ACURA PHARMACEUTICALS, INC
Form 10-K
June 07, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2017**

Or

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 1-10113

ACURA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**11-0853640**
(State or other jurisdiction of Incorporation or organization)	(I.R.S. Employer Identification No.)
616 N. North Court, Suite 120, Palatine, Illinois	**60067**
(Address of principal administrative office)	(Zip code)

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

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

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

Common Stock, par value $0.01 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ¨ No x

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 x

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 x

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

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

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

¨ Large Accelerated Filer ¨ Accelerated Filer
¨ Non-Accelerated Filer x Smaller Reporting Company.

¨ Emerging Growth Company

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

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

Based on the last sale price on the OTCQB Market of the Common Stock of $0.56 on June 30, 2017 (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 $4.2 million.

As of June 6, 2018, the registrant had 21,033,528 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, 2017

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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 fund or obtain funding for our continuing operations, including the development of our products utilizing our Limitx and Impede technologies;
- our ability to remain in compliance with our obligations under our term loan with Oxford Finance LLC, or to obtain a waiver from Oxford Finance LLC for our failure to comply with our covenants contained in such term loan agreement;
- the expected results of clinical studies relating to LTX-03 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;
- whether Limitx will retard the release of opioid active ingredients as dose levels increase;
- whether the extent to which products formulated with the Limitx technology deter abuse will be determined sufficient by the FDA to support approval or labelling describing abuse deterrent features;
- whether our Limitx technology can be expanded into extended-release formulations;
- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo® Tablets and our Nexafed® products;
- the pricing and price discounting that may be offered by Egalet for Oxaydo;
- the results of our development of our Limitx Technology;
- our or our licensees' ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of, timing of commercial launch and competitive environment for any of our products;
- expectations regarding potential market share for our products;
- our ability to develop and enter into additional license agreements for our product candidates using our technologies;
- our exposure to product liability and other lawsuits in connection with the commercialization of our products;
- the increasing cost of insurance and the availability of product liability insurance coverage;
- the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties;
- the ability of our patents to protect our products from generic competition and our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation;
- whether the FDA will agree with or accept the results of our studies for our product candidates;
- the ability to fulfill the FDA requirements for approving our product candidates for commercial manufacturing and distribution in the United States, including, without limitation, the adequacy of the results of the laboratory and clinical studies completed to date, the results of laboratory and clinical studies we may complete in the future to support FDA approval of our product candidates and the sufficiency of our development process to meet over-the-counter ("OTC") Monograph standards, as applicable;
- the adequacy of the development program for our product candidates, including whether additional clinical studies will be required to support FDA approval of our product candidates;
- changes in regulatory requirements;
- adverse safety findings relating to our commercialized products or product candidates in development;

- whether the FDA will agree with our analysis of our clinical and laboratory studies;
- whether further studies of our product candidates will be required to support FDA approval;
- whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications and whether we will be able to promote the features of our abuse discouraging technologies; and
- whether Oxaydo or our Aversion and Limitx product candidates will ultimately deter abuse in commercial settings and whether our Nexafed products and Impede technology product candidates will disrupt the processing of pseudoephedrine into methamphetamine.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expe “plans,” “anticipates,” “believes,” “indicates,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in 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 a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Aversion® and Limitx™ Technologies are 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. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, or collectively Egalet, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is currently approved by the U. S. Food and Drug Administration, or FDA, for marketing in the United States in 5mg and 7.5mg strengths. Egalet launched Oxaydo in the United States late in the third quarter of 2015.

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. We have a third pseudoephedrine product in development utilizing our Impede Technology. On March 16, 2017, we and MainPointe Pharmaceuticals, LLC, or MainPointe, entered into a License, Commercialization and Option Agreement, or the MainPointe Agreement, pursuant to which we granted MainPointe an exclusive license to our Impede technology in the U.S. and Canada to commercialize our Nexafed products. The MainPointe Agreement also grants MainPointe the option to expand the licensed territory to the European Union, Japan and South Korea and to add additional pseudoephedrine-containing products utilizing our Impede technology. MainPointe is controlled by John Schutte, who became our largest shareholder pursuant to a private placement completed in July 2017.

On June 28, 2017, Bayer Healthcare LLC, or Bayer, terminated a 2015 License and Development Agreement in which we granted Bayer an exclusive worldwide license to our Impede technology for use in an undisclosed methamphetamine resistant PSE containing product. As a result of the termination, MainPointe has the option to license our Impede Technology with respect to such product in the United States and Canada upon payment of a fee. MainPointe has not yet exercised this option.

Our third abuse deterrent technology, Limitx, is designed to retard the release of active drug ingredients when too many tablets are accidently 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, 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, the results for which were announced in January 2018, 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 while 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. Study AP-LTX-300, or Study 300, was inconclusive in its results due to observed issues with drug release from over-encapsulated test product. We submitted an Investigational New Drug Application, or 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. The FDA has designated the development program for LTX-04 as Fast Track, which is designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. However, we intend to advance LTX-03, which combines the hydrocodone micro-particles, acetaminophen and buffer ingredients into a single tablet, as our lead Limitx product candidate due to its larger market size and its known prevalence of oral excessive tablet abuse and we have voluntarily placed the IND for LTX-04 on inactive status.

According to the 2017 CDC Drug Surveillance Report, opioid analgesics are one of the largest prescription drug markets in the United States with 214 million prescriptions dispensed in 2016. Prescription opioids are also the most widely abused drugs with 12 million people abusing or misusing these products annually. Oxaydo will compete in the immediate-release opioid product segment. Because immediate-release 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 immediate-release opioid product segment were approximately 194 million prescriptions, of which approximately 95% was attributable to generic products. Immediate-release oxycodone tablets represent approximately 30 million of these prescriptions or almost 1.7 billion tablets. The FDA approved label for our Oxaydo product describes the unique, and we believe promotable, abuse deterrent features of our product which we believe makes prescribing our product attractive to some healthcare providers.

In 2014, the United States retail market for over-the-counter market, or OTC, cold and allergy products containing the pseudoephedrine oral nasal decongestant was approximately $0.7 billion. In 2014, the DEA reported 9,339 laboratory incidents involving the illegal use of OTC pseudoephedrine products to manufacture the highly addictive drug methamphetamine, or meth. According to the Substance Abuse and Mental Health Services Administration, users of methamphetamine surged in 2016 to 684,000 people up from 440,000 people in 2012. As of March 16, 2017, sales of Nexafed and Nexafed Sinus are covered under the MainPointe Agreement, for which we receive a royalty.

On March 23, 2015, we announced preliminary top line results from our pilot clinical study demonstrating bioequivalence of our Nexafed extended release tablets to Johnson & Johnson’s Sudafed® 12-hour Tablets. In October 2016, we received FDA recommendations on our meth-resistant testing protocols for our Nexafed extended release tablets which utilizes our Impede 2.0 enhanced meth-resistant technology. Our Impede 2.0 Technology has demonstrated, in the direct conversion, or “one-pot”, methamphetamine conversion process performed by an independent pharmaceutical services company, the ability to reduce meth-yields, on average, by 75% compared to Sudafed® Tablets. We can now scale-up our manufacture batch size at a contract manufacturer which will allow 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 a 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 5050(b)(2) NDA submission. The Company intends to upgrade this formulation with its Impede 2.0 technology before determining any advancement in development.

Our objective is to establish, either directly or through third-party licensees, the Nexafed franchise in the United States with multiple product offerings, including both immediate and extended release products utilizing both single and combinations of active ingredients. We aim to make meth-resistant PSE product the standard of care in all U.S. pharmacies. In addition to the MainPointe Agreement, we may license our Impede technology to commercial partners

to extend our internal development resources to develop difficult to formulate products, such as extended-release.

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 goal is to become a leading specialty pharmaceutical company focused on addressing the growing societal problem of pharmaceutical drug abuse by developing a broad portfolio of products with abuse deterrent features and benefits. Specifically, we intend to:

- *Capitalize on our experience and expertise in the research and development of technologies that address medication abuse and misuse*. 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 continue to invest in improvements in these technologies and innovate new technologies, including our Limitx technology, to address medication abuse and misuse.

- *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 in the prescription opioid and OTC cold/allergy markets 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 Egalet 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 for commercialization (and granted MainPointe options to other Impede products), and we are seeking licensing partners for our products in development utilizing our Limitx, Aversion and Impede technologies. While we had developed a small infrastructure to commercialize our OTC products that utilize the Impede Technology, this infrastructure has been discontinued in conjunction with our entering into the MainPointe Agreement.

- *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.

Abuse of Prescription Opioid Products and Development of Abuse Deterrent Formulations

Prescription opioids drugs, such as morphine and oxycodone, have a long history of use for the management of pain. Because they are highly effective, they are one of the largest prescribed drug categories in the U.S. However, a side effect of high doses of opioids is euphoria, or “a high”. For these reasons, opioids are the most misused or abused

prescription drugs in the U.S. Opioids are offered in a variety of dosages including immediate-release tablets (or capsules), extended-release tablets (or capsules), patches and other formats. Abusers will often manipulate or tamper with the formulations to achieve their high, including:

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

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

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

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

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

Abuse deterrent formulations of opioid dosages incorporate physical and/or chemical barriers or functionality in the formulations to prevent or discourage an abuser from inappropriately administering the product. The extent and manner in which any of the features of abuse deterrent opioids may be described in the FDA approved label for our pipeline products will be dependent on the results of and the acceptance by the FDA of our and our licensees' studies for each product.

Development of our Limitx and Aversion (if recommenced) product candidates will require one or more abuse deterrent studies consistent with the FDA 2015 published guidance for industry on the evaluation and labeling of abuse-deterrent opioids (the "2015 Guidance"). These studies may include in vitro laboratory studies to determine, among other things, syringeability of the formulation, extractability of the opioid, and particle size of the crushed product. It is also expected that development will include human abuse liability studies comparing the abuse liability of our product candidates to currently marketed products. Because our products use known active ingredients in approved dosage strengths, the safety and efficacy of the opioid will need to be established by a series of pharmacokinetic studies demonstrating: (a) bioequivalence to an approved reference drug, (b) food effect of our formulations, and (c) dose proportionality of our formulation. A product candidate that does not achieve satisfactory pharmacokinetic results may require a phase III clinical pain 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 products, if approved, to perform an epidemiology study to assess the in-market impact on abuse of our formulation.

Limitx™ Technology

Limitx Technology is intended to address oral ETA or accidental consumption of multiple tablets and provide a margin of safety during accidental over-ingestion of tablets. Limitx is also expected to exhibit barriers to abuse by snorting and injection.

The FDA's 2015 Guidance singles out immediate-release combination products with acetaminophen as being predominately abused by the oral route and that reducing nasal snorting of these products may not be meaningful. The initial Limitx formulation (LTX-04) utilizes hydromorphone as its sole active ingredient. During 2017 we redirected our development focus from LTX-04 to a hydrocodone/APAP product utilizing our Limitx Technology (LTX-03). In August 2015, April 2016, and May 2017 the United States Patent and Trademark Office, or USPTO, issued to us patents 9,101,636, 9,320,796 and 9,662,393, respectively, covering, among other things, our Limitx Technology.

Development of our Limitx Technology was supported by a $300 thousand grant by the National Institute on Drug Abuse of the National Institutes of Health for Phase I development, which entailed the development of an optimized formulation of LTX-04 suitable for commercial manufacture and human testing.

NIDA Disclaimer: Research on LTX-04 was supported by the National Institute On Drug Abuse of the National Institutes of Health under Award Number R44DA037921. The results and content of any such research is solely the responsibility of Acura and does not necessarily represent the official views of the National Institutes of Health.

The LTX-04 development program is also designated as Fast Track by the FDA for its potential to address an unmet medical need but we have voluntarily placed the IND for LTX-04 on inactive status to pursue development of LTX-03.

Limitx Technology Products in Development

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

Limitx Technology Product	**Status**
Immediate-release hydromorphone HCI (LTX-04)	Two Phase I exploratory pharmacokinetic studies completed
	Initial buffer dose ranging study completed October 2017
Immediate-release hydrocodone bitartrate with acetaminophen (LTX-03)	
	Follow on dose ranging study completed in January 2018
Immediate-release oxycodone HCl (LTX-01) & (LTX-02)	Formulation development in process
Immediate-release non-opioid drug (LTX-09)	Formulation development in process

Study 400

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

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

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

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

On December 14, 2016, we announced that we had received advice from the FDA on the continued development of LTX-04 following the FDA's review of summary data from Study 400. The FDA confirmed our intention to reformulate LTX-04 to provide increased drug levels following an intended 1 or 2 tablet dose, noting that a scientific bridge of bioequivalence to the reference product will support a finding of safety and efficacy. The FDA also recommended that we identify studies to measure the clinical impact on abuser behavior and overdose outcome (such

as drug liking and respiratory depression) associated with the reduction in Cmax when three or more LTX-04 tablets were ingested. The FDA's advice also identified longer term studies necessary for submitting a NDA for LTX-04, including in vitro extraction studies, drug interaction studies, additional pharmacokinetic studies assessing the impact of food and beverages, and a category 3 abuse liability study.

Study 401

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

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

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

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

Study 300

Study 300, completed in October 2017, yielded unreliable and inconclusive results due to inconsistent drug release from over-encapsulated test product.

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.

We intend to advance LTX-03 to clinical development for a New Drug Application (NDA). Therefore, we submitted an Investigational New Drug Application, or IND with respect to LTX-03, to the FDA in the first quarter of 2018, which became effective in April 2018. We are also commencing the scale-up of the commercial manufacturing process as to-be-marketed formulations are required for all NDA development work. We may run additional exploratory studies before manufacturing scale-up is complete to further understand the Limitx technology.

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 November 2024. 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 Egalet pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is approved in 5mg and 7.5mg strengths. Egalet launched Oxaydo in the United States late in the third quarter of 2015.

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

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

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

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

Egalet has advised that late in the fourth quarter of 2016 it filed a supplemental NDA for Oxaydo with the FDA to support an abuse-deterrent label claim for the intravenous route of abuse. Egalet reported that it submitted a prior approval supplement to support approval of 10 and 15 mg dosage strengths which was accepted by the FDA on April 18, 2017. On June 20, 2017, Egalet announced that it had received a complete response letter from the FDA in response to this prior approval supplement. Eaglet has advised that the FDA is requesting more information regarding the effect of food on Oxaydo 15mg and the intranasal abuse-deterrent properties of Oxaydo 10mg and 15mg and have publicly stated that it is working to determine next steps to respond to such letter.

Egalet commenced shipping Oxaydo in October 2015 and we are advised that Egalet is actively promoting Oxaydo to targeted opioid prescribing physicians.

Egalet Agreement Covering Oxaydo

On January 7, 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, or Egalet, entered into a Collaboration and License Agreement, or the Egalet 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 Egalet Agreement, we transferred the approved NDA for Oxaydo to Egalet and Egalet is granted an exclusive license under our intellectual property rights for development and commercialization of Oxaydo worldwide, or the Territory, in all strengths, subject to our right to co-promote Oxaydo in the United States.

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

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

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

KemPharm Agreement Covering Opioid Prodrugs

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

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

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

Aversion Technology Development Opioid Products

On April 9, 2015, we announced the indefinite suspension of further development of our Aversion hydrocodone/APAP product candidate, in order to focus our time and available resources on the development of our Limitx technology product candidates. We currently have 6 additional opioids at various stages of formulation development using the Aversion Technology which are not being actively developed.

Abuse of Pseudoephedrine Products

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

Impede 1.0 Technology

Our Impede 1.0 Technology, 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.

Studies sponsored by us at an international, independent laboratory demonstrated our Impede 1.0 Technology prevents the extraction of PSE from tablets for conversion into methamphetamine using what we believe are the two most common extraction methods, each requiring extraction of PSE as an initial step. Laboratory tests conducted on our behalf by an independent Clinical Research Organization, or CRO, using the “one-pot” method demonstrated that our Impede Technology disrupted the direct conversion of PSE from the tablets into methamphetamine. The study compared the amount of pure methamphetamine hydrochloride produced from Nexafed and Johnson & Johnson’s Sudafed® tablets. Using one hundred 30 mg tablets of both products, multiple one-pot tests and a variety of commonly used solvents, the study demonstrated an average of 38% of the maximum 2.7 grams of pure methamphetamine hydrochloride was recovered from Nexafed. Comparatively, approximately twice as much pure methamphetamine hydrochloride was recovered from Sudafed tablets. Both products yielded a substantial amount of additional solids such that the purity of the total powder provided contained approximately 65% methamphetamine hydrochloride.

Impede 2.0 Technology

We have developed a next generation, or Impede 2.0 Technology to improve the meth-resistance of our technology. We have completed one-pot, direct conversion meth testing performed by our CRO on the following commercially available products and on our Nexafed Impede 2.0 extended-release product, with the following results:

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 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. We have completed a project to integrate Impede 2.0 Technology into our commercially available Nexafed 30mg tablet while moving supply to an alternate contract manufacturer. We have completed process validation on this new formulation and we believe MainPointe launched the new formulation into the market in the 3rd quarter of 2017.

Nexafed Products

The Nexafed products currently marketed, 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 and 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. However, as meth-resistant products become pervasive, we believe meth cooks will migrate to other, larger selling, PSE containing products.

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. Prior to the MainPointe Agreement completed in March 2017, we capitalized on this consumer-pharmacist interaction at the point of sale by soliciting distribution to pharmacies and educating and encouraging pharmacists to recommend Nexafed to their customers. Under the terms of the MainPointe Agreement, MainPointe controls the marketing and sale of our Nexafed products.

We launched Nexafed commercially in mid-December 2012 into the United States OTC market for cold and allergy products. Prior to the MainPointe Agreement, we distributed our Nexafed products through several regional and national drug wholesalers for redistribution to pharmacies, which included the three largest U.S. drug wholesalers: McKesson, Cardinal Health and AmerisourceBergen and we also shipped directly to the warehouses of certain pharmacy chains. Prior to the MainPointe Agreement, Nexafed was stocked in approximately 13,900 pharmacies or about approximately 21% of the estimated 65,000 U.S. pharmacy outlets. Initial adoption was primarily in independent pharmacies in predominately rural communities with high meth awareness. Chain pharmacies, with more centralized control of the pharmacy operations, began adopting in mid-2013, including Kroger, Publix, Fruth and Bartells. Some pharmacists actively recommended Nexafed to their customers while some replaced all 30mg PSE products, brand and generic, with Nexafed. Rite Aid, the nation's fourth largest pharmacy operator, began purchasing Nexafed in late 2013. In late 2014, Kmart and Kroger initiated chain-wide stocking of Nexafed.

In February 2015, we began initial shipments of Nexafed Sinus Pressure + Pain. Prior to the MainPointe Agreement, we were marketing this product consistent with our Nexafed marketing efforts to pharmacists concerned with meth abuse of their products. We are not aware of any branded non-prescription product that contains PSE and acetaminophen believing that brands containing these ingredients have either been discontinued or reformulated with phenylephrine. We expect Nexafed Sinus Pressure + Pain to compete primarily against Advil® Cold and Sinus (PSE/ibuprofen) and to a lesser extent Aleve®-D and Sudafed® Pressure + Pain which are extended-release products.

Nexafed and Nexafed Sinus Pressure + Pain products are marketed under FDA's regulations applicable to OTC Monograph products. Nexafed and Nexafed Sinus Pressure + Pain tablets are offered in 24-count blister packaged cartons.

MainPointe Agreement covering Nexafed Products

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

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

MainPointe has the option to expand the licensed territory beyond the United States and Canada to the European Union (and the United Kingdom), Japan and South Korea for payments of $1.0 million, $500 thousand and $250 thousand, respectively. In addition, MainPointe has the option to add to the MainPointe Agreement certain additional products, or Option Products, containing PSE and utilizing the Impede technology for a fee of $500 thousand per product (for all product strengths), including the product candidate Loratadine with pseudoephedrine (following termination of the Bayer Agreement). 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.

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.

Impede Technology Products in Development

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

Impede Technology Product	**Status**
Nexafed 30mg with Impede 2.0 Technology	Manufacturing validation complete. We believe MainPointe launched commercial shipments in third quarter of 2017
Immediate-release pseudoephedrine HCl in combination with other cold and allergy active ingredients	Nexafed Sinus Pressure + Pain launched and licensed to MainPointe
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	Final formulation development in process

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 intends to upgrade this formulation with its Impede 2.0 technology before determining any advancement in development.

Our objective is to establish, either directly or through third-party licensees, the Nexafed franchise in the United States with multiple product offerings, including both immediate and extended release products utilizing both single and combinations of active ingredients. We aim to make meth-resistant PSE product the standard of care in all U.S. pharmacies. In addition to the MainPointe Agreement, we may license our Impede technology to commercial partners to extend our internal development resources to develop difficult to formulate products, such as extended-release.

Bayer Agreement

On June 15, 2015, we and Bayer entered into a License and Development Agreement, or the Bayer Agreement, pursuant to which we granted Bayer an exclusive worldwide license to our Impede® Technology for use in an undisclosed methamphetamine resistant pseudoephedrine-containing product and providing for the joint development of such product using our Impede Technology for the U.S. market. We received reimbursement of certain our development expenses, and were entitled to success-based development and regulatory milestone payments, and low mid-single digit royalties on the net sales of the developed product. On June 28, 2017, we received Bayer's written notice terminating the Bayer Agreement. Bayer exercised its convenience termination right prior to the completion of our development obligations under the Bayer Agreement, which we believe is as a result of Bayer's de-prioritization of development of the methamphetamine resistant PSE-containing product contemplated in the Agreement. As a result of the termination, MainPointe has the option to license such product in the U.S. and Canada upon payment to us of $500 thousand (additional amounts would be due for expansion of the territory – See "–MainPointe Agreement covering Nexafed Products", above), together with royalty of 7.5% of net sales of such product, under the MainPointe Agreement.

U.S. Market Opportunity for Impede PSE Products

PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy products. PSE is sold in products as the only active ingredient in both immediate and extended-release products. In addition, PSE is combined with other cold, sinus and allergy ingredients such as pain relievers, cough suppressants and antihistamines. PSE also competes against phenylephrine, an alternate nasal decongestant available in non-prescription products. In 2014, a data service reported approximately $0.7 billion in retail sales of non-prescription products containing PSE. The top retail selling PSE OTC cold/allergy products in 2014 were:

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

Sudafed 12 Hour	J&J	PSE[2]	$ 82.3
Sudafed 30mg	J&J	PSE	$ 70.4

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

[2] Extended release PSE formulations

The 2014 market for 30mg PSE tablets, including store brands was approximately 470 million tablets or 19 million boxes of 24 tablets. Prior to the MainPointe Agreement, we priced Nexafed at $4.39 for a box of 24 tablets and Nexafed Sinus Pressure + Pain at $7.95 for a box of 24 tablets. MainPointe controls the price of Nexafed and Nexafed Sinus under the terms of the MainPointe Agreement.

The market for cold, sinus and allergy products is highly competitive and many products have strong consumer brand recognition and, in some cases, prescription drug heritage. Category leading brands are often supported by national mass marketing and promotional efforts. Consumers often have a choice to purchase a less expensive store brand. Store brands contain the same active ingredients as the more popular national brands but are not supported by large marketing campaigns and are offered at a lower price. Non-prescription products are typically distributed through retail outlets including drug store chains, food store chains, independent pharmacies and mass merchandisers. The distribution outlets for PSE products are highly consolidated. According to Chain Drug Review, the top 50 drug, food and mass merchandising chains operate approximately 40,000 pharmacies in the U.S., of which 58% are operated by the four largest chains. Stocking decisions and pharmacists recommendations for these chain pharmacies are often centralized at the corporate headquarters.

Product Labeling for Impede Technology Products

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

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

U.S. Market Opportunity for Opioid Analgesic Products

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

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

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

compared to ER opioid products, we have initially focused on developing IR opioid products utilizing our Aversion and Limitx Technologies. A summary of the IR opioid product prescription data for 2016 is provided below:

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

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

2 IMS Health, 2016

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

Product Labeling for Abuse-Deterrent Opioid Products

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

We or our licensee may seek to include descriptions of studies that characterize the abuse-deterrent properties in the label for our Aversion and Limitx Technology products in development. Although the FDA approved label for Oxaydo contains limitations on exposing Oxaydo tablets to water and other solvents and administration through feeding tubes, the FDA approved Oxaydo label does not contain a description of the I.V. injection studies we performed to characterize the abuse deterrent properties of Oxaydo. Egalet has committed to the FDA to undertake epidemiological studies to assess the actual consequences of abuse of Oxaydo in the market. Under the terms of the Egalet Agreement, we share a minority portion of the fees and expenses relating to such FDA required

epidemiological studies, provided Egalet complies with the sections of the agreement relating thereto. The extent to which a description of the abuse-deterrent properties or results of epidemiological or other studies will be added to or included in the FDA approved product label for our products in development will be the subject of our discussions with the FDA as part of the NDA review process, even after having obtained approval of Oxaydo. Further, because the FDA closely regulates promotional materials, even if FDA initially approves labeling that includes a description of the abuse deterrent 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.

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
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

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
7,476,402 (US)	Pharmaceutical compositions of certain combinations of kappa and mu opioid receptor agonists and other ingredients intended to deter opioid analgesic product misuse and abuse	Jan. 2009	Nov. 2023
8,822,489 (US)	Pharmaceutical compositions of certain abuse deterrent products that contain polymers, surfactant and polysorb 80	Jul. 2014	Nov. 2023
2,004,294,953 (AUS)	Abuse deterrent pharmaceuticals	Apr. 2010	Nov. 2024
2,010,200,979 (AUS)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,547,334 (CAN)	Abuse deterrent pharmaceuticals	Aug. 2010	Nov. 2024
2,647,360 (CAN)	Abuse deterrent pharmaceuticals	May 2012	Apr. 2027
175,863 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
221,018 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
1694260 (EUR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024

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

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
8,901,113 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Dec. 2014	Feb. 2032
9,757,466 (US)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Sep. 2017	Feb. 2032
2010300641 (AUS)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sep. 2030
2,775,890 (CAN)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jun. 2016	Sep. 2030
2,488,029 (EUR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Mar. 2016	Sep. 2030
218533 (ISR)	Pharmaceutical compositions suitable for reducing the chemical conversion of precursor compounds	Jan. 2016	Sep. 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 Egalet Agreement, the KemPharm Agreement, and the MainPointe 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.

