 the closing sales price of our common stock was $0.33.

Holders

There were approximately 240 holders of record of our common stock as of March 17, 2021 including approximately 80 holders who were nominees for an undetermined number of beneficial owners based upon a review of a securities position listing provided by our transfer agent in September 2017. There were approximately 4,400 beneficial holders of our common stock as of January 2021.

Dividend Policy

The payment of cash dividends is subject to the discretion of our Board of Directors and is dependent upon many factors, including our earnings, our capital needs and our general financial condition. Historically, we have not paid any cash dividends.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included elsewhere in this Report. Operating results are not necessarily indicative of results that may occur in the future periods. Certain statements in this Report under this Item 7, Item 1, "Business", Item 1A, "Risk Factors" and elsewhere 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 or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. See page 1 of this Report under the caption "Forward-Looking Statements" for a description of the most significant of such factors.

Company's Present Financial Condition

At December 31, 2020, we had cash of $413 thousand compared to $862 thousand of cash at December 31, 2019. We had an accumulated deficit of approximately $389.2 million and $388 million at December 31, 2020 and December 31, 2019, respectively. We had a loss from operations of $758 thousand and a net loss of $1.2 million for the year ended December 31, 2020, compared to a loss from operations of $725 thousand and a net loss of $3.8 million for the year ended December 31, 2019.

On June 28, 2019, we entered into License, Development and Commercialization Agreement (the "Agreement") with Abuse Deterrent Pharma, LLC, which was amended in October 2020. The Agreement, as amended, grants AD Pharma exclusive commercialization rights in the United States to LTX-03. Financial arrangements include monthly license payments to Acura by AD Pharma of $350,000 from inception through April 2020 and $200,000 thereafter until July 31, 2021 or FDA's acceptance of a New Drug Application ("NDA") for LTX-03 and reimbursement by AD Pharma of Acura's LTX-03 outside development expenses. Upon commercialization of LTX-03, Acura will be entitled to stepped royalties on sales and is eligible for certain sales related milestones. However, if the NDA application for LTX-03 is not accepted by the FDA by July 31, 2021, AD Pharma has the option of terminating the Agreement and taking ownership of the intellectual property. Acura currently expects the submission and FDA acceptance of the NDA to occur after July 31, 2021 and has notified AD Pharma of this revised timeline. Acura is currently in discussions with AD Pharma to amend the Agreement. There can be no assurance that AD Pharma will agree to extend the NDA filing acceptance date or that they will not take ownership of the intellectual property.

Our losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and sales, marketing and general corporate expenses. Research and development activities include costs of pre-clinical studies, clinical trials, and clinical trial product supplies associated with our product candidates as well as cost sharing expenses of line extension studies and post-marketing studies under the Assertio Agreement. Sales and marketing expenses include costs associated with the Nexafed product line advertising incurred prior to our entering into the MainPointe Agreement, salaries and other personnel-related costs include the stock-based compensation associated with stock options and restricted stock units granted to employees and non-employee directors.

The ultimate impact of the COVID-19 pandemic is highly uncertain and we do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company's financial condition, liquidity, and future results of operations. (See further COVID-19 discussion in Note 1 to the Financial Statements).

Results of Operations for the Years Ended December 31, 2020 and 2019.

	December 31			
	2020	2019	Change	
	$000's		$000's	Percent
Revenues:				
Royalties	$ 109	$ 372	$ (263)	(71)%
Collaboration from related party	238	185	53	29
License fees from related party	3,000	$ 2,100	900	43
Product sales	223	-	223	-
Total revenues	3,570	2,657	913	34
Expenses:				
Research and development	1,781	1,505	226	18
General and administrative	2,547	1,877	670	36
Total expenses	4,328	3,382	946	28
Operating loss	(758)	(725)	33	5
Interest expense	(450)	(449)	1	-
Loss on debt extinguishment	-	(2,600)	(2,600)	(100)
Loss before provision for income taxes	(1,208)	(3,774)	(2,566)	(68)
Provision for income taxes	-	-	-	-
Net loss	$ (1,208)	$ (3,774)	$ (2,566)	(68)%

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 $3.0 million and $2.1 million of license fees revenue during the years ended 2020 and 2019, 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 $238 thousand and $185 thousand of collaboration revenue during the years ended 2020 and 2019, 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 $102 thousand and $351 thousand of royalty revenue for Oxaydo during the years ended 2020 and 2019, respectively. 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 $7 thousand and $21 thousand of royalty revenue on Nexafed during 2020 and 2019, respectively.

Product Sales

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.

Operating Expenses

Research and Development

Research and development expense (“R&D”) for 2020 and 2019 was primarily with respect to our LIMITx Technology development activity 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, our facility costs, and a percentage share of selected cost sharing expenses under the license agreement with Assertio. Also included in 2019 year end results is share-based compensation expenses of approximately $21 thousand. Excluding share-based compensation expense, our R&D expenses increased approximately $0.3 million between reporting periods, all related 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. Included in each of the 2020 and 2019 results are share-based compensation expenses of approximately $53 thousand and $117 thousand, respectively. Excluding the share-based compensation expense our general and administrative expenses increased by approximately $0.7 million between reporting periods, resulting primarily from a $668 thousand intangible asset impairment charge offset by $137 thousand decrease in resulting ongoing amortization expense on this asset, resumption of board of director fee payments for the entire year of 2020 resulting in increase of $43 thousand over 2019 expense, and resumption of general and patent legal services for the entire year of 2020 resulting in increase of $170 thousand over 2019 expense.

Non-Operating Expense

Debt Extinguishment

On June 28, 2019, we modified the $5.0 million related party loan with Mr. Schutte and the accounting method used for the changes to the loan resulted in the recognition of a $2.6 million loss on debt extinguishment.

Interest Expense

For 2020 and 2019, we incurred interest expense of $450 thousand and $449 thousand, respectively, on our $6.0 million convertible debt.

Income Taxes

Our results for 2020 and 2019 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

As of December 31, 2020, we had cash of $413 thousand, working capital deficit of $6.6 million and an accumulated deficit of $389.2 million. We 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 March 30, 2021 our cash balance was approximately $350 thousand.

Currently, the License, Development and Commercialization Agreement dated June 28, 2019 (the "Agreement"), as amended, requires AD Pharma to pay a monthly license payment of $350,000 from AD Pharma to us for a period from inception up to April 2020 at which time the payment is $200,000 per month through July 2021, and pay all outside development costs for LTX-03. AD Pharma is delinquent in remitting monthly license payments for December, 2020 thru March, 2021 and approximately $100 thousand of reimbursable LTX-03 development expenses. Failure to make these payments are an event of default under the Agreement, as amended. Based upon representations by AD Pharma, we anticipate receipt of these past due amounts by April 30, 2021 and payment obligations through July, 2021, for which no assurance can be given.

Included in the AD Pharma Agreement, as amended, 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 Agreement and take ownership of the LIMITx intellectual property. Failure to meet this date will be 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 now occur after July 31, 2021 and has notified AD Pharma of this revised timeline. Acura is currently in discussions with AD Pharma to amend the Agreement. There can be no assurance that AD Pharma will agree to extend the NDA filing acceptance date or that they will not take ownership of the intellectual property. Pending resolution of this matter, we have presented the $6.0 million convertible debt as a current liability at December 31, 2020. Whether or not AD Pharma exercises their right to terminate the 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 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.

Cash Flows

Comparison of Years Ended December 31, 2020 and 2019

The following table summarizes our cash flows for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,	
	2020	**2019**
Net cash (used in) provided by:		
Operating activities	$ (719)	$ (618)
Investing activities	-	-
Financing activities	270	1,389
Net (decrease) increase in cash	$ (449)	$ 771

Cash Flows from Operating Activities

Net cash used in operating activities was $0.7 million for the year ended December 31, 2020 and consisted primarily of a net loss of $1.2 million. This net loss was partially offset by non-cash items such as $36 thousand in share-based compensation expense, $56 thousand of depreciation expense, $668 thousand impairment charge on an intangible asset, $70 thousand of intangible asset amortization expense and $223 write-down of product sales return allowance liability, with $118 thousand in net cash outflows from changes in operating assets and liabilities. Cash outflows from changes in operating assets and liabilities of $118 thousand were primarily due to increases of $400 thousand in license fee receivable, $119 thousand in collaboration revenue receivable and $17 thousand in prepaid expenses and other current assets along with a decrease of $160 thousand in accounts payable and accrued expenses. These cash outflows were partially offset by a decreases of $52 thousand in royalty receivable, and $68 thousand in income tax receivable, along with increases of $449 thousand in accrued interest and $10 thousand in other current liabilities.

