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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, 2021

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 executive offices)	(Zip Code)

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

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value	ACUR	OTC Market — Expert Market

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 every Interactive Data File required to be submitted 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 file such files). Yes ☐ No ☒

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

☐ Large Accelerated Filer	☐ Accelerated Filer
☒ Non-Accelerated Filer	☒ Smaller Reporting Company.
	☐ Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 of the registrant's Common Stock on the OTC Market - OTCQB of $0.66 on June 30, 2021 (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 $4.9 million.

As of April 30, 2023, the registrant had 66,001,783 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, 2021

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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 from AD Pharma or others for our continuing operations, including the development of our products utilizing our LIMITx™ and Impede® technologies;
- whether we can renegotiate the date by which we are required to obtain FDA acceptance, currently November 30, 2023, for an NDA for LTX-03 by our agreement with AD Pharma on which we depend to finance operations;
- whether our licensing partners will develop any additional products and utilize Acura for such development;
- the expected results of clinical studies relating to LTX-03, a LIMITx hydrocodone bitartrate and acetaminophen combination product, or any successor product candidate, the date by which such studies will be complete and the results will be available and whether LTX-03 will ultimately receive FDA approval;
- our business could be adversely affected by health epidemics in regions where third parties for which we rely, as in CROs or CMOs, have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely;
- whether LIMITx will retard the release of opioid active ingredients as dose levels increase;
- whether the extent to which products formulated with the LIMITx Technology reduce respiratory depression will be determined sufficient by the FDA to support approval or labelling describing safety features;
- our and our licensee's ability to successfully launch and commercialize our products and technologies;
- the results and timing of our development of our LIMITx Technology, including, but not limited to, the submission of a New Drug Application and/or FDA filing acceptance;
- our or our licensees' ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of, timing of commercial launch and competitive environment for any of our products;
- expectations regarding potential market share for our products;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
- our exposure to product liability and other lawsuits in connection with the commercialization of our products;
- the increasing cost of insurance and the availability of product liability insurance coverage;
- the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- whether the FDA will agree with or accept the results of our studies for our product candidates;
- the ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development process to meet over-the-counter ("OTC") Monograph standards, as applicable;
- the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates;
- changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;
- whether the FDA will agree with our analysis of our clinical and laboratory studies;
- whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and whether we will be able to promote the features of our technologies; and
- whether our product candidates will ultimately perform as intended in commercial settings.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "continue," "could," "estimate," "expect," "indicate," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "suggest," "target," "will," "would," and other similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to known and unknown risks and uncertainties. Given these

uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in Item 1A of this Report. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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

PART I

ITEM 1. BUSINESS

Overview

We are an innovative drug delivery company engaged in the research, development and commercialization of technologies and products intended to address safe use of medications. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Limitx™ Technology is being developed to minimize the risk of overdose, our Aversion® Technology is intended to address methods of abuse associated with opioid analgesics while our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine, or PSE, into methamphetamine. Oxaydo tablets (oxycodone HCl, CII), which utilizes the Aversion Technology, is the first approved immediate-release oxycodone product in the United States with abuse deterrent labeling. Nexafed brand products utilize our Impede Technology.

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

On June 28, 2019 we entered into a License, Development and Commercialization Agreement to the Limitx patent LTX-03, as amended in October 2020, July 2021, February 2022, November 2022 and December 15, 2022 (the "AD Pharma Amended Agreement"), with Abuse Deterrent Pharma, LLC (“AD Pharma”). Under the Amended AD Pharma Amended Agreement, AD Pharma also has an option to license the Limitx patents for LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam) for exclusive commercialization rights in the United States, which are not subject to any development agreement or responsibilities by Acura. The AD Pharma Amended Agreement required AD Pharma to pay us a monthly license payment for LTX-03 of $350 thousand for a period from inception up to April 2020 at which time the payment became $200 thousand per month. The monthly license payments ended on July 31, 2021 under the AD Pharma Amended Agreement. The AD Pharma Amended Agreement required AD Pharma to reimburse us all our outside development costs we incurred for LTX-03. At December 31, 2021, AD Pharma was delinquent in remitting $50 thousand of the license fee for the month of July 2021 and approximately $78 thousand of reimbursable LTX-03 development expenses. In March 2022, Acura received the delinquent license fee and delinquent development expenses from AD Pharma.

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

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

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

Our Strategy

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

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

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

- *Commercialize our products by licensing to strategically focused companies in the United States and other geographic territories*. We have licensed our Oxaydo product to Assertio for commercialization, have licensed our Aversion Technology to KemPharm for use in certain of its prodrug products, have licensed our Nexafed products utilizing our Impede Technology to MainPointe/AD Pharma for commercialization (and granted MainPointe and AD Pharma options to other Impede products), and we entered into an agreement with AD Pharma for the development and commercialization of LTX-03 and grants them exclusive commercialization rights in the United States to LTX-03 as well as to Limitx patents for LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam), which are not subject to any development agreement or responsibilities by Acura.

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

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

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

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

The CDC also identified rising overdose deaths resulting from “polysubstance” drug use. Polysubstance drug use occurs with exposure to more than one drug, with or without the person’s knowledge. This growing issue also means that an opioid-involved overdose often occurs in combination with exposure to other opioids and/or other non-opioid substances. Some examples of polysubstance exposures found in combination in overdose deaths include illicitly manufactured fentanyl (IMF) and heroin; illicitly manufactured fentanyl and cocaine; heroin and methamphetamine; and prescription or illicit opioids and benzodiazepines. Recent data indicate that the involvement of opioids in stimulant-involved deaths is increasing. Nearly three-quarters (72.7%) of cocaine-involved overdose deaths also involved an opioid in 2017. Although increases in psychostimulant-involved deaths have occurred

Prescription opioids drugs, such as morphine and oxycodone, have a long history of use for the management of pain. Because they are highly effective, they are one of the largest prescribed drug categories in the U.S. However, a side effect of high doses of opioids is euphoria, or “a high”. For these reasons, opioids are the most misused or abused prescription drugs in the U.S. Opioids are offered in a variety of dosages including immediate-release tablets (or capsules), extended-release tablets (or capsules), patches and other formats. Those who misuse or abuse drugs will often do so in one of the following manners:

- Oral Excessive Tablet Abuse (ETA). Generally recognized as the most prevalent route of administration by abusers, the abuser simply orally ingests more tablets (or capsules) than is recommended for pain relief.

- Oral Manipulated Tablet Abuse (MTA). Extended-release tablets or patches are sometimes crushed, chewed or otherwise physically or chemically manipulated to defeat the extended-release mechanism and provide an immediate-release of the opioid for oral ingestion.

- Nasal snorting. Crushed tablets are insufflated for absorption of the drug through the nasal tissues.

- Injection. The opioid is physically or chemically removed from the dosage and injected into the vein using a syringe.

- Poly-substance. Opioids are sometimes used in conjunction with alcohol, methamphetamine, or other drugs to accentuate the high.

- Overdose. Drug abusers may accidentally introduce excessive quantities of drugs in their systems or combine drugs that may heighten the chance of adverse effects of drugs. Some patients may over ingest drugs accidentally or with the express intent of suicide.

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

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

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

Further development will likely also entail additional safety and/or efficacy assessment as may be identified by the FDA for each specific formulation during the Investigational New Drug application, or IND, or NDA phase of development. In accordance with the FDA's 2015 Guidance, we will likely have a post-approval requirement for each of our opioid products, if approved, to perform an epidemiology study to assess the in-market impact on abuse of our formulation and most approved opioid products are subject to an FDA approved risk evaluation and mitigations strategy (REMS).

Overdose Risk Mitigation - Products and Development

Any drug may initiate severe unwanted side effects when overdosed. For example, a known and FDA labelled side effect of the overdose of opioids is respiratory depression. High doses of opioids can affect the respiratory center of the brain resulting in a slowing and/or shallowing of the breathing which increases carbon dioxide (CO2) in the blood stream. Opioids also impact ancillary CO2 monitoring of the blood preventing the body from taking corrective action. The increased CO2 and resulting decrease in oxygen in the blood systematically shuts down body systems and may result in death.

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

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

LIMITx™ Technology

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

LIMITx Technology Products in Development

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

LIMITx Technology Products	Status
Immediate-release hydrocodone bitartrate with acetaminophen (LTX-03)	FDA registration/clinical batches complete. Completed 18 months of an on-going shelf life study which passed quality assurance testing. IND active as of April 2018. Dosing completed for Study 311. Topline results expect in late 2nd quarter of 2023.
Immediate-release oxycodone HCl (LTX-01) & (LTX-02)	Formulation development in process.
Immediate-release non-opioid drug (LTX-09)	Formulation development in process.
Immediate-release hydromorphone HCI (LTX-04)	Two Phase I exploratory pharmacokinetic studies completed. IND no longer active.

LTX-03 Development

Study 301

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

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

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

Manufacturing

We have completed with AD Pharma, commercial scale-up of the LTX-03 manufacturing process at a contract manufacturing organization. In February 2021, we completed manufacturing three NDA required registration/clinical batches of the to-be-marketed LTX-03 formulation on the commercial scale manufacturing equipment with quality assurance testing of the product pending before these batches can be deemed successful and ready for use. In February 2023 we reported 18 month results from an ongoing shelf-life stability study in which LTX-03 stored at controlled room temperature passed requisite quality control tests but noted the presence of a known hydrocodone derivative product and some unknown impurities that were within normally accepted FDA standards, although the unknown impurities were increasing in concentration compared to the 12 month testing.

IND Update

We submitted an Investigational New Drug Application, or IND with respect to LTX-03, to the FDA in the first quarter of 2018, which became effective in April 2018. In February 2021, we submitted to the FDA an update to the LTX-03 IND with our proposed clinical protocols for further development of LTX-03. We subsequently revised the proposed clinical study program based upon a review of the FDA Advice Letter received in October 2021. The revised clinical protocol includes:

- Study 310 - A one tablet, single dose pharmacokinetic study in fasted, healthy adult subjects;
- Study 311 - A 2, 5 and 9 tablet single dose pharmacokinetic study in fasted, healthy adult subjects;
- Study 312 - A one tablet, single dose pharmacokinetic study in fed, healthy adult subjects; and
- Study 313 – A one tablet, single dose pharmacokinetic NDA bridging study for the active ingredients.

These studies also contains design components to evaluate certain pharmacologic data with respect to, among other things, acidic beverages and drug interactions. The design of these studies was based on an Advice Letter received from the FDA but no guarantees can be made that these studies, even if successful, will be sufficient to warrant FDA approval. Final design elements of these studies and whether these studies will be run to collect the targeted information are subject to agreement by AD Pharma, who has ultimate decision making authority under the AD Pharma Amended Agreement. We may obtain the necessary information from these studies from alternate sources including, but not limited to, published literature or prior studies we have performed.

We have entered into various service agreements with vendors to enroll, dose and analyze Study 311, including with AD Pharma to serve as study manager and clinical monitor. Dosing in Study 311 completed in March 2023 and we are awaiting results of the blood sample analysis which is expected in late 2nd quarter of 2023.

Non-clinical Study APT-RDR-300

Study APT-RDR-300 was a non-clinical study of respiratory depression in which five groups of 11 Sprague-Dawley rats were orally administered doses of hydrocodone ranging from 100mg of drug per kg of body weight (mg/kg) up to 300 mg/kg and one group receiving placebo. 8 subjects in each group were measured for opioid induced respiratory depression (OIRD) assessing peripheral oxygen saturation (SpO2) of the blood over a 4 hour observation period. 36 subjects were analyzed as successfully completing the dosing. The additional 3 subjects in each group provided blood samples analyzed for hydrocodone at 0.5, 1.0, 2.0 and 4.0 hours post-dosing.

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

Non-clinical Study APT-RDR-301

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

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

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

Clinical Study AP-LTX-311

In February 2023 we started enrollment for our first clinical study for the investigational drug LTX-03 (hydrocodone bitartrate and acetaminophen) tablets using Acura's LIMITx technology. The study, AP-LTX-311 or Study 311, is designed to evaluate the levels of hydrocodone and acetaminophen in the blood plasma when taken at doses in excess of normal therapeutic doses. Dosing for this study was completed in March, 2023 and the Company expects topline results from Study 311 to be available in the third quarter of 2023.

Study 311 is a phase 1 pharmacokinetic study in fasted healthy adult subjects who will be taking 2, 5 and 9 tablet doses. Study 311 is targeted to have 20 subjects complete all doses which will be administered in crossover fashion over a 4 week dosing period, with one week washout between doses. All subjects will receive an intravenous naloxone blockade during drug administration to negate the pharmacologic effects of the opioid hydrocodone. The Company expects to compare the results from the LTX-03 doses to the known, well-characterized pharmacokinetic results for hydrocodone and acetaminophen from the published literature with the intent to demonstrate lower levels of hydrocodone exposure for LTX-03 compared to the currently marketed comparator product as increasing number of tablets are ingested. The acetaminophen active ingredient is not incorporated into the LIMITx technology in the LTX-03 tablet and is not expected to be substantially different from the comparator product.

AD Pharma Amended Agreement covering LTX-03

On June 28, 2019 we entered into a License, Development and Commercialization Agreement to the Limitx patent LTX-03, as amended in October 2020, July 2021, February 2022, November 2022, December 15, 2022 and June 15, 2023 (the "AD Pharma Amended Agreement"), with Abuse Deterrent Pharma, LLC ("AD Pharma"), for 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. Under the AD Pharma Amended Agreement, AD Pharma also has an option to license the Limitx patents for LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam) for exclusive commercialization rights in the United States, which are not subject to any development agreement or responsibilities by Acura.

The Agreement grants AD Pharma exclusive commercialization rights in the United States to LTX-03. The AD Pharma Amended Agreement required AD Pharma to pay us a monthly license payment for LTX-03 of $350 thousand for a period from inception up to April 2020 at which time the payment became $200 thousand per month. The monthly license payments ended on July 31, 2021 under the AD Pharma Amended Agreement. The AD Pharma Amended Agreement required AD Pharma to reimburse us all our outside development costs we incurred for LTX-03. Upon commercialization of LTX-03, Acura receives stepped royalties on sales and is eligible for certain sales related milestones. At December 31, 2021, AD Pharma was delinquent in remitting $50 thousand of the license fee for the month of July 2021 and approximately $78 thousand of reimbursable LTX-03 development expenses. In March 2022, Acura received the delinquent license fee and delinquent development expenses from AD Pharma.

AD Pharma may terminate the AD Pharma Amended Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by November 30, 2023, AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property. Should AD Pharma choose not to exercise this option to terminate and the NDA for LTX-03 is subsequently accepted by the FDA, such option expires.

During the period December, 2021 to October, 2022, John Schutte loaned the Company $1,925,000 as evidenced by a series of unsecured promissory notes bearing interest at 5.25% maturing at December 31, 2023. On October 31, 2022, Mr. Schutte assigned these notes to Abuse Deterrent Pharma, LLC ("AD Pharma), of which Mr. Schutte is the Managing Partner. On November 10, 2022, AD Pharma and Acura Pharmaceuticals, Inc. ("we" "Acura" or the "Company), entered into an Amended Consolidated and Restated Secured Promissory Note (the "Note") that encompasses the entire principle and accrued interest of the notes assigned by Mr. Schutte as well as any additional loans from AD Pharma to the Company. This Note bears interest at 5.25% and matures on December 31, 2023, at which time all principal and interest is due. Events of default under the Note include, among other items, bankruptcy events, failure to pay interest and principal when due and such failure continues for 5 days, and if Acura is generally not, or is unable to, or admits in writing its inability to, pay its debts as they become due. If any amount payable hereunder is not paid when due (without regard to any applicable grace periods), whether at stated maturity, by acceleration, or otherwise, including upon an event of default, such overdue amount shall bear interest at the rate per annum of 7.5% from the date of such non-payment until such amount is paid in full. This Note totaled $2,569,279 at December 31, 2022. For the period January through May, 2023, AD Pharma has made additional loans to us totaling $900 thousand. Based upon discussions with AD Pharma, it is the Company's expectation that AD Pharma will continue to provide such financing although no assurance can be made that such will be the case.

Aversion Technology

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

Oxaydo Tablets

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

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

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

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

Further, the Oxaydo product label guides patients not to crush and dissolve the tablets or pre-soak, lick or otherwise wet the tablets prior to administration. Similarly, caregivers are advised not to crush and dissolve the tablets or otherwise use Oxaydo for administration via

nasogastric, gastric or other feeding tubes as it may cause an obstruction. We believe that Assertio has shifted focus to marketing other products in their portfolio and deemphasized the marketing Oxaydo such that Oxaydo is no longer a promoted product.

Assertio Agreement Covering Oxaydo

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

Assertio paid us an upfront payment of $5.0 million upon signing of the Assertio Agreement and a $2.5 million milestone in October 2015 in connection with the launch of Oxaydo. In addition, we are entitled to receive from Assertio a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on Oxaydo net sales during such year. Assertio's royalty payment obligations commenced on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA's Orange Book remains with respect to the Product).