In 2012 and 2013, we received Paragraph IV Certification Notices from five generic sponsors of ANDAs for a generic drug listing our Oxaydo product as the reference listed drug. The Paragraph IV Notices referred to our 920, 726 and 439 Patents, which cover our Aversion® Technology and our Oxaydo product. We filed suit against each of such generic sponsors, Watson Laboratories, Inc., Par Pharmaceutical, Inc., Impax Laboratories, Inc., Sandoz Inc. and Ranbaxy Inc., in the United States District Court for the District of Delaware alleging infringement of our 726 Patent listed in the FDA's Orange Book. Our litigation against Watson Laboratories was dismissed by us following Watson Laboratories' change of its Paragraph IV Certification to a Paragraph III Certification, indicating it would not launch its generic product until the expiry of our applicable Patents. Our litigation against each of the remaining generic sponsors was settled during the period October 2013 through May 2014 on an individual basis, upon mutual agreement between us and such generic sponsors. None of such settlements impacted the validity or enforceability of our Patents. See "Item 1A. Risk Factors – Generic manufacturers are using litigation and regulatory means to seek

approval for generic versions of Oxaydo, which could cause Egalet's sales to suffer and adversely impact our royalty revenue" for a discussion of the settlements and license grants relating to such patent litigation. Notwithstanding the settlement of these prior infringement actions, it is possible that other generic manufacturers may also seek to launch a generic version of Oxaydo and challenge our patents. Any determination in such infringement actions that our patents covering our Aversion Technology and Oxaydo are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents could have a material adverse effect on our operations and financial condition.

In April, 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc., or collectively Purdue, commenced a patent infringement lawsuit against us and our Oxaydo product licensee Egalet in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's U.S. Patent No. 8,389,007, or the 007 Patent. In April 2016, Purdue commenced a second patent infringement lawsuit against us and Egalet in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's newly issued U.S. Patent No. 9,308,171, or the 171 Patent. The actions regarding the 007 Patent and the 171 Patent are collectively referred to as the "Actions". On April 6, 2016, we filed a petition for Inter Parties Review, or IPR Review, with the USPTO seeking to invalidate Purdue's 007 Patent.

On May 20, 2016, we, Purdue and Egalet entered into a settlement agreement to settle the Actions and the IPR Review. Under the Settlement Agreement 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. See the discussion under "Item 3. Legal Proceedings" below for a summary of the settlement agreement with Purdue. The Settlement Agreement specifically excludes our patents related to our Impede and Limitx technologies from the scope of our patents subject to the Settlement Agreement.

Reference is made to the Risk Factors contained in this Report 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. Egalet is responsible for commercial manufacture of Oxaydo under the Egalet Agreement. We expect that future opioid product candidates developed and licensed by us will be commercially manufactured by our licensees or other qualified third party contract manufacturers.

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

Competition

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

We believe potential competitors may be developing opioid abuse deterrent technologies and products. Such potential competitors include, but may not be limited to, Pain Therapeutics, Pfizer Inc., Purdue Pharma, Atlantic Pharmaceuticals, Egalet Corporation, KemPharm, Shionogi, Nektar Therapeutics, Signature Therapeutics, QRx Pharma, Tris Pharma, Pisgah Labs, Teva Pharmaceuticals, Sun Pharmaceuticals, Ensysce Biopharma, Inspirion Delivery Sciences and Collegium Pharmaceuticals. Egalet, our partner for Oxaydo, has developed and is marketing at least one other analgesic product and is developing other analgesic products, all of which compete for development and commercialization resources for Oxaydo, which may adversely impact the sales of Oxaydo.

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

We are also aware that some large pharmaceutical companies in the past have sought to develop PSE technologies or products that resist conversion into methamphetamine.

In addition to our license agreement with MainPointe, we may consider licensing our Impede Technology or 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). 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. Accordingly, manufacturers must continue to expend time, money and effort in all applicable areas relating to quality assurance and regulatory compliance, including production and quality control to comply with cGMPs. Failure to so comply risks delays in approval of drug products and possible FDA enforcement actions, such as an injunction against shipment of products, the seizure of non-complying products, criminal prosecution and/or any of the other possible consequences described above. We are subject to periodic inspection by the FDA and DEA, which inspections may or may not be announced in advance.

The FDA Drug Approval Process

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

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

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

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

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

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

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

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

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 September 25, 2017, for the 2018 fiscal year, the user fee for an application fee requiring clinical data, such as an NDA is $2,421,495. 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 2018 such fee is $304,162 per product strength), but applicants may not be assessed more than five prescription drug program fees for a fiscal year, for prescription drugs identified in a single application. For example, an applicant that has 10 drug products identified in an approved NDA for 10 different strengths of tablet dosage form products is eligible for an assessment for a maximum of 5 program fees. PDUFA VI also eliminated fees for drug application supplements and, establishment fees.

The FDA requires drug manufacturers to establish and maintain quality control procedures for manufacturing, processing and holding drugs and investigational products, and products must be manufactured in accordance with defined specifications. Before approving an NDA, the FDA usually will inspect the facility(ies) at which the active

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

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

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

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

In addition, we, our suppliers and our licensees are required to comply with extensive FDA requirements both before and after approval. For example, we or our licensees are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning the advertising and promotion of our products, which, as discussed above, may significantly affect the extent to which we can include statements or

claims referencing our abuse deterrent technology in product labeling and advertising. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to avoid the product being rendered misbranded and/or adulterated under the FD&C Act as a result of manufacturing problems. In addition, discovery of any material safety issues may result in changes to product labeling or restrictions on a product manufacturer, potentially including removal of the product from the market.

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

FDA's OTC Monograph Process

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

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

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

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

A product marketed pursuant to an OTC Monograph must be registered with the FDA and have a National Drug Code listing which is required for all marketed drug products. After marketing, the FDA may test the product or otherwise investigate the manufacturing and development of the product to ensure compliance with the OTC Monograph.

Should the FDA determine that a product is not marketed in compliance with the OTC Monograph or is advertised outside of its regulations, the FDA may require corrective action up to and including market withdrawal and market recall.

DEA Regulation

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

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

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

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

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

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

Individual states may, and in some cases have, imposed stricter requirements on the sale of drug products containing Listed Chemicals, including requiring a doctor's prescription prior to dispensing such products to a customer.

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

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

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

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

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

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

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

Other Healthcare Laws and Compliance Requirements

We and our licensees that commercialize our products are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral

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

Segment Reporting

We operate in one business segment; the research, development and manufacture of innovative abuse deterrent, orally administered pharmaceutical products.

Environmental Compliance

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

Employees

We have 14 full-time employees, 9 of whom are engaged in the research, development and manufacture of product candidates utilizing our proprietary Aversion, Impede, and Limitx Technologies. The remaining employees are engaged in administrative legal, accounting, finance, marketing, market research, and business development activities. All of our senior management and most of our other employees have had prior experience in pharmaceutical or biotechnology companies. None of our employees are covered by collective bargaining agreements. We believe that our relations with our employees are good.

ITEM 1A. RISK FACTORS

Our future operating results may vary substantially from anticipated results due to a number of factors, many of which are beyond our control. The following discussion highlights some of these factors and the possible impact of these factors on future results of operations. If any of the following factors actually occur, our business, financial condition or results of operations could be materially harmed. In that case, the value of our common stock could decline substantially and you may lose all or part of your investment.

Risks Related to Our Business and Industry

We have a history of operating losses and may not achieve profitability sufficient to generate a positive return on shareholders' investment; our auditors have included in their 2017 audit report an explanatory paragraph as to substantial doubt as to our ability to continue as a going concern.

We had a net loss of $5.7 million, $7.4 million, and $5.0 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of June 6, 2018 we had approximately $0.5 million of cash, cash equivalents, and refundable deposits and expect such amounts will only be sufficient to fund operations into late June 2018. Our auditors have included in their report relating to our 2017 financial statements a "going concern" explanatory paragraph as to substantial doubt of our ability to continue as a going concern that assumes the realization of our assets and the satisfaction of our liabilities and commitments in the normal course of business. Our future profitability will depend on several factors, including:

- our receipt of royalties relating to Egalet's sale of Oxaydo;

- MainPointe's successful marketing and sale of our Nexafed products and other products utilizing our Impede Technology, and market acceptance, increased demand for and sales of our Nexafed products;

- our receipt of milestone payments and royalties relating to our Limitx Technology products in development from future licensees, of which no assurance can be given; and

- the receipt of FDA approval and the successful commercialization by future licensees (if any) of products utilizing our Limitx Technology and our ability to commercialize our Impede Technology without infringing the patents and other intellectual property rights of third parties.

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

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

Even if Egalet succeeds in commercializing Oxaydo, if MainPointe is successful in commercializing our Nexafed products, or if we or a licensee succeed in developing and commercializing one or more of our pipeline Limitx or Impede Technology products, we expect to continue using cash reserves for the foreseeable future. Our expenses may increase in the foreseeable future as a result of continued research and development of our 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 profitability. If Egalet does not successfully commercialize Oxaydo, if MainPointe does not successfully commercialize the Nexafed products, or if we or our licensee (if any) cannot successfully develop, obtain regulatory approval and commercialize our products in development, including our Limitx product candidates, 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 over at least the next several years. Our cash utilization amount is highly dependent on the progress of our product development programs, particularly, the results of our preclinical and clinical studies of our Limitx product candidates and the cost, timing and outcomes of regulatory approval for our Limitx product candidates. In addition, the further development of our ongoing clinical trials will depend on upcoming analysis and results of those studies and our financial resources at that time. As of June 6, 2018 we had approximately $0.5 million of cash, cash equivalents, and refundable deposits and expect such amounts will only be sufficient to fund operations into late June 2018.

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. 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 could materially harm our business, financial condition and results of operations. In the absence of the receipt of additional financing or payments under third-party license or collaborative agreements during June 2018, 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, including: 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 term loan, the lender may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.

In December 2013, we (including our wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc. (“APT”), entered into a loan and security agreement with Oxford Finance LLC, or Oxford, pursuant to which we borrowed $10 million from Oxford. Our loan and security agreement with Oxford was amended on January 7, 2015 in connection with our collaboration and license agreement with Egalet, on October 13, 2016 in connection with our license agreement with KemPharm, on March 16, 2017 in connection with our license agreement with MainPointe, and in the second quarter 2018 in connection with an aggregate loan of $1.0 million extended to us by John Schutte, a principal of MainPointe and our largest shareholder. Under the Oxford loan agreement, as amended, we are subject to a variety of affirmative and negative covenants. These covenants include required financial reporting, providing an unqualified auditor’s opinion together with our annual financial statements within 120 days of the end of our fiscal year (the unqualified audit opinion covenant), limitations on certain dispositions and licensing of assets and limitations on the incurrence of additional debt. To secure our performance of our obligations under this loan and security agreement, we granted Oxford a security interest in all of our assets, and pledged to Oxford the stock of APT. Our failure to comply with the terms of the loan and security agreement, including the unqualified audit opinion covenant, the occurrence of a material adverse change in our business, operations or condition (financial or otherwise) or prospects, if we are not solvent, the material impairment in our prospect of repayment, a material impairment in the perfection or priority of the Oxford’s lien on our assets or the value of Oxford’s collateral, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our loan, coupled with prepayment penalties, an additional interest payment of $795 thousand, potential foreclosure on our assets, and other adverse results.

Pursuant to the amendment to the loan and security agreement with Oxford entered into in connection with the MainPointe license agreement, among other things, Oxford waived compliance with the unqualified audit opinion covenant for our 2016 financial statements, in exchange for which we granted Oxford a lien on our intellectual property. In connection with an $1.0 million loan extended to us by Mr. Schutte in the second quarter of 2018, which is subordinated to our obligations to Oxford under the Loan Agreement, pursuant to the fourth amendment to the Loan Agreement, Oxford granted a similar waiver of compliance with the unqualified audit opinion covenant for our 2017 financial statements and extended the period in which we could deliver financial statements for 2017 to 160 days after

year’s end (instead of 120 days). We are required to make equal monthly installments of principal and accrued interest of $260 thousand sufficient to amortize the term loan through the maturity date of December 1, 2018, when an additional one-time interest payment of $795 thousand (which is not included in the amortization payments), will be due and payable. There is no assurance that we will have sufficient funds to make the requisite amortization and interest payments when due, including at maturity.

If Oxford were to declare an event of default, including as result of our failure to make a required amortization payment, Oxford would have the option, among other things, of accelerating the debt under our loan and security agreement and in such event, and in the event we do not make the additional interest payment of $795 thousand required on the maturity date of December 1, 2018, foreclosing on the Company's assets pledged as collateral for the term loan. Any declaration of an event of default by Oxford, or our failure to pay all principal and interest on or before the maturity date, would significantly harm our business and would likely cause the price of our common stock to decline. In our most recent amendment of the Loan Agreement, Oxford made no commitment not to declare an Event of Default on account of our financial condition and there is no assurance Oxford will not attempt to do so at any time.

We are largely dependent on our successful development of our Limitx product candidates and on the commercial success of Oxaydo.

We anticipate that, for at least fiscal 2018 and 2019, our ability to generate revenues and become profitable will depend in large part on our successful development of our Limitx product candidates and on the commercial success of our only FDA approved product, Oxaydo. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead Limitx product candidate, LTX-03, and other Limitx product candidates in development. We completed our first two Phase I clinical studies for LTX-04, an opioid hydromorphone HCI, in mid-2016. We have changed our primary development focus from immediate-release hydromorphone products (i.e., LTX-04, described above) to immediate-release hydrocodone products (*i.e.*, LTX-03) because hydrocodone bitartrate is more likely to be abused in oral excessive tablet abuse, or ETA, and completed two pharmokinetic studies for LTX-03 during 2017 and the first week of 2018. We are also engaged in formulation development or early preclinical development for other Limitx product candidates. Accordingly, our business is currently substantially dependent on the successful development, clinical testing, regulatory approval and commercialization of our Limitx product candidates, which may never occur. If our clinical studies for LTX-03 are not successful we may determine that further clinical development of LTX-03 or other Limitx product candidates should be discontinued. If clinical studies for these product candidates produce unsuccessful results and we are forced or elect to cease their development, our business and prospects would be substantially harmed. We expect that any revenues from our Limitx product candidates will be derived from upfront payments, milestone payments and royalties under license agreements with one or more pharmaceutical company partners, of which no assurance can be given.

The commercial success of Oxaydo will depend on many factors, including our and our licensee Egalet's ability to:

- obtain and increase market demand for, and sales of, Oxaydo;
- obtain acceptance of Oxaydo by physicians and patients;

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obtain and maintain adequate levels of coverage and reimbursement for Oxaydo from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;

- maintain compliance with regulatory requirements;
- price Oxaydo competitively and enter into price discounting contracts with third-party payors;
- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms;
- manufacture and supply Oxaydo to meet commercial demand, including obtaining sufficient quota from the DEA;
- maintain intellectual property protection for Oxaydo and obtain favorable drug listing treatment by the FDA to minimize generic competition; and
- obtain approval for additional dosage strengths of Oxaydo.

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There can be no assurance that Egalet will devote sufficient resources to the further development, marketing and commercialization of Oxaydo. Egalet's marketing of Oxaydo may result in low market acceptance and insufficient demand for, and sales of, the product. To date we have only minimal royalties from the sale of Oxaydo. In addition, Egalet has filed a prior approval supplement for OXAYDO® 10 mg and 15 mg dosage strengths, but received a complete response letter from the FDA, and according to a recent filing is working to determine next steps to respond to such filing. Egalet has advised that the FDA is requesting more information regarding the effect of food on Oxaydo 15mg and the intranasal abuse-deterrent properties of Oxaydo 10mg and 15mg. If Egalet fails to successfully commercialize Oxaydo and increase sales, we may be unable to generate sufficient revenues to sustain or grow our business and we may never become profitable, and our business, financial condition and results of operations will be materially adversely affected.

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

We commenced the launch and commercial distribution of Nexafed in mid-December 2012 and launched our Nexafed Sinus Pressure + Pain product in February 2015. Our Nexafed products compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than MainPointe in marketing their competing products. Category leading brands are often supported by regional and national advertising and promotional efforts. Our Nexafed products will compete with national brands as well as pharmacy store brands that are offered at a lower price. There can be no assurance that MainPointe will succeed in commercializing our Nexafed products, or that the pricing of our Nexafed products will allow us to generate significant royalty revenues. Regulations have been enacted in several state or local jurisdictions requiring a doctor's prescription to obtain pseudoephedrine products. An expansion of such restrictions to other jurisdictions or even nationally will adversely impact MainPointe's ability to market our Nexafed products as over-the-counter, or OTC, products and negatively impact royalty payments to us from Nexafed products sales. There can be no assurance that MainPointe will devote sufficient resources to marketing and commercialization of our Nexafed products. MainPointe's failure to successfully commercialize our Nexafed® products will have a material adverse effect on our business and financial condition.

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

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

Oxaydo. Even if we are successful at replacing the commercialization capabilities of Egalet, our revenues and/or royalties from Oxaydo could be adversely impacted.

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

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

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

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

Our failure to continue the development of our Limitx opioid product candidates including hydrocodone/acetaminophen, or to successfully establish a license agreement with a pharmaceutical company for the development and commercialization of such products, will adversely impact our ability to develop, market and sell our Limitx technology products and our revenues and business will be materially adversely affected.

We are engaged in the development of product candidates utilizing or Limitx technology, including planning Phase 1 studies for our hydrocodone/acetaminophen lead product candidate. Our plan for developing, manufacturing and commercializing our Limitx opioid products includes entering into an agreement similar to the Egalet Agreement with a strategically focused pharmaceutical company. There can be no assurance, however, that our early-stage development of our Limitx product candidates will be successful, or even if successful, that we will be successful in entering into such an agreement. Pending any such agreement, and subject to available funding, we expect to continue the development of our Limitx product candidates on our own. The continued development of our Limitx product candidates will likely require additional financing, which may not be available on acceptable terms, or at all. In the absence of available financing, or our failure to successfully enter into a license agreement with a pharmaceutical company to develop and commercialize our Limitx products, we may have to limit the size or scope of, or delay or abandon, the development of some or all of our product candidates, which would adversely impact our financial condition and results of operations.

We must rely on current cash reserves, royalties from Egalet on Egalet's sales of Oxaydo, royalties from MainPointe on its sales of Nexafed products to fund operations.

To fund our continued operations, we expect to rely on our current cash resources, capital raising, royalty payments under the Egalet Agreement relating to Oxaydo, and royalty payments under the MainPointe Agreement relating to our Nexafed products, and milestones and royalty payments that may be made under future license agreements with other pharmaceutical company partners for our product candidates in development, of which no assurances can be given. No assurance can be given that current cash reserves, royalties from Egalet on Oxaydo net sales, or royalties from MainPointe on Nexafed products net sales will be sufficient to fund continued operations and the development of

our product candidates until such time as we generate revenues from any of our products in development. Moreover, no assurance can be given that we will be successful in raising additional financing or, if financing is obtained, that such financing will be sufficient to fund operations until we generate sufficient revenues from Oxaydo and Nexafed products, or until product candidates utilizing our Limitx or Impede Technologies may be commercialized. In the event our cash reserves are insufficient to fund continued operations, we may need to suspend some or all of our product development efforts or possibly discontinue operations. Since the termination of the Bayer Agreement in June 2017 (which we believe is as a result of Bayer's de-prioritization of development of the methamphetamine resistant pseudoephedrine-containing product contemplated in the Agreement), which was a potential source of milestones and royalties, the MainPointe Agreement and the Egalet Agreement have increased in importance as potential sources of revenue,

Our and our licensees' ability to market and promote Oxaydo and Limitx technology products by describing the abuse deterrent features of such products will be determined by the FDA approved label for such products.

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

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

label for Oxaydo may substantially limit our licensee's ability to differentiate Oxaydo from other immediate release oxycodone products, which would have a material adverse effect on market acceptance of Oxaydo and on our business and results of operations.

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

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

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

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

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

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

products and require FDA approval prior to sale, of which no assurance can be provided. In such case, the label for our Nexafed products or other Impede Technology products would be subject to FDA review and approval and there can be no assurance that we or our licensees will be able to market Nexafed or other Impede Technology products with labeling sufficient to differentiate it from products that have comparable therapeutic profiles. If we or our licensees are unable to advertise and promote the extraction characteristics of Nexafed or other Impede Technology products, we or our licensees may be unable to compete with national brands and pharmacy chain store brands.

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

We are committing a majority of our resources to the development of products utilizing our Limitx and Impede Technologies. Notwithstanding the receipt of FDA approval of Oxaydo and the results of our numerous clinical and laboratory studies for Oxaydo, our Nexafed products, and our Limitx and Impede Technology products in development, there can be no assurance that Oxaydo, our Nexafed products or any other product utilizing our Limitx, Impede or Aversion Technologies will perform as tested and limit or impede the actual abuse or misuse of such products in commercial settings. Moreover, there can be no assurance that the post-approval epidemiological study required by the FDA as a condition of approval of Oxaydo will show a reduction in the consequences of abuse and misuse by patients for whom Oxaydo is prescribed. To date, Egalet has not achieved sufficient market share for Oxaydo to support a full epidemiological study. The failure of Oxaydo, our Nexafed products or other products utilizing our Limitx and Impede Technologies to limit or impede actual abuse or misuse in practice will have a material adverse impact on market acceptance for such products and on our financial condition and results of operations.

Relying on third party contract research organizations, or CROs may result in delays in our pre-clinical, clinical or laboratory testing. If pre-clinical, clinical or laboratory testing for our product candidates are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines.

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

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

and/or negative or unanticipated results of clinical trials.

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

Clinical trials are expensive and at times, difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Further, if participating subjects or patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we, our licensees or the FDA believes that participating patients are being exposed to unacceptable health risks, we or our licensees may suspend the clinical trials. Failure can occur at any stage of the trials, and we or our licensees could encounter problems causing the abandonment of clinical trials or the need to conduct additional clinical studies, relating to a product candidate.

Even if our clinical trials and laboratory testing are completed as planned, their results may not support commercially viable product label claims. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their intended use. Such failure may cause us or our licensees to abandon a product candidate and may delay the development of other product candidates.

We have no commercial manufacturing capacity and rely on third-party contract manufacturers to produce commercial quantities of our products.

We do not have the facilities, equipment or personnel to manufacture commercial quantities of our products and therefore must rely on our licensees or other qualified third-party contract manufactures with appropriate facilities and equipment to contract manufacture commercial quantities of products utilizing our Limitx and Impede Technologies. These licensees and third- party contract manufacturers are also subject to cGMP regulations, which impose extensive procedural and documentation requirements. Any performance failure on the part of our licensees or contract manufacturers could delay commercialization of any approved products, depriving us of potential product revenue.

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

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

We or our licensees may not obtain required FDA approval; the FDA approval process is time-consuming and expensive.

The development, testing, manufacturing, marketing and sale of pharmaceutical products are subject to extensive federal, state and local regulation in the United States and other countries. Satisfaction of all regulatory requirements typically takes years, is dependent upon the type, complexity and novelty of the product candidate, and requires the expenditure of substantial resources for research, development and testing. Substantially all of our operations are subject to compliance with FDA regulations. Failure to adhere to applicable FDA regulations by us or our licensees would have a material adverse effect on our operations and financial condition. In addition, in the event we are successful in developing product candidates for distribution and sale in other countries, we would become subject to regulation in such countries. Such foreign regulations and product approval requirements are expected to be time

consuming and expensive. In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA’s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. If these executive actions impose constraints on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

We or our licensees may encounter delays or rejections during any stage of the regulatory review and approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the product candidates to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of a NDA, the FDA may refuse to file the application, deny approval of the application, require additional testing or data and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. For instance, the FDA's approval of Oxaydo is conditioned on us or Egalet conducting a post-approval epidemiological study to assess the actual abuse levels and consequences of Oxaydo in the market. The Prescription Drug User Fee Act, or PDUFA, sets time standards for the FDA's review of NDAs. The FDA's timelines described in the PDUFA guidance are flexible and subject to change based on workload and other potential review issues and may delay the FDA's review of an NDA. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we or our licensees desire and could affect the marketability of our products.

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

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

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

We must maintain FDA approval to manufacture clinical supplies of our product candidates at our facility; failure to maintain compliance with FDA requirements may prevent or delay the manufacture of our product candidates

and costs of manufacture may be higher than expected.

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

We develop our products, and manufacture clinical supplies, at a single location. Any disruption at this facility could adversely affect our business and results of operations.

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

Our operations are subject to environmental, health and safety, and other laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

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

Our failure to successfully establish new license agreements with pharmaceutical companies for the development and commercialization of our other products in development may adversely impair our ability to develop, market and sell such products.

The Egalet Agreement grants Egalet 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 Egalet Agreement, the KemPharm Agreement and the MainPointe Agreement with other pharmaceutical company partners for the development and commercialization of our Limitx, Impede and Aversion Technologies in the United States and worldwide. However, there can be no assurance that we will be successful in entering into such license agreements in the future. If we are unable to enter into such agreements, our ability to develop and commercialize our product candidates, and our financial condition and results of operations, would be materially adversely affected.

If our licensees do not satisfy their obligations, we will be unable to develop our licensed product candidates.

As part of the Egalet Agreement, the KemPharm Agreement, the MainPointe Agreement, or any license agreement we may enter into relating to any of our Limitx or Impede Technology products in development or our Aversion technology, we will not have day-to-day control over the activities of our licensees with respect to any product candidate. If a licensee fails to fulfill its obligations under an agreement with us, we may be unable to assume the development and/or commercialization of the product covered by that agreement or to enter into alternative arrangements with another third party. In addition, we may encounter delays in the commercialization of the products

that are the subject of a license agreement. Accordingly, our ability to receive any revenue from the products covered by such agreements will be dependent on the efforts of our licensee. We could be involved in disputes with a licensee, which could lead to delays in or termination of, our development and/or commercialization programs and result in time consuming and expensive litigation or arbitration. In addition, any such dispute could diminish our licensee's commitment to us and reduce the resources they devote to developing and/or commercializing our products. If any licensee terminates or breaches its agreement, or otherwise fails to complete its obligations in a timely manner, our chances of successfully developing and/or commercializing our product candidates would be materially adversely effected. Additionally, due to the nature of the market for Oxaydo and our Limitx and Impede product candidates, it may be necessary for us to license a significant portion of our product candidates to a single company, thereby eliminating our opportunity to commercialize other product candidates with other licensees.