Net cash used in operating activities was $0.6 million for the year ended December 31, 2019 and consisted primarily of a net loss of $3.8 million, capitalized debt discount of $13 thousand and a loss on debt extinguishment of $2.6 million. This net loss was partially offset by non-cash items such as $108 thousand in share-based compensation expense, $66 thousand of debt discount and debt issue cost amortization expense, $66 thousand of depreciation expense, and $207 thousand of intangible asset amortization expense with $154 thousand in net cash outflows from changes in operating assets and liabilities. Cash outflows from changes in operating assets and liabilities of $154 thousand were primarily due to $78 thousand increase in collaboration revenue receivable and $379 thousand decrease in accounts payable and accrued expenses. These cash outflows were partially offset by a decreases of $55 thousand in royalty receivables, $67 thousand in income tax receivable, $394 thousand in accrued interest and $44 thousand in prepaid expenses and other current assets and increases of $18 thousand in other current liabilities.

Cash Flows from Investing Activities

We had no investing activities for the years ended December 31, 2020 and 2019.

Cash Flows from Financing Activities

Net cash provided by financing activities was $269 thousand for the year ended December 31, 2020 and consisted of the proceeds from a loan under the CARESs Act.

Net cash provided by financing activities was $1.4 million for the year ended December 31, 2020 and consisted of the net proceeds from loans provided by Mr. Schutte.

Related Party Loans from Mr. Schutte

At June 28, 2019, we entered into a Promissory Note (the "Note") with Mr. Schutte that consolidated existing promissory notes that were due to mature at January 2, 2020 issued to John Schutte into a single note for $6.0 million (after including accrued and unpaid interest). To secure our performance of our obligations under the Note, we granted Mr. Schutte a security interest in all of our assets. Terms of the consolidated Note provide for a July 1, 2023 maturity date, interest at fixed rate of 7.5% per annum with all payments of principle and interest deferred to maturity. The Note is convertible into Acura common stock at $0.16 per share. As additional consideration, Mr. Schutte received a warrant to purchase 10 million shares of the Company's common stock at a price of $0.01 per share.

With our consent, Mr. Schutte assigned and transferred to Abuse Deterrent Pharma, LLC ("AD Pharma") all of his right, title and interest in this Note, its associated Security Agreement and the Warrant to purchase 10.0 million common shares of our stock, effective June 28, 2019. Mr. Schutte is an investor in AD Pharma.

Off-Balance Sheet Arrangements

We do not engage in transactions or arrangements with unconsolidated or other special purpose entities.

Critical Accounting Policies

The preparation of our financial statements in accordance with United States generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses in our financial statements and accompanying notes. We evaluate our estimates on an ongoing basis, including those estimates related to contract agreements, research collaborations and investments. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The following items in our financial statements require significant estimates and judgments:

Going Concern

In connection with the preparation of the consolidated financial statements for the years ended December 31, 2020 and December 31, 2019, the Company conducted an evaluation as to whether there were conditions and events, considered in the aggregate, which raised substantial doubt as to the entity's ability to continue as a going concern within one year after the date of the issuance, or the date of availability, of the financial statements to be issued, noting that there did appear to be evidence of substantial doubt of the entity's ability to continue as a going concern as further discussed in Note 1 to the consolidated financial statements.

Revenue Recognition

The Company's revenues are comprised of amounts earned under its license and collaboration agreements, royalties, and until March 2017 did previously include the Nexafed products' net product sales. The Company adopted Accounting Standards Codification Topic 606—Revenue from Contracts with Customers, or Topic 606, on January 1, 2018, resulting in a change to its accounting policy for revenue recognition.

Under ASC 606, 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.

The Company may enter into license and collaboration agreements which 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. These license and collaboration agreements may contain customer options for the license of additional products and territories. The options in the agreement may need to be evaluated to determine the option's standalone selling prices. Some of the license and collaboration agreements may contain a license to the technology as well as licenses to tradenames or trademarks. The licenses to the tradenames or trademarks will need to be evaluated in context of the entire contract. The commercial sales-based milestones and sales royalties earned under the license and collaboration agreements are recorded in the period of the related sales by the licensee.

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 CROs based on agreed upon terms and may include payments in advance of a study starting date. Payments in advance will be reflected in the financial statements as prepaid expenses. We review and charge to expense the amounts for 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 to us. The accrued CRO costs are subject to revisions by us as the study progresses towards completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known to us.

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 measured using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance against deferred income tax assets is required 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 December 31, 2019, 100% of the remaining deferred income tax assets are offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that 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 a benefit from income taxes in such period would be recognized.

Share-based Compensation Expense

Compensation cost related to stock-based payment transactions is measured based on fair value of the equity or liability instrument issued. For purposes of estimating the fair value of each stock option unit on the date of grant, we utilized the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, 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 its historical public market closing prices). Our accounting for stock-based compensation for restricted stock units, or RSUs, is based on the fair-value method. The fair value of the RSUs is the market price of our common stock on the date of grant, less its exercise cost. In May 2017, the FASB issued ASU No. 2017-09 which provides guidance as to how an entity should apply modified accounting in Topic 718 when changing the terms and conditions of its share-based payment awards. The guidance clarifies that modification accounting will be applied if the value, vesting conditions or classification of the award changes. The ASU is effective for annual reporting periods, including interim periods within those annual periods, beginning after December 15, 2017 but early adoption is permitted. The Company adopted this new standard on January 1, 2018 which did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncements

See Note 2 Summary of Significant Accounting Policies - Recent Accounting Pronouncements of the Notes to Financial Statements (Part II, Item 8 of this Form 10-K) for further discussion.

Capital Expenditures

We did not have any capital expenditures during 2020 or 2019.

Impact of Inflation

We believe that inflation did not have a material impact on our operations for the periods reported.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Some of the securities that we may invest in may be subject to market risk. Our primary objective in our cash management activities is to preserve principal while at the same time maximizing income we receive from our investments. A change in the prevailing interest rates may cause the principal amount of the investments to fluctuate. As of December 31, 2020, we had no investments in marketable securities or holdings of derivative financial or commodity instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements of Acura Pharmaceuticals, Inc. and Subsidiary and the Report of the Independent Registered Public Accounting Firm thereon, to be filed pursuant to Item 8 are included in Item 15.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. As of the end of the period covered by this Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) under the Exchange Act). Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective in alerting them in a timely manner to material information required to be disclosed in our periodic reports filed with the Securities and Exchange Commission.

Management's Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designated by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013 Framework). Based on our assessment, our Chief Executive Officer and our Chief Financial Officer both believe that, as of December 31, 2020, our internal control over financial reporting is effective based on those criteria.

The Company's independent registered public accounting firm was not required to and did not express an opinion on the effectiveness of the Company's internal control over financial reporting.

Changes in Internal Control over Financial Reporting. There was no change in our internal control over financial reporting that occurred during the Fourth Quarter 2020 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Reference is made to our 2021 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2020 with respect to Directors, Executive Officers and Corporate Governance, which is incorporated herein by reference and made a part hereof in response to the information required by Item 10.

ITEM 11. EXECUTIVE COMPENSATION

Reference is made to our 2021 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2020 with respect to Executive Compensation, which is incorporated herein by reference and made a part hereof in response to the information required by Item 11.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Reference is made to our 2021 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2020 with respect to the to the security ownership of certain beneficial owners and management and related stockholder matters, which is incorporated herein by reference and made a part hereof in response to the information required by Item 12.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Reference is made to our 2021 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2020 with respect to certain relationships and related transactions and direct independence, which is incorporated herein by reference and made a part hereof in response to the information required by Item 13.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Reference is made to our 2021 Proxy Statement to be filed with the within 120 days after the year ended December 31, 2020 with respect to auditor fees, which is incorporated herein by reference and made a part in response to the information required by Item 14.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

1. Financial Statements: See Index to Consolidated Financial Statements on page F-1.
2. Financial Statement Schedules: None
3. Exhibits: See Exhibits Index on page E-1.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 31, 2021

ACURA PHARMACEUTICALS, INC.

By: /s/ Robert B. Jones
Robert B. Jones
President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title(s)	Date
/s/Robert B. Jones Robert B. Jones	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2021
/s/Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2021
/s/ George K. Ross George K. Ross	Director	March 31, 2021
/s/ William G. Skelly William G. Skelly	Director	March 31, 2021
/s/ Immanuel Thangaraj Immanuel Thangaraj	Director	March 31, 2021
/s/ Bruce F Wesson Bruce F. Wesson	Director	March 31, 2021

ACURA PHARMACEUTICALS, INC.
EXHIBIT INDEX

The following exhibits are included as a part of this Annual Report on Form 10-K or incorporated herein by reference.

