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, 2019**

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
☒ Non-Accelerated Filer
☐ 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 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 $0.1410 on June 28, 2019 (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 $1.0 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, 2020, the registrant had 21,650,294 shares of Common Stock, par value $0.01, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None.

Acura Pharmaceuticals, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2019

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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;
- 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 deter abuse or overdose will be determined sufficient by the FDA to support approval or labelling describing safety and/or abuse deterrent 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 pricing and price discounting that may be offered by Zyla Life Sciences' or Zyla (formerly known as Egalet Corporation) for Oxaydo;
- the results of our development of our LIMITx Technology;
- 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 Oxaydo or our Aversion, Impede and LIMITx products will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede Technology product candidates will disrupt the processing of pseudoephedrine into methamphetamine.

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 or are developing three proprietary platform technologies which can be used to develop multiple products. Our LIMITx™ Technology is being developed to minimize the risks associated with drug 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.

Our LIMITx Technology is development stage technology 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. This is accomplished by binding the active ingredient in an acid soluble micro-particle and combining the micro-particles with a buffering (antacid) agent into a tablet. As more tablets are introduced into the GI tract, the stomach pH is increased and the dissolution of the micro-particles is compromised. FDA draft guidance on opioids specifically highlights the benefits of the risk mitigation of opioid overdose which we believe our LIMITx technology addresses. 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. Study 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. 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 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 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 and completion of development of LTX-03. The Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03.

All opioids are labeled for respiratory depression/death risk of overdose. According to the CDC, suicide deaths in the US increased 25% to 45,000 from 1999 to 2016 with over half having no prior mental health symptoms. Approximately 15% of suicides are due to poisoning, which includes opioid overdosing. The prevalence of chronic pain in suicide decedents topped 10% in 2014. Forensic data for hydrocodone deaths indicates the median blood level at the time of death is 16 fold the maximum blood level (Cmax) for a 10mg hydrocodone dose. The physiology of opioid induced respiratory depression has been described in animal models. The correlation between Cmax and respiratory depression and death has not been documented although Acura has completed a small animal study demonstrating an association between opioid Cmax and onset of acute respiratory depression which increases the probability of death.

Oxaydo Tablets (oxycodone HCl, CII), which utilizes our Aversion Technology, is the first FDA approved immediate-release oxycodone product in the United States with abuse deterrent labeling. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation (now known as Zyla Life Sciences), or collectively Zyla, pursuant to which we exclusively licensed to Zyla worldwide rights to manufacture and commercialize 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. Zyla launched Oxaydo in the United States late in the third quarter of 2015 and we are receiving royalties on net sales. We are not actively developing product candidates utilizing our Aversion Technology.

According to the 2017 CDC Drug Surveillance Report, opioid analgesics are one of the largest prescription drug markets in the United States with 214 million prescriptions dispensed in 2016. Prescription opioids are also the most widely abused drugs with 12 million people abusing or misusing these products annually. According to IMS Health, in 2016, sales in the immediate-release opioid product segment, where our products are expected to compete, were approximately 194 million prescriptions, of which approximately 95% was attributable to generic products with no known safety features.

Nexafed, our first Impede Technology product, was launched into the United States market in December 2012 and Nexafed Sinus Pressure + Pain product was introduced 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 John Schutte (Mr. Schutte), who became our largest shareholder pursuant to a private placement completed in July 2017. On January 1, 2020, MainPointe assigned to AD Pharma, all of its right, title and interest in the Agreement between MainPointe and Acura dated March 16, 2017. We understand MainPointe continues to market the Nexafed products for AD Pharma. We are not actively developing product candidates utilizing our Impede Technology.

In 2014, the United States retail market for over-the-counter market, or OTC, cold and allergy products containing the pseudoephedrine oral nasal decongestant was approximately $0.7 billion. In 2014, the DEA reported 9,339 laboratory incidents involving the illegal use of OTC pseudoephedrine products to manufacture the highly addictive drug methamphetamine, or meth. According to the Substance Abuse and Mental Health Services Administration, users of methamphetamine surged in 20167 to 774,000 people up from 440,000 people in 2012.

We conduct research, development, laboratory, non-commercial 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 goal is to become a leading specialty pharmaceutical company focused 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 Zyla 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, 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

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-pharmacy. 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 pipeline 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 opioid 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 patient 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 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 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.

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)	Initial buffer dose ranging study completed October 2017 Follow on dose ranging study completed in January 2018 Manufacturing scale-up initiated. Formulation and manufacturing process optimized for commercial scale. Certain ancillary manufacturing equipment is on order.
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.

Study 400

Study 400 was a two cohort, open label, crossover design pharmacokinetic study of LTX-04 in healthy adult subjects. Study 400 measured the rate and extent of absorption of the active drug ingredient into the bloodstream with the maximum concentration, or Cmax, typically associated with an increase in drug abuse. Cohort 1 enrolled 30 subjects who were randomized into three subgroups of 10 taking either 1, 2 or 3 tablets. Each subgroup subject orally swallowed the planned number of tablets in a randomized manner taking single doses of two different test formulations of LTX-04 (designated as LTX-04P and LTX-04S and distinguished by their respective acid neutralizing capacity) and Purdue Pharma's marketed drug Dilaudid® as a comparator. The 1, 2 and 3 tablets subgroups in Cohort 1 completed 8, 10 and 8 subjects, respectively.

Cohort 2 enrolled 30 subjects who were randomized into three subgroups of 10 taking either 4, 6 or 8 tablets. Each subgroup subject orally swallowed the planned number of tablets in a randomized manner taking single doses of LTX-04P and the marketed drug Dilaudid as a comparator. The 4, 6 and 8 tablets subgroups in Cohort 2 completed 8, 9 and 8 subjects, respectively.

All tablets contained 2mg of hydromorphone hydrochloride. All subjects received doses of naltrexone and there was a one week washout between doses. Blood samples were taken at pre-designated time-points after dosing and were subsequently analyzed for the concentration of hydromorphone contained in the sample. All subjects in Cohort 1 had continuous pH (a measure of acid concentration) monitoring of their gastric fluid. The objective of Cohort 1 was to determine if adequate active drug entered the blood stream when one or two LIMITx tablets were swallowed and to begin assessing the ability of the LIMITx Technology to start retarding the release of active ingredients when three tablets are ingested. The objective of Cohort 2 was to further explore the extent the release of the hydromorphone active ingredient from LTX-04P tablets is retarded as the dose level increases to abusive levels.

The topline results from Study 400 demonstrated that a single tablet dose delivered a Cmax of 45% and 50% lower than the reference drug for LTX-04S and LTX-04P, respectively. For an 8 tablet dose, the Cmax for LTX-04P was 59% lower than the reference drug. Doses between 1 and 8 tablets had similar reduction in Cmax compared to the reference. The extent of drug absorption, measure by area under the curve (AUC) was consistent between the LIMITx products and the reference.

On December 14, 2016, we announced that we had received advice from the FDA on the continued development of LTX-04 following the FDA's review of summary data from Study 400. The FDA confirmed our intention to reformulate LTX-04 to provide increased drug levels following an intended 1 or 2 tablet dose, noting that a scientific bridge of bioequivalence to the reference product will support a finding of safety and efficacy. The FDA also recommended that we identify studies to measure the clinical impact on abuser behavior and overdose outcome (such as drug liking and respiratory depression) associated with the reduction in Cmax when three or more LTX-04 tablets were ingested. The FDA's advice also identified longer term studies necessary for submitting a NDA for LTX-04, including in vitro extraction studies, drug interaction studies, additional pharmacokinetic studies assessing the impact of food and beverages, and a category 3 abuse liability study.

Study 401

Study 401, completed in June 2017, also was a two cohort, open label, crossover design pharmacokinetic study in fasted, health adult subjects. Study 401 utilized a modified LTX-04 formulation containing micro-particles intended to improve drug delivery with one and two tablet dosing (LTX-04P3). Study 401 measured the rate and extent of absorption of the active drug ingredient into the blood stream with the Cmax typically associated with an increase in drug abuse. 27 subjects completed Cohort 1 swallowing a single dose tablet of LTX-04 compared to a generic hydromorphone tablet. 13 subjects completed Cohort 2 swallowing 7 LTX-04 and generic tablets doses. 15 subjects followed an undisclosed, exploratory protocol.

All tablets contained 2 mg of hydromorphone hydrochloride. All subjects received dosages of naltrexone and/or naloxone and there was a one week washout between dosages. Blood samples were taken at pre-designated time-points after dosing and were subsequently analyzed for the concentration of hydromorphone contained in the sample. The objective of Cohort 1 was to determine if adequate active drug entered the bloodstream when one LIMITx tablet was swallowed. The objective of Cohort 2 was to explore the extent to which the release of the hydromorphone active ingredient from LTX-04 tablets is retarded at a seven tablet dose (oral excess abuse levels). A safety assessment of LIMITx hydromorphone would be made from both study cohorts.

The topline results from Study 401 demonstrated that Cmax for a one tablet LTX-04P3 dose was approximately 50% less than the active comparator. The Cmax for the 7 tablet LTX-04P3 dose was 65% below the comparator. Study 401 also included a 7 tablet dose of LTX-04P3 taken simultaneously with an agent known to increase gastric emptying time (i.e. increase retention time of the ingredients in the stomach) which demonstrated an increase in Tmax (time of Cmax) of over 1 hour compared to LTX-04P3 taken without this agent. Since the micro-particles used in Study 401 release drug much faster than the micro-particles used in Study 400, we have concluded that the buffer levels used in both studies were excessive and is retarding the release of drug even with a single dose. Also, given that manipulating the duration of stomach acidity with a gastric emptying agent produced a significant increase in Tmax which is indicative of a delayed release of drug from LTX-04P3, we concluded the LIMITx micro-particles are working as designed in that when we neutralize the stomach acid we are slowing the release of drug and subsequent absorption of drug into the blood stream.

We believe the results from Study 400 and 401 indicate the micro-particle are working as designed but that we used too much buffer for even a single tablet and did not achieve full release of the drug at a 1 tablet dose.

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.

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. 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 50% 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.

We intend to advance LTX-03 to clinical development for a New Drug Application (NDA). Therefore, 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. We have completed a manufacturing formulation and manufacturing process optimization study for LTX-03. We are currently conducting the scale-up of the commercial manufacturing process as to-be-marketed formulations are required for all NDA development work. We are currently awaiting delivery of certain ancillary equipment for use in manufacturing the drug micro-particles before scale-up work can commence. Among other things, we believe we will have to demonstrate a scientific link between Cmax reductions and a reduction in the risk of respiratory depression.

AD Pharma Agreement covering LTX-03

On June 28, 2019 we announced a License, Development and Commercialization Agreement (the "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. AD Pharma retains commercialization rights from which Acura will be entitled to receive royalties and potential sales related milestones.

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 the earlier of November 30, 2020 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 may terminate the Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by November 30, 2020, 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.

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). 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 47.5% of our common stock (after giving effect to the exercise of warrants he holds). 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 Zyla pursuant to which we exclusively licensed to Zyla worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is approved in 5mg and 7.5mg strengths. Zyla commenced shipping Oxaydo in the United States in October 2015.

The 2017 market for immediate-release oxycodone products was approximately 30 million dispensed prescriptions or 1.7 billion tablets. The current market is predominately serviced by generic formulations that contain no abuse deterrent features and sell for approximately $0.10 to $0.40 per tablet, depending on strength. Immediate-release opioids are prescribed by a broad cross-section of healthcare providers including primary care physicians, surgeons and pain specialists. We believe Oxaydo, given its differentiated label compared to generic products, can offer an alternative for opioid prescribing physicians concerned with the abuse or diversion for abuse of their prescriptions even at premium pricing to generics

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.

Although we believe these abuse deterrent characteristics differentiate Oxaydo from immediate-release oxycodone products currently on the market, consistent with FDA guidance which requires epidemiology studies to support a claim of abuse deterrence, the clinical significance of the difference in drug liking and difference in response to taking the drug again in this study has not been established. There is no evidence that Oxaydo has a reduced abuse liability compared to immediate release oxycodone. We and Zyla 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.

Zyla Agreement Covering Oxaydo

On January 7, 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, now known as Zyla Life Sciences or Zyla, entered into a Collaboration and License Agreement, or the Zyla 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 Zyla Agreement, we transferred the approved NDA for Oxaydo to Zyla and Zyla 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 Zyla Agreement, we and Zyla formed a joint steering committee to oversee commercialization strategies and the development of product line extensions. Zyla 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. Zyla is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Zyla has final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Zyla may develop Oxaydo for other countries and in additional strengths, in its discretion.

Zyla paid us an upfront payment of $5.0 million upon signing of the Zyla 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 Zyla 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. Zyla'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 Zyla to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Zyla Agreement expires upon the expiration of Zyla's royalty payment obligations in all countries. Either party may terminate the Zyla Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Zyla 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 Zyla Agreement with respect to the U.S. and other countries if Zyla materially breaches its commercialization obligations. Zyla may terminate the Zyla Agreement for convenience on 120 days prior written notice, which termination may not occur prior to the second anniversary of Zyla'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 Zyla Agreement provides for the transition of development and marketing of Oxaydo from Zyla to us, including the conveyance by Zyla to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Zyla's supply of Oxaydo for a transition period.

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, 2019 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 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.

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. In 2014, a data service reported approximately $0.7 billion in retail sales of non-prescription products containing PSE. The top retail selling PSE OTC cold/allergy products in 2014 were:

Reference Brand[1]	Brand Company	Active Ingredient(s)	2014 Retail Sales ($ Millions)
Claritin-D	Bayer	PSE & Loraditine[2]	$ 208.0
Allegra-D	Chattem	PSE & Fexofenadine[2]	$ 101.3
Zyrtec-D	Pfizer	PSE & Ceterizine[2]	$ 101.7
Advil Sinus	Pfizer	PSE & Ibuprofen	$ 58.4
Sudafed 12 Hour	J&J	PSE[2]	$ 82.3
Sudafed 30mg	J&J	PSE	$ 70.4

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

[2] Extended release PSE formulations

The 2014 market for 30mg PSE tablets, including store brands was approximately 470 million tablets or 19 million boxes of 24 tablets. 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. The distribution outlets for PSE products are highly consolidated. According to Chain Drug Review, the top 50 drug, food and mass merchandising chains operate approximately 40,000 pharmacies in the U.S., of which 58% are operated by the four largest chains. Stocking decisions and pharmacists recommendations for these chain pharmacies are often centralized at the corporate headquarters.

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

The misuse and abuse of opioid analgesics continues to constitute a dynamic and challenging threat to the United States and is the nation's fastest growing drug problem. During 2017, the US Government declared opioid abuse as an epidemic and national health emergency. According to the 2017 Centers on Disease Control Drug Surveillance Report, 11.8 million Americans aged 12 and over abused or misused prescription opioids in 2016. Further, this Report calculates that, on average, 115 Americans die every day from an opioid overdose. The majority of drug overdose deaths (66%) involve an opioid. Immediate release, or IR, opioid products comprise the vast majority of this abuse compared with extended release, or ER, opioid products**.**

It is estimated that more than 75 million people in the United States suffer from pain and the FDA estimates more than 61 million people receive a prescription for the opioid hydrocodone annually. For many pain sufferers, opioid analgesics provide their only pain relief. As a result, opioid analgesics are among the largest prescription drug classes in the United States with over 214 million tablet and capsule prescriptions dispensed in 2016 of which approximately 194 million were for IR opioid products and 204 million were for ER opioid products. However, physicians and other health care providers at times are reluctant to prescribe opioid analgesics for fear of misuse, abuse, and diversion of legitimate prescriptions for illicit use.

We expect our Aversion and LIMITx Technology opioid products, to compete primarily in the IR opioid product 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. A summary of the IR opioid product prescription data for 2016 is provided below:

IR Opioid Products[1]	2016 US Prescriptions (Millions)[2]	% of Total
Hydrocodone	90	43%
Oxycodone	55	26%
Tramadol	43	21%
Codeine	15	7%
4 Others	5	3%
Total	208	100%

[1] Includes all salts and esters of the opioid and opioids in combination with other active ingredients such as acetaminophen.

[2] IMS Health, 2016

Despite considerable publicity regarding the abuse of OxyContin® extended-release tablets and other ER opioid products, U.S. government statistics suggest that far more people have used IR opioid products non-medically than ER opioid products. These statistics estimate that nearly four times as many people have misused the IR opioid products Vicodin®, Lortab® and Lorcet® (hydrocodone bitartrate/acetaminophen brands and generics) than OxyContin®.

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. Zyla 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
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
2,925,304 (EUR)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Sep. 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	July 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	July 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	June 2018	Dec. 2035
2010300641 (AUS)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	June 2016	Sept. 2030
2,775,890 (CAN)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	June 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	June 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 Zyla 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. Reference is made to the Risk Factors contained in this report under Item 1A.

On May 20, 2016, we, Purdue Pharma L.P. and Zyla 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 Zyla products, including, in some circumstances, Oxaydo® and other products using Acura's Aversion® Technology if licensed to Zyla. Reference is made to the Risk Factors contained in this report under Item 1A.

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. Zyla is responsible for commercial manufacture of Oxaydo under the Zyla 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, Nektar Therapeutics, Signature Therapeutics, QRx Pharma, Tris Pharma, Pisgah Labs, Teva Pharmaceuticals, Sun Pharmaceuticals, 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® 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, 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 2, 2019, for the 2020 fiscal year, the user fee for an application fee requiring clinical data, such as an NDA is $2,942,965. 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 2020 such fee is $325,424 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 abuse deterrent 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. 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 manufacture of innovative abuse deterrent, orally administered pharmaceutical products.

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.

Employees

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. None of our employees are covered by collective bargaining agreements. We believe that our relations with our employees are good.

ITEM 1A. RISK FACTORS

Our future operating results may vary substantially from anticipated results due to a number of factors, many of which are beyond our control. The following discussion highlights some of these factors and the possible impact of these factors on future results of operations. If any of the following factors actually occur, our business, financial condition or results of operations could be materially harmed. In that case, the value of our common stock could decline substantially and you may lose all or part 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 $3.8 million, $3.8 million, and $5.7 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of March 30, 2020 we had approximately $1.2 million of cash. The Agreement with AD Pharma provides us monthly license payments of $350,000 from July 2019 through November 2020 as well as reimbursement for all outside development costs for LTX-03. 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:

- the receipt of monthly license payments from AD Pharma for the entire18 month period ending November 30, 2020; and
- our receipt of royalties relating to Zyla's sale of Oxaydo, of which no assurance can be given; and
- MainPointe's successful marketing and sale of our Nexafed products and other products utilizing our Impede Technology, and market acceptance, increased demand for and sales of our Nexafed products, of which no assurance can be given; and
- our receipt of milestone payments and royalties relating to our LIMITx Technology products in development from future licensees, of which no assurance can be given; and
- 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 our Impede Technology 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 our 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.

We cannot assure you that Oxaydo or our Nexafed products will be successfully commercialized or our LIMITx Technology or Impede Technology products in development will be successfully developed or be approved for commercialization by the FDA.

Even if Zyla succeeds in commercializing Oxaydo, if MainPointe is successful in commercializing our Nexafed products, or if we and AD Pharma succeed in developing and commercializing one or more of our pipeline LIMITx or Impede 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 Zyla does not successfully commercialize Oxaydo, if MainPointe does not successfully commercialize the Nexafed products, or 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 currently are expected to continue over at least the next several years. Our cash utilization amount is highly dependent on the progress of our product development programs, particularly, the results of our preclinical and clinical studies of our LIMITx product candidates and the cost, timing and outcomes of regulatory approval for our LIMITx product candidates. In addition, the further development of our ongoing clinical trials will depend on upcoming analysis and results of those studies and our financial resources at that time. As of March 30, 2020 our cash balance was approximately $1.2 million. Additionally, the Agreement with AD Pharma calls for monthly license payments of $350,000 from July 2019 through November 2020 and as well as their payment of all outside development costs for LTX-03. 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.

Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic, in regions where third parties for which we rely, as in CROs or CMOs, have significant research, development or manufacturing facilities, concentrations of clinical trial sites or other business operations, causing disruption in supplies and services.

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. On January 30, 202 0, 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 of LTX-03.

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 hospital resources toward the COVID-19 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 and 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.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. 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. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

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). To secure our performance of our obligations under the Note, we granted Mr. Schutte 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. With our consent, Mr. Schutte assigned and transferred to Abuse Deterrent Pharma, LLC ("AD Pharma") (an entity controlled by him, all of his right, title and interest in this Note and associated Security Agreement effective June 28, 2019. 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.

We are largely dependent on our successful development of our LIMITx product candidates.

Our ability to generate revenues and become profitable will depend in large part on our successful development of our LTX-03 as licensed to AD Pharma and potentially other LIMITx product candidates and on the commercial success of our only FDA approved product, Oxaydo, of which no assurance can be given 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. We completed our first two Phase I clinical studies for LTX-04, an opioid hydromorphone HCI, in mid-2016. We have changed our primary development focus from immediate-release hydromorphone products (i.e., LTX-04, described above) to immediate-release hydrocodone products (*i.e.*, LTX-03) because hydrocodone bitartrate is more likely to be abused in oral excessive tablet abuse, or ETA, and completed two pharmokinetic studies for LTX-03 during 2017 and the first week of 2018. We are also engaged in formulation development or early preclinical development for other LIMITx product candidates. 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.

If MainPointe/AD Pharma is not successful in commercializing our Nexafed Products, our revenues and business will suffer.

Our Nexafed products compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than MainPointe in marketing their competing products. Category leading brands are often supported by regional and national advertising and promotional efforts. Our Nexafed products compete with national brands as well as pharmacy store brands that are offered at a lower price. There can be no assurance that MainPointe will succeed in commercializing our Nexafed products, or that the pricing of our Nexafed products will allow us to generate significant royalty revenues. Regulations have been enacted in several state or local jurisdictions requiring a doctor's prescription to obtain pseudoephedrine products. An expansion of such restrictions to other jurisdictions or even nationally will adversely impact MainPointe's ability to market our Nexafed products as over-the-counter, or OTC, products and negatively impact royalty payments to us from Nexafed products sales. There can be no assurance that MainPointe will devote sufficient resources to marketing and commercialization of our Nexafed products. MainPointe's failure to successfully commercialize our Nexafed® products may have an adverse effect on our business and financial condition.

If Zyla is not successful in commercializing Oxaydo, our revenues and our business will suffer.

Pursuant to our Collaboration and License Agreement with Zyla, or the Zyla Agreement, Zyla is responsible for manufacturing, marketing, pricing, promotion, selling and distribution of Oxaydo. If the Zyla Agreement is terminated in accordance with its terms, including due to a party's failure to perform its obligations or responsibilities under the Agreement, then we would need to commercialize Oxaydo ourselves, for which we currently have no infrastructure, or alternatively enter into a new agreement with another pharmaceutical company, of which no assurance can be given. If we are unable to build the necessary infrastructure to commercialize Oxaydo ourselves, which would substantially increase our expenses and capital requirements, which we are currently unable to fund, or are unable to find a suitable replacement commercialization partner, we would be unable to generate any revenue from Oxaydo. Even if we are successful at replacing the commercialization capabilities of Zyla, our revenues and/or royalties from Oxaydo could be adversely impacted.

Zyla's third party manufacturing facility currently is the sole commercial source of supply of Oxaydo. If Zyla's manufacturing facility fails to obtain sufficient DEA quotas for oxycodone, fails to source adequate quantities of active and inactive ingredients, fails to comply with regulatory requirements, or otherwise experiences disruptions in commercial supply of Oxaydo, product revenue and our royalties could be adversely impacted.

Zyla has various products in development and also markets other products, for which Oxaydo will vie for such licensee's development, promotional, marketing, and selling resources. If Zyla fails to commit sufficient promotional, marketing and selling resources to Oxaydo, our expected royalties could be adversely impacted. Additionally, there can be no assurance that Zyla will commit the resources required for the successful commercialization of Oxaydo.

The market for our opioid product candidates is highly competitive with many marketed non-abuse deterrent brand and generic products and other abuse deterrent product candidates in development. If Zyla prices Oxaydo inappropriately, fails to position Oxaydo properly, targets inappropriate physician specialties, or otherwise does not provide sufficient promotional support, product revenue and our royalties could be materially adversely impacted.

Zyla's promotional, marketing and sales activities in connection with Oxaydo are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program. The federal 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. If Zyla's activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, Zyla may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of its activities with regard to the commercialization of Oxaydo, which could harm the commercial success of Oxaydo and have a material adverse effect on our business, financial condition and results of operations.

Our failure to meet the development timelines in the License Agreement with AD Pharma, including FDA acceptance of NDA submission for LTX-03 by November 30, 2020, 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.

We are engaged in the development of product candidates utilizing our LIMITx Technology, including planning studies for LTX-03, our hydrocodone/acetaminophen lead product candidate which has been licensed to AD Pharma. This License requires that the IND application for LTX-03 be accepted by the FDA within 18 months from June 28, 2019. Failure to do so gives AD Pharma the option to terminate this Agreement and take ownership of the LIMITx intellectual property. AD Pharma's seizure of the LIMITx IP would have a material adverse impact our financial condition and results of operations.

Our and our licensees' ability to market and promote Oxaydo and LIMITx Technology products by describing the abuse deterrent or other beneficial features of such products will be determined by the FDA approved label for such products.

The commercial success of Oxaydo and our LIMITx Technology products in development will depend upon our and our licensees' ability to obtain FDA approved labeling describing such products' abuse deterrent features or other 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. In April 2015, the FDA published guidance for industry on the evaluation and labeling of abuse-deterrent opioids. While the 2015 FDA Guidance is non-binding on the FDA, it outlines FDA's current thinking on the development and labeling of abuse-deterrent products. The 2015 FDA Guidance provides for three distinct levels of pre-marketing studies that are potentially eligible for inclusion in the labeling: (1) laboratory-based in vitro manipulation and extraction studies, (2) pharmacokinetic studies, and (3) clinical abuse potential studies. The 2015 FDA Guidance further prescribes additional post-approval or epidemiology studies to determine whether the marketing of a product with abuse-deterrent properties results in meaningful reductions in abuse, misuse, and related adverse clinical outcomes, including addiction, overdose, and death in the post-approval setting, which can also be included in the labeling. FDA notes "the science of abuse deterrence is relatively new. Both the technologies involved and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. For these reasons, FDA will take a flexible, adaptive approach to the evaluation and labeling of potentially abuse-deterrent opioid products".

We or our licensee may seek to include descriptions of studies that characterize the abuse-deterrent properties or safety features in the label for our Aversion and LIMITx Technology products in development. We have committed to the FDA to undertake epidemiological studies to assess the actual consequences of abuse of Oxaydo in the market. However, the extent to which a description of the abuse deterrent properties or 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 and our licensees' discussions with, and agreement by, the FDA as part of the new drug application, or NDA, review process for each of our product candidates. The outcome of those discussions with the FDA will determine whether we or our licensees will be able to market our products with labeling that sufficiently differentiates them from other products that have comparable therapeutic profiles. While the FDA approved label for Oxaydo includes the results from a clinical study which evaluated the effects of nasally snorting crushed Oxaydo and commercially available oxycodone tablets and limitations on wetting or dissolving Oxaydo, it does not, however, include the results of our laboratory studies intended to evaluate Oxaydo's potential to limit extraction of oxycodone HCl from dissolved Oxaydo Tablets and resist conversion into an injectable, or IV solution. According to filings made by Zyla, a supplemental new drug application ("sNDA") was submitted by Zyla in December 2016 for Oxaydo to support an abuse-deterrent label claim for the intravenous route of abuse, and in February 2017, Zyla filed a prior approval supplement ("PAS") with data on new dosage strengths of 10 mg and 15 mg of Oxaydo. Zyla reported they received a complete response letter from the FDA in June of 2017 where the FDA requested more information regarding the effect of food on Oxaydo 15 mg and the intranasal abuse deterrent properties of Oxaydo 10 and 15 mg. Zyla reported that based on discussions with the FDA regarding the sNDA, Zyla believed a contemporary intranasal human abuse potential study would be needed to complete the sNDA, and given that the issues involved in the sNDA and PAS are intertwined, Zyla disclosed that they are evaluating their options and the costs associated to proceed on the abuse deterrent label and/or the additional dosage strengths. The absence of the results of these extraction and syringe studies in the FDA approved label for Oxaydo may substantially limit our licensee's ability to differentiate Oxaydo from other immediate release oxycodone products, which would have a material adverse effect on market acceptance of Oxaydo and on our business and results of operations.

Notwithstanding the FDA approved labeling for Oxaydo, there can be no assurance that our LIMITx Technology products in development will receive FDA approved labeling that describes the beneficial safety features of such products. If the FDA does not approve labeling containing such information, we or our licensees will not be able to promote such products based on their safety features, may not be able to differentiate such products from other immediate release opioid products containing the same active ingredients, and may not be able to charge a premium above the price of such other products, which could materially adversely affect our business and results of operations.

Further, because the FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse deterrent characteristics of our product, as in the case of Oxaydo, the FDA's Office of Prescription Drug Promotion, or OPDP, will continue to review the acceptability of promotional claims and product advertising campaigns for our marketed products. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of Oxaydo from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution, which could harm the commercial success of our product and materially affect our business, financial condition and results of operations.

Our product candidates are unproven and may not be approved by the FDA.

We are committing a majority of our resources to the development of product candidates utilizing our LIMITx and Impede Technologies. Notwithstanding the receipt of FDA approval of Oxaydo and our marketing of our Nexafed products, there can be no assurance that any product candidate utilizing our Impede or LIMITx Technologies will meet FDA's standards for commercial distribution. Further, there can be no assurance that other product candidates that may be developed using LIMITx, Impede or Aversion Technologies will achieve the targeted end points in the required clinical studies, demonstration of acceptable manufacturing, quality and product expiration standards, or perform as intended in other pre-clinical and clinical studies or lead to an NDA submission or filing acceptance. Our failure to successfully develop and achieve final FDA approval of our product candidates in development will have a material adverse effect on our financial condition.

If the FDA disagrees with our determination that certain of our products meet the over-the-counter, or OTC, Monograph requirements, once those products are commercialized, they may be removed from the market; the FDA or the U.S. Federal Trade Commission, or FTC, may object to our advertisement and promotion of the extraction characteristics and benefits of our Nexafed products.