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

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

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

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

- the relative advantages and disadvantages of our products compared to competitive products;
- the relative timing to commercial launch of our products compared to competitive products;
- the relative safety and efficacy of our products compared to competitive products;
- the product labeling approved by the FDA for our products;
- the perception of health care providers of their role in helping to prevent abuse and their willingness to prescribe abuse-deterrent products to do so;
- the willingness of third party payers to reimburse for our prescription products;
- the willingness of pharmacy chains to stock our products;
- the willingness of pharmacists to recommend our Nexafed products to their customers; and
- the willingness of consumers to pay for our products.

Oxaydo and our Nexafed Products compete, and our other product candidates, if successfully developed and commercially launched will compete, with both currently marketed and new products launched in the future by other companies. Physicians and other prescribers may not be inclined to prescribe our prescription products unless our

products demonstrate commercially viable advantages over other products currently marketed for the same indications. Pharmacy chains may not be willing to stock any of our products and pharmacists may not recommend Nexafed products to consumers. Further, consumers may not be willing to purchase our products. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

If we, our licensees or others identify serious adverse events or deaths relating to any of our products once on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate revenues.

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

Our revenues may be adversely affected if we fail to obtain insurance coverage or adequate reimbursement for our products from third-party payers.

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

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

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;

- An increase in the minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- A new Medicare Part D coverage gap discount program, under which manufacturers must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- Extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research;

- A revision to the definition of "average manufacturer price" for reporting purposes; and

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

At this time, it remains uncertain what the full impact of these provisions will be on the pharmaceutical industry generally or our business in particular. The full effects of these provisions will become apparent as these laws are implemented and the Centers for Medicare & Medicaid Services and other agencies issue applicable regulations or guidance as required by the Healthcare Reform Law. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

In addition, since its enactment, there have been judicial and Congressional challenges to certain aspects of the Healthcare Reform Law, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. The Trump administration and members of the U.S. Congress have indicated that they may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Healthcare Reform Law. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. It is uncertain the extent to which any such changes may impact our business or financial condition.

If we are unable to establish sales and marketing capabilities for our products that are not licensed to third parties, our revenues and our business will suffer.

We do not currently have an extensive organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. If we do not license the commercialization of a product, we may have to build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish or fund adequate sales, marketing and distribution capabilities, whether independently or with third parties, it will impair our ability to sell products and have a material adverse effect on our operations.

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 Egalet Agreement, the KemPharm Agreement and the MainPointe Agreement, our licensees control the price of the licensed products, and we expect that our licensees, if any, of our products in development, will control the price of such products and may provide price discounts and price reductions in its discretion. Such price discounts and reductions will reduce the net sales of our licensed products and, correspondingly, our royalty payments under such license agreements. In addition, if any of our large customers is acquired or merged with another provider of similar products, we may lose that customer’s business

Our success depends on our ability to protect our intellectual property.

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

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

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

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

We may become involved in patent litigation or other intellectual property proceedings relating to our Aversion, Impede or Limitx Technologies or product candidates, which could result in liability for damages or delay or stop our development and commercialization efforts.

The pharmaceutical industry has been characterized by significant litigation and other proceedings regarding patents, patent applications and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include:

- litigation or other proceedings we or our licensee(s) may initiate against third parties to enforce our patent rights or other intellectual property rights, including the Paragraph IV Proceedings described below in the next risk factor;
- litigation or other proceedings we or our licensee(s) may initiate against third parties seeking to invalidate the patents held by such third parties or to obtain a judgment that our products do not infringe such third parties' patents;
- litigation or other proceedings third parties may initiate against us or our licensee(s) to seek to invalidate our patents or to obtain a judgment that third party products do not infringe our patents;

- if our competitors file patent applications that claim technology also claimed by us, we may be forced to participate in interference, inter partes or opposition proceedings to determine the priority of invention and whether we are entitled to patent rights on such invention; and
- if third parties initiate litigation claiming that our products infringe their patent or other intellectual property rights, we will need to defend against such proceedings.

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

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management's attention. 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 could 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 may be required would materially harm our business, financial condition and results of operations. If a legal action is brought against us or our licensees, we could incur substantial defense costs, and any such action might not be resolved in our favor. If such a dispute is resolved against us, we may have to pay the other party large sums of money and use of our technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited. Even prior to resolution of such a dispute, use of our technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited.

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

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

licensees may seek a license to use the patented technology. If we are unable to obtain such a license, of which no assurance can be given, we or our licensees may be restricted or prevented from commercializing our Aversion products.

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

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

We cannot assure you that our technologies, products and/or actions in developing our products will not infringe third-party patents. Our failure to avoid infringing third-party patents and intellectual property rights in the development and commercialization of our products would have a material adverse effect on our operations and financial condition.

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

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

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

On September 20, 2012, we announced that we had received a Paragraph IV Certification Notice under 21 U.S.C. 355(j) (a Paragraph IV Notice) from a generic sponsor of an ANDA for a generic drug listing Oxaydo (formerly known as Oxecta) as the reference listed drug. Since such date, we have received similar Paragraph IV Notices from four other generic pharmaceutical companies that have filed ANDAs listing Oxaydo as the reference drug. The Paragraph IV Notices refer to our U.S. Patent Numbers 7,201,920, 7,510,726 and 7,981,439, which cover our Aversion Technology and Oxaydo. The Paragraph IV Notices state that each generic sponsor believes that such patents are invalid, unenforceable or not infringed. On October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. – Florida (Watson), Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc., and on April 29, 2013, we initiated suit against Ranbaxy, Inc., each in the United States District Court for the District of Delaware alleging infringement of our U.S. Patent No. 7,510,726 listed in the FDA's Orange Book. The commencement of such litigation prohibits the FDA from granting approval of the filed ANDAs until the earliest of 30 months from the date the FDA accepted the application for filing, or the conclusion of litigation. In January 2013, we dismissed our suit against Watson on the grounds that Watson had amended its ANDA from a Paragraph IV Certification to a Paragraph III Certification, which indicated its intent not to market its generic Oxaydo product in advance of our patent expiring.

On October 9, 2013, we announced that we had entered into distinct Settlement Agreements with each of Par and Impax, to settle our patent infringement action pending against them in the United States District Court for the District of Delaware. In the suit, we alleged that a generic Oxaydo product for which each of Par and Impax is separately seeking approval to market in the United States pursuant to an ANDA filing with the FDA infringes a U.S. patent owned by us. Par is the first filer of an ANDA for a generic Oxaydo product and is entitled to the 180-day first filer exclusivity under applicable law and FDA regulations.

Under the terms of the Settlement Agreement with Par, Par may launch its generic Oxaydo product in the U.S., through the grant of a non-exclusive, royalty-bearing license from us that would trigger on January 1, 2022. We currently have Orange Book patents that are due to expire between November 2023 and March 2025. In certain limited circumstances, our license to Par would become effective prior to January 1, 2022. Par is required to pay us royalties in the range of 10% to 15% of Par's net profits from the sale of its generic Oxaydo product.

Under the Settlement Agreement with Impax, Impax may launch its generic Oxaydo product in the U.S., through the grant of a non-exclusive, royalty-free license from us that would trigger 180 days following the first sale of a generic Oxaydo product in the U.S. by an entity that is entitled to the 180 day first-filer exclusivity under applicable law and FDA regulations (or if no entity is entitled to such 180 day exclusivity period, the date on which a generic Oxaydo product is first sold in the U.S. or November 27, 2021, whichever date occurs first). In certain circumstances, our license to Impax would become effective prior to such time.

On May 8, 2014, we announced that we had entered into a Settlement Agreement with Ranbaxy Inc. to settle our patent infringement action pending in the United States District Court for the District of Delaware. In the suit, we alleged that a generic of our Oxaydo product for which Ranbaxy is seeking approval to market in the United States pursuant to an ANDA filed with the FDA infringes U.S. patents owned by us. The Settlement Agreement provides that Ranbaxy's current generic of our Oxaydo product that is the subject of its ANDA filing does not infringe our Orange Book listed patents with the FDA. We have not provided Ranbaxy a license to our patents and we may re-commence patent infringement litigation against Ranbaxy if Ranbaxy changes the formulation of its current generic Oxaydo product.

On May 21, 2014, we announced that we had entered into a Settlement Agreement with Sandoz Inc. to settle our patent infringement action pending against Sandoz in the United States District Court for the District of Delaware. In the suit, we alleged that a generic of our Oxaydo product for which Sandoz is seeking approval to market in the United States pursuant to an ANDA filed with the FDA infringes a U.S. patent owned by us. Under the Settlement Agreement, Sandoz may launch its generic to the Oxaydo product in the U.S., through the grant of a non-exclusive license from us that would trigger 180 days following the first sale of a generic to the Oxaydo product in the U.S. by an entity that is entitled to the 180 day first-filer exclusivity under applicable law and FDA regulations (or if no entity is entitled to such 180 day exclusivity period, the date on which a generic to the Oxaydo product is first sold in the U.S). In certain circumstances, our license to Sandoz would become effective prior to such time. Sandoz is not obligated to pay us a royalty if its current formulation of its generic to the Oxaydo product is approved by the FDA. In

the event Sandoz changes or modifies the structure of its generic Oxaydo product, or materially changes or modifies the amounts or type of any excipient used in the Sandoz formulation disclosed in its ANDA filing with the FDA as of July 30, 2013, Sandoz is required to pay us a royalty based upon the Net Profits (as defined in the Settlement Agreement) derived from the net sales of such changed or modified Sandoz generic Oxaydo product in the United States.

It is possible that other generic manufacturers may also seek to launch a generic version of Oxaydo and challenge our patents. Any determination in any such infringement actions that our patents covering our Aversion Technology and Oxaydo are invalid or unenforceable, in whole or in part, or that the products covered by generic sponsors' ANDAs do not infringe our patents could have a material adverse effect on our operations and financial condition.

We may be exposed to product liability claims and claims regarding marketing of products and may not be able to obtain or maintain adequate product liability insurance and some claims may not be covered by insurance.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products, and in particular opioid products. Manufacturers and distributors of prescription opioid medications, are the subject of lawsuits and have received subpoenas and other requests for information from various state and local government agencies regarding the sales and marketing of opioid medications. While we would not expect to be implicated in any such action or investigations, since our business is focused on abuse deterrence, there can be no assurance that we will not be so implicated. Product liability claims or marketing related claims might be made by patients, health care providers or others that sell or consume our products or insurance companies that insure those affected by our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale. We currently have clinical trial product liability insurance on a claims-made basis for our subject clinical trials and have product liability insurance for the Nexafed and Oxaydo products. This coverage may not be adequate to cover any product liability claims. Product liability coverage and other insurance is expensive. In the future, we may not be able to maintain such product liability insurance or other insurance at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims or other claims. In addition our insurance may not cover certain marketing related claims and excludes certain products from product liability coverage. See litigation discussed below under “Item 3. Legal Proceedings” of this Report. Any claims that are not covered by product liability insurance or other insurance could have a material adverse effect on our business, financial condition and results of operations.

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

We face significant competition, which may result in others developing or commercializing products before or more successfully than we do.

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

which may result in our licensee's costs of manufacturing being higher than our competitors' costs. If our products are unable to capture and maintain market share, we or our licensees may not achieve significant product revenues and our financial condition and results of operations will be materially adversely affected.

We believe potential competitors may be developing opioid abuse deterrent technologies and products. Such potential competitors include, but may not be limited to, Pain Therapeutics, Pfizer Inc., Purdue Pharma, Atlantic Pharmaceuticals, Egalet Corporation, KemPharm, Shionogi, Nektar Therapeutics, Signature Therapeutics, QRx Pharma, Tris Pharma, Pisgah Labs, Teva Pharmaceuticals, Sun Pharmaceuticals, Inspirion Delivery Sciences, and Collegium Pharmaceuticals, Inc. These companies appear to be focusing their development efforts on ER Opioid Products, except for Atlantic Pharmaceuticals, Pisgah Labs, Inspirion and KemPharm.

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

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

Key personnel are critical to our business and our success depends on our ability to retain them.

We are dependent on our management and scientific team, including Robert Jones, our President and Chief Executive Officer, Peter A. Clemens, our Chief Financial Officer, and Albert W. Brzeczko, Ph.D., our Vice President of Technical Affairs. We may not be able to 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.

Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioid and regulatory efforts to combat abuse, could decrease the potential market for Oxaydo, and, if approved, our Limitx product candidates.

Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are commonplace. Law enforcement and regulatory agencies may apply policies that seek to limit the availability of opioids. Such efforts may inhibit Egalet's ability to commercialize Oxaydo and, if approved, our Limitx product candidate. Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs, the limitations of abuse resistant formulations, public inquiries and investigations into prescription drug abuse, litigation or regulatory activity, sales, marketing, distribution or storage of our drug products could harm our reputation. Such negative publicity could reduce the potential size of the market for our product candidates and Oxaydo and decrease the revenues and royalties we are able to generate from their sale. Similarly, to the extent opioid abuse becomes less prevalent or a less urgent public health issue, regulators and third-party payers may not be willing to pay a premium for abuse deterrent formulations of opioids.

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

We are increasingly dependent on information technology and our systems and infrastructure face certain risks, including cybersecurity and data storage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit confidential information, and it is critical that we do so in a secure manner in order to maintain the confidentiality and integrity of such confidential

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

Prior ownership changes limit our ability to use our tax net operating loss carryforwards.

Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of Net Operating Loss ("NOL"), carryforwards and other tax attributes. In addition, under the Tax Cuts and Jobs Act of 2017, NOL usage in any given year will be limited to 80% of taxable income, without regard to the NOL deduction, and losses incurred in 2018 and forward may not be carried back but can be carried forward indefinitely, but losses incurred prior to 2018 can only be carried forward for 20 years. We have determined that we have undergone ownership changes in both 2004 and 2017 (as defined by Section 382 of the Internal Revenue Code) and as a result, our use of NOL carryforwards on an annual basis will be very limited. 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 quarterly 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 future quarters or years, 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 2017, our stock traded as high as $1.40 per share and as low as $0.29 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors could include:

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

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

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

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

We do not have a history of paying dividends on our common stock.

Historically, we have not declared and paid any cash dividends on our common stock. In addition, our Loan and Security Agreement with Oxford Finance LLC restricts our ability to pay dividends during the term of such Agreement. 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 March 30, 2018, our two largest shareholders own an aggregate of approximately 12,651,543 shares (including 1,782,531 shares underlying warrants) (representing approximately 56% of our outstanding shares). If some or all of such shares are sold by such stockholders, it may have the effect of depressing the trading price of our common stock. In addition, such sales could make it more difficult for us to raise capital if needed in the future.

Approximately 47.5% of our common stock is owned by a single individual, who is also a principal of MainPointe Pharmaceuticals LLC, and that individual is also party to our Second Amended and Restated Voting Agreement.

A significant amount of our common stock is owned by a single individual, John Schutte. On July 24, 2017, we completed a $4.0 million private placement with him for the sale of 8,912,655 shares and warrants to purchase 1,782,531 shares at an exercise price of $0.528 and expiring on July 24, 2022. In the second quarter of 2018, Mr. Schutte lent us an aggregate of $1.0 million on an unsecured basis until our obligations to Oxford have been satisfied in full, and thereafter on a secured basis with a security interest in all of our assets. 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 following the termination of the Bayer Agreement. Further, as part of the closing of the Transaction, we, Essex Woodlands Health Ventures V, L.P. ("Essex") and Galen Partners III, L.P. ("Galen"), which has subsequently sold its shares, amended and restated the existing Voting Agreement between the parties to provide for Mr. Schutte to join as a party so that he can designate a director (he has not done so). The combination of Mr. Schutte's share ownership, control of one of our key licensing partners, and the right to designate a director to oversee the long-term affairs of our company, and right to have a security interest in all of our assets after the Oxford obligations have been satisfied in full, gives him the potential to have considerable influence over our business and affairs. As a result, Mr. Schutte, in view of his ownership percentage of our common stock, will as a practical matter be 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 we may 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 holder vote.

Our common stock is deemed a "penny stock," which would make it more difficult for our investors to sell their shares.

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

At times, our shares of common stock have been thinly traded, so you may be unable to sell at or near ask prices or even at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.

Our common stock is quoted on the OTC Markets OTC Pink tier (after being removed from the OTCQB where it was previously quoted). Our common stock experiences periods when it could be considered "thinly-traded." This situation may be attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days, weeks or months when trading activity in our shares is minimal, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common stock will be sustained, or that current trading levels will be sustained or not diminish.

We are a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a "smaller reporting company," meaning that we are not an investment company, an asset- backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than $75 million, or in the absence of any public float had annual revenues of less than $50 million during the most recently completed fiscal year. "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 2017 fiscal year that remain unresolved.

ITEM 2. PROPERTIES

We lease from an unaffiliated Lessor, approximately 1,600 square feet of administrative office space at 616 N. North Court, Suite 120, Palatine, Illinois 60067. The lease agreement expired on March 31, 2017; effective April 1, 2017, the office space is leased on a month-to-month basis. The lease agreement provides for rent, property taxes, common area maintenance, and janitorial services on a monthly basis of approximately $2 thousand per month. We utilize this lease space for our administrative and business development functions.

We conduct research, development, laboratory, development scale and NDA submission batch scale manufacturing and other activities relating to developing product candidates using Aversion, Impede and Limitx Technologies at the facility we own located at 16235 State Road 17, Culver, Indiana. At this location, our wholly-owned subsidiary APT, 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

Purdue Pharma Settlement

In April 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc., or collectively Purdue, commenced a patent infringement lawsuit against us and our Oxaydo product licensee Egalet US, Inc. and its parent Egalet Corporation in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's U.S. Patent No. 8,389,007, or the 007 Patent. In April 2016, Purdue commenced a second patent infringement lawsuit against us and Egalet in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's newly issued U.S. Patent No. 9,308,171, or the 171 Patent. The actions regarding the 007 Patent and the 171 Patent are collectively referred to as the "Actions". On April 6, 2016, we filed a petition for Inter Partes Review, or IPR Review, with the U.S. Patent and Trademark Office, or USPTO, seeking to invalidate Purdue's 007 Patent.

On May 20, 2016, Purdue on behalf of themselves and certain affiliates, Egalet Corporation, on behalf of itself and its affiliates and we, on behalf of ourselves and our affiliates entered into a settlement agreement, or the Settlement Agreement, to settle the Actions and the IPR Review. Under the Settlement Agreement the parties dismissed or withdrew the Actions, requested that the USPTO terminate the IPR Review and exchanged mutual releases. No payments were made under the Settlement Agreement.

The Settlement Agreement also provides that Purdue will not, in the future, assert certain Purdue U.S. patents, including the 007 Patent, the 171 Patent and related technologies, or collectively the Purdue Patents, against any Acura Settlement Product or Egalet Settlement Product (except generally in an action or interference by Acura or Egalet challenging a Purdue Patent). Acura Settlement Products and Egalet Settlement Products are certain immediate-release and extended-release products, including Oxaydo. In addition, the Settlement Agreement provides that Purdue will not challenge, with certain exceptions, the Acura/Egalet Patents with respect to the Purdue Settlement Products (as defined below) and that Purdue provides Acura and/or Egalet certain waivers of non-patent marketing exclusivity with respect to Purdue Settlement Products.

The Settlement Agreement also provides that Acura and Egalet will not, in the future, assert certain Acura and/or Egalet U.S. patents, or collectively the Acura/Egalet Patents, including Acura's Aversion® Technology patents, against any Purdue Settlement Products (except generally in an action or interference by Purdue challenging an Acura/Egalet Patent). Purdue Settlement Products are certain immediate-release and extended-release products. In addition, the Settlement Agreement provides that Acura and Egalet will not challenge, with certain exceptions, the Purdue Patents with respect to the Acura Settlement Products and Egalet Settlement Products and that Acura and Egalet provide Purdue certain waivers of non-patent marketing exclusivity with respect to the Acura Settlement Products and Egalet Settlement Products. In addition, Purdue has certain rights to negotiate to exclusively distribute an authorized generic version of certain Egalet Settlement Products, including, in some circumstances, Oxaydo® and other products using Acura's Aversion® Technology if licensed to Egalet.

The Settlement Agreement specifically excludes our patents related to our Impede® and Limitx™ technologies from the scope of the Acura/Egalet Patents under the Settlement Agreement.

In December 2014, we entered into an agreement with Purdue Pharma L.P. to settle a patent interference action regarding certain intellectual property held by Acura (U.S. Patent No. 8,101,630). The dispute centered upon the issue of which company has priority in developing the invention. The parties agreed to forgo protracted litigation and the uncertainties arising therefrom by entering an agreement whereby we conceded Purdue Pharma's claim of priority in exchange for certain financial consideration to us including an immediate non-refundable payment of $500 thousand. In June 2015, we received an additional $250 thousand payment from Purdue Pharma relating to the December 2014 agreement.

Reglan®/Metoclopramide Litigation

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

In the lawsuits filed to date, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by us. We discontinued manufacture and distribution of generic metoclopramide more than 20 years

ago. In addition, we believe the June 23, 2011 decision by the U.S. Supreme Court in *PLIVA v. Mensing ("Mensing* decision") holding that state tort law failure to warn claims against generic drug companies are pre-empted by the 1984 Hatch-Waxman Act Amendments and federal drug regulations will assist us in favorably resolving these cases.

In New Jersey, Generic Defendants, including Acura, filed dispositive motions based on the *Mensing* decision, which the Court granted with a limited exception. In June 2012, the New Jersey trial court dismissed all of the New Jersey cases pending against us with prejudice.

In Pennsylvania, the trial court proceedings were stayed on January 12, 2017. On June 15, 2017, the Court entered an Order approving a stipulation which dismisses nearly all of the individual cases against us based upon lack of product identification without prejudice and provides for these cases to be dismissed finally, with prejudice, on June 15, 2018, or at an earlier date in each individual case, if all parties are dismissed. Acura is in the process of seeking voluntary dismissal without prejudice of the *de minimis* number of remaining Pennsylvania cases pending against Acura on the basis of lack of product identification. We expect that these remaining few cases will be dismissed based on lack of product identification and the Court will finally dismiss the Pennsylvania-based litigation against us with prejudice in 2018. Legal fees related to this matter are currently covered by our insurance carrier.

In California, on May 24, 2016, the Court entered an Order approving a stipulation which stays the individual cases against us and provides for an agreed upon dismissal protocol for all cases where is a lack of product identification. On January 13, 2017, the Court also entered a general stay of this entire litigation. To date, none of these plaintiffs have confirmed they ingested any of the generic metoclopramide manufactured by us. Therefore, we expect that the lawsuits filed against us will be dismissed voluntarily with prejudice in 2018. Legal fees related to this matter are currently covered by our insurance carrier.

As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of December 31, 2017 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

DES Litigation

On April 12, 2018, an action was commenced against the Company and over twenty-five other pharmaceutical manufacturers in New York State Supreme Court, New York County, captioned *Cotto et al. v. Abbott Laboratories, Inc., et al* (index 153339/2018). The Complaint contains seven causes of action, including negligence, strict liability, and breach of warranty, wrongful death, among others, in connection with the alleged exposure of the deceased plaintiff in utero to diethylstilbestrol (DES) in the 1950s as the result of the ingestion of the drug by her mother or grandmother. The plaintiffs are the personal representative of the deceased and her two daughters. The plaintiffs were unable to determine which of the defendants produced the DES used by the deceased, but regardless seeks to hold all defendants jointly and severally liable. The Complaint seeks $10.0 million in compensatory and $10.0 million in punitive damages on each of five counts and damages in an amount to be determined for wrongful death and additional punitive damages in an unstated amount. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of December 31, 2017. We are presently unable to determine if any potential loss would be covered by any of our current or former insurance carriers.

ITEM 4. MINE SAFETY DISLCOSURES

Not Applicable.

PART II

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

Market and Market Prices of Common Stock

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

Commencing on February 23, 2017, our common stock is quoted on the OTCQB under the symbol "ACUR", however commencing June 4, 2018 it is quoted on the OTC Markets OTC Pink tier. The downgrade was a result of the late filing of this Annual Report on Form 10-K beyond any applicable grace periods.

Set forth below for the periods indicated are the high and low sales prices for trading in our common stock on the NASDAQ Capital Market as reported by the NASDAQ Capital Market.

Period	Sale Prices	
	High	Low
2016 Fiscal Year		
First Quarter	$2.83	$1.61
Second Quarter	3.52	1.71
Third Quarter	2.18	1.40
Fourth Quarter	1.65	0.71
2017 Fiscal Year		
First Quarter (through February 22, 2017)	$1.40	$0.50

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

Period	Sales Prices	
	High	Low
2017 Fiscal Year		
First Quarter (from February 23, 2017)	$0.75	$0.46
Second Quarter	0.65	0.40
Third Quarter	0.57	0.40
Fourth Quarter	0.51	0.29
2018 Fiscal Year		
First Quarter (through March 29, 2018)	$0.87	$0.36

On March 29, 2018, the closing sales price of our common stock was $0.51.

Holders

There were approximately 301 holders of record of our common stock as of March 29, 2018 including approximately 82 holders who are 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. This number, however, does not reflect the ultimate number of beneficial holders of our common stock.

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. In addition, our Loan and Security Agreement with Oxford Finance LLC restricts our ability to pay dividends during the term of such Agreement.

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data presented below for the years ended December 31, 2017, 2016, 2015, 2014, and 2013 are derived from our audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2017 and 2016 and for each of the years in the two-year period ended December 31, 2017, and the reports thereon, are included elsewhere in this Report. The selected financial information presented for our 2015, 2014 and 2013 operations and for our 2015, 2014 and 2013 balance sheets are derived from our audited Consolidated Financial Statements not presented in this Report.