The Assertio Agreement expires upon the expiration of Assertio's royalty payment obligations in all countries. Either party may terminate the Assertio Agreement in its entirety if the other party breaches a payment obligation, or otherwise materially breaches the Assertio Agreement, subject to applicable cure periods, or in the event the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy or otherwise seeks relief under applicable bankruptcy laws. We also may terminate the Assertio Agreement with respect to the U.S. and other countries if Assertio materially breaches its commercialization obligations. Assertio may terminate the Assertio Agreement for convenience on 120 days prior written notice.

As part of a 2020 restructuring by Assertio, it is our understanding that Assertio has decided to reduce selling efforts pertaining to Oxaydo and it is no longer being promoted by them and as such, we expect royalties to decline over the remainder of the Agreement. Assertio reported net sales of Oxaydo in 2021 of approximately $2.6 million resulting in approximately $130 thousand in royalties to us. The royalties payable to us under the agreement will expire in 2025.

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. As of April 30, 2023 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.

Aversion Technology Development Opioid Products

We have no ongoing development activities with respect to our Aversion Technology.

Abuse of Pseudoephedrine Products

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

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

Impede Technology Products

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

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

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

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

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

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

Nexafed Products and the MainPointe Agreement

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

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

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

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

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

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

Other Impede Technology Products

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

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

In July 2015, we had a pre-IND meeting with the FDA to discuss the results from our pharmacokinetic and meth-resistance testing studies to determine the development path for our extended-release development product. The FDA acknowledged the potential value of the development of risk-mitigating strategies for new formulations of pseudoephedrine products while also recognizing an approved "meth-deterrent" extended release pseudoephedrine product would be novel in the over-the-counter (OTC) setting. The FDA did not

make a formal determination whether “meth-resistant” claims would be appropriate but is open to consider such an appropriately worded, evidence-based claim directed to the consumer and/or retailer. As recommended by the FDA, we have submitted additional “meth-resistant” testing information to the FDA for review prior to submitting an IND. In October 2016, we received FDA recommendations on our meth-resistant testing protocols for our Nexafed extended release tablets. We can now scale-up our manufacture batch size at a contract manufacturer which allows us to submit an IND to the FDA for our Nexafed extended release tablets, however, we have not yet committed to that level of development.

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

U.S. Market Opportunity for Impede PSE Products

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

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

[1] Branded product only. Does not include store brand sales.
[2] Extended release PSE formulations

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

Product Labeling for Impede Technology Products

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

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

U.S. Market Opportunity for Opioid Analgesic Products

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

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

Product Labeling for Products Using Our Technologies

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

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

Patents and Patent Applications

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

Patent No. (Jurisdiction)	Subject matter	Issued	Expires
9,101,636 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Aug. 2015	Nov. 2033
9,320,796 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Apr. 2016	Nov. 2033
9,662,393 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	May 2017	Nov. 2033
10,441,657 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Sept. 2019	Nov. 2033
10,688,184 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when 3 or more doses are consumed	Jun. 2020	Nov. 2033
11,083,794 (US)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Aug. 2021	Nov. 2033
2,892,908 (CAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Apr. 2016	Nov. 2033
5,922,851 (JAPAN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Apr. 2016	Nov. 2033
ZL201380062421.0 (CHN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Jul. 2018	Nov. 2033
201711090908.6 (CHN)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Oct.2020	Nov. 2033
2,925,304 (EUR)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Sept. 2018	Nov. 2033
2013352162 (AUS)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Dec. 2018	Nov. 2033
202210206 (AUS)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Sep. 2022	Nov. 2033
366159 (MEX)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Jul. 2019	Nov. 2033
238713 (ISR)	Abuse deterrent products wherein the release of active ingredient is retarded when excessive doses are consumed	Jul. 2019	Nov. 2033

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

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

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

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
2,004,294,953 (AUS)	Abuse deterrent pharmaceuticals	Apr. 2010	Nov. 2024
2,010,200,979 (AUS)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024

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

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

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

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

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

Reference is made to the Risk Factors contained in this Report on Form 10-K for the year ended December 31, 2021 for a discussion, among other things, of patent applications and patents owned by third parties, including claims that may encompass our Aversion

Technology and Oxaydo tablets, and the risk of infringement, interference or opposition proceedings that we may be subject to arising from such patents and patent applications.

Research and Manufacturing

We conduct research, development, manufacture of laboratory clinical trial supplies, and warehousing activities at our operations facility in Culver, Indiana and lease an administrative office in Palatine, Illinois. The 25,000 square foot Culver facility is registered with the DEA to perform research, development and manufacture of certain DEA-scheduled active pharmaceutical ingredients and finished dosage form products. We have obtained quotas for supply of DEA-scheduled active pharmaceutical ingredients from the DEA and develop finished dosage forms in our Culver facility. We manufacture clinical trial supplies of drug products in our Culver facility. In addition to internal capabilities and activities, we engage numerous clinical research organizations, or CROs, with expertise in regulatory affairs, clinical trial design and monitoring, clinical data management, biostatistics, medical writing, laboratory testing and related services. Assertio is responsible for commercial manufacture of Oxaydo under the Assertio Agreement. We expect that future opioid product candidates developed and licensed by us will be commercially manufactured by our licensees or other qualified third party contract manufacturers.

Prior to our entering into the MainPointe Agreement, we relied on two contract manufacturers to manufacture, package and supply our commercial quantities of Nexafed and Nexafed Sinus Pressure + Pain products. We assigned our existing supply agreement to MainPointe in accordance with the terms of the MainPointe Agreement.

Competition

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

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

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

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

Government Regulation

All pharmaceutical firms, including us, are subject to extensive regulation by the federal government, principally by the FDA under the Federal Food, Drug and Cosmetic Act, or the FD&C Act, and, to a lesser extent, by state and local governments. Before our prescription products and some OTC products may be marketed in the U.S., they must be approved by the FDA for commercial distribution. Certain OTC products must comply with applicable FDA regulations, known as OTC Monographs, in order to be marketed, but do not require FDA review and approval before marketing. Additionally, we are subject to extensive regulation by the DEA under the Controlled Substances Act, the Combat Methamphetamine Act of 2005, and related laws and regulations for research, development, manufacturing,

marketing and distribution of controlled substances and certain other pharmaceutical active ingredients that are regulated as Listed Chemicals. Extensive FDA, DEA, and state regulation of our products and commercial operations continues after drug product approvals, and the requirements for our continued marketing of our products may change even after initial approval. We are also subject to regulation under federal, state and local laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, state, federal and foreign regulations, including possible future regulations of the pharmaceutical industry. We cannot predict the extent to which we may be affected by legislative and other regulatory developments concerning our products and the healthcare industry in general.

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

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

The FDA Drug Approval Process

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

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

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

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

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

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

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

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

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

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

According to FDA's fee schedule, posted on August 3, 2020, for the 2021 fiscal year, the user fee for an application fee requiring clinical data, such as an NDA was $2,875,842. The FDA's fee schedule, posted on August 16, 2021, for the 2022 fiscal year, the user fee for an application fee requiring clinical data was $3,117,218. The FDA's fee schedule, posted on October 7, 2022, for the 2023 fiscal year, the user fee for an application fee requiring clinical data is $3,242,026. The FDA adjusts PDUFA user fees on an annual basis. A written request can be submitted for a waiver of the application fee for the first human drug application that is filed by a small business. Where we are subject to these fees, they are significant expenditures that may be incurred in the future and must be paid at the time of submission of each application to FDA.

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

In terms of program fees, subject to certain exceptions, each sponsor is required to pay the annual fee for each new prescription drug approved as of 1 October of each fiscal year (for 2021 such fee was $336,432 per product strength, for 2022 such fee was $369,413 and for 2023 such fee is $393,933), but applicants may not be assessed more than five prescription drug program fees for a fiscal year, for prescription drugs identified in a single application. For example, an applicant that has 10 drug products identified in an approved NDA for 10 different strengths of tablet dosage form products is eligible for an assessment for a maximum of 5 program fees. PDUFA VI also eliminated fees for drug application supplements and establishment fees.

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

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

The terms of approval of any NDA for our product candidates, including the indication and product labeling (and, consequently permissible advertising and promotional claims we can make) may be more restrictive than what is sought in the NDA or what is desired by us. Additionally, the FDA conditioned approval of our Oxaydo product on our commitment to conduct Phase 4 epidemiological studies to assess the actual abuse levels of Oxaydo in the market. The testing and FDA approval process for our product candidates

requires substantial time, effort, and financial resources, and we cannot be sure that any approval will be granted on a timely basis, if at all.

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

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

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

FDA's OTC Monograph Process

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

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

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

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

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

DEA Regulation

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

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

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

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

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II and List I Chemicals. Distributions of any Schedule I or II controlled substance must also be accomplished using special order forms, with copies provided to the DEA. Each entity distributing controlled substances is responsible for monitoring the use of such products to identify and control diversion and misuse. Because Oxaydo tablets are Schedule II they are subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much oxycodone active ingredient may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of oxycodone that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We or our licensees

must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance and List I Chemicals. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our or our licensees' quota of an active ingredient may not be sufficient to meet commercial demand or complete the manufacture or purchase of material required for clinical trials. Any delay or refusal by the DEA in establishing our or our licensees' quota for controlled substances or List I Chemicals could delay or stop our clinical trials or product launches, or interrupt commercial sales of our products which could have a material adverse effect on our business, financial position and results of operations.

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

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

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

Many of the Healthcare Reform Law's most significant reforms were implemented in 2014, with others thereafter, and their details will be shaped significantly by implementing regulations, some of which have yet to be finalized. If such reforms result in an increase in the proportion of uninsured patients who are prescribed products resulting from our proprietary or partnered programs, this could adversely impact future sales of our products and our business and results of operations. Where patients receive insurance coverage under any of the new options made available through the Healthcare Reform Law, the possibility exists that manufacturers may be required to pay

Medicaid rebates on that resulting drug utilization, a decision that could impact manufacturer revenues. In addition, the Administration has also announced delays in the implementation of key provisions of the Healthcare Reform Law. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

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

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

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

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payers, that an

adequate level of coverage or payment will be available so that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably.

In 2022, the U.S. Congress adopted legislation directed at allowing the Medicare Part D drug program to negotiate discounts from approved drug manufacturers which could impact the prices we or our licensees charge to Medicare, the largest healthcare insurer in the U.S.

Other Healthcare Laws and Compliance Requirements

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

Segment Reporting

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

Environmental Compliance

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

Human Capital Management

We have 9 full-time employees, 6 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, and business development activities. All of our senior management and most of our other employees have prior experience in pharmaceutical or biotechnology companies. We strive to maintain a safe, healthy and respectful workplace. We offer competitive compensation coupled with attractive health benefits. The average tenure of our employees is approximately 20 years. Since 2018, three employees have separated from the Company and none were replaced. We believe engaging experienced pharmaceutical scientists in our Culver, IN facility could be difficult given its less populated geography and lack of other pharmaceutical companies in the immediate area.

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

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

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

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business and Industry

We have a history of operating losses and may not be able to generate a positive return on shareholders' investment; there is substantial doubt as to our ability to continue as a going concern: We had a net loss of $0.9 million, $1.2 million, and $3.8 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of June, 30 2023 our cash on hand balance was approximately $165 thousand. Our future viability will depend on several factors, including:

- the receipt of additional funding from AD Pharma to support operations thru the receipt of FDA approval of LTX-03 and its successful commercialization by AD Pharma; (ii) 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 (iii) our ability to commercialize all our Impede and LIMITx Technology products without infringing the patents and other intellectual property rights of third parties, of which no assurance can be given.

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

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

We will be required to raise additional funds to finance our operations and remain a going concern; we may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us; if we fail to raise additional funding we will cease operations and/or seek protection under applicable bankruptcy laws: Our operations to date have consumed substantial amounts of cash. Negative cash flows from our operations are expected to continue until such time as royalties from AD Pharma's sale of LTX-03 occur which is not expected until 2023 at the earliest. Our cash utilization amount is highly dependent on the progress of our product development programs, particularly, the results of our and clinical studies and the cost, timing and outcomes of regulatory approval for our LIMITx product candidates. As of June 30, 2023 our cash on hand balance was approximately $165 thousand. The AD Pharma Amended Agreement provided us a monthly license payment of $350 thousand from AD Pharma for a period from inception up to April 2020 at which time the payment became $200 thousand per month and ended in July 2021. The AD Pharma Amended Agreement

required AD Pharma to reimburse us all our outside development costs we incurred 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.

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: On November 10, 2022, we (including our wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc. (“APT”)), entered into a Promissory Note and Security Agreement with Abuse Deterrent Pharma, LLC. This Note includes a security interest in all of our assets. Our failure to comply with the terms of the loan agreement, if we file bankruptcy, failure to pay interest and principal when due on December 31, 2023, or upon failure to meet certain timelines as defined in the License, Development and Commercialization Agreement could result in the acceleration of payment of our loan, foreclosure on our assets, and other adverse results. Any declaration of an event of default by AD Pharma could result in the transfer of our business to AD Pharma without additional consideration and the loss by our shareholders of their entire interest.

Our failure to meet the development timelines in the AD Pharma Amended Agreement, including FDA acceptance of NDA submission for LTX-03 by November 30, 2023, will allow AD Pharma the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property which will adversely impact our ability to develop, market and sell our LIMITx Technology products and our revenues and business will be materially adversely affected: The AD Pharma Amended Agreement requires that the new drug application for LTX-03 be accepted by the FDA by November 30, 2023. Failure to do so gives AD Pharma the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property.

We are largely dependent on our successful development of LIMITx product candidates which are unproven and may not be approved by the FDA: We expect that a substantial portion of our efforts and expenditures over the next few years, if we obtain additional funding, will be devoted to our lead LIMITx product candidate, LTX-03, and other LIMITx product candidates in development. Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approval and commercialization of our LIMITx product candidates, which may never occur. If our clinical studies for LTX-03 are not successful we may determine that further clinical development of LTX-03 or other LIMITx product candidates should be discontinued. Also, the failure of clinical studies for LTX-03 may cause AD Pharma to terminate the AD Pharma Amended Agreement. We expect

that any revenues from our LIMITx product candidates, specifically LTX-03 will be derived from upfront payments, milestone payments and royalties under license agreements with AD Pharma, of which no assurance can be given.

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

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

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

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

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

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

performance failure on the part of our licensees or contract manufacturers could delay commercialization of any approved products, depriving us of potential product revenue.

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

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

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

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

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

We develop our products, and manufacture clinical and commercial supplies, at a single location. Any disruption at these facilities could adversely affect our business and results of operations: We rely on our Culver, Indiana facility for developing our product candidates and the manufacture of clinical supplies of our product candidates. Our marketed products are manufactured at a single contract manufacturing organization. If any of these facilities are damaged or destroyed, or otherwise subject to disruption, it would

require substantial lead-time to repair or replace. If our Culver facility were affected by a disaster, we would be forced to rely entirely on CROs and third-party contract manufacturers for an indefinite period of time. Although we believe we possess adequate insurance for damage to our property and for the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. Any disruptions or delays to our clinical or commercial supplies could impair our ability to develop our product candidates, which could adversely affect our business and results of operations.

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

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

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

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

- the relative advantages and disadvantages of our products compared to competitive products;
- the relative timing to commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products

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

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

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

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

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

- Encouragement for the development of comparative effectiveness research, which may reduce the extent of reimbursement for our products if such research results in any adverse findings.

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

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

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

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

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

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

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

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

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

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

We may be exposed to product liability claims and claims regarding marketing of products and may not be able to obtain or maintain adequate product liability insurance and some claims may not be covered by insurance: Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products, and in particular opioid

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

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

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

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

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

Our products are subject to regulation by the U.S. Drug Enforcement Administration, or DEA, and such regulation may affect the development and sale of our products: The DEA regulates certain finished drug products and active pharmaceutical ingredients, including certain opioid active pharmaceutical ingredients and pseudoephedrine HCl that are contained in our products. Consequently,

their manufacture, research, shipment, storage, sale and use are subject to a high degree of regulation. Furthermore, the amount of active ingredients we can obtain for our clinical trials is limited by the DEA and our quota may not be sufficient to complete clinical trials. There is a risk that DEA regulations may interfere with the supply of the products used in our clinical trials.

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

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

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

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

We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data storage risks: Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit confidential information, and it is critical that we do so in a secure manner in order to maintain the confidentiality and integrity of such confidential information. Our information technology systems are potentially vulnerable to service interruptions and security breaches from inadvertent or intentional

actions by our employees, partners, vendors, or from attacks by malicious third parties. Maintaining the secrecy of this confidential, proprietary, and/or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful access or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination or misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material effect on our business, financial position, results of operations and/or cash flow.

