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, 2016**

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number 1-10113

ACURA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

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

Based on the last sale price on the NASDAQ Capital Market of the Common Stock of $1.85 on June 30, 2016 (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 $13.7 million.

As of March 31, 2017, the registrant had 11,883,339 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, 2016

Tablet of Contents

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-04, the date by which such study results will be available and whether LTX-04 will ultimately receive FDA approval;
- whether Limitx will retard the release of opioid active ingredients as dose levels increase;
- whether we will be able to reformulate LTX-04 to provide an efficacious level of drug when one or two tablets are taken;
- whether we will be able to reformulate LTX-04 to improve its abuse deterrent performance;
- 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;
- whether we can successfully develop a product under our agreement with Bayer;
- the results of our development of our Limitx Technology;
- 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,” “expects,” “plans,” “anticipates,” “believes,” “indicates,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in 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 and only 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 multiple pseudoephedrine products in development utilizing our Impede Technology. On June 15, 2015, we and Bayer Healthcare LLC, or 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. 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.

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. We have completed our first clinical study, Study AP-LTX-400, or Study 400, of our lead Limitx immediate release oral abuse deterrent drug candidate using the opioid hydromorphone HCI (LTX-04). Study 400 was a two cohort, open label, crossover design pharmacokinetic study in healthy adult subjects. The FDA has designated the LTX-04 development program 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. On April 13, 2016 and June 8, 2016 we announced that topline interim results from cohorts 1 and 2, respectively, of Study 400 for one test formulation of LTX-04 successfully demonstrated the release of the active opioid ingredient was reduced when three or more tablets were ingested, but that additional formulation development will be required for LTX-04 to deliver a sufficient amount of the active ingredient when one or two tablets are administered. 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 maximum drug concentration, or Cmax, when three or more LTX-04 tablets were ingested. We identified a subpopulation of participants in Study 400 that demonstrated increased reductions in Cmax when taking LTX-04, or faster drug absorbers. The FDA noted that to label a product for a particular subpopulation, including faster drug absorbers, prescribers should be able to understand that only a subset of their patients may benefit from use of the product. We intend to advance updated formulations of LTX-04 to a second pharmacokinetic study which is expected to commence in second quarter 2017. We intend to develop LTX-04 through proof of concept and then rapidly advance a formulation of a product with greater prevalence of oral excessive tablet abuse, or ETA, such as immediate-release hydrocodone with acetaminophen.

Opioid analgesics are one of the largest prescription drug markets in the United States with 222 million prescriptions dispensed in 2016. Prescription opioids are also the most widely abused drugs with 11 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 208 million prescriptions and $2.7 billion, of which approximately 98% was attributable to generic products. Immediate-release oxycodone tablets represent 20.1 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. We are advised that Egalet has approximately 71 sales representatives promoting Oxaydo to a target group of approximately 11,500 opioid prescribing physicians.

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 2013 to 595,000 people up from 440,000 in 2012. At March 15, 2017, Nexafed, our 30mg pseudoephedrine hydrochloride immediate-release tablet, were stocked in approximately 21% of the estimated 65,000 U.S. pharmacies. Many of these pharmacies are either actively recommending Nexafed to their patients or carry Nexafed as their only 30mg pseudoephedrine product.

We have an active development program to develop an extended-release version of our Impede Technology to capitalize on higher sales products in the category. We also are investigating new technologies that would improve on our meth-resistant capabilities. 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.

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 with our internal resources or license to strategically focused companies in the United States and other geographic territories*. We have developed a small infrastructure to commercialize our OTC products that utilize the Impede Technology. 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 we are seeking licensing partners for our products in development utilizing our Limitx, Aversion and Impede technologies.

- *Maintain an efficient internal cost structure*. Our internal cost structure is focused on discovering new technologies and developing product formulations using those technologies. We also have a small, focused OTC marketing and sales team. 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.

- *In-license or acquire technologies and/or products to expand our portfolio of technologies and products*. We intend to pursue the in-license or acquisition of product candidates and technologies that will allow us to expand our portfolio of products. Such in-licensing or acquisition transactions, if successfully completed, of which no assurance can be given, may include product candidates or technologies for pain relief, addiction, and other drugs.

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 FDA's 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. We have initiated formulation development of a hydrocodone/APAP product candidate utilizing our Limitx Technology (LTX-03). In August 2015, the United States Patent and Trademark Office, or USPTO, issued to us patent 9,101,636 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 is 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.

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)	Phase I exploratory pharmacokinetic study completed
Immediate-release hydrocodone bitartrate with acetaminophen (LTX-03)	Formulation development in process
Immediate-release oxycodone HCl (LTX-01) & (LTX-02)	Formulation development in process

The initial LTX-04 clinical study, or 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 interim results from Study 400 test formulation LTX-04P, successfully demonstrated the release of the active opioid ingredient was reduced when three or more intact tablets were ingested, but that additional formulation development will be required for LTX-04P to deliver a sufficient amount of the active ingredient to patients when one or two tablets are administered. Specifically, the topline interim results of Study 400 demonstrated:

- Subjects in Study 400 had an average 22% reduction in relative Cmax when 3 or more tablets were ingested as shown in the table below.

Study 400 – Mean Ratio of Cmax (ng/mL) by Dosing Group
Compared to the 1 Tablet Group for the Same Formulation

	Dosing in mg	DILAUDID	LTX-04P	Change
2 Tablet Group	2x	1.9x	2.2x	15%
3 Tablet Group	3x	4.8x	3.8x	-22%
4 Tablet Group	4x	6.4x	4.8x	-25%
6 Tablet Group	6x	6.2x	5.2x	-15%
8 Tablet Group	8x	8.4x	6.8x	-18%
Average 3-8				-22%

- All Subjects in cohort 2 had extent of drug absorption (measured by AUC) for LTX-04P comparable to Dilaudid when the same number of tablets were ingested. Likewise, the time to maximum plasma concentration, or Tmax, was comparable at all doses to Dilaudid.

- Subjects taking one or two tablets of both LTX-04 test formulations had comparable extent of drug absorption (measured by AUC) as the same number of tablets of Dilaudid. However, these tablets delivered approximately 50% less peak plasma concentration (Cmax) than Dilaudid. As such, the LTX-04 test formulations were considered to not have achieved equivalent blood levels of drug and will require further development. All study drugs were generally well tolerated and no serious adverse events were observed.

Further analysis of the 3, 4, 6 and 8 tablet subgroups in Study 400 identified a subpopulation of patients in which LTX-04P appeared to demonstrate enhanced reduction in drug absorption as compared to Dilaudid. This subpopulation is characterized by their propensity to absorb the opioid in Dilaudid quickly, reaching maximum drug concentration in the blood in 30 minutes or less, while, on average, having maximum blood levels of drug 1.8 times that of the slower drug absorbing subjects. This subpopulation may represent a more vulnerable abuse population as speed of drug absorption and higher peak drug levels in the blood are typically associated with more drug abuse and possibly addiction.

In the faster absorbing subpopulation of subjects, assuming each subject should have an expected Cmax for LTX-04P consistent with the average seen in the 1 and 2 tablets subgroups of 53% of Dilaudid, the subpopulations demonstrated:

- 82% of subjects had an estimated reduction in Cmax associated with Limitx
- 38% average estimated reduction in Cmax associated with Limitx
- 66% maximum reduction in estimated Cmax observed in two of 17 subjects
- 1.6x average increase in Tmax associated with Limitx

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. We identified a subpopulation of participants in Study 400 that demonstrated increased reductions in Cmax when taking LTX-04, or faster drug absorbers. The FDA noted that to label a product for a particular subpopulation, including faster drug absorbers, prescribers should be able to understand that only a subset of their patients may benefit from use of the product. 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.