Drugs that have been deemed safe and effective by the FDA for use by the general public without a prescription are classified as OTC drug products. Certain OTC drug products may be commercialized without premarket review by the FDA if the standards set forth in the applicable regulatory monograph are met. An OTC monograph provides the marketing conditions for the applicable OTC drug product, including active ingredients, labeling, and other general requirements, such as compliance with current Good Manufacturing Practices, or cGMP and establishment registration. Any product which fails to conform to each of the general conditions in a monograph is subject to regulatory action. Further, although the FDA regulates OTC drug product labeling, the FTC regulates the advertising and marketing of OTC drug products. We believe that our Nexafed products licensed to MainPointe are classified for OTC sale under an FDA OTC monograph, which will allow for their commercialization without submitting an NDA or abbreviated new drug application, or ANDA to the FDA. We have also determined that, provided MainPointe adheres to the FDA's requirements for OTC monograph products, including product labeling, we can advertise and promote the extraction characteristics and benefits of our Nexafed products which are supported by our research studies. No assurance can be given, however, that the FDA will agree that our Nexafed products may be sold under the FDA's OTC monograph product regulations or that the FDA or FTC will not object to MainPointe's advertisement and promotion of our Nexafed products' extraction characteristics and benefits. If the FDA determines that our Nexafed products do not conform to the OTC monograph or if MainPointe fails to meet the general conditions, once commercialized, the products may be removed from the market and we and MainPointe may face various actions including, but not limited to, restrictions on the marketing or distribution of such products, warning letters, fines, product seizure, or injunctions or the imposition of civil or criminal penalties. Any of these actions may materially and adversely affect our financial condition and operations. Additionally, the FDA has announced that it is considering material changes to how it regulates OTC drug products and held a hearing in late March 2014 for public comment. Changes to the existing OTC regulations could result in a requirement that an NDA or ANDA be filed for our Nexafed products or other Impede Technology products in order to commercialize such products. If the FDA requires the submission of a NDA or ANDA to obtain marketing approval for our Nexafed® products or other Impede Technology products, this would result in substantial additional costs, suspend the commercialization of our Nexafed products and require FDA approval prior to sale, of which no assurance can be provided. In such case, the label for our Nexafed products or other Impede Technology products would be subject to FDA review and approval and there can be no assurance that we or our licensees will be able to market Nexafed or other Impede Technology products with labeling sufficient to differentiate it from products that have comparable therapeutic profiles. If we or our licensees are unable to advertise and promote the extraction characteristics of Nexafed or other Impede Technology products, we or our licensees may be unable to compete with national brands and pharmacy chain store brands.

Our LIMITx, Impede and Aversion Technology products may not be successful in limiting or impeding abuse or misuse or provide additional safety upon commercialization.

We are committing a majority of our resources to the development of products utilizing our LIMITx and Impede Technologies. Notwithstanding the receipt of FDA approval of Oxaydo and the results of our numerous clinical and laboratory studies for Oxaydo, our Nexafed products, and our LIMITx and Impede Technology products in development, there can be no assurance that Oxaydo, our Nexafed products or any other product utilizing our LIMITx, Impede or Aversion Technologies will perform as tested and limit or impede the actual abuse or misuse of such products or provide other benefits in commercial settings. Moreover, there can be no assurance that the post-approval epidemiological study required by the FDA as a condition of approval of Oxaydo will show a reduction in the consequences of abuse and misuse by patients for whom Oxaydo is prescribed. To date, Zyla has not achieved sufficient market share for Oxaydo to support a full epidemiological study. The failure of Oxaydo, our Nexafed products or other products utilizing our LIMITx and Impede Technologies to limit or impede actual abuse or misuse or provide other safety benefits in practice will have a material adverse impact on market acceptance for such products and on our financial condition 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. 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 LIMITx and Impede 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, including our licensed Nexafed 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. 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. 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. For instance, the FDA's approval of Oxaydo is conditioned on us or Zyla conducting a post-approval epidemiological study to assess the actual abuse levels and consequences of Oxaydo in the market. The Prescription Drug User Fee Act, or PDUFA, sets time standards for the FDA's review of NDAs. The FDA's timelines described in the PDUFA guidance are flexible and subject to change based on workload and other potential review issues and may delay the FDA's review of an NDA. 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.

Even if we comply with all the FDA regulatory requirements, we or our licensees may not obtain regulatory approval for any of our product candidates in development. For example, we previously submitted a NDA to the FDA for an Aversion Technology product containing niacin, intended to provide impediments to over-ingesting the product. Such niacin containing product was not approved by the FDA. If we or our licensees fail to obtain regulatory approval for any of our product candidates in development, we will have fewer commercialized products and correspondingly lower revenues.

Even if regulatory approval of our products in development is received, such approval may involve limitations on the indicated uses or promotional claims we or our licensees may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles but without abuse deterrent features (see risk factor above entitled "Our and our licensees ability to market and promote Oxaydo and LIMITx Technology products by describing the abuse deterrent features of such products will be determined by the FDA approved label for such products"). Such events would have a material adverse effect on our operations and financial condition. We may market certain of our products without the prior application to and approval by the FDA. The FDA may subsequently require us to withdraw such products and submit NDA's for approval prior to re-marketing.

The FDA also has the authority to revoke or suspend approvals of previously approved products for cause, to debar companies and individuals from participating in the drug-approval process, to request recalls of allegedly violative products, to seize allegedly violative products, to obtain injunctions to close manufacturing plants allegedly not operating in conformity with current cGMP and to stop shipments of allegedly violative products. In the event the FDA takes any such action relating to our products, such actions would have a material adverse effect on our operations and financial condition.

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 installed the equipment necessary to manufacture clinical trial supplies of our LIMITx and Impede Technology product candidates in tablet formulations at our Culver, Indiana facility. To be used in clinical trials, all of our product candidates must be manufactured in conformity with cGMP regulations. All such product candidates must be manufactured, packaged, and labeled and stored in accordance with cGMPs. 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 supplies, at a single location. Any disruption at this facility 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. If the Culver, Indiana facility were 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. Moreover, any disruptions or delays at our Culver, Indiana facility could impair our ability to develop our product candidates utilizing the Impede or LIMITx Technologies, 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 Zyla Agreement grants Zyla 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, Zyla 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.

As part of the AD Pharma Agreement, the Zyla Agreement, the KemPharm Agreement, the MainPointe Agreement, or any license agreement we may enter into relating to any of our LIMITx or Impede Technology products in development or our Aversion Technology, we do not have day-to-day control over the activities of our licensees with respect to any product candidate. 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, due to the nature of the market for Oxaydo and our LIMITx and Impede product candidates, it may be necessary for us to license a significant portion of our product candidates to a single company, thereby eliminating our opportunity to commercialize other product candidates with other licensees.

If we fail to maintain our license agreement with Zyla, we may have to commercialize Oxaydo on our own and if we fail to maintain the license agreement with AD Pharma we may have to commercialize Nexafed Products on our own.

Our plan for manufacturing and commercializing Oxaydo currently requires us to maintain our license agreement with Zyla. In addition to other customary termination provisions, the Zyla Agreement provides that Zyla may terminate the Zyla Agreement upon certain notice periods. If Zyla elects to terminate the Zyla Agreement, or if we are otherwise unable to maintain our existing relationship with Zyla, we would have to commercialize Oxaydo ourselves for which we currently have no infrastructure, or alternatively enter into a new agreement with another pharmaceutical company, of which no assurance can be given. Our ability to commercialize Oxaydo on our own may require additional financing, which may not be available on acceptable terms, or at all. While, there is no provision for MainPointe to elect to terminate its license agreement without cause, if it should fail to perform thereunder and we terminated the agreement, then we would have to commercialize the Nexafed Products on our own. Although prior to entering into the MainPointe agreement we had been commercializing certain Nexafed Products on our own, we would have to reestablish our capabilities, which will require additional financing which may not be available on acceptable terms, if at all.

The market may not be receptive to products incorporating our Aversion, Impede or LIMITx Technologies.

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 Aversion, Impede or LIMITx Technologies 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 perception of health care providers of their role in helping to prevent abuse and their willingness to prescribe abuse-deterrent products to do so;
- the willingness of third party payers to reimburse for our prescription products;
- the willingness of pharmacy chains to stock our products;
- the willingness of pharmacists to recommend our Nexafed products to their customers; and
- the willingness of consumers to pay for our products.

Oxaydo and our Nexafed Products compete, and our other product candidates, such as LTX-03, if successfully developed and commercially launched will compete, with both currently marketed and new products launched in the future by other companies. Physicians and other prescribers may not be inclined to prescribe our prescription products unless our products demonstrate commercially viable advantages over other products currently marketed for the same indications. Pharmacy chains may not be willing to stock any of our products and pharmacists may not recommend Nexafed products to consumers. Further, consumers may not be willing to purchase our products. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

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 serious 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 Aversion, Impede or LIMITx 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 increasingly are limiting both coverage and the level of reimbursement for new drugs. 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, 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. 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.

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 Zyla 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 also rely on or intend to rely on our or our licensees' trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. However, our trademark applications may not be approved. Third parties may also oppose our or our licensees' trademark applications or otherwise challenge our use of the trademarks. In the event that our or our licensees' trademarks are successfully challenged, we or our licensees could be forced to rebrand our product, which could result in loss of brand recognition and could require us or our licensees to devote resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks, or we may not have adequate resources to enforce our trademarks.

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 Paragraph IV Proceedings described below in the next risk factor;
- 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 proceeding, 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 are aware of certain United States and international pending patent applications owned by third parties with claims potentially encompassing Oxaydo and our other products. If such patent applications result in valid and enforceable issued patents, containing claims in their current form or otherwise encompassing our products we or our licensees may be required to obtain a license to such patents, should one be available, or alternatively, alter our products so as to avoid infringing such third-party patents. If we or our licensees are unable to obtain a license on commercially reasonable terms, or at all, we or our licensees could be restricted or prevented from commercializing our products. Additionally, any alterations to our products or our technologies could be time consuming and costly and may not result in technologies or products that are non-infringing or commercially viable.

We are aware of an issued United States patent owned by a third party having claims encompassing the use of one of our Aversion inactive ingredients. We are also aware of an issued United States patent owned by a third party having claims encompassing a pharmaceutical preparation containing viscosity producing ingredients that can be drawn into a syringe when dissolved in 10mL’s or less of aqueous solution. While we believe that our Aversion products do not infringe these patents, or that such patents are otherwise invalid, there can be no assurance that we or our licensees will not be sued for infringing these patents, and if sued, there can be no assurance that we or our licensees will prevail in any such litigation. If we or our licensees are found to infringe either or both of these patents, we or our licensees may seek a license to use the patented technology. If we are unable to obtain such a license, of which no assurance can be given, we or our licensees may be restricted or prevented from commercializing our Aversion products.

We are aware of certain issued United States patents owned by a third party having claims encompassing a process used to manufacture oxycodone HCl of high purity and pharmaceutical products resulting therefrom. As required by the FDA, Oxaydo contains a similar high purity oxycodone HCl manufactured by a supplier that is not the owner or licensee of such patents. The owner of these patents has filed patent infringement actions relating to these patents against companies that have filed abbreviated new drug applications with the FDA for extended-release versions of oxycodone HCl. To our knowledge, the patent owner has not initiated any patent infringement actions against the sellers of immediate-release oxycodone HCl products or their suppliers of oxycodone HCl, however, we cannot be certain that these immediate-release products actually utilize a high purity oxycodone. We cannot provide assurance that our licensee or its oxycodone HCl supplier will not be sued for infringing these patents. In the event of an infringement action, our licensee and their oxycodone HCl supplier would have to either: (a) demonstrate that the manufacture of the oxycodone HCl used in Oxaydo does not infringe the patent claims, (b) demonstrate the patents are invalid or unenforceable, or (c) enter into a license with the patent owner. If our licensee or their oxycodone HCl supplier is unable to demonstrate the foregoing, or obtain a license to these patients, our licensee may be required or choose to withdraw Oxaydo from the market.

We are aware of a certain issued United States patent owned by a third party having claims similar to our second generation Impede Technology directed to ingredient amounts that are generally more than the amounts used in our technology. While we believe our technology does not infringe this patent, we cannot provide assurance that we will not be sued under such patent or if sued, that we will prevail in any such suit.

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.

Generic manufacturers are using litigation and regulatory means to seek approval for generic versions of Oxaydo, which could cause Zyla's sales to suffer and adversely impact our royalty revenue.

Under the Hatch-Waxman Act, the FDA can approve an Abbreviated New Drug Application ("ANDA") for a generic version of a branded drug and what is referred to as a Section 505(b)(2) NDA, for a branded variation of an existing branded drug, without requiring such applicant to undertake the full clinical testing necessary to obtain approval to market a new drug. In November 2017 the FDA issued guidance for the industry on obtaining approval for generic versions of opioids that reference products whose labeling describes abuse-deterrent properties. An ANDA applicant usually needs to only submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients, or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug. Under the 2017 FDA guidance when a potential ANDA applicant develops a generic solid oral opioid drug product, the potential ANDA applicant should evaluate its proposed generic drug to show that it is no less abuse deterrent than the reference drug with respect to all of the potential routes of abuse.

The Hatch-Waxman Act requires an applicant for a drug that references one of our branded drugs to notify us of their application if they assert in their application that the patents we have listed in the Orange Book will not be infringed or otherwise are invalid or unenforceable (a Paragraph IV Certification). Upon receipt of this notice, we or our licensee will have 45 days to bring a patent infringement suit known as a Paragraph IV Proceeding in federal district court against such applicant. If such a suit is commenced, the FDA is generally prohibited from granting approval of the ANDA or Section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic applicant's favor or expiration of the patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) NDAs. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove this uncertainty. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the applicant for the patents subject to the litigation.

In 2012 and 2013, we received Paragraph IV Certification Notices under 21 U.S.C. 355(j) (a Paragraph IV Notice) from 5 different generic sponsors of an ANDA for a generic drug listing Oxaydo as the reference listed drug. We initiated patent infringement proceedings against all 5. In 2013 and 2014, Watson Laboratories, Inc. – Florida (Watson) withdrew their Paragraph IV certification and we settled our litigation with Par Pharmaceutical, Inc., Impax Laboratories, Inc. Sandoz Inc., and Ranbaxy, Inc. Par is the first filer of an ANDA for a generic Oxaydo product and is entitled to the 180-day first filer exclusivity under applicable law and FDA regulations.

Under the terms of the Settlement Agreement with Par, Par may launch its generic Oxaydo product in the U.S., through the grant of a non-exclusive, royalty-bearing license from us that would trigger on January 1, 2022.

It is possible that other generic manufacturers may also seek to launch a generic version of Oxaydo and challenge our patents. Any determination in any such infringement actions that our patents covering our Aversion Technology and Oxaydo are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents could 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. While we would not expect to be implicated in any such action or investigations, since our business is focused on abuse deterrence, there can be no assurance that we will not be so implicated. 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. 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. See litigation discussed below under "Item 3. Legal Proceedings" of this Report. 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.

The pharmaceutical industry is characterized by frequent litigation. Those companies with significant financial resources will be better able to bring and defend any such litigation. No assurance can be given that we would not become involved in future litigation, in addition to the ongoing Reglan/Metoclopramide mass tort litigation and DES (diethylstilbestrol) litigation discussed below under "Item 3. Legal Proceedings" of this Report, including litigation relating to products we manufactured or distributed several years and decades ago when we manufactured and sold a broad range of prescription and over the counter products. Such litigation may have material adverse consequences to our 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.

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, Nektar Therapeutics, Signature Therapeutics, QRx Pharma, Tris Pharma, Pisgah Labs, Teva Pharmaceuticals, Sun Pharmaceuticals, Inspirion Delivery Sciences, and Collegium Pharmaceuticals, Inc. These companies appear to be focusing their development efforts on ER Opioid Products, except for Atlantic Pharmaceuticals, Pisgah Labs, Inspirion and KemPharm.

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 and Impede Technologies. The commercial success of products utilizing such technologies 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 and Impede Technologies. 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 and Impede Technologies 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 Oxaydo, and, if approved, 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. Such efforts may inhibit Zyla's ability to commercialize Oxaydo and, if approved, our LIMITx product candidate. 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 Oxaydo and decrease the revenues and royalties we are able to generate from their sale. Similarly, to the extent opioid abuse becomes less prevalent or a less urgent public health issue, regulators and third-party payers may not be willing to pay a premium for abuse deterrent formulations of opioids.

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 President Trump, 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 may limit our ability to use our tax net operating loss carryforwards as part of an 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 2019, our stock traded as high as $0.63 per share and as low as $0.11 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 sales of Oxaydo;
- announcements regarding the progress of our preclinical and clinical programs;
- our licensee's success in the commercialization of our Nexafed products;
- announcements regarding the sales of our Nexafed products;
- 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, 2020, our two largest shareholders own an aggregate of 12,651,582 shares (including 1,782,531 shares underlying warrants) (representing approximately 54.6% 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. In addition, such sales could make it more difficult for us to raise capital if needed in the future.

Approximately 45.6% 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 is also party to our Second Amended and Restated Voting Agreement.

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, as part of the closing of the Transaction, we, Galen Partners III, L.P., and Essex Woodlands Health Ventures V, L.P. ("Essex") amended and restated the existing Voting Agreement between the parties to provide for Mr. Schutte to join as a party so that he can 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 Abuse Deterrent Pharma, LLC ("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 2019 fiscal year that remain unresolved.

ITEM 2. PROPERTIES

We lease 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 on a monthly basis 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 and NDA submission batch 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

Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to us, was named along with numerous other companies as a defendant in cases filed in three separate state coordinated litigations pending in Pennsylvania, New Jersey and California, respectively captioned In re: Reglan®/Metoclopramide Mass Tort Litigation, Philadelphia County Court of Common Pleas, January Term, 2010, No. 01997; In re: Reglan Litigation, Superior Court of New Jersey, Law Division, Atlantic County, Case No. 289, Master Docket No. ATL-L-3865-10; and Reglan/Metoclopramide Cases, Superior Court of California, San Francisco County, Judicial Council Coordination Proceeding No. 4631, Superior Court No.: CJC-10-004631. In addition, we were served with a similar complaint by two individual plaintiffs in Nebraska federal court, which plaintiffs voluntarily dismissed in December 2014. In this product liability litigation against numerous pharmaceutical product manufacturers and distributors, including Acura, plaintiffs claim injuries from their use of the Reglan brand of metoclopramide and generic metoclopramide.

None of the plaintiffs in the lawsuits filed to date have confirmed that they ingested any of the generic metoclopramide manufactured by us. We discontinued manufacture and distribution of generic metoclopramide more than 20 years ago. All of these lawsuits have been effectively dismissed with the exception of less than ten pending Philadelphia cases that we expect will be finally dismissed without the need for any action by us. We expect that the Court will finally dismiss the small number of remaining Pennsylvania-based cases against us with prejudice by the end of the first quarter of 2020. Legal fees related to this matter have been covered by our insurance carrier. Based upon the current status and evaluation, we have not accrued for any potential loss related to these matters as of December 31, 2019.

ITEM 4. MINE SAFETY DISLCOSURES

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 2016 fiscal year and through February 22, 2017, our common stock was traded on the Nasdaq Capital Market under the symbol "ACUR". On February 23, 2017, our common stock was delisted from the Nasdaq Capital Market due to our failure to comply with Nasdaq's Listing Rule 5550(b)(1), which requires that we maintain $2.5 million in stockholders' equity for continued listing (or meet the alternatives of market value of listed securities of $35 million or net income from continuing operations). NASDAQ had granted us a grace period through February 10, 2017, to regain compliance with Listing Rule 5550(b)(1), but we were unable to regain compliance within such period.

Commencing on February 23, 2017, our common stock was quoted on the OTCQB under the symbol "ACUR", however commencing June 4, 2018 and lasting until July 2, 2018 it was quoted on the OTC Markets OTC Pink tier. The downgrade was a result of the late filing of our 2017 Annual Report on Form 10-K beyond any applicable grace periods. The Company regained compliance with the OTCQB and effective July 3, 2018 it was quoted on the OTCQB. However, commencing May 20, 2019 as a result of late filing of our 2018 Annual Report on Form 10-K our common stock was again 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.

Period	**Sales Prices**	
	High	**Low**
2019 Fiscal Year		
First Quarter	$ 0.29	$ 0.11
Second Quarter	0.28	0.13
Third Quarter	0.45	0.14
Fourth Quarter	0.63	0.20
2020 Fiscal Year		
First Quarter thru March 27, 2020	$ 0.47	$ 0.12

On March 27, 2020 the closing sales price of our common stock was $0.22.

Holders

There were approximately 275 holders of record of our common stock as of March 18, 2020 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 4,600 beneficial holders of our common stock as of March 16, 2020.

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, 2019, we had cash of $862 thousand compared to $91 thousand of cash at December 31, 2018. We had an accumulated deficit of approximately $388 million and $384.2 million at December 31, 2019 and December 31, 2018, respectively. We had a loss from operations of $725 thousand and a net loss of $3.8 million for the year ended December 31, 2019, compared to a loss from operations of $3.9 million and a net loss of $3.8 million for the year ended December 31, 2018.

On June 28, 2019, we entered into License, Development and Commercialization Agreement (the "Agreement") with Abuse Deterrent Pharma, LLC. 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 the earlier of November 30, 2020 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 November 30, 2020, AD Pharma has the option of terminating the Agreement and taking 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 Zyla Agreement. Sales and marketing expenses include costs associated with the Nexafed product line advertising incurred prior to our entering into the MainPointe Agreement on March 16, 2017, 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 Note 15 to the Financial Statements).

Results of Operations for the Years Ended December 31, 2019 and 2018.

	December 31			
	2019	2018	Change	
	$000's		$000's	Percent
Revenues:				
License fee revenue	$ 2,100	$ -	$ 2,100	-%
Collaboration revenue	185	-	185	-
Royalty revenue	372	410	(38)	(9)
Total revenues, net	2,657	410	2,247	548
Operating Expenses:				
Research and development	1,505	1,759	(254)	(14)
General and administrative	1,877	2,566	(689)	(27)
Total operating expenses	3,382	4,325	(943)	(22)
Operating loss	(725)	(3,915)	(3,190)	(82)
Non-Operating income (expense):				
Interest expense, net	(449)	(223)	226	101
(Loss) gain on debt extinguishment	(2,600)	296	2,896	978
Total other income (expense), net	(3,049)	73	3,122	4,277
Loss before provision for income taxes	(3,774)	(3,842)	(68)	(2)
Provision for income taxes	-	-	-	-
Net loss	$ (3,774)	$ (3,842)	$ (68)	(2)%

Revenues

License Fees

From the period, June 28, 2019 to December 31, 2019, we received license fees under the license and development agreement from AD Pharma totaling $2.1 million for LTX-03. No license fees were received in 2018.

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 $185 thousand of collaboration revenue during 2019. We were not providing research and development services under any of our license agreements during 2018.

Royalty Revenue

In connection with our license agreement with Zyla for Oxaydo Tablets, we earn a royalty based on product net sales. We recognized $351 thousand and $386 thousand of royalty revenue from Oxaydo during the years ended 2019 and 2018, respectively.

In connection with our license agreement with MainPointe for our Nexafed product line, we earn a royalty based on product net sales. We recognized $21 thousand and $24 thousand of royalty revenue from Nexafed during 2019 and 2018, respectively.

Operating Expenses

Research and Development

Research and development expense ("R&D") for 2019 and 2018 was with respect to our LIMITx Technology and Impede Technology development activity and included, 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, our facility costs, and a percentage share of selected cost sharing expenses under the license agreement with Zyla. Also included in each of 2019 and 2018 year end results are share-based compensation expenses of approximately $21 thousand and $65 thousand, respectively. Excluding share-based compensation expense, our R&D expenses decreased approximately $0.2 million between reporting periods, resulting primarily from the salary reductions enacted in 2018 and unpaid leave of absences during 2019. During 2018 we completed Study AP-LTX-301 but performed no additional clinical studies. We commenced the scale-up of the commercial manufacturing process on our LIMITx Technology in the second quarter of 2018 as to-be-marketed formulations are required for all NDA development work but was suspended during the fourth quarter of 2018. We resumed the scale-up activities effective with the licensing of LTX-03 to AD Pharma on June 28, 2019.

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 2019 and 2018 results are share-based compensation expenses of approximately $117 thousand and $165 thousand, respectively. Excluding the share-based compensation expense our general and administrative expenses decreased by approximately $0.6 million between reporting periods, resulting primarily from the decrease legal activities, corporate insurance and from salary reductions enacted in 2018 and unpaid leave of absences during 2019.

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. In October 2018 we borrowed $1.8 million from Mr. Schutte and used $1.5 million from the loan proceeds to settle and pay-off in full the Oxford Loan for $1.5 million. We recognized a net gain of $296 thousand on the debt settlement.

Interest Expense, net

For 2019 and 2018, we incurred net interest expense of $449 thousand and $223 thousand, respectively, on our term loans.

Income Taxes

Our results for 2019 and 2018 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. As a result of the Tax Cuts and Jobs Act of 2017, the $135 thousand Federal alternative minimum taxes we paid in a prior year is refundable to the Company in prescribed percentages and time periods beginning with our tax year ended December 31, 2018. In July 2019 we received a $67 thousand tax refund.

Liquidity and Capital Resources

As of December 31, 2019, we had cash of $862 thousand, working capital of $104 thousand and an accumulated deficit of $388 million. We had a loss from operations of $725 thousand and a net loss of $3.8 million for the year ended December 31, 2019. 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, 2020 our cash balance was approximately $1.2 million.

Additionally, the License, Development and Commercialization Agreement dated June 28, 2019 (the "Agreement") requires AD Pharma to pay us monthly license payments of $350,000 from July 2019 through November 2020 and pay all outside development costs for LTX-03. However, the Agreement allows AD Pharma to terminate the Agreement "for convenience". Should AD Pharma exercise their right to terminate the Agreement, we would 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. Our independent auditors have included in their report relating to our 2019 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, 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 2019 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 Zyla 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, 2019 and 2018

The following table summarizes our cash flows for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,	
	2019	**2018**
Net cash (used in) provided by:		
Operating activities	$ (618)	$ (3,908)
Investing activities	-	-
Financing activities	1,389	1,779
Net increase (decrease) in cash and cash equivalents	$ 771	$ (2,129)

Cash Flows from Operating Activities

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.

Net cash used in operating activities was $3.9 million for the year ended December 31, 2018 and consisted primarily of a net loss of $3.8 million, capitalized debt discount of $172 thousand and a gain on the debt extinguishment of $296 thousand. This net loss was partially offset by non-cash items such as $218 thousand in share-based compensation expense, $87 thousand of debt discount and debt issue cost amortization expense, $73 thousand of depreciation expense, and $207 thousand of intangible asset amortization expense with $183 thousand in net cash outflows from changes in operating assets and liabilities. Cash outflows from changes in operating assets and liabilities of $896 thousand were primarily due to $66 thousand increase in royalty receivable and $830 thousand decreases in both accrued interest and accrued expenses. These cash outflows were partially offset by a $109 thousand decrease in prepaid expenses and other current assets and increase of $604 in accounts payable.

Cash Flows from Investing Activities

We had no investing activities for the years ended December 31, 2019 and 2018.

Cash Flows from Financing Activities

Net cash provided by financing activities was $1.4 million for the year ended December 31, 2019 and consisted of the net proceeds from loans provided by Mr. Schutte.

Net cash provided by financing activities was $1.8 million for the year ended December 31, 2018 and consisted of the $4.350 million net proceeds from loans provided by Mr. Schutte partially offset by $2.6 million principal repayments and debt retirement on the loan with Oxford Finance.

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, 2019 and December 31, 2018, 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, 2018, 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 2019 or 2018.

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, 2019, 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. We have conducted an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(e). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including our subsidiary) required to be included in our periodic Securities and Exchange Commission filings.

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, 2019. 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, 2019, 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 2019 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

The name, age and position of our directors, executive officers and key employees as of March 30, 2019 are as follows:

Name	Age	Position
Robert B. Jones	61	President, Chief Executive Officer and Director
Peter A. Clemens	67	Senior Vice President, Chief Financial Officer and Secretary
Albert W. Brzeczko, Ph.D.	63	Vice President, Pharmaceutical Sciences
Robert A. Seiser	56	Vice President, Treasurer, and Corporate Controller
James F. Emigh	64	Vice President of Corporate Development
Bruce F. Wesson[(1) (2)]	77	Director
William G. Skelly[(1)(2)]	69	Director
Immanuel Thangaraj[(2)]	49	Director
George K. Ross[(1)]	78	Director

(1) Member of audit committee.
(2) Member of compensation committee.

Robert B. Jones has been our President and Chief Executive Officer since July 7, 2011. From April 2011 through July 6, 2011, Mr. Jones was our Interim President and Chief Executive Officer. Mr. Jones was our Senior Vice President and Chief Operating Officer from April 2008 to April 2011. From May, 2003 to March, 2008, Mr. Jones served first as the Vice President, Finance and then as Vice President, Strategy and Business Analysis of Adolor Corporation. From November 2000 to May 2003 he served as Vice President, Finance and then as Chief Operating Officer of Opt-E-Script, Inc., a privately held personalized medicine company, where Mr. Jones was responsible for all commercialization activities. Prior to that, Mr. Jones was Vice President, Sales and Marketing for Purepac Pharmaceutical Company. Mr. Jones received his M.B.A. from the University of North Carolina and a B.S. from Cornell University. Mr. Jones was appointed a director of the Company in July 2011.

Peter A. Clemens has been Senior Vice President, Chief Financial Officer and Secretary since April 2004. Mr. Clemens was our Vice President, Chief Financial Officer and Secretary from February 1998 to March 2004 and a member of our Board of Directors from June, 1998 to August, 2004. Mr. Clemens is Certified Public Accountant (Inactive) and earned a Bachelor of Business Administration degree from the University of Notre Dame and a Masters of Business Administration from Indiana University.

Albert W. Brzeczko, Ph.D., has been Vice President, Pharmaceutical Sciences, of APT since January 2019 and has been Vice President, Technical Affairs of APT from February 2009 through 2018. From 1999 through 2009, Dr. Brzeczko was Vice President, Global Pharma New Product Development and Pharma Technologies for International Specialty Products, Inc., a contract services group specializing in the development of technologies for the bioenhancement of poorly soluble drugs. Prior to 1999, Dr. Brzeczko held various positions of increasing responsibility in pharmaceutical product development with UPM Pharmaceuticals, Banner Pharmacaps, Mylan Laboratories, and DuPont Merck. Dr. Brzeczko received a Bachelor of Science degree in biochemistry and a Ph.D. in pharmaceutical sciences from the University of Maryland.

Robert A. Seiser has been a Vice President, Treasurer and Corporate Controller since April 2004. Mr. Seiser joined us in March 1998 as our Treasurer and Corporate Controller. Mr. Seiser is a Certified Public Accountant (Inactive) and earned a Bachelor of Business Administration degree from Loyola University of Chicago.

James F. Emigh has been Vice President of Corporate Development since October 2011. From April 2004 to October 2011, Mr. Emigh was our Vice President of Marketing and Administration. Prior to such time, Mr. Emigh was our Vice President of Sales and Marketing. Mr. Emigh joined us in May, 1998, serving first as Executive Director of Customer Relations and then as Vice President of Operations. Mr. Emigh holds a Bachelor of Pharmacy degree from Washington State University and a Masters of Business Administration from George Mason University.