Prior ownership changes have limited our ability to use our tax net operating loss carryforwards as part of a corporate restructure or reorganization: Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of Net Operating Loss ("NOL") carryforwards and other tax attributes. In addition, under the Tax Cuts and Jobs Act of 2017, NOL usage in any given year will be limited to 80% of taxable income, without regard to the NOL deduction, and losses incurred in 2018 and forward may not be carried back but can be carried forward indefinitely, but losses incurred prior to 2018 can only be carried forward for 20 years. We have determined that we have undergone ownership changes in both 2004 and 2017 and most likely had additional ownership change in 2021 (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 most likely extremely 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 2021, our stock traded as high as $0.75 per share and as low as $0.15 per share. During 2022 our stock traded as high as $0.60 per share and as low as $0.01 per share. The trading price of our common stock is likely to continue to exhibit wide fluctuations in response to various factors, some of which are beyond our control. These factors could include:

- results from our pre-clinical and clinical development programs, including our LIMITx product candidates;
- FDA actions related to our products in development;
- FDA actions related to any of our potential products;
- announcements regarding the progress of our preclinical and clinical programs;
- announcements regarding the execution of license agreements with third parties for our products or product candidates;
- failure of any of our products in development, if approved, to achieve commercial success;
- quarterly variations in our results of operations or those of our competitors;
- our ability to develop and market new and enhanced products on a timely basis;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies;

- additions or departures of key personnel;
- commencement of, or our involvement in, litigation;
- the inability of our contract manufacturers to provide us with adequate commercial supplies of our products;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board or management;
- general economic conditions and slow or negative growth of our market; and
- political instability, natural disasters, war and/or events of terrorism.

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

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

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

Any future sale of a substantial number of shares in a capital raising transaction could depress the trading price of our stock: In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the then current trading price of our common stock. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the then current trading price of our common stock. As of April 30, 2023, our two largest shareholders own an aggregate of 61,897,030 shares (including 10,000,000 shares underlying warrants) (representing approximately 83.7% of our outstanding shares, including shares issuable upon exercise of these warrants but not including any other warrants, options or convertible debt outstanding to other entities). If some or all of such shares are sold by such stockholders, it may have the effect of depressing the trading price of our common stock and could make it more difficult for us to raise capital if needed in the future.

As of April 30, 2023, approximately 13.6% of our common stock, is owned by a single individual, who is also a principal of AD Pharma LLC and MainPointe Pharmaceuticals LLC, and that individual has right to designate a director: A significant amount of our common stock is owned by a single individual, Mr. Schutte. On July 24, 2017, we completed a $4.0 million private placement with him for the sale of 8,912,655 shares. Mr. Schutte is a principal of MainPointe. In March 2017, we granted MainPointe an exclusive license to our Impede Technology to commercialize our Nexafed® and Nexafed® Sinus Pressure + Pain Products in the United States and Canada. MainPointe also has options to expand the territory and products covered for additional sums. Further, Mr. Schutte has the right to designate a director (he has not done so).

During the period December, 2021 to October, 2022, John Schutte loaned the Company $1,925,000 as evidenced by a series of unsecured promissory notes bearing interest at 5.25% maturing at December 31, 2023. On October 31, 2022, Mr. Schutte assigned these notes to Abuse Deterrent Pharma, LLC ("AD Pharma), of which Mr. Schutte is the Managing Partner. On November 10, 2022, AD Pharma and Acura Pharmaceuticals, Inc. ("we" "Acura" or the "Company), entered into an Amended Consolidated and Restated Secured Promissory Note (the "Note") that encompasses the entire principle and accrued interest of the notes assigned by Mr. Schutte as well as an additional loan of $350,000 from AD Pharma to the Company. AD Pharma made a loan of $250,000 to us in December 2022 and for the period January through May, 2023, made additional loans to us totaling $900 thousand. This Note totaling $3,469,279 bears interest at 5.25%

and matures on December 31, 2023, at which time all principal and interest is due. Events of default under the Note include, among other items, bankruptcy events, failure to pay interest and principal when due and such failure continues for 5 days, and if Acura is generally not, or is unable to, or admits in writing its inability to, pay its debts as they become due. If any amount payable hereunder is not paid when due (without regard to any applicable grace periods), whether at stated maturity, by acceleration, or otherwise, including upon an event of default, such overdue amount shall bear interest at the rate per annum of 7.5% from the date of such non-payment until such amount is paid in full.

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 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: Effective May 17, 2022 the Company's common stock was downgraded from the OTCQB to the OTC Markets Group OTC Pink tier because we did not file Annual Report on Form 10-K for 2021. On July 20, 2022 the Company was notified that, effective July 21, 2022, its common stock would be further downgraded from the OTC Markets Group OTC Pink tier to the OTC Expert Market of the OTC Markets Group because the Company was delinquent in making current information publicly available as required by SEC Rule 15c2-11. This occurred because the Company failed to file its Quarterly Report on Form 10-Q for the first quarter ended March 31, 2022 within the applicable grace periods provided by the OTC Markets Group. Both of these reports could not be filed within the prescribed time period because of delays in the completion of management's evaluation of the Company's liquidity including the ability to meet day-to-day operating obligations. Additionally, the Company has failed to file its Quarterly Report on Form 10-Q for each of the second quarter ended June 30, 2022 and the third quarter ended September 30, 2022 and its Annual Report on Form 10-K for 2022. The Company has failed to file its Quarterly Report on Form 10-Q for the first quarter ended March 31, 2023.

Because of the restrictions imposed on securities quoted on the OTC Expert Market, most investors will not be able to publicly sell their shares. Additionally, they will not have access to bid and ask prices or other information, including trading volume. As such, OTC Expert Market shares are illiquid.

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 2021 fiscal year that remain unresolved.

ITEM 2. PROPERTIES

We rent from an unaffiliated Lessor, approximately 1,600 square feet of administrative office space at 616 N. North Court, Suite 120, Palatine, Illinois 60067 on a month-to-month basis. The lease agreement provides for rent, property taxes, common area maintenance,

and janitorial services of approximately $2 thousand per month. We utilize this lease space for our administrative and business development functions.

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

ITEM 3. LEGAL PROCEEDINGS

Not Applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market and Market Prices of Common Stock

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

Effective May 17, 2022 the Company's common stock was downgraded from the OTCQB to the OTC Markets Group OTC Pink tier because we did not file Annual Report on Form 10-K for 2021. On July 20, 2022 the Company was notified that, effective July 21, 2022, its common stock would be further downgraded from the OTC Markets Group OTC Pink tier to the OTC Expert Market of the OTC Markets Group because the Company was delinquent in making current information publicly available as required by SEC Rule 15c2-11. This occurred because the Company failed to file its Quarterly Report on Form 10-Q for the first quarter ended March 31, 2022 within the applicable grace periods provided by the OTC Markets Group. Both of these reports could not be filed within the prescribed time period because of delays in the completion of management's evaluation of the Company's liquidity including the ability to meet day-to-day operating obligations. Additionally, the Company has failed to file its Quarterly Report on Form 10-Q for each of the second quarter ended June 30, 2022 and the third quarter ended September 30, 2022 and its Annual Report on Form 10-K for 2022. The Company has failed to file its Quarterly Report on Form 10-Q for the first quarter ended March 31, 2023.

Because of the restrictions imposed on securities quoted on the OTC Expert Market, most investors will not be able to publicly sell their shares. Additionally, they will not have access to bid and ask prices or other information, including trading volume. As such, OTC Expert Market shares are illiquid.

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 OTC Pink tier.

Period	Sales Prices	
	High	Low
2020 Fiscal Year		
First Quarter	$ 0.43	$ 0.22
Second Quarter	$ 0.40	$ 0.14
Third Quarter	$ 0.35	$ 0.22
Fourth Quarter	$ 0.30	$ 0.18
2021 Fiscal Year		
First Quarter	$ 0.50	$ 0.15
Second Quarter	$ 0.75	$ 0.32
Third Quarter	$ 0.74	$ 0.48
Fourth Quarter	$ 0.60	$ 0.50
2022 Fiscal Year		
First Quarter	$ 0.60	$ 0.29
Second Quarter	$ 0.54	$ 0.25
Third Quarter thru July 20, 2022	$ 0.52	$ 0.25
Third Quarter from July 21, 2022 thru September 30, 2022	$ 0.48	$ 0.01
Fourth Quarter	$ 0.05	$ 0.01
2023 Fiscal Year		
First Quarter	$ 0.05	$ 0.01
Second Quarter thru April 30, 2023	$ 0.05	$ 0.01

(1) Common stock was listed on the OTC Expert Market effective July 21, 2022. Quotations in OTC Expert Market securities are restricted from public viewing. Only broker-dealers and professional or sophisticated investors are permitted to view quotations in Expert Market securities.

Holders

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

Dividend Policy

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

ITEM 6. RESERVED

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, 2021, we had cash of $65 thousand compared to $413 thousand of cash at December 31, 2020. We had an accumulated deficit of approximately $390.1 million and $389.2 million at December 31, 2021 and December 31, 2020, respectively. We had a loss from operations of $1.2 million and a net loss of $876 thousand for the year ended December 31, 2021, compared to a loss from operations of $758 thousand and a net loss of $1.2 million for the year ended December 31, 2020.

On June 28, 2019 we entered into a License, Development and Commercialization Agreement, as amended in October 2020, July 2021, February 2022, November 2022, December 15, 2022, and June 15, 2023 (the "AD Pharma Amended Agreement"), with Abuse Deterrent Pharma, LLC ("AD Pharma") for the completion of development of LTX-03. The AD Pharma Amended grants AD Pharma exclusive commercialization rights in the United States to LTX-03. Under the AD Pharma Amended Agreement, AD Pharma also has an option to license the Limitx patents for LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam) for exclusive commercialization rights in the United States, which are not subject to any development agreement or responsibilities by Acura. The AD Pharma Amended Agreement required AD Pharma to pay us a monthly license payment for LTX-03 of $350 thousand for a period from inception up to April 2020 at which time the payment became $200 thousand per month. The monthly license payments ended on July 31, 2021 under the AD Pharma Amended Agreement. The AD Pharma Amended Agreement required AD Pharma to reimburse us all our outside development costs we incurred for LTX-03. Upon commercialization of LTX-03, Acura will be entitled to stepped royalties on sales and is eligible for certain sales related milestones. The AD Pharma Amended Agreement, requires the NDA for LTX-03 be accepted by the FDA by November 30, 2023 or AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property. Should AD Pharma choose not to exercise this option to terminate and the NDA for LTX-03 is subsequently accepted by the FDA, such option to terminate AD Pharma Amended Agreement expires. The AD Pharma Amended Agreement allows AD Pharma to terminate the AD Pharma Amended Agreement anytime for "convenience on 30 days prior written notice".

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

Results of Operations for the Years Ended December 31, 2021 and 2020.

	December 31		Change	
	2021	2020		
Revenues:	$000's		$000's	Percent
Royalties	$ 132	$ 109	$ 23	21 %
License fees from related party	1,400	3,000	(1,600)	(53)
Collaboration from related party	31	238	(207)	(87)
Product sales	—	223	(223)	(100)
Total revenues	1,563	3,570	(2,007)	(56)
Expenses:				
Research and development	1,524	1,781	(257)	14
General and administrative	1,250	2,547	(1,297)	(51)
Total expenses	2,774	4,328	(1,554)	(51)
Operating loss	(1,211)	(758)	453	60
Gains on forgiveness of loans under CARES Act	535	—	535	—
Interest expense	(200)	(450)	(250)	(56)
Loss before provision for income taxes	(876)	(1,208)	(332)	(28)
Provision for income taxes	—	—		
Net loss	$ (876)	$ (1,208)	(332)	(28)

Revenues

Royalty Revenue

In connection with our license agreement with Assertio for Oxaydo, we earn a royalty based on their net product sales, as defined in the license agreement. We recognized $130 thousand and $102 thousand of royalty revenue for Oxaydo during the years ended 2021 and 2020, respectively. We expect future lower royalties from lower net product sales of Oxaydo as Assertio has indicated Oxaydo is a non-promoted product.

In connection with our license agreement with MainPointe for our Nexafed product line, we earn a royalty based on product net sales. We recognized $2 thousand and $7 thousand of royalty revenue on Nexafed during 2021 and 2020, respectively.

License Fees

We recognize license fees under the AD Pharma Amended Agreement for LTX-03. The monthly license payments ended on July 31, 2021 under the AD Pharma Amended Agreement. We recognized $1.4 million and $3.0 million of license fees revenue during the years ended 2021 and 2020, respectively.

Collaboration Revenue

Collaboration revenue is derived from reimbursement of development expenses under our collaboration agreement for LTX-03 with AD Pharma, and are recognized when costs are incurred pursuant to the AD Pharma Amended Agreement. During 2021 development activities by us were focused and directed towards, among other activities, submission in February 2021 to the FDA an update to the LTX-03 IND with our proposed clinical protocols for further development of LTX-03. We subsequently revised the proposed clinical study program based upon a review of the FDA Advice Letter received in October 2021. Final design elements of these studies and whether these studies will be run to collect the targeted information are subject to agreement by AD Pharma, who has ultimate decision making authority under the AD Pharma Amended Agreement. We may enter into various service agreements with vendors for Study 311, including with AD Pharma to serve as study manager and clinical monitor. We recognized $31 thousand and $238 thousand of collaboration revenue during the years ended 2021 and 2020, respectively.

Product Sales

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

Operating Expenses

Research and Development

Research and development expense ("R&D") for 2021 and 2020 was primarily with respect to our LIMITx Technology development activity under license with AD Pharma and can include, among other items, costs of preclinical and non-clinical internal and external activities, clinical study programs, clinical supplies and its related formulation and design costs, salaries and other personnel related expenses of our employees, consultants, our facility costs, and a percentage share of selected cost sharing expenses under the license agreement with Assertio. Our R&D expenses decreased approximately $0.3 million between reporting periods, all related to the LTX-03 development activities. Final design elements of these clinical study programs and whether these studies will be run to collect the targeted information are subject to agreement by AD Pharma, who has ultimate decision making authority under the AD Pharma Amended Agreement. We may enter into various service agreements with vendors for Study 311, including with AD Pharma to serve as study manager and clinical monitor.

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 2021 and 2020 results are share-based compensation expenses of approximately $109 thousand and $53 thousand, respectively. Excluding the share-based compensation expense our general and administrative expenses decreased by approximately $1.4 million between reporting periods, resulting primarily from lower fees in legal and accounting professional fees, lower wage expenses resulting from employee attrition, cessation of cost sharing expenses under product license agreement and the significant reduction of intangible asset amortization expense primarily resulting from the asset's impairment charge recorded in 2020.

Non-Operating Expense

Interest Expense

For 2021 and 2020, we incurred interest expense of $200 thousand and $450 thousand, respectively on our various related-party debt financings. Our interest expense decreased in 2021 because in June 2021 the $6.0 million promissory note and its $877 thousand of accrued interest held by AD Pharma was converted into 42,984,375 shares of the Company's common stock.

Income Taxes

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

Liquidity and Capital Resources

As of December 31, 2021, our cash on hand balance was $65 thousand, working capital deficit of $143 thousand and an accumulated deficit of $390.1 million. We had a loss from operations of $1.2 million and a net loss of $879 thousand for the year ended December 31, 2021. 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 June 30, 2023 our cash on hand balance was approximately $165 thousand.

The License, Development and Commercialization Agreement, as amended in October 2020, July 2021, February 2022, November 2022, and December 15, 2022 (the "AD Pharma Amended Agreement"), with Abuse Deterrent Pharma, LLC (“AD Pharma”) required AD Pharma to pay us a monthly license payment for LTX-03 of $350 thousand for a period from inception up to April 2020 at which time the payment became $200 thousand per month. The monthly license payments ended on July 31, 2021 under the AD Pharma Amended Agreement. The AD Pharma Amended Agreement also required AD Pharma to reimburse us all our outside development costs we incurred for LTX-03. At December 31, 2021, AD Pharma was delinquent in remitting $50 thousand of the July 2021 license fee and approximately $78 thousand of reimbursable LTX-03 development expenses. In March 2022, Acura received the delinquent license fee and delinquent development expenses from AD Pharma.