We have completed reformulation work on the Limitx Technology micro-particles and have two candidates which we believe will improve the drug delivery with one and two tablet dosing. We intend to advance these new formulations of LTX-04 to a second pharmacokinetic study which is expected to commence in second quarter 2017. Subsequent to the completion of Study 400, we observed discoloration of the LTX-04 tablets which we have corrected with a new tablet formulation for dosing in the next clinical study. We intend to develop LTX-04 through proof of concept and then rapidly advance a formulation of a product with greater prevalence of oral ETA, such as immediate-release hydrocodone with acetaminophen.

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 five issued U.S. patents, which expire between 2023 and 2025. Our Aversion Technology products are intended to provide the same therapeutic benefits of the active drug ingredient as currently marketed products containing the same active pharmaceutical ingredient.

Oxaydo Tablets

Oxaydo (oxycodone HCI tablets) is a Schedule II narcotic indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. On January 7, 2015, we entered into a Collaboration and License Agreement with 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. On September 15, 2016, Egalet announced that a new 15 mg strength of Oxaydo that they are developing achieved bioequivalence to a reference dose in support of a potential NDA supplement filing.

The 2015 market for immediate-release oxycodone products was 20.1 million dispensed prescription 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 us that it has commenced formulation work on a 15mg dosage strength for Oxaydo, has achieved bioequivalence of this new strength to a reference formulation, and has set a target date for submission of this new dosage strength to the FDA in the second half of 2017. Egalet has also 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.

We are advised that Egalet commenced promoting Oxaydo in September 2015 and has since expanded its target physician group to approximately 11,500 immediate-release opioid prescribing physicians using approximately 71 sales representatives. Commercial shipments of Oxaydo commenced in early October 2015. Egalet has further advised us that they have implemented a co-pay support program in which any non-government insurance covered patient receiving an Oxaydo prescription will be eligible to receive a credit such that their out-of-pocket cost, or co-pay, is limited to $15 per prescription. Egalet is in the early stages of promoting Oxaydo to physicians and addressing the challenges of establishing retail pharmacy stocking of a Schedule II narcotic.

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 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 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 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 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 expect to perform process validation on this new formulation in the first half of 2017 and that MainPointe will introduce the new formulation into the market pursuant to the MainPointe Agreement.

Nexafed Products

Our Nexafed product line consists of immediate release tablets which currently utilize our patented Impede 1.0 Technology. Nexafed is a 30mg pseudoephedrine tablet and Nexafed Sinus Pressure + Pain is a 30/325mg pseudoephedrine and acetaminophen tablet. 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 the MainPointe Agreement, 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. We also used telemarketing, direct mail, and online and journal advertising to educate pharmacists about Nexafed and encourage pharmacists to recommend Nexafed to their customers. Under the terms of the MainPointe Agreement, MainPointe will control 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. We also shipped directly to the warehouses of certain pharmacy chains. At March 15, 2017, 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 recommend Nexafed to their customers while some have 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.

We estimate that at March 15, 2017, approximately 56% of Nexafed stocking pharmacies are repeat customers, excluding Rite Aid and Kroger which purchase directly from us and we therefore do not have individual store data.

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.

We understand that in 2014, a majority of pharmacies in West Virginia voluntarily began selling only meth-resistant products for the single-ingredient immediate-release PSE offerings. In 2015, newspapers reported about 60% of single-ingredient immediate-release PSE sales in West Virginia were for meth-resistant formulations. In March 2016, Indiana enacted legislation, subject to adoption of rule and policy making by the Indiana Board of Pharmacy, to require state pharmacists to use professional discretion when selling PSE-containing cold and allergy products, including encouraging the use of new meth-resistant formulations, in an effort to help reduce local methamphetamine production. According to media reports, Rite Aid pharmacies and many independent pharmacies in small a geographic region in Maine have, at the request of local authorities and community leaders, removed all traditional pseudoephedrine-containing products from their shelves and stock only meth-resistant formulations such as Nexafed.

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 $425,000 for the net book value of 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 million, $500,000 and $250,000, 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 $500,000 per product (for all 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.

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	Transferring to alternate supplier and scaling-up to commercial supply
Immediate-release pseudoephedrine HCl in combination with other cold and allergy active ingredients	Nexafed Sinus Pressure + Pain launched and licensed to MainPointe Other formulations being considered
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
Extended-release combination products	Formulations being considered
Methamphetamine resistant pseudoephedrine – containing product	In development pursuant to Bayer Agreement

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.

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. The Bayer Agreement also grants Bayer first right to negotiate a license to the Impede® Technology for certain other products. We are eligible to receive reimbursement of certain our development expenses, success-based development and regulatory milestone payments, and low mid-single digit royalties on the net sales of the developed product in countries with patent coverage and a reduced royalty elsewhere.

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 will control 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 controlled prescription drugs, or CPDs, in general, and opioid analgesics in particular, continues to constitute a dynamic and challenging threat to the United States and is the nation's fastest growing drug problem. Results from the 2013 National Drug Threat Assessment conducted by the U.S. Drug Enforcement Administration, or DEA, report that CPD rates of abuse remain high, with individuals abusing CPDs at a higher prevalence rate than any illicit drug except marijuana. Opioid analgesics are the most common type of CPDs taken illicitly and are the CPDs most commonly involved in overdose incidents. According to the Drug Abuse Warning Network (DAWN), the estimated number of emergency department visits involving nonmedical use of prescription opiates/ opioids increased 112 percent—84,671 to 179,787— between 2006 and 2010. 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 45 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 222 million tablet and capsule prescriptions dispensed in 2016 of which approximately 208 million were for IR opioid products and 14 million were for ER opioid products. However, physicians and other health care providers at times are reluctant to prescribe opioid analgesics for fear of misuse, abuse, and diversion of legitimate prescriptions for illicit use.

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

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

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

[2] IMS Health, 2016

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

Product Labeling for 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 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. 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 patent 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
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

We have the following issued patent 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
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, the Bayer Agreement, 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 "Item 1A. 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.

We rely 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, is also developing other analgesic products, all of which will 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, 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, or 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.

Each NDA requires payment of a user fee, pursuant to the requirements of the Prescription Drug User Fee Act, or PDUFA, as periodically amended. According to FDA's fee schedule, effective on October 1, 2016, for the 2017 fiscal year, the user fee for an application fee requiring clinical data, such as an NDA is $2,038,100. The FDA adjusts PDUFA user fees on an annual basis. PDUFA also imposes annual product and facility fees. 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, but no waivers for product or establishment fees are available. 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.

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. FDA is in 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 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.

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 15 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 2016 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 $7.4 million, $5.0 million and $13.2 million for the years ended December 31, 2016, 2015 and 2014, respectively. Our current unrestricted cash and cash equivalents will not be sufficient to fund the development of our products utilizing our Limitx and Impede Technologies, and our related operating expenses beyond mid-2017 while maintaining compliance with the $2.5 million compensating balance requirement under our term loan with Oxford Finance LLC. Our auditors have included in their report relating to our 2016 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-04, 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.

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. Our current unrestricted cash and cash equivalents will not be sufficient to fund the development of our products utilizing our Limitx and Impede Technologies, and our related operating expenses beyond mid-2017 while maintaining compliance with the $2.5 million compensating balance requirement under our term loan with Oxford Finance LLC.

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.

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., or 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 and on March 16, 2017 in connection with our license agreement with MainPointe. 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, limitations on the incurrence of additional debt, and the requirement to maintain at least $2.5 million in cash reserves until we raise an additional $6.0 million following the execution of our license agreement with KemPharm 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 through the issuance and sale of our equity securities. 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, 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 $795,000, potential foreclosure on our assets, and other adverse results.

If Oxford were to declare an event of default, it would have the option, among other things, of accelerating the debt under our loan and security agreement and foreclosing on the Company's assets pledged as collateral for the term loan. Any declaration of an event of default would significantly harm our business and would likely cause the price of our common stock to decline.

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 2017 and 2018, 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-04, and other Limitx product candidates in development. We completed our first Phase I clinical study for LTX-04 in mid-2016 and are engaged in formulation development or early preclinical development for our 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-04 are not successful we may determine that further clinical development of LTX-04 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;
- 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; and
- maintain intellectual property protection for Oxaydo and obtain favorable drug listing treatment by the FDA to minimize generic competition.