Bruce F. Wesson has been a member of our Board of Directors since March 1998. From January 1991 until June 30, 2011, Mr. Wesson was a Partner of Galen Associates, a health care venture firm, and a General Partner of Galen Partners III, L.P. Prior to January 1991, he was Senior Vice President and Managing Director of Smith Barney, Harris Upham & Co. Inc., an investment banking firm. From May 2006 until June 2016 he served on the Board of Derma Sciences, Inc. From June 1999 until January 2016 he served as director of the Board of MedAssets, Inc. and for over eight years until January 2016 served as Vice Chairman of MedAssets, Inc. Mr. Wesson earned a Bachelor of Arts degree from Colgate University and a Masters of Business Administration from Columbia University.

William G. Skelly has been a member of our Board of Directors since May 1996 and served as our Chairman from October 1996 through June 2000. Since 1990, Mr. Skelly has served as Chairman, President and Chief Executive Officer of Central Biomedia, Inc. and its subsidiary SERA, Inc. From 1985 to 1990, Mr. Skelly served as President of Martec Pharmaceutical, Inc. Mr. Skelly earned a Bachelor of Arts degree from Michigan State University and a Masters of Business Administration from the University of Missouri-Kansas City.

Immanuel Thangaraj has been a member of our Board of Directors since December 2002. Mr. Thangaraj has been a Managing Director of Essex Woodlands Health Ventures, a venture capital firm specializing in the healthcare industry, since 1997. Prior to joining Essex Woodlands Health Ventures, he helped establish a telecommunication services company, for which he served as its CEO. Mr. Thangaraj holds a Bachelor of Arts and a Masters in Business Administration from the University of Chicago.

George K. Ross has been a member of our Board of Directors since January, 2008. Since April 2002, Mr. Ross has been a consultant to early stage businesses and a financial investor. From April 1, 2015 until its sale in March 2017, Mr. Ross was an advisor to GP Shopper LLC, a provider of mobile solutions for retail and brands. From July 2005 through December 2010 he served as Executive Director, Foundations and Partnerships for World Vision U.S. in New York City. His business career has included senior financial officer and board member positions with both public and private companies in diverse industries. Mr. Ross was Executive Vice President and Chief Financial Officer and a board member of Tier Technologies Inc. from February 1997 to January 2000, which became a public company during this period. Mr. Ross is a Certified Public Accountant (Inactive) and earned a Bachelor of Arts degree from Ohio Wesleyan University and a Masters of Business Administration from Ohio State University.

The term of office of each director will continue until the next annual meeting of shareholders and until such person's successor has been elected and qualified. Officers are appointed by the Board of Directors and serve at the discretion of the Board, although the employment of Robert B. Jones, our President and Chief Executive Officer and Peter A. Clemens, our Senior Vice President and Chief Financial Officer are subject to the provisions of their respective Employment Agreements.

Director Independence

Our shares of common stock were listed on The NASDAQ Capital Market until February 22, 2017 and were quoted on the OTCQB market until June 4, 2018**.** From June 4, 2018 through July 2, 2018 our stock was quoted on the OTC Markets' OTC Pink Tier, when we regained compliance with the OTCQB Market and resumed quotation on the OTCQB Market on July 3, 2018. Since May 20, 2019 our stock was been quoted on the OTC Markets' OTC Pink Tier due to our failure to comply with the filing deadlines for our 2018 Form 10K and 2019 Form 10-Qs. In March, 2020 we regained compliance with the OTCQB Market and resumed quotation on the OTXQB Market on March 20, 2020. In 2016 we were subject to the Nasdaq Stock Market independence standards and we continue to follow those standards in determining whether a director is independent for Board or Committee purposes. Under the rules of The NASDAQ Stock Market, which we were subject to until February 22, 2017, independent directors must comprise a majority of our Board of Directors. In addition, the rules of The NASDAQ Stock Market require that, subject to specified exceptions, each member of the Audit and Compensation Committees of our Board of Directors be independent. Audit Committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or Exchange Act. Under the rules of The Nasdaq Stock Market, a director will only qualify as an "independent director" if, in the opinion of our Board of Directors, that person does have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered to be independent for purposes of Rule 10A-3, a member of the Audit Committee of our Board of Directors may not, other than in his or her capacity as a member of the Audit Committee, the Board of Directors or any other committee of our Board of Directors:

- accept, directly or indirectly, any consulting, advisory, or other compensatory fee from us or any of our subsidiaries; or

- be an affiliated person of us or any of our subsidiaries.

Our Board of Directors has undertaken a review of its composition, the composition of its committees and the independence of each director. In connection with this review, our Board of Directors determined that each of Messrs. Wesson, Skelly, Thangaraj and Ross, representing four of our five directors, satisfies the independence requirements of The NASDAQ Stock Market and Rule 10A-3 of the Exchange Act. In making this determination, our Board of Directors considered the relationships that each non-employee director has with us and all other facts and circumstances our Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our share capital by each non-employee director and their affiliates. In addition, our Board of Directors considered information that was provided by each director concerning his or her background, employment and affiliations, including relationships with our stockholders.

Corporate Governance

Our Board of Directors has established an Audit Committee, a Compensation Committee and a Nominating Committee. Our Audit Committee and our Compensation Committee operate under written charters approved by our Board of Directors, copies of which are available on our website and will be made available in print to any shareholder who requests it. Currently, our entire Board serves as our Nominating Committee. A brief description of these committees is provided below.

Audit Committee

The Audit Committee is composed of Mr. Ross, Chairman, and Messrs. Wesson and Skelly. The Audit Committee is responsible for selecting the Company's registered independent public accounting firm, approving the audit fee payable to the auditors, working with independent auditors and other corporate officials, reviewing the scope and results of the audit by, and the recommendations of, our independent auditors, approving the services provided by the auditors, reviewing our financial statements and reporting on the results of the audits to the Board, reviewing our insurance coverage, financial controls and filings with the SEC, including, meeting quarterly prior to the filing of our quarterly and annual reports containing financial statements filed with the SEC, and submitting to the Board its recommendations relating to our financial reporting, accounting practices and policies and financial, accounting and operational controls.

In assessing the independence of the Audit Committee in 2019, our Board reviewed and analyzed the standards for independence provided in NASDAQ Marketplace Rule 5605 and applicable SEC regulations. Based on this analysis, our Board has determined that each of Messrs. Ross, Wesson and Skelly satisfies such standards for independence. Our Board also determined that Mr. Ross is a "financial expert" as provided in NASDAQ Marketplace Rule 5605(c)(3) and SEC regulations.

Compensation Committee

The Compensation Committee is composed of Mr. Skelly, Chairman, and Messrs. Wesson and Thangaraj. This committee is responsible for consulting with and making recommendations to the Board of Directors about executive and director compensation and compensation of employees. In 2019 the Compensation Committee did not retain a compensation consulting firm, to assist in evaluating stock option and other incentives for our directors, executive officers and other employees.

Our Board determined that each of Messrs. Skelly, Wesson and Thangaraj were independent directors under the Nasdaq Marketplace Rules. The Board has also determined that each of Messrs. Skelly, Thangaraj and Wesson meet the more stringent independence standards for compensation committees imposed under NASDAQ Rule 5605(d)(2)(A).

Nominating Committee

Currently our entire Board of Directors functions as our nominating committee. As needed, the Board will perform the functions typical of a nominating committee, including the identification, recruitment and selection of nominees for election to our Board. Our Board determined that all members of the Board were independent other than Mr. Jones, our CEO. We believe that a nominating committee separate from the Board is not necessary at this time given our relative size, the size of our Board, and our opinion that an additional committee of the Board would not add to the effectiveness of the evaluation and nomination process. The Board's process for recruiting and selecting nominees for Board members, if required, would be to identify individuals who are thought to have the business background and experience, industry specific knowledge and general reputation and expertise allowing them to contribute as effective directors to our governance, and who would be willing to serve as directors of a public company. To date, we have not engaged any third party to assist in identifying or evaluating potential nominees. If a possible candidate is identified, the individual will meet with each member of the Board and be sounded out concerning his/her possible interest and willingness to serve, and Board members would discuss amongst themselves the individual's potential to be an effective Board member. If the discussions and evaluation are positive, the individual would be invited to serve on the Board. To date, no shareholder has presented any candidate for Board membership for consideration, and we do not have a specific policy on shareholder-recommended director candidates. The Board believes its process for evaluation of nominees proposed by shareholders would be no different than the process of evaluating any other candidate, and therefore the Board believes it is appropriate to not have a policy on shareholder-recommended director candidates. The Board of Directors does not have a policy regarding diversity in identifying nominees for director.

The experience, qualifications, attributes or skills that led the Board to conclude that the current board members should serve are: (i) their pharmaceutical industry and senior level management experience in the case of Messrs. Jones, Skelly, and Wesson; (ii) financial and senior level management expertise in the case of Mr. Ross, and (iii) their experience in overseeing management as principals of private equity firms in the case of Messrs. Wesson, and Thangaraj. Although our Certificate of Incorporation provides for a maximum of 11 directors, in accordance with the terms of a Second Amended and Restated Voting Agreement dated as of July 24, 2017 executed by us, Mr. Schutte ("Schutte"), and Essex Woodlands Health Ventures V, L.P. ("Essex"), (the "Second Amended and Restated Voting Agreement"), we have agreed that the Board of Directors shall be comprised of not more than seven members (or such greater number that is required to assure that we have a majority of independent directors after giving effect to the various designation rights described herein), one of whom shall be the designee of Schutte, one of whom shall be the designee of Essex, one of whom is our Chief Executive Officer and three of whom are independent directors. Mr. Thangaraj serves as the designee of Essex. The Second Amended and Restated Voting Agreement provides that each of Schutte's, and Essex's right to designate one director will terminate when it or its affiliates (determined separately for each of Schutte and Essex) fail to hold at least 600,000 shares of our common stock (or warrants exercisable for such shares). The Board is required to nominate an independent director upon forfeiture of a designation right. Mr. Schutte has not designated a nominee.

Compensation Committee Interlocks and Insider Participation

No member of the Compensation Committee was or currently is, an officer or employee of the Company, and no member of the Compensation Committee had any relationship with us requiring disclosure under Item 404 of SEC Regulation S-K. None of our executive officers has served on the Board of Directors or Compensation Committee of any other entity that has or had one or more executive officers who served as a member of our Board of Directors.

Separation of Roles of Chairman and CEO

Mr. Jones serves as Chief Executive Officer. Our Chairman of our Board of Directors resigned on March 11, 2013. A replacement Chairman has not been elected to date. We believe the separation of offices is beneficial because a separate chairman (i) can provide the Chief Executive Officer with guidance and feedback on his performance, (ii) provides a more effective channel for the Board to express its views on management, (iii) allows the chairman to focus on shareholder interests and corporate governance while the Chief Executive Officer leads the Company's strategy development and implementation. It is our intention to seek to add to our Board additional members having significant senior level pharmaceutical experience, and that one of such additional Board members will be entrusted by the Board to serve as Chairman.

Board's Role in Risk Assessment

The Board as a whole engages in risk oversight as part of its functions. As an emerging pharmaceutical development company we face numerous risks identified in this Annual Report on Form 10-K, many of which are outside of our control. In addition, the Audit Committee reviews our insurance coverage and the Board and Audit Committee regularly monitor our liquidity position and operating expenses and review our capital-funding needs. The Company believes the Board leadership structure effectively enables it to oversee risk management.

Shareholder Communications to the Board

Shareholders who wish to send communications to our Board of Directors may do so by sending them in care of our Secretary at Acura Pharmaceuticals, Inc., 616 N. North Court, Suite 120 Palatine, Illinois 60067. The envelope containing such communication must contain a clear notation indicating that the enclosed letter is a *"Shareholder-Board Communication"* or *"Shareholder-Director Communication"* or similar statement that clearly and unmistakably indicates the communication is intended for the Board. All such communications must clearly indicate the author as a shareholder and state whether the intended recipients are all members of the Board or just certain specified directors. Our Secretary will have the discretion to screen and not forward to Directors communications which the Secretary determines in his or her discretion are communications unrelated to our business or our governance, commercial solicitations, or communications that are offensive, obscene, or otherwise inappropriate. The Secretary will, however, compile all shareholder communications which are not forwarded and such communications will be available to any Director.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our Directors and executive officers, and persons who own beneficially more than ten percent (10%) of our common stock, to file reports of ownership and changes of ownership with the SEC. Copies of all filed reports are required to be furnished to us pursuant to Section 16(a). Based solely on the reports received by us and on written representations from reporting persons, we believe that our Directors, executive officers and greater than ten percent (10%) beneficial owners of our common stock complied with all Section 16(a) filing requirements during the year ended December 31, 2019.

Code of Ethics

Our Code of Ethics applicable to our principal executive officer, principal financial officer, principal accounting officer and all of our other employees is available on our website, www.acurapharm.com, by clicking on "Corporate Governance" under the "Investors" tab.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table and Discussion of Employment and Incentive Arrangements

The following table sets forth a summary of the compensation paid by us for services rendered in all capacities to us during each of the two fiscal years ended December 31, 2019, to our Chief Executive Officer, and the two most highly compensated executive officers other than the Chief Executive Officer who were serving as executive officers at the end of the last completed fiscal year (collectively, the "2019 named executive officers") whose total annual compensation for 2019 exceeded $100,000:

Name and Principal Position	Year	Salary[3] ($)	Bonus ($)	RSU Stock Awards[1] ($)	Stock Option Awards[2] ($)	Non-equity incentive plan compensation ($)	Total ($)
Robert B. Jones,	2019	123,000	---	---	---	---	123,000
President and CEO	2018	273,000	---	21,150	4,750	---	298,900
Peter A. Clemens	2019	164,000	---	---	---	---	164,000
SVP & CFO	2018	220,000	---	16,920	3,800	---	240,720
Albert W. Brzeczko VP, Pharmaceutical Sciences	2019	180,000	---	---	---	---	180,000
of Acura Pharmaceutical Technologies, Inc.	2018	257,000	---	14,382	13,230	---	284,612

(1) The RSU Stock Award grant date fair values are computed in accordance with FASB ASC Topic 718. The 2018 values represent (A) our last sale price of $0.1510 on 12/11/2018 less $.01 par value multiplied by (B) the number of shares underlying RSUs (150,000, 120,000 and 102,000, in the case of Messrs. Jones, Clemens and Brzeczko, respectively). There were no RSU stock awards in 2019.

(2) The Stock Option grant date fair values are computed in accordance with FASB ASC Topic 718. The 2018 values represent (A) the computed grant date fair value of the option of $0.0950 multiplied by (B) the number of underlying option shares (50,000, 40,000, and 34,000, in the case of Messrs. Jones, Clemens and Brzeczko, respectively). To calculate the 2018 grant date fair value, we considered an assumed risk free interest rate of 2.8% and a historical volatility percentage for our common stock of 76%, with an expected divided yield of 0%, an expected term of 5 years, and the option exercise price of $0.1510. There were no stock option awards in 2019.

(3) Salary of $123,000, $164,000 and $180,000 for Messrs. Jones, Clemens and Brzeczko, respectively, reflects impact of certain voluntary salary reductions enacted in 2018 and unpaid leave of absences during 2019. The current base salary is $150,000, $200,000 and $220,000 for Messrs. Jones, Clemens and Brzeczko, respectively.

Other Compensatory Arrangements

Our executive officers participate in medical, dental, life and disability insurance plans provided to all of our employees.

Bonus/Non-Equity Incentive Plan

Each of Messrs. Jones, Clemens and Brzeczko are eligible for annual bonuses. Each of Mr. Jones' and Mr. Clemens' bonuses are weighted at 100% to achievement of organizational goals, while the bonuses for other employees, including for Dr. Brzeczko are weighted 50% to the achievement of organizational goals and 50% to the achievement of individual goals. In 2019 and 2018 our cash position did not allowed us to award bonuses under our non-equity incentive compensation plan or otherwise increase salaries as reflected in the "Non-equity Incentive Compensation" column of the Summary Compensation Table.

Material organizational goals for 2020 include securing a commercial manufacturer for LTX-03, completing all clinical activities for LTX-03 and submission and acceptance by the FDA of the NDA for LTX-03 by November 30, 2020 and securing a licensing partner for other LIMITx products in development.

Material organizational goals for 2019 included completing a strategic transaction, partnership or financings to maximize value to the Company's shareholders and debt holder, advance commercial manufacturing scale-up of LTX-03, execute clinical studies for LTX-03, maintain compliance with SOX and successfully manage our intellectual property.

No compensation will be earned with respect to a performance measure unless a performance "floor" for that measure is exceeded; the incentive opportunity with respect to a measure will be earned if the target is achieved; achievement between the floor and the target results in a lower amount of award with respect to that performance measure. An amount larger than the incentive opportunity for each performance measure can be earned, up to and possibly exceeding a specified limit, for exceeding the target for that measure. Depending on market conditions and other circumstances, performance criteria may be modified during the course of the year, and other performance criteria reweighted.

In ascertaining the achieved level of performance against the targets, the effects of certain extraordinary events, as determined by the Compensation Committee, such as (i) major acquisitions and divestitures, (ii) significant one-time charges, and (iii) changes in accounting principles required by the Financial Accounting Standards Board, are "compensation neutral" for the year in which they occurred; that is, they are not taken into account in determining the degree to which the targets are met in that year.

The Compensation Committee may, after a review of an executive's performance, recommend to the Board that a bonus award be made to such executives based upon other non-enumerated performance targets (whether or not they are parties to employment agreements). This could result in the award of salary increases or bonuses above a targeted range amount.

Employment Agreements

Robert B. Jones commenced employment with us on April 7, 2008 pursuant to an Employment Agreement dated March 18, 2008 as our Senior Vice President and Chief Operating Officer. On April 28, 2011, Mr. Jones was appointed our Interim President and Chief Executive Officer. On July 7, 2011, Mr. Jones was named President and Chief Executive Officer. Mr. Jones' annual salary is $150,000 (a temporary reduction from his salary under the Employment Agreement of $393,000 because of our need to preserve cash). The term of the Employment Agreement is currently scheduled to expire December 31, 2020, and provides for automatic one year renewals in the absence of written notice to the contrary from us (which would give Mr. Jones the right to terminate his employment for Good Reason) or Mr. Jones at least ninety days prior to the expiration of the initial term or any subsequent renewal period. Pursuant to the Employment Agreement Mr. Jones is eligible for annual bonuses of up to 100% of his base salary on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. In 2018 and 2019, Mr. Jones did not receive a bonus.

On December 11, 2014, December 10, 2015, December 8, 2016, August 9, 2017 and December 11, 2018, we granted Mr. Jones stock options to purchase 50,400 shares, 70,000 shares, 47,000 shares, 47,000 shares and 50,000 shares of our common stock, respectively, in each case exercisable at the fair market value of our common stock at the date of grant and vesting in equal installments over 24 months, except that the August 9, 2017 grant vested in one installment on August 9, 2018; and the December 11, 2018 grant will vest in one installment on December 11, 2019 (in each case, subject to earlier exercisability as set forth in the table below entitled "Events Affecting Stock Option Vesting and Exercise"). "Fair market value" is the closing price for a share of the common stock on the exchange or quotation system which reports or quotes the closing prices for a share of the common stock (or alternate methodologies if no such quote is available).

On December 11, 2017 and December 11, 2018, we granted Mr. Jones 41,000 and 150,000 Restricted Stock Units exchangeable for shares of the Company's common stock on a 1-for-1 basis after payment of $.01 par value per share, respectively. The 41,000 Restricted Stock Units vested on December 11, 2018. The 150,000 Restricted Stock Units will vest on December 11, 2019 or earlier if Mr. Jones' service as an employee is terminated by us without Cause (as defined in the 2017 Restricted Stock Unit Award Plan) or due to his death or Disability (as defined in the 2017 Restricted Stock Unit Award Plan) or a qualifying change of control occurs. Distributions in respect of such vested Restricted Stock Units will be made in three equal installments, and in the case of the December 11, 2017 grant, will occur on the first business day of each of January 2020, 2021, and 2022, and in the case of the December 11, 2018 grant, will occur on the first business day of each of January 2021, 2022, and 2023, or earlier upon a qualifying change of control which also meets certain criteria of Section 409A of the Internal Revenue Code.

The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause. In the event that we terminate the Employment Agreement without Cause or Mr. Jones terminates the Employment Agreement for Good Reason, we are required to pay Mr. Jones an amount equal to the bonus for such year, calculated on a pro-rata basis assuming full achievement of the bonus criteria for such year (to the extent it has not already been paid), as well as Mr. Jones' base salary for one year (such salary amount being the "Severance Pay"). Pursuant to an amendment to Mr. Jones' Employment Agreement entered into in 2012, in case of termination without Cause and for Good Reason or for voluntary termination more than two years after a Change of Control, such Severance Pay and bonus is payable in equal monthly installments over a period of twelve months, with the first six installments payable six months and one day after termination, if mandated by applicable law, which requires certain payments to certain officers of a public company ("specified employees") to be made commencing six months after termination. However, if such termination is without Cause, for Good Reason or for voluntary termination within two years of a qualifying Change of Control, then the Severance Pay and bonus is payable in a lump sum six months and one day after termination (unless a six month delay is not required by applicable law in which case it is payable 31 days after termination). In addition, upon a termination without Cause or for Good Reason or voluntarily after a Change of Control, any shares remaining unvested under stock options and restricted stock units granted to Mr. Jones will vest in full and Mr. Jones will be entitled to continued coverage under our then-existing benefit plans, including medical and life insurance, for twelve months from the date of termination.

The Employment Agreement restricts Mr. Jones from disclosing, disseminating or using for his personal benefit or for the benefit of others, confidential or proprietary information (as defined in the Employment Agreement) and, provided we have not breached the terms of the Employment Agreement, from competing with us at any time prior to one year after the termination of his employment with us. In addition, Mr. Jones has agreed not to (and not to cause or direct any person to) hire or solicit for employment any of our employees or those of our subsidiaries or affiliates (i) for six months following the termination of his employment by us without Cause or by him for Good Reason, prior to a Change of Control, (ii) for twelve months following the termination of his employment for Cause, prior to a Change of Control, or (iii) twenty-four months following a Change of Control. The table entitled "Events Affecting Stock Option Vesting and Exercise," below, summarizes the vesting and exercisability of Mr. Jones' options following a number of termination scenarios or a Change of Control.

Peter A. Clemens is employed pursuant to an Employment Agreement effective as of March 10, 1998, as amended, which provides that Mr. Clemens will serve as our Senior Vice President and Chief Financial Officer for a term currently scheduled to expire December 31, 2020, and provides for automatic one year renewals in the absence of written notice to the contrary from the Company or Mr. Clemens at least ninety (90) days prior to the expiration of any renewal period. Pursuant to a 2008 amendment to the Employment Agreement, our non-renewal of the Employment Agreement is considered as a termination without Cause for all purposes under the Employment Agreement. Mr. Clemens' annual salary is $200,000 (a temporary reduction from his salary under the Employment Agreement of $286,000 because of our need to preserve cash). His maximum bonus under our bonus plan is 70% of base salary. Mr. Clemens' bonus is based on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors.

On December 11, 2014, December 10, 2015, December 8, 2016 August 9, 2017 and December 11, 2018 we granted Mr. Clemens options to purchase 36,000 shares, 50,000 shares, 34,000 shares, 34,000 shares and 40,000 shares of our common stock, respectively, in each case at an exercise price equal to the fair market value of our common stock at the date of grant and vesting in equal installments over 24 months, except that the August 9, 2017 grant vested in one installment on August 9, 2018; and the December 11, 2018 grant will vest in one installment on December 11, 2019 (in each case, subject to earlier exercisability as set forth in the table below entitled "Events Affecting Stock Option Vesting and Exercise"). "Fair market value" is the closing price for a share of the common stock on the exchange or quotation system which reports or quotes the closing prices for a share of the common stock (or alternate methodologies if no such quote is available).

On December 11, 2017 and December 11, 2018, we granted Mr. Clemens 28,000 and 120,000 Restricted Stock Units, respectively, exchangeable for shares of the Company's common stock on a 1-for-1 basis shares after payment of $.01 par value per share. The 28,000 Restricted Stock Units vested on December 11, 2018. The 120,000 Restricted Stock Units will vest on December 11, 2019 or earlier if Mr. Clemens' service as an employee is terminated by us without Cause (as defined in the 2017 Restricted Stock Unit Award Plan) or due to his death or Disability (as defined in the 2017 Restricted Stock Unit Award Plan) or a qualifying change of control occurs. Distributions in respect of such vested Restricted Stock Units will be made in three equal installments, and in the case of the December 11, 2017 grant, will occur on the first business day of each of January 2020, 2021, and 2022, and in the case of the December 11, 2018 grant, will occur on the first business day of each of January 2021, 2022, and 2023, or earlier upon a qualifying change of control which also meets certain criteria of Section 409A of the Internal Revenue Code.

The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause. In the event the Employment Agreement is terminated by us without Cause or by Mr. Clemens for Good Reason, we are required to pay Mr. Clemens an amount equal to twice his then base salary, payable in the case of termination without Cause or for Good Reason six months and one day after termination (unless he is not a specified employee at termination in which case payment is in a lump sum within 30 days following termination) and to continue to provide Mr. Clemens coverage under our then existing benefit plans, including medical and life insurance, for a term of 24 months. The Employment Agreement permits Mr. Clemens to terminate the Employment Agreement in the event of a Change in Control (as defined in the Employment Agreement), in which case he would receive the same payments on the same schedule as on a termination for Good Reason. In addition, Mr. Clemens' estate is entitled to six month's salary upon his death as well as a pro rata bonus for the number of months he worked in the year of his death. The Employment Agreement also restricts Mr. Clemens from disclosing, disseminating or using for his personal benefit or for the benefit of others confidential or proprietary information (as defined in the Employment Agreement) and, provided we have not breached the terms of the Employment Agreement, from competing with us at any time prior to two years after the earlier to occur of the expiration of the term and the termination of his employment. In addition, for a period of two years from and after the effective date of the termination of his employment with us (for any reason whatsoever), (i) induce or attempt to influence any employee of the Corporation or any of its subsidiaries or affiliates to leave its employ, or (ii) aid any person, business, or firm, including a supplier, a competitor, licensor or customer of or our manufacturer for the Corporation, in any attempt to hire any person who shall have been employed by us or any of our subsidiaries or affiliates within the period of one year of the date of any such requested aid. The table entitled "Events Affecting Stock Option Vesting and Exercise," below, summarizes the vesting and exercisability of Mr. Clemens' options following a number of termination scenarios or a Change of Control.

For purposes of Mr. Jones and Mr. Clemens severance pay, a Change of Control is generally defined, with certain exceptions, as

- acquisition by a person or group of more than 50% of our outstanding shares
- a merger, reorganization, consolidation of exchange, other than one in which current holders of our voting securities hold more than 50% of our voting securities
- a merger in which we are not the surviving corporation
- a sale or license of substantially all of our assets

- Acura going private (i.e. no longer files reports under the Exchange Act), unless the relevant employee (e.g., Jones, in the case of Jones' severance and Clemens in the case of Clemens' severance) "participates" in such transaction

Events Affecting Stock Option Vesting and Exercise (For Messrs. Jones and Clemens)

Event	Vesting of All Options (Options are exercisable upon vesting)	Exercisability of Options
Termination due to Death	Options vest for one month after death; after that no additional vesting	Vested options immediately exercisable for one year following termination
Termination by Company Without Cause or by Employee for Good Reason or termination by Employee following Change of Control	All options fully vest.	Vested options immediately exercisable for one year following termination Vested options exercisable for 12 months for Mr. Jones (twenty four months in the case of Mr. Clemens)
Termination due to Disability	No additional vesting	Vested options immediately exercisable for one year following termination
Termination by the Company for Cause or by executive other than for Good Reason	No additional vesting	Vested options immediately exercisable for 40 days following termination
Change of Control	Options fully vest for Mr. Jones and Mr. Clemens.	Vested options immediately exercisable

Dr. Brzeczko is not party to an employment agreement. Dr. Brzeczko was hired pursuant to an offer letter pursuant to which he received a $40,000 signing bonus and commencing 2016 and thereafter, is eligible for annual bonuses of up to 50% of his base salary (increased from 35% in effect during 2015). Dr. Brzeczko's bonus is based on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. In 2018 and 2019 he received no bonus.

Upon commencement of his employment on February 9, 2009, Dr. Brzeczko received 4,800 RSUs vesting in equal installments over 24 months, and stock options exercisable for 19,200 shares of common stock vesting in equal installments over 24 months. Dr. Brzeczko's annual salary is $220,000 (a temporary reduction from his salary of $291,000 because of our need to preserve cash). Dr. Brzeczko is eligible for and over the years of his employment, Dr. Brzeczko has received annual option grants.

On December 8, 2016 August 9, 2017 and December 11, 2018 we granted Dr. Brzeczko options to purchase 35,000 shares, 35,000 shares, 35,000 shares, and 34,000 shares of our common stock, respectively, in each case at an exercise price equal to the fair market value of our common stock at the date of grant and vesting in equal installments over 24 months, except that the August 9, 2017 grant vested in one installment on August 9, 2018; and the December 11, 2018 grant will vest in one installment on December 11, 2019 (in each case, subject to earlier exercisability as set forth in the table below entitled "Events Affecting Stock Option Vesting and Exercise"). "Fair market value" is the closing price for a share of the common stock on the exchange or quotation system which reports or quotes the closing prices for a share of the common stock (or alternate methodologies if no such quote is available).

On December 11, 2017 and December 11, 2018, we granted Dr. Brzeczko 28,000 and 102,000 Restricted Stock Units exchangeable for shares of the Company's common stock on a 1-for-1 basis after payment of $.01 par value per share, respectively. The 28,000 Restricted Stock Units vested on December 11, 2018. The 102,000 Restricted Stock Units will vest on December 11, 2019 or earlier if Dr. Brzeczko's service as an employee is terminated by us without Cause (as defined in the 2017 Restricted Stock Unit Award Plan) or due to his death or Disability (as defined in the 2017 Restricted Stock Unit Award Plan) or a qualifying change of control occurs. Distributions in respect of such vested Restricted Stock Units will be made in three equal installments, and in the case of the December 11, 2017 grant, will occur on the first business day of each of January 2020, 2021, and 2022, and in the case of the December 11, 2018 grant, will occur on the first business day of each of January 2021, 2022, and 2023, or earlier upon a qualifying change of control which also meets certain criteria of Section 409A of the Internal Revenue Code.