During the period December, 2021 to October, 2022, John Schutte loaned the Company $1,925,000 as evidenced by a series of unsecured promissory notes bearing interest at 5.25% maturing at December 31, 2023. On October 31, 2022, Mr. Schutte assigned these notes to Abuse Deterrent Pharma, LLC (“AD Pharma), of which Mr. Schutte is the Managing Partner. On November 10, 2022, AD Pharma and Acura Pharmaceuticals, Inc. (“we” “Acura” or the “Company), entered into an Amended Consolidated and Restated Secured Promissory Note (the “Note”) that encompasses the entire principle and accrued interest of the notes assigned by Mr. Schutte as well as any additional loans from AD Pharma to the Company. This Note bears interest at 5.25% and matures on December 31, 2023, at which time all principal and interest is due. Events of default under the Note include, among other items, bankruptcy events, failure to pay interest and principal when due and such failure continues for 5 days, and if Acura is generally not, or is unable to, or admits in writing its inability to, pay its debts as they become due. If any amount payable hereunder is not paid when due (without regard to any applicable grace periods), whether at stated maturity, by acceleration, or otherwise, including upon an event of default, such overdue amount shall bear interest at the rate per annum of 7.5% from the date of such non-payment until such amount is paid in full. This Note totaled $2,569,279 at December 31, 2022. For the period January through May, 2023, AD Pharma has made additional loans to us totaling $900 thousand. Based upon discussions with AD Pharma, it is the Company’s expectation that AD Pharma will continue to provide such financing although no assurance can be made that such will be the case.

There can be no assurance that AD Pharma will agree to further make extensions to the NDA filing acceptance date or that they will not take ownership of the intellectual property. Whether or not AD Pharma exercises their right to terminate the AD Pharma Amended Agreement, we need to raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company’s continuing product development efforts will have a material adverse effect on the Company’s financial condition and results of operations.

In view of the matters described above, management has concluded that substantial doubt exists with respect to the Company’s ability to continue as a going concern within one year after the date the financial statements are issued and our independent registered public accounting firm have included in their report relating to our 2021 financial statements a “going concern” explanatory paragraph as to substantial doubt of our ability to continue as a going concern.

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

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

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

Cash Flows

Comparison of Years Ended December 31, 2021 and 2020

The following table summarizes our cash flows for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	$ (742)	$ (719)
Investing activities	—	—
Financing activities	394	270
Net decrease in cash	$ (348)	$ (449)

Cash Flows from Operating Activities

For the year ended December 31, 2021, the net cash used in operating activities was $742 thousand and consisted primarily of a net loss of $879 thousand. This net loss and the $535 thousand gains on forgiveness of loans under CARES Act was partially offset by non-cash items such as $58 thousand in share-based compensation expense, $47 thousand of depreciation expense, $17 thousand of amortization expense on right-of-use asset, $47 thousand impairment charge on an intangible asset, and $26 thousand of intangible asset amortization expense along with $477 thousand in net cash inflows from changes in operating assets and liabilities.

The net cash inflow from changes in operating assets and liabilities of $477 thousand for the year ended December 31, 2021 was due to decreases of $350 thousand in license fee receivable from related party, $119 thousand in collaboration revenue receivable from related party along with increases of $161 thousand in accounts payable, $199 thousand in accrued interest and $52 thousand in other current liabilities. These cash inflows were partially offset by increases of $10 thousand in prepaid expenses and other current assets and a decrease of $394 thousand in accrued expenses.

For the year ended December 31, 2020, the net cash used in operating activities was $0.7 million for the year ended December 31, 2020 and consisted primarily of a net loss of $1.2 million. This net loss was partially offset by non-cash items such as $36 thousand in share-based compensation expense, $56 thousand of depreciation expense, $668 thousand impairment charge on an intangible asset, $69 thousand of intangible asset amortization expense and $223 write-down of product sales return allowance liability, with $117 thousand in net cash outflows from changes in operating assets and liabilities.

The net cash outflow from changes in operating assets and liabilities of $117 thousand for the year ended December 31, 2020 was due to increases of $400 thousand in license fee receivable, $119 thousand in collaboration revenue receivable and $17 thousand in prepaid expenses and other current assets along with a decrease of $160 thousand in accounts payable and accrued expenses. These cash outflows were partially offset by decreases of $52 thousand in royalty receivable and $68 thousand in income tax receivable, along with increases of $449 thousand in accrued interest and $10 thousand in other current liabilities.

Cash Flows from Investing Activities

We had no investing activities for the years ended December 31, 2021 and 2020.

Cash Flows from Financing Activities

Net cash provided by financing activities was $394 thousand for the year ended December 31, 2021 and consisted primarily of proceeds from a loan under the CARES Act of $266 thousand and a $150 thousand loan provided to the Company by Mr. Schutte. Net cash provided by financing activities was $270 thousand for the year ended December 31, 2020 and consisted of the proceeds from a loan under the CARES Act. The Company received approval for forgiveness on both of these loans in each of the third quarter and fourth quarter 2021 by the U.S. Small Business Administration.

Related Party Loans from Mr. Schutte and Abuse Deterrent Pharma, LLC

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 provided 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. AD Pharma is an entity controlled by Mr. Schutte, of which Mr. Schutte is the managing partner and investor.

During the period December, 2021 to October, 2022, John Schutte loaned the Company $1,925,000 as evidenced by a series of unsecured promissory notes bearing interest at 5.25% maturing at December 31, 2023. On October 31, 2022, Mr. Schutte assigned these notes to Abuse Deterrent Pharma, LLC ("AD PHARMA), of which Mr. Schutte is the managing partner. On November 10, 2022, AD Pharma and the Company entered into an Amended Consolidated and Restated Secured Promissory Note (the "November 2022 Note") that encompasses the entire principle and accrued interest of the notes assigned by Mr. Schutte as well as ay additional loans from AD Pharma to the Company. This Note bears interest at 5.25% and matures on December 31, 2023, at which time all principal and interest is due. Events of default under the Note include, among other items, bankruptcy events, failure to pay interest and principal when due and such failure continues for 5 days, and if Acura is generally not, or is unable to, or admits in writing its inability to, pay its debts as they become due. If any amount payable hereunder is not paid when due (without regard to any applicable grace periods), whether at stated maturity, by acceleration, or otherwise, including upon an event of default, such overdue amount shall bear interest at the rate per annum of 7.5% from the date of such non-payment until such amount is paid in full. This Note totaled $2,569,279 at December 31, 2022. For the period January through May, 2023, AD Pharma has made additional loans totaling $900 thousand. Based upon discussions with AD Pharma, it is the Company's expectation that AD Pharma will continue to provide such financing although no assurance can be made that such will be the case.

At April 30, 2023, John Schutte individually, and AD Pharma own approximately 13% and 64%, respectively of the outstanding common stock of the Company.

Critical Accounting Estimates

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:

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 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 asset and 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, 2021, 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.

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 2021 or 2020.

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, 2021, we had no investments in marketable securities or holdings of derivative financial or commodity instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

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

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. 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, 2021, 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 2021 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not Applicable.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

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 April 30, 2023 are as follows:

Name	Age	Position
Robert B. Jones	63	President, Chief Executive Officer and Director
Peter A. Clemens	70	Senior Vice President, Chief Financial Officer and Secretary
Albert W. Brzeczko, Ph.D.	66	Vice President, Pharmaceutical Sciences
Robert A. Seiser	59	Vice President, Treasurer, and Corporate Controller
Bruce F. Wesson[(1) (2)]	80	Director
William G. Skelly[(1)(2)]	72	Director
Immanuel Thangaraj[(2)]	52	Director
George K. Ross[(1)]	81	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.

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

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 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 2021, 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 Mr. Thangaraj; (iii) their experience in overseeing management as principals of private equity firms in the case of Mr. Wesson and Mr. Thangaraj. In addition, pursuant to the Second and Amended and Restated Voting Agreement, described in "Certain Relationships and Related Transactions and Director Independence" the Board is required to nominate and recommend for election one designee of John Schutte and one designee of Essex Woodlands Health Ventures V, L.P. ("Essex"), as long as each holds 600,000 shares of our common stock (including warrants to purchase shares). Mr. Thangaraj serves as the designee of Essex. As of April 30, 2023, Mr. Schutte has not exercised his right to designate a director.

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, 2021, 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 "2021 named executive officers") whose total annual compensation for 2021 exceeded $100,000:

Name and Principal Position	Year	Salary[1] ($)	Bonus ($)	RSU Stock Awards[2] ($)	Stock Option Awards[2] ($)	Non-equity incentive plan compensation ($)	Total ($)
Robert B. Jones, President and CEO	2021	150,000	—	—	—	—	150,000
	2020	150,000	—	—	—	—	150,000
Peter A. Clemens SVP & CFO	2021	200,000	—	—	—	—	200,000
	2020	200,000	—	—	—	—	200,000
Albert W. Brzeczko VP, Pharmaceutical Sciences of Acura Pharmaceutical Technologies, Inc.	2021	220,000	—	—	—	—	220,000
	2020	220,000	—	—	—	—	220,000

(1) The base salaries for Messrs. Jones, Clemens and Brzeczko reflects voluntary temporary salary reductions enacted in 2018.

(2) There were no RSU or Stock Option awards in 2021 or 2020.

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. Mr. Jones' and Mr. Clemens' bonuses are weighted at 100% and 70%, respectively, 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 2021 and 2020 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 2022 include completing all clinical activities for LTX-03 and submission and acceptance by the FDA of the NDA for LTX-03 by December 31, 2022.

Material organizational goals for 2021 included advancing 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 for 2021 and 2022 is $150,000 (a voluntary temporary reduction from his salary under the Employment Agreement of $393,000 enacted in 2018 because of our need to preserve cash). The term of the Employment Agreement is currently scheduled to expire December 31, 2023, 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 2021 and 2020, Mr. Jones did not receive a bonus.

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, 2023, 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 for 2021 and 2022 is $200,000 (a voluntary temporary reduction from his salary under the Employment Agreement of $286,000 enacted in 2018 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. In 2021 and 2020, Mr. Clemens did not receive a bonus.

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 engages in a going private transaction (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 is eligible for annual bonuses of up to 50% of his base salary. 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 2021 and 2020 Dr. Brzeczko did not receive a bonus.

Dr. Brzeczko's annual salary for 2021 and 2022 is $220,000 (a voluntary temporary reduction from his salary of $291,000 enacted in 2018 because of our need to preserve cash).

Stock Option Plans

We maintain two stock option plans adopted in 2008 and 2016, respectively. Our option plans are administered by the Compensation Committee. The Compensation Committee 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”) although such Discounted Options have never been granted "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. Our grants to directors 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 73,200 unissued shares allocated to the Plan were terminated. As of December 31, 2021, stock options to purchase 574,328 shares of common stock were outstanding under the 2008 Stock Option Plan where 24,000 options were non-qualified and 550,328 options were ISOs. The weighted average exercise price per share for all outstanding options under the 2008 Stock Option Plan as of December 31, 2021 was $4.49.

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, 2021, stock options to purchase 456,356 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, 2021 was $0.51.

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.

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. There are approximately 2,100 RSU issued and outstanding under the 2014 RSU Plan at December 31, 2021.

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. 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. There are approximately 390,000 RSU issued and outstanding under the 2017 RSU Plan at December 31, 2021.

Because there were no further shares available for issuance under the 2014 RSU and 2017 RSU Plans, our shareholders approved the 2021 Restricted Stock Unit Award Plan on May 25, 2021. The description of the 2021 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 and 2017 RSU Plans, with the significant differences noted under such captions.

The 2021Restricted Stock Unit Award Plan

The Company's 2021 Restricted Stock Unit Award Plan (the "2021 RSU Plan") was approved by the Company's Board of Directors on March 29, 2021 and approved by shareholders on May 25, 2021. Under the 2021 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 2021 RSU Plan is 2,500,000 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 2021 RSU Plan shall have been terminated, become available for further grant under the 2021 RSU Plan. The 2021 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. Unless terminated earlier by the Board of Directors, the RSUs may be distributed under the 2021 RSU Plan until December 31, 2031, however we expect that RSUs available under the Plan will have been distributed within the next five years. At December 31, 2021, we had granted RSUs under the 2021 RSU Plan providing for our issuance of an aggregate of 266,664 shares of our common stock and there are 2,233,336 remaining shares available for grant.

Purpose. The 2021 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 is intended to give 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 2021 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 2021 RSU Plan, to establish, adopt and revise such rules, regulations and forms and agreements and to interpret the 2021 RSU Plan and make all determinations relating to the 2021 RSU Plan as it may deem necessary or advisable. The Board/Committee also has the authority, subject to the provisions of the 2021 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 2021 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 2021 RSU Plan. All decisions, determinations and interpretations of the Board/Committee are binding and conclusive on participants in the 2021 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 2021 RSU Plan, and it is expected that RSU awards under the 2021 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 2021 RSU Plan, employees or consultants of the Company also mean employees or consultants of the Company's subsidiary. As of April 30, 2023 all of the Company's nine full-time employees and four Non-Employee Directors of the Company are eligible participants ("Participants") in the 2021 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 2021 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 2021 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 2021 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 2021, it will be generally be distributed the first business day of January 2022. 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 or 2021 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., 33% of RSUs to be paid in 2024, 2025 and 2026). 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 2021 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 2021 RSU Plan.

Outstanding Equity Awards at 2021 Year End

The following table presents information regarding outstanding RSU and stock option awards at December 31, 2021 for each of the 2021 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	47,000	—	$ 0.450	08/08/2022	—	$ —
	18,000	—	$ 13.05	12/13/2022		
	50,000	—	$ 0.151	12/11/2023		
	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		
Peter A. Clemens	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		
Albert W. Brzeczko	35,000	—	$ 0.450	08/08/2022	—	$ —
	14,000	—	$ 13.05	12/13/2022		
	34,000	—	$ 0.151	12/11/2023		
	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		

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, 2021:

2021 DIRECTOR COMPENSATION

Director	Fees Earned or Paid in Cash ($)	Stock Awards (in form of Restricted Stock Units) ($)[1]	Option Awards ($)[2]	Total ($)
William G. Skelly	$ 23,750	$ 24,000	—	$ 47,750
Bruce F. Wesson	$ 21,250	$ 24,000	—	$ 45,250
Immanuel Thangaraj	$ 15,000 [3]	$ 24,000	—	$ 39,000
George K. Ross	$ 26,250	$ 24,000	—	$ 50,250

(1) Represents the grant date fair value of $0.36 for restricted stock units, or RSUs with respect to the 66,666 RSUs granted to Messrs. Skelly, Wesson, Thangaraj and Ross under our 2021 RSU Plan based on a closing common stock price of $0.37 on May 25, 2021 less $0.01 par value purchase price.

As of December 31, 2021, Messrs. Skelly, Wesson, Thangaraj and Ross each held 66,666 fully vested RSUs and are distributable to them on January 3, 2022.

(2) Each of Messrs. Skelly, Wesson, Thangaraj and Ross held vested options with respect to 6,000 underlying shares as of December 31, 2021.

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

Directors receive the following compensation:

- 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 2021 award, the Board reevaluated the minimum stock price and it was changed to $0.75 resulting in each director being awarded 66,666 RSUs. The Company's closing stock price on May 25, 2021 of $0.37 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 April 30, 2023, 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 2021 exceeded $100,000 (the "2021 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 April 30, 2023, there were 66,001,783 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 stock options, warrants or restricted stock units for computing the percentage of the person holding such stock options, warrants or restricted stock units, but are not deemed outstanding for computing the percentage of any other person. There were no stock options or restricted stock units exchangeable within 60 days of May 31, 2023.

Name of Beneficial Owner	Amount Owned	Percent of Class [1]
John Schutte		
c/o MainPointe Pharmaceuticals, LLC		
2604 River Green Circle		
Louisville, KY 40206	8,912,655	13.5 %
Abuse Deterrent Pharma, LLC		
2604 River Green Circle		
Louisville, KY 40206	52,984,375 [2]	69.7 %
Essex Woodlands Health Ventures Fund V, L.P.		
21 Waterway Avenue, Suite 225		
Woodlands, TX 77380	1,956,396 [3]	3.0 %
Robert B. Jones	848,455 [4]	1.3 %
William G. Skelly	525,989 [5]	0.8 %
Bruce F. Wesson	792,048 [6]	1. 2 %
Peter A. Clemens	640,430 [7]	1.0 %
Immanuel Thangaraj	397,647 [8]	0.6 %
Albert W. Brzeczko	608,801 [9]	0.9 %
George K. Ross	445,503 [10]	0.7 %
All Officers and Directors as a Group (8 persons)	4,708,261 [11]	7.1 %

(1) Shows percentage ownership assuming (i) such party converts all of its currently convertible securities or securities convertible within 60 days of May 31, 2023 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 2021 named executive officer has been pledged as collateral security.

(2) Includes a warrant to purchase 10,000,000 shares at $0.01 per share held by AD Pharma.

(3) 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. Immanuel Thangaraj may be deemed to have dispositive power and voting power with respect to the securities held by the Essex. Mr. Thangaraj disclaims beneficial ownership of such securities except to the extent of his respective pecuniary interests therein.

(4) Includes 244,900 shares subject to stock options exercisable within 60 days of May 31, 2023. Does not include RSUs.

(5) Does not include RSUs.

(6) Does not include RSUs.

(7) Includes 135,000 shares subject to stock options exercisable within 60 days of May 31, 2023. Does not include RSUs.