There can be no assurance that Egalet will devote sufficient resources to the 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. If Egalet fails to successfully commercialize Oxaydo and generate 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 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 hydromorphone HCI or 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 Phase 1 exploratory pharmacokinetic studies for our hydromorphone HCI 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 and payments that may be made under the Bayer Agreement to fund operations.

To fund our continued operations, we expect to rely on our current cash resources, royalty payments under the Egalet Agreement relating to Oxaydo, royalty payments under the MainPointe Agreement relating to our Nexafed products, collaboration reimbursement, milestones and royalty payments that may be made under the Bayer Agreement, 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, royalties from MainPointe on Nexafed products net sales, and payments under the Bayer agreement 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.

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. 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 recently 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. 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.

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, the Bayer 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.

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.

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 product candidates, if successfully developed and commercially launched, will compete with both currently marketed and new products launched in the future by other companies. Health care providers may not accept or utilize any of our products. 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 the newly elected administration has indicated it intends to replace portions of the Healthcare Reform Law. This could affect reimbursement for our product and introduces numerous uncertainties into the industry's operations.

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. For example, for the year ended December 31, 2016 Rite Aid accounted for approximately 55% of our Nexafed revenue. Walgreens is not currently a customer of Nexafed and is in the process of acquiring Rite Aid. Following Walgreens' acquisition of Rite Aid, it is possible that MainPointe could lose the Nexafed revenue derived from Rite Aid, and we would lose the corresponding royalty payments under the MainPointe Agreement, unless Walgreens elects to purchase Nexafed.

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. 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.

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 may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by patients, health care providers or others that sell or consume our products. These claims may be made even with respect to those products that possess regulatory approval for commercial sale. We are currently covered by clinical trial product liability insurance on a claims-made basis and for product liability insurance covering our sale and distribution of our Nexafed products. This coverage may not be adequate to cover any product liability claims. Product liability coverage is expensive. In the future, we may not be able to maintain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims. Any claims that are not covered by product liability 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 discussed below under "Item 3. Legal Proceedings" of this Report. 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 and Collegium Pharmaceuticals, Inc. These companies appear to be focusing their development efforts on ER Opioid Products, except for Atlantic Pharmaceuticals, Pisgah Labs, 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 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.

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, or NOL, carryforwards and other tax attributes. We have determined that an ownership change (as defined by Section 382 of the Internal Revenue Code) did occur as a result of a capital restructuring that occurred in 2004. 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 2016, our stock traded as high as $3.52 per share and as low as $0.71 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 included in our current registration statement could depress the trading price of our stock, lower our value and make it more difficult for us to raise capital.

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 15, 2017, our three largest shareholders owned an aggregate of approximately 5,178,000 shares of our common stock (representing approximately 44% of our outstanding shares). All of such shares are available for resale by such stockholders. If some or all of such shares are sold by 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.

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 Section 15(g) of 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 $4.00 per share, other than companies that have had average revenue of at least $6,000,000 for the last three years or that have tangible net worth of at least $5,000,000 ($2,000,000 if the company 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 currently quoted on the OTCQB and 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 and 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 2016 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 has a term expiring March 31, 2017. The lease agreement provides for rent, property taxes, common area maintenance, and janitorial services on an annualized basis of approximately $25,000 per year. We utilize this lease space for our administrative, marketing and business development functions. Effective April 1, 2017, the office space is leased on a month to month basis.

We conduct research, development, laboratory, development scale and NDA submission batch scale manufacturing and other activities relating to developing product candidates using Aversion and Impede Technologies at the facility we own located at 16235 State Road 17, Culver, Indiana. At this location, our wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc., 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, has been 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 Pennsylvania action, over 200 lawsuits were filed against Acura and Halsey Drug Company alleging that plaintiffs developed neurological disorders as a result of their use of the Reglan brand and/or generic metoclopramide. In the New Jersey action, plaintiffs filed approximately 150 lawsuits against us, but served less than 50 individual lawsuits upon us. In the California action, there are 89 pending cases against us, with more than 445 individual plaintiffs.

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 19 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, and California, Generic Defendants, including us, also filed dispositive motions based on the *Mensing* decision.

In Pennsylvania, on November 18, 2011, the trial court denied Generic Defendants' dispositive preemption motions, without prejudice. In July 2013, the Pennsylvania Superior Court issued an adverse decision, and a subsequent appeal to the Pennsylvania Supreme Court was denied. On December 16, 2014, the Generic Defendants filed a Joint Petition for Certiorari with the United States Supreme Court captioned *Teva Pharmaceuticals USA, Inc. et al. v. Dorothy Bentley, et al.*, No. 14-711 (U.S.) seeking reversal of the Pennsylvania state court decision. On April 27, 2015, the U.S. Supreme Court denied this Petition and this matter has been returned to the trial court for further proceedings.

From July, 2015 to date, the court has taken procedural steps to narrow this litigation, including requests for plaintiffs to voluntarily discontinue cases, such as those filed against us, where there is no case-specific product identification. The trial court proceedings were stayed on January 12, 2017. We are in the process of obtaining voluntary dismissal without prejudice of all of the Pennsylvania cases pending against us. We expect that the Court will approve these dismissals within the next few months before the close of the second quarter of 2017 and should finally dismiss the Pennsylvania-based litigation against us with prejudice later this year. Legal fees related to this matter are currently covered by our insurance carrier.

In California, the trial court entered a May 25, 2012 Order denying Generic Defendants' dispositive preemption motions. The Generic Defendants' appeals from this order were denied by the California appellate courts. In May 2014, the California Court denied a subsequent demurrer and motion to strike seeking dismissal of plaintiffs' manufacturing defect and defective product claims to the extent that they are barred by federal preemption based upon the June 2013 *Bartlett* decision. Thus far, we and most Generic Defendants have not been required to file answers or other responsive pleadings in each individual case in which they are named defendants. 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 within the next three to six months. 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, 2016 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

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 each our 2015 and 2016 fiscal years 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 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". All prices in the tables below are adjusted for the 1-for-5 reverse split of our common stock effected on August 27, 2015.

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
2015 Fiscal Year		
First Quarter	$ 5.75	$ 2.25
Second Quarter	6.75	3.70
Third Quarter	4.80	2.27
Fourth Quarter	2.85	1.62
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 bid prices for our common stock in the OTCQB. All prices set forth below represent inter-dealer quotations, without adjustment for retail mark-up, mark-down or commission, and may not represent the prices of actual transactions.

Period	Bid Prices	
	High	Low
2017 Fiscal Year		
First Quarter (February 23, 2017 through March 15, 2017)	$ 0.70	$ 0.46

On March 15, 2017, the closing bid price of our common stock was $0.51.

Holders

There were approximately 310 holders of record of our common stock as of January 31, 2017 there, including approximately 91 holders who are nominees for an undetermined number of beneficial owners based upon a review of the securities position listing provided by our transfer agent. 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, 2016, 2015, 2014, 2013 and 2012 are derived from our audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2016 and 2015 and for each of the years in the two-year period ended December 31, 2016, and the reports thereon, are included elsewhere in this Report. The selected financial information presented for our 2014, 2013 and 2012 operations and for our 2014, 2013 and 2012 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 28, 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	2016	2015	2014	2013	2012
Revenues, net	$ 4,464	$ 8,587	$ 751	$ 123	$ -
Cost and expenses:					
Cost of sales	477	986	428	364	-
Research and development[(1)]	4,028	2,608	4,582	4,923	3,726
Selling, marketing, general and administrative[(2)]	6,516	8,994	7,940	8,926	6,013
Interest expense	893	1,157	1,212	9	-
Investment income	60	166	198	194	79
Other income (expense)	2	3	4	4	(8)
Loss before provision for income taxes	(7,388)	(4,989)	(13,209)	(13,901)	(9,668)
Provision for income taxes	-	-	-	-	-
Net loss applicable to common stockholders	$ (7,388)	$ (4,989)	$ (13,209)	$ (13,901)	$ (9,668)
Loss per share of common stock: Basic	$ (0.62)	$ (0.46)	$ (1.35)	$ (1.45)	$ (1.00)
Loss per share of common stock: Diluted	$ (0.62)	$ (0.46)	$ (1.35)	$ (1.45)	$ (1.00)
Weighted average shares used in computing net loss per share: Basic	11,870	10,796	9,779	9,553	9,504
Weighted average shares used in computing net loss per share: Diluted	11,870	10,796	9,779	9,553	9,504

(1) Includes stock-based compensation expense from all types of awards of approximately $170, $160, $220, $315 and $375 for years 2016, 2015, 2014, 2013 and 2012, respectively.
(2) Includes stock-based compensation expense from all types of awards of approximately $450, $480, $700, $900 and $1,360 for years 2016, 2015, 2014, 2013 and 2012, respectively.