Stock Option Plans

We maintain two stock option plans adopted in 2008 and 2016, respectively. Our option plans are administered by the Board of Directors. The Board of Directors selects the employees, directors and consultants to be granted options under the plans and, subject to the provisions of each plan, determines the terms and conditions and number of shares subject to each option. Any of our employees or employees of our subsidiary are eligible to receive incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, or the Code ("ISOs"). Non-qualified stock options may be granted to employees as well as non-employee directors and consultants under the plans as determined by the Board. Any person who has been granted an option may, if they are otherwise eligible, be granted an additional option or options.

Each grant of an option is evidenced by an option agreement, and each option agreement specifies whether the option is an ISO or a non-qualified stock option and incorporates such other terms and conditions as the Board of Directors acting in its absolute discretion deems consistent with the terms of the plan, including, without limitation, a restriction on the number of shares of Common Stock subject to the option which first become exercisable during any calendar year.

To the extent that the aggregate fair market value of the common stock of the Company underlying a grant of ISOs (determined as of the date such an ISO is granted), which first become exercisable in any calendar year, exceeds $100,000, such Options shall be treated as non-qualified stock options. This $100,000 limitation shall be administered in accordance with the rules under Section 422(d) of the Code.

Upon the grant of an option to an employee, director or consultant the Board will fix the number of shares of common stock that the optionee may purchase upon exercise of the option and the price at which the shares may be purchased. The option exercise price for ISOs shall not be less than the fair market value of the common stock at the time the option is granted, except that the option exercise price shall be at least 110% of the fair market value where the option is granted to an employee who owns more than 10% of the voting power of all of our classes of stock or any parent or subsidiary. The option exercise price for non-qualified stock options granted under the plans may be less than the fair market value of our common stock ("Discounted Options"). "Fair market value" is the closing price for a share of the common stock on the exchange or quotation system which reports or quotes the closing prices for a share of the common stock (or alternate methodologies if no such quote is available).

All options available to be granted under each plan must be granted within ten years after shareholder approval of the applicable plan. The Board will determine the actual term of the options but no option will be exercisable after the expiration of 10 years from the date of grant. No ISO granted to an employee who owns more than 10% of the combined voting power of all of our outstanding classes of stock may be exercised after five years from the date of grant. Historically, our grants to employees generally vest 1/24th each month, although under the plans any vesting schedule is permissible as determined by the Compensation Committee or the Board. However our option grants to employees dated August 9, 2017 and December 11, 2018 vest 12 months from issuance instead of ratably over 24 months. Our grants to director generally vest in equal quarterly installments over the calendar year. Since 2015 our option agreements include vesting upon a change of control (as defined in the 2016 Stock Option Plan). In addition, the plans provide options may be accelerated by the Board of Directors in their discretion, including, upon a change of control, a proposed dissolution or liquidation of the Company, in the event of a proposed sale of all or substantially all of the assets of the Company, or a merger of the Company.

All of our option plans allow the participant to elect to exercise options on a net exercise basis by allowing shares subject to the option to be withheld by the Company in satisfaction of the option exercise price, and to satisfy the participant's withholding tax payment obligations relating to the option exercise.

Options granted to employees, directors or consultants under the plans may be exercised during the optionee's lifetime only by the optionee during his employment or service with us or for a period not exceeding one year if the optionee ceased employment or service as a director or consultant because of permanent or total disability within the meaning of Section 22(e)(3) of the Code. Options may be exercised by the optionee's estate, or by any person who acquired the right to exercise such option by bequest or inheritance from the optionee for a period of twelve months from the date of the optionee's death. If such option shall by its terms expire sooner, such option shall not be extended as a result of the optionee's death.

The 2008 Stock Option Plan

The Company's 2008 Stock Option Plan was adopted by the Board of Directors on March 14, 2008 and approved by our shareholders on April 30, 2008. The 2008 Stock Option Plan permits the grant of ISO's and non-qualified stock options to purchase up to 1,200,000 shares of our common stock. On June 25, 2009, the 2008 Stock Option Plan was amended to allow participants to require us to withhold common stock upon exercise of options for payment of exercise price and statutory minimum withholding taxes. In April 2018 the 2008 Stock Option Plan expired and the remaining 196,200 unissued shares allocated to the Plan were terminated. As of December 31, 2019, stock options to purchase 791,893 shares of common stock are outstanding under the 2008 Stock Option Plan and 48,000 options are non-qualified and 743,893 options are ISOs. The weighted average exercise price per share for all outstanding options under the 2008 Stock Option Plan as of December 31, 2019 was $7.28.

The 2016 Stock Option Plan

The Company's 2016 Stock Option Plan, as amended, was adopted by the Board of Directors and approved by our shareholders in April 2016. The 2016 Stock Option Plan permits the grant of ISO's and non-qualified stock options to purchase in the aggregate up to 600,000 shares of our common stock. As of December 31, 2019, stock options to purchase 564,356 shares of common stock are outstanding under the 2016 Stock Option Plan and all are ISOs. Up to 60,000 shares underlying options may be granted to any participant in a calendar year under the 2016 Stock Option Plan. The weighted average exercise price per share for all outstanding options under the 2016 Stock Option Plan as of December 31, 2019 was $0.47.

Restricted Stock Unit Award Plan

The 2014 Restricted Stock Unit Award Plan

The Company's 2014 Restricted Stock Unit Award Plan (the "2014 RSU Plan") was approved by the Company's Board of Directors in February 2014 and by our shareholders in May 2014. Under the 2014 RSU Plan, a Restricted Stock Unit ("RSU") represents the right to receive (upon payment of $0.01 par value per share) a share of the Company's common stock (or under certain circumstances, cash in lieu thereof ("Cash Settled RSUs")) at a designated time or upon designated events.

The maximum aggregate number of shares which may be subject to RSUs granted under the 2014 RSU Plan is 400,000 shares of authorized, but unissued or reacquired common stock. Payment of Cash Settled RSUs will reduce such limit. If an RSU should expire or become forfeited for any reason without the underlying shares of common stock or cash subject to such RSU having been distributed, the underlying shares shall, unless the 2014 RSU Plan shall have been terminated, become available for further grant under the 2014 RSU Plan. Unless terminated earlier by the Board of Directors, the RSUs may be distributed under the 2014 RSU Plan until April 30, 2024.

As of March 30, 2020 we had granted RSUs under the 2014 RSU Plan providing for our issuance of an aggregate of 400,000 shares of our common stock and there are no remaining shares available for grant. At March 30, 2020, approximately 3,156 RSU awards remain outstanding under our 2014 RSU Plan.

Because there were a limited number of shares available for issuance under the 2014 RSU Plan, our shareholders approved the 2017 Restricted Stock Unit Award Plan in November 2017. The description of the 2017 Restricted Stock Unit Award Plan, under the captions, "Terms", "Administration", "Amendment and Termination", and "Adjustment upon Capitalization and Merger", below are similar to the provisions of the 2014 RSU Plan, with the significant differences noted under such captions.

The 2017 Restricted Stock Unit Award Plan

The Company's 2017 Restricted Stock Unit Award Plan (the "2017 RSU Plan") was approved by the Company's Board of Directors on September 8, 2017 and approved by shareholders on November 8, 2017. Under the 2017 RSU Plan, a Restricted Stock Unit ("RSU") represents the right to receive (upon payment of $0.01 par value per share) a share of the Company's common stock (or under certain circumstances, cash in lieu thereof ("Cash Settled RSUs")) at a designated time or upon designated events.

Number of RSUs that may be granted. The maximum aggregate number of shares which may be subject to RSUs granted under the 2017 RSU Plan is 1,500,000 shares of authorized, but unissued, or reacquired common stock. (See "Adjustments Upon Changes in Capitalization or Merger" below.) If an RSU should expire or become forfeited for any reason without the underlying shares of common stock or cash subject to such RSU having been distributed, the underlying shares shall, unless the 2017 RSU Plan shall have been terminated, become available for further grant under the 2017 RSU Plan. The 2017 RSU Plan has no limit on the number of RSUs that may be granted to an individual employee, consultant or director in any calendar year. Payment of Cash Settled RSUs (as hereinafter defined) will reduce such limit. As of March 30, 2020 we had granted RSUs under the 2017 RSU Plan providing for our issuance of an aggregate of 1,500,000 shares of our common stock and there are no remaining shares available for grant. At March 30, 2020, approximately 839,000 awards remain outstanding under our 2017 RSU Plan.

Purpose. The 2017 RSU Plan is intended to assist the Company in securing and retaining employees, consultants and directors by allowing them to participate in the ownership and growth of the Company through the RSUs. The granting of RSUs serves as partial consideration for and gives key employees, directors and consultants an additional inducement to, remain in the service of the Company and will provide them with an increased incentive to work for the Company's success. Cash Settled RSUs give Non-Employee Directors the ability to pay tax on their other RSUs distributed simultaneously therewith. Employees have a separate right to have stock withheld in payment of withholding taxes.

Administration

The 2017 RSU Plan is administered by the Company's Board of Directors, or, except with respect to matters involving non-employee Directors ("Non-Employee Directors"), the Compensation Committee, provided it is comprised of not less than two members of the Board, each of whom must be Non-Employee Directors as that term is defined in Rule 16b-3(b)(3)(i) of the Exchange Act (the "Committee").

Powers of the Board/Committee. The Board/Committee has the authority, subject to the provisions of the 2017 RSU Plan, to establish, adopt and revise such rules, regulations and forms and agreements and to interpret the 2017 RSU Plan and make all determinations relating to the 2017 RSU Plan as it may deem necessary or advisable. The Board/Committee also has the authority, subject to the provisions of the 2017 RSU Plan, to delegate ministerial, day-to-day administrative details and non-discretionary duties and functions to officers and employees of the Company. In the administration of the 2017 RSU Plan with respect to Non-Employee Directors, the Board has all of the authority and discretion otherwise granted to the Committee with respect to the administration of the 2017 RSU Plan. All decisions, determinations and interpretations of the Board/Committee are binding and conclusive on participants in the 2017 RSU Plan and on their legal representatives and beneficiaries.

Director Participation in the RSU Plan. Non-Employee Directors are eligible to receive RSU grants under the 2017 RSU Plan, and it is expected that RSU awards under the 2017 RSU Plan will represent the annual equity compensation component of Non-Employee Directors' compensation.

RSU Plan Eligibility. RSUs may be granted to any of the Company's Non-Employee Directors, any of the Company's employees or consultants, or any employees or consultants of any of the Company's subsidiary corporations, including officers (collectively, "Eligible Participants"). For purposes of the 2017 RSU Plan employees or consultants of the Company also mean employees or consultants of the Company's subsidiary. As of March 30, 2020 all of the Company's 12 full-time employees and four Non-Employee Directors of the Company will be eligible participants ("Participants") in the 2017 RSU Plan. Any Eligible Participant who has been granted an RSU may be granted additional RSUs. The RSU Plan does not confer any rights upon any Participant with respect to continuation of employment or service as an employee, consultant or a Non-Employee Director.

Terms

RSU Award Agreement. Each RSU granted under the 2017 RSU Plan is evidenced by a written award agreement ("RSU Award Agreement"), which contains the terms and conditions of the specific RSU granted.

Vesting of RSUs. RSUs generally vest as set forth in the RSU Award Agreement. In addition, unless expressly provided otherwise in the RSU Award Agreement, each RSU immediately vests and is nonforfeitable to the Participant upon the occurrence of any of the following events:

(1) a Participant's service as an employee of the Company is terminated by the Company without Cause (as defined) or due to the Participant's death or disability (as defined), or in the case of a Non-Employee Director, upon the Participant's death or Disability or if the Participant is not renominated as a director (other than for "Cause" or refusal to stand for re-election) or is not elected by the Company's stockholders, if nominated; or

(2) a qualifying change of control, referred to as a Change in Control-Plan (as defined in the 2017 RSU Plan)

Accelerated vesting does not directly translate into accelerated distribution of shares subject to an RSU Award. For instance if the Company terminates an employee's employment without Cause, such employee's RSUs will immediately vest (unless otherwise provided in the RSU Award Agreement) but, absent a qualifying change of control the employee will not commence to receive the shares underlying his RSU award until the scheduled distribution date.

Distribution of Shares Underlying RSUs. Under the 2017 RSU Plan, (unless an award provides otherwise, vesting is accelerated as provided above under "Vesting of RSUs" or a Change of Control-Plan occurs as described below), stock underlying vested RSUs is generally distributed on the first business day of the year after they vest. Hence, if an award to a Non-Employee Director vests as scheduled in full over four quarters during 2019, it will be generally be distributed the first business day of January 2020. However, the Company may set other distribution dates, with respect to awards to Participants, including Non-Employee Directors. Under the 2014 RSU Plan Non-Employee Directors (but not other Participants) could designate the length of the deferrals. This is not the case with the 2017 RSU Plan, where only the Company can set the distribution dates for all Participants. Non-Employee-Directors may elect to take payment in cash instead of stock for up to 40% of the RSUs in an award (rendering such RSUs as "Cash Settled RSUs"). With respect to Participants for whom the Company is required to withhold taxes (generally employees) the Company may mandate such Participants or such Participants may elect that the Company withhold stock otherwise payable on exchange of an RSU to pay withholding taxes (this differs from the 2014 RSU Plan where the Company could not mandate withholding stock to pay withholding taxes). The cash payment election or withholding election may be made at any time before distribution, but any such cash payment or withholding is subject to any limits on redemption under any preferred stock, loan or other financing agreement. The Company has the option of establishing a RSU award that defers distributions to a Participant, including in installments (e.g., 25% of RSUs to be paid in 2019, 2020, 2021 and 2022). If a Change of Control-Plan which is also a Change in Control-409A occurs, all vested shares of common stock underlying an RSU (after payment or withholding of $0.01 per share par value) will be distributed by the Company to the holder of the RSU at or about the time of the Change in Control-Plan. No dividends accrue on shares of common stock underlying RSUs prior to distribution. Participants need not be employees, consultants or directors of the Company on a distribution date. A Change in Control-409A for distribution purposes is generally the same as a Change in Control-Plan for vesting purposes, except that in order to have a Change in Control-409A for distribution purposes, a change in control qualifying under Section 409A of the Code must occur. In lieu of requiring cash payment of par value, the Company may, in its discretion or shall at the Participant's request, accept payment of any such par value by withholding from stock payments a number of whole shares of stock whose value is equal to the amount of such par value, provided the same does not cause the Redemption Limit to be exceeded.

Non Transferability of RSUs. RSUs may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner by the Participant other than by will or by the laws of descent or distribution and the Committee may, in its discretion, authorize all or a portion of the RSUs to be granted to a Participant to be on terms which permit transfer by such Participant to (i) the spouse, children or grandchildren of the awardee (the "Immediate Family Members"), (ii) a trust or trusts for the exclusive benefit of such Immediate Family Members, or (iii) a partnership in which such Immediate Family Members are the only partners, provided that (x) there may be no consideration for any such transfer, (y) subsequent transfers of transferred RSUs shall be prohibited except those made by will or by the laws of descent or distribution, and (z) such transfer is approved in advance by the Committee (or Board in absence of a Committee). A married Participant may generally designate only a spouse as a beneficiary unless spousal consent is obtained.

Termination of Status as an Employee or Non-Employee Director. See "Vesting of RSUs", above for a discussion of vesting upon termination of employment or service as a Non-Employee Director.

Dividend and Voting Rights. Unless other provided in an RSU Award Agreement, Participants have no dividend rights and no voting rights with respect to the shares underlying RSUs until the RSUs settle in shares of common stock.

Amendment and Termination of the RSU Plan

The Board may terminate and, without shareholder approval, unless the same is required by the rules of the exchange where the Company's stock trades, or applicable law, amend the 2017 RSU Plan.

Adjustments upon Changes in Capitalization or Merger

Upon or in contemplation of any reclassification, recapitalization, stock split (including a stock split in the form of a stock dividend) or reverse stock split; any merger, combination, consolidation or other reorganization; any split-up; spin-off, or similar extraordinary dividend distribution with respect to the common stock (whether in the form of securities or property); any exchange of stock or other securities of the Company, or any similar, unusual or extraordinary corporate transaction with respect to the common stock; or a sale of substantially all the assets of the Company as an entirety; then the Board shall proportionately adjust any or all of (a) the number and type of shares of common stock (or other securities or property) that thereafter may be made the subject of RSUs, (b) the number, amount and type of shares of common stock (or other securities or property) payable with respect to RSUs, and (c) and the number and type of RSUs (both credited and vested) under the 2017 RSU Plan.

Outstanding Equity Awards at 2019 Year End

The following table presents information regarding outstanding restricted stock unit and stock option awards at December 31, 2019 for each of the 2019 named executive officers.

	Stock Option Awards				Stock Awards (in Form of Restricted Stock Units)	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Restricted Stock Units that have not vested (#)	Market value of shares of units of stock that have not vested ($)
Robert B. Jones					----	$ ----
	50,000	---	$ 15.10	12/15/2020		
	16,000	---	$ 18.60	12/14/2021		
	47,000	---	$ 0.450	08/08/2022		
	18,000	---	$ 13.05	12/13/2022		
	27,500	---	$ 7.75	12/11/2023		
	50,400	---	$ 2.60	12/10/2024		
	70,000	---	$ 2.01	12/09/2025		
	47,000	---	$ 0.915	12/07/2026		
	50,000	---	$ 0.151	12/11/2023		
Peter A. Clemens		---			----	$ ----
	8,000	---	$ 15.10	12/15/2020		
	7,000	---	$ 18.60	12/14/2021		
	34,000	---	$ 0.450	08/08/2022		
	10,000	---	$ 13.05	12/13/2022		
	15,000	---	$ 7.75	12/11/2023		
	36,000	---	$ 2.60	12/10/2024		
	50,000	---	$ 2.01	12/09/2025		
	34,000	---	$ 0.915	12/07/2026		
	40,000		$ 0.151	12/11/2023		
Albert W. Brzeczko		---			---	$ ----
	6,400	---	$ 15.10	12/15/2020		
	7,000	---	$ 18.60	12/14/2021		
	14,000	---	$ 13.05	12/13/2022		
	35,000	---	$ 0.450	08/08/2022		
	15,000	---	$ 7.75	12/11/2023		
	28,800	---	$ 2.60	12/10/2024		
	50,000	---	$ 2.01	12/09/2025		
	35,000	---	$ 0.915	12/07/2026		
	34,000	---	$ 0.151	12/11/2023		

Director Compensation

The following table sets forth a summary of the compensation paid by us to our Directors (other than Robert Jones, whose compensation, is reflected in the Summary Compensation Table) for services rendered in all capacities to us during the fiscal year ended December 31, 2019:

2019 DIRECTOR COMPENSATION

Director	Fees Earned or Paid in Cash ($)[4]	Stock Awards (in form of Restricted Stock Units) ($)[1]	Option Awards ($)[2]	Total ($)
William G. Skelly	$ 11,875	$ 10,833	---	$ 22,708
Bruce F. Wesson	$ 10,625	$ 10,833	---	$ 21,458
Immanuel Thangaraj	$ 6,833 (3)	$ 10,833	---	$ 17,666
George K. Ross	$ 13,125	$ 10,833	---	$ 23,958

(1) Represents the grant date fair value of restricted stock units, or RSUs with respect to the 83,333 RSUs granted to Messrs. Skelly, Wesson, Thangaraj and Ross under our 2017 RSU Plan based on a closing common stock price of $0.14 on January 2, 2019 less $0.01 par value.

In January 2019, based on a closing common stock price of $0.1147 on December 31, 2018 less $0.01 par value, Messrs. Skelly, Wesson, Thangaraj and Ross each realized approximately $6,980 by exchanging 66,666 RSUs at 0.01 par value per share received from their 2018 grant for 66,666 shares of common stock.

As of December 31, 2019, Messrs. Skelly, Wesson, Thangaraj and Ross each held 83,333 fully vested RSUs and are distributable to them on January 2, 2020.

(2) Each of Messrs. Skelly, Wesson, Thangaraj and Ross held vested options with respect to 12,000 underlying shares as of December 31, 2019.

(3) Director fees for Mr. Thangaraj are remitted to Essex Woodlands.

(4) In order to conserve cash, the directors waived their fees for the first and second quarter 2019 while reducing their fees by fifty percent beginning with the third quarter 2019.

Had the Directors not waived a portion of their cash compensation they would have received the following compensation under the reduced percentage:

- the annual retainer for each non-employee director of $15,000;
- there are no separate Board meeting fees;
- an additional retainer for the Chairman of the Board (unfilled at present) of $10,000;
- Audit Committee members receive a retainer of $3,750 per year (with no separate per meeting fee);
- Audit Committee Chairperson receives an additional annual retainer of $5,000 (in addition to the $3,750 retainer as an Audit Committee member);
- Compensation Committee members receive an annual retainer of $2,500 with no separate per meeting fee;
- Compensation Committee Chairperson receives a $2,500 annual retainer (in addition to the $2,500 retainer for Compensation Committee members); and

In addition, commencing in 2014, directors receive annual equity awards valued at $50,000 in the form of stock options or RSUs. For RSUs this is determined by dividing $50,000 by the greater of (i) the Company's closing stock price on the date of grant, or (ii) the minimum stock price or floor (if any) imposed by the Board.

- For the 2018 award, the Board decided there would be a minimum stock price of $0.75, and as a result, each director was awarded 66,666 RSUs. The Company's closing stock price on January 2, 2018 of $0.75 was not used. These awards were distributed to them on January 2, 2019.

- For the 2019 award and beyond, the Board decided the minimum stock price will be $1.00, but in each case, subject to reevaluation by them. For the 2019 award, the Board reevaluated the minimum stock price and it was changed to $0.60 resulting in each director being awarded 83,333 RSUs. The Company's closing stock price on January 2, 2019 of $0.1395 was not used.

- For the 2020 award, the Board reevaluated the minimum stock price and it was changed to $0.91 resulting in each director being awarded 54,790 RSUs. The Company's closing stock price on January 2, 2020 of $0.28 was not used.

We also reimburse directors for travel and lodging expenses, if any, incurred in connection with attendance at Board meetings. Directors who are also our employees receive no additional or special remuneration for their services as directors.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership of the common stock, as of February 15, 2020, for individuals or entities in the following categories: (i) each of the Company's Directors; (ii) the Company's principal executive officer, and the next two highest paid executive officers of the Company whose total annual compensation for 2019 exceeded $100,000 (the "2019 named executive officers"); (iii) all Directors and executive officers as a group; and (iv) each person known by the Company to be a beneficial owner of more than 5% of the common stock. Unless indicated otherwise, each of the shareholders has sole voting and investment power with respect to the shares beneficially owned. At February 15, 2020, there were 21,650,294 shares of our common stock outstanding. Shares of common stock issuable pursuant to stock options, warrants and restricted stock units exercisable or exchangeable within 60 days are deemed outstanding and held by the holder of such options warrants or restricted stock units for computing the percentage of the person holding such options, warrants or restricted stock units, but are not deemed outstanding for computing the percentage of any other person. There were no restricted stock units or common stock options exchangeable within 60 days of February 15, 2020.

Name of Beneficial Owner	Amount Owned	Percent of Class [1]
John Schutte c/o MainPointe Pharmaceuticals, LLC 333 E. Main Street, Suite 200 Louisville, KY 40202	10,695,186 [2]	45.6%
Abuse Deterrent Pharma, LLC 333 E. Main Street, Suite 220 Louisville, KY 40202	47,400,000 [3]	68.6%
Essex Woodlands Health Ventures Fund V, L.P. 21 Waterway Avenue, Suite 225 Woodlands, TX 77380	1,956,396 [4]	9.0%
Robert B. Jones	802,122 [5]	3.6%
William G. Skelly	346,867 [6]	1.6%
Bruce F. Wesson	612,926 [7]	2.8%
Peter A. Clemens	595,377 (8)	2.7%
Immanuel Thangaraj	218,525 [9]	1.0%
Albert W. Brzeczko	550,534 [10]	2.5%
George K. Ross	266,381 [11]	1.2%
All Officers and Directors as a Group (9 persons)	4,376,850[12]	19.3%

* Represents less than 1% of the outstanding shares of the Company's common stock.

(1) Shows percentage ownership assuming (i) such party converts all of its currently convertible securities or securities convertible within 60 days of February 15, 2020 into the Company's common stock, and (ii) no other Company security holder converts any of its convertible securities. No shares held by any Director or 2019 named executive officer has been pledged as collateral security.

(2) Includes warrants to purchase 1,782,531 shares held by Mr. Schutte.

(3) Includes both a warrant to purchase 10,000,000 shares at $0.01 per share and 37,500,000 shares issuable upon conversion of $6.0 million Note at $0.16 per share held by AD Pharma.

(4) Mr. Thangaraj is the Board designee of Essex Woodlands Health Ventures Fund V, L.P. ("Essex"). Essex Woodlands Health Ventures V, L.L.C., a Delaware limited liability company is the general partner of Essex. Martin P. Sutter and Immanuel Thangaraj may be deemed to have shared dispositive power and voting power with respect to the securities held by the Essex. Messrs. Sutter and Thangaraj disclaim beneficial ownership of such securities except to the extent of their respective pecuniary interests therein.

(5) Includes 375,900 shares subject to stock options exercisable within 60 days of February 15, 2020. Does not include RSUs.

(6) Includes 9,000 shares subject to stock options exercisable within 60 days of February 15, 2020. Does not include RSUs.

(7) Includes 9,000 shares subject to stock options exercisable within 60 days of February 15, 2020. Does not include RSUs.

(8) Includes 234,000 shares subject to stock options exercisable within 60 days of February 15, 2020. Does not include RSUs.

(9) Includes 9,000 shares subject to stock options exercisable within 60 days of February 15, 2020. Mr. Thangaraj's holdings do not include securities held by Essex. Mr. Thangaraj disclaims beneficial ownership in securities held by Essex except to the extent of his pecuniary interest therein. Does not include RSUs.

(10) Includes 225,200 shares subject to stock options exercisable within 60 days of February 15, 2020. Does not include RSUs.

(11) Includes 9,000 shares subject to stock options exercisable within 60 days of February 15, 2020. Does not include RSUs.

(12) Includes 1,083,734 shares which Directors and executive officers have the right to acquire within 60 days of February 15, 2020 through exercise of outstanding stock options. Does not include RSUs.

Securities Authorized For Issuance under Equity Compensation Plans

The following table includes information as of December 31, 2019 relating to our 2008 Stock Option Plan, our 2016 Stock Option Plan, our 2014 Restricted Stock Unit Award Plan, and our 2017 Restricted Stock Award Plan, which comprise all of our equity compensation plans. The table provides the number of securities to be issued upon the exercise of outstanding options and distributions under outstanding Restricted Stock Unit Awards under such plans, the weighted-average exercise price of outstanding options and the number of securities remaining available for future issuance under such equity compensation plans:

Plan Category	Number Of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (Column a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (Column b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column a (Column c)
Stock Option Equity Compensation Plans Approved by Security Holders	1,356,251	$ 4.45	34,478
Stock Option Equity Compensation Plans Not Approved by Security Holders	---	---	---
Restricted Stock Unit Equity Compensation Plans Approved by Security Holders	1,017,333	$ 0.01	---
Restricted Stock Unit Equity Compensation Plans Not Approved by Security Holders	---	---	---
TOTAL	2,373,584	$ 2.55	34,478

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

Certain Relationships and Related Transactions

The Company and certain investors are party to a Voting Agreement. As amended in October 2012 (but prior to the 2017 amendment), the Voting Agreement provided our Board of Directors will be comprised of not more than seven (7) members one of whom shall be the CEO, three of whom would be independent under Nasdaq standards, and that Essex had the right to designate one director as a member of our Board of Directors as long as such shareholder held 600,000 shares of our common stock (including warrants to purchase shares), provided that once such shareholder no longer held such securities, the additional forfeited seat would become a seat for an independent director to thereafter be nominated and elected 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 Company's shareholders at the next annual meeting. The Voting Agreement provided that if the majority of the Board of Directors were not independent under Nasdaq Marketplace Rules then, the Board would be expanded so that additional independent directors would be added. At the time of the October 2012 amendment, Mr. Thangaraj became the designee of Essex, as one of three remaining successors to GCE Holdings, LLC (an entity controlled by others including Essex). In addition, Essex has the right to designate a member to any committee of our Board of Directors, provided that in the case of the Audit and Compensation committees they are independent under applicable NASDAQ rules.

Mr. Schutte is chief executive officer and owner of MainPointe Pharmaceuticals, LLC. ("MainPointe"), a Kentucky limited liability company. In March 2017, prior to Mr. Schutte becoming a shareholder, we entered into a License, Commercialization and Option Agreement (the "MainPointe Agreement") with MainPointe to commercialize Nexafed® and Nexafed® Sinus Pressure + Pain in the United States and Canada. Nexafed® and Nexafed® Sinus Pressure + Pain utilize our Impede Technology and were previously marketed by us in the United States. Our Impede Technology is directed at minimizing the extraction and conversion of pseudoephedrine, or PSE, into methamphetamine. Under the terms of the Agreement we transferred existing inventory and equipment relating to such products to MainPointe and licensed our Impede Technology intellectual property rights to MainPointe for such products as well as certain future PSE-containing products. MainPointe is responsible for all development, manufacturing and commercialization activities with respect to products covered by the Agreement.

On signing, MainPointe paid us an upfront licensing fee of $2.5 million plus approximately $425,000 for inventory and equipment being transferred. We will receive a 7.5% royalty on 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 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, $500,000 and $250,000, respectively. In addition, MainPointe has the option to add to the Agreement certain additional products, or Option Products, containing PSE and utilizing the Impede Technology for a fee of $500,000 per product (for all such product strengths). If the territory has been expanded prior to the exercise of a product option, the option fee will be increased to $750,000 per product. If the territory is expanded after the payment of the $500,000 product option fee, a one-time $250,000 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 July 24, 2017 we completed the sale to Mr. Schutte of 8,912,655 shares and warrants to purchase 1,782,531 shares exercisable at $0.528 per share and expiring in July 23, 2022 for $4 million and amended the Voting Agreement described above (as so amended the “Second Amended and Restated Voting Agreement”) in connection with that purchase. The Second Amended and Restated Voting Agreement provides that our Board of Directors will be comprised of not more than seven (7) members, one of whom shall be the CEO, three of whom would be independent under Nasdaq standards, and that each of Mr. Schutte and Essex had the right to designate one director as a member of our Board of Directors as long as such shareholder continues to hold 600,000 shares of our common stock (including warrants to purchase shares), provided that 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. The Second Amended and Restated Voting Agreement provides that in the event the majority of the Board of Directors were not independent under Nasdaq Marketplace Rules then, the Board would be expanded so that additional independent directors would be added. In addition, each of Essex and Mr. Schutte has the right to designate a member to any committee of our Board of Directors, provided that in the case of the Audit and Compensation committees they are independent under applicable NASDAQ rules.