(8) 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.

(9) Includes 162,800 shares subject to stock options exercisable within 60 days of May 31, 2023. Does not include RSUs.

(10) Does not include RSUs.

(11) Includes 748,284 shares which Directors and executive officers have the right to acquire within 60 days of May 31, 2023 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, 2021 relating to our 2008 Stock Option Plan, our 2016 Stock Option Plan, our 2014 Restricted Stock Unit Award Plan, our 2017 Restricted Stock Award Plan and our 2021 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	1,030,684	$ 2.73	48,478
Stock Option Equity Compensation Plans Not Approved by Security Holders	—	—	—
Restricted Stock Unit Equity Compensation Plans Approved by Security Holders	658,658	$ 0.01	—
Restricted Stock Unit Equity Compensation Plans Not Approved by Security Holders	—	—	—
TOTAL	1,689,342	$ 1.67	48,478

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 of $4.0 million to Mr. Schutte consisting of 8,912,655 common shares and warrant to purchase 1,782,531 common shares exercisable at $0.528 per share expiring on July 23, 2022, 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 had a maturity date of January 2, 2020, at which time all principal and interest was 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 Promissory 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 Promissory 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. AD Pharma is an entity controlled by Mr. Schutte, of which Mr. Schutte is the managing partner and investor.

On June 28, 2019 we entered into a License, Development and Commercialization Agreement, as amended in October 2020, July 2021, February 2022, November 2022, and December 15, 2022 (the "AD Pharma Amended Agreement"), with Abuse Deterrent Pharma, LLC (“AD Pharma”) for the completion of development of LTX-03 (hydrocodone bitartrate with acetaminophen) immediate-release tablets utilizing Acura’s patented LIMITx™ technology. AD Pharma is an entity controlled by Mr. Schutte, of which Mr. Schutte is the managing partner and investor.

The AD Pharma Amended Agreement, grants AD Pharma exclusive commercialization rights in the United States to LTX-03. The AD Pharma Amended Agreement required AD Pharma to pay us a monthly license payment for LTX-03 of $350 thousand for a period from inception up to April 2020 at which time the payment became $200 thousand per month. The monthly license payments ended on July 31, 2021 under the AD Pharma Amended Agreement. The AD Pharma Amended Agreement required AD Pharma to reimburse us all our outside development costs we incurred for 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, 2023, 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 to terminate the AD Pharma Amended Agreement expires.

The AD Pharma Amended Agreement allows AD Pharma to terminate the AD Pharma Amended Agreement anytime for “convenience on 30 days prior written notice”.

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 2021, 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 2021 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 2021 and 2020 were as follows:

	2021	2020
Audit Fees	$ 155,267	$ 145,952
Audit-Related Fees	—	—
Tax Fees	595	39,700
All Other Fees	—	—
Total for BDO USA, LLP	$ 155,862	$ 185,652

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.

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: June 30, 2023

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)	June 30, 2023
/s/Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	June 30, 2023
/s/ George K. Ross George K. Ross	Director	June 30, 2023
/s/ William G. Skelly William G. Skelly	Director	June 30, 2023
/s/ Immanuel Thangaraj Immanuel Thangaraj	Director	June 30, 2023
/s/ Bruce F Wesson Bruce F. Wesson	Director	June 30, 2023

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
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).
4.5	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).
10.03	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)
10.07	Form of Mortgage dated December 27, 2013 (incorporated by reference to Exhibit 10.8 to the Form 10-K filed March 3, 2014).
10.08	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 filed March 2, 2015).
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).

Exhibit Number	Exhibit Description
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).
†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 (incorporated by reference to Exhibit 10.44 to the Form 10-K 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 Peter 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 Peter 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 Peter Clemens (incorporated by reference to Exhibit 10.28 to the Form 10-K 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 Peter 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 Peter Clemens (incorporated by reference to Exhibit 10.24 to the Form 10-K 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).
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).

Exhibit Number	Exhibit Description
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).
10.49	Promissory Note dated June 28, 2019 issued to John Schutte (incorporated by reference to Exhibit 10.49 to our Form 10-Q filed February 20, 2020).
10.50	License, Development and Commercialization Agreement is made and entered into as of June 28, 2019 by the Registrant and between Abuse Deterrent Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.50 to our Form 10-K filed March 31, 2020).
10.51	Common Stock Warrant issued June 28, 2019 to John Schutte (incorporated by reference to Exhibit 10.51 to our Form 10-K filed March 31, 2020).
10.52	Assignment of Promissory Note, Warrant and Security Agreement issued June 28, 2019 by John Schutte to Abuse Deterrent Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.52 to our Form 10-K filed March 31, 2020).
10.53	Amended License, Development and Commercialization Agreement is made and entered into as of October 16, 2020 by the Registrant and between Abuse Deterrent Pharmaceuticals, LLC. (First Amendment). (incorporated by reference to Exhibit 10.53 to our Form 10-K filed March 31, 2021).
10.54 *	Amendment #2 to the License, Development and Commercialization Agreement is made and entered into as of June 17, 2021 by the Registrant and between Abuse Deterrent Pharma, LLC.
10.55	Promissory Note dated December 21, 2021 issued to John Schutte.(incorporated by reference to Exhibit 99.1 to our Form 8-K filed December 28, 2021).
10.56	Promissory Note dated January 3, 2022 issued to John Schutte.(incorporated by reference to Exhibit 99.1 to our Form 8-K filed January 4, 2022).
10.57	Promissory Note dated January 31, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8K filed February 1, 2022).
10.58 *	Third Amendment to the Amended License, Development and Commercialization Agreement is made and entered into as of February 28, 2022 by the Registrant and between Abuse Deterrent Pharma, LLC.
10.59	Promissory Note dated March 31, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed April 4, 2022).
10.60	Promissory Note dated April 29, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed May 2, 2022).
10.61	Promissory Note dated May 20, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed May 23, 2022).
10.62	Promissory Note dated June 10, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed June 13, 2022).
10.63	Promissory Note dated July 6, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed July 11, 2022).
10.64	Promissory Note dated July 18, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed July 19, 2022).

Exhibit Number	Exhibit Description
10.65	Promissory Note dated August 23, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed August 26, 2022).
10.66	Promissory Note dated September 20, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed September 26, 2022).
10.67	Promissory Note dated October 13, 2022 issued to John Schutte. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed October 17, 2022).
10.68 *	Amended, Consolidated and Restated Secured Promissory Note dated November 10, 2022 issued to John Schutte.
10.69	Amended, Consolidated and Restated Secured Promissory Note dated November 10, 2022 issued to Abuse Deterrent Pharma, LLC for aggregating $2,569,279 reflecting a $250,000 loan received December 22, 2022. (incorporated by reference to Exhibit 99.2 to our Form 8-K filed December 27, 2022).
10.70 *	Amended Loan Schedule to the Amended, Consolidated and Restated Secured Promissory Note dated November 10, 2022 issued to Abuse Deterrent Pharma, LLC on May 19, 2023 aggregating $3,469,279.
11	Fourth Amendment to the Amended License, Development and Commercialization Agreement is made and entered into as of November 10, 2022 by the Registrant and between Abuse Deterrent Pharma, LLC. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed December 27, 2022).
11.1	Fifth Amendment to the Amended License, Development and Commercialization Agreement is made and entered into as of December 15, 2022 by the Registrant and between Abuse Deterrent Pharma, LLC. (incorporated by reference to Exhibit 99.3 to our Form 8-K filed December 27, 2022).
†11.2	Registrant's 2021 Restricted Stock Unit Award Plan. (incorporated by reference to Appendix A to our Proxy Statement filed on April 12, 2021).
11.3	Sixth Amendment to the Amended License, Development and Commercialization Agreement is made and entered into as of June 15, 2023 by the Registrant and between Abuse Deterrent Pharma, LLC. (incorporated by reference to Exhibit 99.1 to our Form 8-K filed June 28, 2023).
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 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

Exhibit Number	Exhibit Description
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
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

*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, 2021 and 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended (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, 2021 and 2020, 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 stockholders' deficit, and has negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matter

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

Evaluation of Going Concern Uncertainty

As described in Note 1 to the Company's financial statements, the Company has had recurring losses and negative cash flows from operations since inception and expects to continue to incur net losses for the foreseeable future. This matter is also described in the "Going Concern Uncertainty" section of our report.

We identified management's evaluation of going concern uncertainty and the related financial statement disclosures as a critical audit matter. Management is required to make subjective judgments and assumptions in preparing a forecast of future cash flows and providing complete and accurate disclosures related to the Company's going concern evaluation. Auditing these judgments and assumptions involved especially challenging auditor judgment due to the nature and extent of audit evidence and effort required to address these matters.

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

- Assessing the reasonableness of management's key assumptions in forecasting future cash flows by comparing the key assumptions to historical results, the ongoing development pipeline, and contractual arrangements.

- Evaluating the adequacy of management's disclosure in the financial statements regarding the Company's evaluation of going concern by comparing the disclosure to other audit evidence obtained to determine whether such evidence is consistent with or contradictory to the Company's disclosure.

/s/ BDO USA, LLP

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

Chicago, Illinois

June 30, 2023

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2021 and 2020
(in thousands except par value)

	2021	2020
Assets:		
Cash	$ 65	$ 413
Royalty receivable	30	30
Collaboration receivable from related party	78	197
License fees receivable from related party	50	400
Prepaid expenses and other current assets	149	139
Total current assets	372	1,179
Finance lease right-of-use	50	—
Property, plant and equipment, net	438	484
Intangible asset, net	—	73
Total assets	$ 860	$ 1,736
Liabilities:		
Accounts payable	$ 192	$ 31
Accrued expenses	238	631
Finance lease liability - current	33	—
Loan under CARES Act	—	164
Other current liabilities	52	18
Accrued interest to related party	—	678
Convertible debt to related party, net of discounts	—	6,000
Total current liabilities	515	7,522
Finance lease liability - noncurrent	17	—
Loan under CARES Act - noncurrent	—	105
Promissory note to related party	150	—
Total liabilities	$ 682	$ 7,627
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock - $0.01 par value per share; 100,000 shares authorized, 65,093 and 21,650 shares issued and outstanding at December 31, 2021 and 2020, respectively	651	216
Additional paid-in capital	389,610	383,097
Accumulated deficit	(390,083)	(389,204)
Total stockholders' equity (deficit)	178	(5,891)
Total liabilities and stockholders' equity (deficit)	$ 860	$ 1,736

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2021 and 2020
(in thousands except per share amounts)

	2021	2020
Revenues:		
Royalties	$ 132	$ 109
Collaboration from related party	31	238
License fees from related party	1,400	3,000
Product sales	—	223
Total revenues	1,563	3,570
Expenses:		
Research and development	1,524	1,781
General and administrative	1,253	2,547
Total expenses	2,777	4,328
Operating loss	(1,214)	(758)
Gains on forgiveness of loans under CARES Act	535	—
Interest expense to related party	(200)	(450)
Loss before provision for income taxes	(879)	(1,208)
Provision for income taxes	—	—
Net loss	$ (879)	$ (1,208)
Net loss per share:		
Basic	$ (0.02)	$ (0.04)
Diluted	$ (0.02)	$ (0.04)
Weighted average number of shares outstanding:		
Basic	56,801	32,320
Diluted	56,801	32,320

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
YEARS ENDED DECEMBER 31, 2021 and 2020
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Number of Shares	Par Value			
Balance at January 1, 2021	**21,650**	**$ 216**	**$ 383,097**	**$ (389,204)**	**$ (5,891)**
Net loss	—	—	—	(879)	(879)
Net distribution of common stock pursuant to RSU award plan	405	4	9	—	13
Exercise of stock options	54	1	(1)	—	—
Non-cash share-based compensation	—	—	58	—	58
Conversion of convertible debt principal	37,500	375	5,625	—	6,000
Conversion of convertible debt interest	5,484	55	822	—	877
Balance at December 31, 2021	**65,093**	**$ 651**	**$ 389,610**	**$ (390,083)**	**$ 178**

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

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2021 and 2020
(in thousands)

	2021	2020
Cash Flows from Operating Activities:		
Net loss	$ (879)	$ (1,208)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	47	56
Non-cash share-based compensation	58	36
Amortization of intangible asset	26	69
Amortization of right-of-use asset	17	—
Impairment charge on intangible asset	47	668
Sales returns liability	—	(223)
Gains on forgiveness of loans under CARES Act	(535)	—
Changes in assets and liabilities:		
Royalty receivable	—	52
Collaboration revenue receivable from related party	119	(119)
License fee receivable from related party	350	(400)
Prepaid expenses and other current assets	(10)	(17)
Income taxes refundable	—	68
Accounts payable	161	(206)
Accrued expenses	(394)	46
Accrued interest on convertible debt to related party	199	449
Other current liabilities	52	10
Net cash used in operating activities	(742)	(719)
Cash Flows from Financing Activities:		
Proceeds from distribution of RSU awards	3	3
Statutory minimum payroll withholding taxes paid on the distribution of shares pursuant to RSU awards	(8)	(2)
Proceeds from loans received under CARES Act	266	269
Proceeds from issuance of promissory note to related party	150	—
Payments on finance lease	(17)	—
Net cash provided by financing activities	394	270
Net decrease in cash	(348)	(449)
Cash at beginning of year	413	862
Cash at end of year	$ 65	$ 413
Supplemental Disclosures of Cash Flow Information:		
Cash interest payments on loans	$ —	$ —
Cash paid for income taxes	$ —	$ —

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2021 and 2020

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 a 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). US commercialization rights to LTX-03, LTX-02 and LTX-09 are licensed to Abuse Deterrent Pharma, LLC (See Note 3).

- Our Aversion Technology has been licensed to Assertio Holdings Inc. or Assertio (formerly known as Zyla Life Sciences and previously as Egalet Corporation) for use in Oxaydo® Tablets (oxycodone HCl, CII). 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, 2021, we had cash on hand balance of $65 thousand, working capital deficit of $143 thousand and an accumulated deficit of $390.1 million. We had a loss from operations of $1.2 million and a net loss of $879 thousand for the year ended December 31, 2021. We have suffered recurring losses from operations and have not generated positive cash flows from operations. We anticipate operating losses to continue for the foreseeable future.

On June 28, 2019 we entered into a License, Development and Commercialization Agreement to the Limitx patent LTX-03, as amended in October 2020, July 2021, February 2022, November 2022, December 15, 2022 and June 15, 2023 (the "AD Pharma Amended Agreement"), with Abuse Deterrent Pharma, LLC ("AD Pharma"). Under the AD Pharma Amended Agreement, AD Pharma also has a license to the Limitx patents for LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam) for exclusive commercialization rights in the United States, which are not subject to any development agreement or responsibilities by Acura. The AD Pharma Amended Agreement required AD Pharma to pay us a monthly license payment for LTX-03 of $350 thousand for a period from inception up to April 2020 at which time the payment became $200 thousand per month. The monthly license payments ended on July 31, 2021 under the AD Pharma Amended Agreement. The AD Pharma Amended Agreement required AD Pharma to reimburse us all our outside development costs we incurred for LTX-03. Whether or not AD Pharma exercises their right to terminate the AD Pharma Amended Agreement, we need to raise additional financing or enter into license or collaboration 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 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.

At December 31, 2021, AD Pharma was delinquent in remitting $50 thousand of the July 2021 license fee and approximately $78 thousand of reimbursable LTX-03 development expenses. Failure to make any of these payments is an event of default under the AD Pharma Amended Agreement if Acura provides a default notification to AD Pharma. Acura did not provide such default notification and in March 2022, Acura received the delinquent license fee and delinquent development expenses from AD Pharma.

The AD Pharma Amended Agreement, requires the New Drug Application ("NDA") for LTX-03 be accepted by the FDA by November 30, 2023 or AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property (See Note 15). 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 to terminate AD Pharma Amended Agreement expires.

The AD Pharma Amended Agreement allows AD Pharma to terminate the AD Pharma Amended Agreement anytime for "convenience on 30 days prior written notice".

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

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying 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, royalty receivable, collaboration revenue receivable and license fee receivable. The Company maintains deposits in federally insured financial institutions which deposits can be at times 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

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date. Fair value measurement establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value.

The Company determined the fair value of financial assets and liabilities using the fair value hierarchy that describes three levels of inputs that may be used to measure fair value, as follows:

- Level 1—Quoted prices in active markets for identical assets and liabilities;
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial instruments consist primarily of cash, royalty, collaboration revenue and license fee receivables, trade accounts payable and related party debt. The carrying amounts of these financial instruments, other than related party debt, are representative of their respective fair values due to their relatively short maturities. The carrying value of related party debt approximates fair value due to its recent issuance in December 2021. The estimated fair value of the related party debt is considered a Level 2 fair value measurement.

Segment Reporting

The Company operates and manages its business as one operating segment which is the research, development and commercialization of technologies and products intended to address safe use of medications. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. All long-lived assets are maintained in the United States of America.