The information set forth below has been retroactively adjusted to reflect a one-for-five reverse stock split effected by us on August 27, 2015, is qualified by reference to, and should be read in conjunction with, the Consolidated Financial Statements and related notes thereto included elsewhere in this Report and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

OPERATING DATA (in thousands) except per share data	2017	2016	2015	2014	2013
Revenues, net	$2,966	$4,464	$8,587	$751	$123
Cost and expenses:					
Cost of sales	128	477	986	428	364
Research and development [1]	3,721	4,028	2,608	4,582	4,923
Selling, marketing, general and administrative [2]	4,342	6,516	8,994	7,940	8,926
Interest expense	596	893	1,157	1,212	9
Interest and investment income	4	60	166	198	194
Other income	-	2	3	4	4
Loss before provision for income taxes	(5,817)	(7,388)	(4,989)	(13,209)	(13,901)
Provision (benefit) for income taxes	(135)	-	-	-	-
Net loss applicable to common stockholders	$(5,682)	$(7,388)	$(4,989)	$(13,209)	$(13,901)
Loss per share of common stock: Basic	$(0.36)	$(0.62)	$(0.46)	$(1.35)	$(1.45)
Loss per share of common stock: Diluted	$(0.36)	$(0.62)	$(0.46)	$(1.35)	$(1.45)

Weighted average shares outstanding used in computing net loss per share: Basic	15,903	11,870	10,796	9,779	9,553
Weighted average shares outstanding used in computing net loss per share: Diluted	15,903	11,870	10,796	9,779	9,553

(1) Includes stock-based compensation expense from all types of awards of approximately $140, $170, $160, $220, and $315 for years 2017, 2016, 2015, 2014 and 2013, respectively.

(2) Includes stock-based compensation expense from all types of awards of approximately $360, $450, $480, $700 and $900 for years 2017, 2016, 2015, 2014 and 2013, respectively.

BALANCE SHEET DATA (in thousands)	2017	2016	2015	2014	2013
Working capital (deficit) [3]	$(2,065)	$(700)	$8,391	$10,239	$26,346
Total assets	4,604	8,208	16,961	16,195	28,630
Total liabilities	4,631	7,025	9,061	11,143	10,707
Accumulated deficit	(380,380)	(374,698)	(367,310)	(362,321)	(349,112)
Stockholders' (deficit) equity	$(27)	$1,183	$7,900	$5,052	$17,923

(3) Excludes cash compensating balance requirement of $2,500 at December 31, 2016 and 2015.

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 Overview

We are a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Aversion® and Limitx™ Technologies are 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. On January 7, 2015, we entered into a Collaboration and License Agreement with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation, or collectively Egalet, pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo. Oxaydo is currently approved by the U. S. Food and Drug Administration, or FDA, for marketing in the United States in 5mg and 7.5mg strengths. Egalet launched Oxaydo in the United States late in the third quarter of 2015.

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. We have a third pseudoephedrine product in development utilizing our Impede Technology. 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 (MainPointe has an option to license other Impede Technology following termination of the Bayer Agreement). The MainPointe Agreement also grants MainPointe the option to expand the licensed territory to the European Union, Japan and South Korea and to add additional pseudoephedrine-containing products utilizing our Impede technology. MainPointe is controlled by John Schutte, who became our largest shareholder pursuant to a private placement completed in July 2017 and became a creditor in May 2018.

On June 28, 2017, Bayer Healthcare LLC, or Bayer, terminated a 2015 License and Development Agreement in which we granted Bayer an exclusive worldwide license to our Impede technology for use in an undisclosed methamphetamine resistant product. As a result of the termination, MainPointe has the option to license our Impede technology with respect to such product in the United States and Canada upon payment of a fee. MainPointe has not yet exercised this option.

Our third abuse deterrent technology, Limitx, is designed to retard the release of active drug ingredients when too many tablets are accidently 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, or Cmax, was reduced in healthy fasted adult subjects by 50% to 65% when excessive buffer levels were ingested, or a situation consistent with the over-ingestion of tablets. Study AP-LTX-301, or Study 301, the results for which were announced in January 2018, 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 while 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. Study AP-LTX-300, or Study 300, was inconclusive in its results due to observed issues with drug release from over-encapsulated test product. We submitted an Investigational New Drug Application, or 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. The FDA has designated the development program for LTX-04 as Fast Track, which is designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. However, we intend to advance LTX-03, which combines the hydrocodone micro-particles, acetaminophen and buffer ingredients into a single tablet, as our lead Limitx product candidate due to its larger market size and its known prevalence of oral excessive tablet abuse. We have voluntarily placed the IND for LTX-04 on inactive status

We are actively seeking a licensing partner for our Limitx product candidates.

Company’s Present Financial Condition

At December 31, 2017, we had cash and cash equivalents of $2.2 million compared to $2.7 million of unrestricted cash and cash equivalents at December 31, 2016. Under our term loan with Oxford Finance LLC, we were required to maintain a $2.5 million compensating balance until such time as we raise an additional $6.0 million (excluding payments under our KemPharm Agreement) through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions. We satisfied such condition on July 24, 2017, when we received a $4.0 million equity investment. We had an accumulated deficit of approximately $380.4 million and $367.3 million at December 31, 2017 and December 31, 2016, respectively. We had a loss from operations of $5.2 million and a net loss of $5.7 million for the year ended December 31, 2017, compared to a net loss from operations of $6.6 million and net loss of $7.4 million for the year ended December 31, 2016. As of June 6, 2018 after giving effect to a $1.0 million loan from John Schutte, our cash, cash equivalents, and refundable deposits was approximately $0.5 million and expect such amounts will only be able to fund operations into late June 2018.

We expect to continue to incur substantial losses for the foreseeable future as we continue to develop our clinical and preclinical product candidates. To fund further operations and product development activities, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. No assurance can be given that we will be successful in obtaining any such financing or in securing license or collaboration agreements with third parties on acceptable terms, if at all, or if secured, that such financing or license or collaboration agreements will provide payments to the Company sufficient to fund continued operations. In the absence of such financing or third-party license or collaboration agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

Our 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 Egalet Agreement. Sales and marketing expenses include costs associated with the Nexafed product line advertising incurred prior to our entering into the MainPointe Agreement on March 16, 2017, salaries and other personnel-related costs include the stock-based compensation associated with stock options and restricted stock units granted to employees and non-employee directors.

Results of Operations for the Years Ended December 31, 2017 and 2016.

	December 31			
	2017	2016	Change	
	$000's		$000's	Percent
Revenues:				
License fee revenue	$2,500	$3,500	$(1,000)	(29)%
Collaboration revenue	59	392	(333)	(85)
Royalty revenue	300	149	151	101
Product sales, net	107	423	(316)	(75)
Total revenues, net	2,966	4,464	(1,498)	(34)
Cost and expenses:				
Cost of sales	128	451	(323)	(72)
Inventory reserve expense for write-downs	-	26	(26)	(100)
Research and development	3,721	4,028	(307)	(8)
Selling, marketing, general and administrative	4,342	6,516	(2,174)	(33)
Total cost and expenses	8,191	11,021	(2,830)	(26)
Operating loss	(5,225)	(6,557)	(1,322)	(20)
Non-Operating income (expense):				
Interest and investment income	4	60	(56)	(93)
Interest expense	(596)	(893)	(297)	(33)
Other income	-	2	(2)	(100)
Total other expense, net	(592)	(831)	(239)	(29)
Loss before provision for income taxes	(5,817)	(7,388)	(1,571)	(21)
Provision (benefit) for income taxes	(135)	-	135	100
Net loss	(5,682)	$(7,388)	(1,706)	(23)%

Revenue

License Fees

In March 2017, MainPointe Pharmaceuticals LLC paid us a licensing fee of $2.5 million under our collaboration and license agreement with it pursuant to which we granted MainPointe an exclusive license to our Impede Technology to commercialize our Nexafed products in the U.S. and Canada.

In October 2016, KemPharm, Inc. paid us a licensing fee of $3.5 million under our worldwide license agreement pursuant to which we licensed our Aversion® Technology to KemPharm, Inc. for its use in the development and commercialization of three products using two of KemPharm's prodrug candidates.

Collaboration Revenue

Collaboration revenue is derived from research and development services we perform under various license and development agreements. We recognized $59 thousand and $392 thousand of collaboration revenue during the years ended 2017 and 2016, respectively. We are not currently providing research and development services under any of our license agreements.

Royalty Revenue

In connection with our license agreement with Egalet for Oxaydo Tablets, we earn a royalty based on product net sales. Egalet's first commercial sale of Oxaydo occurred in October 2015. We recognized $281 thousand and $149 thousand of royalty revenue from Oxaydo during the years ended 2017 and 2016, respectively.

In connection with our license agreement with MainPointe for our Nexafed product line, we earn a royalty based on product net sales. MainPointe's first commercial sale of Nexafed occurred in March 2017. We recognized $19 thousand of royalty revenue from Nexafed during 2017.

Net Product Sales

Nexafed® was launched by us in December 2012. Nexafed® Sinus Pressure + Pain was launched by us in February 2015. In March 2017, we licensed the Nexafed product line to MainPointe. We recorded $107 thousand and $423 thousand of net product sales during the years 2017 (through March 16, 2017) and 2016, respectively.

Cost and Expenses

Cost of Sales

Our cost of sales on the Nexafed product line includes third-party manufacturing costs, third-party warehousing and product distribution charges. Our cost of sales for 2017 (through March 16, 2017) and 2016 were $128 thousand and

$451 thousand, respectively. In March 2017 we licensed the Nexafed product line to MainPointe.

Inventory reserve expense for the year ended 2016 was $26 thousand. We did not incur any reserve expense on our inventory during the year ended 2017. We have no inventories on hand at December 31, 2017.

Research and Development

Research and development expense ("R&D") for 2017 was primarily for our Limitx Technology and Impede Technology development activity and may include, among other items, costs of preclinical and non-clinical internal and external activities, clinical study trials, clinical supplies and its related formulation and design costs, salaries and other personnel related expenses of our employees, our facility costs, and a percentage share of selected cost sharing expenses under the license agreement with Egalet. For the years ended 2017 and 2016, there is $86 thousand and $186 thousand, respectively of cost sharing expenses from clinical studies for product line extensions (additional strengths) on Oxaydo and $118 thousand and $140 thousand, respectively of potential cost sharing expenses for a FDA required post-marketing study on Oxaydo. Also included in each of 2017 and 2016 year end results are non-cash share-based compensation expenses of $139 thousand and $166 thousand, respectively. Excluding the share-based compensation expense, our R&D expenses decreased approximately $300 thousand between reporting periods. During 2016 we completed Study AP-LTX-400 while we substantially completed our project to integrate Impede 2.0 Technology into our Nexafed 30mg tablet while moving supply to an alternate contract manufacturer. During 2017 we completed Study AP-LTX-401 and Study AP-LTX-300 and substantially completed our Study AP-LTX-301 by the end of 2017.

General, Administrative, Selling and Marketing

We had limited selling and marketing expenses for 2017 associated with advertising and marketing activities on the Nexafed product line, which was licensed to MainPointe in March 2017. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the 2017 and 2016 results are non-cash share-based compensation expenses of $324 thousand and $420 thousand, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased by approximately $2.1 million between reporting periods, resulting primarily from the elimination of advertising and marketing activities on the Nexafed product line as well as decreases in patent and general legal activities, including the elimination of ongoing legal and litigation expenses incurred with respect to our litigation with Purdue Pharma which was settled in May 2016.

Non-Operating Expense

During the years ended 2017 and 2016, non-operating expense consisted principally of interest expense on our term loan.

Income Taxes

Our results for 2017 and 2016 include no federal or state income tax benefit provisions due to 100% allowances placed against our deferred tax assets for the uncertainty of their future utilization. As a result of the Tax Cuts and Jobs Act of 2017, the $135 thousand Federal alternative minimum taxes we paid in a prior year is refundable to the Company in prescribed percentages and time periods and therefore, we recorded a non-current receivable for a like amount.

Liquidity and Capital Resources

At December 31, 2017, we had cash and cash equivalents of $2.2 million. As of June 6, 2018 we had approximately $0.5 million of cash, cash equivalents, and refundable deposits and expect such amounts will only be sufficient to fund operations into late June 2018.

To fund further operations beyond June 2018, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. The Company is exploring a variety of capital raising and other transactions to provide additional funding to continue operations. These include potential private offerings of common stock to institutional investors. The Company is also actively seeking a licensing partner for its Limitx Technology, with the objective of receiving an upfront license fee, development milestone payments and royalties on the net sales of products utilizing the Limitx Technology, similar to the Egalet Agreement and the now terminated Bayer Agreement. The Company is also exploring licensing or selling select assets and intellectual property in an effort to raise capital and reduce operating expenses. Finally, the Company is evaluating the potential for a strategic transaction which may involve the Company being acquired in a merger or asset purchase transaction. 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. Our auditors have included in their report relating to our 2017 financial statements a “going concern” explanatory paragraph as to substantial doubt of our ability to continue as a going concern. In the absence of such financing or third-party license or collaboration agreements, there will be substantial doubt about the Company’s ability to continue as a going concern and 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, 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 milestone payments and royalties under the Egalet 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, 2017 and 2016

The following table summarizes our cash flows for the years ended December 31, 2017 and 2016 (in thousands):

	Year Ended December 31,	
	2017	2016
Net cash (used in) provided by:		
Operating activities	$(4,510)	$(5,563)
Investing activities	309	10,798
Financing activities	1,240	(2,539)
Net (decrease) increase in cash	$(2,961)	$2,696

Cash Flows from Operating Activities

Net cash used in operating activities was $4.5 million for the year ended December 31, 2017 and consisted primarily of a net loss of $5.7 million. This net loss was partially offset by $464 thousand in noncash share-based compensation expense, $306 thousand of noncash debt discount and debt issue cost amortization expense, $87 thousand of noncash depreciation expense, $49 thousand provision expense for sales returns and approximately $270 thousand in net cash inflows from changes in operating assets and liabilities. Cash inflows from changes in operating assets and liabilities were primarily due to a net increase of $226 between accounts payable, accrued expenses, accrued interest, and other liabilities primarily driven by our commercial operations, clinical studies and interest obligations, a net decrease between trade receivables, collaboration and royalty receivables of $81 thousand, and a decrease in inventory of $103 thousand. These inflows were partially offset by cash outflows due to increases in deposits and other assets of $142 thousand.

Net cash used in operating activities was $5.6 million for the year ended December 31, 2016 and consisted primarily of a net loss of $7.4 million. This net loss was partially offset by $588 thousand in noncash share-based compensation expense, $352 thousand of noncash debt discount and debt issue cost amortization expense, $138 thousand of noncash

depreciation expense, $99 thousand sales returns provision expense, $108 thousand inventory and fixed assets impairment provision expenses, $31 thousand marketable securities bond premium amortization expense and approximately $510 thousand in net cash inflows from changes in operating assets and liabilities. Cash inflows from changes in operating assets and liabilities were primarily due to a net increase of $277 thousand between accounts payable, accrued expenses, accrued interest and other liabilities primarily driven by our commercial operations, clinical studies and interest obligations, as well as net decrease of $324 thousand in prepaid expenses and other assets. These inflows were partially offset by cash outflows due to a net increase between trade receivables, accrued investment income, and collaboration and royalty receivables of $32 thousand and an increase in inventory of $59 thousand.

Cash Flows from Investing Activities

Net cash provided by investing activities for the year ended December 31, 2017 was 309 thousand and consisted of $103 thousand and $206 thousand from the transfer of equipment and inventory, respectively, under Nexafed license agreement we completed in March 2017.

Net cash provided by investing activities for the year ended December 31, 2016 was $10.8 million and consisted primarily of $10.9 million from the sales and maturities of marketable securities. The cash inflows were partially offset by $75 thousand in purchases of capital equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $1.2 million for the year ended December 31, 2017 and consisted of the $4.0 million net proceeds from the issuance of Common Stock to John Schutte in July 2017, partially offset by $2.8 million of repayments against the loan maturing December 1, 2018 we have with Oxford.

Net cash used in financing activities for the year ended December 31, 2016 was $2.5 million of repayments against the loan maturing December 1, 2018 we have with Oxford.

Contractual Obligations and Commitments

The following table presents our expected cash payments on contractual obligations outstanding as of December 31, 2017:

	Payments due by period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Employment agreements	$ 679	$ 679	$ -	$ -	$ -
Service agreements	279	279	-	-	-
Severance agreement	10	10	-	-	-
RSU awards	10	10	-	-	-
Debt interest	911	911	-	-	-
Debt principal	2,740	2,740	-	-	-
Total	$ 4,629	$ 4,629	$ -	$ -	$ -

Term Loan with Oxford Finance

On December 27, 2013, we and our subsidiary, APT entered into a Loan and Security Agreement, or the Loan Agreement, with Oxford Finance LLC, or Oxford, as collateral agent and as a lender, pursuant to which the Oxford made a term loan to us in the principal amount of $10.0 million, or the Term Loan, subject to the terms and conditions set forth in the Loan Agreement. We used the proceeds of the Loan Agreement for general working capital and to fund our business requirements.

The full principal amount of the Term Loan was funded on December 27, 2013. The Term Loan accrues interest at a fixed rate of 8.35% per annum (with a default rate of 13.35% per annum). We were required to make monthly interest−only payments until April 1, 2015 and starting on April 1, 2015, we are required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through the maturity date of December 1, 2018. As of December 31, 2017, the outstanding principal balance of the Term Loan was $2.7 million. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on December 1, 2018. As security for our obligations under the Loan Agreement, we granted Oxford a security interest in substantially all of our existing and after−acquired assets, exclusive of intellectual property assets. Pursuant to the Loan Agreement, we are not allowed to pledge our intellectual property assets to others.

On January 7, 2015, we and Oxford entered into an amendment, or the First Amendment, to the Loan Agreement. Pursuant to the First Amendment, (i) the exercise price of the warrants issued to Oxford on the date of funding the Term Loan to purchase 59,561 shares of our common stock was lowered from $7.98 to $2.52 per share (such reduced amount being equal to the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the First Amendment and after giving effect to our one-for-five reverse stock split), (ii) we agreed to maintain a $2.5 million cash balance until such time as we have repaid $5.0 million in principal of the Term Loan, and (iii) Oxford consented to the terms of our Collaboration and License Agreement with Egalet relating to our Oxaydo product.

On October 13, 2016, we and Oxford entered into a second amendment to the Loan Agreement, or the Second Amendment. Pursuant to the Second Amendment, (i) the requirement that we maintain a $2.5 million cash balance reserve until such time as $5 million in principal was repaid under the Term Loan, has been modified so that the $2.5 million cash balance reserve remains in place until we raise an additional $6.0 million (excluding payments received under the KemPharm Agreement) through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions, provided that at least $3.0 million of such amount must be raised through the issuance and sale of our equity securities, and (ii) Oxford consented to the terms of our Agreement with KemPharm.

On March 16, 2017, we and Oxford entered into a third amendment to the Loan Agreement, or the Third Amendment. Pursuant to the Third Amendment (i) we granted Oxford a lien on our intellectual property, (ii) Oxford provided a waiver of compliance with the unqualified audit opinion covenant in connection with our receipt of our auditor's opinion with a going concern explanatory paragraph for our 2016 financial statements and (iii) Oxford consented to the terms of the MainPointe Agreement.

In the second quarter of 2018, in connection with the total of a $1.0 million loan extended to us by John Schutte, we and Oxford entered into a fourth amendment to the Loan Agreement, or the Fourth Amendment. Pursuant to the Fourth Amendment, Oxford provided a waiver of compliance with the unqualified audit opinion covenant in connection with our receipt of our auditor's opinion with a going concern explanatory paragraph for our 2017 financial statements and allowed us to deliver financial statements up to 160 days after year end, instead of 120 days after year end.

We may voluntarily prepay the Term Loan in full, but not in part, and any prepayment is subject to a prepayment premium equal to 1% of the principal prepaid. In addition, at the maturity, termination or upon voluntary or mandatory prepayment of the Term Loan, we must pay Oxford an additional one-time interest payment of $795 thousand. We are accruing additional monthly interest expense over the term of the loan for this additional one-time interest payment using the loan's effective cash interest rate. As of December 31, 2017 and December 31, 2016, we have accumulated and accrued $700 thousand and $559 thousand, respectively, of this additional interest.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, limits or restrictions on our ability to incur liens, incur indebtedness, pay dividends, redeem stock, and merge or consolidate and dispose of assets. In addition, we must submit on an annual basis to Oxford, within 120 days after the end of its fiscal year, audited consolidated financial statements, together with an unqualified audit opinion from an independent registered public accounting firm, or the unqualified audit opinion covenant. Failure to comply with the unqualified audit opinion covenant is a breach of the Loan Agreement and unless such covenant or breach is waived, Oxford would have the option of declaring an event of default, accelerating our indebtedness under the Loan Agreement and initiating enforcement collection actions, foreclosing on collateral (which includes most assets of the Company) and, among other things, preventing the Company from using any funds in its bank or securities accounts. Per the term loan agreement an audit opinion with an explanatory paragraph noting substantial doubt about the Company's ability to continue in business (the "going concern opinion") is deemed to violate the unqualified audit opinion covenant. Oxford provided a waiver of compliance with the unqualified audit opinion covenant in connection with our receipt of our auditor's going concern opinion for our 2016 and 2017 financial statements and extended the period in which we could deliver financial statements for 2017 to 160 days after year's end (instead of 120 days). Separately, we had a covenant to have $2.5 million in cash reserves per the terms of the Oxford loan, but that was extinguished by our July 2017 private placement to Mr. Schutte of 8,912,655 shares and warrants to purchase 1,782,531 shares exercisable at $0.528 per share and expiring in July 23, 2022 for $4 million.

The Loan Agreement contains other customary events of default (some of which are subject to applicable grace or cure periods) that entitle Oxford to cause our indebtedness under the Loan Agreement to become immediately due and payable. These include, among others, non−payment defaults, covenant defaults, a material adverse change affecting us or our operations, bankruptcy and insolvency defaults and material judgment defaults.

The warrants to purchase 59,561 shares of our common stock we issued to Oxford in connection with the Term Loan, having an exercise price of $2.52 per share (as adjusted pursuant to the First Amendment and after giving effect to our one-for-five reverse stock split), are immediately exercisable for cash or by net exercise and will expire December 27, 2020.

Loan from John Schutte

In the second quarter of 2018, we borrowed a total of $1.0 million from John Schutte and issued a promissory note, or the Schutte Note, in that principal amount to him. The Schutte Note bears interest at prime plus 2.0%, and matures on January 2, 2020, at which time all principal and interest is due and is unsecured until all of our obligations to Oxford are satisfied, at which time we are required to grant Mr. Schutte a security interest in all of our assets. Events of Default under the Schutte Note are limited to bankruptcy defaults and failure to pay interest and principal when due on January 2, 2020. In addition, Mr. Schutte and Oxford entered into a subordination agreement, approved by us and APT pursuant to which Mr. Schutte subordinated the Schutte Note to our obligations to Oxford under the Loan Agreement. The Schutte Note may be prepaid at any time in whole or in part, however while Oxford's loan is outstanding such prepayment will require Oxford's consent.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies

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

Going Concern

In connection with the preparation of the consolidated financial statements for the years ended December 31, 2016 and December 31, 2017, the Company conducted an evaluation as to whether there were conditions and events, considered in the aggregate, which raised substantial doubt as to the entity's ability to continue as a going concern within one year

after the date of the issuance, or the date of availability, of the financial statements to be issued, noting that there did appear to be evidence of substantial doubt of the entity's ability to continue as a going concern as further discussed in Note 1 to the consolidated financial statements.

Revenue Recognition

We may generate license fee revenue, milestone revenue, collaboration revenue, and royalty revenue from license, commercialization and research and development agreements. As of March 16, 2017, we no longer manufacture Nexafed as we granted MainPointe an exclusive license to our Impede technology to commercialize our Nexafed products in the U.S. and Canada; prior to such date we generated revenue from our product sales of our Nexafed product line that we marketed and distributed ourselves.

Revenue is generally realized or realizable and earned when there is persuasive evidence an arrangement exists, delivery has occurred or services rendered, the price is fixed and determinable, and collection is reasonably assured. The Company had recorded revenue from its Nexafed product line sales, prior to entering into the MainPointe Agreement on March 16, 2017, when the price was fixed and determinable at the date of sale, title and risk of ownership had been transferred to the customer, and returns could be reasonably estimated.

License fee revenue can be derived from the licensing of our technologies, such as pursuant to which we licensed our Aversion® technology to KemPharm in 2016 for its use in the development and commercialization of three products using two of KemPharm's prodrug candidates or to which we licensed our Nexafed product line using our Impede Technology to MainPointe. The license fee payments received under the agreements were non-refundable and non-creditable when made and we had no further requirements to earn the payment. The amounts were recognized as revenue when received.

Collaboration revenue can be derived from research and development services we provide from time to time and are recognized when those services are incurred pursuant to the agreements. The research and development services provided under the collaboration were priced at fair value at our service's hourly labor rates pursuant to the collaboration agreement. We are not currently providing research and development services under any of our license agreements.

Royalty revenue can be derived from our licensing agreements, such as under our Collaboration and License Agreement with Egalet to commercialize Oxaydo based on Oxaydo net sales, and our License Agreement with MainPointe Pharmaceuticals LLC to commercialize our Nexafed product line, during each calendar year over the term of the agreements. We recognize royalty revenue each calendar quarter based on net sales reported to us in accordance with the agreement.

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 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 include preclinical laboratory experiments and clinical trial studies. Other activity costs include regulatory consulting, regulatory legal counsel, cost of acquiring, developing and manufacturing pre-clinical trial materials, and the costs of manufacturing scale-up. Internal R&D cost 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.

Income Taxes

We account for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities and are measured using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance against deferred income tax assets is required if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At December 31, 2017, 100% of the remaining deferred income

tax assets are offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and a benefit from income taxes in such period would be recognized.

Share-based Compensation Expense

Compensation cost related to stock-based payment transactions is measured based on fair value of the equity or liability instrument issued. For purposes of estimating the fair value of each stock option unit on the date of grant, we utilized the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of our common stock (as determined by reviewing its historical public market closing prices). Our accounting for stock-based compensation for restricted stock units, or RSUs, is based on the fair-value method. The fair value of the RSUs is the market price of our common stock on the date of grant, less its exercise cost. In May 2017, the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation (ASC 718) - Scope of Modification Accounting*. The amendments provide guidance as to how an entity should apply modified accounting in Topic 718 when changing the terms and conditions of its share-based payment awards. The guidance clarifies that modification accounting will be applied if the value, vesting conditions or classification of the award changes. The ASU is effective for annual reporting periods, including interim periods within those annual periods, beginning after December 15, 2017 but early adoption is permitted. We did not elect to adopt the standard early and do not anticipate that the standard will have a material effect, if any, on our consolidated financial statements and related disclosures.