We borrowed an aggregate $6.0 million (including accrued interest) as of June 28, 2019 from Mr. Schutte, a related-party, and issued various promissory notes (the Schutte Notes). The Schutte Notes bear interest at prime plus 2.0%, and mature on January 2, 2020, at which time all principal and interest is due, and was 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. On October 5, 2018 we borrowed $1.8 million from Mr. Schutte and used $1.5 million of the loan to fully pay-off the debt outstanding under the Oxford Loan Agreement and therefore, all our assets are pledged as collateral under the Schutte Notes, 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 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 instead of January 2, 2020 in the previous notes, 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 shares.

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.

On June 28, 2019, we entered into License, Development and Commercialization Agreement (the "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 and completion of development of LTX-03. Mr. Schutte is an investor in AD Pharma.

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 the earlier of November 30, 2020 or FDA’s acceptance of a New Drug Application (“NDA”) for LTX-03 and reimbursement by AP Pharma of Acura’s LTX-03 outside development expenses. Upon commercialization of LTX-03, Acura is eligible to receive stepped royalties on sales and certain sales related milestones.

AD Pharma may terminate the Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by November 30, 2020, 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.

Our Board has not adopted formalized written policies and procedures for the review or approval of related party transactions. As a matter of practice, however, our Board has required that all related party transactions, be subject to review and approval by a committee of independent directors established by the Board. The Board's practice is to evaluate whether a related party (including a director, officer, employee, Essex or other significant shareholder) will have a direct or indirect interest in a transaction in which we may be a party. Where the Board determines that such proposed transaction involves a related party, the Board may establish a committee comprised solely of independent directors to review and evaluate such proposed transaction. Currently, the Board is comprised of 4 independent directors and the CEO and as such, the entire Board, with the exception of the CEO, may perform the function of an Independent Committee. In this capacity, the 4 independent directors are authorized to review any and all information deemed necessary and appropriate to evaluate the fairness of the transaction to us and our shareholders (other than the interested related party to such transaction), including meeting with management, retaining third- party experts (including counsel and financial advisors if determined necessary) and evaluating alternative transactions, if any. They are also empowered to negotiate the terms of such proposed related party transaction on our behalf. The proposed related party transaction may proceed only following the approval and recommendation of the 4 independent directors. Following such approval, the related party transaction is subject to final review and approval of the Board as a whole. As the transactions described above with Abuse Deterrent Pharma LLC and Mr. Schutte involved a related party (Mr. Schutte being a significant shareholder at the time such transactions were entered into), such transactions were reviewed and approved solely by the Board as a whole.

Director Independence

In assessing the independence of our Board members, our Board has reviewed and analyzed the standards for independence required under the NASDAQ Capital Market, including NASDAQ Marketplace Rule 5605 and applicable SEC regulations. Based on this analysis, our Board has determined that during 2019, each of Messrs. Bruce F. Wesson, Immanuel Thangaraj, William Skelly and George Ross met the standards for independence provided in the listing requirements of the NASDAQ Capital Market and SEC regulations.

Our Board has determined that during 2019 with respect to our Compensation Committee that Messrs. Skelly, Wesson, and Thangaraj meet the standards for independence described above and that Messrs. Skelly, Wesson and Thangaraj meet the additional independence standards of NASDAQ Rule 5605 relating to Compensation Committees.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our registered independent public accounting firm is BDO USA, LLP. The fees billed by this firm in 2019 and 2018 were as follows:

	2019	2018
Audit Fees	$ 150,486	$ 145,989
Audit-Related Fees	-	-
Total Audit and Audit-Related Fees	150,486	145,989
Tax Fees	39,200	39,200
All Other Fees	-	-
Total for BDO USA, LLP	$ 189,686	$ 185,189

Audit Fees include professional services rendered in connection with the annual audit of our financial statements, and the review of the financial statements included in our Form 10-Qs for the related periods. Additionally, Audit Fees include other services that only an independent registered public accounting firm can reasonably provide, such as services associated with our SEC registration statements or other documents filed with the SEC or used in connection with financing activities. We had no Audit-Related Fees which would include accounting consultations related to accounting, financial reporting or disclosure matters not classified as Audit Fees. Tax Fees include tax compliance, tax advice and tax planning services. These services related to the preparation of various state income tax returns, our federal income tax return, and reviews of IRC Section 382.

Audit Committee's Pre-Approval Policies and Procedures

Consistent with policies of the SEC regarding auditor independence and the Audit Committee Charter, the Audit Committee has the responsibility for appointing, setting compensation and overseeing the work of the registered independent public accounting firm (the "Firm"). The Audit Committee's policy is to pre-approve all audit and permissible non-audit services provided by the Firm. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The Audit Committee may also pre-approve particular services on a case-by-case basis. In assessing requests for services by the Firm, the Audit Committee considers whether such services are consistent with the Firm's independence, whether the Firm is likely to provide the most effective and efficient service based upon their familiarity with the Company, and whether the service could enhance the Company's ability to manage or control risk or improve audit quality.

All of the tax services provided by BDO USA, LLP in 2019 and 2018 and related fees (as described in the captions above) were approved in advance by the Audit Committee.

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 30, 2020

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 30, 2020
/s/Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2020
/s/ George K. Ross George K. Ross	Director	March 30, 2020
/s/ William G. Skelly William G. Skelly	Director	March 30, 2020
/s/ Immanuel Thangaraj Immanuel Thangaraj	Director	March 30, 2020
/s/ Bruce F Wesson Bruce F. Wesson	Director	March 30, 2020

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).
†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.
10.51 *	Common Stock Warrant issued June 28, 2019 to John Schutte.
10.52 *	Assignment of Promissory Note, Warrant and Security Agreement issued June 28, 2019 by John Schutte to 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, 2019 and 2018, the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, 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, 2019 and 2018, and the results of its operations and its cash flows for the years then ended**,** 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 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.

/s/ BDO USA, LLP

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

Chicago, Illinois

March 30, 2020

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2019 and 2018
(in thousands except par value)

	2019	2018
Assets:		
Cash	$ 862	$ 91
Royalty receivable	82	137
Collaboration revenue receivable from related party	78	-
Prepaid expenses and other current assets	122	166
Income tax receivable	34	67
Total current assets	1,178	461
Income tax receivable	34	68
Property, plant and equipment, net (Note 5)	540	606
Intangible asset, net of accumulated amortization of $1,190 and $983 (Note 3)	810	1,017
Total assets	$ 2,562	$ 2,152
Liabilities:		
Accounts payable	$ 237	$ 605
Accrued expenses (Note 6)	585	596
Other current liabilities (Note 11)	29	11
Sales returns liability	223	223
Total current liabilities	1,074	1,435
Convertible debt to related party, net of discounts (Note 7)	6,000	4,224
Accrued interest to related party (Note 7)	229	110
Total liabilities	$ 7,303	$ 5,769
Commitments and contingencies (Note 14)		
Stockholders' deficit:		
Common stock - $0.01 par value per share; 100,000 shares authorized, 21,300 and 21,034 shares issued and outstanding at December 31, 2019 and 2018, respectively	213	210
Additional paid-in capital	383,042	380,395
Accumulated deficit	(387,996)	(384,222)
Total stockholders' deficit	(4,741)	(3,617)
Total liabilities and stockholders' deficit	$ 2,562	$ 2,152

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2019 and 2018
(in thousands except per share amounts)

	2019	2018
Revenues:		
Royalties	$ 372	$ 410
Collaboration	185	-
License fees	2,100	-
Total revenues	2,657	410
Operating expenses:		
Research and development	1,505	1,759
General and administrative	1,877	2,566
Total operating expenses	3,382	4,325
Operating loss	(725)	(3,915)
(Loss) gain on debt extinguishment (Note 7)	(2,600)	296
Interest expense, net (Note 7)	(449)	(223)
Loss before provision for income taxes	(3,774)	(3,842)
Provision for income taxes	-	-
Net loss	$ (3,774)	$ (3,842)
Net loss per share (Note 13):		
Basic	$ (0.14)	$ (0.18)
Diluted	$ (0.14)	$ (0.18)
Weighted average number of shares outstanding:		
Basic	26,720	21,146
Diluted	26,720	21,146

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
YEARS ENDED DECEMBER 31, 2019 and 2018
(in thousands)

	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)

	Common Stock				
	Number of Shares	Par Value	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2018	20,796	$ 208	$ 380,145	$ (380,380)	$ (27)
Net loss	-	-	-	(3,842)	(3,842)
Non-cash share-based compensation	-	-	218	-	218
Net distribution of common stock pursuant to restricted stock unit award plan	238	2	32	-	34
Balance at December 31, 2018	21,034	210	380,395	$ (384,222)	$ (3,617)

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2019 and 2018
(in thousands)

	2019	2018
Cash Flows from Operating Activities:		
Net loss	$ (3,774)	$ (3,842)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	66	73
Non-cash share-based compensation	108	218
Capitalized debt discount	(13)	(172)
Amortization of debt discount and deferred debt issue costs	66	87
Amortization of intangible asset	207	207
Loss (gain) on debt extinguishment	2,600	(296)
Loss on disposals of property, plant and equipment	1	-
Changes in assets and liabilities:		
Royalty receivable	55	(66)
Collaboration revenue receivable from related party	(78)	-
Prepaid expenses and other current assets	44	109
Income tax receivable	67	-
Accounts payable	(368)	602
Accrued expenses	(11)	(343)
Accrued interest on loan	-	(566)
Accrued interest on related party loans	394	110
Other current liabilities	18	2
Sales returns liability	-	(31)
Net cash used in operating activities	(618)	(3,908)
Cash Flows from Financing Activities:		
Proceeds from distribution of restricted stock units	14	2
Proceeds from related party loans	1,375	4,350
Principal payments loan	-	(2,573)
Net cash provided by financing activities	1,389	1,779
Net increase (decrease) in cash	771	(2,129)
Cash at beginning of year	91	2,220
Cash at end of year	$ 862	$ 91
Supplemental Disclosures of Cash Flow Information:		
Cash interest payments on loan	$ -	$ 759

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
YEARS ENDED DECEMBER 31, 2019 and 2018

Supplemental disclosures of noncash 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.

Year Ended December 31, 2018

1. The imputed interest on the below market rate element of the related party loans aggregating $4,350 made to the Company, amounted to $172, and was recorded in interest income with a corresponding like amount recorded as debt discount against the principal amount of the loan.

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 Zyla Life Sciences or Zyla (formerly known 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).

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, 2019, we had cash of $862 thousand, working capital of $104 thousand and an accumulated deficit of $388 million. We had a loss from operations of $725 thousand and a net loss of $3.8 million for the year ended December 31, 2019. 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 with Abuse Deterrent Pharma, LLC ("AD Pharma"), a License, Development and Commercialization Agreement (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, the required monthly license payments by AD Pharma will only continue until November 2020 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. Should AD Pharma exercise their right to terminate the AD Pharma Agreement, we would 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.

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.

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 and cash equivalents, royalty receivables and collaboration revenue 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, royalties and collaboration 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 loan at December 31, 2019 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 non-cash and cash-portioned instruments issued to our employees and directors comprised the following (in thousands):

	Year Ended December 31,	
	2019	**2018**
Research and development expense:		
Stock option awards	$ 8	$ 38
RSU awards	13	27
	$ 21	$ 65
General and administrative expense:		
Stock option awards	12	61
RSU awards	105	104
	$ 117	$ 165
Total share-based compensation expense	$ 138	$ 230

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. We had no impairment charges during the years 2019 or 2018.

License Fee Revenue

On signing the AD Pharma Agreement in June 2019, Acura will receive a monthly license payment of $350 thousand by AD Pharma for 18 months until November 2020. The first license payment was received July 2, 2019. If the NDA filing for LTX-03 is not accepted by the FDA by November 30, 2020, 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 license fee payments are non-refundable and non-creditable when made by AD Pharma and we had no further requirements to earn the payment. The license payment amount is recognized as revenue when received (See Note 3). During 2019 we recognized $2.1 million of license fee revenue from AD Pharma.

Collaboration Revenue

Collaboration revenue is derived from reimbursement of development expenses, such as under our 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 agreements. We recognized $185 thousand of collaboration revenue during the year 2019. We did not have collaboration revenue during the year 2018.

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 Zyla 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 Zyla in accordance with the agreement. Zyla’s first commercial sale of Oxaydo occurred in October 2015 and we have recorded royalties of $351 thousand and $386 thousand on net sales for the years 2019 and 2018, respectively (See Note 3).

In connection with the MainPointe Agreement, which occurred on March 16, 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 $21 thousand and $24 thousand for the years 2019 and 2018 (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 at December 31, 2018. On June 28, 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. During the years ended 2019 and 2018, we recognized interest expense from the amortization of debt issuance costs and debt discount of $66 thousand and $87 thousand, respectively.

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, 2019 and 2018.

In connection with our development and scale-up of LTX-03 under the AD Pharma Agreement (See Note 3) we entered into obligations under non-cancelable arrangements at December 31, 2019 aggregating $502 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, 2019 and 2018, 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.

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 12) and a stock warrant exercisable for 10.0 million shares having an exercise price of $0.01 per share (See Note 8). Diluted EPS is based on the treasury stock method and computed based on the same number of shares used in the basic share calculation and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and stock warrants, assuming the exercise of all in-the-money stock options and warrants. Common stock equivalents are excluded from the computation where their inclusion would be anti-dilutive. As the Company reported a net loss in 2019 and 2018 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.

Customer Concentration

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

In June 2019 we signed a license, development and commercialization agreement with AD Pharma. Acura will receive a monthly license payment of $350 thousand by AD Pharma for 18 months until November 2020. The first license payment was received July 2, 2019. If the NDA filing for LTX-03 is not accepted by the FDA by November 30, 2020, 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. AD Pharma does have the right to terminate the agreement anytime for "convenience on 30 days prior written notice" and the license fee payments will stop. 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.

Recent Accounting Pronouncements

New accounting standards which have been adopted on or before December 31, 2019

Collaborative Arrangements

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements* (ASC 808): Clarifying the Interaction between ASC 808 and ASC 606, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements. This ASU adds unit-of-account guidance in ASC 808 to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606, and requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under ASC 606 is precluded if the collaborative arrangement participant is not a customer. The Company early adopted ASC 808 which was to be effective for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. The Company early adopted ASC 808 during third quarter 2019. The adoption of ASC 808 did not have an impact on the Company's financial statements.

Leases

In February 2016, the FASB issued ASU 2016-02, *Leases* (ASC 842), which establishes a comprehensive new lease accounting model. The new standard will require most leases (with the exception of leases with terms of one year or less) to be recognized on the balance sheet as a lease liability with a corresponding right-of-use asset. Leases will be classified as an operating lease or a financing lease. The classification of the lease will affect the pattern of expense recognition in the income statement such that operating leases are expensed using the straight-line method whereas financing leases will be treated similarly to a capital lease under the current standard. The standard also requires disclosures to help investors and other financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. In July 2018, the FASB issued ASU No. 2018-10, "Codification Improvements to Topic 842, Leases" (ASU 2018-10), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, "Leases (Topic 842)-Targeted Improvements" (ASU 2018-11), which addressed implementation issues related to the new lease standard. These and certain other lease-related ASUs have generally been codified in ASC 842. ASC 842 supersedes the lease accounting requirements in Accounting Standards Codification Topic 840, Leases (ASC 840).

The Company adopted ASC 842 using the modified retrospective transition approach during Q1 2019, which allows the Company to not adjust the comparative periods presented. The Company has elected to adopt the package of transition practical expedients and, therefore, has not reassessed whether existing or expired contracts contain a lease or the lease classification for existing or expired. The Company did not elect the practical expedient to use hindsight for leases existing at the adoption date. Upon adoption, operating leases would be reported on the balance sheet as a gross-up of assets and liabilities, however the Company has elected, as an accounting policy, to not recognize ROU assets and lease liabilities for all short-term leases that have a lease term of 12 months or less. The adoption of ASC 842 did not have an impact on the Company's financial statements as the Company has no leases with a term of more than 12 months.

New accounting standards which have not yet been adopted on or before December 31, 2019

Fair Value Measurements

In August 2018, the FASB issued 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 is currently evaluating the impact that the standard will have on the financial statements and related footnote disclosures.

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.

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 with Abuse Deterrent Pharma, LLC ("AD Pharma"), a License, Development and Commercialization Agreement (the "AD Pharma Agreement"), 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 for 18 months until November 2020. 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 November 30, 2020, 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.

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. The Option Product exercise price of $500 thousand is waived if the exercise of the option occurs by June 28, 2024 (five years from the effective date of the AD Pharma Agreement).

On June 28, 2019 Mr. John Schutte assigned and transferred to AD Pharma his $6.0 million promissory note, 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. (See Note 8). Mr. Schutte is our largest shareholder and directly owns approximately 47.5% 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.

Zyla 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. The recoverability of the Aversion intangible asset is contingent upon future Zyla royalty revenues to us. We have recorded amortization expense of $207 thousand in each of the years ended December 31, 2019 and 2018. Annual amortization of the patent for its remaining life is expected to approximate $207 thousand per year.

In January 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation (now known as Zyla Life Sciences), or collectively Zyla, entered into a Collaboration and License Agreement (the "Zyla 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 Zyla Agreement, we transferred the approved New Drug Application, or NDA, for Oxaydo to Zyla and Zyla 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 Zyla Agreement Zyla is responsible for the fees and expenses relating to the product line extensions of Oxaydo, provided that Zyla 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. Zyla will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States. Zyla is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Zyla will have final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Zyla may develop Oxaydo for other countries and in additional strengths, in its discretion.

Zyla paid us a $5.0 million license fee upon signing of the Zyla 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 Zyla 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. Zyla'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 Zyla to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

The Zyla Agreement expires upon the expiration of Zyla's royalty payment obligations in all countries. Either party may terminate the Zyla Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Zyla 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 Zyla Agreement with respect to the U.S. and other countries if Zyla materially breaches its commercialization obligations. Zyla may terminate the Zyla Agreement for convenience on 120 days prior written notice, which termination may not occur prior to the second anniversary of Zyla'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 Zyla Agreement provides for the transition of development and marketing of Oxaydo from Zyla to us, including the conveyance by Zyla to us of the trademarks and all regulatory filings and approvals relating to Oxaydo, and for Zyla'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. The Option Product exercise price of $500 thousand is waived if the exercise of the option occurs by June 28, 2024 (five years from the effective date of the AD Pharma Agreement).

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.

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, 2019 or 2018.

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.

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 Zyla 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 for the development and license of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura's patented LIMITx™ having a monthly license payment of $350 thousand from AD Pharma to us for a period of up to 18 months until November 2020. AD Pharma will pay directly for or reimburse Acura to the extent Acura pay's for, all out-of-pocket development expenses. The first license payment was received July 2, 2019.

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

Royalty revenues by licensee are summarized below:

	For the Year Ended December 31,	
	2019	**2018**
	(in thousands)	
Zyla (Oxaydo)	$ 351	$ 386
MainPointe (Nexafed)	21	24
Royalty revenues	$ 372	$ 410

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, 2019 or 2018. 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,	
	2019	**2018**
Building and improvements	$ 1,273	$ 1,273
Scientific equipment	597	598
Computer hardware and software	106	107
Machinery and equipment	274	275
Land and improvements	162	162
Other personal property	70	70
Office equipment	27	27
	2,509	2,512
Less: accumulated depreciation	(1,969)	(1,906)
Total property, plant and equipment, net	$ 540	$ 606

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 $66 thousand and $73 thousand for each of the years ended December 31, 2019 and 2018, respectively.

NOTE 6 – ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	December 31, 2019	2018
Cost sharing expenses under license agreements	$ 363	$ 237
Other fees and services	15	36
Payroll, payroll taxes and benefits	13	6
Professional services	151	132
Financed premiums on insurance policies	-	102
Clinical, non-clinical and regulatory services	20	63
Property taxes	9	7
Franchise taxes	14	13
Total	$ 585	$ 596

NOTE 7 – DEBT

Fully Paid Loan

In December 2013, we entered into a Loan and Security Agreement (the "Oxford Loan Agreement") with Oxford Finance LLC ("Oxford" or the "Lender"), for a term loan to the Company in the principal amount of $10.0 million (the "Term Loan"). The Oxford Term Loan accrued interest at a fixed rate of 8.35% per annum (with a default rate of 13.35% per annum). The Company was required to make monthly interest−only payments until April 1, 2015 ("Amortization Date") and beginning on the Amortization Date, the Company began to make payments of principal and accrued interest in equal monthly installments of $260 thousand, sufficient to amortize the Term Loan through the maturity date of December 1, 2018. All unpaid principal and accrued and unpaid interest with respect to the Term Loan was due and payable in full on December 1, 2018. As security for its obligations under the initial Oxford Loan Agreement (prior to the Third Amendment), the Company granted the Lender a security interest in substantially all of its existing and after−acquired assets, exclusive of its intellectual property assets. Upon the execution of the Oxford Loan Agreement, we issued to the Lender warrants to purchase an aggregate of up to 60 thousand shares of our common stock at an exercise price equal to $7.98 per share (after adjustment for our one-for-five reverse stock split) (the "Warrants"). We recorded $400 thousand as debt discount associated with the relative fair value of the Warrants and amortized it to interest expense over the term of the loan using the loan's effective interest rate. The Warrants were immediately exercisable for cash or by net exercise and will expire December 27, 2020.

In January 2015, we and Oxford amended the Oxford Loan Agreement providing for the exercise price of the Warrants to be lowered from $7.98 to $2.52 per share (the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the amendment and after giving effect to our one-for-five reverse stock split) and we recorded additional debt discount of $33 thousand representing the fair value of the Warrant modification.

The Company was obligated to pay customary lender fees and expenses, including a one-time facility fee of $50 thousand and the Lender's expenses, in connection with the Oxford Loan Agreement. Combined with the Company's own expenses and a $100 thousand consulting placement fee, the Company incurred a total $231 thousand in deferred debt issue costs. We amortized these costs, including debt modification additional costs, into interest expense over the term of the Term Loan using the loan's effective interest rate of 10.16%.

In October 2018 we borrowed $1.8 million from Mr. Schutte and used loan proceeds to negotiate, settle and pay-off in full the Oxford Loan for $1.5 million. We recognized a net gain from debt settlement of $296 thousand on principal and interest which has been reflected in our statement of operations as non-operating income. All security interests of Oxford with respect to the Oxford Term Loan have been released.

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 promissory note, 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 events of default under the $6.0 million note are limited to bankruptcy defaults, failure to pay interest and principal when due on July 1, 2023 or upon failure to meet certain timelines as defined in the agreement. The $6.0 million note may be prepaid at any time in whole or in part but only with the consent of the noteholder.

Our debt interest expense for the twelve months ended December 31, 2019 and 2018 consisted of the following (in thousands):

Interest expense:	Year Ended December 31, 2019	2018
Fully paid term loan	$ -	$ 194
Related party term loans	392	110
Debt discount	66	74
Debt issue costs	-	13
Financed insurance premiums	4	4
Total interest expense	$ 462	$ 395
Less: imputed interest income on related party loans	(13)	(172)
Total interest expense, net	$ 449	$ 223

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. The Transaction was completed through a private placement to an accredited investor and was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended and/or Regulation D promulgated under the Securities Act of 1933.

MainPointe Pharmaceuticals LLC

Investor is a principal 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 years ended 2019 and 2018 is $21 thousand and $24 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.

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.

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 promissory note, 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 (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. Financial arrangements include:

- Monthly license payments to Acura by AD Pharma of $350 thousand up to the earlier of 18 months 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;
- Upon commercialization of LTX-03, Acura receives stepped royalties on sales and is eligible for certain sales related milestones; and
- Acura authorizes 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).

AD Pharma may terminate the AD Pharma Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by November 30, 2020, 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.

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). 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 years 2019 or 2018.

NOTE 10 – COMMON STOCK PURCHASE WARRANTS

Our warrant activity during the years ended December 31, 2019 and 2018 is shown below (in thousands except price data):

	December 31,			
	2019		2018	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, Jan. 1	1,842	$ 0.59	1,842	$ 0.59
Issued	10,000	0.01	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Modification	-	-	-	-
Outstanding, Dec. 31	11,842	$ 0.10	1,842	$ 0.59

In connection with the issuance of the $10.0 million secured promissory notes in December 2013, we issued common stock purchase warrants (“warrants”) exercisable for 60 thousand shares of our common stock having an exercise price of $2.52 per share (after giving effect to our one-for-five reverse stock split) with an expiration date in December 2020. These warrants contain a cashless exercise feature (See Note 7).

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 8). 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.

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 7 and Note 8). The warrant was assigned and transferred by Mr. Schutte to AD Pharma on June 28, 2019.

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, 2019 and 2018 and for the year then ended consisted of the following (in thousands except exercise price):

	Year Ended December 31,			
	2019		2018	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, Jan. 1	1,560	$ 7.38	1,494	$ 12.33
Granted	-	-	232	0.15
Exercised	-	-	-	-
Forfeited	(34)	4.09	(3)	0.56
Expired	(170)	30.83	(163)	42.75
Outstanding, Dec. 31	1,356	$ 4.45	1,560	$ 7.38
Exercisable, Dec. 31	1,356	$ 4.45	1,328	$ 8.64

The following table summarizes information about unvested stock options outstanding at December 31, 2019 (in thousands except price data):

	Number of Options Not Exercisable	Weighted Average Fair Value
Outstanding at Jan. 1, 2019	232	$ 0.10
Granted	-	-
Vested	(223)	0.10
Forfeited	(9)	0.10
Outstanding at Dec. 31, 2019	-	$ -

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

The assumptions used in the Black-Scholes model to determine fair value for the 2018 stock option grants were:

Expected dividend yield	0.0%
Risk-free interest rates	2.8%
Average expected volatility	76%
Expected term (years)	5
Weighted average grant date fair value	$ 0.10

There was no intrinsic value contained in the stock option awards which vested and were outstanding at December 31, 2019. The total remaining unrecognized compensation cost on unvested option awards outstanding at December 31, 2019 was approximately $20 thousand, and is expected to be recognized in the Company's operating expense in varying amounts over the next eleven months remaining in the requisite service period.

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 recorded as a liability in the Company's consolidated balance sheet as they vest and being marked-to-market each reporting period until they are distributed. The liability was $29 thousand and $11 thousand at December 31, 2019 and 2018, 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, 2019 and 2018, and for the year then ended consisted of the following (in thousands):

	Year Ended December 31,			
	2019		2018	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, Jan. 1	951	459	462	262
Granted	333	-	759	-
Distributed	(267)	(267)	(262)	(262)
Vested	-	825	-	459
Forfeited	-	-	(8)	-
Outstanding, Dec. 31	1,017	1,017	951	459

2017 Restricted Stock Unit Award Plan

Our 2017 RSU Plan was approved by shareholders in November 2017 and permits the grant of up to 1.5 million shares of our common stock pursuant to awards under the 2017 RSU Plan. As of December 31, 2019, approximately 219 thousand shares are 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 will vest 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 will occur 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 will vest 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, 61 thousand RSUs were distributed to our employee representing one third of their 2017 award with 51 thousand RSUs settled in common stock and 10 thousand RSUs used to settle the purchase price and employee 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. As of December 31, 2019, there are no longer shares available for award under the 2014 RSU Plan.

Information about the awards under the 2014 RSU Plan during 2018 and 2019 is as follows:

- In January 2017, we awarded approximately 60 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 2017. The portion of the RSU awards which are subject to cash settlement are also subject to marked-to market accounting and the liability recorded in the Company's consolidated balance sheet as an estimate for such cash settlement was $41 thousand at December 31, 2017. The RSU award was settled on January 2, 2018.
- In December 2018, we awarded 4 thousand RSUs to our employees. Such RSU awards will vest 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.

Information about the distribution of shares under the 2014 RSU Plan is as follows:

- In January 2017, 1 thousand RSUs from the May 2014 award and 66 thousand RSUs from the January 2016 award were distributed. There were 1 thousand RSUs from the May 1 2014 award and 22 thousand RSUs from the January 2016 award which remained deferred until a future distribution date, which occurred on January 1, 2018. Of the 67 thousand RSUs distributed, 49 thousand RSUs were settled in common stock and 18 thousand RSUs were settled in cash.
- In January 2018, 262 thousand RSUs from the 2014 RSU Plan were distributed. Of the approximately 262 thousand RSUs distributed, 238 thousand RSUs were settled in common stock and 24 thousand RSUs were settled in cash.

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.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Act") was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017 and requiring adjustment to 2017 deferred taxes. The Company has calculated its best estimate of the impact of the Act in its 2017 year-end income tax provision in accordance with its understanding of the Act and guidance available as of that date and as a result had no adjustment to record as an additional income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of US GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In accordance with SAB 118, the Company remeasured its deferred tax assets and liabilities and adjusted its deferred tax balances to reflect the lower enacted U.S. corporate tax rate resulted in an income tax expense of $26.6 million which was included as a discrete item in the 2017 income tax provision. Overall, there was no impact to the 2017 tax provision as a result of the offsetting reduction of the valuation allowance. The period for determination of accounting implications of the 2017 Tax Act closed on December 22, 2018. The Company has completed their analysis and did not have any material true-ups on the positions taken in the 2017 tax provision.

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,	
	2019	**2018**
Benefit at U.S. statutory tax rate	$ (792)	$ (807)
State taxes (benefit), net of federal effect	(138)	(141)
State research and development tax credits	(2)	-
Federal research and development tax credits	(23)	(23)
Share-based compensation	4	22
Other	-	17
Change in valuation allowance	951	932
(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 $167.8 million gross Federal NOLs at December 31, 2019 (of which approximately $160.2 million was generated prior to January 1, 2018). Because we believe the ability for us to use these NOLs generated prior to January 1, 2018 to offset any future taxable income is severely limited as prescribed under Internal Revenue Code ("IRC") Section 382, we had estimated and recorded an amount for the likely limitation to our deferred tax asset in the fourth quarter of 2017, thereby reducing the aggregate estimated benefit of the Federal NOLs available to us of approximately $1.0 million at December 31, 2017. We believe the gross Federal NOL benefit we generated prior to January 1, 2018 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 and 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 may further limit our utilization of our NOLs.

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

	December 31,	
	2019	**2018**
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	$ 2,622	$ 2,174
- State	869	862
Research and development tax credits		
- Federal	1,207	1,184
- State	8	-
Share-based compensation	72	71
Other, net	177	151
Total deferred taxes	4,955	4,442
Valuation allowance	(4,955)	(4,442)
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, 2019 and 2018, 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, 2019 and 2018, 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, 2019, the Company's tax years of 2016, 2017 and 2018 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 2016.