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 12.

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. We account for forfeitures as they occur.

Our total share-based compensation expense recognized in the Company's annual results of operations for years ended December 31, 2021 and 2020 was $110 thousand and $53 thousand, respectively, for RSU awards issued to our non-employee directors. This expense was from both non-cash and cash-portioned RSUs and was recorded in general and administrative expenses.

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

Intangible and Long-Lived Assets

Long-lived assets such as the intangible asset and property, plant and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of the assets to be held and used is measured by a comparison of the carrying amount of the asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying value of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. During the first quarter 2020 a triggering event occurred with the decline in royalty cash flows under our license and collaboration agreement with Assertio Holdings Inc. (See Note 3), and we performed an impairment test which indicated that the carrying value of the intangible asset was greater than the fair value. The fair value calculation of the intangible asset included significant estimates and assumptions related to the amount and timing of projected future cash flows and in the situation when the asset is determined to not be recoverable, the discount rate. The impairment test resulted in a $668 thousand impairment charge against the intangible asset, which was determined using our estimate of discounted royalty cash flows remaining under our license agreement with Assertio, and recorded a like amount to general and administrative expense. During the fourth quarter 2021 another triggering event occurred resulting in an additional $47 thousand impairment against the intangible asset.

Leases

Leases are recorded on the consolidated balance sheets as financed lease – “right-of-use” assets and financed lease liabilities. The related right-of-use assets are amortized on a straight-line basis over the lesser of the lease term or the estimated useful life of the asset. Leases are classified as either operating or finance leases and lease expense is recognized within “general and administrative expenses” or will be recognized within “research and development” expenses if it is associated with operations at our subsidiary. Finance leases are treated as the purchase of an asset on a financing basis. See Note 12 for additional information regarding leases.

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. 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.

Collaboration revenue is derived from reimbursement of development expenses, as under our collaboration agreement with AD Pharma, and are recognized when costs are incurred pursuant to the agreements. The ongoing research and development services being provided under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration agreement. We recognized $31 thousand and $238 thousand of collaboration revenue under the AD Pharma Amended Agreement during the years ended December 31, 2021 and 2020, respectively.

Royalty Revenue

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

In connection with our license and collaboration agreement with Assertio to commercialize Oxaydo tablets we will receive a stepped royalty at percentage rates ranging from mid-single digits to double-digits based on Oxaydo net sales during each calendar year over the term of the agreement (excluding net sales resulting from any co-promotion efforts by us). We recognize royalty revenue each calendar quarter based on net sales reported to us by Assertio in accordance with the agreement. Assertio's first commercial sale of Oxaydo occurred in October 2015. We have recorded royalties of $130 thousand and $102 thousand during the years ended December 31, 2021 and 2020, respectively. (See Note 3).

In connection with the MainPointe Agreement, which occurred in March 2017, we are receiving a royalty of 7.5% on net sales of the licensed products over the term of the agreement. Such royalty shall be payable for sales made during each calendar quarter and payment will be remitted within forty-five (45) days after the end of the quarter to which it relates. We have recorded royalties of $2 thousand and $7 thousand during the years ended December 31, 2021 and 2020, respectively. (See Note 3).

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, 2021 or 2020.

Income Taxes

We account for income taxes under the asset and 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, 2021 and 2020, 100% of all remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

Customer Concentration

Under the AD Pharma Amended Agreement, AD Pharma also has a license to the Limitx patents for LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam) for exclusive commercialization rights in the United States, which are not subject to any development agreement or responsibilities by Acura. The AD Pharma Amended Agreement required AD Pharma to pay us a monthly license payment for LTX-03 of $350 thousand for a period from inception up to April 2020 at which time the payment became $200 thousand per month. The monthly license payments ended on July 31, 2021 under the AD Pharma Amended Agreement. The AD Pharma Amended Agreement required AD Pharma to reimburse us all our outside development costs we incurred for LTX-03.

The AD Pharma Amended Agreement, requires the NDA for LTX-03 be accepted by the FDA by November 30, 2023 or AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property. Should AD

Pharma choose not to exercise this option to terminate and the NDA for LTX-03 is subsequently accepted by the FDA, such option to terminate AD Pharma Amended Agreement expires.

The AD Pharma Amended Agreement allows AD Pharma to terminate the AD Pharma Amended Agreement anytime for "convenience on 30 days prior written notice".

Under our agreement with MainPointe, we earn royalties from MainPointe sale of the licensed product line Nexafed.

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

Recent Accounting Pronouncements

New accounting standards which have not yet been adopted on or before December 31, 2021

Credit Losses

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

Convertible Debt

In August, 2020, the FASB issued ASU 2020-06, "Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity". ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock. The ASU is effective for the fiscal year beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact that the standard will have on the financial statements and related footnote disclosures.

NOTE 3 – LICENSE AND COLLABORATION AGREEMENTS

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

AD Pharma Amended Agreement covering LTX-03

Under the AD Pharma Amended Agreement, AD Pharma also has a license to the Limitx patents for LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam) for exclusive commercialization rights in the United States, which are not subject to any development agreement or responsibilities by Acura. The AD Pharma Amended Agreement required AD Pharma to pay us a monthly license payment for LTX-03 of $350 thousand for a period from inception up to April 2020 at which time the payment became $200 thousand per month. The monthly license payments ended on July 31, 2021 under the AD Pharma Amended Agreement. The AD Pharma Amended Agreement required AD Pharma to reimburse us all our outside development costs we incurred for LTX-03.

The AD Pharma Amended Agreement, requires the NDA for LTX-03 be accepted by the FDA by November 30, 2023 or AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property (See Note 15). 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 to terminate AD Pharma Amended Agreement expires.

The AD Pharma Amended Agreement allows AD Pharma to terminate the AD Pharma Amended Agreement anytime for "convenience on 30 days prior written notice".

At December 31, 2021, AD Pharma was delinquent in remitting $50 thousand of the license fee for the month of July 2021 and approximately $78 thousand of reimbursable LTX-03 development expenses. Failure to make any of these payments is an event of default under the AD Pharma Amended Agreement and if Acura provides a default notification to AD Pharma. Acura did not provide such default notification and in March 2022, Acura received the delinquent license fee and delinquent development expenses from AD Pharma.

AD Pharma retains commercialization rights to LTX-03 from which Acura will receive stepped royalties on sales and potential sales related milestones. Upon commercialization of LTX-02 and LTX-09 (alprazolam), which are not subject to any development agreement or responsibilities by Acura, Acura will receive stepped royalties on sales and is eligible for certain sales related milestones.

We had also previously granted authority to MainPointe to assign to AD Pharma the option and the right to add to the Nexafed® Agreement, an Option Product, and the Option Product exercise price of $500 thousand was waived if the exercise of the option occurred by June 28, 2024 (five years from the effective date). Effective with an amendment made in October 2020 to the AD Pharma Amended Agreement, this option and right was rescinded.

Assertio Agreement covering Oxaydo

In April 2014, we terminated an agreement with Pfizer which resulted in the return to us of Aversion Oxycodone (formerly known as Oxecta®) and all Aversion product rights in exchange for a one-time termination payment of $2.0 million. Our termination payment of $2.0 million was recorded in our financial statements as an intangible asset and was 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 Assertio royalty revenues to us. During the first quarter 2020 a triggering event occurred with the decline in royalty cash flows from Assertio, and we performed an impairment test which indicated that the carrying value of the intangible asset was greater than the fair value. The impairment test resulted in a $668 thousand impairment charge against the intangible asset, which was determined using our estimate of discounted royalty cash flows remaining under our license agreement with Assertio, and recorded a like amount to general and administrative expense. During the fourth quarter 2021, another triggering event occurred resulting in a $47 thousand impairment charge against the intangible asset. At December 31, 2021 the intangible asset was fully impaired and amortized. We have recorded amortization expense of $26 thousand and $69 thousand in each of the years ending December 31, 2021 and 2020, respectively.

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

	December 31, 2021	December 31, 2020
Intangible asset – Aversion	2,000	2,000
Less: accumulated amortization	(1,285)	(1,259)
Less: impairment charges	(715)	(668)
Net	$ —	$ 73

In January 2015, we and Assertio, entered into the Assertio Agreement to commercialize Aversion Oxycodone under our tradename Oxaydo. Oxaydo is approved by the FDA for marketing in the United States in 5 mg and 7.5 mg strengths. Under the terms of the Assertio Agreement, we transferred the approved NDA for Oxaydo to Assertio and Assertio is granted an exclusive license under our intellectual property rights for development and commercialization of Oxaydo worldwide (the "Territory") in all strengths. Egalet launched Oxaydo in the United States late in the third quarter of 2015. Assertio will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States. Assertio may develop Oxaydo for other countries and in additional strengths, in its discretion.

We will be entitled to a one-time $12.5 million sales-based milestone payment when worldwide Oxaydo net sales reach $150 million in a calendar year. We are entitled to receive from Assertio a stepped royalty at percentage rates ranging from mid-single digits to double-digits based on Oxaydo net sales during each calendar year (excluding net sales resulting from our co-promotion efforts). In any calendar year of the agreement in which net sales exceed a specified threshold, we will receive a double digit royalty on all Oxaydo net sales in

that year (excluding net sales resulting from our co-promotion efforts). Assertio's royalty payment obligations commenced on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States or the date when no valid and enforceable listable patent in the FDA's Orange Book remains with respect to Oxaydo). Royalties will be reduced upon the entry of generic equivalents, which may occur as soon as January 2025, as well as for payments required to be made by Assertio to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

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

MainPointe Agreement covering Nexafed Products and assignment thereof to AD Pharma

In March 2017, we and MainPointe entered into the MainPointe Agreement, pursuant to which we granted MainPointe an exclusive license to our Impede Technology to commercialize both of our Nexafed and Nexafed Sinus Pressure + Pain product ("Nexafed products") in the U.S. and Canada. 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 containing PSE and utilizing the Impede Technology ("Option Products") 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 one of the Option Products, 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 to the Nexafed® Agreement, an Option Product, and the Option Product exercise price of $500 thousand was waived if the exercise of the option occurred by June 28, 2024 (five years from the effective date). Effective with an amendment made in October 2020 to the AD Pharma Amended Agreement, this option and right was rescinded.

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

On January 1, 2020, MainPointe assigned to AD Pharma, an entity controlled by Mr. Schutte, of which Mr. Schutte is the managing partner and investor, with Acura's consent, all of its right, title and interest in the MainPointe Agreement between MainPointe and Acura; which was subsequently rescinded by AD Pharma in October 2020.

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. As of December 31, 2021, the option to extend the KemPharm Agreement to cover two additional prodrug candidates remains unexercised.

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. As of December 31, 2021, we are unaware if our Aversion(R) Technology to KemPharm is being used in the development and commercialization of the three products.

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, 2021 or 2020.

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

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

Sales-based Milestones and Royalty Revenues

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.

Product Sales, net of allowance

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

Disaggregation of Total Revenues

The Company has two license agreements for currently marketed products containing its technologies; the Oxaydo product containing the Aversion Technology has been licensed to Assertio, and the Nexafed products containing the Impede Technology which have been licensed to MainPointe. The Company has a third license agreement with AD Pharma for three products containing our LIMITx™ technology, LTX-03, LTX-02 and LTX-09, for which only LTX-03 is under development. The monthly license fee payments to us under the AD Pharma Amended Agreement ended on July 31, 2021. We have recorded $1.4 million and $3.0 million of license fees for LTX-03 for the year ended December 31, 2021 and 2020, respectively.

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:

	Year Ended December 31,	
	2021	2020
Assertio (Oxaydo)	$ 130	$ 102
MainPointe - related party (Nexafed)	2	7
Royalty revenues	$ 132	$ 109

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, 2021 or 2020. Contract assets may be reported in future periods under prepaid expenses or other current assets on the consolidated balance sheet. Contract liabilities may be reported in future periods consisting of deferred revenue as presented on the consolidated balance sheet.

NOTE 5 – PROPERTY, PLANT AND EQUIPMENT

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

	December 31, 2021	December 31, 2020
Building and improvements	$ 1,273	$ 1,273
Scientific equipment	597	597
Computer hardware and software	105	106
Machinery and equipment	274	274
Land and improvements	162	162
Other personal property	68	70
Office equipment	27	27
	2,506	2,509
Less: accumulated depreciation	(2,068)	(2,025)
Total property, plant and equipment, net	$ 438	$ 484

We do not have leasehold improvements. We have one finance lease. (See Note 12). 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 $47 thousand and $56 thousand for each of the years ended December 31, 2021 and 2020, respectively.

NOTE 6 – ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	December 31, 2021	December 31, 2020
Cost sharing expenses under license agreements	$ —	$ 428
Other fees and services	26	24
Payroll, payroll taxes and benefits	—	8
Professional services	137	117
Financed premiums on insurance policies	55	28
Property taxes	10	9
Franchise taxes	10	17
Total	$ 238	$ 631

NOTE 7 – DEBT

Related Party Convertible Loan

At December 31, 2018, we had borrowed an aggregate of $4.35 million from Mr. Schutte, a related-party. From January 1, 2019 and through June 27, 2019, we borrowed additional amounts from Mr. Schutte for an aggregate $650 thousand and issued various promissory notes to him with the same terms and conditions from the previous loans. These promissory notes aggregated to $5.0 million and on June 28, 2019 we restructured them 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 them into a single promissory note with a fixed interest rate of 7.5%, maturity date of July 1, 2023, and granted principal and interest conversion rights into shares of our common stock at a price of $0.16 per share ("the 7.5% Note"). The principal amount of the loan is convertible into 37.5 million shares of our common stock. We also 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 7.5% 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.

On June 9, 2021, we received notice of conversion from AD Pharma for the 7.5% Note and approximately $877 thousand of accrued but unpaid interest on the 7.5% Note. The principal and interest were converted into 42,984,375 shares of the Company's common stock. Our interest expense for the year ended December 31, 2021 and 2020 was $200 thousand and $450 thousand, respectively.

AD Pharma owns 66% of our common stock at December 31, 2021. AD Pharma is an entity controlled by Mr. Schutte, of which Mr. Schutte is the managing partner and investor.

Paycheck Protection Program

1st PPP Loan

On April 13, 2020, the Company received a loan (the "1st Loan") from JP Morgan Chase Bank in the aggregate amount of $269 thousand, pursuant to the Paycheck Protection Program ("PPP") under Division A, Title I of the CARES Act, which was enacted March 27, 2020. Under the terms of the PPP, certain amounts of the 1st Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. The Company received approval for forgiveness under the PPP in July 2021 by the Small Business Administration and this amount was included as income in the third quarter of 2021.

2nd PPP Loan

On March 16, 2021, the Company received a loan (the "2nd Loan") from JP Morgan Chase Bank in the aggregate amount of $266 thousand, pursuant to the PPP under Division A, Title I of the CARES Act. The 2nd Loan, in the form of a promissory note, matures after five years. Under the terms of the PPP, certain amounts of the 2nd Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. The Company received approval for forgiveness under the PPP in October 2021 by the Small Business Administration and this amount has been included as income in the fourth quarter of 2021.

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, 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 were 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 expired five years after issuance (subject to earlier expiration in event of certain acquisitions). In July 2017 we 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 had accounted these warrants as equity. These warrants expired unexercised in July 2022.

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

MainPointe Pharmaceuticals LLC

Mr. Schutte is the principal owner of MainPointe. In March 2017, we granted MainPointe an exclusive license to our Impede Technology to commercialize our Nexafed® and Nexafed® Sinus Pressure + Pain Products in the United States and Canada for an upfront licensing fee of $2.5 million. The Company is receiving a 7.5% royalty on sales of licensed products. MainPointe also has options to expand the territory and products covered for additional sums. Included in the reported royalty revenue for the year ended 2021 and 2020 is $2 thousand and $7 thousand, respectively of royalty revenue from MainPointe. (See Note 2). On January 1, 2020, MainPointe assigned to AD Pharma, an entity controlled by Mr. Schutte, of which Mr. Schutte is the managing partner and investor, with Acura’s consent, all of its right, title and interest in the MainPointe Agreement between MainPointe and Acura; which was subsequently rescinded by AD Pharma in October 2020.

Loans with Mr. John Schutte and AD Pharma – Series 7.5%

We had borrowed an aggregate of $6.0 million from Mr. Schutte, a related-party. On June 28, 2019, the promissory note was assigned by Mr. Schutte to AD Pharma. On June 9, 2021, we received notice of conversion from AD Pharma for the $6.0 million promissory note and approximately $877 thousand of accrued but unpaid interest. The principal and interest were converted into 42,984,375 shares of the Company’s common stock.