Exhibit Number	Exhibit Description
1.1	Placement Agency Agreement dated June 30, 2015 between Roth Capital Partners LLC and the Registrant (incorporated by reference to Exhibit 1.1 to our Form 8-K filed July 1, 2015)
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on June 25, 2009).
3.2	Certificate of Amendment Reverse Splitting Common Stock and restating but not changing text of part of Article III of Restated Certificate of Incorporation (incorporated by Reference to Exhibit 3.1 to the Form 8-K filed December 4, 2007).
3.3	Certificate of Amendment Reverse Splitting Common Stock and restating but not changing text of part of Article III of Restated Certificate of Incorporation (incorporated by Reference to Exhibit 3.1 to the Form 8-K filed August 27, 2015).
3.4	Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Form 8-K filed on May 14, 2018).
4.1	Form of Common Stock Certificate (incorporated by Reference to Exhibit 4.1 to the Form S-3 filed on March 9, 2016)
4.2	Amended and Restated Warrant A-1 issued to Oxford Finance LLC on January 7, 2015 (incorporated by reference to Exhibit 10.9 to our Form 10-K filed March 2, 2015).
4.3	Amended and Restated Warrant A-2 issued to Oxford Finance LLC on January 7, 2015 (incorporated by reference to Exhibit 10.10 to our Form 10-K filed March 2, 2015).
4.4	Amended and Restated Warrant A-3 issued to Oxford Finance LLC on January 7, 2015 (incorporated by reference to Exhibit 10.11 to our Form 10-K filed March 2, 2015).
4.5	Form of Common Stock Warrant issued to John Schutte on July 24, 2017 (incorporated by reference Exhibit 4.1 to our Form 8-K filed July 28, 2017)
10.1	Manufacturing Services Agreement dated as of July 19, 2011 between the Registrant and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to our Form 8-K filed July 27, 2011) (confidential treatment has been granted for portions of this Exhibit).
10.2	Securities Purchase Agreement dated as of August 20, 2007 ("PIPE SPA") among the Registrant, Vivo Ventures Fund VI, L.P., Vivo Ventures VI Affiliates Fund, L.P., GCE Holdings LLC, and certain other signatories thereto (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 21, 2007).
10.3	Subscription Agreement dated as of July 24, 2017 between the Registrant and John Schutte (incorporated by reference to Exhibit 10.1 to our Form 8-K filed July 28, 2017)

Exhibit Number	Exhibit Description
10.4	Loan and Security Agreement dated as of December 27, 2013 between Acura Pharmaceuticals, Inc., Acura Pharmaceutical Technologies, Inc., and Oxford Finance LLC (incorporated by reference to Exhibit 10.6 to the Form 10-K filed March 3, 2014).
10.5	First Amendment to Loan and Security Agreement entered into as of January 7, 2015 between Oxford Finance LLC, the Registrant and Acura Pharmaceutical Technologies, Inc. (incorporated by reference to Exhibit 10.8 to our Form 10-K filed March 2, 2015).
10.6	Second Amendment to Loan and Security Agreement entered into as of October 13, 2016 between Oxford Finance LLC, the Registrant and Acura Pharmaceutical Technologies, Inc. (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 filed February 3, 2017, File No. 333-215885)
10.7	Form of Mortgage dated December 27, 2013 (incorporated by reference to Exhibit 10.8 to the Form 10-K filed March 3, 2014).
10.8	Collaboration and License Agreement entered into as of January 7, 2015 between the Registrant, Egalet US, Inc., Egalet Limited and with respect to Section 17.21, Egalet Corporation (certain information has been omitted and filed separately with the Securities and Exchange Commission and confidential treatment has been granted with respect to the omitted portion) (incorporated by reference to Exhibit 10.13 to the Form 10-K for the year ending December 31, 2014, filed March 2, 2015).
10.9	License and Development Agreement dated as of June 5, 2015 between the Registrant and Bayer HealthCare LLC (certain information has been omitted and filed separately with the Securities and Exchange Commission and confidential treatment has been granted with respect to the omitted portion) (incorporated by reference to Exhibit 10.1 to our Form 10-Q/A filed February 16, 2016).
10.10	Amended and Restated Voting Agreement dated as of February 6, 2004 among the Registrant, Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P., and others (incorporated by reference to Exhibit 10.5 of the Form 8-K filed on February 10, 2004 (the "February 2004 Form 8-K")).
10.11	Joinder and Amendment to Amended and Restated Voting Agreement dated November 9, 2005 between the Registrant, GCE Holdings, Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Galen Partners III, L.P. and others (incorporated by reference to Exhibit 10.1 to the Form 8-K filed November 10, 2005).
10.12	Second Amendment to Amended and Restated Voting Agreement dated as of January 24, 2008 between the Registrant and GCE Holdings, LLC (incorporated by reference to Exhibit 10.1 to the Form 8-K filed January 28, 2008).
10.13	Third Amendment to Amended and Restated Voting Agreement dated as of October 1, 2012 between the Registrant, Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P., and others (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on October 3, 2012).
10.14	Second Amended and Restated Voting Agreement executed July 2017 and dated as of July 24, 2017 (incorporated by reference to Exhibit 10.1 to the 8-K dated filed August 1, 2017)

Exhibit Number	Exhibit Description
†10.15	Registrant's 1998 Stock Option Plan, as amended (incorporated by reference to Appendix C to the Registrant's Proxy Statement filed on May 12, 2009).
†10.16	Registrant's 2005 Restricted Stock Unit Award Plan, as amended (incorporated by reference to Appendix B to the Registrant's Proxy Statement filed on April 2, 2008).
†10.17	Registrant's 2014 Restricted Stock Unit Award Plan, (incorporated by reference to Appendix A to the Registrant's Proxy Statement filed on March 12, 2014).
†10.18	Registrant's 2017 Restricted Stock Unit Award Plan, (incorporated by reference to Exhibit 10.1 to the 8-K filed on November 14, 2017).
†10.19	Registrant's 2008 Stock Option Plan, as amended on June 25, 2009 (incorporated by reference to Appendix B to our Proxy Statement filed on May 12, 2009).
†10.20	Registrant's 2016 Stock Option Plan (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on April 28, 2016).
†10.21	Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens ("Clemens") (incorporated by reference to Exhibit 10.44 to the Form 10-K for the period ending December 31, 2007, filed on April 15, 1998).
†10.22	First Amendment to Employment Agreement made as of June 28, 2000 between the Registrant and Clemens (incorporated by reference to Exhibit 10.44A to the Registrant's Form 10-K filed on February 21, 2006).
†10.23	Second Amendment to Executive Employment Agreement between Registrant and Clemens, dated as of January 5, 2005 (incorporated by reference to Exhibit 99.1 to the Registrant's Form 8-K filed January 31, 2005).
†10.24	Third Amendment to Executive Employment Agreement dated December 22, 2005 between Registrant and Clemens (incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed December 23, 2005).
†10.25	Fourth Amendment to Executive Employment Agreement dated December 16, 2007 between Registrant and Clemens (incorporated by reference to Exhibit 10.28 to the Form 10-K for the year ending December 31, 2007, filed on March 5, 2008).
†10.26	Fifth Amendment to Executive Employment Agreement executed July 9, 2008 between Registrant and Clemens (incorporated by reference to Exhibit 10.4 to our Form 8-K filed on July 10, 2008).
†10.27	Sixth Amendment to Executive Employment Agreement executed December 14, 2012 between the Registrant and Clemens (incorporated by reference to Exhibit 10.2 to our Form 8-K filed on December 17, 2012).
†10.28	Seventh Amendment to Executive Employment Agreement executed December 12, 2013 between the Registrant and Clemens (incorporated by reference to Exhibit 10.24 to the Form 10-K for the year ending December 31, 2013 filed on March 3, 2014).

Exhibit Number	Exhibit Description
†10.29	Employment Agreement dated as of March 18, 2008 between the Registrant and Robert B. Jones (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on March 24, 2008).
†10.30	Amendment to Executive Employment Agreement dated as of April 28, 2011 between the Registrant and Robert B. Jones (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed July 28, 2011).
†10.31	Amendment to Executive Employment Agreement between Registrant and Robert B. Jones made as of July 7, 2011 (incorporated by reference to Exhibit 10.2 to our Form 10-Q filed July 28, 2011).
†10.32	Second Amendment to Executive Employment Agreement between Registrant and Robert B. Jones executed December 14, 2012 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed December 17, 2012).