BALANCE SHEET DATA (in thousands)	2016	2015	2014	2013	2012
Working capital (deficit)[3]	$ (700)	$ 8,391	$ 10,239	$ 26,346	$ 26,572
Total assets	8,208	16,961	16,195	28,630	29,054
Total liabilities	7,025	9,061	11,143	10,707	1,424
Accumulated deficit	(374,698)	(367,310)	(362,321)	(349,112)	(335,211)
Stockholders' equity	$ 1,183	$ 7,900	$ 5,052	$ 17,923	$ 27,630

(3) Excludes 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 and only 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 multiple pseudoephedrine products in development utilizing our Impede Technology. On June 15, 2015, we and Bayer Healthcare LLC, or 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. 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.

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. We have completed our first clinical study, Study AP-LTX-400, of our lead Limitx immediate release oral abuse deterrent drug candidate using the opioid hydromorphone HCI (LTX-04). Study AP-LTX-400, or Study 400, was a two cohort, open label, crossover design pharmacokinetic study in healthy adult subjects. The FDA has designated the LTX-04 development program 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. On April 13, 2016 and June 8, 2016 we announced that topline interim results from cohorts 1 and 2, respectively, of Study 400 for one test formulation of LTX-04 successfully demonstrated the release of the active opioid ingredient was reduced when three or more tablets were ingested, but that additional formulation development will be required for LTX-04 to deliver a sufficient amount of the active ingredient when one or two tablets are administered. 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 maximum drug concentration, or Cmax, when 3 or more LTX-04 tablets were ingested. We identified a subpopulation of participants in Study 400 that demonstrated increased reductions in Cmax when taking LTX-04, or faster drug absorbers. The FDA noted that to label a product for a particular subpopulation, including faster drug absorbers, prescribers should be able to understand that only a subset of their patients may benefit from use of the product. We intend to advance updated formulations of LTX-04 to a second pharmacokinetic study which is expected to commence in second quarter 2017 with a new tablet formulation that addresses certain formulation stability issues. We intend to develop LTX-04 through proof of concept and then rapidly advance a formulation of a product with greater prevalence of oral excessive tablet abuse, or ETA, such as immediate-release hydrocodone with acetaminophen. We are actively seeking a licensing partner for our Limitx product candidates.

Company's Present Financial Condition

At December 31, 2016, we had unrestricted cash and cash equivalents of $2.7 million compared to $10.8 million of unrestricted cash, cash equivalents and marketable securities at December 31, 2015. Under our term loan with Oxford Finance LLC, we are 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 had an accumulated deficit of approximately $374.7 million and $367.3 million at December 31, 2016 and December 31, 2015, respectively. We had a loss from operations of $6.6 million and a net loss of $7.4 million for the year ended December 31, 2016, compared to a net loss from operations of $4.0 million and net loss of $5.0 million for the year ended December 31, 2015. As of March 30, 2017, our unrestricted cash and cash equivalents was $3.7 million (which is after the deduction of the $2.5 million compensating balance requirement under our term loan with Oxford). Our current unrestricted cash and cash equivalents will not be sufficient to fund the development of our products utilizing our Limitx and Impede Technologies, and our related operating expenses beyond mid-2017 while maintaining compliance with the $2.5 million compensating balance requirement under our term loan with Oxford Finance LLC.

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, 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, 2016 and 2015.

	December 31			
	2016	2015	Change	
	$000's		$000's	Percent
Revenues:				
License fee revenue	$ 3,500	$ 5,250	$ (1,750)	(33)%
Milestone revenue	-	2,500	(2,500)	(100)
Collaboration revenue	392	170	222	131
Royalty revenue	149	5	144	2,880
Product sales, net	423	662	(239)	(36)
Total revenues, net	4,464	8,587	(4,123)	(48)
Cost and expenses:				
Cost of sales	451	656	(205)	(31)
Inventory reserve expense for write-downs	26	330	(304)	(92)
Research and development	4,028	2,608	1,420	54
Selling, marketing, general and administrative	6,516	8,994	(2,478)	(28)
Total operating expenses	11,021	12,588	(1,567)	(12)
Operating loss	(6,557)	(4,001)	2,556	64
Non-Operating income (expense):				
Investment income	60	166	(106)	(64)
Interest expense	(893)	(1,157)	(264)	(23)
Other income	2	3	(1)	(33)
Total other expense	(831)	(988)	(157)	(16)
Loss before provision for income taxes	(7,388)	(4,989)	2,399	48
Provision for income taxes	-	-	-	-
Net loss	$ (7,388)	$ (4,989)	$ 2,399	48%

Revenue and Cost of Sales

License Fees

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 paid us $3.5 million upon signing the KemPharm Agreement.

On January 7, 2015, we and Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation (collectively, "Egalet") entered into a Collaboration and License Agreement to commercialize Oxaydo tablets (formerly known as Oxecta) utilizing our Aversion® Technology. Egalet paid us an upfront payment of $5.0 million upon signing the agreement.

The Company received a $250 thousand payment from Purdue Pharma L.P. in June 2015 relating to a December 2014 agreement to settle a patent interference action on U.S. Patent No. 8,101,630 issued to Acura.

Milestone Revenue

Milestone revenue is contingent upon the achievement of certain pre-defined events in the development agreements. Milestone payments are recognized as revenue upon achievement of the "at risk" milestone events, which represent the culmination of the earnings process related to that milestone. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones are substantially at risk at the inception of an agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment. Each milestone payment is non-refundable and non-creditable when made. In October 2015, Egalet paid us a $2.5 million milestone payment in connection with the first commercial sale of Oxaydo.

Collaboration Revenue

Collaboration revenue is derived from reimbursement of development expenses under various development agreements, such as the collaboration agreement with Bayer, and are recognized when costs are incurred pursuant to the collaboration agreement. We recognized $392 thousand and $170 thousand of collaboration revenue during the years ended 2016 and 2015, respectively.

Royalty Revenue

In connection with our Collaboration and License Agreement with Egalet to commercialize Oxaydo tablets we receive 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). Egalet's first commercial sale of Oxaydo occurred in October 2015. We recognized $149 thousand and $5 thousand of royalty revenue during the years ended 2016 and 2015, respectively.

Net Product Sales

Nexafed® was launched by us in December 2012. Nexafed® Sinus Pressure + Pain was launched by us in February 2015. The Company sells the Nexafed® product line in the United States to wholesale pharmaceutical distributors and as well as directly to chain drug stores. The product line is 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 has been extended to thirty-six months for Nexafed product supplied from one of the Company's contract manufacturers.

Given the limited sales history of Nexafed, we could not reliably estimate expected returns of the product at the time of shipment to certain customers and accordingly we had deferred revenue. As of December 31, 2014, we had $353 thousand of deferred revenue on our balance sheet related to Nexafed shipments which occurred since its commercial launch. During the first quarter ended March 31, 2015, we determined we had obtained sufficient sales returns history to reasonably estimate future returns. As a result of this change, we recorded a one-time adjustment in the first quarter ended March 2015 to recognize revenue that had previously been deferred, resulting in additional net revenue of $314 thousand. Revenue is being recognized at the time the product is sold to a customer. We recorded $423 thousand and $662 thousand of net product sales during the years ended 2016 and 2015, respectively.