Loans with Mr. John Schutte – Series 5.25%

In December 2021, the Company received a $150 thousand loan from Mr. Schutte, a related-party. We have issued an unsecured promissory note to him. The promissory note bears interest at 5.25% (‘Schutte 5.25% Note”), and matures on December 31, 2023, at which time all principal and interest is due. Events of default under the Schutte 5.25% Note include, among other items, bankruptcy events, failure to pay interest and principal when due and such failure continues for 5 days, and if Acura is generally not, or is unable to, or admits in writing its inability to, pay its debts as they become due. If any amount payable hereunder is not paid when due (without regard to any applicable grace periods), whether at stated maturity, by acceleration, or otherwise, including upon an event of default, such overdue amount shall bear interest at the rate per annum of 7.5% from the date of such non-payment until such amount is paid in full.

During 2022 our additional borrowings from Mr. Schutte were $1.775 million. On November 10, 2022, Mr. Schutte assigned the promissory notes to AD Pharma. In November and December 2022, our borrowings from AD Pharma were $600 thousand. During 2023 our additional borrowings from AD Pharma were $900 thousand. (See Subsequent Event Note 15.)

AD Pharma Amended Agreement covering LTX-03

On June 28, 2019 we entered into the AD Pharma Amended Agreement with AD Pharma for the 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. Under the AD Pharma Amended Agreement, AD Pharma also has a license to the Limitx patents for LTX-02 (oxycodone/acetaminophen) and LTX-09 (alprazolam) for exclusive commercialization rights in the United States, which are not subject to any development agreement or responsibilities by Acura.

The AD Pharma Amended Agreement, requires the NDA for LTX-03 be accepted by the FDA by November 30, 2023 or AD Pharma has the option to terminate the AD Pharma Amended Agreement and take ownership of the LIMITx intellectual property. Should AD Pharma choose not to exercise this option to terminate and the NDA for LTX-03 is subsequently accepted by the FDA, such option to terminate AD Pharma Amended Agreement expires.

The AD Pharma Amended Agreement allows AD Pharma to terminate the AD Pharma Amended Agreement anytime for "convenience on 30 days prior written notice". (See Note 3).

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. Acura did not contribute a matching contribution nor a profit sharing contribution to the Plan during the year ended December 31 2021 or 2020.

NOTE 10 – COMMON STOCK PURCHASE WARRANTS

Our warrant activity during the years ended December 31, 2021 and 2020 is shown below (in thousands except price data):

	December 31,			
	2021		2020	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, Jan. 1	11,782	$ 0.09	11,842	$ 0.10
Issued	—	—	—	—
Exercised	—	—	—	—
Expired	—	—	(60)	2.52
Modification	—	—	—	—
Outstanding, Dec. 31	11,782	$ 0.09	11,782	$ 0.09

As part of our July 2017 private placement transaction with Mr. Schutte, we issued warrants to purchase 1,782,531 shares of our common stock. The warrants are immediately exercisable at a price of $0.528 per share and expire five years after issuance in July 2022. (See Note 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. These warrants expired unexercised in July 2022.

In June 2019 as part of the changes made to the loan agreements we had with Mr. Schutte, each having an original due date of January 2, 2020, we issued to him a warrant to purchase 10.0 million shares of our common stock exercisable at a price of $0.01 per share and expire five years after issuance in June 2024. We obtained a valuation of fair value on the warrant and $1.145 million was allocated to the warrant and accounted for as equity. (See Note 7 and Note 8). The warrant for 10.0 million shares 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, 2021 and 2020 and for the year then ended consisted of the following (in thousands except exercise price):

	Year Ended December 31,			
	2021		2020	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, Jan. 1	1,254	$ 3.46	1,356	$ 4.45
Granted	—	—	—	—
Exercised	(94)	0.20	—	—
Forfeited	—	—	—	—
Expired	(129)	11.69	(102)	16.54
Outstanding, Dec. 31	1,031	$ 2.73	1,254	$ 3.46
Exercisable, Dec. 31	1,031	$ 2.73	1,254	$ 3.46

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.

At December 31, 2021, all the approximately 1.03 million outstanding stock option awards are exercisable and the weighted average remaining contractual term of them is 2.76 years. There was approximately $58 thousand of intrinsic value contained in the stock option awards outstanding at December 31, 2021. The total intrinsic value of the 94 thousand stock option awards exercised during 2021 was $22 thousand.

Restricted Stock Unit Award Plans

We have two Restricted Stock Unit Award Plans for our employees and non-employee directors, a 2021 Restricted Stock Unit Award Plan (the "2021 RSU Plan) and a 2017 Restricted Stock Unit Award Plan (the "2017 RSU Plan). Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. Our non-employee director awards allow for non-employee directors to receive payment in cash, instead of stock, for up to 40% of each RSU award. The portion of the RSU awards subject to cash settlement is recorded as a current liability in the Company's consolidated balance sheet as they vest and are being marked to market each reporting period until they are distributed. The liability was $52 thousand and $18 thousand at December 31, 2021 and December 31, 2020, 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, 2021 and 2020, and for the year then ended consisted of the following (in thousands):

	Year Ended December 31,			
	2021		2020	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, Jan. 1	839	839	1,017	1,017
Granted	267	—	219	—
Distributed	(447)	(447)	(397)	(397)
Vested	—	267	—	219
Forfeited	—	—	—	—
Outstanding, Dec. 31	659	659	839	839

2021 Restricted Stock Unit Award Plan

Our 2021 RSU Plan was approved by shareholders in May 2021 and permits the grant of up to 2.50 million shares of our common stock pursuant to awards under the 2021 RSU Plan. As of December 31, 2021 there were 2.23 million shares remaining available for award under the 2021 RSU Plan.

Information about the award activity under the 2021 RSU Plan is as follows:

- In May 2021, we awarded approximately 66 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. The awards vested 50% at the end of calendar quarter June 30, 2021 and 25% at the end of each calendar quarter in 2021 thereafter. The grant date fair value of the RSU awards was $96 thousand and the aggregate intrinsic value of the common share of the RSU awards vested during the year was $131 thousand. Settlement of this RSU did occur on January 4, 2022. The portion of the RSU awards which was 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 having been recorded to stock compensation expense in the general and administration operating category of our consolidated statements of operations.

2017 Restricted Stock Unit Award Plan

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

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

- In December 2017, we awarded 200 thousand RSUs to our employees. Such RSU awards vested 100% after one full year of service. Distributions of the vested RSU awards to the employees were made in three equal installments on the first business day of each of January 2020, 2021, and 2022.
- In December 2018, we awarded 488 thousand RSUs to our employees. Such RSU awards vested 100% after one full year of service. Distributions of the vested RSU awards to the employees were made in three equal installments on the first business day of each of January 2021, 2022, and 2023.
- 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. The awards vested 25% at the end of each calendar quarter in 2019. Settlement of this RSU award did occur 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 consolidated statements of operations.

- 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. The awards vested 25% at the end of each calendar quarter in 2020. Settlement of this RSU award did occur on January 4, 2021, the first business day of the year after vesting. The portion of the RSU awards which are subject to cash settlement will also be subject to marked to market accounting having a liability recorded on the Company's consolidated balance sheet with quarterly adjustments recorded to stock compensation expense in the general and administration operating category of our consolidated statements of operations.

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

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

NOTE 12 – LEASES

In June 2021, the Company entered into a finance lease for a scientific piece of equipment for a term of 24 months with equal monthly payments of $3 thousand. The lease commenced on June 21, 2021 and ends on June 20, 2023. The Company uses the rate implicit in the lease as the discount rate for the finance lease. The weighted average remaining lease term for the Company's finance lease is 1.5 years as of December 31, 2021. The present value of the lease is $50 thousand.

Future minimum lease commitments under the Company's non-cancelable finance lease as of December 31, 2021 is as follows (in thousands):

Year ending December 31,	
2022	$ 33
2023	17
Total undiscounted lease payments	50
Less: imputed interest	—
Present value of lease liability	$ 50

The following table reflects supplemental balance sheet information related to the lease as of December 31, 2021 and 2020 (in thousands):

	Financial Statement Classification	December 31, 2021	December 31, 2020
Assets			
Finance lease right-of-use	Other long-term assets	$ 50	$ —
Liabilities			
Finance lease liability - current	Other current liabilities	$ 33	$ —
Finance lease liability - noncurrent	Other long-term liabilities	17	—
Total lease liability		50	$ —

NOTE 13 – INCOME TAXES

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

Provision for Income Taxes

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

	December 31,	
	2021	2020
Benefit at U.S. statutory tax rate	$ (185)	$ (254)
State taxes (benefit), net of federal effect	(55)	(76)
State research and development tax credits	(16)	(18)
Federal research and development tax credits	(42)	(76)
PPP loan forgiveness	(112)	—
Other	97	(120)
Change in valuation allowance	313	544
(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 U.S. federal NOLs. We have approximately $126 million gross U.S. federal NOLs at December 31, 2021, which is prior to any limitation on its utilization. Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. We have determined that we have undergone an ownership change in 2004 and 2017 and most likely had an additional ownership change in 2021. We believe the gross federal NOL benefit available to offset taxable income was less than $150 thousand annually prior to 2021. On June 9, 2021 we believe the conversion of the $6.0 million Promissory Note into 42,984,375 shares of the Company’s common stock created still another ownership change which most likely significantly limited our utilization of these NOLs. As prescribed under Internal Revenue Code, any unused federal NOL benefit from the annual limitation can be accumulated and carried forward to the subsequent year and will expire if not used in accordance with the NOL carried forward term of 20 years or 2037 if generated before 2018, while our Federal NOLs generated after 2017 can be carried forward indefinitely. Additionally, the NOL deduction for taxable years beginning after December 21, 2020, is limited to 80% of taxable income. Future common stock transactions, such as the exercise of common stock purchase warrants, may cause additional ownership changes under IRC Section 382 which will most likely continue to further limit and restrict the amount of our NOLs we can utilize to offset taxable income.

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

	December 31,	
	2021	2020
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	2,667	2,269
- State	969	903
Research and development tax credits		
- Federal	1,325	1,283
- State	51	31
Share-based compensation	52	104
Debt extinguishment	—	636
Finance lease liability	14	—
Other, net	294	301
Total deferred tax asset	5,372	5,527
Valuation allowance	(5,358)	(5,527)
Net deferred tax assets	$ 14	$ —
Deferred tax liabilities:		
Finance lease right-of-use	(14)	—
Total deferred tax liabiliites	(14)	—
Net deferred taxes	$ —	$ —

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 December 31, 2021 and 2020, all our remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of NOL carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

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, 2021 and 2020, 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, 2021, the Company's tax years of 2018, 2019 and 2020 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 2018.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the option to deduct research and development expenditures currently and requires taxpayers to amortize them over five years for domestically incurred expenditures and over fifteen years for foreign incurred expenditures, pursuant to IRC Section 174. During 2022 will be reviewing those activities and expenses associated with our research and development ready-facility in Culver, Indiana under the AD Pharma Amended Agreement as it relates to IRC Section 174.

NOTE 14 – BASIC AND DILUTED NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing net income or loss by the weighted average common shares outstanding during a period, including shares weighted related to both vested Restricted Stock Units ("RSUs") which settle in shares (See Note 11) and a stock warrant exercisable for 10.0 million shares having an exercise price of $0.01 per share (See Note 7). Diluted net income (loss) per share 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 common stock equivalents, which are potential issuances 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. Also, any RSU which could be settled in cash are excluded from both the basic and diluted computations. As the Company reported a net loss in 2021 and 2020 the effects of common stock equivalents were excluded as their inclusion in the diluted net loss per share calculation would have been antidilutive. The weighted-average common share outstanding diluted computation is not impacted during any period where the exercise price of a stock option, common stock warrant or convertible loan is greater than the average market price of our common stock.

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

	Year Ended December 31,	
	2021	2020
Loss per share – basic and diluted		
Numerator: net loss	$ (879)	$ (1,208)
Denominator (weighted):		
Common shares	46,358	21,650
Vested RSUs - share settled	443	670
Common stock purchase warrant	10,000	10,000
Basic and diluted weighted average shares outstanding	56,801	32,320
Loss per share – basic and diluted	$ (0.02)	$ (0.04)
Excluded securities (non-weighted):		
Common shares issuable:		
Stock options	1,031	1,254
Common stock purchase warrants	1,782	1,782
Convertible loan	—	37,500
Total excluded common shares	2,813	40,536

NOTE 15 – SUBSEQUENT EVENTS

Promissory Notes

During the period December, 2021 to October, 2022, John Schutte loaned the Company $1.925 million as evidenced by a series of unsecured promissory notes bearing interest at 5.25% maturing at December 31, 2023. On October 31, 2022, Mr. Schutte assigned these notes to AD Pharma an entity controlled by Mr. Schutte, of which Mr. Schutte is the managing partner and investor.

On November 10, 2022, AD Pharma and the Company entered into an Amended Consolidated and Restated Secured Promissory Note (the "November 2022 Note") that encompasses the entire principle and accrued interest of the notes assigned by Mr. Schutte as well as an additional loan of $350 thousand from AD Pharma to the Company. The November 2022 Note totaling approximately $2.319 million, bears interest at 5.25%, and matures at December 31, 2023. The Company received an additional $250 thousand loan from AD Pharma on each of December 22, 2022, January 19, 2023, February 22, 2023 and March 20, 2023, and a loan of $150 thousand on May 19, 2023, making the aggregate balance of the November 2022 Note to be $3.469 million

On December 15, 2022, the AD Pharma Agreement was further amended to to extend the FDA's acceptance date of a NDA for LTX-03 to June 30, 2023. On June 15, 2023, the AD Pharma Agreement was then again further amended to extend the FDA's acceptance date of a NDA for LTX-03 to November 30, 2023 ("NDA Acceptance Date") ("Amended Agreement"). AD Pharma may terminate the Amended Agreement at any time. Additionally, if the NDA for LTX-03 is not accepted by the FDA by the NDA Acceptance Date, AD Pharma may terminate the Amended Agreement and take ownership of the intellectual property rights of LTX-03 from the Company. Should AD Pharma choose not to exercise this option to terminate the Amended Agreement and the NDA for LTX-03 is subsequently accepted by the FDA, such option to terminate the Amended Agreement expires.

OTC Markets Group Stock Listing Requirements

Effective May 17, 2022 our common stock was downgraded from the OTCQB Market to the OTC Pink Market of the OTC Markets Group because we did not file our annual report on Form 10-K for 2021 within the applicable grace periods provided by the OTC Markets Group. We have also not filed our quarterly report on Form 10-Q for the first quarter ended March 31, 2022. Effective July 21, 2022, our common stock was downgraded from the OTC Pink Market to the OTC Expert Market of the OTC Markets Group because the Company was delinquent in making current information publicly available as required by SEC Rule 15c2-11. The Company did not file its annual report on Form 10-K for 2021 and its quarterly report on Form 10-Q for the first quarter ended March 31, 2022 within the applicable grace periods provided by the OTC Markets Group. The Company has failed to file its quarterly reports on Form 10-Q for each of the quarterly periods ending June 30, 2022, September 30, 2022, and March 31, 2023 as well as its annual report on Form 10-K for 2022.

Because of the restrictions imposed on securities quoted on the Expert Market, most investors will not be able to publicly sell their shares. Additionally, investors will not have access to bid and ask prices or other information, including trading volume. As such, Expert Market shares are illiquid.

ERC Refund

In May 2023, the Company received refunds aggregating approximately $235 thousand under the employee retention credit ("ERC") under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), as modified in December 2020 by the Taxpayer Certainty and Disaster Tax Relief Act of 2020 ("Relief Act"). The refunds were used to fund company operations.

Exhibit 10.54

AMENDMENT #2
TO LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This AMENDMENT (the "**Amendment #2**") to the LICENSE, DEVELOPMENT and COMMERCIALIZATION AGREEMENT (the "**Agreement**") dated June 28, 2019 between Acura Pharmaceuticals, Inc. ("**Acura**"), a New York corporation, having a place of business at 616 N. North Court, Suite 120, Palatine, IL 60067, and Abuse Deterrent Pharma, LLC ("**AD Pharma**"), a Kentucky partnership having a place of business at with offices at 333 E. Main Street, Suite 220, Louisville, Kentucky 40202, is made as of June 17, 2021.

RECITALS

WHEREAS, Acura and AD Pharma are parties to the Agreement as amended on October 16, 2020 ("**Amendment #1**"); and;

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

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

ARTICLE 1
AMENDMENTS TO AGREEMENT

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

3. By February 28, 2022, Acura must gain filing acceptance by the FDA of a Regulatory Approval Application for the Product.

For the avoidance of doubt, Section 3.1.1 of the Agreement as amended by Amendment #1, will not change and AD Pharma's Maximum Pre-Regulatory Application Submission Payment will remain at Six Million Five Hundred Thousand Dollars ($6,500,000) by monthly payments as set forth therein through July 2021.