Exhibit Number	Exhibit Description
10.33	Form of Securities Purchase Agreement entered into between the Registrant and institutional investors on June 30, 2015 (incorporated by reference to Exhibit 10.1 of our Form 8-K filed July 1, 2015).
10.34	Consent and Third Amendment to Loan and Security Agreement entered into as of May 12, 2017 between Oxford Finance LLC, the Registrant and Acura Pharmaceutical Technologies, Inc. (incorporated by reference to Exhibit 10.2 to our Form 10-Q filed May 12, 2017).
10.35	License, Commercialization and Option Agreement is made and entered into as of March 16, 2017 by and between MainPointe Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.34 to our Form 10-K filed June 7, 2018).
10.36	Promissory Note dated May 7, 2018 issued to John Schutte (incorporated by reference to Exhibit 10.35 to our Form 10-Q filed August 14, 2018).
10.37	Subordination Agreement dated as of May 7, 2018 between John Schutte and Oxford Finance, LLC, approved by Registrant and Acura Pharmaceutical Technologies, Inc. (incorporated by reference to Exhibit 10.36 to our Form 10-Q filed August 14, 2018).
10.38	Fourth Amendment dated as of June 6, 2018 to Loan and Security Agreement dated as of December 27, 2013, as amended, between the Registrant, Acura Pharmaceutical Technologies, Inc. and Oxford Finance, LLC (incorporated by reference to Exhibit 10.37 to our Form 10-Q filed August 14, 2018).
10.39	Promissory Note dated June 28, 2018 issued to John Schutte (incorporated by reference to Exhibit 10.38 to our Form 10-Q filed August 14, 2018).
10.40	Promissory Note dated August 2, 2018 issued to John Schutte (incorporated by reference to Exhibit 10.39 to our Form 10-Q filed November 27, 2018).
10.41	Promissory Note dated September 13, 2018 issued to John Schutte (incorporated by reference to Exhibit 10.40 to our Form 10-Q filed November 27, 2018).
10.42	Promissory Note dated October 5, 2018 issued to John Schutte (incorporated by reference to Exhibit 10.42 to our Form 10-K filed September 16, 2019).
10.43	Promissory Note dated November 21, 2018 issued to John Schutte (incorporated by reference to Exhibit 10.43 to our Form 10-K filed September 16, 2019).
10.44	Promissory Note dated December 20, 2018 issued to John Schutte (incorporated by reference to Exhibit 10.44 to our Form 10-K filed September 16, 2019).
10.45	Promissory Note dated January 28, 2019 issued to John Schutte (incorporated by reference to Exhibit 10.45 to our Form 10-K filed September 16, 2019).
10.46	Promissory Note dated March 25, 2019 issued to John Schutte (incorporated by reference to Exhibit 10.46 to our Form 10-Q filed October 1, 2019).
10.47	Promissory Note dated May 1, 2019 issued to John Schutte (incorporated by reference to Exhibit 10.47 to our Form 10-Q filed February 10, 2020).

Exhibit Number	Exhibit Description
10.48	Promissory Note dated June 12, 2019 issued to John Schutte (incorporated by reference to Exhibit 10.48 to our Form 10-Q filed February 10, 2020).
10.49	Promissory Note dated June 28, 2019 issued to John Schutte (incorporated by reference to Exhibit 10.49 to our Form 10-Q filed February 20, 2020).
10.50	License, Development and Commercialization Agreement is made and entered into as of June 28, 2019 by the Registrant and between Abuse Deterrent Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.50 to our Form 10-K filed March 31, 2020).
10.51	Common Stock Warrant issued June 28, 2019 to John Schutte (incorporated by reference to Exhibit 10.51 to our Form 10-K filed March 31, 2020).
10.52	Assignment of Promissory Note, Warrant and Security Agreement issued June 28, 2019 by John Schutte to Abuse Deterrent Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.52 to our Form 10-K filed March 31, 2020).
10.53 *	Amended License, Development and Commercialization Agreement is made and entered into as of October 16, 2020 by the Registrant and between Abuse Deterrent Pharmaceuticals, LLC.
14.1	Code of Ethics (incorporated by reference to Exhibit 14.1 of the Form 8-K filed on December 10, 2007).
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21 to the Form 10-K for the fiscal year ended December 31, 2006 filed on March 15, 2007).
23.1*	Consent of Independent Registered Public Accounting Firm.
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*	Certification of 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 Extension Calculation Linkbase
101.LAB *	XBRL Extension Label Linkbase
101.PRE *	XBRL Extension Presentation Linkbase
101.DEF *	XBRL Taxonomy Extension Definition Linkbase

*Filed or furnished herewith.
† Management contract or compensatory plan or arrangement

ACURA PHARMACEUTICALS, INC
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report Of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Acura Pharmaceuticals, Inc.
Palatine, Illinois

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Acura Pharmaceuticals, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, accumulated stockholders' deficit, and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Intangible Asset Impairment

As described in Note 2 to the consolidated financial statements, the Company's recognized an impairment charge of $668 thousand in the consolidated statement of operations for the year ended December 31, 2020. Intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of these assets is measured by comparing the carrying amount of the asset to the estimated projected future cash flows expected to be generated by the asset. If the carrying value of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Based on the recoverability test, Management was required to calculate the fair value of the intangible asset. The fair value calculation of the intangible asset included significant estimates and assumptions related to the amount and timing of projected future cash flows and in the situation when the asset is determined to not be recoverable, the discount rate.

We identified the finite-lived intangible asset impairment assessment as a critical audit matter. The principal consideration for our determination that performing procedures relating to the finite-lived intangible asset impairment assessment is a critical audit matter is the significant judgment required by management in developing the assumptions used in assessing the recoverability of this asset, including the (1) forecasted revenues used in the projected future cash flows and (2) discount rate.

Auditing these elements involved a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating evidence related to management's future cash flow projections and the discount rate assumption, including the involvement of our valuation specialists.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the reasonableness of management's forecasted revenue projections by (1) comparing to historical revenues and (2) evaluating whether these assumptions were consistent with other areas of the audit.

- Utilizing personnel with specialized knowledge and skills in valuation to assist in:

    - Evaluating the appropriateness of the methodology used to value the intangible assets;

    - Testing the mathematical accuracy of the calculations performed;

    - Developing an independent estimate of the risk-adjusted discount rate used by management based on a market participant perspective.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2004.

Chicago, Illinois

March 31, 2021

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2020 and 2019
(in thousands except par value)

	2020	2019
Assets:		
Cash	$ 413	$ 862
Royalty receivable	30	82
Collaboration revenue receivable from related party	197	78
License fee receivable from related party	400	-
Prepaid expenses and other current assets	139	122
Income tax receivable	-	34
Total current assets	1,179	1,178
Income tax receivable	-	34
Property, plant and equipment, net (Note 5)	484	540
Intangible asset, net (Note 3)	73	810
Total assets	$ 1,736	$ 2,562
Liabilities:		
Accounts payable	$ 31	$ 237
Accrued expenses (Note 6)	631	585
Loan under CARES Act	164	-
Other current liabilities (Note 11)	18	29
Sales returns liability	-	223
Convertible debt to related party, net of discounts (Note 7)	6,000	-
Accrued interest to related party (Note 7)	678	-
Total current liabilities	7,522	1,074
Convertible debt to related party, net of discounts (Note 7)	-	6,000
Accrued interest to related party (Note 7)	-	229
Loan under CARES Act – non current	105	-
Total liabilities	$ 7,627	$ 7,303
Commitments and contingencies		
Stockholders' deficit:		
Common stock - $0.01 par value per share; 100,000 shares authorized, 21,650 and 21,300 shares issued and outstanding at December 31, 2020 and 2019, respectively	216	213
Additional paid-in capital	383,097	383,042
Accumulated deficit	(389,204)	(387,996)
Total stockholders' deficit	(5,891)	(4,741)
Total liabilities and stockholders' deficit	$ 1,736	$ 2,562

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2020 and 2019
(in thousands except per share amounts)

	2020	2019
Revenues:		
Royalties	$ 109	$ 372
Collaboration from related party	238	185
License fees from related party	3,000	2,100
Product sales (Note 4)	223	-
Total revenues	3,570	2,657
Expenses:		
Research and development	1,781	1,505
General and administrative	2,547	1,877
Total expenses	4,328	3,382
Operating loss	(758)	(725)
Loss on debt extinguishment (Note 7)	-	(2,600)
Interest expense (Note 7)	(450)	(449)
Loss before provision for income taxes	(1,208)	(3,774)
Provision for income taxes	-	-
Net loss	$ (1,208)	$ (3,774)
Net loss per share (Note 13):		
Basic	$ (0.04)	$ (0.14)
Diluted	$ (0.04)	$ (0.14)
Weighted average number of shares outstanding:		
Basic	32,320	26,720
Diluted	32,320	26,720

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
YEARS ENDED DECEMBER 31, 2020 and 2019
(in thousands)

	Common Stock				
	Number of Shares	Par Value	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2020	21,300	$ 213	$ 383,042	$ (387,996)	$ (4,741)
Net loss	-	-	-	(1,208)	(1,208)
Net distribution of common stock pursuant to restricted stock unit award plan	350	3	19	-	22
Non-cash share-based compensation	-	-	36	-	36
Balance at December 31, 2020	21,650	$ 216	$ 383,097	$ (389,204)	$ (5,891)

	Common Stock				
	Number of Shares	Par Value	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2019	21,034	$ 210	$ 380,395	$ (384,222)	$ (3,617)
Net loss	-	-	-	(3,774)	(3,774)
Net distribution of common stock pursuant to restricted stock unit award plan	266	3	12	-	15
Non-cash share-based compensation	-	-	108	-	108
Debt premium from debt modification	-	-	1,382	-	1,382
Issuance of warrant	-	-	1,145	-	1,145
Balance at December 31, 2019	21,300	$ 213	$ 383,042	$ (387,996)	$ (4,741)