Cost and Expenses

Cost of Sales

Cost of sales includes third-party acquisition costs, third-party warehousing and product distribution charges and inventory reserve expense for the Nexafed product line. During the first quarter ended March 31, 2015, we determined we had obtained sufficient sales returns history to reasonably estimate future returns. As a result of this change, we recorded a one-time adjustment in the first quarter ended March 2015 to recognize revenue that had previously been deferred, resulting in additional cost of sales of $255 thousand. For the years ended 2016 and 2015, cost of sales was $451 thousand and $656 thousand, respectively.

Inventory reserve expense for the years ended 2016 and 2015, is $26 thousand and $330 thousand, respectively. The expense in 2016 was for $26 thousand of finished goods for distribution and sale on Nexafed®. The expense in 2015 was for $260 thousand of raw and package materials purchased from Pfizer at the time we reacquired Oxaydo from Pfizer and for $70 thousand of finished goods held for distribution and sale on our Nexafed® product line.

Research and Development

Research and development expense (R&D) for 2016 was primarily for our Limitx and our Impede Technologies development including costs of preclinical and non-clinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs as well as approximately $190 thousand of cost sharing expenses of clinical studies for product line extensions (additional strengths) of Oxaydo for the United States under the Egalet Agreement and approximately $140 thousand of cost sharing expenses of the FDA required post-marketing study for Oxaydo under the Egalet Agreement. The initial LTX-04 clinical study, Study AP-LTX-400, or Study 400, was completed during the 2016 for expenses of approximately $1.0 million. R&D expense for 2015 was primarily for our Aversion and our Impede Technologies development including costs of preclinical and non-clinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in each of 2016 and 2015 results are non-cash share-based compensation expenses of approximately $0.2 million. Excluding the share-based compensation expense, our R&D expenses increased approximately $1.4 million between reporting.

General, Administrative, Selling and Marketing

Selling and marketing expenses for 2016 was primarily of advertising and marketing activities on the Nexafed product. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in each of the 2016 and 2015 results are non-cash share-based compensation expenses of approximately $0.4 million and $0.5 million, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased by approximately $2.4 million between reporting periods, resulting primarily from decreases in advertising and marketing activities and offset by increases in our patent legal and litigation expenses with Purdue Pharma and the cost sharing expenses under the Egalet Agreement. On May 20, 2016, a settlement agreement was entered into between Purdue Pharma 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.

Non-Operating Income (Expense)

During the years ended 2016 and 2015, non-operating expense consisted principally of interest expense on our term loan from Oxford Finance LLC, less investment income derived from our investments in marketable securities.

Income Taxes

Our results for 2016 and 2015 include no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Liquidity and Capital Resources

At December 31, 2016, we had unrestricted cash and cash equivalents of $2.7 million compared to unrestricted cash, cash equivalents, and marketable securities of $10.8 million at December 31, 2015. Under our term loan with Oxford, we are required to maintain a $2.5 million compensating balance. As of March 30, 2017, our unrestricted cash and cash equivalents was $3.7 million (which is after the deduction of the $2.5 million compensating balance requirement under our term loan with Oxford). We estimate that our unrestricted working capital, together with milestone and royalty payments, if any, that may be made under the Egalet Agreement, the KemPharm Agreement, the Bayer Agreement and the MainPointe Agreement, will be sufficient to fund our continuing operations through mid-2017 while maintaining compliance with the $2.5 million compensating balance requirement under our term with Oxford.

To fund further operations and product development activities beyond mid-2017, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. The Company intends to explore a variety of capital raising and other transactions to provide additional funding to continue operations. These include a registered public offering of the Company's common stock, for which the Company filed a registration statement on Form S-1 with the SEC on February 3, 2017, and 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 and Bayer Agreements. 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 2016 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 Bayer Agreement, the KemPharm Agreement, the MainPointe Agreement and similar agreements 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.

The following table presents our expected cash payments on contractual obligations outstanding as of December 31, 2016:

	Payments due by period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	$ 6	$ 6	$ -	$ -	$ -
Contract manufacturing services	46	46	-	-	-
Employment agreements	679	679	-	-	-
Service agreements	-	-	-	-	-
RSU awards	27	26	1	-	-
Debt interest	1,265	335	930	-	-
Debt principal	5,500	2,521	2,979	-	-
Total	$ 7,704	$ 3,794	$,3910	$ -	$ -

Term Loan with Oxford Finance

On December 27, 2013, we and our subsidiary, Acura Pharmaceutical Technologies, Inc. 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 are using 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, 2016, the outstanding principal balance of the Term Loan was $5.5 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.

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.

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 to our $2.5 million cash reserve covenant, 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 $2.5 million cash reserve requirement or 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 financial statements. There can be no assurance that Oxford will grant such a waiver in any subsequent period.

The Loan Agreement contains 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.

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 year ended December 31, 2016, 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 generate revenue from product sales of our Nexafed product line, and license, commercialization and research and development agreements that we have entered or may enter into from time to time. We may generate license fee revenue, milestone revenue, collaboration revenue, and royalty revenue from license, commercialization and research and development agreements.

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 records revenue from its Nexafed product line sales when the price is fixed and determinable at the date of sale, title and risk of ownership have been transferred to the customer, and returns can be reasonably estimated.

Nexafed was launched in mid-December 2012 and Nexafed Sinus Pressure + Pain was launched in February 2015. We sell our Nexafed products in the United States to wholesale pharmaceutical distributors as well as directly to chain drug stores. Our Nexafed products are sold subject to the right of return usually for a period of up to twelve months after the product expiration. Given the limited sales history of our Nexafed products, we could not reliably estimate expected returns of the product at the time of shipment to certain customers. During 2014, we continued deferring the recognition of revenue. During the first quarter of 2015, we determined we had obtained sufficient sales returns history to reasonably estimate future product returns from those customers. We recorded a one-time adjustment in the first quarter of 2015 to recognize revenue and cost of sales that had previously been deferred and recorded a liability for future sales returns. We review our sales return liability against sales returns activity each calendar quarter. Both products had an initial shelf life of twenty-four months from the date of manufacture, which shelf life has been extended to thirty-six months for Nexafed product supplied to us during 2016 from one of the Company's contract manufacturers.

License fee revenue is derived from the licensing of our technologies, such as 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 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.

Milestone revenue is contingent upon the achievement of certain pre-defined events in the development agreements. Milestone payments are recognized as revenue upon achievement of the "at risk" milestone events, which represent the culmination of the earnings process related to that milestone. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones are substantially at risk at the inception of an agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment. Each milestone payment is non-refundable and non-creditable when made and is recognized as revenue when received.

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 recognize royalty revenue in connection with our Collaboration and License Agreement with Egalet to commercialize Oxaydo 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.

Research and Development

Research and Development ("R&D") expenses include internal R&D activities, external Contract Research Organization ("CRO") services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations 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. We review and accrue CRO expenses and clinical trial study expenses 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. Accrued CRO costs are subject to revisions as such studies progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. During 2015, we entered into a cancelable arrangement for contract manufacturing services on a project to integrate Impede 2.0 technology into our commercially available Nexafed 30mg tablet while moving supply to an alternate contract manufacturer. Approximately $50 thousand was remaining under this agreement at December 31, 2016. At December 31, 2016 our remaining obligations under cancelable CRO arrangements were approximately $0.2 million, for services to be incurred as subjects are enrolled and progress through the studies. We did not have prepaid CRO costs and clinical trial study expenses at either December 31, 2016 or 2015.

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. Because we realized taxable income in 2011 we were able to utilize a portion of our net operating loss carryforwards. At December 31, 2016, 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.

Stock Compensation

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.

Capital Expenditures

Our capital expenditures during 2016 and 2015 were approximately $75 thousand and $214 thousand, respectively. Capital expenditures were primarily attributable to the purchase of machinery and equipment for the Nexafed product line in 2016 and 2015.