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 2017. Our capital expenditures during 2016 were approximately $75 thousand and were primarily attributable to the purchase of machinery and equipment for the Nexafed product line.

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 our investments to fluctuate. We have no holdings of derivative financial and commodity instruments. As of December 31, 2017, we had no investments in marketable securities.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

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

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. 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, 2017, 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 2017 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The name, age and position of our directors, executive officers and key employees as of March 30, 2018 are as follows:

Name	Age	Position
Robert B. Jones	59	President, Chief Executive Officer and Director
Peter A. Clemens	65	Senior Vice President, Chief Financial Officer and Secretary
Albert W. Brzeczko, Ph.D.	61	Vice President, Technical Affairs
Robert A. Seiser	54	Vice President, Treasurer, and Corporate Controller
James F. Emigh	62	Vice President of Corporate Development
Bruce F. Wesson[(1) (2) (3)]	75	Director
William G. Skelly[(1)(2) (3)]	67	Director
Immanuel Thangaraj[(2)]	47	Director
George K. Ross[(1) (3)]	76	Director

(1) Member of audit committee.
(2) Member of compensation committee.
(3) Member of strategic transaction 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 a Certified Public Accountant

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, Technical Affairs of APT since February 2009. 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 and earned a Bachelor of Business Administration degree from Loyola University of Chicago.

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

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

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

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

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

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

Director Independence

Our shares of common stock were listed on The NASDAQ Capital Market until February 22, 2017 and were quoted on the OTCQB market until June 4, 2018**.** Our stock is currently quoted on the OTC Markets OTC pink tier. In 2016 we were subject to the Nasdaq Stock Market independence standards and we continue to follow those standards in determining whether a director is independent for Board or Committee purposes. Under the rules of The NASDAQ Stock Market, which we were subject to until February 22, 2017, independent directors must comprise a majority of our Board of Directors. In addition, the rules of The NASDAQ Stock Market require that, subject to specified exceptions, each member of the Audit and Compensation Committees of our Board of Directors be independent. Audit Committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or Exchange Act. Under the rules of The Nasdaq Stock Market, a director will only qualify as an “independent director” if, in the opinion of our Board of Directors, that person does have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

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

- accept, directly or indirectly, any consulting, advisory, or other compensatory fee from us or any of our subsidiaries; or
- be an affiliated person of us or any of our subsidiaries.

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

Corporate Governance

Our Board of Directors has established an Audit Committee, a Compensation Committee and a Strategic Transaction Committee. Currently, our entire Board serves as our 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. A brief description of these committees is provided below.

Audit Committee

The Audit Committee is composed of George K. Ross, Chairman, Bruce F. Wesson and William G. 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 2017, 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 William Skelly, Chairman, Bruce F. Wesson and Immanuel 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 2016 the Compensation Committee retained the Hay Group, an independent compensation consulting firm, to assist in evaluating stock option and other incentives for our executive officers and other employees. The retention of the Hay Group was not recommended by management.

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).

Strategic Transaction Committee

The Strategic Transaction Committee is composed of George K. Ross, Bruce F. Wesson and William G. Skelly. The Strategic Transaction Committee reviews, evaluates and recommends to the Board, for the Board's evaluation and determination, potential acquisitions, divestitures, capital raising transactions, joint ventures and strategic alliances, and licensing and collaboration transactions. All members of this Committee are considered by our Board as independent directors. The Strategic Transaction Committee does not have a Chair.

Nominating Committee

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

The experience, qualifications, attributes or skills that led the Board to conclude that the current board members should serve are: (i) their pharmaceutical industry and senior level management experience in the case of Messrs. Jones, Skelly, and Wesson; (ii) financial and senior level management expertise in the case of Mr. Ross, and (iii) their experience in overseeing management as principals of private equity firms in the case of Messrs. Wesson, and Thangaraj. Although our Certificate of Incorporation provides for a maximum of 11 directors, in accordance with the terms of a Second Amended and Restated Voting Agreement dated as of July 24, 2017 executed by us, John Schutte ("Schutte"), Essex Woodlands Health Ventures V, L.P. ("Essex") and Galen Partners III, L.P. ("Galen"), (the "Second Amended and Restated Voting Agreement"), we have agreed that the Board of Directors shall be comprised of not more than seven members (or such greater number that is required to assure that we have a majority of independent directors after giving effect to the various designation rights described herein), one of whom shall be the designee of

Schutte, one of whom shall be the designee of Essex, and one of whom shall be the designee of Galen, one of whom is our Chief Executive Officer and three of whom are independent directors. Mr. Thangaraj serves as the designee of Essex. The Second Amended and Restated Voting Agreement provides that each of Schutte's, Essex's and Galen's right to designate one director will terminate when it or its affiliates (determined separately for each of Schutte, Essex and Galen) fail to hold at least 600,000 shares of our common stock (or warrants exercisable for such shares). The Board is required to nominate an independent director upon forfeiture of a designation right. Galen has not designated a nominee since the resignation of its director designee effective December 31, 2012 and lost its right to designate a director at the end of December, 2017 upon the disposition of its shares. Mr. Schutte has not designated a nominee.

Compensation Committee Interlocks and Insider Participation

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

Separation of Roles of Chairman and CEO

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

Board's Role in Risk Assessment

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

Shareholder Communications to the Board

Shareholders who wish to send communications to our Board of Directors may do so by sending them in care of our Secretary at Acura Pharmaceuticals, Inc., 616 N. North Court, Suite 120 Palatine, Illinois 60067. The envelope containing such communication must contain a clear notation indicating that the enclosed letter is a "Shareholder-Board Communication" or "Shareholder-Director Communication" or similar statement that clearly and unmistakably indicates the communication is intended for the Board. All such communications must clearly indicate

the author as a shareholder and state whether the intended recipients are all members of the Board or just certain specified directors. Our Secretary will have the discretion to screen and not forward to Directors communications which the Secretary determines in his or her discretion are communications unrelated to our business or our governance, commercial solicitations, or communications that are offensive, obscene, or otherwise inappropriate. The Secretary will, however, compile all shareholder communications which are not forwarded and such communications will be available to any Director.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our Directors and executive officers, and persons who own beneficially more than ten percent (10%) of our common stock, to file reports of ownership and changes of ownership with the SEC. Copies of all filed reports are required to be furnished to us pursuant to Section 16(a). Based solely on the reports received by us and on written representations from reporting persons, we believe that our Directors, executive officers and greater than ten percent (10%) beneficial owners of our common stock complied with all Section 16(a) filing requirements during the year ended December 31, 2017, except that Galen Partners III, LP filed a late Form 4 on January 2, 2018, reflecting the sale of its shares on or about 12/14/2017.

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, 2017, 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 "2017 named executive officers") whose total annual compensation for 2017 exceeded $100,000:

Name and Principal Position	Year	Base Salary ($)	Bonus ($)	**Stock Awards[1] ($)**	**Option Awards[2] ($)**	Non-equity incentive plan compensation ($)	Total ($)
Robert B. Jones,	2016	393,000	—	—	36,237	—	429,237
President and CEO	2017	393,000	—	13,530	14,617	—	421,147
Peter A. Clemens	2016	286,000	—	—	26,214	—	312,214
SVP & CFO	2017	286,000	20,000	9,240	10,574	—	325,814
Albert W. Brzeczko	2016	291,000	—	—	26,985	—	317,985
VP, Technical Affairs of Acura Pharmaceutical Technologies, Inc.	2017	291,000	—	9,240	10,885	—	311,125

(1) Grant date fair values are computed in accordance with FASB ASC Topic 718. Values represent (A) our last sale price of $0.34 on 12/11/2017 less $.01 par value multiplied by (B) the number of shares underlying RSUs (41,000, 28,000 and 28,000, in the case of Messrs. Jones, Clemens and Brzeczko, respectively).

(2) The 2016 entries reflect the grant date fair value of options with respect to 47,000, 34,000, and 35,000 underlying shares to Messrs. Jones, Clemens and Brzeczko, respectively. The 2017 entries reflect the grant date fair value of options with respect to 47,000, 34,000, and 35,000 underlying shares to Messrs. Jones, Clemens and Brzeczko, respectively. Grant date fair values are computed in accordance with FASB ASC Topic 718. To calculate grant date fair value, we consider an assumed risk free interest rate and a historical volatility percentage for our common stock, with an expected divided yield of 0% and an expected term of 10 years, with respect to option granted in 2016 and an expected term of 5 years with respect to options granted in 2017. For options issued in 2016 we used a risk free interest rate of 2.34% and historical volatility of 85.27%. For options issued in 2017 we used a risk free interest rate of 1.8% and historical volatility of 88%. In all cases we excluded the possibility of forfeiture. We calculated values based on 10 year option terms for options issued in 2016 and 5 year option terms for options issued in 2017.

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Other Compensatory Arrangements

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

Bonus/Non-Equity Incentive Plan

Each of Messrs. Jones, Clemens and Brzeczko are eligible for annual bonuses. Each of Mr. Jones' and Mr. Clemens' bonuses are weighted 100% to achievement of organizational goals, while the bonuses for other employees, including for Dr. Brzeczko are weighted 50% to the achievement of organizational goals and 50% to the achievement of individual goals. Amounts paid are reflected in the "Non-equity Incentive Compensation" column of the Summary Compensation Table.

Material organizational goals for 2016 were advancing the success of Nexafed on the U.S. market, developing Impede Technology products, the continued development of our Limitx technology product candidates, executing partnerships around our Aversion or Impede technologies, executing partnerships/transactions around our Limitx technology, compliance with SOX, successfully managing our intellectual property, the execution of transactions to further build our cash, and meeting year-end cash targets. The Compensation Committee determined that 20% of the organizational goals were met in 2016. However because of our desire to preserve cash, no bonuses were paid in 2016 to Messrs. Jones, Clemens or Brzeczko.

Material organizational goals for 2017 were advancing Limitx reformulations and at Board's discretion executing certain clinical studies, successfully completing ongoing development using Impede technology for a third party and receiving the associated milestone, engaging in a strategic transaction for Nexafed and Nexafed Sinus (so as to maintain the products' sales and distribution levels), executing strategic transaction, partnership or financings to maximize value to our shareholders and debt holder, compliance with SOX and successfully managing our intellectual property. The receipt of a milestone to successfully complete ongoing development work using Impede technology was not achieved as the Bayer agreement was terminated. The milestone for engaging in a strategic transaction for Nexafed and Nexafed sinus products was achieved through our transaction with MainPointe Pharmaceuticals, LLC. In addition, we engaged in one $4 million financing, which at least partially met the goal of engaging in financings. See "Certain Relationships and Related Transactions, and Director Independence" for a description of the transaction with MainPointe Pharmaceuticals, LLC and the $4 million financing. The Board concluded that 36% of organizational goals were met. Our 2017 named executive officers did not receive any payments under our non-equity incentive plan, except that Mr. Clemens received a $20,000 bonus outside of such plan.

Material organizational goals for 2018 include conducting clinical trials on our LTX-03 compound, complete ongoing development using Impede technology, executing strategic transaction, partnership or financings to maximize value to the Company's shareholders and debt holder, compliance with SOX and successfully managing 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' salary was increased from $392,000 to $393,000 commencing January 1, 2016. The term of the Employment Agreement is currently scheduled to expire December 31, 2018, 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 2016, Mr. Jones did not receive a bonus. On December 11, 2014, December 10, 2015, December 8, 2016, and August 9, 2017 we granted Mr. Jones stock options to purchase 50,400 shares, 70,000, 47,000 and 47,000 shares of our common stock, respectively, in each case exercisable at the fair market value of our common stock at the date of grant and vesting in equal installments over 24 months, except that the August 9, 2017 grant vests in one installment on August 9, 2018 (in each case, subject to earlier exercisability as set forth in the table below entitled "Events Affecting Stock Option Vesting and Exercise"). On December 11, 2017, we granted Mr. Jones 41,000 Restricted Stock Units exchangeable for 41,000 shares of the Company on a 1-for-1 basis after payment of $.01 par value per share. The Restricted Stock Units vest on December 11, 2018 or earlier if Mr. Jones' service as an employee is terminated by us without Cause (as defined in the 2017 Restricted Stock Unit Award Plan) or due to his death or Disability (as defined in the 2017 Restricted Stock Unit Award Plan) or a qualifying change of control occurs. Distributions in respect of such vested Restricted Stock Units will be made in three equal installments on the first business day of each of January 2020, 2021, and 2022 or earlier upon a qualifying change of control which also meets certain criteria of Section 409A of the Internal Revenue Code. The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause. In the event that we terminate the Employment Agreement without Cause or Mr. Jones terminates the Employment Agreement for Good Reason, we are required to pay Mr. Jones an amount equal to the bonus for such year, calculated on a pro-rata basis assuming full achievement of the bonus criteria for such year (to the extent it has not already been paid), as well as Mr. Jones' base salary for one year (such salary amount being the "Severance Pay"). Pursuant to an amendment to Mr. Jones'

Employment Agreement entered into in 2012, in case of termination without Cause and for Good Reason or for voluntary termination more than two years after a Change of Control, such Severance Pay and bonus is payable in equal monthly installments over a period of twelve months, with the first six installments payable six months and one day after termination, if mandated by applicable law, which requires certain payments to certain officers of a public company ("specified employees") to be made commencing six months after termination. However, if such termination is without Cause, for Good Reason or for voluntary termination within two years of a qualifying Change of Control, then the Severance Pay and bonus is payable in a lump sum six months and one day after termination (unless a six month delay is not required by applicable law in which case it is payable 31 days after termination). In addition, upon a termination without Cause or for Good Reason or voluntarily after a Change of Control, any shares remaining unvested under stock options and restricted stock units granted to Mr. Jones will vest in full and Mr. Jones will be entitled to continued coverage under our then-existing benefit plans, including medical and life insurance, for twelve months from the date of termination.

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

Peter A. Clemens is employed pursuant to an Employment Agreement effective as of March 10, 1998, as amended, which provides that Mr. Clemens will serve as our Senior Vice President and Chief Financial Officer for a term currently scheduled to expire December 31, 2018, 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 current base salary under the Employment Agreement is $286,000 (increased from $285,000 effective January 1, 2016). His maximum bonus under our bonus plan is 70% of base salary. Mr. Clemens' bonus is based on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. On August 9, 2017 we granted Mr. Clemens a special bonus outside the bonus plan of $20,000 for his efforts in the negotiation and closing of our July 2017 private equity financing. On December 11, 2014, December 10, 2015, December 8, 2016 and August 9, 2017 we granted Mr. Clemens options to purchase 36,000 shares, 50,000 shares, 34,000 shares and 34,000 shares of our common stock, respectively, in each case at an exercise price equal to the fair market value of our common stock at the date of grant and vesting in equal installments over 24 months, except that the August 9, 2017 grant vests in one installment on August 9, 2018 (in each case, subject to earlier exercisability as set forth in the table below entitled "Events Affecting Stock Option Vesting and Exercise"). On December 11, 2017, we granted Mr. Clemens 28,000 Restricted Stock Units exchangeable for 28,000 shares of the Company on a 1-for-1 basis after payment of $.01 par value per share. The Restricted Stock Units vest on December 11, 2018 or earlier if Mr. Clemens' service as an employee is terminated by us without Cause (as defined in the 2017 Restricted Stock Unit Award Plan) or due to his death or Disability (as defined in the 2017 Restricted Stock Unit Award Plan) or a qualifying change of control occurs. Distributions in respect of such vested Restricted Stock Units will be made in three equal installments on the first business day of each of January 2020, 2021, and 2022 or earlier upon a qualifying change of control which also meets certain criteria of Section 409A of the Internal Revenue Code.

The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause. In the event the Employment Agreement is terminated by us without Cause or by Mr. Clemens for Good Reason, we are required to pay Mr. Clemens an amount equal to twice his then base salary, payable in the case of termination without Cause or for Good Reason six months and one day after termination (unless he is not a specified employee at termination in which case payment is in a lump sum within 30 days following termination) and to continue to provide Mr. Clemens coverage under our then existing benefit plans, including medical and life insurance, for a term of 24 months. The Employment Agreement permits Mr. Clemens to terminate

the Employment Agreement in the event of a Change in Control (as defined in the Employment Agreement), in which case he would receive the same payments on the same schedule as on a termination for Good Reason. In addition, Mr. Clemens' estate is entitled to six month's salary upon his death as well as a pro rata bonus for the number of months he worked in the year of his death. The Employment Agreement also restricts Mr. Clemens from disclosing, disseminating or using for his personal benefit or for the benefit of others confidential or proprietary information (as defined in the Employment Agreement) and, provided we have not breached the terms of the Employment Agreement, from competing with us at any time prior to two years after the earlier to occur of the expiration of the term and the termination of his employment. In addition, for a period of two years from and after the effective date of the termination of his employment with us (for any reason whatsoever), (i) induce or attempt to influence any employee of the Corporation or any of its subsidiaries or affiliates to leave its employ, or (ii) aid any person, business, or firm, including a supplier, a competitor, licensor or customer of or our manufacturer for the Corporation, in any attempt to hire any person who shall have been employed by us or any of our subsidiaries or affiliates within the period of one year of the date of any such requested aid. The table entitled "Events Affecting Stock Option Vesting and Exercise," below, summarizes the vesting and exercisability of Mr. Clemens' options following a number of termination scenarios or a Change of Control.

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

- acquisition by a person or group of more than 50% of our outstanding shares
- a merger, reorganization, consolidation of exchange, other than one in which current holders of our voting securities hold more than 50% of our voting securities
- a merger in which we are not the surviving corporation
- a sale or license of substantially all of our assets
- Acura going private (i.e. no longer files reports under the Exchange Act), unless the relevant employee (e.g., Jones, in the case of Jones' severance and Clemens in the case of Clemens' severance) "participates" in such transaction

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

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

Change of Control	Options fully vest for Mr. Jones and Mr. Clemens.	Vested options immediately exercisable

Dr. Brzeczko is not party to an employment agreement. Dr. Brzeczko was hired pursuant to an offer letter pursuant to which he received a $40,000 signing bonus and commencing 2016 and thereafter, is eligible for annual bonuses of up to 50% of his base salary (increased from 35% in effect during 2015). Dr. Brzeczko's bonus is based on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. In 2017 he received no bonus. Upon commencement of his employment on February 9, 2009, he received 4,800 RSUs vesting in equal installments over 24 months, and stock options exercisable for 19,200 shares of common stock vesting in equal installments over 24 months. Dr. Brzeczko's annual salary is $291,000 (increased from $290,000 effective January 1, 2016). Dr. Brzeczko is eligible for and over the years of his employment, Dr. Brzeczko has received annual option grants. On December 8, 2016, Dr. Brzeczko was granted stock options exercisable at the fair market value on date of grant for 35,000 shares of common stock, vesting in equal installments over 24 months and on August 9, 2017 Dr. Brzeczko was granted stock options exercisable at the fair market value on date of grant for 35,000 shares of common stock, vesting in one installment in 12 months from grant and expiring five years from issuance. If a change of control occurs (which constitutes a change of control under the stock option agreements) previously unvested options vest and become exercisable with respect to all underlying shares held by Dr. Brzeczko. On December 11, 2017, we granted Dr. Brzeczko 28,000 Restricted Stock Units exchangeable for 28,000 shares of the Company on a 1-for-1 basis after payment of $.01 par value per share. The Restricted Stock Units vest on December 11, 2018 or earlier if Dr. Brzeczko's service as an employee is terminated by us without Cause (as defined in the 2017 Restricted Stock Unit Award Plan) or due to his death or Disability (as defined in the 2017 Restricted Stock Unit Award Plan) or a qualifying change of control occurs. Distributions in respect of such vested Restricted Stock Units will be made in three equal installments on the first business day of each of January 2020, 2021, and 2022 or earlier upon a qualifying change of control which also meets certain criteria of Section 409A of the Internal Revenue Code.

Stock Option Plans

We maintain three stock option plans adopted in 1998, 2008 and 2016, respectively. Our option plans are administered by the Board of Directors. The Board of Directors selects the employees, directors and consultants to be granted options under the plans and, subject to the provisions of each plan, determines the terms and conditions and number of shares subject to each option. Any of our employees or employees of our subsidiary are eligible to receive incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, or the Code ("ISOs"). Non-qualified stock options may be granted to employees as well as non-employee directors and consultants under the plans as determined by the Board. Any person who has been granted an option may, if they are otherwise eligible, be granted an additional option or options.

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

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

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

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

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

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

The 1998 Stock Option Plan

The 1998 Stock Option Plan was adopted by the Board of Directors in April 1998 and approved by our shareholders in June 1998. The 1998 Stock Option Plan, as amended, provided for the grant of stock options to purchase up to 400,000 shares of our common stock. As of December 31, 2017, stock options to purchase 18,000 shares of common stock are outstanding under the 1998 Stock Option Plan. Of such option grants 6,000 are ISO's and 12,000 are non-qualified options. No exercise price of an ISO was set at less than 100% of the fair market value of the underlying common stock.

In April 2008 the 1998 Stock Option Plan expired and the remaining 4,382 unissued shares allocated to the Plan were terminated. The average per share exercise price for all outstanding options under the 1998 Stock Option Plan as of December 31, 2017 was $36.07.

The 2008 Stock Option Plan

The 2008 Stock Option Plan was adopted by the Board of Directors on March 14, 2008 and approved by our shareholders on April 30, 2008. 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. The 2008 Stock Option Plan permits the grant of ISO's and non-qualified stock options to purchase in the aggregate up to 1,200,000 shares of our common stock. As of December 31, 2017, stock options to purchase 1,122,593 shares of common stock had been granted (and not forfeited) under the 2008 Stock Option Plan. Of such option grants, 715,631 are ISOs and 406,962 are non-qualified options. The average per share exercise price for all outstanding options under the 2008 Stock Option Plan as of December 31, 2017 was $15.61.

The 2016 Stock Option Plan

The 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, 2017, stock options to purchase 353,356 shares of common stock had been granted (and were not forfeited) under the 2016 Stock Option Plan. Of such option grants, 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 average per share exercise price for all outstanding options under the 2016 Stock Option Plan as of December 31, 2017 was $0.67.

Restricted Stock Unit Award Plan

The 2014 Restricted Stock Unit Award Plan

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

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

As of March 30, 2018 we had granted RSUs under the 2014 RSU Plan providing for our issuance of up to an aggregate of 396,844 shares of our common stock. At March 30, 2018, no RSU awards were outstanding under our 2014 RSU Plan. To date we have only issued RSUs under the 2014 RSU Plan to our Non-Employee Directors. Because there were less than 4,000 shares available for issuance under the 2014 RSU Plan, in November 2017, our shareholders approved the 2017 Restricted Stock Unit Award Plan. We do not intend to issue any more RSUs under the 2014 RSU Plan.

The description of the 2017 Restricted Stock Unit Award Plan, under the captions, "Terms", "Administration", "Amendment and Termination", and "Adjustment upon Capitalization and Merger", below are similar to the provisions of the 2014 RSU Plan, with the significant differences noted under such captions.

The 2017 Restricted Stock Unit Award Plan

The Company's 2017 Restricted Stock Unit Award Plan (the "2017 RSU Plan") was approved by the Company's Board of Directors on September 8, 2017 and approved by shareholders on November 8, 2017. Under the 2017 RSU Plan, a Restricted Stock Unit ("RSU") represents the right to receive (upon payment of $0.01 par value per share) a share of the

Company's common stock (or under certain circumstances, cash in lieu thereof ("Cash Settled RSUs")) at a designated time or upon designated events.

Number of RSUs that may be granted. The maximum aggregate number of shares which may be subject to RSUs granted under the 2017 RSU Plan is 1,500,000 shares of authorized, but unissued, or reacquired common stock. (See "Adjustments Upon Changes in Capitalization or Merger" below.) If an RSU should expire or become forfeited for any reason without the underlying shares of common stock or cash subject to such RSU having been distributed, the underlying shares shall, unless the 2017 RSU Plan shall have been terminated, become available for further grant under the 2017 RSU Plan. The 2017 RSU Plan has no limit on the number of RSUs that may be granted to an individual employee, consultant or director in any calendar year. Payment of Cash Settled RSUs (as hereinafter defined) will reduce such limit. As of March 30, 2018 approximately 467,000 RSUs have been granted under the 2017 RSU Plan. Unless terminated earlier by the Board of Directors, the RSUs may be distributed under the 2017 RSU Plan until November 7, 2027, however we expect that RSUs available under the Plan will have been distributed within the next four years. The 2017 RSU Plan allows for amendment by the Board of Directors, provided shareholder approval for the amendment is not required under the rules of an exchange on which our stock is listed or applicable law.

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

Administration

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

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

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

RSU Plan Eligibility. RSUs may be granted to any of the Company's Non-Employee Directors, any of the Company's employees or consultants, or any employees or consultants of any of the Company's subsidiary corporations, including officers (collectively, "Eligible Participants"). For purposes of the 2017 RSU Plan employees or consultants of the Company also mean employees or consultants of the Company's subsidiary. As of March 30, 2018 all of the Company's 14 full-time employees and four Non-Employee Directors of the Company will be eligible participants ("Participants") in the 2017 RSU Plan. Any Eligible Participant who has been granted an RSU may be granted additional RSUs. The RSU Plan does not confer any rights upon any Participant with respect to continuation of employment or service as an employee, consultant or a Non-Employee Director.

Terms.