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2020 and 2019
(in thousands)

	2020	2019
Cash Flows from Operating Activities:		
Net loss	$ (1,208)	$ (3,774)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	56	66
Non-cash share-based compensation	36	108
Capitalized debt discount	-	(13)
Amortization of debt discount and deferred debt issue costs	-	66
Amortization of intangible asset	69	207
Loss on debt extinguishment	-	2,600
Impairment charge on intangible asset	668	-
Loss on disposal of equipment	-	1
Sales returns liability	(223)	-
Changes in assets and liabilities:		
Royalty receivable	52	55
Collaboration revenue receivable from related party	(119)	(78)
License fee receivable – related party	(400)	-
Prepaid expenses and other current assets	(17)	44
Income taxes refundable	68	67
Accounts payable	(206)	(368)
Accrued expenses	46	(11)
Accrued interest on related party loans	449	394
Other current liabilities	10	18
Net cash used in operating activities	(719)	(618)
Cash Flows from Financing Activities:		
Proceeds from distribution of RSU awards	3	14
Statutory minimum payroll withholding taxes paid on the distribution of shares pursuant to RSU awards	(2)	-
Proceeds from loan under CARES Act	269	-
Proceeds from related party loans	-	1,375
Net cash provided by financing activities	270	1,389
Net (decrease) increase in cash	(449)	771
Cash at beginning of year	862	91
Cash at end of year	$ 413	$ 862
Supplemental Disclosures of Cash Flow Information:		
Cash interest payments on loan	$ -	$ -

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
YEARS ENDED DECEMBER 31, 2020 and 2019

Supplemental disclosures of non-cash investing and financing activities (amounts presented are rounded to the nearest thousand):

Year Ended December 31, 2019

1. The imputed interest on the below market rate element of the $650 related party loans made to the Company through June 27, 2019, amounted to $13, and was recorded in interest income with a corresponding like amount recorded as debt discount against the principal amount of the loan.

2. On June 28, 2019, modifications made to the $5,000 related party loan resulted in a debt extinguishment. A $2,600 loss on debt extinguishment was recorded comprising $1,145 for a common stock purchase warrant issued to the related party lender, the excess fair value premium on the newly issued convertible debt of $1,382, and the write-off of unamortized debt discount of $73.

3. Accrued interest payable of $275 on the related party $5,000 loan was rolled into principal under modifications made to the loan occurring on June 28, 2019.

See accompanying Notes to 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") is an innovative drug delivery company engaged in the research, development and commercialization of technologies and products intended to address safe use of medications. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Limitx™ Technology is intended to minimize the risks and side effects associated with overdose by retarding the release of active drug ingredients when too many tablets are accidently or purposefully ingested. Our Aversion® Technology is intended to address methods of product tampering associated with opioid abuse by incorporating gelling ingredients and irritants into tablets to discourage abuse by snorting and provide barriers to abuse by injection. Our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine tablets into methamphetamine.

- Our Limitx Technology is in development with immediate-release tablets containing hydrocodone bitartrate and acetaminophen (also known as LTX-03) as the lead product candidate due to its large market size and its known prevalence of oral excessive tablet abuse and overdose. The technology is designed to retard the release of active opioid drug 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. US commercialization rights to LTX-03 are licensed to Abuse Deterrent Pharma, LLC (See Note 3).

- Our Aversion Technology has been licensed to Assertio Holdings Inc. or Assertio (formerly known as Zyla Life Sciences and previously as Egalet Corporation) 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 December 31, 2020, we had cash of $413 thousand, working capital deficit of $6.6 million and an accumulated deficit of $389 million. We 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 entered into a License, Development and Commercialization Agreement with Abuse Deterrent Pharma, LLC ("AD Pharma") which was amended in October 2020 (the "AD Pharma Agreement"). AD Pharma has the right to terminate the AD Pharma Agreement for "convenience on 30 days prior written notice". Under the AD Pharma Agreement, as amended, the required monthly license payments by AD Pharma will only continue until July 2021 if AD Pharma does not exercise their right to terminate the AD Pharma Agreement. To fund further operations, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies or explore a variety of capital raising and other transactions to provide additional funding. 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 and the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. 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. Whether or not AD Pharma exercises their right to terminate the AD Pharma Agreement, we need to raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. The Company's ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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.

AD Pharma is delinquent in remitting monthly license payments of $200 thousand for each of December, 2020 thru March, 2021 and approximately $100 thousand of reimbursable LTX-03 development expenses. Failure to make these payments are an event of default under the Agreement, as amended.

AD Pharma may terminate the 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 Agreement and take ownership of the LIMITx intellectual property. Importantly, such failure to meet this date will be 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 is currently in discussions with AD Pharma to amend the existing Agreement. Also, we have presented the $6.0 million convertible debt as a current liability at December 31, 2020.

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. The recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying consolidated balance sheets is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its funding 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.

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, as further discussed throughout the notes to financial statements, our contract manufacturer did delay the installation of the auxiliary manufacturing equipment needed for LTX-03 development during 2020 for several weeks due to COVID-19 risk mitigation strategies implemented in New Jersey which 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 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting

The consolidated financial statements include the accounts of our wholly-owned subsidiary, Acura Pharmaceutical Technologies Inc., after elimination of intercompany accounts and transactions. Amounts presented have been rounded to the nearest thousand, where indicated, except share and per share data.

Use of Estimates

Management is required to make certain estimates and assumptions in order to prepare consolidated financial statements in conformity with GAAP. Such estimates and assumptions affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates. Management periodically evaluates estimates used in the preparation of the consolidated financial statements for continued reasonableness. Appropriate adjustments, if any, to the estimates used are made prospectively based on such periodic evaluations.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash, royalty receivable, collaboration revenue receivable and license fee receivable. The Company maintains deposits in federally insured financial institutions which are in excess of federally insured limits. However, management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Fair Value Measurements

The Company's financial instruments consist primarily of cash, royalty, collaboration revenue and license fee receivables, trade accounts payable, and debt. The carrying amounts of these financial instruments, other than our debt, are representative of their respective fair values due to their relatively short maturities. On June 28, 2019, we restructured the $5.0 million related party 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, and reported the debt using fair value for the changes to the loan resulting in the recognizing a $2.6 million loss on debt extinguishment. The fair value of the $6.0 million convertible debt at December 31, 2020 has not materially changed from its valuation of fair value of $7.4 million.

Share-based Compensation Expense

We have several share-based compensation plans covering stock options and RSUs for our employees and directors, which are described more fully in Note 11.

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 both non-cash and cash-portioned instruments issued to our employees and directors comprised the following (in thousands):

	Year Ended December 31,	
	2020	2019
Research and development expense:		
Stock option awards	$ -	$ 8
RSU awards	-	13
	$ -	$ 21
General and administrative expense:		
Stock option awards	$ -	$ 12
RSU awards	53	105
	$ 53	$ 117
Total share-based compensation expense	$ 53	$ 138

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation. We have no leasehold improvements. Betterments are capitalized and maintenance and repairs are charged to operations as incurred. When a depreciable asset is retired from service, the cost and accumulated depreciation is removed from the respective accounts.

Depreciation expense is recorded on a straight-line basis over the estimated useful lives of the related assets. The estimated useful lives of the major classification of depreciable assets are:

Building and improvements	10 - 40 years
Land and improvements	20 - 40 years
Machinery and equipment	7 - 10 years
Scientific equipment	5 - 10 years
Computer hardware and software	3 - 10 years

Intangible and Long-Lived Assets

Long-lived assets such as the intangible asset and property, plant and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of the assets to be held and used is measured by a comparison of the carrying amount of the asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying value of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. During the first quarter 2020 a triggering event occurred with the decline in royalty cash flows under our Collaboration and License Agreement with Assertio Holdings Inc. (See Note 3), and we performed an impairment test which indicated that the carrying value of the intangible asset was greater than the fair value. The fair value calculation of the intangible asset included significant estimates and assumptions related to the amount and timing of projected future cash flows and in the situation when the asset is determined to not be recoverable, the discount rate. 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.

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 is $200 thousand per month through July 2021. 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. 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 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 Agreement anytime for "convenience on 30 days prior written notice" and the license fee payments will stop. The monthly license fee from AD Pharma is non-refundable and non-creditable. A license fee is recognized as revenue each month whether or not paid by AD Pharma as we had no further requirements to earn the payment for the month (See Note 3). During 2020 and 2019 we recognized $3.0 million and $2.1 million, respectively, of license fee revenue. AD Pharma will pay directly for or reimburse Acura to the extent Acura pay's for, all out-of-pocket development expenses under the AD Pharma agreement.