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, 2016, 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, 2016. 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, 2016, 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 2016 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 15, 2017 are as follows:

Name	Age	Position
Robert B. Jones	58	President, Chief Executive Officer and Director
Peter A. Clemens	64	Senior Vice President, Chief Financial Officer and Secretary
Albert W. Brzeczko, Ph.D.	60	Vice President, Technical Affairs
Robert A. Seiser	53	Vice President, Treasurer, and Corporate Controller
James F. Emigh	61	Vice President of Corporate Development
J. Bradley Rivet	63	Vice President of Marketing
Bruce F. Wesson[1] [2] [3]	74	Director
William G. Skelly[1][2] [3]	66	Director
Immanuel Thangaraj[2]	46	Director
George K. Ross[1] [3]	75	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 Acura Pharmaceutical Technologies, Inc. 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.

J. Bradley Rivet has been Vice President of Marketing since October 2011. Prior to such time, Mr. Rivet was Vice President of Effcon Laboratories Inc. Mr. Rivet has also held various management positions with aaiPharma Inc. and Burroughs Welcome Co. Mr. Rivet received his Bachelor of Science degree from Louisiana State 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. Since April 1, 2015 Mr. Ross has been 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. Our shares are currently quoted on the OTCQB market**.** 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 2016, 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. In addition, pursuant to the Voting Agreement, as amended, described in "Certain Relationships and Related Transactions" we are required to elect one designee of Galen Partners III, L.P. ("Galen"), one designee of Care Capital Investments II, LP ("Care Capital") and one designee of Essex Woodlands Health Ventures V, L.P. ("Essex"), as long as they held the requisite amount of equity. Mr. Thangaraj serves as the designee of Essex. Care Capital is no longer entitled to designate a director, as it no longer holds the requisite amount of our equity, a right which it has not, in any event, recently exercised since the resignation of its designee. As of March 15, 2017, Galen had not nominated a Board designee to replace its designee who had previously resigned.

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, 2016.

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*, under the menu item "Code of Ethics" appearing under the "Corporate" 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, 2016, 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 "2016 named executive officers") whose total annual compensation for 2016 exceeded $100,000:

Name and Principal Position	Year	Base Salary ($)	Bonus ($)	Option Awards[1] ($)	Non-equity incentive plan compensation ($)	Total ($)
Robert B. Jones,	2015	392,000	—	120,680	215,600	728,280
President and CEO	2016	393,000	—	36,237	—	429,237
Peter A. Clemens	2015	285,000	—	86,200	109,700	480,900
SVP & CFO	2016	286,000	—	26,214	—	312,214
Albert W. Brzeczko	2015	290,000	—	86,200	68,500	444,700
VP, Technical Affairs of Acura Pharmaceutical Technologies, Inc.	2016	291,000	—	26,985	—	317,985

(1) The 2015 entries reflect the grant date fair value of options with respect to 70,000, 50,000 and 50,000, underlying shares issued to Messrs. Jones, Clemens and Brzeczko, respectively. 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. 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. For options issued in 2015 we used a risk free interest rate of 2.22% and historical volatility of 89.04%. For options issued in 2016 we used a risk free interest rate of 2.34% and historical volatility of 85.27%. In all cases we excluded the possibility of forfeiture and calculated values based on 10 year option terms.

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.

The organizational goals for 2015 were the licensing of our Oxaydo® product, progress toward submitting a New Drug Application for our hydrocodone with acetaminophen product with the FDA, the success of Nexafed on the U.S. market, developing a next generation of our Impede Technology, licensing additional products utilizing our Aversion and Impede technologies, progression of our research and development programs, compliance with the Sarbanes – Oxley Act of 2002, or SOX, meeting year-end cash targets and the execution of transactions to further build our business. In 2015, we licensed the Oxaydo product to Egalet Corporation and affiliates, we entered into a license agreement with Bayer Healthcare LLC with respect to our Impede Technology and advanced our Limitx™ and Impede research programs. We also raised net proceeds of approximately $7.1 million in a registered direct offering to enable us to meet year end cash targets. In sum and as a result of the foregoing, the Compensation Committee determined that 55% of the organizational goals were met in 2015.

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 are advancing LimitX reformulations and at Board's discretion execute certain clinical studies, successfully complete ongoing development using Impede technology for a third party and receive the associated milestone, engage in a strategic transaction for Nexafed and Nexafed Sinus, execute strategic transaction, partnership or financing 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, 2017, and provides for automatic one (1) 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 (90) 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. See "—Bonus/Non-Equity Incentive Plan." On December 12, 2013, December 11, 2014, December 10, 2015 and December 8, 2016 we granted Mr. Jones stock options to purchase 27,500 shares, 50,400 shares, 70,000 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 (subject to earlier exercisability as set forth in the table below entitled "Events Affecting Stock Option Vesting and Exercise"). 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 (12) 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 (12) 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 (6) 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 (12) months following the termination of his employment for Cause, prior to a Change of Control, or (iii) twenty-four (24) 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, 2017, and provides for automatic one (1) 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 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. See "—Bonus/Non-Equity Incentive Plan. In 2016, Mr. Clemens was not awarded a bonus. On December 12, 2013, December 11, 2014, December 10, 2015 and December 8, 2016 we granted Mr. Clemens options to purchase 15,000 shares, 36,000 shares, 50,000 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 (subject to earlier exercisability as set forth in the table below entitled "Events Affecting Stock Option Vesting and Exercise"). 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 (2) 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 (1) 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), in a transaction not involving the relevant employee (e.g., Jones, in the case of Jones' severance and Clemens in the case of Clemens' severance)

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 options issued in 2015 and 2016 vest for 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 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. See "—Bonus/Non-Equity Incentive Plan." In 2016 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. 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.

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 he is 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 with ten years after shareholder approval. 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 plans any vesting schedule is permissible. Our grants to director generally vest ¼ each calendar quarter. 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 the merger of the Company.

All of our option plans at the election of the participant, allow the participant to be able 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 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, 2016, stock options to purchase 18,000 shares of Common Stock had been granted under the 1998 Stock Option Plan. Of such option grants, 4,630 are ISO's and 13,370 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 is $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 1998 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, 2016, stock options to purchase 1,195,795 shares of Common Stock had been granted under the 2008 Stock Option Plan. Of such option grants, 788,831 are ISOs and 406,964 are non-qualified options. The average per share exercise price for all outstanding options under the 2008 Stock Option Plan is $ 15.16.

The 2016 Stock Option Plan

The 2016 Stock Option Plan, as amended was adopted by the Board of Directors on or about April 12, 2016 and approved by our shareholders on April 28, 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, 2016, stock options to purchase 183,522 shares of Common Stock had been granted under the 2016 Stock Option Plan. Of such option grants, 181,564 are ISOs and 1,958 are non-qualified options. 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 is $0.915.

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 on February 27, 2014 and by stockholders on May 1, 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. The 2014 RSU Plan allows for amendment by the Board of Directors, provide shareholder approval for the amendment is not required under NASDAQ rules or applicable law.

The 2014 RSU Plan is intended to assist the Company in securing and retaining key 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.

The 2014 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").

The Board/Committee has the authority, subject to the provisions of the 2014 RSU Plan, to establish, adopt and revise such rules, regulations and forms and agreements and to interpret the 2014 RSU Plan and make all determinations relating to the 2014 RSU Plan as it may deem necessary or advisable. The Board/Committee also has the authority, subject to the provisions of the 2014 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 2014 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 2014 RSU Plan.

All decisions, determinations and interpretations of the Board/Committee are binding and conclusive on participants in the 2014 RSU Plan and on their legal representatives and beneficiaries.

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"). As of March 15, 2017 all of the Company's 15 full-time employees and four Non-Employee Directors of the Company are eligible participants ("Participants") in the 2014 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.

Each RSU granted under the 2014 RSU Plan is evidenced by a written award agreement ("RSU Award Agreement"), which contains the terms and conditions of the specific RSU granted.