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

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

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

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

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

Distribution of Shares Underlying RSUs. Under the 2017 RSU Plan, (unless an award provides otherwise, vesting is accelerated as provided above under "Vesting of RSUs" or a Change of Control-Plan occurs as described below), stock underlying vested RSUs is generally distributed on the first business day of the year after they vest. Hence, if an award to a Non-Employee Director vests as scheduled in full over four quarters during 2018, it will be generally be distributed the first business day of January 2019. However, the Company may set other distribution dates, with respect to awards to Participants, including Non-Employee Directors. Under the 2014 RSU Plan Non-Employee Directors (but not other Participants) could designate the length of the deferrals. This is not the case with the 2017 RSU Plan, where only the Company can set the distribution dates for all Participants. Non-Employee-Directors may elect to take payment in cash instead of stock for up to 40% of the RSUs in an award (rendering such RSUs as "Cash Settled RSUs"). With respect to Participants for whom the Company is required to withhold taxes (generally employees) the Company may mandate such Participants or such Participants may elect that the Company withhold stock otherwise payable on exchange of an RSU to pay withholding taxes (this differs from the 2014 RSU Plan where the Company could not mandate withholding stock to pay withholding taxes). The cash payment election or withholding election may be made at anytime 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. Under the Company's current loan agreement with Oxford Finance LLC, there is an annual limit of $350,000 ("Redemption Limit") on the amount of redemptions the Company may make (which includes payment on Cash Settled RSUs, withholding of stock for taxes and par value). The Company has the option of establishing a RSU award that defers distributions to a Participant, including in installments (e.g., 25% of RSUs to be paid in 2019, 2020, 2021 and 2022). If a Change of Control-Plan which is also a Change in Control-409A occurs, all vested shares of common stock underlying an RSU (after payment or withholding of $0.01 per share par value) will be distributed by the Company to the holder of the RSU at or about the time of the Change in Control-Plan. No dividends accrue on shares of common stock underlying RSUs prior to distribution. Participants need not be employees, consultants or directors of the Company on a distribution date. A Change in Control-409A for distribution purposes is generally the same as a Change in Control-Plan for vesting purposes, except that in order to have a Change in Control-409A for distribution purposes, a change in control qualifying under Section 409A of the Code must occur. In lieu of requiring cash payment of par value, the Company may, in its discretion or shall at the Participant's request, accept payment of any such par value by withholding from stock payments a number of whole shares of stock whose value is equal to the amount of such par value, provided the same does not cause the Redemption Limit to be exceeded.

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

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

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

Amendment and Termination of the RSU Plan

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

Adjustments upon Changes in Capitalization or Merger

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

Outstanding Equity Awards at 2017 Year End

The following table presents information regarding outstanding restricted stock unit and stock option awards at December 31, 2017 for each of the 2017 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(3)	Market value of shares of units of stock that have not vested(4)
Robert B. Jones	6,000	—		$ 43.20	04/06/2018	41,000	16,148
	32,000	—		$ 49.35	05/23/2018		
	32,000	—		$ 31.45	04/23/2019		
	50,000	—		$ 15.10	12/15/2020		
	16,000	—		$ 18.60	12/14/2021		
	18,000	—		$ 13.05	12/13/2022		
	27,500	—		$ 7.75	12/11/2023		
	50,400	—		$ 2.60	12/10/2024		
	70,000	—		$ 2.01	12/09/2025		
	25,458(1)	21,542	(1)	$ 0.915	12/09/2026		
	—	47,000	(2)	$ 0.45	08/08/2022		
Peter A. Clemens	20,000	—		$ 49.35	05/23/2018	28,000	10,898
	24,000	—		$ 31.45	04/23/2019		
	8,000	—		$ 15.10	12/15/2020		
	7,000	—		$ 18.60	12/14/2021		
	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		
	18,417(1)	15,558	(1)	$ 0.915	12/09/2026		
	—	34,000	(2)	$ 0.45	08/08/2022		
Albert W. Brzeczko	19,200	—		$ 28.50	02/08/2019	28,000	10,898
	6,400	—		$ 15.10	12/15/2020		
	7,000	—		$ 18.60	12/14/2021		
	14,000	—		$ 13.05	12/13/2022		
	15,000	—		$ 7.75	12/11/2023		
	28,800	—		$ 2.60	12/10/2024		

50,000	16,041	(1)	$ 2.01	12/09/2025
18,958	(1) 35,000	(2)	$ 0.915	12/09/2026
—			$ 0.45	08/08/2022

(1) 1/24th of total option issuance (vested and unvested) becomes exercisable on the last day of each month after issuance, and under certain other circumstances.

(2) Options vest on August 9, 2018.

(3) Restricted Stock Units vest on December 11, 2018 or earlier under certain circumstances. Distributions in respect of vested Restricted Stock Units will be made in three equal installments on the first business day of each of January 2020, 2021, and 2022 or earlier upon a qualifying change of control which also meets certain criteria of Section 409A of the Internal Revenue Code.

(4) Based on market price of $0.40 at December 29, 2017, less $0.01 par value, multiplied by number of units.

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, 2017:

2017 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	$ 47,500		$ 50,000	—	$97,500
Bruce F. Wesson	$ 42,500		$ 50,000	—	$92,500
Immanuel Thangaraj	$ 28,750	[3][4]	$ 50,000	—	$78,750
George K. Ross	$ 52,500		$ 50,000	—	$102,500

(1) Represents the grant date fair value of restricted stock units, or RSUs with respect to the 59,523 RSUs granted to Messrs. Skelly, Wesson, Thangaraj and Ross under our 2014 RSU Plan based on a closing price of $0.84 on January 3, 2017.

Each director realized $8,800 on March 31, 2017, $8,184 on June 30, 2017, $6,547 on September 30, 2017 and $5,803 on December 31, 2017 as a result of the vesting of 14,880.75 RSUs on each of such dates (based on closing prices of our common stock of $0.60 on March 31, 2017, $0.56 on June 30, 2017, $0.45 on September 29, 2017 and $0.40 on December 29, 2017).

Additionally, in January 2017, Mr. Skelly exchanged 13,216 RSUs at $0.01 par value per share, for 13,216 shares of common stock and exchanged 8,810 RSUs for approximately $6,800 in cash. In January 2017, Mr. Wesson exchanged 22,026 RSUs at $0.01 par value per share, for 22,026 shares of common stock. In January 2017, Mr. Thangaraj exchanged 13,216 RSUs at $0.01 par value per share, for 13,216 shares of common stock and exchanged 8,810 RSUs for approximately $6,800 in cash. In January 2017, Mr. Ross exchanged 735 RSUs at $0.01 par value per share, for 735 shares of common stock and exchanged 490 RSUs for approximately $400 in cash.

As of December 31, 2017, Messrs. Skelly and Wesson, Thangaraj each held 59,523 fully vested RSUs and Mr. Ross held 82,774 fully vested RSUs.

(2) Each of Messrs. Skelly, Wesson, Thangaraj and Ross held vested options with respect to 18,000 underlying shares as of December 31, 2017.

(3) Committee and board meeting attendance fees waived.

(4) Directors fees paid to Mr. Thangaraj are remitted to Essex Woodlands.

Our Director compensation program is as follows:

- the annual retainer for each non-employee director of $30,000;
- there are no separate Board meeting fees;
- an additional retainer for the Chairman of the Board (unfilled at present) of $20,000;
- Audit Committee members receive a retainer of $7,500 per year (with no separate per meeting fee);
- Audit Committee Chairperson receives an additional annual retainer of $10,000 (in addition to the $7,500 retainer as an Audit Committee member);
- Compensation Committee members receive an annual retainer of $5,000 with no separate per meeting fee;
- Compensation Committee Chairperson receives a $5,000 annual retainer (in addition to the $5,000 retainer for Compensation Committee members); and
- Strategic Transaction Committee Members receive a $250 per meeting fee.

The annual retainer fees are payable in four equal installments at the end of each calendar quarter during the year.

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 (i) greater of the Company's closing stock price on the date of grant, and (ii) the minimum stock price (if any) imposed by the Board. For the 2014 and 2016 award there was no minimum stock price. For the 2015 award the minimum stock price was set at $4.85, and as a result Directors received less than $50,000 of value. For the 2017 award, in which each director received 59,523 RSUs, the minimum stock price was set at $0.83, but as the closing price of the stock on the date of grant was higher, and the directors received the full $50,000 of value. For 2018, the Board has decided there will be a minimum stock price or floor of $0.75 and as a result each nonemployee director received 66,666 Restricted Stock Units on January 2, 2018. For 2019 and beyond the floor will be $1.00, in each case, subject to reevaluation by the Board. Directors who are also our employees receive no additional or special remuneration for their services as Directors. We also reimburse Directors for travel and lodging expenses, if any, incurred in connection with attendance at Board meetings.

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 March 15, 2018, 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 2017 exceeded $100,000 (the "2017 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 March 30, 2018, there were 21,033,528 shares of our common stock outstanding. Shares of common stock issuable pursuant to stock options, warrants and restricted stock units exercisable or exchangeable within 60 days are deemed outstanding and held by the holder of such options warrants or restricted stock units for computing the percentage of the person holding such options, warrants or restricted stock units, but are not deemed outstanding for computing the percentage of any other person. There were no restricted stock units exchangeable within 60 days of March 15, 2018.

Name of Beneficial Owner	Amount Owned		**Percent of Class** [(1)]	
John Schutte c/o MainPointe Pharmaceuticals, LLC 333 E. Main Street Louisville, KY 40202	10,695,186	(2)	47.5	%
Essex Woodlands Health Ventures Fund V, L.P. 21 Waterway Avenue, Suite 225 Woodlands, TX 77380	1,956,357	(3)	9.4	%
Robert B. Jones	747,746	(4)	3.5	%
William G. Skelly	202,868	(5)	1.0	%
Bruce F. Wesson	468,927	(6)	2.2	%
Peter A. Clemens	549,215	(7)	2.6	%
Immanuel Thangaraj	74,526	(8)	*	%
Albert W. Brzeczko	481,191	(9)	2.3	%
George K. Ross	159,339	(10)	*	%
All Officers and Directors as a Group (9 persons)	3,652,397	(11)	16.7	%

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

(1) Shows percentage ownership assuming (i) such party converts all of its currently convertible securities or securities convertible within 60 days of March 15, 2018 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 2017 named executive officer has been pledged as collateral security.

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

(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. Martin P. Sutter and Immanuel Thangaraj may be deemed to have shared dispositive power and voting power with respect to the securities held by the Essex. Messrs. Sutter and Thangaraj disclaim beneficial ownership of such securities except to the extent of their respective pecuniary interests therein.

(4) Includes 335,191 shares subject to stock options exercisable within 60 days of March 15, 2018. Does not include RSUs.

(5) Includes 18,000 shares subject to stock options exercisable within 60 days of March 15, 2018. Does not include RSUs.

(6)

Includes 18,000 shares subject to stock options exercisable within 60 days of March 15, 2018. Does not include RSUs.

(7) Includes 194,082 shares subject to stock options exercisable within 60 days of March 15, 2018. Does not include RSUs.

(8) Includes 18,000 shares subject to stock options exercisable within 60 days of March 15, 2018. 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 165,191 shares subject to stock options exercisable within 60 days of March 15, 2018. Does not include RSUs.

(10) Includes 18,000 shares subject to stock options exercisable within 60 days of March 15, 2018. Does not include RSUs.

(11) Includes 972,899 shares which Directors and executive officers have the right to acquire within 60 days of March 15, 2018 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, 2017 relating to our 1998 Stock Option Plan, our 2008 Stock Option Plan, our 2016 Stock Option Plan, our 2014 Restricted Stock Unit Award Plan, and our 2017 Restricted Stock Award Plan, which comprise all of our equity compensation plans. The table provides the number of securities to be issued upon the exercise of outstanding options and distributions under outstanding Restricted Stock Unit Awards under such plans, the weighted-average exercise price of outstanding options and the number of securities remaining available for future issuance under such equity compensation plans:

Plan Category	Number Of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (Column a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (Column b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column a (Column c)
Stock Option Equity Compensation Plans Approved by Security Holders	1,493,949	$ 12.33	245,478
Stock Option Equity Compensation Plans Not Approved by Security Holders	—	—	—
Restricted Stock Unit Equity Compensation Plans Approved by Security Holders	461,343	$ 0.01	1,061,908
Restricted Stock Unit Equity Compensation Plans Not Approved by Security Holders	—	—	—
TOTAL	1,955,292	$ 9.42	1,307,386

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 each of Galen, Care Capital Investments II, LP ("Care Capital") and 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, Messrs. Azad, Markham and Thangaraj, became the designees of Galen, Care Capital and Essex, respectively, as successors to GCE Holdings, LLC (an entity controlled by Galen, Care and Essex). Mr. Azad resigned effective December 31, 2012 and has not been replaced by Galen. Mr. Markham resigned effective March 11, 2013 and was never replaced by Care Capital. Neither Care Capital nor Galen is currently entitled to designate a director as they no longer hold the requisite amount of our equity. In addition, Essex has (and Galen and Care Capital had) the right to designate a member to any committee of our Board of Directors, provided that in the case of the Audit and Compensation committees they are independent under applicable NASDAQ rules.

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

On signing, MainPointe paid us an upfront licensing fee of $2.5 million plus approximately $425,000 for inventory and equipment being transferred. We will receive a 7.5% royalty on sales of licensed products. The royalty payment for each product will expire on a country-by-country basis when the Impede® patent rights for such country have expired or are no longer valid; provided that if no Impede patent right exists in a country, then the royalty term for that

country will be the same as the royalty term for the United States. After the expiration of a royalty term for a country, MainPointe retains a royalty free license to our Impede® technology for products covered by the Agreement in such country.

MainPointe has the option to expand the territory beyond the United States and Canada to the European Union (and the United Kingdom), Japan and South Korea for payments of $1.0 million, $500,000 and $250,000, respectively. In addition, MainPointe has the option to add to the Agreement certain additional products, or Option Products, containing PSE and utilizing the Impede technology for a fee of $500,000 per product (for all such product strengths). If the territory has been expanded prior to the exercise of a product option, the option fee will be increased to $750,000 per product. If the territory is expanded after the payment of the $500,000 product option fee, a one-time $250,000 fee will be due for each product. If a third party is interested in developing or licensing rights to an Option Product, MainPointe must exercise its option for that product or its option rights for such product will terminate.

On July 24, 2017 we completed the sale to Mr. Schutte of 8,912,655 shares and warrants to purchase 1,782,531 shares exercisable at $0.528 per share and expiring in July 23, 2022 for $4 million and amended the Voting Agreement described above (as so amended the "Second Amended and Restated Voting Agreement") in connection with that purchase The Second Amended and Restated Voting Agreement was entered into following Care Capital's no longer holding 600,000 shares but prior to Galen's no longer holding 600,000 shares. 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 Galen, John 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 Galen, Essex and John 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. As of late December, 2017, Galen no longer held the requisite amount of shares (when it completed the sale of 2,195,734 shares, at a price of $0.10 per share, severally to various officers, employees and non-employee directors of the Company) to designate a director to the Board or a Committee, a right which it had not recently exercised.

In the second quarter of 2018, we borrowed a total of $1.0 million from John Schutte and issued a promissory note, or the Schutte Note, in that principal amount to him. The Schutte Note bears interest at prime plus 2.0%, and matures on January 2, 2020, at which time all principal and interest is due, and is unsecured until all of our obligations to Oxford are satisfied, at which time we are required to grant Mr. Schutte a security interest in all of our assets. Events of Default under the Schutte Note are limited to bankruptcy defaults and failure to pay interest and principal when due on January 2, 2020. In addition, Mr. Schutte and Oxford Finance, LLC, or Oxford, entered into a subordination agreement, approved by us and APT pursuant to which Mr. Schutte subordinated the Schutte Note to our obligations to Oxford under our loan and security agreement with Oxford, or the Loan Agreement. The Schutte Note may be prepaid at any time in whole or in part at any time, however while Oxford's loan is outstanding such prepayment will require Oxford's consent. Also, in connection with the loan, we and Oxford entered into a fourth amendment to the Loan Agreement, or the Fourth Amendment. Pursuant to the Fourth Amendment, Oxford provided a waiver of compliance with the unqualified audit opinion covenant in connection with our receipt of our auditor's opinion with a going concern explanatory paragraph for our 2017 financial statements and allowed us to deliver financial statements up to 160 days after year end, instead of up to 120 days after year end.

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, Galen, 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 formally establishes a committee

comprised solely of independent directors to review and evaluate such proposed transaction, or the Independent Committee. The Independent Committee is authorized to review any and all information it deems 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 appropriate by the Independent Committee) and evaluating alternative transactions, if any. The Independent Committee is 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 Independent Committee. Following the Independent Committee's approval, the related party transaction is subject to final review and approval of the Board as a whole, with any interested director abstaining from such action. As the transactions described above with MainPointe and Mr. Schutte did not involve a related party at the time such transactions were entered into, the Board determined that an Independent Committee was not necessary and such transactions were reviewed and approved solely by the Board as a whole. With respect to the $1.0 million loan provided by Mr. Schutte, an independent committee reviewed and approved the transaction.

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 2017, 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 2017 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 2017 and 2016 were as follows:

	2017	2016
Audit Fees	$149,898	$173,558
Audit-Related Fees	-	-
Total Audit and Audit-Related Fees	149,898	173,558
Tax Fees	41,090	63,990
All Other Fees	-	-
Total for BDO USA, LLP	$190,988	$237,548

Audit Fees include professional services rendered in connection with the annual audit of our financial statements, and the review of the financial statements included in our Form 10-Qs for the related periods. Additionally, Audit Fees include other services that only an independent registered public accounting firm can reasonably provide, such as services associated with our SEC registration statements or other documents filed with the SEC or used in connection with financing activities. We had no Audit-Related Fees which would include accounting consultations related to accounting, financial reporting or disclosure matters not classified as Audit Fees.

Tax Fees include tax compliance, tax advice and tax planning services. These services related to the preparation of various state income tax returns, our federal income tax return, and reviews of IRC Section 382.

Audit Committee's Pre-Approval Policies and Procedures

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

All of the audit-related, tax and other services provided by BDO USA, LLP in 2017 and 2016 and related fees (as described in the captions above) were approved in advance by the Audit Committee.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

Date: June 7, 2018 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 7, 2018
/s/ Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	June 7, 2018
/s/ William G. Skelly William G. Skelly	Director	June 7, 2018
/s/ Bruce F Wesson Bruce F. Wesson	Director	June 7, 2018
/s/ George K. Ross George K. Ross	Director	June 7, 2018

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ACURA PHARMACEUTICALS, INC

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report Of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Acura Pharmaceuticals, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Acura Pharmaceuticals Inc. (the "Company") and subsidiary as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiary at December 31, 2017 and 2016, and the results of their operations and their cash flows for the years then ended December 31, 2017**,** 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, deficiencies in working capital and equity and has not generated positive cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ BDO USA, LLP

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

Chicago, Illinois

June 7, 2018

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2017 and 2016

(in thousands, except par value)

	2017	2016
Assets:		
Cash and cash equivalents	$2,220	$2,681
Restricted cash equivalents (Note 7)	-	2,500
Trade accounts receivable (net of allowances of $- and $7)	-	23
Collaboration revenue receivable	-	79
Royalty receivable	71	50
Inventories (net of allowances of $- and $32) (Note 4)	-	309
Prepaid expenses and other current assets	275	268
Total current assets	2,566	5,910
Income tax receivable	135	-
Property, plant and equipment, net (Note 5)	679	867
Intangible asset (net of accumulated amortization of $776 and $569) (Note 3)	1,224	1,431
Total assets	$4,604	$8,208
Liabilities:		
Accounts payable	$3	$77
Accrued expenses (Note 6)	939	703
Accrued interest - current	700	-
Other current liabilities	41	27
Sales returns liability	254	304
Debt – current portion (net of discounts) (Note 7)	2,694	2,376
Total current liabilities	4,631	3,487
Debt – non-current portion (net of discounts) (Note 7)	-	2,979
Accrued interest – non-current portion	-	559
Total liabilities	4,631	7,025
Commitments and contingencies (Note 14)		
Stockholders' (deficit) equity:		
Common stock - $.01 par value per share; 100,000 shares authorized, 20,796 and 11,834 shares issued and outstanding at 2017 and 2016, respectively	208	118

Additional paid-in capital	380,145	375,763
Accumulated deficit	(380,380)	(374,698)
Total stockholders' (deficit) equity	(27)	1,183
Total liabilities and stockholders' (deficit) equity	$4,604	$8,208

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

YEARS ENDED DECEMBER 31, 2017 and 2016

(in thousands, except per share amounts)

	2017	2016
Revenues:		
License fee revenue	$2,500	$3,500
Collaboration revenue	59	392
Royalty revenue	300	149
Product sales, net	107	423
Total revenues, net	2,966	4,464
Cost and expenses:		
Cost of sales (excluding inventory provisions)	128	451
Inventory provisions (Note 4)	-	26
Research and development	3,721	4,028
Selling, marketing, general and administrative	4,342	6,516
Total costs and expenses	8,191	11,021
Operating loss	(5,225)	(6,557)
Non-operating income (expense):		
Interest and investment income	4	60
Interest expense (Note 7)	(596)	(893)
Other income	-	2
Total other expense, net	(592)	(831)
Loss before income taxes	(5,817)	(7,388)
Provision (benefit) for income taxes	(135)	-
Net loss	$(5,682)	$(7,388)
Other comprehensive income:		
Unrealized gains on marketable securities	-	65
Comprehensive loss	$(5,682)	$(7,323)
Net loss per share:		
Basic	$(0.36)	$(0.62)
Diluted	$(0.36)	$(0.62)
Weighted average number of shares outstanding:		
Basic	15,903	11,870
Diluted	15,903	11,870

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN ACCUMULATED STOCKHOLDERS' EQUITY (DEFICIT)

YEARS ENDED DECEMBER 31, 2017 and 2016

(in thousands)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	$ Amount	Capital	Deficit	Income (Loss)	Total
Balance at January 1, 2016	11,801	$ 118	$ 375,157	$ (367,310)	$ (65)	$ 7,900
Net loss	-	-	-	(7,388)	-	(7,388)
Other comprehensive income	-	-	-	-	65	65
Noncash share-based compensation	-	-	588	-	-	588
Net distribution of common stock pursuant to restricted stock unit award plan	33	-	18	-	-	18
Balance at December 31, 2016	11,834	$ 118	$ 375,763	$ (374,698)	$ -	$ 1,183
Net loss	-	-	-	(5,682)	-	(5,682)
Noncash share-based compensation	-	-	464	-	-	464
Issuance of shares and warrants under private placement	8,913	89	3,911	-	-	4,000
Net distribution of common stock pursuant to restricted stock unit award plan	49	1	7	-	-	8
Balance at December 31, 2017	20,796	$ 208	$ 380,145	$ (380,380)	$ -	$ (27)

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2017 and 2016

(in thousands)

	2017	2016
Cash Flows from Operating Activities:		
Net loss	$(5,682)	$(7,388)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	87	138
Provision to reduce inventory to net realizable value	-	26
Provision for sales returns	49	99
Provision for fixed asset impairment	-	82
Noncash share-based compensation	464	588
Amortization of debt discount and deferred debt issue costs	99	145
Amortization of bond premium in marketable securities	-	31
Amortization of intangible asset	207	207
(Gain) loss on disposals of property, plant and equipment	(2)	1
(Gain) on sales of marketable securities	-	(2)
Changes in assets and liabilities:		
Trade accounts receivable, net	23	19
Collaboration revenue receivable	79	(43)
Royalty receivable	(21)	(45)
Accrued investment income	-	37
Inventories	103	(59)
Prepaid expenses and other current assets	(7)	149
Income tax receivable	(135)	-
Other assets	-	175
Accounts payable	(74)	(33)
Accrued expenses	236	139
Accrued interest – current and long term	141	172
Other current liabilities	22	(1)
Sales returns liability	(99)	-
Net cash used in operating activities	(4,510)	(5,563)
Cash Flows from Investing Activities:		
Proceeds from sales and maturities of marketable securities	-	10,873
Proceeds from transfer of equipment to licensee	103	-
Proceeds from transfer of inventory to licensee	206	-
Capital expenditures	-	(75)
Net cash provided by investing activities	309	10,798
Cash Flows from Financing Activities:		
Proceeds from distribution of restricted stock units	-	1

Principal payments on loan maturing December 1, 2018	(2,760)	(2,540)
Issuance of common stock	4,000	-
Net cash provided by (used in) financing activities	1,240	(2,539)
Net (decrease) increase in cash and cash equivalents	(2,961)	2,696
Cash and cash equivalents at beginning of year	5,181	2,485
Cash and cash equivalents at end of year	$2,220	$5,181
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest on loan maturing December 1, 2018	$355	$576
Income taxes, net of refunds	$-	$-

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

YEARS ENDED DECEMBER 31, 2017 and 2016

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

Year Ended December 31, 2017

1. There are no supplemental disclosure activities.

Year Ended December 31, 2016

2. There are no supplemental disclosure activities.

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 and 2016

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", or "Our") is a specialty pharmaceutical company engaged in the research and development of technologies and products intended to address medication abuse and misuse. We have discovered and developed three proprietary platform technologies which can be used to develop multiple products. Our Limitx™ Technology is intended to address methods of product tampering associated with opioid abuse 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 into methamphetamine.

- Our Limitx Technology is in development with the immediate-release hydrocodone bitartrate and acetaminophen as a lead Limitx product candidate due to its larger market size than our prior lead product and its known prevalence of oral excessive tablet abuse.

- Our Aversion Technology has been licensed to Egalet Corporation for use in Oxaydo® Tablets (oxycodone HCl, CII), and is the first approved immediate-release oxycodone product in the United States with abuse deterrent labeling. Oxaydo is currently approved by the FDA for marketing in the United States in 5mg and 7.5mg strengths. Egalet launched Oxaydo in the United States late in the third quarter of 2015. (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, or MainPointe, our Impede Technology in the United States and Canada to commercialize our Nexafed products (with options to acquire other Impede Technology Products and other territories), pursuant to a License, Commercialization and Option Agreement, or the MainPointe Agreement, entered into on March 16, 2017. (see Note 3).

Basis of Presentation 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, 2017, we had cash and cash equivalents of $2.2 million, working capital deficit of $2.1 million and an accumulated deficit of $380.4 million. We had a loss from operations of $5.2 million and a net loss of $5.7 million for the year ended December 31, 2017. 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.

We have a term loan with Oxford Finance LLC (“Oxford” or the “Lender”) and as of December 31, 2017 and May 14, 2018, the outstanding principal balance is $2.7 million and $1.8 million, respectively. A $795 thousand balloon interest payment is due to Oxford on December 1, 2018. Our term loan agreement with Oxford contains customary affirmative and negative covenants. One such covenant is that the Company must submit on an annual basis to Oxford, within 120 days after the end of its fiscal year, audited consolidated financial statements, together with an unqualified audit opinion from an independent registered public accounting firm, or the Unqualified Audit Opinion Covenant. Per the term loan agreement an audit opinion with an explanatory paragraph noting substantial doubt about the Company’s ability to continue in business (the “going concern opinion”) is deemed to violate the Unqualified Audit Opinion Covenant. Failure to comply with the Unqualified Audit Opinion Covenant is a breach of the term loan agreement and unless such covenant or breach is waived, Oxford would have the option of accelerating the debt under the term loan agreement and initiating enforcement collection actions, foreclosing on collateral (which includes most assets of the Company) and, among other things, preventing the Company from using any funds in its bank or securities accounts. On March 16, 2017, we and Oxford entered into a third amendment to the Loan Agreement, or the Third Amendment. Pursuant to the Third Amendment (i) we granted Oxford a lien on our intellectual property, (ii) Oxford provided a waiver of compliance with the Unqualified Audit Opinion Covenant in connection with our receipt of our auditor’s going concern opinion for our 2016 financial statements and (iii) Oxford consented to the terms of the MainPointe Agreement.