NOTE 13 – NET (LOSS) INCOME PER SHARE

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,	
	2019	**2018**
Earnings (loss) per share – basic and diluted		
Numerator: net loss	$ (3,774)	$ (3,842)
Denominator (weighted):		
Common shares	21,300	21,033
RSUs - vested	296	113
Common stock purchase warrant	5,124	-
Basic and diluted weighted average shares outstanding	26,720	21,146
Earnings (loss) per share – basic and diluted	$ (0.14)	$ (0.18)
Excluded securities (non-weighted):		
Common shares issuable:		
RSUs – vested and nonvested	-	482
Stock options – vested and nonvested	1,356	1,560
Common stock purchase warrants	1,842	1,842
Convertible loan	37,500	-
Total excluded common shares	40,698	3,884

NOTE 14 – COMMITMENTS AND CONTINGENCIES

Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to us, was named along with numerous other companies as a defendant in cases filed in three separate state coordinated litigations pending in Pennsylvania, New Jersey and California, respectively captioned In re: Reglan®/Metoclopramide Mass Tort Litigation, Philadelphia County Court of Common Pleas, January Term, 2010, No. 01997; In re: Reglan Litigation, Superior Court of New Jersey, Law Division, Atlantic County, Case No. 289, Master Docket No. ATL-L-3865-10; and Reglan/Metoclopramide Cases, Superior Court of California, San Francisco County, Judicial Council Coordination Proceeding No. 4631, Superior Court No.: CJC-10-004631. In addition, we were served with a similar complaint by two individual plaintiffs in Nebraska federal court, which plaintiffs voluntarily dismissed in December 2014. In this product liability litigation against numerous pharmaceutical product manufacturers and distributors, including Acura, plaintiffs claim injuries from their use of the Reglan brand of metoclopramide and generic metoclopramide.

None of the plaintiffs in the lawsuits filed to date have confirmed that they ingested any of the generic metoclopramide manufactured by us. We discontinued manufacture and distribution of generic metoclopramide more than 20 years ago. All of these lawsuits have been effectively dismissed with the exception of less than ten pending Philadelphia cases that we expect will be finally dismissed without the need for any action by us. We expect that the Court will finally dismiss the small number of remaining Pennsylvania-based cases against us with prejudice by the end of the first quarter of 2020. Legal fees related to this matter have been covered by our insurance carrier. Based upon the current status and evaluation, we have not accrued for any potential loss related to these matters as of December 31, 2019.

Facility Lease

The Company leases administrative office space in Palatine, Illinois on a month to month basis at the rate of approximately $2 thousand per month.

NOTE 15 – SUBSEQUENT EVENTS

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. The ultimate impact of coronavirus is highly uncertain and subject to change. The Company does not yet know the full extent of 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.

Exhibit 10.50

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This License, Development and Commercialization Agreement ("**Agreement**") is made and entered into as of June 28, 2019 (the "**Effective Date**") by and between Abuse Deterrent Pharmaceuticals, LLC, with offices at 333 E. Main Street, Suite 220, Louisville, Kentucky 40202 ("**AD Pharma**"), and Acura Pharmaceuticals, Inc., with offices at 616 N. North Court, Palatine IL 60067 ("**Acura**"). AD Pharma and Acura each are referred to herein as a "Party" and collectively as the "Parties."

WITNESSETH:

WHEREAS, Acura has developed LIMITx™ Technology intended to retard the release of drug from tablets when multiple tablets are ingested;

WHEREAS, AD Pharma and its Affiliates have substantial expertise in the distribution, sales and marketing of healthcare products;

WHEREAS, Acura wishes to grant to AD Pharma, and AD Pharma wishes to obtain, the rights to the LIMITx™ Technology to develop and commercialize the Product in the Territory (each as herein defined);

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE I
DEFINITIONS

1.1 "**Acura Indemnitees**" is defined in Section 5.3

1.2 "**Affiliate**" means any corporation or other entity, which directly or indirectly controls, is controlled by or is under common control with a Party. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than Fifty Percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than Fifty Percent (50%) of the members of the governing body of the corporation or other entity. Notwithstanding the foregoing, a private equity or venture capital firm with an ownership interest in an entity shall not be an Affiliate by reason of such ownership and portfolio companies of a private equity firm or a venture capital firm shall not be Affiliates or a Party by virtue of the private equity firm or venture capital firm being Affiliates of a Party.

1.3 "**[*****] Product**" means an immediate release pharmaceutical product containing [*****] as its sole active ingredient and utilizing the LIMITX™ Technology in [*****] dosage strengths.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

1.4 "**Applicable Law**" means, with respect to any Person, any domestic or foreign, federal, state or local statute, treaty, law, ordinance, rule, regulation, administrative interpretation, order, writ, injunction, judicial decision, decree or other requirement of any governmental authority, including any rules, regulations or other requirements of the Regulatory Authorities in the Territory, applicable to such Person or any of such Person's respective properties, assets, officers, directors, employees, consultants or agents.

1.5 "**Bankrupt Party**" is defined in Section 10.2.1.

1.6 "**Claims**" is defined in Section 5.2.

1.7 "**Commercially Reasonable Efforts**" means the efforts and resources which would be used (including the promptness in which such efforts and resources would be applied) by a Party consistent with its normal business practices and in compliance with Applicable Law and the exercise of prudent scientific and business judgment, which in no event shall be less than the level of efforts and resources standard in the pharmaceutical industry for a company similar in size and scope to such Party, with respect to a product or potential product at a similar stage in its development and with similar market potential or product life cycle taking into account efficacy, safety, commercial value, the competitiveness of alternative products of Third Parties that are in the marketplace, and the Patent Rights and other proprietary position of such product.

1.8 "**Confidential Information**" is defined in Section 4.1 below.

1.9 "**Competing Product**" means a prescription product that contains hydrocodone and acetaminophen in a solid, oral dosage form, other than the Product or Product Line Extension.

1.10 "**Control**" means, with respect to Intellectual Property Rights, ownership or the possession of the ability by license or otherwise to assign or grant a license or sublicense to or disclose such Intellectual Property Rights without violating the terms of any agreement or other arrangement, express or implied, with any Third Party.

1.11 "**Effective Date**" has the meaning set forth above.

1.12 "**FD&C Act**" means that federal statute entitled the Federal Food, Drug, and Cosmetic Act and enacted in 1938 as Public Law 75-717, as such may have been amended, and which is contained in Title 21 of the C.F.R. Section 301 et seq.

1.13 "**FDA**" means the United States Food and Drug Administration, or any successor thereto.

1.14 "**Field**" means prescription ("Rx") products.

1.15 "**GAAP**" means generally accepted accounting principles in effect in the United States from time to time applied on a consistent basis.

1.16 "**Gross Sales**" means the U.S. Dollar value (with sales in foreign currency converted as per Section 3.7) of all consideration to which AD Pharma, its Affiliates and licensees is entitled for the sale of the Product and Product Line Extension. In the event AD Pharma sells the Product or Product Line Extension for less than fair market value, the fair market value of such Product or Product Line Extension (as if there had been a sale for fair market value to a Third Party) shall be included in Gross Sales.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

1.17 "**Indemnified Party**" is defined in Section 5.4(a)

1.18 "**Indemnifying Party**" is defined in Section 5.4(a).

1.19 "**Intellectual Property Rights**" means Know-How, registered trademarks, trademark applications, unregistered trademarks, trade dress, copyrights, and Patent Rights.

1.20 "**Know-How**" means information Controlled by Acura and related to retarding the release of active ingredients from pharmaceutical product when multiple dosages are ingested and encompassing manufacturing techniques, process, quality information, batch records (un-redacted master and executed), formulation composition and excipient specifications, formation development reports; batch summaries, and analytical methods and development/validation.

1.21 "**LIMITx™ Regulatory Application Submission Timeline**" is defined in Section 3.1.4.

1.22 "**LIMITx™ Patent Rights**" means the Patent Rights set forth on Exhibit A, that disclose or claim Acura's LIMITx™ Technology and that are Controlled by Acura or its Affiliates during the Term, including issued patents resulting from such applications, and all divisionals, continuations, continuations-in-part, substitutions, reissues, reexaminations, extensions, registrations, patents and applications to which priority is claimed, patent term extensions and renewals of the foregoing, including foreign counterparts thereof.

1.23 "**LIMITx™ Technology**" means the technology for retarding the release of active ingredients from pharmaceutical product when multiple dosages are ingested as reflected in the LIMITX™ Patent Rights and any related Know-How that is Controlled by Acura as of the Effective Date or at any time during the Term, including any technology retarding the release of active ingredients from pharmaceutical product when multiple dosages are ingested Controlled by Acura during the Term that would infringe the LIMITx™ Patent Rights if utilized by a third party.

1.24 "**Losses**" is defined in Section 5.2.

1.25 "**AD Pharma Indemnitees**" is defined in Section 5.2.

1.26 "**Milestone Payments**" is defined in Section 3.4.

1.27 "**Net Sales**" means the Gross Sales reduced by deductions, without duplication, for each of the following to the extent actually incurred, allowed or accrued, and without duplication (a) returns, (b) cash discounts, (c) coupons, (d) listing fees, (e) credits, (f) trade rebates, (g) shipping costs, (h) sales and excise taxes, other consumption taxes, and (i) other governmental charges. Net Sales, as set forth in this definition, shall be calculated applying, in accordance with GAAP, AD Pharma's standard accounting practices for selling AD Pharma's other products.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

1.28 "**Nexafed® Agreement**" is defined in Section 3.12.

1.29 "**Paragraph IV Certification**" means a certification under and pursuant to 21 U.S.C. Section 355(j)(2)(A)(vii)(IV) of the FD&C Act or pursuant to 21 U.S.C. Section 355(b)(2) (A)(iv) of the FD&C Act.

1.30 "**Party**" means AD Pharma and Acura individually or jointly as "**Parties**".

1.31 "**Patent Challenge**" is defined in Section 9.4.

1.32 "**Patent Rights**" means patents and patent applications, and all divisionals, continuations, continuations-in-part, substitutions, reissues, reexaminations, extensions, registrations, supplementary protection certificates, patents and applications to which priority is claimed, patent term extensions and renewals of the foregoing, including foreign counterparts thereof.

1.33 "**Person**" means an individual, a corporation, a general partnership, a limited partnership, a limited liability company, a limited liability partnership, an association, a trust or any other entity or organization.

1.34 "**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.

1.35 "**Product Line Extension**" means any product containing the combination of hydrocodone bitartrate and acetaminophen utilizing the LIMITx™ Technology that contains dosage strengths other than those contained in the Product but excludes any additional active ingredients.

1.36 "**Qualified Settlement Offer**" is defined in Section 5.4(b).

1.37 "**Regulatory Approval**" means the license or final FDA, or equivalent foreign governmental authority, marketing approval necessary as a prerequisite for marketing a Product in a country in the Territory.

1.38 "**Regulatory Approval Application**" means shall mean any filing(s) made with the Regulatory Authority in any country in the Territory for Regulatory Approval of the marketing, manufacture and sale (and pricing when applicable) of a Product in such country.

1.39 "**Regulatory Authority**" means the FDA in the U.S., and any health regulatory authority(ies) in any other country in the Territory that is a counterpart to the FDA and has responsibility for granting regulatory approval for the marketing, manufacture, and sale of a Product in such country, including, but not limited to, pricing and reimbursement approvals, and any successor(s) thereto, as well as any state or local health regulatory authorities having jurisdiction over any activities contemplated by the Parties.

1.40 "**Regulatory Materials**" is defined in Section 2.6.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

1.41 "**Related LIMITX™ Technology Product**" is defined in Section 7.7(a).

1.42 "**Royalty Payment**" is defined in Section 3.2.1.

1.43 "**Royalty Report**" is defined in Section 3.4.

1.44 "**Royalty Term**" shall be on a Product-by-Product, Product Line Extension by Product Line Extension, and country-by-country basis and, with respect to each country, will begin on the Effective Date and will expire on the later of the date that (i) the LIMITx™ Patent Rights in such country are not Valid; or (ii) is the scheduled expiration of the Royalty Term for the United States for a country in which there are not any LIMITx™ Patent Rights, provided that all Royalty Terms shall terminate upon termination of this Agreement pursuant to Section 9.2.

1.45 "**Term**" has the meaning set forth in Section 9.1.

1.46 "**Territory**" means the United States, its territories and possessions.

1.47 "**Third Party**" means any entity other than Acura and its Affiliates and AD Pharma and its Affiliates.

1.48 "**Title 11**" is defined in Section 10.2.1.

1.49 "**Valid**" means, with respect to a LIMITx™ Patent Rights in a particular country, such LIMITx™ Patent Rights have not (A) expired or been cancelled, (B) been declared invalid or unenforceable by a decision of a court or other appropriate body of competent jurisdiction, from which no appeal is or can be taken, (C) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (D) been abandoned or disclaimed either affirmatively or by operation of law.

ARTICLE II
LICENSE AND COMMERCIALIZATION

2.1 License.

2.1.1 Acura hereby grants AD Pharma an exclusive (even as to Acura), sub-licensable (subject to Section 2.10), royalty-bearing right and license under the LIMITx™ Technology to develop, manufacture, have manufactured, distribute, have distributed, sell, have sold, market, have marketed, commercialize and have commercialized the Product and Product Line Extensions in the Field in the Territory.

2.1.2 Acura hereby licenses to AD Pharma, on a non-exclusive basis the use of the mark LIMITx™ in the Field and Territory solely for the commercialization of the Product and Product Line Extension.

2.1.3 The licenses granted herein shall expire upon termination of this Agreement but shall survive expiration of this Agreement.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

2.1.4 If Acura decides to accept an unsolicited offer from a Third Party or determines it will solicit an agreement to license, in any European Union country, the United Kingdom, Japan, or Australia, any right(s) to develop, manufacture, have manufactured, distribute, have distributed, sell, have sold, market, have marketed, commercialize and/or have commercialized the Product and any Product Line Extension, Acura will immediately deliver notice to AD Pharma of such offer or determination to solicit. Such notice shall be in writing and specify the action Acura has decided to pursue including any offeror(s), if applicable, and the terms and conditions of any license being considered by Acura (the "**Foreign License Notice**"). The Foreign License Notice must be delivered to AD Pharma prior to Acura considering the execution of any document (including without limitation agreements, Memoranda of Understanding or Letters of Intent) related to the subject matter of the Foreign License Notice. Acura's acceptance of such unsolicited offer or implementation of its determination to solicit shall be subject to the following conditions:

(a) AD Pharma shall have forty-five (45) days from receipt of the Foreign License Notice in which to notify Acura that it elects to exercise any of the following rights, for which any period of negotiation shall be for ninety (90) days following AD Pharma's delivery of a Request Following Unsolicited Offer or Request Following Determination to Solicit, as defined in this Section:

(i) if the action specified in the Foreign License Notice involves receipt of an unsolicited offer from a Third Party for an exclusive license involving the Product or any Product Line Extension, AD Pharma shall have the right to accept a license upon the same terms and conditions as set forth in the unsolicited offer described in the Foreign License Notice, and its acceptance shall be made in writing;

(ii) if the action specified in the Foreign License Notice involves receipt of an unsolicited offer from a Third Party for a non-exclusive license involving the Product or any Product Line Extension, AD Pharma shall have the right either to accept a license upon the same terms and conditions as set forth in the unsolicited offer described in the Foreign License Notice, or to request Acura to negotiate in good faith and on an exclusive basis to agree upon terms and conditions for an exclusive license (the "**Request Following Unsolicited Offer**") granting AD Pharma the exclusive right to develop, manufacture, have manufactured, distribute, have distributed, sell, have sold, market, have marketed, commercialize and have commercialized the Product and any Product Line Extension in the same countries as set forth in such unsolicited offer described in the Foreign License Notice, and AD Pharma's acceptance of license or Request Following Unsolicited Offer hereunder (as the case may be) shall be made in writing;

(iii) if the action specified in the Foreign License Notice involves a determination that Acura will solicit an agreement granting a license involving the Product or any Product Line Extension in any European Union country, the United Kingdom, Japan, or Australia, AD Pharma shall have the right to negotiate with Acura in good faith and on an exclusive basis to agree upon terms and conditions for an exclusive or non-exclusive license in the same country or countries (the "**Request Following Determination to Solicit**"), and the Request Following Determination to Solicit shall be made in writing.

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(b) After ninety (90) days from delivery of a Request Following Unsolicited Offer or Request Following Determination to Solicit, if the Parties have not executed a definitive agreement (in the form of either an amendment to this Agreement or a new agreement) then Acura shall not enter into an agreement with a Third Party to license, in any European Union country, the United Kingdom, Japan, or Australia, any right(s) to develop, manufacture, have manufactured, distribute, have distributed, sell, have sold, market, have marketed, commercialize and/or have commercialized the Product and any Product Line Extension on terms (when taken as a whole) that are less favorable to Acura than the terms of the last proposal rejected by either of the Parties without first providing to AD Pharma a written copy of such terms, and AD Pharma shall have forty-five (45) days to accept a license upon the same terms and conditions.

2.2 No Other Rights and Retained Rights.

This Agreement confers no right, license or interest by implication, estoppel, or otherwise under any Patent Rights, Confidential Information, Know-How or other Intellectual Property Rights (including but not limited to trade secrets, formulations, manufacturing processes, data) that was owned by a Party prior to signing the Agreement except as expressly set forth in this Article II. Each Party hereby expressly retains and reserves all rights and interests with respect to patents, Confidential Information, technology or other Intellectual Property Rights not expressly granted to the other Party hereunder.

2.3 AD Pharma to use CRE. AD Pharma shall use Commercially Reasonable Efforts to market and sell the Product in the Territory upon Regulatory Approval and introduce the Product into interstate commerce within 180 days of such Regulatory Approval. AD Pharma shall use Commercially Reasonable Efforts to file with the FDA the Regulatory Approval Application for the Product and to gain Regulatory Approval for such Product.

AD Pharma shall use Commercially Reasonable Efforts to develop, obtain any necessary Regulatory Approval and commercialize a Product Line Extension in the Territory, provided such decision to advance Product Line Extension(s) shall be the sole responsibility of AD Pharma. AD Pharma shall comply with all Applicable Laws in the development, commercialization (including, without limitation, packaging, sale, distribution, advertising, disposition and marketing of the Product and Product Line Extension, and product packaging) and AD Pharma shall use all legends, notices, and markings as required by Applicable Law.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

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 [*****] 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.

2.4 AD Pharma Responsibility for All Commercialization Costs and Expenses. During the Term, AD Pharma shall have the sole obligation and responsibility, and at its sole cost and expense, for all aspects of manufacturing and commercializing, including without limitation, scale up and validation of the production process, testing packaging and labelling the Product and Product Line Extension, and any costs associated with storage, release and Third Party logistics. As part of such responsibilities, AD Pharma shall have the sole responsibility to obtain or to coordinate with and provide to its contract manufacturer such information and materials as shall be reasonably necessary to obtain sufficient quota for active pharmaceutical ingredients from the Drug Enforcement Administration, and similar foreign agencies.

2.5 AD Pharma Responsible for Product Development Costs and Expenses. During the Term, AD Pharma shall pay for or reimburse Acura to the extent Acura pay's for all out-of-pocket Product development expenses (excluding any Product Line Extension). The Parties shall be responsible for maintaining and paying for their own internal staff and infrastructure related to Product development.

2.6 Regulatory Approvals and Fees.

2.6.1 AD Pharma shall be the sole owner of the Product Regulatory Application and Regulatory Approval thereof, registration materials, clinical documentation, and any and all country specific dossiers for the Product and Product Line Extension in the Territory (the "**Regulatory Materials**"). AD Pharma shall be responsible for maintaining the Product and Product Line Extension Regulatory Approvals, and pay any and all fees and expenses in connection therewith including, without limitation, any filing fees, establishment fees, annual product fees, active pharmaceutical supplier fees, post-approval studies and any fees associated with the amendment of a Regulatory Approval, any costs and expenses associated with regulatory changes requested by a Regulatory Authority relating to a Product, Product Line Extension, or Regulatory Approvals, subject to Section 2.7.2. Notwithstanding the foregoing, AD Pharma may, in its sole discretion, transfer, sell or convey the Regulatory Materials, in whole or in part, to a third-party provided that: (a) such third-party agrees to be bound by the terms of this Agreement governing the Regulatory Materials, (b) AD Pharma remains fully responsible for the compliance by such third party with the terms and conditions of this Agreement, including without limitation the non-compete provisions of Section 2.9, (c) any and all rights to the Regulatory Materials retained by AD Pharma are fully assignable to Acura in the event of termination or expiration of this Agreement.

2.7 Coordination of Efforts. Acura and AD Pharma will form a joint steering committee to coordinate the strategies, activities, timelines and budgets for the development and commercialization of the Product and Product Line Extension, if any. In the course of such meetings, each Party shall have one vote on any matter before the committee, except, however, the Party responsible for any budgetary item as determined by this Agreement shall have sole decision making authority with regard to that budget and the underlying activities. In the event said committee is unable to decide any matter, the matter will promptly be referred to dispute resolution in Section 10.1.

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2.8 Right of Reference.

2.8.1 Acura grants AD Pharma a right of reference to preclinical and clinical data and reports, and any adverse event reports regarding the Products and all other necessary data, reports and information, in each case Controlled by Acura for the purpose of obtaining, and/or maintaining Regulatory Approval of, or commercializing or manufacturing a Product or Product Line Extension, without any additional compensation.

2.8.2 AD Pharma grants Acura a perpetual right of reference to preclinical and clinical data and reports, any adverse event reports regarding the Product and Product Line Extension and such other data, reports and information, in each case Controlled by AD Pharma for the purpose of obtaining and/or maintaining Regulatory Approval of products utilizing the LIMITx™ Technology without any additional compensation.

2.9 Non-Compete. AD Pharma, its Affiliates, and sublicensees will not develop, file a Regulatory Approval Application or seek Regulatory Approval of or launch, market or sell or assist a Third Party in the development of, launch, market or sale of a Competing Product in the Territory during the Royalty Term.

2.10 Sublicenses. AD Pharma may grant sublicenses through multiple tiers, under any or all of the rights granted in Section 2.1, to its Affiliates and to Third Parties. Each agreement in which AD Pharma grants a sublicense under Section 2.1 shall be consistent with the relevant terms and conditions of this Agreement. AD Pharma shall provide notice to Acura of the proposed sublicense prior to execution thereof which notice shall state the subject of the sublicense (including the portion of the Territory and products being sublicensed) and AD Pharma shall provide Acura a copy of such sublicense, with suitable redaction of confidential information contained therein, within thirty (30) days after execution thereof. AD Pharma shall be and remain fully responsible for the compliance by sublicensees with the terms and conditions of this Agreement, including without limitation and non-compete provisions of Section 2.9.

2.11 Technology Transfer. LIMITx™ Technology. Acura shall provide AD Pharma with a technology transfer which shall consist of the manufacturing Know-How encompassed in the LIMITx™ Technology relating to the Product. Such transfer shall be at least as comprehensive as any technology transfer actually provided by Acura to any Third Party related to the manufacture of the Product. Acura hereby authorizes any Third Party with whom it has contracted for the manufacture of the Product at any scale to release to AD Pharma any and all information disclosed by Acura to the Third Party, and such authorization applies regardless of any designations (e.g., Confidential, Proprietary, Trade Secret, and the like) placed upon such disclosed information.

2.12 Complaints; Recalls. Each of AD Pharma and Acura shall inform the other Party as promptly as practicable of any Product and Product Line Extension complaints. All communications relating to the performance or condition of the Product or Product Line Extension, and all communications relating to adverse experiences in association with, but not necessarily due to, the Product or Product Line Extension which are received by Acura or AD Pharma shall be forwarded to the other Party. In the event of any recall of or field notification after the Effective Date with respect to any Product or Product Line Extension, each of AD Pharma and Acura shall make available to the other Party during normal business hours and upon reasonable advance notice such records and other information as reasonably requested by such other Party in connection with any recall. AD Pharma shall be solely responsible at its cost and expense for any recalls or withdrawals of Product or Product Line Extension sold by it. AD Pharma shall be responsible for all required regulatory activities in the Territory.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

2.13 Trademarks; Logos.

2.13.1 AD Pharma shall assume full responsibility, at its sole cost and expense for prosecuting or litigating any infringement of the LIMITx™ trademark and shall be entitled to retain all recoveries in connection therewith except it shall remit to Acura 15% of such recoveries after deduction from such recoveries of fees and expenses in enforcing such trademark rights.

2.13.2 AD Pharma hereby acknowledges the exclusive ownership by Acura of the LIMITx trademark furnished by Acura for use in connection with the Product and Product Line Extension. AD Pharma shall not, during the Term or thereafter, register, use, or attempt to obtain any right in and to the LIMITx trademark or in and to any name, logo or trademark confusingly similar thereto. Acura will use Commercially Reasonable Efforts to obtain formal registration of the LIMITx trademark in the United States in advance of the commercial use of such trademark by AD Pharma.

2.13.3 Acura shall have the right to exercise quality control over AD Pharma's use of the LIMITx trademark to a degree reasonably necessary to maintain the validity of the trademark and to protect the goodwill associated therewith.

2.13.4 AD Pharma shall, in its packaging, sale, marketing, advertising, disposition and distribution of any Product, Product Line Extension and product packaging adhere to a level of quality regarding the maintenance of the validity of the LIMITx trademark and the protection of the goodwill associated therewith consistent with the reasonable standards of quality otherwise set by Acura.

ARTICLE III
PAYMENTS AND ROYALTIES

3.1 Pre-FDA Application Payments by AD Pharma.

3.1.1 In an aggregate amount not to exceed Six Million Three Hundred Thousand Dollars ($6,300,000)(the “Maximum Pre-Regulatory Application Submission Payment”), each month AD Pharma shall pay Acura Three Hundred Fifty Thousand Dollars ($350,000) in non-refundable, non-creditable payments to Acura in immediately available funds, with such payments to begin within Five (5) days of the Effective Date, and continuing on the monthly anniversary of the Effective Date until the earlier of eighteen (18) 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).

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3.1.2 If Acura succeeds in gaining filing acceptance by the FDA of a Regulatory Approval Application for the Product before the Maximum Pre-Regulatory Application Submission Payment is reached based on monthly payments of Three Hundred Fifty Thousand Dollars under Section 3.1.1, then AD Pharma shall cease making such monthly payments; provided, however that AD Pharma shall in this case make a one-time payment to Acura within thirty (30) days of such filing acceptance by the FDA, with such one-time payment calculated by subtracting the sum of all such monthly payments actually made from the Maximum Pre-Regulatory Application Submission Payment.

3.1.3 If Acura fails to gain filing acceptance by the FDA of a Regulatory Approval Application for the Product before the end of the LIMITx™ Regulatory Application Submission Timeline, as defined in Section 3.1.4, then AD Pharma (i) is not obligated to continue such monthly payments thereafter, and (ii) may terminate this Agreement for breach by providing written notice specifying the breach as the failure by Acura to gain filing acceptance by the FDA of a Regulatory Approval Application for the Product within the LIMITx™ Regulatory Application Submission Timeline, provided that for such termination under this (ii) to be effective, it must occur before FDA has accepted the Regulatory Approval Application for the Product. In the event this Agreement terminates for Acura's failure to gain filing acceptance by the FDA of a Regulatory Approval Application for the Product within the LIMITx™ Regulatory Application Submission Timeline:

(a) The provision in Section 9.2 allowing a period of time (i.e., thirty (30) days) to remedy the breach shall not apply; and

(b) Notwithstanding any other provision(s) herein, Acura's ownership of the LIMITx™ Patent Rights shall transfer automatically to AD Pharma without payment of any further consideration. Contingent upon termination of this Agreement under Section 3.1.3, Acura hereby assigns and transfers its entire right, title and interest in the LIMITx™ Patent Rights to AD Pharma, and Acura agrees to execute or procure any further necessary assurance of the title to said LIMITx™ Patent Rights at any time, upon request and at the expense of AD Pharma, including but not limited to the delivery of any testimony in any legal proceedings and the execution of all papers that may be necessary or desirable to perfect the title to said LIMITx™ Patent Rights in the name of AD Pharma, or such other party as AD Pharma designates.

3.1.4 If at any time in AD Pharma's sole discretion, Acura fails to adhere to the LIMITx™ Regulatory Application Submission Timeline then AD Pharma may terminate this Agreement under either or both of Section 9.2 for breach, or Section 9.3 for convenience. The "**LIMITx™ Regulatory Application Submission Timeline**" means the completion by Acura of all activities set forth in Schedule 1, on or before the deadline identified for each activity. For the avoidance of doubt, a missed deadline for any one or more of the deadlines set forth in Schedule 1 shall constitute a failure to adhere to the LIMITx™ Regulatory Application Submission Timeline. Also, based on the frequency of monthly payments by AD Pharma set forth in Section 3.1.1, and unless adjustment is made under Section 3.1.2, the LIMITx™ Regulatory Application Submission Timeline can last no longer than the last day of the calendar month that occurs seventeen (17) months after the Effective Date.

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3.2 Consents of AD Pharma.

3.2.1 Any transfer by Acura of the LIMITx™ Patent Rights to a Third Party for indications outside the scope of the Product and Product Line Extension (including without limitation a license, assignment, security interest, or otherwise) shall be subject to AD Pharma's written consent, which shall not be unreasonably withheld or delayed. AD Pharma acknowledges that any such transfer of rights under this Section to which it has consented shall survive any transfer of the LIMITx™ Patent Rights under Section 3.1.3(b).

3.2.2 At any time prior to FDA acceptance of the Regulatory Approval Application for the Product, in the event Acura has a bona fide offer for financing for Acura, AD Pharma consents that it will negotiate in good faith any amendments to this Agreement required by such third-party financer, provided that AD Pharma will be under no obligation to enter into such amendments.

3.3 Royalties. The following payments shall be payable by AD Pharma to Acura 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.

3.3.1 Royalty Payment. For each Product and Product Line Extension in the Territory during the Royalty Term for a country in the Territory, AD Pharma shall pay to Acura a royalty of [*****] Percent ([*****]% [*****]) on all Net Sales in the Territory on the first $[*****] ([*****]) US Dollars in Net Sales in a calendar year and [*****] Percent ([*****]%) on Net Sales in excess of [*****]US Dollars. Such royalty shall be payable for sales made during each calendar quarter, and while the Royalty Term for the United States is in effect, be no less than [*****] Dollars ($[*****]) for each such calendar quarter (which shall accrue on a daily basis during a quarter), and payment will be remitted within forty-five (45) days after the end of the quarter to which it relates. The royalty payment under this Section 3.2.1 is referred to as the "**Royalty Payment**." Notwithstanding the foregoing, should the FDA approved label for the Product not include a description of the pharmacokinetic profile, clinical results or benefits, or other marketable feature of the LIMITx Technology, then the minimum royalty payment in each quarter shall be [*****] dollars ($[*****]) until such information is included in the label.