RSUs generally vest as set forth in the RSU Award Agreement.

In addition, unless expressly provided otherwise in the RSU Award Agreement or an employment or consulting 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 Change in Control (as defined in the 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 Change in Control, he will not commence to receive the shares underlying his RSU award until the scheduled distribution date.

RSU awards are generally distributed on the first business day of the year after they vest. For example, if an award vests quarterly during 2017, it will be distributed on the first business day of 2018. Non-Employee Directors may irrevocably elect to defer distributions to a specified date or dates and 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). The cash payment election may be made at anytime before distribution, but any such cash payment is subject to any limits on redemption under any loan or other financing agreement. The deferral election must be made by the December 31 of the year before the grant, except that in the case of a grant in 2014, the deferral election may be made within 30 days of the date of the Non-Employee Director's eligibility to participate in the 2014 RSU Plan. If the deferral election is made in the first year of eligibility of a Non-Employee Director under the Plan, then it shall only apply to RSUs granted for service earned from the first day of the calendar quarter commencing after such election until the end of such calendar year. A Non-Employee Director could specify multiple deferral dates with a percentage of RSUs to be paid on each such date. Unlike the case with Non-Employee Directors, under the 2014 RSU Plan, neither employees nor consultants have the option of deferring distributions. However, the Company has the option of establishing a RSU award that defers distributions to an employee or a consultant, including in installments (e.g., 25% of RSUs to be paid in 2017, 2018, 2019 and 2020). If a Change of Control occurs, all vested shares of Common Stock underlying an RSU (after payment 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. 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 for distribution purposes is generally the same as a Change in Control for vesting purposes, except that in order to have a Change in Control for distribution purposes, a change in control qualifying under Section 409A of the Code must occur.

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 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.

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.

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 2014 RSU Plan.

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 2014 RSU Plan.

As of March 15, 2017 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 15, 2017, 261,344 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.

Outstanding Equity Awards at 2016 Year-End

The following table presents information regarding outstanding stock and stock option awards at December 31, 2016 for each of the 2016 named executive officers.

Name	Stock Option Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Option Exercise Price ($)		Option Expiration Date
Robert B. Jones	6,000	—	$	43.20	04/06/2018
	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
	37,917	32,083	$	2.01	12/09/2025
	1,958	45,042	$	0.915	12/09/2026
Peter A. Clemens	20,000	—	$	49.35	05/23/2018
	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
	27,083	22,917	$	2.01	12/09/2025
	1,417	32,583	$	0.915	12/09/2026
Albert W. Brzeczko	19,200	—	$	28.50	02/08/2019
	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
	27,083	22,917	$	2.01	12/09/2025
	1,458	33,541	$	0.915	12/09/2026

(1) In any row for which there are unexercisable options, $1/24^{th}$ of total option issuance in such row becomes exercisable on the last day of each month.

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, 2016:

2016 DIRECTOR COMPENSATION

Director	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Option Awards ($)[2]	Total ($)
William G. Skelly	$ 48,750	$ 50,000	—	$ 98,750
Bruce F. Wesson	$ 43,750	$ 50,000	—	$ 93,750
Immanuel Thangaraj	$ 30,000[3] [4]	$ 50,000	—	$ 81,250
George K. Ross	$ 53,500	$ 50,000	—	$ 103,500

(1) Represents the grant date fair value of restricted stock units, or RSUs with respect to the 22,026 RSUs granted to Messrs. Skelly, Wesson, Thangaraj and Ross under our 2014 RSU Plan based on a closing price of $2.27 on January 4, 2016.

Each director realized $15,528 on March 31, 2016, $10,132 on June 30, 2016, $5,011 on September 30, 2016 and $4,167 on December 31, 2016 as a result of the vesting of 5,506.5 RSUs on each of such dates (based on closing prices of our common stock of $2.83 on March 31, 2016, $1.85 on June 30, 2016, $0.92 on September 30, 2016 and $0.77 on December 30, 2016).

Additionally, in January 2016, Mr. Skelly exchanged 8,247 RSUS and $0.01 par value per share issued under the 2014 RSU plan, for 8,247 shares of Common Stock and 2,062 RSUs for $5,134 in cash. In January 2016, Mr. Wesson exchanged 10,309 RSUs and $0.01 par value per share issued under the 2014 RSU plan, for 10,309 shares of Common Stock. In January 2016, Mr. Thangaraj exchanged 6,185 shares of Common Stock and $4,124 RSUs for $10,269 in cash. In January 2016, Mr. Ross exchanged 8,074 RSUS and $0.01 par value per share issued under the 2014 RSU plan, for 8,074 shares of Common Stock and 3,460 RSUs for $8,615 in cash.

As of December 31, 2016, Messrs. Skelly and Wesson, Thangaraj each held 22,026 fully vested RSUs and Mr. Ross held 24,276 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, 2016.

(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. The Board monitors the stock so that a minimum can be established in the event of exaggerated fluctuations. 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, 2017, 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 2016 exceeded $100,000 (the "2016 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 15, 2017, there were 11,883,339 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, 2017.

Name of Beneficial Owner	Amount Owned	Percent of Class (1)
Galen Partners III, LP 680 Washington Boulevard, Stamford, CT 06901	2,195,735(2)	18.5%
Essex Woodlands Health Ventures Fund V, L.P. 21 Waterway Avenue, Suite 225 Woodlands, TX 77380	1,956,357(3)	16.5%
Deerfield Special Situations Fund, L.P 780 Third Avenue, 37th Floor New York, NY 10017	1,025,641(4)	8.6%
Robert B. Jones	303,829(5)	2.5%
William G. Skelly	46,345(6)	*
Bruce F. Wesson	76,670(7)	*
Peter A. Clemens	217,681(8)	1.8%
Immanuel Thangaraj	41,812(9)	*
Albert W. Brzeczko	138,307(10)	1.1%
George K. Ross	52,816(11)	*
All Officers and Directors as a Group (10 persons)	1,185,276(12)	9.3%

* Represents less than 1% of the outstanding shares of the Company's Common Stock.

(1) Shows percentage ownership assuming (i) such party converts all of its currently convertible securities or securities convertible within 60 days of March 15, 2017 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 2016 named executive officer has been pledged as collateral security.

(2) Includes 2,006,538 shares held by Galen Partners III, LP, 180,936 shares held by Galen Partners International III, LP and 8,261 shares held by Galen Employee Fund III, L.P. (collectively, "Galen"). Claudius, L.L.C. serves as the sole General Partner of Galen Partners, III LP and Galen Partners International III, LP and has sole voting and investment control over the shares held by such funds and may be deemed to beneficially own the shares held by such funds. Galen Management, L.L.C. serves as the sole General Partner of Galen Employee Fund III, L.P. and has sole voting and investment control over the shares held by Galen Employee Fund III, L.P. and may be deemed to beneficially own the shares held by Galen Employee Fund III, L.P. Claudius L.L.C. and each Galen entity disclaims beneficial ownership of the shares reported herein, except to the extent of its respective pecuniary interest therein. L. John Wilkerson, David W. Jahns, and Zubeen Shroff exercise voting, investment and dispositive rights over our securities held of record by Galen. The information reported with respect to Galen and Claudius LLC is based on a Form 4 filed on June 18, 2015**.**

(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) Deerfield Management Company, L.P., as the investment advisor of, and Deerfield Mgmt, L.P., as the general partner of, Deerfield Special Situations Fund, L.P. and James Flynn share power to dispose or direct disposition of and to vote or direct the vote of shares held by Deerfield Special Situations Fund, L.P. The foregoing information in this footnote is based on Amendment No.1 to Schedule 13-G filed by Deerfield Management Company, L.P., Deerfield Mgmt, L.P., Deerfield Special Situations Fund, L.P. and James Flynn on February 14, 2017.

(5) Includes 291,274 shares subject to stock options exercisable within 60 days of March 15, 2017.

(6) Includes 18,000 shares subject to stock options exercisable within 60 days of March 15, 2017. Does not include RSUs.