1.2 Section 3.1.4 is hereby amended by deleting the last sentence of such Section.

ARTICLE 2
MISCELLANCEOUS

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

2.2 **Amendments**. Except as expressly amended by this Amendment #2, the Agreement and Amendment #1 shall remain unmodified and in full force and effect.

2.3 **Entire Agreement**. This Amendment #2, the Agreement, the Schedules attached to the Agreement and Amendment #1 constitute the entire agreement of the Parties with respect to the subject matter hereof and supersede all prior understandings and writings between the Parties relating thereto.

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

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

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

ACURA PHARMACEUTICALS, INC.

By: /s/ Robert B. Jones, 6/12/2021
Name: Robert B. Jones
Title: CEO and President

Abuse Deterrent Pharma, LLC

By: /s/ John L. Schutte, 7/22/2021
Name: John Schutte
Title: Managing Partner

Exhibit 10.58

AMENDMENT #3
TO LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This AMENDMENT (the "**Amendment #3**") to the LICENSE, DEVELOPMENT and COMMERCIALIZATION AGREEMENT (the "**Agreement**") dated June 28, 2019 between Acura Pharmaceuticals, Inc. ("**Acura**"), a New York corporation, having a place of business at 616 N. North Court, Suite 120, Palatine, IL 60067, and Abuse Deterrent Pharma, LLC ("**AD Pharma**"), a Kentucky limited liability company, having a place of business at 333 E. Main Street, Suite 220, Louisville, Kentucky 40202, is made as of February 28, 2022.

RECITALS

WHEREAS, Acura and AD Pharma are parties to the Agreement as amended on October 16, 2020 ("**Amendment #1**") and June 17, 2021 ("**Amendment #2**"); and;

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

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

ARTICLE 1
AMENDMENTS TO AGREEMENT

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

3. By December 31, 2022, Acura must gain filing acceptance by the FDA of a Regulatory Approval Application for the Product.

ARTICLE 2
MISCELLANEOUS

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

2.2 **Amendments**. Except as expressly amended by this Amendment #3, the Agreement, Amendment #1 and Amendment #2 shall remain unmodified and in full force and effect.

2.3 **Entire Agreement.** This Amendment #3, the Agreement, the Schedules attached to the Agreement, Amendment #1 and Amendment #2 constitute the entire agreement of the Parties with respect to the subject matter hereof and supersede all prior understandings and writings between the Parties relating thereto.

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

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

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

ACURA PHARMACEUTICALS, INC.

By: /s/ Robert B. Jones
Name: Robert B. Jones
Title: CEO & President

ABUSE DETERRENT PHARMA, LLC

By: /s/ John Schutte
Name: John Schutte
Title: Managing Partner

Exhibit 10.68

AMENDED, CONSOLIDATED AND RESTATED
SECURED PROMISSORY NOTE

November 10, 2022

FOR VALUE RECEIVED, ACURA PHARMACEUTICALS, INC., a New York corporation having its principal place of business at 616 N. North Court, Suite 120, Palatine, Illinois, as maker (the "**Company**"), hereby unconditionally promises to pay to the order of Abuse Deterrent Pharma, LLC, a Kentucky limited liability company having its principal place of business at 2604 River Green Circle, Louisville, Kentucky 40206, or its assigns (the "**Noteholder**"), the aggregate principal sum of **TWO MILLION THREE HUNDRED NINETEEN THOUSAND TWO HUNDRED SEVENTY-NINE DOLLARS** (**$2,319,279**), in lawful money of the United States of America, together with interest thereon, as provided in this Promissory Note (this "**Note**").

This Note amends, consolidates, restates and replaces the promissory notes made by the Company in the aggregate original principal amount of One Million Nine Hundred Twenty-Five Thousand Dollars ($1,925,000), as set forth on Exhibit A attached hereto, and assigned to the Noteholder (collectively, the "**Prior Notes**"). This Note is not intended to be, and shall not be construed as, a novation of the indebtedness evidenced by the Prior Notes. The principal amount of this Note includes the interest previously accrued on the Prior Notes as of the date of the issuance of this Note. This Note shall be entitled to the benefits (in the same priority) of, *inter alia*, any security at any time granted and pledged by the Company to the Noteholder in conjunction with the original execution and delivery of the Prior Notes or predecessor notes or by the Company or any other person at any time thereafter. This Note also evidences an additional loan from the Noteholder to the Company made on the date hereof in the original principal amount of Three Hundred Fifty Thousand Dollars ($350,000).

1. Definitions. Unless defined elsewhere in this Note, capitalized terms used herein shall have the meanings set forth in this Section 1.

"**Contingent Obligation**" means any direct or indirect liability, contingent or not, of the Company for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by the Company, or for which the Company is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of the Company; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect the Company against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Company in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Indebtedness**" means (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

"**Permitted Indebtedness**" means (a) the Company's Indebtedness to the Noteholder under this Note; (b) Subordinated Debt; (c) Indebtedness existing on the date hereof and disclosed on the Perfection Certificate(s) delivered in accordance with the Security Agreement; (d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business; (e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by the Company to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Two Hundred Fifty Thousand Dollars ($250,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made); (f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of the Company's business; and (g) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (e) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon the Company.

"**Person**" means any individual, corporation, limited liability company, trust, joint venture, association, company, limited or general partnership, unincorporated organization, governmental authority or other entity.

"**Subordinated Debt**" is Indebtedness incurred by the Company subordinated to all Indebtedness of the Company to the Noteholder (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to the Noteholder, entered into between the Noteholder, the Company, and the other creditor), on terms acceptable to the Noteholder.

2. Maturity Date; Prepayment.

2.1 Maturity Date. The Company agrees to pay the principal sum of this Note and interest on the unpaid principal sum of this Note on December 31, 2023 (the "**Maturity Date**"). Time shall be of the essence with respect to all of the Company's obligations under this Note.

2.2 Prepayment. This Note may not be prepaid by the Company (either in whole or in part) without the prior written consent of the Noteholder in its sole discretion.

2.3 Payment Mechanics. All payments of interest and principal shall be made in lawful money of the United States of America on the date on which such payment is due by wire transfer of immediately available funds to the Noteholder's account at a bank specified by the Noteholder in writing. All payments on this Note shall be applied first to the payment of any expenses or charges payable hereunder, and next to accrued interest, and then to the principal

balance hereof, or in such other order as the Noteholder may elect in its sole discretion.

2.4 Rescission. If at any time any payment made against this Note (whether payment is made by the Company, any guarantor, or any other Person) is rescinded or must otherwise be restored or returned upon the insolvency, bankruptcy, or reorganization of the Company or such other Person who made the payment, or otherwise, or if any check or other written order to pay any amount to the Noteholder is dishonored or returned as unpaid by the bank against whom it is drawn, the Company's obligation to make such payment shall be reinstated as though such payment had not been made.

2.5 Election to Apply to Alprazolam Product and Oxycodone Product. In the event the Noteholder elects to add the Alprazolam Product or Oxycodone Product, or both, as an additional licensed product under the License, Development and Commercialization Agreement dated as of June 28, 2019, as amended, by and between the Company and the Noteholder (the "**License Agreement**"), the Noteholder shall have the right, in its sole discretion, upon written notice to the Company at any time, to have One Million Dollars ($1,000,000) of the amount payable hereunder be applied, in lieu of payment to the Noteholder, to amounts payable by the Noteholder in respect of each such license (i.e. a total of Two Million Dollars ($2,000,000) in the event the Noteholder elects to add both the Alprazolam Product and Oxycodone Product as additional licensed products).

3. Interest. The outstanding principal amount of this Note shall bear interest at a fixed rate equal to five and one-quarter percent (5.25%) per annum and shall accrue and be payable at the Maturity Date. If any amount payable hereunder is not paid when due (without regard to any applicable grace periods), whether at stated maturity, by acceleration, or otherwise, including upon an Event of Default, such overdue amount shall bear interest at a rate equal to seven and one-half percent (7.5%) per annum from the date of such non-payment until such amount is paid in full. All computations of interest shall be made on the basis of 365 or 366 days, as the case may be, and the actual number of days elapsed.

4. Limitation. Notwithstanding anything to the contrary contained herein, all agreements and communications between the Company and Noteholder are hereby and shall automatically be limited so that, after taking into account all amounts deemed interest, the interest contracted for, charged or received by Noteholder shall never exceed the maximum legal rate of interest permitted by law.

5. Events of Default. The occurrence of any of the following shall constitute an "**Event of Default**" hereunder:

(a) The Company fails to pay any principal or interest or any other amount payable hereunder when due and such failure continues for 5 days;

(b) The Company fails to perform any other covenant or obligation set forth in this Note or the Security Agreement;

(c) The License Agreement is terminated by the Noteholder pursuant to Section 3.1.3

or 3.1.4 thereof;

(d) The Company fails to pay when due any of its indebtedness for borrowed money (other than indebtedness under this Note) in a principal amount exceeding $100,000, or any interest or premium thereon, when due and such failure continues after the applicable grace period, if any, specified in the agreement or instrument relating to such indebtedness;

(e) The Company commences any voluntary case, proceeding, or other action (i) under any existing or future law relating to bankruptcy, insolvency, reorganization, or other relief of debtors, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it as bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition, or other relief with respect to it or its debts, or (ii) seeking appointment of a receiver, trustee, custodian, conservator, or other similar official for it or for all or any substantial part of its assets, or the Company makes a general assignment for the benefit of its creditors;

(f) There is commenced against the Company any involuntary case, proceeding, or other action of a nature referred to in (e) above which (i) results in the entry of an order for relief or any such adjudication or appointment or (ii) remains undismissed, undischarged, or unbonded for a period of 30 days;

(g) There is commenced against the Company any case, proceeding, or other action seeking issuance of a warrant of attachment, execution, or similar process against all or any substantial part of its assets which results in the entry of an order for any such relief which has not been vacated, discharged, or stayed or bonded pending appeal within 30 days from the entry thereof;

(h) The Company takes any action in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth in (e), (f) or (g) above;

(i) The Company is generally not, or is unable to, or admits in writing its inability to, pay its debts as they become due; or

(j) A final non-appealable judgment or decree for money in excess of $100,000 (to the extent not paid or covered by insurance) is entered against the Company and such judgment or decree has not been vacated, discharged, or stayed or bonded pending appeal within 30 days from the entry thereof.

6. Remedies. Upon the occurrence of an Event of Default and at any time thereafter during the continuance of such Event of Default, the Noteholder may at its option, by written notice to the Company (a) declare the entire principal amount of this Note, together with all accrued interest thereon and all other amounts payable under this Note, immediately due and payable and/or (b) exercise any or all of its rights, powers, or remedies under applicable law; *provided, however* that, if an Event of Default described in any of (e) through (i) above shall occur, the principal of and accrued interest on this Note shall become immediately due and payable without any notice, declaration, or other act on the part of the Noteholder.

7. Negative Covenants. The Company shall not do any of the following without the prior written consent of the Noteholder in its sole discretion:

(a) create, or authorize the creation of, or issue or obligate itself to issue any securities (other than the issuance of stock options, restricted stock units or other equity incentive grants of the Company pursuant to the terms of stock option plans, restricted stock unit plans or similar plans, provided such issuances do not exceed, in the aggregate, 1,250,000 shares during the period of eighteen (18) months commencing on the date of this Note);

(b) create, incur, assume, or be liable for any Indebtedness, other than Permitted Indebtedness; or

(c) issue any press release or make any public statement other than as required to satisfy its statutory or regulatory filing and reporting obligations or to comply with any other legal or regulatory requirements to which the Company is subject, provided that the Company takes reasonable steps to minimize the extent of any such disclosure.

8. Transfer. This Note may be assigned, transferred, or negotiated by the Noteholder to any individual or entity, at any time, without notice to or the consent of the Company. The Company shall not have the right to assign, delegate or transfer its rights or obligations under this Note without the prior written consent of Noteholder, and any attempted assignment, delegation or transfer without such consent shall be null and void. This Note shall inure to the benefit of and be binding upon the parties hereto and their permitted assigns.

9. Miscellaneous.

9.1 Governing Law; Jurisdiction. This Note, and any claim, controversy, dispute or cause of action (whether in contract or tort or otherwise) based upon, arising out of or relating to this Note and the transactions contemplated hereby and thereby shall be governed by the laws of the Commonwealth of Kentucky, without giving effect to conflict of law provisions. The Company hereby consents to the jurisdiction of any state or federal court located within the County of Jefferson, Commonwealth of Kentucky, and irrevocably agrees that, subject to the Noteholder's sole and absolute election, any case or proceeding relating to Title 11 of the United States Code and any actions relating to the indebtedness evidenced hereby shall be litigated in such courts, and the Company waives any objection that it may have based on improper venue or forum non conveniens to the conduct of any proceeding in any such court. Nothing contained in this paragraph shall affect the right of the Noteholder to bring any action or proceeding against the Company or its property in the courts of any other jurisdiction.

9.2 **Waiver of Jury Trial**. **THE COMPANY ACKNOWLEDGES THAT THE TIME AND EXPENSE REQUIRED FOR TRIAL BY JURY EXCEED THE TIME AND EXPENSE REQUIRED FOR A BENCH TRIAL AND HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, AND AFTER HAVING CONSULTED (OR HAVING HAD AMPLE OPPORTUNITY TO CONSULT) ITS LEGAL COUNSEL**

CONCERNING THE CONSEQUENCES OF SUCH WAIVER, ANY RIGHT IT MAY HAVE TO TRIAL BY JURY IN ANY ACTION OR OTHER PROCEEDING BROUGHT TO ENFORCE OR COLLECT OR OTHERWISE IN CONNECTION WITH THIS NOTE OR ANY RELATED DOCUMENTS.

9.3 Waiver of Notice. The Company hereby waives presentment, demand for payment, protest, notice of dishonor, notice of protest or nonpayment, notice of acceleration of maturity, and diligence in connection with the enforcement of this Note or the taking of any action to collect sums owing hereunder.

9.4 Amendments and Waivers. This Note may not be modified, amended, waived, extended, changed, discharged or terminated orally or by any act or failure to act on the part of the Company or Noteholder, but only by an agreement in writing signed by both Noteholder and the Company. Any waiver of the terms hereof shall be effective only in the specific instance and for the specific purpose given.

9.5 No Waiver; Cumulative Remedies. No failure to exercise and no delay in exercising on the part of the Noteholder, of any right, remedy, power or privilege hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege. The rights, remedies, powers and privileges herein provided are cumulative and not exclusive of any rights, remedies, powers and privileges provided by law.

9.6 Severability. If any term or provision of this Note is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Note or invalidate or render unenforceable such term or provision in any other jurisdiction.

9.7 Security. This Note is secured by and entitled to the benefits of that certain Security Agreement dated as of the date hereof by and between the Company and the Noteholder, as the same may be amended or restated and including any successor agreement (the "**Security Agreement**").

[End of text; signature page follows.]

IN WITNESS WHEREOF, the Company has executed this Amended, Consolidated and Restated Secured Promissory Note as of November 10, 2022.

ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens
Name: Peter A. Clemens
Title: Senior Vice President & CFO

Exhibit A

Date	Loan #	Principal	Aggregated Principal
12/21/2021	1	$ 150,000	$ 150,000
1/3/2022	2	$ 125,000	$ 275,000
1/31/2022	3	$ 200,000	$ 475,000
3/31/2022	4	$ 150,000	$ 625,000
4/29/2022	5	$ 150,000	$ 775,000
5/20/2022	6	$ 100,000	$ 875,000
6/10/2022	7	$ 100,000	$ 975,000
7/6/2022	8	$ 150,000	$ 1,125,000
7/18/2022	9	$ 150,000	$ 1,275,000
8/23/2022	10	$ 250,000	$ 1,525,000
9/20/2022	11	$ 150,000	$ 1,675,000
10/13/2022	12	$ 250,000	$ 1,925,000
		$ 1,925,000	

Exhibit 10.70

Amended Loan Schedule to Secured Promissory Note dated November 10, 2022 between Acura Pharmaceuticals, Inc and Abuse Deterrent Pharma, LLC

	Date	Principal	Aggregated Principal
Original Secured Promissory Note	11/10/2022	$ 2,319,279	$ 2,319,279
Additional loans to be included:			
Loan #1	12/22/2022	$ 250,000	$ 2,569,279
Loan #2	1/19/2023	$ 250,000	$ 2,819,279
Loan #3	2/22/2023	$ 250,000	$ 3,069,279
Loan #4	3/20/2023	$ 250,000	$ 3,319,279
Loan #5	5/19/2023	$ 150,000	$ 3,469,279

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-8 (Nos. 333-256677, 333-221645, 333-213017, 333-195612, and 333-151620) of Acura Pharmaceuticals, Inc. of our report dated June 30, 2023, relating to the consolidated financial statements which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
Chicago, Illinois
June 30, 2023

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: June 30, 2023

/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: June 30, 2023

/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, 2021 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.

June 30, 2023

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, 2021 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.

June 30, 2023

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