During the second quarter of 2018, we borrowed a a total of $1.0 million from John Schutte, a principal of MainPointe and our largest shareholder, and in conjunction with such loan, we entered into of a fourth amendment to our term loan agreement with Oxford, pursuant to which Oxford granted a similar waiver of compliance with the Unqualified Audit Opinion Covenant for our 2017 financial statements and extended the period in which we could deliver financial statements for 2017 to 160 days after year's end (instead of 120 days). (see Notes 7 and 15). With the net proceeds of approximately $1.0 million to the Company resulting from the loan from Mr. Schutte, we expect our cash will only be sufficient to fund operations into late June 2018.

These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. We must seek sources to raise additional financing and seek to enter into license or collaboration agreements with third parties relating to our technologies. The Company is exploring a variety of capital raising and other transactions to provide additional funding to continue operations. These include potential private offerings of common stock to accredited and/or institutional investors and licensing transactions with pharmaceutical company partners for our proprietary technologies, including Limitx. We are actively seeking a licensing partner for our Limitx technology, with the objective of receiving an upfront license fee, development milestone payments and royalties on the net sales of products utilizing the Limitx technology, similar to the Egalet Agreement. We are also exploring licensing or selling select assets and intellectual property in an effort to raise capital and reduce operating expenses. Finally, the Company continues to evaluate the potential for a strategic transaction which may involve the Company being acquired in a merger or asset purchase transaction. No assurance can be given that we will be successful in completing any one or more of such transactions on acceptable terms, if at all, or if completed, that such transactions will provide payments to the Company sufficient to fund continued operations. In the absence of the Company's completion of one or more of such transactions, there will be substantial doubt about the Company's ability to continue as a going concern within one year after the date these financial statements are issued, and the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. An extended delay or cessation of the Company's continuing product development efforts will have a material adverse effect on the Company's financial condition and results of operations.

In view of the matters described above, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying 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.

Reclassifications

Certain reclassifications have been made to the prior year’s amounts to conform to the current year's presentation.

Use of Estimates

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

Concentration of Credit Risk

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

Cash and Cash Equivalents

The Company considers cash and cash equivalents to include cash in financial institutions and money market funds, and considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Our cash and cash equivalents are governed by our investment policy as approved by our Board of Directors. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term nature.

Fair Value Measurements

The Company's financial instruments consist primarily of cash and cash equivalents, receivables from trade, royalties and collaboration, trade accounts payable, and our long-term debt. The carrying amounts of these financial instruments are representative of their respective fair values due to their relatively short maturities.

Share-based Compensation Expense

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

We measure our compensation cost related to share-based payment transactions based on fair value of the equity or liability instrument issued. 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 market price of our common stock on the date of grant, less its exercise cost.

Our share-based compensation expense recognized in the Company's results of operations from all types of noncash and cash-portioned instruments issued comprised the following (in thousands):

	Year Ended December 31,	
	2017	2016
Research and development expense:		
Stock option awards	$ 136	$ 167
RSU awards	3	-
	$ 139	$ 167
Selling, marketing, general and administrative expense:		
Stock option awards	203	301
RSU awards	156	143
	$ 359	$ 444
Total share-based compensation expense	$ 498	$ 611

Property, Plant and Equipment

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

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

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

Intangible and Long-Lived Assets

Long-lived assets such as the intangible asset and property, plant and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of the assets to be held and used is measured by a comparison of the carrying amount of the asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying value of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. We recorded an impairment charge of $82 thousand in the fourth quarter of 2016 on equipment having a net book value of a like amount. We had no impairment charges during the year 2017.

License Fee Revenue

On signing the MainPointe Agreement in March 2017, MainPointe paid us an upfront licensing fee of $2.5 million. The payment was non-refundable and non-creditable when made and we had no further requirements to earn the payment. The amount was recognized as revenue when received. (see Note 3).

In October 2016, the Company 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 two of KemPharm's prodrug candidates. KemPharm has also been granted an option to extend the KemPharm Agreement to cover two additional prodrug candidates. KemPharm paid us $3.5 million upon signing the KemPharm Agreement. The payment was non-refundable and non-creditable when made and we had no further requirements to earn the payment. The amount was recognized as revenue when received. (see Note 3).

Collaboration Revenue

Collaboration revenue is derived from reimbursement of development expenses, such as under our agreement with Bayer, and are recognized when costs are incurred pursuant to the agreements. The ongoing research and development services being provided under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration agreements. We recognized $59 thousand and $392 thousand of collaboration revenue during the year 2017 and 2016, respectively.

Royalty Revenue

We recognize revenue from royalties based on our licensees' sales of our products or products using our technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

In connection with our Collaboration and License Agreement with Egalet 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 Egalet in accordance with the agreement. Egalet’s first commercial sale of Oxaydo occurred in October 2015 and we have recorded royalties of $281 thousand and $149 thousand on net sales for the years 2017 and 2016, respectively. (see Note 3).

In connection with the MainPointe Agreement, which occurred on March 16, 2017, we are receiving a royalty of 7.5% on net sales of the licensed products over the term of the agreement. Such royalty shall be payable for sales made during each calendar quarter and payment will be remitted within forty-five (45) days after the end of the quarter to which it relates. We have recorded royalties of $19 thousand for the year 2017. (see Note 3).

Net 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, 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. Both products had an initial shelf life of twenty-four months from the date of manufacture, which shelf life had been extended to thirty-six months for Nexafed product supplied to us during 2016 from one of the Company’s contract manufacturers. Prior to entering into the MainPointe Agreement, we recognized revenue from our Nexafed product line sales when the price was fixed and determinable at the date of sale, title and risk of ownership were transferred to the customer, and returns could be reasonably estimated, which generally occurred at the time of product shipment.

Advertising and Shipping/Handling Costs

The Company records the cost of its advertising efforts in marketing expenses when services are performed or goods are delivered. We record shipping and handling costs in selling expenses. As of mid-March 2017 we no longer manufacture, distribute or sell the Nexafed product line as the Company granted MainPointe an exclusive license to our Impede technology to commercialize our Nexafed products in the U.S. and Canada. The amounts recorded as selling expenses from the shipments of the Nexafed product line during each of the years 2017 and 2016 were not material.

Deferred Debt Issuance Costs and Debt Discount

Deferred debt issuance costs include costs of debt financing undertaken by the Company, including legal fees, placement fees and other direct costs of the financing. Debt discount is the value attributable to warrants issued in conjunction with the financing. Debt issuance costs and debt discount are amortized into interest expense over the term of the related debt using the effective interest method. Deferred debt issuance costs and debt discount are presented on the balance sheets as a direct reduction against the debt.

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 nor did we have prepaid clinical trial study expenses at either December 31, 2017 or 2016. We did not have any obligations under non-cancelable arrangements at December 31, 2017.

Income Taxes

We account for income taxes under the liability method. Under this method, deferred income tax assets and liabilities are determined based on differences between the financial reporting and the income tax basis of assets and liabilities and are measured using the enacted income tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, net operating loss and tax credit carryforwards are reported as deferred income tax assets. The realization of deferred income tax assets is dependent upon future earnings. A valuation allowance is required against deferred income tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets may not be realized. At December 31, 2017 and 2016, 100% of all remaining net deferred income tax assets were offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that additional amounts of our deferred income tax assets would likely be realized, the valuation allowance would be reduced in the period in which such determination is made and an additional benefit from income taxes in such period would be recognized.

Basic and Diluted Net Loss Per Share

Basic net 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 vested Restricted Stock Units ("RSUs"). (see Note 12). Diluted net 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 potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and stock warrants, assuming the exercise of all in-the-money stock options and warrants. Common stock equivalents are excluded from the computation where their inclusion would be anti-dilutive. No such adjustments were made for 2017 or 2016 as the Company reported a net loss for each year and including the effects of common stock equivalents in the diluted net loss per share calculation would have been antidilutive.

Customer Concentration

In March 2017, we licensed our Nexafed product line to MainPointe Pharmaceuticals LLC. Until that time our accounts receivable arose from our sales of our Nexafed product line and represent amounts due from wholesalers in the health care and pharmaceuticals industries and from chain drug stores. The Company has performed a credit evaluation of its customers and we have not experienced any losses on uncollectable accounts in 2017 or 2016.

Sales to certain of our customers during 2016 accounting for 10% or more of our annual product sales, whether the product shipment was recognized immediately as a sales or as a deferred sale, is presented below.

Customer	2016
Rite Aid Corporation	55 %
Cardinal Health, Inc.	13 %
McKesson Corporation	10 %

Trade accounts receivable from certain of our customers at December 31, 2016 accounting for 10% or more of our gross accounts receivable is presented below.

Customer	2016
AmerisourceBergen Corporation	35 %
McKesson Corporation	24 %
Cardinal Health, Inc.	19 %
The Kroger Co.	18 %
Rite Aid Corporation	**

Recent Accounting Pronouncements

New accounting standards which have been adopted on or before December 31, 2017

Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15 which explicitly requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist which raise substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures. The amendments in this update are effective for the first annual period ending after December 15, 2017, and for annual periods and interim periods thereafter. Early application is permitted. The Company early adopted the guidance for its financial statement disclosures in the fourth quarter of 2016.

Statements of Cash Flows - Restricted Cash

In November 2016, the FASB issued ASU 2016-18 which requires that at statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The new standard will be effective for annual and interim periods, within those fiscal years beginning after December 15, 2017 but early adoption is permitted. The Company early adopted the guidance in the first quarter of 2017 which did not have a material impact on the Company's consolidated financial statements or related footnote disclosures.

Business Combinations – Clarifying the Definition of a Business

In January 2017, the FASB issued ASU No. 2017-01 which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments in this update provide a screen to determine when an integrated set of assets and activities (collectively referred to as a "set"), is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. ASU 2017-01 is effective for annual periods beginning after December 15, 2017, but early application of the amendments in this update is allowed. The amendments in this update should be applied prospectively on or after the effective date. The Company early adopted this new standard on January 1, 2017 which did not have a material impact on the Company's consolidated financial statements.

Simplication of Employee Share-Based Payment Accounting

In March 2016, the FASB issued ASU 2016-09 which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 is to be applied either prospectively, retrospectively or using a modified retrospective transition approach depending on the area covered in this update. The new standard was effective for annual and interim periods, within those fiscal years, beginning after December 15, 2016. The Company adopted the guidance in the first quarter of 2017 which did not have a material impact on the Company's consolidated financial statements.

Simplifying the Measurement of Inventory

In July 2015, the FASB issued ASU No. 2015-11, which simplifies the measurement of inventory, applying to inventories for which cost is determined by methods other than last-in first-out (LIFO) and the retail inventory method (RIM), specifying that an entity should measure inventory at the lower of cost and net realizable value instead of at the lower of cost or market. The amendments in this ASU were effective for annual and interim periods, within those fiscal years, beginning after December 15, 2016. The Company adopted the guidance of the standard in the first quarter of 2017 which did not have a material impact on the Company's consolidated financial statements.

New accounting standards which have not yet been adopted on or before December 31, 2017

Revenue from Contracts with Customers

In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date,* which deferred the effective date of ASU 2014-09 for all entities by one year. This update is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim periods within those reporting periods. The ASU permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The ASU also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required for customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. We have completed the process of evaluating the effect of the adoption and determined there were no changes required to our reported revenues as a result of the adoption. The majority of our revenue arrangements generally consist of performance obligations related to license our drug technologies. Based on our evaluation process and review of our contracts with customers, the timing and amount of revenue recognized under the new standard is materially consistent with our revenue recognition policy under previous guidance. We adopted the new standard effective January 1, 2018, using the modified retrospective approach, and will expand our consolidated financial statement disclosures in order to comply with ASU 2014-09. We have determined the adoption of the new guidance will not have a material impact on our results of operations, cash flows, or financial position.

Scope of Modification Accounting, Stock Based Compensation

In May 2017, the FASB issued ASU No. 2017-09 which provides guidance as to how an entity should apply modified accounting in Topic 718 when changing the terms and conditions of its share-based payment awards. The guidance

clarifies that modification accounting will be applied if the value, vesting conditions or classification of the award changes. The ASU is effective for annual reporting periods, including interim periods within those annual periods, beginning after December 15, 2017 but early adoption is permitted. The Company has not adopted the standard and does not anticipate that the standard will have a material effect, if any, on our consolidated financial statements and related disclosures.

Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments

In August 2016, the FASB issued ASU 2016-15 which clarifies existing guidance on how companies present and classify certain cash receipts and cash payments in the statement of cash flows by addressing specific cash flow issues in an effort to reduce diversity in practice, including guidance on debt prepayment or extinguishment costs and contingent consideration payments made after a business combination. This update is effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company expects that the standard will not have an impact on the Company’s consolidated financial statements and related footnote disclosures.

Leases

In February 2016, the FASB issued ASU 2016-02 which establishes a comprehensive new lease accounting model. The new standard will require most leases (with the exception of leases with terms of one year or less) to be recognized on the balance sheet as a lease liability with a corresponding right-of-use asset. Leases will be classified as an operating lease or a financing lease. Operating leases are expensed using the straight-line method whereas financing leases will be treated similarly to a capital lease under the current standard. The new standard will be effective for annual and interim periods, within those fiscal years, beginning after December 15, 2018 but early adoption is permitted. The new standard must be presented using the modified retrospective transition method existing at or entered into after the beginning of the earliest comparative period presented in the financial statements, but it does not require transition accounting for leases that expire prior to the date of initial application. Upon adoption, operating leases will be reported on the balance sheet as a gross-up of assets and liabilities. The Company is currently evaluating the impact that the standard will have on the consolidated financial statements and related footnote disclosures.

NOTE 3 – LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENTS

MainPointe Agreement covering Nexafed Product Line

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 our Nexafed products in the U.S. and Canada. We also conveyed to MainPointe our existing inventory and equipment relating to our Nexafed products. MainPointe is responsible for all development, manufacturing and commercialization activities with respect to products covered by the Agreement.

On signing the MainPointe Agreement, MainPointe paid us an upfront licensing fee of $2.5 million plus approximately $309 thousand for inventories and equipment being transferred to them. The MainPointe Agreement also provides for our receipt of a 7.5% royalty on net sales of the licensed products. The royalty payment for each product will expire on a country-by-country basis when the Impede® patent rights for such country have expired or are no longer valid; provided that if no Impede patent right exists in a country, then the royalty term for that country will be the same as the royalty term for the United States. After the expiration of a royalty term for a country, MainPointe retains a royalty free license to our Impede® technology for products covered by the Agreement in such country.

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

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.

KemPharm Agreement Covering Certain Opioid Prodrugs

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

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

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

Egalet Agreement covering Oxaydo

In April 2014, we terminated an agreement with Pfizer and the return to us of Aversion Oxycodone (formerly known as Oxecta®) and all Aversion product rights in exchange for a one-time termination payment of $2.0 million. Our termination payment of $2.0 million has been recorded in our consolidated financial statements as an intangible asset and is being amortized over the remaining useful life of the patent covering Aversion Oxycodone, which was 9.7 years as of the date the agreement was terminated. We have recorded annual amortization expense of $208 thousand for each of the years 2017 and 2016. Annual amortization of the patent for the years 2018 through 2021 is expected to approximate $208 thousand each year.

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

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

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

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

Terminated Bayer Agreement Covering Methamphetamine Resistant Pseudoephedrine-containing Product

In June 2015, we and Bayer entered into a License and Development Agreement (the "Bayer Agreement") granting Bayer an exclusive worldwide license to our Impede Technology for use in an undisclosed methamphetamine resistant pseudoephedrine–containing product (the "Bayer Licensed Product") and providing for the joint development of such product utilizing our Impede Technology for the U.S. market. In June 2017, we received Bayer's notice of termination of the Bayer Agreement pursuant to its convenience termination right exercised prior to the Company's completion of its product development obligations under the Bayer Agreement. We have received reimbursement of certain of our development costs under the Bayer Agreement.

Following Bayer's termination of the Bayer Agreement the Bayer License Product is now subject to MainPointe's option rights under the MainPointe Agreement.

NOTE 4 – INVENTORIES

We did not have inventories at December 31, 2017 as all our inventories were transferred to MainPointe under the MainPointe Agreement in March 2017. (See Note 3). Inventories at December 31, 2016 are stated at the lower of cost (first-in, first-out method) or net realizable value. We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results.

Our purchases of ingredients and other materials required in our development and clinical trial activities are expensed as incurred.

Inventories at December 31, 2016 are summarized as follows (in thousands):

	December 31, 2016
Raw and packaging materials	$ 98
Finished goods	243
Total	341
Less: reserve for finished goods	(32)
Net inventories	$ 309

Inventory reserve activity during the years ended December 31, 2017 and 2016 was as follows (in thousands):

	2017	2016
Beginning of year	$32	$70
Reserve expense - finished goods	-	26
	32	96
Inventory write-offs - finished goods	(32)	(64)
End of year	$-	$32

NOTE 5 – PROPERTY, PLANT AND EQUIPMENT

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

	December 31,	
	2017	2016
Building and improvements	$1,273	$1,273
Scientific equipment	598	598
Computer hardware and software	107	109
Machinery and equipment	275	568
Land and improvements	162	162
Other personal property	70	70
Office equipment	27	27
	2,512	2,807
Less: impairment reserve	-	(82)
Less: accumulated depreciation	(1,833)	(1,858)
Total property, plant and equipment, net	$679	$867

The impairment reserve of $82 thousand at December 31, 2016 was for specific machinery and other equipment which was used in the production of our Nexafed product line and which was not conveyed to MainPointe under the MainPointe Agreement. During 2017, we applied the reserve against the disposal of these specific assets. We do not have leasehold improvements nor do we have capitalized leases. Costs of betterments are capitalized while maintenance costs and repair costs are charged to operations as incurred. When a depreciable asset is retired from service, the cost and accumulated depreciation will be removed from the respective accounts.

Depreciation expense was approximately $0.1 million for each of the years ended December 31, 2017 and 2016.

NOTE 6 – ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	December 31,	
	2017	2016
Cost sharing expenses under license agreements	$ 328	$ 150
Other fees and services	36	47
Payroll, payroll taxes and benefits	70	116
Professional services	149	232
Clinical, non-clinical and regulatory services	326	131
Marketing, advertising, and promotion	-	10
Property taxes	16	16
Franchise taxes	14	1
Total	$ 939	$ 703

NOTE 7 – DEBT

Loan due December 1, 2018

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

In January 2015, we and Oxford entered into an amendment to the Loan Agreement. Pursuant to the amendment, (i) the exercise price of the warrants was lowered from $7.98 to $2.52 per share (the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the amendment and after giving effect to our one-for-five reverse stock split) and we recorded additional debt discount of $33 thousand representing the fair value of the warrant modification, (ii) we agreed to maintain $2.5 million cash reserves until such time as we have repaid $5.0 million in principal of the Term Loan, and (iii) the Lender consented to the terms of our Collaboration and License Agreement with Egalet relating to our Oxaydo product.

In October 2016, we and Oxford entered into a second amendment to the Loan Agreement (the "Second Amendment"). Pursuant to the Second Amendment, (i) the requirement that we maintain a $2.5 million cash balance reserve until such time as $5.0 million in principal was repaid under the Term Loan was modified so that the $2.5 million cash balance reserve remains in place until we raise an additional $6.0 million (excluding payments received under the KemPharm Agreement) through the issuance of equity securities and from upfront payments under license, joint venture, collaboration or other partnering transactions, provided that at least $3.0 million of such amount must be raised through the issuance and sale of our equity securities, and (ii) the Lender consented to the terms of our Agreement with KemPharm. In July 2017, the Company completed a private placement of its equity units to an investor, each unit consisting of one share of common stock and a warrant to purchase one-fifth of a share of common stock. The net proceeds to the Company from the private offering was approximately $4.0 million. Giving effect to the $2.5 million upfront payment received from MainPointe pursuant to the MainPointe Agreement and the approximate

$4.0 million in net proceeds from the July 2017 private offering, the Company has satisfied the condition in the Second Amendment to the Oxford Loan Agreement to waive the $2.5 million cash reserve requirement.

In March 2017, we and Oxford entered into a third amendment to the Loan Agreement (the “Third Amendment”). Pursuant to the Third Amendment (i) we granted Oxford a lien on our intellectual property, (ii) Oxford provided a waiver of compliance with the Unqualified Audit Opinion Covenant in connection with our receipt of our auditor’s going concern opinion for our 2016 financial statements and (iii) Oxford consented to the terms of the MainPointe Agreement. Under the Loan Agreement, an audit opinion with an explanatory paragraph noting substantial doubt about the Company’s ability to continue in business is deemed to violate the Unqualified Audit Opinion Covenant.

In the second quarter of 2018, in connection with a $1.0 million loan extended by John Schutte, we and Oxford entered into a fourth amendment to the Loan Agreement. Pursuant to the fourth amendment, Oxford provided a waiver of compliance with the unqualified audit opinion covenant in connection with our receipt of our auditor’s opinion with a going concern explanatory paragraph for our 2017 financial statements and allowed us to deliver financial statements up to 160 days after year end, instead of 120 days after year end. See Note 15 for a discussion of this transaction.

The Company may voluntarily prepay the Term Loan in full, but not in part, and any prepayment is subject to a prepayment premium equal to 1% of the principal prepaid. In addition, at the maturity, termination or upon voluntary or mandatory prepayment of the Term Loan the Company must pay the Lender an additional one-time interest payment of $795 thousand. We are accruing additional monthly interest expense over the term of the loan for this additional one-time interest payment using the loan's effective cash interest rate. As of December 31, 2017 and 2016, we have accumulated and accrued $700 thousand and $559 thousand, respectively, of this additional interest.

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

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, limits or restrictions on the Company's ability to incur liens, incur indebtedness, pay dividends, redeem stock, and merge or consolidate and dispose of assets. In addition, it contains customary events of default that entitles the Lender to cause any or all of the Company's indebtedness under the Loan Agreement to become immediately due and payable. The events of default (some of which are subject to applicable grace or cure periods), include, among other things, non−payment defaults, covenant defaults (including breach of the Unqualified Audit Opinion Covenant), a material adverse change in the Company, bankruptcy and insolvency defaults and material judgment defaults.

Our debt activity at December 31, 2017 is summarized below (in thousands):

Current Debt	Current	Long-term	Total
Balance at Jan. 1, 2017	$2,521	$ 2,979	$5,500
Principal payments	(2,760)	-	(2,760)
Classification	2,979	(2,979)	-
Balance at Dec. 31, 2017	$2,740	$ -	$2,740

Debt Discount	Current	Long-term	Total
Balance at Jan. 1, 2017	$ (98)	$ -	$ (98)
Amortization expense	66	-	66
Classification	-	-	-
Balance at Dec. 31, 2017	$ (32)	$ -	$ (32)

Deferred Debt Issuance Costs	Current	Long-term	Total

Balance at Jan. 1, 2017	$(47)	$ -	$(47)
Amortization expense	33	-	33
Classification	-	-	-
Balance at Dec. 31, 2017	$(14)	$ -	$(14)
Current Debt, net at Dec. 31, 2017	$2,694	$ -	$2,694

Our interest expense consisted of the following (in thousands):

	Year Ended December 31,	
	2017	2016
Interest expense:		
Term loan	$ 497	$ 748
Debt discount	66	95
Debt issue costs	33	50
Total interest expense	$ 596	$ 893

NOTE 8 – RELATED PARTY TRANSACTIONS

In July 2017, we completed a $4.0 million private placement with John Schutte (sometimes referred to as the "Investor"), consisting of 8,912,655 units ("Units) of the Company, at a price of $0.4488 per Unit (the "Transaction). Each Unit consists of one share of Common Stock and a Warrant to purchase one fifth (0.2) of a share of Common Stock. The issue price of the Units was equal to 85% of the average last sale price of our Common Stock for the five trading days prior to completion of the Transaction. The Warrants are immediately exercisable at a price of $0.528 per share (which equals the average last sale price of the Company's Common Stock for the five trading days prior to completion of the Transaction) and expire five years after issuance (subject to earlier expiration in event of certain acquisitions). We have assigned a relative fair value of $495 thousand to the warrants out of the total $4.0 million proceeds from the private placement transaction and have accounted these warrants as equity. The Transaction was completed through a private placement to an accredited investor and was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended and/or Regulation D promulgated under the Securities Act of 1933.

Investor is a principal of MainPointe, a Kentucky limited liability company. In March 2017, we granted MainPointe an exclusive license to our Impede technology to commercialize our Nexafed® and Nexafed® Sinus Pressure + Pain Products in the United States and Canada for an upfront licensing fee of $2.5 million plus approximately $309 thousand for transferred inventory and equipment. The Company will receive 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 revenue for the year 2017 is $13 thousand of royalty revenue from MainPointe. (See Note 3).

As part of the closing of the Transaction, the Company, Essex Woodlands Health Ventures V, L.P. ("Essex") and Galen Partners III, L.P. ("Galen") amended and restated the existing Voting Agreement including such parties to provide for the Investor to join as a party (as so amended, the "Second Amended and Restated Voting Agreement"). The Second Amended and Restated Voting Agreement provides that our Board of Directors shall remain comprised of no more than seven members (subject to certain exceptions), (i) one of whom is the Company's Chief Executive Officer, (ii) three of whom are independent under Nasdaq standards, and (iii) one of whom shall be designated by each of Essex, Galen and Investor, and the parties to such agreement would vote for such persons. The right of each of Essex, Galen and Investor to designate one director to our Board will continue as long as he or it and their affiliates collectively hold at least 600,000 shares of our Common Stock (including warrants exercisable for such shares). Immanuel Thangaraj is the designee of Essex. Galen has not designated a director and lost that right in December 2017 when it disposed of its shares. Investor has not designated a director as of the date of filing of this Report. 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.

During the second quarter of 2018, we borrowed a total of $1.0 million from John Schutte and issued a promissory note in that principal amount to him. See Note 15 for a discussion of this transaction.