Collaboration revenue is derived from reimbursement of development expenses, as under our collaboration agreement with AD Pharma, and are recognized when costs are incurred pursuant to the agreements. The ongoing research and development services being provided under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration agreement. We recognized $234 thousand and $185 thousand of collaboration revenue under the AD Pharma agreement during the years ended December 31, 2020 and 2019, respectively.

Royalty Revenue

We recognize revenue from royalties based on our licensees' sales of our products or products using our technologies. Royalties are sales-based royalties which are recognized as the related sales occur. These royalties were promised in exchange for a license of intellectual property.

In connection with our Collaboration and License Agreement with Assertio to commercialize Oxaydo tablets we will receive a stepped royalty at percentage rates ranging from mid-single digits to double-digits based on Oxaydo net sales during each calendar year over the term of the agreement (excluding net sales resulting from any co-promotion efforts by us). We recognize royalty revenue each calendar quarter based on net sales reported to us by Assertio in accordance with the agreement. Assertio's first commercial sale of Oxaydo occurred in October 2015. We have recorded royalties of $102 thousand and $351 thousand during the years ended December 31, 2020 and 2019, respectively. (See Note 3).

In connection with the MainPointe Agreement, which occurred in March 2017, we are receiving a royalty of 7.5% on net sales of the licensed products over the term of the agreement. Such royalty shall be payable for sales made during each calendar quarter and payment will be remitted within forty-five (45) days after the end of the quarter to which it relates. We have recorded royalties of $7 thousand and $21 thousand during the years ended December 31, 2020 and 2019, respectively. (See Note 3).

Deferred Debt Issuance Costs and Debt Discount

Deferred debt issuance costs include costs of debt financing undertaken by the Company, including legal fees, placement fees and other direct costs of the financing. Debt discount can be incurred from value attributable to warrants issued in conjunction with the financing and/or attributable to the below market rate element of the loan if we believe the loan's rate of interest is below current market rates for us, as in the case of the Schutte Loans. Debt issuance costs and debt discount are amortized into interest expense over the term of the related debt using the effective interest method. Deferred debt issuance costs and debt discount are presented on the consolidated balance sheets as a direct reduction against the debt balance. In June 2019, we restructured the $5.0 million related party loan and reported the debt using fair value for the changes to the loan and in doing so, the unamortized debt discount was written off as a loss on debt extinguishment.

Research and Development Activities

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 December 31, 2020 or 2019.

In connection with our development and scale-up of LTX-03 under the AD Pharma Agreement (See Note 3) we have entered into unbilled obligations under non-cancelable arrangements at December 31, 2020 aggregating $75 thousand.

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 the financial reporting and the income tax basis of assets and liabilities and are measured using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. 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 December 31, 2020 and 2019, 100% of all remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss 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.

Customer Concentration

In June 2019 we signed a license, development and commercialization agreement with AD Pharma which was amended in October 2020 (the "AD Pharma Agreement") Acura will receive a monthly license payment of $350 thousand by AD Pharma from inception through April 2020 at which time the monthly payments are $200 thousand thereafter until the earlier of July 31, 2021 or FDA's acceptance of a New Drug Application ("NDA") for LTX-03. AD Pharma may terminate the AD Pharma Agreement at any time" and the license fee payments will stop. 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 Agreement and take ownership of the 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.

Under our agreement with MainPointe, we earn royalties from MainPointe sale of the licensed product line Nexafed, and under our license agreement with Assertio, we earn royalties from Assertio's sale of the licensed product Oxaydo. 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.

Recent Accounting Pronouncements

New accounting standards which have been adopted on or before December 31, 2020

Fair Value Measurements

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. This standard is effective for fiscal years beginning after December 15, 2019, including interim reporting periods within those years, with early adoption permitted. The Company's adoption of ASU 2018-13 did not have a material impact on the financial statements and related footnote disclosures.

New accounting standards which have not yet been adopted on or before December 31, 2020

Credit Losses

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments ("ASU-2016-13")*. ASU 2016-13 affects loans, debt securities, trade receivables, and any other financial assets that have the contractual right to receive cash. The ASU requires an entity to recognize expected credit losses rather than incurred losses for financial assets. ASU 2016-13 is effective for the fiscal year beginning after December 15, 2022, including interim periods within that fiscal year. The Company is currently evaluating the impact that the standard will have on the financial statements and related footnote disclosures.

Convertible Debt

In August, 2020, the FASB issued ASU 2020-06, "Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity". ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock. The ASU is effective for the fiscal year beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact that the standard will have 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 Agreement") with Abuse Deterrent Pharma, LLC (AD Pharma", for the development and license of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura's patented LIMITx™. Acura will receive a monthly license payment of $350 thousand by AD Pharma from inception through April 2020 at which time the monthly payments are $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 pay for and reimburse Acura for all outside development costs on 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 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 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 of the AD Pharma Agreement). Effective with the October 2020 amendment to the AD Pharma Agreement, 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 December 31, 2020, the remaining useful life is 3 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 $70 thousand and $207 thousand in each of the years ending December 31, 2020 and 2019, 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):

	December 31, 2020	December 31, 2019
Intangible asset – Aversion	2,000	2,000
Less: accumulated amortization	(1,259)	(1,190)
Less: impairment charge	(668)	-
Net	$ 73	$ 810

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 to the AD Pharma Agreement, 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 December 31, 2020 or 2019.

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 is $200 thousand per month through July 2021. 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 December, 2020 thru March, 2021 and approximately $200 thousand of reimbursable LTX-03 development expenses. Failure to make these payments are an event of default under the Agreement, as amended. AD Pharma will pay directly for or reimburse Acura to the extent Acura pay's for, all out-of-pocket development expenses.

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 $3.0 million of license fees for LTX-03 during the three months and year ended December 31, 2020, respectively. We have recorded $1.0 million and $2.1 million of license fees for LTX-03 during the three months and year ended December 31, 2019, 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:

	Three months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Assertio (Oxaydo)	$ 30	$ 82	$ 102	$ 351
MainPointe – related party (Nexafed)	(2)	5	7	21
Royalty revenues	$ 28	$ 87	$ 109	$ 372

Contract Balance and Performance Obligations

The Company had no contract assets and contract liability balances under the license and collaboration agreements at either December 31, 2020 or 2019. 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 – PROPERTY, PLANT AND EQUIPMENT

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

	December 31,	
	2020	2019
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
	2,509	2,509
Less: accumulated depreciation	(2,025)	(1,969)
Total property, plant and equipment, net	$ 484	$ 540

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 $56 thousand and $66 thousand for each of the years ended December 31, 2020 and 2019, respectively.

NOTE 6 – ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	December 31,	
	2020	2019
Cost sharing expenses under license agreements	$ 428	$ 363
Other fees and services	24	15
Payroll, payroll taxes and benefits	8	13
Professional services	117	151
Financed premiums on insurance policies	28	-
Clinical, non-clinical and regulatory services	-	20
Property taxes	9	9
Franchise taxes	17	14
Total	$ 631	$ 585

NOTE 7 – DEBT

Related Party Convertible Loan

At December 31, 2018, we had borrowed an aggregate of $4.350 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). The Schutte Notes bear interest at prime plus 2.0%, and were to mature on January 2, 2020, at which time all principal and interest was to be due. The Schutte Notes were unsecured until all obligations to Oxford were satisfied at which time we were required to grant a security interest to Mr. Schutte in all of our assets, including our intellectual property. Because we believed the Schutte Notes' rate of interest was below current market rates for us, we imputed interest on the below market rate element of the loans using the 10.16% interest rate under the Oxford Loan Agreement and this has aggregated to $172 thousand as of December 31, 2018. We recorded these benefits to interest income, with a corresponding like amount as debt discount against the principal amount of the loan. The debt discount will be amortized to interest expense over the term on the loans. At December 31, 2018, the unamortized debt discount balance was $126 thousand and the accrued interest balance was $110 thousand. We recorded a $13 thousand benefit to interest income during 2019 from the $650 thousand borrowings from Mr. Schutte. At June 27, 2019, the unamortized debt discount balance was $73 thousand and the accrued interest balance was $275 thousand. The events of default under the Schutte Notes are limited to bankruptcy defaults and failure to pay interest and principal when due on January 2, 2020. The Schutte Notes could be prepaid at any time in whole or in part.

Included in the $4.350 million loan outstanding from Mr. Schutte as of December 31, 2018 was a borrowing of $1.8 million completed on October 5, 2018 of which we used $1.5 million to fully pay-off the debt outstanding under the Oxford Loan Agreement. All our assets are pledged as collateral under the Schutte Notes, including our intellectual property.