3.4 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 all Products and Product Line Extensions in the Territory (the "**Milestone Payments**"):

3.4.1 AD Pharma shall pay Acura [*****]dollars ($[*****]) the first time aggregate Net Sales in a given calendar year exceeds [*****] dollars ($[*****]); and

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

3.4.2 AD Pharma shall pay Acura [*****] dollars ($[*****]) the first time aggregate Net Sales in a given calendar year exceeds [*****]dollars ($[*****]).

3.5 Royalty Reports. AD Pharma shall prepare in respect of each calendar quarter a report ("**Royalty Report**") that shows for that calendar quarter the Net Sales of Product and Product Line Extension by country and detailing the calculation of Gross Sales and deductions from Gross Sales in arriving at Net Sales. AD Pharma shall submit such statement to Acura within forty-five (45) days of the end of the calendar quarter to which it relates, together with its remittance for Royalty Payments in respect of that quarter. The Royalty Report shall be in the form of Exhibit B.

3.6 Records. During the Term and for two (2) years thereafter, each Party shall keep all usual and proper records and books of account and all usual and proper entries relating to the Product and Product Line Extension. AD Pharma shall maintain (electronically or otherwise) such records and books of account containing all necessary data for the calculation of Royalty Payments due under this Agreement.

3.7 Audits. AD Pharma and its Affiliates and Sublicensees shall maintain complete and accurate records in reasonably sufficient detail to permit Acura to confirm the accuracy of the calculation of royalty payments. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the calendar year to which they pertain for examination, not more often than once each calendar year, by an independent certified public accountant selected by Acura and reasonably acceptable to AD Pharma, for the sole purpose of verifying the accuracy of the financial reports furnished by AD Pharma pursuant to this Agreement. Any such auditor shall enter into a confidentiality agreement with AD Pharma and shall not disclose AD Pharma's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by AD Pharma or the amount of payments due from AD Pharma to Acura under this Agreement. Any amounts shown to be owed but unpaid shall be paid, and any amounts showed to be overpaid will be refunded, within forty-five (45) days from the accountant's report. Acura shall bear the full cost of such audit unless such audit discloses an underpayment to Acura of more than $10,000, in which case AD Pharma shall bear the full cost of such audit. Amounts shall be deemed due on the original due date (e.g., when Royalty Payment was originally due) and interest shall be applied as set forth in Section 3.10.

3.8 Pricing. AD Pharma shall have sole discretion to determine the price, terms and conditions of sales of the Product and Product Line Extension to AD Pharma's customers. AD Pharma shall not price the Product and Product Line Extension in any country for any transaction as part of a bundle that provides greater discounts for the Product and Product Line Extension as compared to any other product in the bundle or otherwise disadvantage the selling price of the Product and Product Line Extension in favor of its products. AD Pharma will not allow any Product or Product Line Extension to serve as a loss leader to induce the sale of other products.

3.9 Currency. All payments required under this Agreement shall be made in U.S. dollars, regardless of the country(ies) in which sales are made or expenses are incurred, via wire transfer of immediately available funds to an account designated in writing by Acura. Whenever, for the purpose of calculating any sums due under this Agreement, conversion from any foreign currency shall be required, such conversion shall be made as follows: the amounts shall be converted into United States dollars using the average rate of exchange for such currencies for the relevant period, such exchange rate shall be the exchange rate taken from The Wall Street Journal as published on the last day of the relevant period for which payments are due, or such other publication as may be agreed between the Parties from time to time.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

3.10 Late Payments. All amounts payable under this Agreement and not paid within thirty (30) days of when due in accordance with the provisions hereof shall bear interest from the due date until paid at the rate equal to the lower of (i) three percent (3%) over the prime rate of interest reported in the East Coast Addition of The Wall Street Journal for the date such amount was due, per annum and (ii) the maximum rate allowed by law. Unless otherwise stated all dollar amounts in this Agreement are in United States dollars.

3.11 Taxes.

3.11.1 In the event that a Party is mandated under the laws of a country to withhold any tax to the tax or revenue authorities in such country in connection with any payment to the other Party, such amount shall be deducted from the payment to be made by such withholding Party, provided, however, that the withholding Party shall take reasonable and lawful actions, at the other Party's sole cost, to avoid and minimize such withholding and promptly notify the other Party so that the other Party may take lawful actions to avoid and minimize such withholding. The withholding Party shall promptly furnish the other Party with copies of any tax certificate or other documentation evidencing such withholding as necessary to satisfy the requirements of the United States Internal Revenue Service related to any application by such other Party for foreign tax credit for such payment. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

3.12 Option under Nexafed® Agreement. The **Nexafed® Agreement** means that certain License, Commercialization and Option Agreement entered into as of March 16, 2017, by and between Acura and MainPointe Pharmaceuticals, LLC ("MainPointe"). Acura authorizes 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); provided, however, that for valuable consideration from AD Pharma to Acura, the receipt of which is fully acknowledged by Acura, AD Pharma and Acura agree that the payment requirements of Section 2.3.1 of the Nexafed® Agreement are waived if exercised within a period of five (5) years from the Effective Date of this Agreement with respect to such Option Product, and AD Pharma shall not be obligated to remit to Acura any payment in order to exercise the option to add Nexafed® 12-hour dosage as an Option Product under the Nexafed® Agreement. Upon execution of the aforementioned option for Nexafed 12-hour dosage, Acura agrees to negotiate in good faith a development Agreement as may be requested by AD Pharma.

3.13 Option for license to [*****] Product. If, within Five (5) Years of the Effective Date, AD Pharma provides written notice to Acura of its desire to add the [*****] Product as an additional licensed product under this Agreement, Acura shall then be obligated to negotiate exclusively with AD Pharma for the grant of a license, which shall be (unless mutually agreed by the Parties) an exclusive (even as to Acura, unless already licensed to a Third Party under Section 3.13.2), sub-licensable (subject to Section 2.10), royalty-bearing right and license under the LIMITx™ Technology to develop, manufacture, have manufactured, distribute, have distributed, sell, have sold, market, have marketed, commercialize and have commercialized the [*****] Product in the Field in the Territory.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

ARTICLE IV
CONFIDENTIALITY AND LIMITATIONS ON USE

4.1 Confidentiality. Each Party agrees that, during the Term and for a period of ten (10) years thereafter (and indefinitely for trade secrets) it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. "**Confidential Information**" means information that the disclosing Party considers confidential and discloses to the receiving Party for the purpose of this Agreement. Confidential Information must be marked or otherwise identified as confidential or proprietary or, under the circumstances surrounding the disclosure, ought in good faith to be treated as confidential or proprietary. Confidential Information may be conveyed in written, graphical, physical or oral form. Confidential Information may include, without limitation, information concerning the study, discovery, design, research, development, manufacture, formulation, extraction, compounding, mixing, processing, testing, control, preservation, storage, finishing, packing, packaging, use, administration, distribution, sale, reimbursement and/or marketing of pharmaceutical products or compounds and potential products or compounds, data from and methodology of pre-clinical and clinical studies, the contents of any submissions to the U.S. Food and Drug Administration (together with any successor agency), marketing plans or computer hardware and software systems and designs and plans for same. Confidential Information may include confidential or proprietary information of a third party that is in the possession of a disclosing Party. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

4.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 4.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary to its employees, agents, consultants, contractors, licensees or Sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(b) such disclosure is reasonably necessary to comply with Applicable Laws, including regulations promulgated by the U.S. Securities and Exchange Commission, applicable security exchanges, court order, administrative subpoena or order; provided that the Party subject to such Applicable Laws shall promptly notify the other Party of such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

4.3 Publicity

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 4.3 or Section 4.2. In addition, a Party may disclose such terms to the extent reasonably necessary to be disclosed to any bona fide potential or actual investor, lender, acquiror, or merger partner for the sole purpose of evaluating an actual or potential investment, acquisition or merger; provided that in connection with such disclosure, such Party shall inform each disclosee of the confidential nature of such Confidential Information and ensure that each such disclosee is contractually obligated to treat such Confidential Information as confidential on terms at least as restrictive as those contained in this Article IV.

(b) The Parties shall make a joint public announcement of the execution of this Agreement in the form attached as Exhibit C, which shall be issued at a mutually agreed time after the Effective Date.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

(c) After release of such press release, if either Party desires to make a public announcement concerning the material terms of this Agreement or any activities hereunder, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review.

(d) The Parties acknowledge that either or both Parties may be obligated to file under Applicable Laws a copy of this Agreement with the U.S. Securities and Exchange Commission or other governmental authorities. Each Party may make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's reasonable comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

ARTICLE V
LIABILITY AND INDEMNIFICATION

5.1 Maximum Liability. Other than a Party's indemnification obligations, breach of the confidentiality provisions and non-compete provisions of Section 2.9, each Party's maximum liability to the other Party for any claim arising from this Agreement for any reason whatsoever (excluding monetary consideration for this Agreement, such as Royalty Payments, Milestone Payments and out-of-pocket costs and expenses) will not exceed the Royalty Payments and Milestone Payments made by AD Pharma to Acura during the twelve (12) month period preceding the date upon which the applicable claim arose .

5.2 Indemnification by Acura. Acura shall defend, indemnify, and hold AD Pharma and its Affiliates and their respective officers, directors and employees (the "**AD Pharma Indemnitees**") harmless from and against any and all damages, losses, liabilities costs or expenses (including reasonable attorneys' fees) ("**Losses**") incurred or sustained by such AD Pharma Indemnitees resulting from any claims, suits, proceedings or causes of action brought by a Third Party (collectively, "**Claims**") against such AD Pharma Indemnitee to the extent arising from or based on or arising from (a) Acura's development of the Product limited to exposure to the Product prior to Regulatory Approval (b) Acura's breach of any of its obligations under this Agreement; (c) the gross negligence or intentional misconduct of Acura; or (d) Acura's breach of any representation or warranty made or given in this Agreement, in each case except for any Claim which arises from or is based on any activity set forth in Section 5.3 for which AD Pharma is obligated to indemnify the Acura Indemnitees under Section 5.3.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

5.3 Indemnification by AD Pharma. AD Pharma shall defend, indemnify, and hold Acura and its Affiliates and their respective officers, directors and employees (the "**Acura Indemnitees**") harmless from and against any and all Losses incurred or sustained by such Acura Indemnitees resulting from any Claims against such Acura Indemnitee brought by a Third Party to the extent arising from or based on or arising from (a) AD Pharma's breach of any of its obligations under this Agreement; (b) any claims arising out of the manufacturing or commercialization of Products or Product Line Extensions; (c) the development of any Product Line Extension; (d) the gross negligence or intentional misconduct of AD Pharma; (e) AD Pharma's breach of any representation or warranty made or given by AD Pharma in this Agreement; (f) as provided in Article VIII; or (g) any actual or alleged infringement of any Third Party copyright, trademark or trade dress rights arising from materials, labeling, marketing or advertising of the Product or Product Line Extension, in each case except to the extent any Claim arises from or is based on any activity set forth in Section 5.2 for which Acura is obligated to indemnify the AD Pharma Indemnitees under Section 5.2.

5.4 Indemnification Procedures.

(a) The Party claiming indemnity under this Article V (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim. The failure to give such prompt written notice shall not, however, relieve the Indemnifying Party of its indemnification obligations, except and only to the extent that the Indemnifying Party forfeits rights or defenses by reason of such failure. The Indemnifying Party shall have the right to participate in, or by giving written notice to the Indemnified Party within 30 days of receipt of written notice of the Claim, to assume the defense of any Claim at the Indemnifying Party's expense and by the Indemnifying Party's own counsel, and the Indemnified Party shall cooperate in good faith in such defense; provided, however, that the Indemnifying Party's right to assume the defense of any Claim shall be subject to the Indemnifying Party acknowledging in writing to the Indemnified Party that the Indemnifying Party is liable under this Article V to provide indemnification. In the event that the Indemnifying Party assumes the defense of any Claim, subject to Section 5.4(b), it shall have the right to take such action as it deems necessary to avoid, dispute, defend, appeal or make counterclaims pertaining to any such Claim in the name and on behalf of the Indemnified Party; provided, that the Indemnified Party shall have the right, at its own cost and expense, to participate in the defense of any such Claim with counsel selected by it subject to the Indemnifying Party's right to control the defense thereof. If the Indemnifying Party elects not to compromise or defend such Claim or fails to notify the Indemnified Party in writing of its election to defend as provided in this Agreement, the Indemnified Party may, subject to Section 5.4(b), pay, compromise, defend such Claim and seek indemnification for any and all Losses based upon, arising from or relating to such Claim. Acura and AD Pharma shall cooperate with each other in all reasonable respects in connection with the defense of any Claim for which indemnification is sought under this Article V, including making available (subject to the provisions of Article IV) records relating to such Claim and furnishing, without expense (other than reimbursement of actual out-of-pocket expenses) to the defending Party, management employees of the non-defending Party as may be reasonably necessary for the preparation of the defense of such Claim.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

(b) The Indemnifying Party shall not enter into settlement of any Claim without the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed), except as provided in this Section 5.4(b). If a firm offer is made to settle a Claim without leading to liability or the creation of a financial or other non-financial obligation on the part of the Indemnified Party and provides, in customary form, for the unconditional release of each Indemnified Party from all liabilities and obligations in connection with such Claim (a "**Qualified Settlement Offer**") and the Indemnifying Party desires to accept and agree to such Qualified Settlement Offer, the Indemnifying Party shall give written notice to that effect to the Indemnified Party. If the Indemnified Party fails to consent to such Qualified Settlement Offer within ten days after its receipt of such notice, the Indemnified Party may continue to contest or defend such Claim and in such event, the maximum liability of the Indemnifying Party as to such Claim shall not exceed the amount of such settlement Qualified Settlement Offer. If the Indemnified Party fails to consent to such Qualified Settlement Offer and also fails to assume defense of such Claim, the Indemnifying Party may settle the Claim upon the terms set forth in such Qualified Settlement Offer to settle such Claim. If the Indemnified Party has assumed the defense pursuant to Section 5.4(b), it shall not agree to any settlement without the written consent of the Indemnifying Party (which consent shall not be unreasonably withheld or delayed).

(c) The procedures set forth in Article VII shall supersede the provisions of this Section 5.4, with respect to matters addressed therein.

5.5 Consequential Damages. Except for breaches of the confidentiality provisions, and breach of the non-compete provision of Section 2.9, under no circumstances whatsoever will either Party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other Party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

ARTICLE VI
NOTICES

6.1 Notices. Any notice or request to be given or furnished under this Agreement by any Party to the other shall be in writing and shall be delivered personally or registered or certified mail, postage prepaid, or by overnight delivery service to the following:

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

TO ACURA: Acura Pharmaceuticals, Inc.
616 N. North Court
Palatine, IL 60067
Attn: Robert B. Jones
Telephone No. 847-705-7709

Copy To: S. Jason Teele
Sills Cummis & Gross P.C.
One Riverfront Plaza
Newark, NJ 07102
Telephone No. 973-643-4779

TO AD Pharma: Abuse Deterrent Pharmaceuticals, LLC
333 E. Main Street, Suite220
Louisville, KY 40202
Attn: John L. Schutte
Telephone No. [*****]

Copy To: Frost Brown Todd Attorneys, LLC
400 West Market St., 3200
Louisville, KY 40202
Attn: William G. Strench
Telephone No. 502-589-5400

6.2 Receipt of Notice. All notices and other communications given to any Party in accordance with the provisions of this Agreement shall be deemed to have been given on the date of receipt if delivered by hand or overnight courier services or sent by telecopy, or on the date five (5) business days after dispatch by certified or registered mail (postage prepaid) if mailed, in each case delivered, sent or mailed (properly addressed) to such Party as provided in this Article VI, or in accordance with the latest unrevoked direction from such Party given in accordance with this Article VI.

ARTICLE VII
PATENT PROSECUTION, INFRINGEMENT

7.1 Ownership of Intellectual Property Rights. Acura shall own all Intellectual Property Rights (including all Know-How and Patent Rights) in the LIMITx™ Technology, provided that if AD Pharma makes any improvements to the LIMITx™ Technology, then AD Pharma shall own such improvements provided that it shall inform Acura of such improvements, and hereby grants Acura a royalty-free, perpetual, sublicensable, non-exclusive license to such improvements to develop, manufacture and commercialize products other than the Products. AD Pharma owns all trademarks and goodwill associated with the marketing and commercialization of the Product and Product Line Extension in the Territory, with the exception of any mark incorporating Acura's corporate name, LIMITx™, or any mark incorporating LIMITx™, which shall be owned by Acura.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

7.2 Patent Prosecution and Maintenance. Acura is responsible for the prosecution and maintenance of the LIMITx™ Patent Rights in its sole discretion and at its own cost and expense. Acura shall provide AD Pharma a reasonable opportunity to review and comment on such prosecution and maintenance efforts regarding LIMITx™ Patent Rights in the Territory that may claim the Product or Product Line Extension, or the making or the use thereof. Acura shall provide AD Pharma with a copy of material communications from any patent authority in the Territory regarding such LIMITx™ Patent Rights within a reasonable time after receipt of such communications and shall provide drafts of any material filings or responses to be made to such patent authorities in a reasonable amount of time in advance of submitting such filings or responses for AD Pharma's review and comment. Acura shall reasonably consider such comments by AD Pharma in connection with the prosecution and maintenance of the LIMITx™ Patent Rights. If Acura decides to cease the prosecution or maintenance of any LIMITx™ Patent Rights that claim a Product or Product Line Extension after it has commenced prosecution of such LIMITx™ Patent Rights in the Territory, Acura shall notify AD Pharma in writing so that AD Pharma may, at its discretion, assume the responsibility for the prosecution or maintenance of such LIMITx™ Patent Rights in the Territory, provided Acura shall own all such resulting patents.

7.3 Infringement of LIMITx™ Patent Rights. Each of AD Pharma and Acura will notify the other Party within five (5) days upon learning of any possible infringement by a Third Party of the LIMITx™ Patent Rights, which infringement may reasonably be expected to affect the commercialization of the Product or Product Line Extension. AD Pharma has the exclusive right (after consultation with Acura), but not the obligation, at AD Pharma's own cost, to take all steps, including legal action, it deems necessary or advisable to eliminate or minimize the effect on the development, manufacture and commercialization of the Product or Product Line Extension of such possible infringement. Acura agrees to cooperate, upon reasonable request of AD Pharma and at AD Pharma's cost, in such steps or legal proceeding. All proceeds realized upon any judgement or settlement in AD Pharma's favor regarding such steps or legal action, net of direct out-of-pocket expenses of the Parties relating thereto, shall be for the benefit of AD Pharma provided AD Pharma shall pay Acura the same royalty on the excess as it is required to pay on Net Sales. Notwithstanding the foregoing, Acura’s consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license or covenant not to sue, relating to the LIMITx™ Patent Rights, or dedication to the public, admission of invalidity or unenforceability, or abandonment of any LIMITx™ Patent Rights.

7.4 Notice by AD Pharma of Intent to Assert; Acura’s Right to Assert.

(a) No later than five (5) business days after learning or being notified of any possible infringement by a Third Party of the LIMITx™ Patent Rights, which infringement may reasonably be expected to affect the commercialization of a Product or Line Extension, AD Pharma shall provide written notice to Acura as to whether AD Pharma will exercise its rights conferred in Section 7.3.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

(b) If AD Pharma does not provide Acura with such written notice within twenty (20) business days or within such time provides notice to Acura electing not to exercise its rights conferred in Section 7.3, then at any time Acura may, but shall not be obligated, to provide AD Pharma written notice as to whether Acura will take steps to eliminate or minimize the consequences of such possible infringement to the commercialization of the Product or Product Line Extension.

(c) If Acura elects, pursuant to Section 7.4(b), to take steps to eliminate or minimize the consequences of such possible infringement to the commercialization of a Product or Product Line Extension, the following shall apply: Acura shall have the exclusive right, at Acura's own cost and expense, to take such steps as it shall determine, including legal action, to eliminate or minimize the consequences of such possible infringement to the commercialization of the Product or Product Line Extension. Acura shall be entitled to any judgement or settlement relating to such action. AD Pharma agrees to join as a named party and cooperate, upon reasonable request of Acura and at Acura's cost and expense, in any such steps or legal proceeding.

7.5 Third Party Challenges to LIMITx™ Patent Rights. Notwithstanding Section 7.3, each of AD Pharma and Acura shall notify the other Party no later than five (5) business days after receiving a Paragraph IV Certification, an Inter Parties or Post Grant review petition, or any other challenge that a LIMITx™ Patent Right is invalid or unenforceable, if such LIMITx™ Patent Right claims the Product or Product Line Extension, or the manufacture, or use thereof. AD Pharma has the right (after consultation with Acura), but not the obligation, at AD Pharma's own cost, to exclusively pursue any negotiations with such Third Party and exclusively control the enforcement or defense of any legal proceeding regarding such challenge. Acura agrees to cooperate, upon reasonable request of AD Pharma and at AD Pharma's cost, in such negotiations or legal proceeding. All proceeds realized upon any judgement or settlement in AD Pharma's favor regarding such negotiations or legal proceeding, net of direct out-of-pocket expenses of the Parties relating thereto, shall be for the benefit of AD Pharma, provided AD Pharma shall pay Acura the same royalty on the excess as it is required to pay on Net Sales. Notwithstanding the foregoing, Acura's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license or covenant not to sue, relating to the LIMITx™ Patent Rights, or dedication to the public, admission of invalidity or unenforceability, or abandonment of the LIMITx™ Patent Rights.

7.6 Notice by AD Pharma to Defend; Acura's Right to Defend.

(a) Notwithstanding Section 7.4, no later than five (5) business days after AD Pharma learns of a Paragraph IV Certification, an Inter Parties or Post Grant review petition, or any other challenge that an LIMITx™ Patent Right is invalid or unenforceable, which LIMITx™ Patent Right claims a Product or Product Line Extension, or the manufacture, or use thereof, AD Pharma shall provide written notice to Acura as to whether AD Pharma will exercise its rights conferred in Section 7.5.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

(b) If AD Pharma does not provide Acura with such written notice within its ten (10) business day period of Section 7.6(a) or within such time provided notice to Acura electing not to exercise its rights conferred in Section 7.5, then Acura may at its option, but shall not be obligated to, notify AD Pharma in writing at any time thereafter whether Acura will undertake the enforcement or defense of any legal proceeding.

(c) If Acura undertakes such defense or enforcement pursuant to Section 7.6(b), the following paragraph shall apply: Acura shall be entitled, at Acura's own cost and expense, to exclusively pursue any negotiations with such Third Party and exclusively control the enforcement or defense of any legal proceeding regarding such challenge. If Acura undertakes the defense or enforcement, Acura shall be entitled to any judgement or settlement relating to such action. AD Pharma agrees to join as a named party and cooperate, upon reasonable request of Acura and at AD Pharma's cost and expense, in any such steps or legal proceeding. Notwithstanding the foregoing, AD Pharma's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that would limit or restrict AD Pharma's rights conferred by this Agreement.

7.7 Allegations of Infringement by Third Parties.

(a) Each of AD Pharma and Acura will forthwith notify the other Party upon learning of any allegation by a Third Party that (i) a Product or Product Line Extension may infringe Third Party intellectual property rights, or (ii) any product that includes the LIMITx™ Technology other than a Product or Product Line Extension (a "**Related LIMITx™ Technology Product**") may infringe Third Party intellectual property rights and the Parties shall in that event consult with each other, including a possible defense strategy.

(b) If the infringement allegation against a Product or Product Line Extension is due to the LIMITx™ Technology, AD Pharma has the obligation to pursue any negotiations with the claimant and to control the defense of any legal proceeding regarding such infringement allegation against the Product at its own cost and expense (including the cost of defense, judgments, damages and settlements) and shall indemnify and hold Acura harmless from same. Acura shall, at AD Pharma's expense, reasonably collaborate with AD Pharma and render any reasonable assistance to AD Pharma in AD Pharma's negotiations with the claimant and defense of any such legal proceeding regarding such allegation of infringement.

(c) If the infringement allegation is against a Related LIMITx™ Technology Product, Acura reserves the limited right to negotiate with the claimant solely in its own name and on its own behalf relating to the Related LIMITx™ Technology Product and defend only itself in any legal proceeding regarding such allegation of infringement as it may relate to the Related LIMITx™ Technology Product at its own cost and expense (including the cost of defense, judgments, damages, and settlements). AD Pharma shall, at AD Pharma's expense, reasonably collaborate with Acura and render any reasonable assistance to Acura in Acura's negotiations with the claimant and Acura's defense of any legal proceeding regarding such allegation of infringement as it may relate to the Related LIMITx™ Technology Product. If Acura elects to undertake negotiation or defense pursuant to this section, Acura is neither authorized nor obligated to negotiate on behalf of or defend AD Pharma.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

7.8 Settlement of Allegations of Infringement. For purposes of Sections 7.7 and 7.8, the Party negotiating with the claimant or defending the legal proceeding is referred to as the "Defending Party" and the other Party is referred to as the "non-Defending Party." The Defending Party shall have the right to exclusively control and manage such claim of infringement (including without limitation, control over the settlement of such action), provided, however, that any such settlement shall also release the non-Defending Party from the claims relating to the claim of infringement (provided that the non-Defending Party executes a mutual release in favor of the party releasing the non-Defending Party). The written consent of the non-Defending Party to the settlement is required if the settlement obligates the non-Defending Party to take or forgo any action (which consent shall not be unreasonably withheld, delayed or conditioned). Without limiting the foregoing, Acura's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license, covenant not to sue relating to, dedication to the public, admission of non-infringement, invalidity or unenforceability or abandonment of Acura's Intellectual Property Rights, including without limitation the LIMITx™ Technology, and AD Pharma's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that that would limit or restrict the ability of AD Pharma to have made, use, offer for sale, sell or otherwise commercialize the Product or Product Line Extension in the Field in the Territory

ARTICLE VIII
REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Cooperation. From time to time, as and when requested by either party hereto, the other party shall execute and deliver, or cause to be executed and delivered, all such documents and instruments and shall take, or cause to be taken, all such further or other actions, as such other Party may reasonably deem necessary or desirable to consummate the transactions contemplated by this Agreement.

8.2 Mutual Representations, Warranties and covenants. Each Party represents and warrants that

(i) it has the full right, power and authority to enter into this Agreement;

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

(ii) that entering into and performing its obligations set forth in this Agreement does not conflict with any other agreement to which it is a party;

(iii) as at the Effective Date, there are no claims, judgments, litigations, suits, actions, disputes, arbitration, judicial or legal, administrative or other proceedings or governmental investigations pending or, to such Party's knowledge, threatened against such Party or any of its Affiliates, and neither such Party nor its Affiliates is a party to any settlement agreement, which would be reasonably expected to materially affect or restrict the ability of such Party to consummate the transactions contemplated under this Agreement and to perform its obligations under this Agreement; and

(iv) neither Party has used or shall use any employee or consultant who has been debarred by any Regulatory Authority or, to such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party promptly upon becoming aware that any of its employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.

8.3 Acura Representations, Warranties. Acura represents and warrants that: (i) it has all rights necessary to validly grant the licenses set forth in Section 2; (ii) the Patent Rights included in the LIMITx™ Technology and set forth on Exhibit A have not expired and any maintenance fees have been paid when due or within any permitted extension; (iii) it is not subject to any court proceedings, judgment or order related to the subject matter of this Agreement; (iv) it has not received any written claim or allegation of infringement from a Third Party for the infringement of Third Party intellectual property rights based on the making, using, or selling of the Product; (v) it has not assigned and/or granted licenses, nor shall it assign and/or grant licenses, to the LIMITx™ Technology to any Third Party that would restrict or impair the rights granted hereunder, and it has not granted to anyone any rights that cover the Product or Product Line Extension in the Territory; (vi) the LIMITx™ Patent Rights are the only Patent Rights Controlled by Acura relating to Products or Product Line Extensions; (vii) to its actual knowledge the LIMITx™ Technology (a) does not infringe any valid claim in a granted patent known to Acura as of the Effective Date owned by a Third Party and (b) has not been misappropriated from a Third Party; (viii) the Nexafed® Agreement has not been terminated or cancelled; and (ix) Acura reaffirms that all Acura Representations and Warranties set forth in the Nexafed® Agreement are true and correct as of the Effective Date of this Agreement to the same degree and with the same force and effect as if they were on the date hereof.

8.4 AD Pharma's Representations Warranties and Covenants. AD Pharma represents, warrants and covenants that (i) it shall develop, manufacture and commercialize the Product and Product Line Extension in accordance with Applicable Law and (ii) neither AD Pharma nor its Affiliates shall engage in a Patent Challenge, or knowingly assist any Third Party to engage in a Patent Challenge with respect to any of the LIMITx™ Patent Rights or intentionally or willfully infringe the LIMITx™ Patent Rights.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

8.5 Disclaimers. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE IX
TERM AND TERMINATION

9.1 Term and Expiration. The "**Term**" of this Agreement shall be from the Effective Date until the earlier of (i) termination of this Agreement pursuant to Section 9.2, 9.3, or 9.4, or (ii) the last to expire Royalty Term.

9.2 Termination for Breach.

Either Party may terminate the Agreement in its entirety by giving written notice of termination at any time, if the other Party fails to fulfill or breaches any material term or condition of this Agreement, and does not remedy the failure or breach within thirty (30) days of receipt of written notice specifying such failure or breach given by the other Party.

9.3 Termination for Convenience. At any time after the Effective Date, AD Pharma may terminate this Agreement in its entirety either with or without cause by providing thirty (30) days advance written notice to Acura.

9.4 Termination for Patent Challenge.

Acura will be permitted to terminate this Agreement by written notice effective upon receipt if AD Pharma or its Affiliates, directly or indirectly through assistance granted to a Third Party, commence any interference or opposition proceeding, challenge in a legal or administrative proceeding the validity or enforceability of, or oppose in a legal or administrative proceeding any extension of or the grant of a supplementary protection certificate with respect to (i) any Patent Rights licensed hereunder (except as a defense against a patent infringement action initiated by Acura or its Affiliates or licensees against AD Pharma or its Affiliates) (each such action, a "**Patent Challenge**").

AD Pharma will include provisions in all agreements granting sublicenses of AD Pharma's rights hereunder (other than agreements with manufacturers, services providers, distributors and other agents) providing that if the sublicensee or its Affiliates undertake a Patent Challenge with respect to any Patent Rights licensed hereunder under which the sublicensee is sublicensed, AD Pharma will be permitted to terminate such sublicense agreement. If a sublicensee of AD Pharma (or an Affiliate of such sublicensee) undertakes a Patent Challenge of any such Patent Right under which such sublicensee is sublicensed (other than sublicensees that are manufacturers, services providers, distributors and other agents), then AD Pharma upon receipt of notice from Acura of such Patent Challenge will terminate the applicable sublicense agreement. If AD Pharma fails to so terminate such sublicense agreement, Acura may terminate AD Pharma's right to sublicense in the country(ies) covered by such sublicense agreement and any sublicenses previously granted in such country(ies) shall automatically terminate. In connection with such sublicense termination, AD Pharma shall cooperate with Acura's reasonable requests to cause such a terminated sublicensee to discontinue activities with respect to the Product and Product Line Extension in such country(ies).