NOTE 9 – EMPLOYEE BENEFIT PLAN

We have a 401(k) and Profit-Sharing Plan (the “Plan”) for our employees. Employees may elect to make a basic contribution of up to 80% of their annual earnings subject to certain regulatory restrictions on their total contribution. The Plan provides that the Company can make discretionary matching contributions along with a discretionary profit-sharing contribution. We did not contribute a matching contribution or a profit sharing contribution to the Plan during the years 2017 or 2016.

NOTE 10 – COMMON STOCK WARRANTS

Our warrant activity during the years ended December 31, 2017 and 2016 is shown below (in thousands except price data):

	December 31, 2017		2016	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, Jan. 1	60	$ 2.52	60	$ 2.52
Issued	1,782	0.53	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Modification	-	-	-	-
Outstanding, Dec. 31	1,842	$ 0.59	60	$ 2.52

In connection with the issuance of the $10.0 million secured promissory notes in December 2013, we issued common stock purchase warrants (“warrants”) exercisable for 60 thousand shares of our common stock having an exercise price of $2.52 per share (after giving effect to our one-for-five reverse stock split) with an expiration date in December 2020. See Note 8 for a discussion of the reduction of the exercise price of these warrants to $2.52 per share. These warrants contain a cashless exercise feature.

As part of our July 2017 private placement transaction with John Schutte, we issued warrants to purchase 1,782,531 shares of our common stock. The Warrants are immediately exercisable at a price of $0.528 per share and expire five years after issuance (see Note 8). We have assigned a relative fair value of $495 thousand to the warrants out of the total $4.0 million proceeds from the private placement transaction and have accounted these warrants as equity.

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, 2017 and 2016 and for the year then ended consisted of the following (in thousands except exercise price):

	Year Ended December 31,			
	2017		2016	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, Jan. 1	1,397	$ 15.67	1,198	$ 15.67
Granted	185	0.45	199	0.92
Exercised	(1)	0.92	-	-
Forfeited or expired	(87)	7.02	-	-
Outstanding, Dec. 31	1,494	$ 12.33	1,397	$ 15.67
Exercisable, Dec. 31	1,224	$ 14.92	1,062	$ 17.41

The following table summarizes information about unvested stock options outstanding at December 31, 2017 (in thousands except price data):

	Number of Options Not Exercisable	Weighted Average Fair Value
Outstanding at Jan. 1, 2017	335	$ 1.18
Granted	185	0.45
Vested	(236)	1.34
Forfeited	(14)	1.05
Outstanding at Dec. 31, 2017	270	$ 0.46

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.

The assumptions used in the Black-Scholes model to determine fair value for the 2017 and 2016 stock option grants were:

	2017	2016
Expected dividend yield	0.0 %	0.0 %
Risk-free interest rates	1.8 %	2.3 %
Average expected volatility	88 %	85 %
Expected term (years)	5	10
Weighted average grant date fair value	$0.31	$0.77

The option awards which are vested and outstanding had an instrinsic value of $0 at December 31, 2017. The total remaining unrecognized compensation cost on unvested option awards outstanding at December 31, 2017 was approximately $100 thousand, and is expected to be recognized in the Company's operating expense in varying amounts over the next eleven months remaining in the requisite service periods. There were 1 thousand option awards exercised during 2017 and there was no option award exercise activity during 2016.

Restricted Stock Unit Award Plans

We have two Restricted Stock Unit Award Plans for our employees and non-employee directors, a 2017 Restricted Stock Unit Award Plan (the "2017 RSU Plan") and a 2014 Restricted Stock Unit Award Plan (the "2014 RSU Plan"). Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. Our non-employee director awards allow for non-employee directors to receive payment in cash, instead of stock, for up to 40% of each RSU award. The portion of the RSU awards subject to cash settlement are recorded as a liability in the Company's balance sheet as they vest and being marked-to-market each reporting period until they are distributed. The liability was $41 thousand and $27 thousand at December 31, 2017 and 2016, 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, 2017 and 2016, and for the year then ended consisted of the following (in thousands):

Year Ended December 31,

	2017		2016	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, Jan. 1	91	91	45	45
Granted	438	-	88	-
Distributed	(67)	(67)	(42)	(42)
Vested	-	238	-	88
Forfeited or expired	-	-	-	-
Outstanding, Dec. 31	462	262	91	91

2017 Restricted Stock Unit Award Plan

Our 2017 RSU Plan was approved by shareholders in November 2017 and permits the grant of up to 1.5 million shares of our common stock pursuant to awards under the 2017 RSU Plan. As of December 31, 2017, approximately 1.3 million shares are available for award under the 2017 RSU Plan.

Information about the awards under the 2017 RSU Plan is as follows:

- In December 2017, we awarded 200 thousand RSUs to our employees. Such RSU awards will vest 100% after one full year of service.

- In January 2018, we awarded approximately 67 thousand RSUs to each of our 4 non-employee directors which also allow for them to receive payment in cash, instead of stock, for up to 40% of each RSU award. Such awards vest 25% at the end of each calendar quarter in 2018. Distributions of stock under the January 2018 award will be distributed on the first business day of the year after vesting.

2014 Restricted Stock Unit Award Plan

Our 2014 RSU Plan was approved by shareholders in May 2014 and permits the grant of up to 400 thousand shares of our common stock pursuant to awards under the 2014 RSU Plan. As of December 31, 2017, approximately 3 thousand shares are available for award under the 2014 RSU Plan.

Information about the awards under the 2014 RSU Plan during 2016 and 2017 is as follows:

- In January 2016, we awarded approximately 22 thousand RSUs to each of our 4 non-employee directors which also allow for them to receive payment in cash, instead of stock, for up to 40% of each RSU award. Such awards vest 25% at the end of each calendar quarter in 2016. The portion of the RSU awards which are subject to cash settlement are also subject to marked-to market accounting and the liability recorded in the Company's balance sheet as an estimate for such cash settlement was $27 thousand at December 31, 2016. Distributions of stock under this award are generally distributed on the first business day of the year after vesting, but such distribution can be deferred until a later date at the election of the non-employee director.
- In January 2017, we awarded approximately 60 thousand RSUs to each of our 4 non-employee directors which also allow for them to receive payment in cash, instead of stock, for up to 40% of each RSU award. Such awards vest 25% at the end of each calendar quarter in 2017. Distributions of stock under this award will be distributed on the first business day of the year after vesting.

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

- In January 2016, 1 thousand RSUs from the May 2014 award and 42 thousand RSUs from the January 2015 award were distributed. There are 2 thousand RSUs from the May 2014 award which remain deferred until a future distribution date. Of the 42 thousand RSUs distributed, 33 thousand RSUs were distributed in common stock and 9 thousand RSUs were settled in cash.
- In January 2017, 1 thousand RSUs from the May 2014 award and 66 thousand RSUs from the January 2016 award were distributed. There are 1 thousand RSUs from the May 1 2014 award and 22 thousand RSUs from the January 2016 award which remain deferred until a future distribution date. Of the 67 thousand RSUs distributed, 49 thousand RSUs were distributed in common stock and 18 thousand RSUs were settled in cash.
- In January 2018, all outstanding RSUs from the 2014 RSU Plan were distributed. There are no outstanding awards which remain deferred until a future distribution date. Of the approximately 261 thousand RSUs distributed, 238

thousand RSUs were distributed in common stock and 24 thousand RSUs were settled in cash.

NOTE 12 – NET LOSS PER SHARE

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

	Year Ended December 31,	
	2017	2016
Net loss per share - basic		
Numerator: net loss	$ (5,682)	$ (7,388)
Denominator (weighted):		
Common shares	15,790	11,834
Vested RSUs	113	36
Basic weighted average shares outstanding	15,903	11,870
EPS - basic	$ (0.36)	$ (0.62)
Net loss per share – assuming dilution		
Numerator: net loss	$ (5,682)	$ (7,388)
Denominator (weighted):		
Common shares	15,790	11,834
Vested RSUs	113	36
Stock options	-	-
Common stock warrants	-	-
Diluted weighted average shares outstanding	15,903	11,870
Net loss per share - diluted	$ (0.36)	$ (0.62)
Excluded dilutive securities:		
Common stock issuable (non-weighted):		
Unvested RSUs	200	-
Stock options	1,494	1,397
Common stock warrants	1,842	60
Total excluded potentially dilutive shares	3,536	1,457

NOTE 13 – INCOME TAXES

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

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of US GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In accordance with SAB 118, the Company has remeasured its deferred tax assets and liabilities and adjusted its deferred tax balances to reflect the lower enacted U.S. corporate tax rate resulted in an income tax expense of $26.6 million which is included as a discrete item in the 2017 income tax provision. Overall, there was no impact to the tax provision as a result of offsetting reduction of the valuation allowance. This deferred tax expense and valuation allowance were provisional amounts and reasonable estimates at December 31, 2017.

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,	
	2017	2016
Benefit at U.S. statutory 34% tax rate	$(1,978)	$(2,512)
State taxes (benefit), net of federal effect	(203)	(254)
State research and development tax credits	105	49
Federal research and development tax credits	(70)	-
Share-based compensation	116	159
Federal AMT tax credit	(135)	-
Other	(3)	2
Tax Cuts and Jobs Act of 2017	26,603	-
Change in valuation allowance	(24,570)	2,556
(Benefit) provision for income taxes	$(135)	$-

Deferred Tax Assets and Valuation Allowance

Deferred tax assets reflect the tax effects of net operating losses ("NOLs"), tax credit carryovers, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The most significant item of our deferred tax assets is derived from our Federal NOLs. We have approximately $167.7 million gross Federal NOLs at December 31, 2017 however we believe the ability for us to use these NOLs to offset any future taxable income is severely limited as prescribed under Internal Revenue Code ("IRC") Section 382. We have estimated and recorded an amount for the likely limitation to our deferred tax asset, thereby reducing the aggregate estimated benefit of the Federal NOLs available to us of approximately $1.0 million. We believe the gross Federal NOL benefit we can utilize to offset taxable income is less than $150 thousand annually. 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. Future common stock transactions may cause another qualifying event under IRC 382 which may further limit our utilization of our NOLs.

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

	December 31,	
	2017	2016
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	$1,028	$47,192
- State	1,276	2,135
Research and development tax credits		
- Federal	1,231	1,161
- State	-	159
Share-based compensation	66	57
Other, net	203	332
Total deferred taxes	3,804	51,036
Valuation allowance	(3,804)	(51,036)
Net deferred tax assets	$-	$-

Realization of deferred tax assets is dependent upon future earnings, if any, and the timing and amount of which may be uncertain. Valuation allowances are placed on deferred tax assets when uncertainty exists on their near term utilization. We make periodic reviews of our valuation allowances and fluctuations can occur. Those fluctuations may be reflected as income tax expenses or benefits in the period they occur. We continue to maintain full valuation allowance against all of our deferred tax assets at December 31, 2017 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 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.

Uncertainty in Income Taxes

We adopted 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. Our adoption of the standard did not result in establishing a contingent tax liability reserve or a corresponding charge to retained earnings. At each of December 31, 2017 and 2016, 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, 2017, the Company’s tax years of 2014, 2015 and 2016

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 2014.

NOTE 14 – COMMITMENTS AND CONTINGENCIES

Reglan®/Metoclopramide Litigation

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

In the lawsuits filed to date, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by us. We discontinued manufacture and distribution of generic metoclopramide more than 20 years ago. In addition, we believe the June 23, 2011 decision by the U.S. Supreme Court in *PLIVA v. Mensing ("Mensing* decision") holding that state tort law failure to warn claims against generic drug companies are pre-empted by the 1984 Hatch-Waxman Act Amendments and federal drug regulations will assist us in favorably resolving these cases.

In New Jersey, Generic Defendants, including Acura, filed dispositive motions based on the *Mensing* decision, which the Court granted with a limited exception. In June 2012, the New Jersey trial court dismissed all of the New Jersey cases pending against us with prejudice.

In Pennsylvania, the trial court proceedings were stayed on January 12, 2017. On June 15, 2017, the Court entered an Order approving a stipulation which dismisses nearly all of the individual cases against us based upon lack of product identification without prejudice and provides for these cases to be dismissed finally, with prejudice, on June 15, 2018, or at an earlier date in each individual case, if all parties are dismissed. Acura is in the process of seeking voluntary dismissal without prejudice of the *de minimis* number of remaining Pennsylvania cases pending against Acura on the basis of lack of product identification. We expect that these remaining few cases will be dismissed based on lack of product identification and the Court will finally dismiss the Pennsylvania-based litigation against us with prejudice in 2018. Legal fees related to this matter are currently covered by our insurance carrier.

In California, on May 24, 2016, the Court entered an Order approving a stipulation which stays the individual cases against us and provides for an agreed upon dismissal protocol for all cases where is a lack of product identification. On January 13, 2017, the Court also entered a general stay of this entire litigation. To date, none of these plaintiffs have confirmed they ingested any of the generic metoclopramide manufactured by us. Therefore, we expect that the lawsuits filed against us will be dismissed voluntarily with prejudice in 2018. Legal fees related to this matter are currently covered by our insurance carrier.

As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of December 31, 2017 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

DES Litigation

On April 12, 2018, an action was commenced against the Company and over twenty-five other pharmaceutical manufacturers in New York State Supreme Court, New York County, captioned *Cotto et al. v. Abbott Laboratories, Inc., et al* (index 153339/2018). The Complaint contains seven causes of action, including negligence, strict liability,

and breach of warranty, wrongful death, among others, in connection with the alleged exposure of the deceased plaintiff in utero to diethylstilbestrol (DES) in the 1950s as the result of the ingestion of the drug by her mother or grandmother. The plaintiffs are the personal representative of the deceased and her two daughters. The plaintiffs were unable to determine which of the defendants produced the DES used by the deceased, but regardless seeks to hold all defendants jointly and severally liable. The Complaint seeks $10.0 million in compensatory and $10.0 million in punitive damages on each of five counts and damages in an amount to be determined for wrongful death and additional punitive damages in an unstated amount. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to these matters as of December 31, 2017. We are presently unable to determine if any potential loss would be covered by any of our current or former insurance carriers.

Purdue Pharma Settlement

In April 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (collectively, "Purdue") commenced a patent infringement lawsuit against us and our Oxaydo product licensee Egalet US, Inc. and its parent Egalet Corporation in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's U.S. Patent No. 8,389,007 (the " 007 patent"). In April 2016, Purdue commenced a second patent infringement lawsuit against us and Egalet in the United States District Court for the District of Delaware alleging our Oxaydo product infringes Purdue's newly issued U.S. Patent No. 9,308,171 (the "171 Patent"). The actions regarding the 007 Patent and the 171 Patent are collectively referred to as the "Actions". On April 6, 2016, we filed a petition for Inter Partes Review (the "IPR Review") with the U.S. Patent and Trademark Office ("USPTO") seeking to invalidate Purdue's 007 Patent.

On May 20, 2016, Purdue on behalf of themselves and certain affiliates, Egalet Corporation, on behalf of itself and its affiliates and we, on behalf of ourselves and our affiliates entered into a settlement agreement (the "Settlement Agreement") to settle the Actions and the IPR Review. Under the Settlement Agreement the parties dismissed or withdrew the Actions, requested that the USPTO terminate the IPR Review and exchanged mutual releases. No payments were made under the Settlement Agreement.

The Settlement Agreement also provides that Purdue will not, in the future, assert certain Purdue U.S. patents, including the 007 Patent, the 171 Patent and related technologies (the "Purdue Patents") against any Acura Settlement Product or Egalet Settlement Product (except generally in an action or interference by Acura or Egalet challenging a Purdue Patent). Acura Settlement Products and Egalet Settlement Products are certain immediate-release and extended-release products, including Oxaydo. In addition, the Settlement Agreement provides that Purdue will not challenge, with certain exceptions, the Acura/Egalet Patents with respect to the Purdue Settlement Products (as defined below) and that Purdue provides Acura and/or Egalet certain waivers of non-patent marketing exclusivity with respect to Purdue Settlement Products.

The Settlement Agreement also provides that Acura and Egalet will not, in the future, assert certain Acura and/or Egalet U.S. patents (the "Acura/Egalet Patents"), including Acura's Aversion® Technology patents, against any Purdue Settlement Products (except generally in an action or interference by Purdue challenging an Acura/Egalet Patent). Purdue Settlement Products are certain immediate-release and extended-release products. In addition, the Settlement Agreement provides that Acura and Egalet will not challenge, with certain exceptions, the Purdue Patents with respect to the Acura Settlement Products and Egalet Settlement Products and that Acura and Egalet provide Purdue certain waivers of non-patent marketing exclusivity with respect to the Acura Settlement Products and Egalet Settlement Products. In addition, Purdue has certain rights to negotiate to exclusively distribute an authorized generic version of certain Egalet Settlement Products, including, in some circumstances, Oxaydo® and other products using Acura's Aversion® Technology if licensed to Egalet.

The Settlement Agreement specifically excludes our patents related to our Impede® and Limitx™ technologies from the scope of the Acura/Egalet Patents under the Settlement Agreement.

In December 2014, the Company entered into an agreement with Purdue Pharma L.P. to settle a patent interference action regarding certain intellectual property held by Acura (U.S. Patent No. 8,101,630). The dispute centered upon the issue of which company has priority in developing the invention. The parties agreed to forgo protracted litigation and the uncertainties arising therefrom by entering an agreement whereby the Company conceded Purdue Pharma's claim of priority in exchange for certain financial consideration to us including an immediate non-refundable payment of $500 thousand. In June 2015, the Company received an additional $250 thousand payment from Purdue Pharma relating to the December 2014 agreement.

Egalet Agreement covering Oxaydo

On January 7, 2015, we and Egalet entered into a Collaboration and License Agreement (the "Egalet Agreement") to commercialize Aversion Oxycodone (formerly known as Oxecta®) 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 Egalet Agreement, we transferred the approved New Drug Application, or NDA, for Oxaydo to Egalet and Egalet is granted an exclusive license under our intellectual property rights for development and commercialization of Oxaydo worldwide (the "Territory") in all strengths, subject to our right to co-promote Oxaydo in the United States. Eaglet launched Oxaydo in the United States late in the third quarter of 2015.

In accordance with the Egalet Agreement, we and Egalet have formed a joint steering committee to coordinate commercialization strategies and the development of product line extensions. Egalet is responsible for the fees and expenses relating to the Oxaydo NDA and product line extensions of Oxaydo, provided that Egalet will pay a substantial majority of the expenses and we will pay for the remaining fees and expenses relating to (i) annual NDA PDUFA product fees, (ii) expenses of the FDA required post-marketing study for Oxaydo and (iii) expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States. Egalet will bear all of the expenses of development and regulatory approval of Oxaydo for sale outside the United States. Egalet is responsible for all manufacturing and commercialization activities in the Territory for Oxaydo. Subject to certain exceptions, Egalet will have final decision making authority with respect to all development and commercialization activities for Oxaydo, including pricing, subject to our co-promotion right. Egalet may develop Oxaydo for other countries and in additional strengths, in its discretion. At December 31, 2017 and 2016, we have accrued approximately $328 thousand and $150 thousand, respectively, of these potential cost sharing reimbursable expenses under the Egalet Agreement.

Facility Lease

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

NOTE 15 – SUBSEQUENT EVENT

Loan Due January 2, 2020

During the second quarter of 2018, we borrowed a total of $1.0 million from John Schutte and issue a promissory note (the Schutte Note), in that principal amount to him. The Schutte Note bears interest at prime plus 2.0%, and matures on January 2, 2020, at which time all principal and interest is due, and is unsecured until all obligations to Oxford are satisfied at which time we are required to grant a security interest to Mr. Schutte in all of our assets. Events of default under the Schutte Note are limited to bankruptcy defaults and failure to pay interest and principal when due on January 2, 2020. In addition, Mr. Schutte and Oxford entered into a subordination agreement, approved by us and our subsidiary, pursuant to which Mr. Schutte subordinated the Schutte Note to our obligations to Oxford under the Oxford Loan Agreement. The Schutte Note may be prepaid at any time in whole or in part, however while Oxford’s loan is outstanding such prepayment will require Oxford’s consent. Also, in connection with the loan, we and Oxford entered into a fourth amendment to the Oxford Loan Agreement. Pursuant to the fourth amendment, Oxford provided a waiver of compliance with the unqualified audit opinion covenant in connection with our receipt of our auditor’s opinion with a going concern explanatory paragraph for our 2017 financial statements and allowed us to deliver financial statements up to 160 days after year end, instead of up to 120 days after year end.

SUPPLEMENTARY DATA - QUARTERLY RESULTS OF OPERATION (Unaudited)

Selected unaudited quarterly consolidated financial data is shown below (in thousands except per share amounts):

	For Three Month Periods Ended			
	Mar. 31, 2017	**June 30, 2017**	**Sept. 30, 2017**	**Dec. 31, 2017**
Net revenues	$2,717	$92	$83	$74
Operating expenses	2,135	2,083	2,145	1,828
Operating income (loss)	582	(1,991)	(2,062)	(1,754)
Net income (loss)	$405	$(2,149)	$(2,200)	$(1,738)
Basic income (loss) per share	$0.03	$(0.18)	$(0.12)	$(0.08)
Diluted income (loss) per share	$0.03	$(0.18)	$(0.12)	$(0.08)

	For Three Month Periods Ended			
	Mar. 31, 2016	**June 30, 2016**	**Sept. 30, 2016**	**Dec. 31, 2016**
Net revenues	$224	$257	$218	$3,765
Operating expenses	3,362	3,336	2,287	2,036
Operating (loss) income	(3,138)	(3,079)	(2,069)	1,729
Net (loss) income	$(3,384)	$(3,288)	$(2,250)	$1,534
Basic (loss) income per share	$(0.28)	$(0.28)	$(0.19)	$0.13
Diluted (loss) income per share	$(0.28)	$(0.28)	$(0.19)	$0.13

(i) Year to date earnings per share may not equal sum of quarters due to rounding.

ACURA PHARMACEUTICALS, INC.

EXHIBIT INDEX

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

Exhibit Number	Exhibit Description
1.1	Placement Agency Agreement dated June 30, 2015 between Roth Capital Partners LLC and the Registrant (incorporated by reference to Exhibit 1.1 to our Form 8-K filed July 1, 2015)
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on June 25, 2009).
3.2	Certificate of Amendment Reverse Splitting Common Stock and restating but not changing text of part of Article III of Restated Certificate of Incorporation (incorporated by Reference to Exhibit 3.1 to the Form 8-K filed December 4, 2007).
3.3	Certificate of Amendment Reverse Splitting Common Stock and restating but not changing text of part of Article III of Restated Certificate of Incorporation (incorporated by Reference to Exhibit 3.1 to the Form 8-K filed August 27, 2015).
3.4	Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Form 8-K filed on May 14, 2018).
4.1	Form of Common Stock Certificate (incorporated by Reference to Exhibit 4.1 to the Form S-3 filed on March 9, 2016)
4.2	Amended and Restated Warrant A-1 issued to Oxford Finance LLC on January 7, 2015 (incorporated by reference to Exhibit 10.9 to our Form 10-K filed March 2, 2015).
4.3	Amended and Restated Warrant A-2 issued to Oxford Finance LLC on January 7, 2015 (incorporated by reference to Exhibit 10.10 to our Form 10-K filed March 2, 2015).
4.4	Amended and Restated Warrant A-3 issued to Oxford Finance LLC on January 7, 2015 (incorporated by reference to Exhibit 10.11 to our Form 10-K filed March 2, 2015).
4.5	Form of Common Stock Warrant issued to John Schutte on July 24, 2017 (incorporated by reference Exhibit 4.1 to our Form 8-K filed July 28, 2017)

10.1	Manufacturing Services Agreement dated as of July 19, 2011 between the Registrant and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to our Form 8-K filed July 27, 2011) (confidential treatment has been granted for portions of this Exhibit).
10.2	Securities Purchase Agreement dated as of August 20, 2007 ("PIPE SPA") among the Registrant, Vivo Ventures Fund VI, L.P., Vivo Ventures VI Affiliates Fund, L.P., GCE Holdings LLC, and certain other signatories thereto (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 21, 2007).
10.3	Subscription Agreement dated as of July 24, 2017 between the Registrant and John Schutte (incorporated by reference to Exhibit 10.1 to our Form 8-K filed July 28, 2017)

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

10.14	Second Amended and Restated Voting Agreement executed July 2017 and dated as of July 24, 2017 (incorporated by reference to Exhibit 10.1 to the 8-K dated filed August 1, 2017)

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

†10.28	Seventh Amendment to Executive Employment Agreement executed December 12, 2013 between the Registrant and Clemens (incorporated by reference to Exhibit 10.24 to the Form 10-K for the year ending December 31, 2013 filed on March 3, 2014).

Exhibit Number	Exhibit Description
†10.29	Employment Agreement dated as of March 18, 2008 between the Registrant and Robert B. Jones (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on March 24, 2008).
†10.30	Amendment to Executive Employment Agreement dated as of April 28, 2011 between the Registrant and Robert B. Jones (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed July 28, 2011).
†10.31	Amendment to Executive Employment Agreement between Registrant and Robert B. Jones made as of July 7, 2011 (incorporated by reference to Exhibit 10.2 to our Form 10-Q filed July 28, 2011).
†10.32	Second Amendment to Executive Employment Agreement between Registrant and Robert B. Jones executed December 14, 2012 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed December 17, 2012).
10.33	Form of Securities Purchase Agreement entered into between the Registrant and institutional investors on June 30, 2015 (incorporated by reference to Exhibit 10.1 of our Form 8-K filed July 1, 2015).
10.34*	License, Commercialization and Option Agreement is made and entered into as of March 16, 2017 by and between MainPointe Pharmaceuticals, LLC
14.1	Code of Ethics (incorporated by reference to Exhibit 14.1 of the Form 8-K filed on December 10, 2007).
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21 to the Form 10-K for the fiscal year ended December 31, 2006 filed on March 15, 2007).
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
31.2*	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
32*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit Number	Exhibit Description
101.INS *	XBRL Instance Document
101.SCH *	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Extension Calculation Linkbase
101.LAB *	XBRL Extension Label Linkbase
101.PRE *	XBRL Extension Presentation Linkbase
101.DEF *	XBRL Taxonomy Extension Definition Linkbase

*Filed or furnished herewith.

† Management contract or compensatory plan or arrangement