On June 27, 2019 the aggregate amount of the loans made to the Company by Mr. Schutte aggregated $5.0 million. On June 28, 2019 we restructured the $5.0 million loan to borrow an additional $725 thousand from Mr. Schutte, which was received on July 2, 2019, 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 loan restructuring was accounted for as debt extinguishment. We obtained a valuation of fair value on the modified loan and warrant and the method of accounting for the loan changes resulted in a $2.6 million loss on debt extinguishment. Of the loss on debt extinguishment, $1.145 million was allocated to the warrant, $1.382 million was related to the premium on the convertible loan, and $73 thousand was assignable to write-off of the original loan's remaining unamortized debt discount. 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. The accrued interest balance at December 31, 2020 and December 31, 2019 was $678 thousand and $229 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 Agreement as defined in the loan agreement. 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 amended AD Pharma 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 Agreement and take ownership of the LIMITx intellectual property. Importantly, such failure to meet this date will be 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 has notified AD Pharma of this revised timeline for NDA submission. Acura is currently in discussions with AD Pharma to amend the existing Agreement. Also, we have presented the $6.0 million convertible debt as a current liability at December 31, 2020.

Our debt interest expense for the year ended December 31, 2020 and 2019 consisted of the following (in thousands):

	Year Ended December 31,	
Interest expense:	2020	2019
Related party term loans	$ 450	$ 392
Debt discount	-	66
Financed insurance premiums	-	4
Total interest expense	$ 450	$ 462
Less: imputed interest income on related party loans	-	(13)
Total interest expense, net	$ 450	$ 449

Paycheck Protection Program

On April 13, 2020, the Company received a loan (the "Loan") from JP Morgan Chase Bank in the aggregate amount of $269 thousand, pursuant to the Paycheck Protection Program under Division A, Title I of the CARES Act, which was enacted March 27, 2020. The Loan, in the form of a promissory note, matures on April 8, 2022. Under the terms of the Paycheck Protection Program ("PPP"), certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. No assurance is provided that forgiveness for any portion of the Loan will be obtained. To the extent that all or part of the 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.

NOTE 8 – RELATED PARTY TRANSACTIONS

Private Placement with Mr. John Schutte

In July 2017, we completed a $4.0 million private placement with Mr. Schutte (sometimes referred to as the "Investor"), 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 the Investor 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 Investor, and the parties to such agreement would vote for such persons. The right of each of Essex, Galen and Investor 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. Investor has not designated a director as of the date of filing of this Report. 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

Investor 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 plus approximately $309 thousand for transferred inventory and equipment. 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 year ended 2020 and 2019 is $9 thousand and $16 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

During the period January 1, 2019 through June 27, 2019 we borrowed an aggregate of $650 thousand from Mr. John 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 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 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 by AP Pharma 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 December, 2020 thru March, 2021 and approximately $200 thousand of reimbursable LTX-03 development expenses. Failure to make these payments are an event of default under the Agreement, as amended.

AD Pharma may terminate the 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 Agreement and take ownership of the LIMITx intellectual property. Importantly, such failure to meet this date will be 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 is currently in discussions with AD Pharma to amend the existing Agreement.

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 9 – EMPLOYEE BENEFIT PLAN

We have a 401(k) and Profit-Sharing Plan (the “Plan”) for our employees. Employees may elect to make a basic contribution of up to 80% of their annual earnings subject to certain regulatory restrictions on their total contribution. The Plan provides that the Company can make discretionary matching contributions along with a discretionary profit-sharing contribution. We did not contribute a matching contribution or a profit sharing contribution to the Plan during the year ended December 31 2020 or 2019.

NOTE 10 – COMMON STOCK PURCHASE WARRANTS

Our warrant activity during the years ended December 31, 2020 and 2019 is shown below (in thousands except price data):

	December 31,			
	2020		2019	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, Jan. 1	11,842	$ 0.10	1,842	$ 0.59
Issued	-	-	10,000	0.01
Exercised	-	-	-	-
Expired	(60)	2.52	-	-
Modification		-	-	-
Outstanding, Dec. 31	11,782	$ 0.09	11,842	$ 0.10

On June 28, 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. 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.

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 (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.

During December 2020, common stock purchase warrants (“warrants”) exercisable for 60 thousand shares of our common stock having an exercise price of $2.52 per share.

NOTE 11 – SHARE-BASED COMPENSATION EXPENSE

Stock Option Plans

We maintain various stock option plans. A summary of our stock option plans as of December 31, 2020 and 2019 and for the year then ended consisted of the following (in thousands except exercise price):

	Year Ended December 31,			
	2020		2019	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, Jan. 1	1,356	$ 4.45	1,560	$ 7.38
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	(34)	4.09
Expired	(102)	16.54	(170)	30.83
Outstanding, Dec. 31	1,254	$ 3.46	1,356	$ 4.45
Exercisable, Dec. 31	1,254	$ 3.46	1,356	$ 4.45

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.

There was approximately $13 thousand of intrinsic value contained in the vested stock option awards outstanding at December 31, 2020.

Restricted Stock Unit Award Plans

We have two Restricted Stock Unit Award Plans for our employees and non-employee directors, a 2017 Restricted Stock Unit Award Plan (the "2017 RSU Plan") and a 2014 Restricted Stock Unit Award Plan (the "2014 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 being marked-to-market each reporting period until they are distributed. The liability is recorded as a current liability in the Company's consolidated balance sheet and was $18 thousand and $29 thousand at December 31, 2020 and December 31, 2019, respectively.

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 Plans as of December 31, 2020 and 2019, and for the year then ended consisted of the following (in thousands):

	Year Ended December 31,			
	2020		2019	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, Jan. 1	1,017	1,017	951	459
Granted	219	-	333	-
Distributed	(397)	(397)	(267)	(267)
Vested	-	219	-	825
Forfeited	-	-	-	-
Outstanding, Dec. 31	839	839	1,017	1,017

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. There are no shares available for award under the 2017 RSU Plan.

Information about the awards 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 will be 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 January 2018, we awarded approximately 67 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 2018. Settlement of this RSU award occurred on January 2, 2019, the first business day of the year after vesting. The portion of the RSU awards which are subject to cash settlement are also 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.

- 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 will be 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 will 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 shares 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 the first distribution of one third of their 2017 award for which 54 thousand RSUs settled in common stock and 10 thousand RSUs were used to settle the purchase price and employee required payroll withholding taxes.
- In January 2021, 219 thousand RSUs were distributed to our non-employee directors from their January 2019 award with 219 thousand RSUs settled in common stock.
- In January 2021, 228 thousand RSUs were distributed to our current and former employees representing the second distribution of one third of their 2017 award and the first distribution of one third of their 2018 award for which 185 thousand RSUs settled in common stock and 43 thousand RSUs were used to settle the purchase price and required payroll withholding taxes.

2014 Restricted Stock Unit Award Plan

Our 2014 RSU Plan was approved by shareholders in May 2014 and permits the grant of up to 400 thousand shares of our common stock pursuant to awards under the 2014 RSU Plan. There are no shares available for award under the 2014 RSU Plan.

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.

Provision for Income Taxes

The reconciliation between our provision for income taxes and the amounts computed by multiplying our loss before taxes by the U.S. statutory tax rate is as follows (in thousands):

	December 31,	
	2020	2019
Benefit at U.S. statutory tax rate	$ (254)	$ (792)
State taxes (benefit), net of federal effect	(76)	(138)
State research and development tax credits	(18)	(2)
Federal research and development tax credits	(76)	(23)
Other	(120)	-
Share-based compensation	-	4
Change in valuation allowance	544	951
(Benefit) provision for income taxes	$ -	$ -

Deferred Tax Assets and Valuation Allowance

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 components of our deferred tax assets are as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	2,269	$ 2,622
- State	903	869
Research and development tax credits		
- Federal	1,283	1,207
- State	31	8
Share-based compensation	104	72
Debt extinguishment	636	-
Other, net	301	177
Total deferred taxes	5,527	4,955
Valuation allowance	(5,527)	(4,955)
Net deferred tax assets	$ -	$ -

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 both December 31, 2020 and 2019, 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.

Uncertainty in Income Taxes

We follow FASB’s statement regarding accounting for uncertainty in income taxes which defined the threshold for recognizing the benefits of tax-return positions in the consolidated financial statements as "more-likely-than-not" to be sustained by the taxing authorities. At each of December 31, 2020 and 2019, we had no liability for income tax associated with uncertain tax positions. If in the future we establish a contingent tax liability reserve related to uncertain tax positions, our practice will be to recognize the interest in interest expense and the penalties in other non-operating expense.

The Company files federal and state income tax returns and in the normal course of business the Company is subject to examination by these taxing authorities. As of December 31, 2020, the Company's tax years of 2017, 2018 and 2019 are subject to examination by the taxing authorities. With few exceptions, we believe the Company is no longer subject to U.S. Federal, State and local examinations by taxing authorities for years before 2017.