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

9.5 Consequences of Expiration and Termination.

9.5.1 Upon expiration of this Agreement with respect to a country, AD Pharma shall retain a non-exclusive, perpetual, irrevocable, fully paid-up and royalty-free license to, develop, have made, sell, promote, or otherwise exploit the Product and Product Line Extension in such country. AD Pharma shall be required to at all times post-expiration of the Agreement with respect to a country either maintain the Regulatory Approvals for the Products or transfer such Regulatory Approvals and associated Regulatory Documentation back to Acura (unless Acura declines such transfer in writing).

9.5.2 Upon termination of this Agreement: (i) all of AD Pharma's licenses with respect to Acura's trademarks and the LIMITx™ Technology shall terminate; (ii) AD Pharma's non-compete contained in Section 2.9 shall terminate immediately; and (iii) all Regulatory Approvals, Regulatory Documentation and regulatory filings shall be transferred back to Acura; (iv) AD Pharma shall transfer to Acura the trademarks associated with Products and Product Line Extensions; and (v) at Acura's request AD Pharma and Acura shall use Commercially Reasonable Efforts to transition the commercialization of the Product; and any Product Line Extension back to Acura so that, among other things, sales of the Product and Product Line Extension are not interrupted and which may include, by way of examples, assignment of any manufacturing and supply agreements to Acura or its designee and providing sales and marketing materials, inventory reports, regulatory communication and health care provider prescribers.

Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.

9.5.3 All of the Parties' rights and obligations under Sections 2.9, 2.13, 3.2, 3.3, 3.4, 3.6, 3.8,3.9, 3.10, 3.12, 3.13 and Articles 4, 5, 6, 7, 9, and 10, shall survive termination or expiration of this Agreement (unless such Section specifically states that it shall only survive expiration but not termination, in which case it shall survive as set forth therein), and all other provisions reasonably construed to survive shall also survive termination or expiration. Where a provision specifies a survival period, such provision shall survive only during such survival period.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

ARTICLE X
MISCELLANEOUS

10.1 Dispute Resolution. AD Pharma and Acura agree to use good faith efforts to resolve any and all disputes arising out of or relating to this Agreement. If any dispute amongst the Parties remains unresolved after ten (10) business days, the chief executive officers of the Parties will meet to address the matter. If the chief executive officers cannot resolve the dispute after forty five (45) days following receipt of notice by one Party from the other of a dispute under this Agreement, then the matter shall by fully and finally resolved by arbitration. A Party that desires to arbitrate a dispute shall serve a written notice upon another requesting arbitration of a dispute pursuant to this Section 10.1. Any such arbitration shall be submitted to final and binding arbitration under the then current commercial arbitration rules of the American Arbitration Association (the "AAA") in accordance with this Section 10.1. The place of arbitration of any dispute shall be New York, New York. Such arbitration shall be conducted by one (1) arbitrator mutually agreed by the Parties but if such agreement cannot be reached within ten (10) days of the commencement of the arbitration, then an arbitrator appointed by the AAA. The arbitrator shall be a person with relevant experience in the pharmaceutical industry. The arbitration proceeding shall be held as soon as practicable but in any event within ninety (90) days of appointment of the arbitrator. Any award rendered by the arbitrators shall be final and binding upon the Parties. Judgment upon any award rendered may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. The arbitrator shall render a formal, binding, non-appealable resolution and award as expeditiously as possible, but not more than forty-five (45) days after the hearing. Each Party shall pay its own expenses of arbitration, and the expenses of the arbitrator shall be equally shared between the Parties unless the arbitrators assess as part of their award all or any part of the arbitration expenses of a Party (including reasonable attorneys' fees) against the other Party. A Party may make application to the Arbitrator for the award and recovery of its fees and expenses (including reasonable attorneys' fees). This Section 10.1 shall not prohibit a Party from seeking injunctive relief from a court of competent jurisdiction in the event of a breach or prospective breach of this Agreement by any other Party which would cause irreparable harm to the first Party.

10.2 Rights in Bankruptcy.

10.2.1 All rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Title 11 of the United States Code ("**Title 11**"), licenses of rights to "intellectual property" as defined in Title 11, and, in the event that a case under Title 11 is commenced by or against either Party (the "**Bankrupt Party**"), the other Party shall have all of the rights set forth in Section 365(n) of Title 11 to the maximum extent permitted thereby. During the Term, each Party shall create and maintain current copies to the extent practicable of all such intellectual property. Without limiting the Parties' rights under Section 365(n) of Title 11, if a case under Title 11 is commenced by or against the Bankrupt Party, the other Party shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the possession of such other Party, shall be promptly delivered to it (i) before this Agreement is rejected by or on behalf of the Bankrupt Party, within thirty (30) days after the other Party's written request, unless the Bankrupt Party, or its trustee or receiver, elects within thirty (30) days to continue to perform all of its obligations under this Agreement, or (ii) after any rejection of this Agreement by or on behalf of the Bankrupt Party, if not previously delivered as provided under clause (i) above. All rights of the Parties under this Section 10.2 and under Section 365(n) of Title 11 are in addition to and not in substitution of any and all other rights, powers, and remedies that each party may have under this Agreement, Title 11, and any other Applicable Laws. The non-Bankrupt Party may perform the obligations of the Bankrupt Party hereunder with respect to such intellectual property, but neither such provision nor such performance by the non-Bankrupt Party shall release the Bankrupt Party from any such obligation or liability for failing to perform it.

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

(b) The Parties agree that they intend the foregoing non-Bankrupt Party rights to extend to the maximum extent permitted by law and any provisions of applicable contracts with Third Parties, including for purposes of Title 11, (i) the right of access to any intellectual property (including all embodiments thereof) of the Bankrupt Party or any Third Party with whom the Bankrupt Party contracts to perform an obligation of the Bankrupt Party under this Agreement, and, in the case of the Third Party, which is necessary for the development, Regulatory Approval and manufacture of Products and (ii) the right to contract directly with any Third Party described in (i) in this sentence to complete the contracted work.

(c) Any intellectual property provided pursuant to the provisions of this Section 10.2 shall be subject to the licenses set forth elsewhere in this Agreement and the payment obligations of this Agreement, which shall be deemed to be royalties for purposes of Title 11.

10.3 No Set-off. Except as expressly set forth in this Agreement, neither Party may set-off or recoup against a payment owed to the other Party, without the consent of the other Party.

10.4 Waivers; Amendment. The failure of either Party to insist, in any one or more instances, upon the performance of any of the terms, covenants or conditions of this Agreement or to exercise any right hereunder, shall not be construed as a waiver or relinquishment of the future performance of any such term, covenant or conditions or the future exercise of such right, and the obligation of the other Party with respect to such future performance shall continue in full force and effect. No item or provision of this Agreement may be altered, amended or waived except by a writing signed by both Parties.

10.5 Assignment. Neither Party shall assign any of its rights or obligations under this Agreement, in whole or in part to any person, firm, partnership, or other entity, except to an Affiliate, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned. Notwithstanding the foregoing, a Party may assign this Agreement in connection with (i) the transfer of all or substantially all of its assets or its LIMITx™ Technology assets (by merger, sale of assets or otherwise) to the transferee thereof or (ii) the sale of its line of business to which this Agreement relates; provided in each instance the transferee agrees to be bound by all obligations of the transferring Party to the other Party hereunder.

10.6 Covenant of Further Assurances. AD Pharma and Acura covenant and agree that subsequent to the execution and delivery of this Agreement and without any additional consideration, each of AD Pharma and Acura shall execute and deliver any further legal instruments and perform such acts which are or may become necessary to effectuate the purposes of this Agreement.

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10.7 Headings. The heading of the Articles and Sections used in this Agreement are included for convenience only and are not to be used in construing or interpreting this Agreement.

10.8 Governing Law. Unless any competent governmental entity or any other applicable laws and regulations require otherwise, this Agreement shall be governed by and construed under the laws of the State of New York as applied to agreements executed and performed solely in New York, without regard to choice-of-law principles thereof.

10.9 Severability. The provisions of this Agreement shall be deemed separate. Accordingly, the invalidity or unenforceability of any particular provision of this Agreement shall not affect the other provisions, and this Agreement shall be construed in all respects as if such invalid or unenforceable provision were omitted, except in cases where such unenforceable provision is a basic prerequisite of any Party or both Parties to enter into this Agreement. The Parties shall in such an instance use their best efforts to replace the unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

10.10 Entire Agreement. This Agreement including all Exhibits and Schedules attached hereto constitutes the entire Agreement between AD Pharma and Acura with respect to the subject matter addressed herein and this Agreement supersedes all prior understandings and agreements, whether oral or written, between the AD Pharma and Acura with respect thereto. Any amendment to any provisions set forth in the Agreement must be in writing, signed by both AD Pharma and Acura and specifically state that it is an amendment.

10.11 Counterparts; Facsimile Signatures. This Agreement may be executed in multiple counterparts, each of which shall be deemed to be an original and of equal force and effect, but all of which taken together shall constitute one and the same instrument. A facsimile, digital, PDF, e-mail or other electronic copy hereof shall suffice as an original Agreement.

10.12 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

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IN WITNESS WHEREOF, AD Pharma and Acura have caused this Agreement to be executed by their duly authorized officers as of the day and year first above written.

ACURA PHARMACEUTICALS, INC.		**ABUSE DETERRENT PHARMA, LLC**	
By:	/s/ Robert B. Jones	By:	/s/ John L. Schutte
Name:	Robert B. Jones	Name:	John L. Schutte
Title:	President & CEO	Title:	Manager
Date:	June 28, 2019	Date:	June 28, 2019

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

SCHEDULE 1

LIMITx™ Regulatory Application Submission Timeline

The following comprise the LIMITx™ Regulatory Application Submission Timeline:

1. By July 30, 2019 or before, Acura shall identify a contract research organization ("CRO") to prepare and test batches of the Product as needed for FDA Regulatory Approval Application of the Product. AD Pharma has the right to approve or disapprove the CRO.

2. By September 30, 2019 or before, Acura shall have entered into a CRO Agreement with the CRO identified and approved as set forth above, including a research protocol providing for preparation and testing of the Product necessary to gain timely filing acceptance by the FDA of a Regulatory Approval Application for the Product. AD Pharma has the right to approve or disapprove such Agreement and research protocol.

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.

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Exhibit A

ACURA PHARMACEUTICALS, INC.
LIMITx™ Patent Summary as of Effective Date

Case	Patent	File/Issue/Expire	Primary Subject	Status
5018-00	US 9,101,636	F-11/27/2013 I-8/11/2015 E-11/27/2033	Drug+acid soluble cationic copolymer+buffering agent to retard release >3 tabs (buffer limited)	
5018-01	US 9,320,796	F-7/2/2015 I-4/26/2016 E-11/27/2033	Drug+acid soluble cationic copolymer+buffering agent to retard release >3 tabs (polymer limited)	
5018-02	US 9,662,393	F-3/18/2016 I-5/30/2017 E-11/27/2033	Drug+acid soluble+buffering agent to retard release >3 tabs (buffer limited)	
5018-03	15/588,982	F-5/8/2017	Drug+acid soluble+buffer to retard release >3 tabs – Broad claims	Notice of Allowance mailed June 3, 2019

Patents and applications summarized in Exhibit A include all types of patents and applications set forth in the defined term, "Patent Rights".

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Exhibit B
Form of Royalty Report.

ROYALTY REPORT
Quarter Reported _____

Licensee Name:
Property:
Territory:
Address:
Contact:
Phone Number:
Fax Number:

CURRENT QUARTER						
Territory or Territories	**Gross Sales**	**Less: Deductions/ Returns***	**Discounts**	**Net Sales**	**Royalty Rate %**	**Royalty**
	$ -	$ -	$ -	$ -	%	$ -
	$ -	$ -	$ -	$ -	%	$ -
	$ -	$ -	$ -	$ -	%	$ -
Total	$ -	$ -	$ -	$ -	%	$ -

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Exhibit C

Acura Pharmaceuticals Licenses LIMITx™ LTX-03

Agreement Provides For Completion of Development and Commercialization
Transaction Valued at up to $21.3 Million, not including Royalties

PALATINE, IL, July 1, 2019: Acura Pharmaceuticals, Inc. (OTC Pink: ACUR) today announced a License, Development and Commercialization Agreement (the "Agreement") with Abuse Deterrent Pharmaceuticals, 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. AD Pharma retains commercialization rights from which Acura will receive royalties and potential sales related milestones.

LTX-03 (hydrocodone with acetaminophen)

Recent reports suggest growing numbers of legitimate pain patients are going undertreated as they can no longer find doctors willing to treat them due to new prescribing guidelines associated with the opioid epidemic. Suicide is increasingly seen as the only remedy for some of these patients through opioid overdose. Our goal with LIMITx is to develop a treatment for effective pain relief at a one or two tablet dose while providing overdose protection by limiting high peak levels of drug in the bloodstream (Cmax) that can lead to respiratory depression and death when more than the recommended dose is ingested. LIMITx works by neutralizing stomach acid with buffering ingredients as increasing numbers of tablets are swallowed thereby reducing the stomach acid available to cause the release and subsequent systemic absorption of the active ingredient from micro-particles contained in the LIMITx tablets. In a human clinical study, formulations of LTX-03 demonstrated, under fasted conditions, analgesic levels of hydrocodone in the blood when taken at a recommended one or two tablet dose but reduced the maximum blood level (Cmax) up to 34% when subjects were exposed to higher buffer ingredient levels. Hydrocodone with acetaminophen remains the single largest prescribed opioid in the U.S. with excess oral ingestion as the most prevalent method of misuse. Clinical studies with hydromorphone (LTX-04) demonstrated reductions in Cmax of up to 65% when up to 8 tablets were ingested. Analysis of forensic data associated with hydrocodone overdose death suggests a typical consumption of approximately 16 immediate-release tablets, well within the number of tablets in an average filled opioid prescription. The Company intends to demonstrate that a meaningful reduction in Cmax associated with oral overdose can mitigate the risk of respiratory depression and death. LTX-03 may offer safety advantages over existing opioid therapies consistent with the Food and Drug Administration’s (FDA) recently proposed new standards for the approval of opioid products.

Financial Terms

The Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03. Financial arrangements include:

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- Monthly license payments by AD Pharma of $350,000 up to the earlier of 18 months 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;
- A $6 million loan which consolidates $5.25 million in prior loans from Mr. John Schutte plus an additional $750 thousand loan upon execution of the Agreement. Terms of the consolidated loan are amended to provide for a July 1, 2023 maturity date, interest at 7.5% with all payments of principle and interest deferred to maturity, conversion rights into Acura common stock at $0.16, the issuance of a warrant to AD Pharma to purchase 10 million shares of the Company's common stock at a price of $0.01 per shares and a security interest in all Acura assets;
- Upon commercialization of LTX-03, Acura receives stepped royalties on sales and is eligible for certain sales related milestones; and
- Acura authorizes 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);

AD Pharma may terminate the Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA within 18 months, AD Pharma may terminate the Agreement and take ownership of the intellectual property.

About Acura Pharmaceuticals

Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and product candidates intended to mitigate the risk of outcomes associated with product misuse. The Company has three proprietary technologies: LIMITx™, AVERSION® and IMPEDE®.

LIMITx utilizes acid neutralizing ingredients to precisely control gastric acidity that limits the release of drug from tablets and its subsequent systemic absorption when multiple tablets are ingested. LIMITx is useful with products whose side effect risks can be mitigated by limiting exposure to a drug in overdose situations.

AVERSION, used in the FDA approved drug OXAYDO® (oxycodone HCl) marketed by Egalet Corporation, utilizes polymers designed to limit the abuse of the product by nasal snorting and injection. AVERSION is also licensed to Kempharm for use in certain of their products.

IMPEDE, used in NEXAFED® (pseudoephedrine HCl) and NEXAFED® Sinus (pseudoephedrine HCl/acetaminophen) marketed by MainPointe Pharmaceuticals, utilizes polymers and other ingredients to disrupt the extraction and processing of pseudoephedrine from the tablets into methamphetamine.

Forward-Looking Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to:

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- our ability to fund or obtain funding for our continuing operations, including the development of our products utilizing our LIMITx and IMPEDE technologies;
- whether our licensees will terminate the license prior to commercialization;
- the expected results of clinical studies relating to LTX-03, IMPEDE ER or any successor product candidate, the date by which such studies will complete and the results will be available and whether any product candidate will ultimately receive FDA approval;
- the ability of LTX-03 single tablets to achieve bioequivalence or to demonstrate efficacy in a clinical study;
- whether our licensing partners will exercise their options to additional products;
- whether LIMITx will retard the release of opioid active ingredients as dose levels increase;
- whether the extent to which products formulated with the LIMITx technology mitigate respiratory depression risk will be determined sufficient by the FDA;
- our and our licensee's ability to successfully launch and commercialize our products and technologies;
- our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of, timing of commercial launch and competitive environment for any of our products;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
- the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support an NDA and FDA approval of our product candidates;
- changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;
- whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and whether we will be able to promote the features of our technologies; and
- whether our product candidates will ultimately perform as intended in commercial settings.

In some cases, you can identify forward- looking statements by terms such as "may," "will", "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "indicates", "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in our filings with the Securities and Exchange Commission.

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Contact:
for Acura Investor Relations
investors@acurapharm.com
847-705-7709

******* Portions of this information have been redacted pursuant to Reg S-K, items 601(b)(10)**

Exhibit 10.51

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTION 5.3 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

COMMON STOCK PURCHASE WARRANT

Company:	ACURA PHARMACEUTICALS, INC., a New York corporation
Number of Shares:	10,000,000
Type/Series of Stock:	Common Stock
Warrant Price:	$0.01 per share
Issue Date:	June 28, 2019
Expiration Date:	June 28, 2024

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, John Schutte c/o MainPointe Pharmaceuticals, LLC, 333 E. Main Street, Suite 200, Louisville, KY 40202 ("**Investor**" and, together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "**Holder**") is entitled to purchase the number of fully paid and non-assessable shares (the "**Shares**") of the above-stated Type/Series of Stock (the "**Class**") of the above-named company (the "**Company**") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant.

SECTION 1. EXERCISE.

1.1 Method of Exercise. Holder may at any time and from time to time exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Fair Market Value. If the Company's common stock is then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "**Trading Market**") and the Class is common stock, the fair market value of a Share shall be the closing price or last sale price of a share of common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If the Company's common stock is not traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

1.3 Delivery of Certificate and New Warrant. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.

1.4 Replacement of Warrant. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

1.5 Treatment of Warrant Upon Acquisition of Company.

(a) Acquisition. For the purpose of this Warrant, "**Acquisition**" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company (ii) any merger of the Company into or consolidation of the Company with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization (or, if such Company stockholders beneficially own a majority of the outstanding voting power of the surviving or successor entity as of immediately after such merger, consolidation or reorganization, such surviving or successor entity is not the Company); or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power.

(b) Treatment of Warrant at Acquisition. In the event of an Acquisition in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a "**Cash/Public Acquisition**"), either (i) Holder shall exercise this Warrant pursuant to Section 1.1 and such exercise will be deemed effective immediately prior to and contingent upon the consummation of such Acquisition or (ii) if Holder elects not to exercise the Warrant, this Warrant will expire immediately prior to the consummation of such Acquisition.

(c) The Company shall provide Holder with written notice of its request relating to the Cash/Public Acquisition (together with such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such contemplated Cash/Public Acquisition giving rise to such notice), which is to be delivered to Holder not less than seven (7) Business Days prior to the closing of the proposed Cash/Public Acquisition.

(d) Upon the closing of any Acquisition other than a Cash/Public Acquisition defined above, the acquiring, surviving or successor entity shall assume the obligations of this Warrant, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, subject to further adjustment from time to time in accordance with the provisions of this Warrant.

(e) As used in this Warrant, "**Marketable Securities**" means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise or convert this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition.

SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

2.1 Stock Dividends, Splits, Etc. If the Company declares or pays a dividend or distribution on the outstanding shares of the Class payable in common stock or other securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Class by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the outstanding shares of the Class are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Warrant Price shall be proportionately increased and the number of Shares shall be proportionately decreased.

2.2 Reclassification, Exchange, Combinations or Substitution. Upon any event whereby all of the outstanding shares of the Class are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, this Warrant will be exercisable for the number, class and series of Company securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, and subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 2.2 shall similarly apply to successive reclassifications, exchanges, combinations substitutions, replacements or other similar events.

2.3 Adjustments for Diluting Issuances. Without duplication of any adjustment otherwise provided for in this Section 2, the number of shares of common stock issuable upon conversion of the Shares shall be subject to anti-dilution adjustment from time to time in the manner set forth in the Company's Articles or Certificate of Incorporation as if the Shares were issued and outstanding on and as of the date of any such required adjustment.

2.4 No Fractional Share. No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.2 above) of a full Share, less (ii) the then-effective Warrant Price.

2.5 Notice/Certificate as to Adjustments. Upon each adjustment of the Warrant Price, Class and/or number of Shares, the Company, at the Company's expense, shall notify Holder in writing within a reasonable time setting forth the adjustments to the Warrant Price, Class and/or number of Shares and facts upon which such adjustment is based. The Company shall, upon written request from Holder, furnish Holder with a certificate of its Chief Financial Officer, including computations of such adjustment and the Warrant Price, Class and number of Shares in effect upon the date of such adjustment.

SECTION 3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 Representations and Warranties. The Company represents and warrants to, and agrees with, the Holder that all Shares which may be issued upon the exercise of this Warrant, and all securities, if any, issuable upon conversion of the Shares, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of shares of the Class, common stock and other securities as will be sufficient to permit the exercise in full of this Warrant and the conversion of the Shares into common stock or such other securities.

3.2 Notice of Certain Events. If the Company proposes at any time to:

(a) declare any dividend or distribution upon the outstanding shares of the Class or common stock, whether in cash, property, stock, or other securities and whether or not a regular cash dividend;

(b) offer for subscription or sale pro rata to the holders of the outstanding shares of the Class any additional shares of any class or series of the Company's stock (other than pursuant to contractual pre-emptive rights);

(c) effect any reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Class; or

(d) effect an Acquisition or to liquidate, dissolve or wind up;

then, in connection with each such event, the Company shall give Holder:

(1) at least seven (7) Business Days prior written notice of the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Class will be entitled thereto) or for determining rights to vote, if any, in respect of the matters referred to in (a) and (b) above; and

(2) in the case of the matters referred to in (c) and (d) above at least seven (7) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event).

SECTION 4. REPRESENTATIONS, WARRANTIES OF THE HOLDER.

The Holder represents and warrants to the Company as follows:

4.1 Purchase for Own Account. This Warrant and the securities to be acquired upon exercise of this Warrant by Holder are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

4.2 Disclosure of Information. Holder is aware of the Company's business affairs and financial condition and has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

4.3 Investment Experience. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

4.4 Accredited Investor Status. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

4.5 The Act. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. Holder understands that this Warrant and the Shares issued upon any exercise hereof must be held indefinitely unless subsequently registered under the Act and qualified under applicable state securities laws, or unless exemption from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.

4.6 No Voting Rights. Holder, as a Holder of this Warrant, will not have any voting rights until the exercise of this Warrant.

SECTION 5. MISCELLANEOUS.

5.1 Term. Subject to the provisions of Section 1.5 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Eastern time, on the Expiration Date and shall be void thereafter.

5.2 Legends. Each certificate evidencing Shares (and each certificate evidencing the securities issued upon conversion of any Shares, if any) shall be imprinted with a legend in substantially the following form:

> THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO INVESTOR DATED JUNE 28, 2019, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

5.3 Compliance with Securities Laws on Transfer. This Warrant and the Shares issued upon exercise of this Warrant (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to an affiliate of Holder, provided that any such transferee is an "accredited investor" as defined in Regulation D promulgated under the Act. Additionally, the Company shall also not require an opinion of counsel if there is no material question as to the availability of Rule 144 promulgated under the Act.

5.4 Transfer Procedure. After receipt by Investor of the executed Warrant, Investor may transfer all or part of this Warrant to one or more of Investor's affiliates (each, an "**Investor Affiliate**"), by execution of an Assignment substantially in the form of Appendix 2. Subject to the provisions of Article 5.3 and upon providing the Company with written notice, Investor, any such Investor Affiliate and any subsequent Holder, may transfer all or part of this Warrant or the Shares issuable upon exercise of this Warrant (or the Shares issuable directly or indirectly, upon conversion of the Shares, if any) to any other transferee, provided, however, in connection with any such transfer, the Investor Affiliate(s) or any subsequent Holder will give the Company notice of the portion of the Warrant being transferred with the name, address and taxpayer identification number of the transferee and Holder will surrender this Warrant to the Company for reissuance to the transferee(s) (and Holder if applicable).

5.5 Notices. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by facsimile or electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 5.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

John Schutte
c/o MainPointe Pharmaceuticals, LLC
333 E. Main Street
Suite 200
Louisville, Kentucky 40202
Email: _____

Notice to the Company shall be addressed as follows until Holder receives notice of a change in address:

ACURA PHARMACEUTICALS, INC.
616 N. North Court, Suite 120
Palatine, Illinois
Attn: Peter A. Clemens
Fax: (847) 705-5399
Email: pclemens@acurapharm.com

With a copy (which shall not constitute notice) to:

Sills Cummis & Gross P.C.
One Riverfront Plaza
Newark, New Jersey 07102
Attn: S. Jason Teele, Esq.
Fax: (973) 643-6500
Email: steele@sillscummis.com

5.6 Waiver. This Warrant and any term hereof may be changed, waived, discharged or terminated (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.

5.7 Attorneys' Fees. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorneys' fees.

5.8 Counterparts; Facsimile/Electronic Signatures. This Warrant may be executed in counterparts, all of which together shall constitute one and the same agreement. Any signature page delivered electronically or by facsimile shall be binding to the same extent as an original signature page with regards to any agreement subject to the terms hereof or any amendment thereto.

5.9 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to its principles regarding conflicts of law.

5.10 Headings. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

5.11 Business Days. "**Business Day**" is any day that is not a Saturday, Sunday or a day which banks in the State of New York or Commonwealth of Virginia are closed.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

"COMPANY"

ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens

Name: Peter A. Clemens
(Print)

Title: Senior Vice President & Chief Financial Officer

"HOLDER"

/s/ John Schutte
JOHN SCHUTTE

[*Signature Page to Warrant to Purchase Stock*]

APPENDIX 1

NOTICE OF EXERCISE

1. The undersigned Holder hereby exercises its right purchase _____ shares of the Common Stock of ACURA PHARMACEUTICALS, INC. (the "**Company**") in accordance with the attached Warrant To Purchase Stock, and tenders payment of the aggregate Warrant Price for such shares as follows:

☐ check in the amount of $_____ payable to order of the Company enclosed herewith

☐ Wire transfer of immediately available funds to the Company's account

☐ Other [Describe] _____

2. Please issue a certificate or certificates representing the Shares in the name specified below:

_____
Holder's Name

_____

_____
(Address)

3. By its execution below and for the benefit of the Company, Holder hereby restates each of the representations and warranties in Section 4 of the Warrant to Purchase Stock as of the date hereof.

HOLDER:

_____

By: _____

Name: _____

Title: _____

Date: _____

Appendix 1

ASSIGNMENT

For value received, Holder hereby sells, assigns and transfers unto

Name: ABUSE DETERRENT PHARMA, LLC

Address: 333 East Main Street, Suite 200,
Louisville, Kentucky 40202

Tax ID: _____

that certain Warrant to Purchase Stock issued by ACURA PHARMACEUTICALS, INC. (the "**Company**"), on June 28, 2019 (the "**Warrant**") together with all rights, title and interest therein.

HOLDER

_____

JOHN SCHUTTE

Date: June 28, 2019

By its execution below, and for the benefit of the Company, ABUSE DETERRENT PHARMA, LLC makes each of the representations and warranties set forth in Article 4 of the Warrant and agrees to all other provisions of the Warrant as of the date hereof.

ABUSE DETERRENT PHARMA, LLC

By: _____

Name: John Schutte

Title: Manager

Exhibit 10.52

Assignment of Promissory Note, Warrant and Security Agreement

For value received, John Schutte ("**Assignor**") hereby assigns and transfers to Abuse Deterrent Pharma, LLC, a Kentucky limited liability company ("**Assignee**"), all of the Assignor's right, title and interest in and to (i) that certain Amended, Consolidated and Restated Convertible Secured Promissory Note (the "**Note**") dated June 28, 2019 made and delivered by Acura Pharmaceuticals, Inc., a New York corporation (the "**Company**"), to Assignor in the aggregate principal sum of **SIX MILLION DOLLARS ($6,000,000)**, (ii) that certain Warrant to purchase common stock dated June 28, 2019 made and delivered by the Company to Assignor, and (iii) that certain Security Agreement dated June 28, 2019 made by the Company in favor of Assignor, each without recourse or any warranty.

Dated: June 28, 2019

ASSIGNOR:

/S/ JOHN SCHUTTE
JOHN SCHUTTE

BY ITS EXECUTION BELOW, AND FOR THE BENEFIT OF THE COMPANY, ASSIGNEE HEREBY MAKES EACH OF THE REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTION 8 OF THE NOTE AND AGREES TO ALL OTHER PROVISIONS OF THE NOTE AND SECURITY AGREEMENT AS OF THE DATE HEREOF.

ASSIGNEE:

ABUSE DETERRENT PHARMA, LLC

By: /s/ John Schutte
John Schutte, Manager

BY ITS EXECUTION BELOW, ACURA PHARMACEUTICALS, INC. HEREBY ACKNOWLEDGES, AGREES AND CONSENTS TO THIS ASSIGNMENT:

ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens

Name: Peter A. Clemens

Title: Senior Vice President & Chief Financial Officer

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, 333-146416 and 333-187075) and Form S-8 (Nos. 333-221645, 333-213017, 333-195612, 333-151653, 333-151620, 333-133172, 333-123615, 333-63288, and 33-98396) of Acura Pharmaceuticals, Inc. of our report dated March 30, 2020, relating to the consolidated financial statements which appear in this Form 10-K. Our report contains an explanatory paragraph regarding the Acura Pharmaceuticals, Inc.'s ability to continue as a going concern.

/s/ BDO USA, LLP
Chicago, Illinois
March 30, 2020

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 30, 2020

/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 30, 2020

/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, 2019 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 30, 2020

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, 2019 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 30, 2020

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