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 7). 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 in 2020 and 2019 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):

	Year Ended December 31,	
	2020	2019
Earnings (loss) per share – basic and diluted		
Numerator: net loss	$ (1,208)	$ (3,774)
Denominator (weighted):		
Common shares	21,650	21,300
RSUs - vested	670	296
Common stock purchase warrant	10,000	5,124
Basic and diluted weighted average shares outstanding	32,320	26,720
Earnings (loss) per share – basic and diluted	$ (0.04)	$ (0.14)
Excluded securities (non-weighted):		
Common shares issuable:		
RSUs	-	-
Stock options	1,254	1,356
Common stock purchase warrants	1,782	1,842
Convertible loan	37,500	37,500
Total excluded common shares	40,536	40,698

NOTE 14 – SUBSEQUENT EVENTS

On March 15, 2021, the Company was granted a loan (the "Loan") from JP Morgan Chase Bank in the aggregate amount of $267 thousand, pursuant to the Paycheck Protection Program under Division A, Title I of the CARES Act, which was enacted March 27, 2020. Under the terms of the Paycheck Protection Program ("PPP"), certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. The Company is continuing to evaluate the criteria and new guidance put out by the Small Business Administration regarding qualifications of loans under the PPP and criteria for meeting loan conditions. No assurance is provided that forgiveness for any portion of the Loan will be obtained.

Exhibit 10.53

AMENDMENT TO LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This AMENDMENT (the "**Amendment**") to the LICENSE, DEVELOPMENT and COMMERCIALIZATION AGREEMENT (the "**Agreement**") dated June 28, 2019 between Acura Pharmaceuticals, Inc. ("**Acura**"), a New York corporation, having a place of business at 616 N. North Court, Suite 120, Palatine, IL 60067, and Abuse Deterrent Pharma, LLC ("**AD Pharma**"), a Kentucky partnership having a place of business at with offices at 333 E. Main Street, Suite 220, Louisville, Kentucky 40202, is made as of October 16, 2020.

RECITALS

WHEREAS, Acura and AD Pharma are parties to the Agreement which became effective on June 28, 2019 and;

WHEREAS, the Parties desire to amend the Agreement as set forth herein to provide for an extension to the LIMITx™ Regulatory Submission Timeline.

NOW THEREFORE, in consideration of the mutual covenants and promises contained in the Agreement and this Amendment and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Acura and AD Pharma agree as follows:

ARTICLE 1
AMENDMENTS TO AGREEMENT

1.1 A new Section 1.50 is hereby added to the Agreement as follows:

"**Oxycodone Product**" means a pharmaceutical product containing the immediate-release combination of oxycodone hydrochloride and acetaminophen utilizing the LIMITX™ Technology in the 5/325mg, 7.5/325mg and 10/325mg dosage strengths.

1.2 Section 1.34 is hereby amended and replaced in its entirety as follows:

"**Product**" means a pharmaceutical product containing the immediate-release combination of hydrocodone bitartrate and acetaminophen utilizing the LIMITX™ Technology in the 5/325mg, 7.5/325mg and 10/325mg dosage strengths (the "**Hydrocodone Product**") along with the Alprazolam Product and the Oxycodone Product.

1.3 Section 2.3 with respect to "Acura to use CRE" is hereby amended and replaced in its entirety as follows:

Acura to use CRE. Acura shall use Commercially Reasonable Efforts to develop the Product in the United States, provided however, that any obligation of Acura to develop the Alprazolam Product and the Oxycodone Product will be subject to a separate development agreement to be negotiated between the Parties. Acura shall comply with all Applicable Laws in the development of the Product. For the avoidance of doubt, Acura's obligations to develop a Product and any related development timelines and milestones shall be strictly limited to the Hydrocodone Product.

1.4 Section 2.11 is hereby amended by inserting at the end:

The foregoing provisions of this Section 2.11 are limited to the Hydrocodone Product.

1.5 Section 3.1.1 of hereby amended and replaced in its entirety as follows:

In an aggregate amount not to exceed Six Million Five Hundred Thousand Dollars ($6,500,000) (the "Maximum Pre-Regulatory Application Submission Payment"), each month AD Pharma shall pay Acura in non-refundable, non-creditable payments in immediately available funds as follows:

- Three Hundred Fifty Thousand Dollars ($350,000) commencing within Five (5) days of the Effective Date and continuing until April 2020; and

- Two Hundred Thousand Dollars ($200,000) commencing in May 2020 and continuing on the monthly anniversary of the Effective Date until the earlier of July 2021 or such monthly payments have occurred or the Maximum Pre-Regulatory Application Submission Payment is reached (as the timing of the latter, but not the amount, may be adjusted in accordance with Section 3.1.2).

1.6 Section 3.4 is hereby amended and replaced in its entirety as follows, provided however that subsection 3.4.1 and 3.4.2 remain as in the Agreement:

Sales Milestone Payments. AD Pharma shall make the following one-time, non-refundable, non-creditable payments within forty-five (45) days after the end of the year to Acura based on the attainment of the Net Sales in such calendar year for each Product and Product Line Extensions individually (i.e. a separate payment for each of the Hydrocodone Product, the Alprazolam Product and the Oxycodone Product) in the Territory (the "**Milestone Payments**"):

1.7 Section 3.12 "Option under Nexafed® Agreement" is hereby deleted in its entirety.

1.8 Section 3.13 "Option for license to Alprazolam Product" is hereby deleted in its entirety.

1.9 Item 3 of Schedule 1 "LIMITx™ Regulatory Application Submission Timeline" is hereby amended and replaced in its entirety as follows:

3. By the last day of the calendar month when the last of the monthly payments for the Maximum Pre-Regulatory Application Submission Payment has occurred, or before, Acura must gain filing acceptance by the FDA of a Regulatory Approval Application for the Product.

For the avoidance of doubt, Schedule 1 is strictly limited to activities and timelines related to the Hydrocodone Product.

ARTICLE 2
MISCELLANCEOUS

2.1 **Governing Law**. This Amendment shall be governed by the laws of the State of New York without regard to its conflict of laws rules or principles.

2.2 **Amendments**. Except as expressly amended hereby, the Agreement shall remain unmodified and in full force and effect.

2.3 **Entire Agreement**. This Amendment, the Agreement and the Schedules attached to the Agreement constitute the entire agreement of the Parties with respect to the subject matter hereof and supersede all prior understandings and writings between the Parties relating thereto.

2.4 **Interpretation**. Any capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings provided in the Agreement.

2.5 **Counterparts**. This Amendment may be executed manually, electronically in Adobe® PDF file format, or by facsimile by the Parties, in any number of counterparts, each of which shall be considered one and the same amendment and shall become effective when a counterpart hereof shall have been signed by each of the Parties and delivered to the other Party.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed in their names by their properly and duly authorized officers or representatives as of the date first written above.

ACURA PHARMACEUTICALS, INC.

s/s Robert B. Jones, 10/12/2020
Name: Robert B. Jones
Title: CEO and President

Abuse Deterrent Pharma, LLC

s/s John Schutte, 10/16/2020
Name: John Schutte
Title: Managing Partner

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Acura Pharmaceuticals, Inc.
Palatine, Illinois

We hereby consent to the incorporation by reference in the Registration Statements on Form S-¬3 (Nos. 333-210039, 333-187075 and 333-146416) and Form S-8 (Nos. 333-221645, 333-213017, 333-195612, and 333-151620) of Acura Pharmaceuticals, Inc. of our report dated March 31, 2021, relating to the consolidated financial statements which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
Chicago, Illinois
March 31, 2021

EXHIBIT 31.1

CERTIFICATION

I, Robert B. Jones, certify that:

1. I have reviewed this Annual Report on Form 10-K of Acura Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 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 subsidiaries, is made known to us by others within those entities, particularly during the period in which this 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 registrant's most recent fiscal quarter (its fourth fiscal quarter) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2021

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

EXHIBIT 31.2

CERTIFICATION

I, Peter A. Clemens, certify that:

1. I have reviewed this Annual Report on Form 10-K of Acura Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 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 subsidiaries, is made known to us by others within those entities, particularly during the period in which this 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 registrant's most recent fiscal quarter (its fourth fiscal quarter) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2021

/s/ Peter A. Clemens
Peter A. Clemens
Senior Vice President and Chief Financial Officer

EXHIBIT 32

CERTIFICATION OF

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

I, Robert B. Jones, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of Acura Pharmaceuticals, Inc. for the fiscal year ended December 31, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report of Form 10-K fairly presents, in all material respects, the financial condition Acura Pharmaceuticals, Inc. as of the dates presented and results of operations of Acura Pharmaceuticals, Inc. for the periods presented.

March 31, 2021

By: /s/ Robert B. Jones
Robert B. Jones
President and Chief Executive Officer

I, Peter A. Clemens, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of Acura Pharmaceuticals, Inc. for the fiscal year ended December 31, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report of Form 10-K fairly presents, in all material respects, the financial condition Acura Pharmaceuticals, Inc. as of the dates presented and results of operations of Acura Pharmaceuticals, Inc. for the periods presented.

March 31, 2021

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