(7) Includes 18,000 shares subject to stock options exercisable within 60 days of March 15, 2017. Does not include RSUs.

(8) Includes 162,499 shares subject to stock options exercisable within 60 days of March 15, 2017.

(9) Includes 18,000 shares subject to stock options exercisable within 60 days of March 15, 2017. Mr. Thangaraj's holdings do not include securities held by Essex. Mr. Thangaraj disclaims beneficial ownership in securities held by Essex except to the extent of his pecuniary interest therein. Does not include RSUs.

(10) Includes 133,107 shares subject to stock options exercisable within 60 days of March 15, 2017.

(11) Includes 18,000 shares subject to stock options exercisable within 60 days of March 15, 2017. Does not include RSUs.

(12) Includes 904,146 shares which Directors and executive officers have the right to acquire within 60 days of March 15, 2017 through exercise of outstanding stock options.

Securities Authorized For Issuance under Equity Compensation Plans

The following table includes information as of December 31, 2016 relating to our 1998 Stock Option Plan, our 2008 Stock Option Plan, our 2016 Stock Option Plan and our 2014 Restricted Stock Unit Award Plans, 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	1,397,315	$ 13.56	416,478
Stock Option Equity Compensation Plans Not Approved by Security Holders	—	—	—
Restricted Stock Unit Equity Compensation Plans Approved by Security Holders	261,345	$ 0.01	3,155
Restricted Stock Unit Equity Compensation Plans Not Approved by Security Holders	—	—	—
TOTAL	1,658,660	$ 11.42	419,633

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

Certain Relationships and Related Transactions

On or about October 1, 2012, GCE Holdings LLC ("GCE") our then approximately 72.5% stockholder distributed (the "GCE Distribution") all of its securities in the Company to its members, including Galen and certain of its affiliates, Care Capital and certain of its affiliates, and Essex. As a result, as of the date of the GCE Distribution, Galen, Care Capital and Essex and their affiliated entities beneficially owned 29.8%, 23.1% and 22.6%, respectively, of our common stock. GCE was the assignee of all shares of the Company's preferred stock (prior to conversion of such preferred stock into common stock) formerly held by each of Galen, Care Capital and certain of their affiliates and Essex. Messrs. Azad, Markham and Thangaraj, each a Director at the time of the GCE Distribution, exercised investment control over the membership interests in GCE held by Galen, Care Capital and Essex, respectively, and correspondingly exercised investment control over our common stock held by GCE prior to the GCE Distribution.

As a condition to the completion of our 2004 debenture offering, we and the investors in our 2004 debentures and the holders of our outstanding 5% convertible senior secured debentures due March 31, 2006 issued by us during the period from 1998 through 2003 executed a certain Voting Agreement dated as of February 6, 2004, or the Voting Agreement. After giving effect to amendments to the Voting Agreement in November 2005, January 2008 and October 1, 2012, the Voting Agreement provides that our Board of Directors will be comprised of not more than seven (7) members and that each of Galen, 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 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. At the time of the October 1, 2012 amendment, Messrs. Azad, Markham and Thangaraj, the former GCE designees, became the designees of Galen, Care Capital and Essex, respectively. 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. Care Capital is no longer entitled to designate a director as it no longer holds the requisite amount of our equity. In addition, each of Galen, Essex has (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.

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.

Each of the transactions described above under the caption "Certain Relationships and Related Transactions" were subject to the review, evaluation, negotiation and approval of an Independent Committee of the Board.

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 2016, 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 2016 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 2016 and 2015 were as follows:

	2016	2015
Audit Fees	$ 173,558	$ 132,753
Audit-Related Fees	-	-
Total Audit and Audit-Related Fees	173,558	132,753
Tax Fees	63,990	43,280
All Other Fees	-	-
Total for BDO USA, LLP	$ 237,548	$ 176,033

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 2016 and 2015 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. All Financial Statements: See Index to Financial Statements
2. Financial Statement Schedules: None
3. Exhibits: See Index to Exhibits

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

Date: March 31, 2017

ACURA PHARMACEUTICALS, INC.

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

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

Signature	Title(s)	Date
/s/Robert B. Jones Robert B. Jones	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2017
/s/Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2017
/s/William G. Skelly William G. Skelly	Director	March 31, 2017
/s/Bruce F Wesson Bruce F. Wesson	Director	March 31, 2017
/s/Immanuel Thangaraj Immanuel Thangaraj	Director	March 31, 2017
/s/George K. Ross George K. Ross	Director	March 31, 2017

ACURA PHARMACEUTICALS, INC
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Acura Pharmaceuticals Inc. as of December 31, 2016 and 2015 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Acura Pharmaceuticals Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has not generated positive cash flows from operations. These factors raise substantial doubt about the Company's 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.

/s/ BDO USA, LLP
Chicago, Illinois
March 31, 2017

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2016 and 2015
(in thousands, except par value)

	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,681	$ -
Cash and cash equivalents – restricted (Note 9)	2,500	2,485
Marketable securities (Note 5)	-	10,837
Trade accounts receivable (net of allowances of $7 and $91)	23	42
Collaboration revenue receivable	79	36
Royalty receivable	50	5
Accrued investment income	-	37
Inventories, net (Note 6)	309	276
Prepaid expenses and other current assets	268	417
Total current assets	5,910	14,135
Property, plant and equipment, net (Note 7)	867	1,013
Intangible asset (net of accumulated amortization of $569 and $362) (Note 4)	1,431	1,638
Other assets	-	175
Total assets	$ 8,208	$ 16,961
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 77	$ 110
Accrued expenses (Note 8)	703	564
Other current liabilities	27	45
Sales returns liability	304	205
Debt – current (Note 9)	2,376	2,320
Total current liabilities	3,487	3,244
Debt – long-term portion (net of debt discount of $98 and $193 and debt issuance costs of $47 and $97 at 2016 and 2015) (Note 9)	2,979	5,430
Accrued interest – non-current portion	559	387
Total liabilities	7,025	9,061
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock - $.01 par value per share; 100,000 shares authorized, 11,834 and 11,801 shares issued and outstanding at 2016 and 2015, respectively	118	118
Additional paid-in capital	375,763	375,157
Accumulated deficit	(374,698)	(367,310)
Accumulated other comprehensive loss	-	(65)
Total stockholders' equity	1,183	7,900
Total liabilities and stockholders' equity	$ 8,208	$ 16,961

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
YEARS ENDED DECEMBER 31, 2016 and 2015
(in thousands, except per share amounts)

	2016	2015
Revenues:		
License fee revenue	$ 3,500	$ 5,250
Milestone revenue	-	2,500
Collaboration revenue	392	170
Royalty revenue	149	5
Product sales, net	423	662
Total revenues, net	4,464	8,587
Cost and expenses:		
Cost of sales (excluding inventory write-down)	451	656
Inventory reserve expense for write-downs (Note 6)	26	330
Research and development	4,028	2,608
Selling, marketing, general and administrative	6,516	8,994
Total costs and expenses	11,021	12,588
Operating loss	(6,557)	(4,001)
Non-Operating income (expense):		
Investment income	60	166
Interest expense (Note 9)	(893)	(1,157)
Other income	2	3
Total other expense, net	(831)	(988)
Loss before provision for income taxes	(7,388)	(4,989)
Provision for income taxes	-	-
Net loss	$ (7,388)	$ (4,989)
Other comprehensive income (loss):		
Unrealized gains (losses) on marketable securities	65	(52)
Comprehensive loss	$ (7,323)	$ (5,041)
Net loss per share:		
Basic	$ (0.62)	$ (0.46)
Diluted	$ (0.62)	$ (0.46)
Weighted average shares outstanding:		
Basic	11,870	10,796
Diluted	11,870	10,796

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2016 and 2015
(in thousands)

	Common Stock		Additional Paid-in		Accumulated Other Comprehensive	
	Shares	$ Amount	Capital	Accumulated Deficit	Income (Loss)	Total
Balance at Jan. 1, 2015	9,770	$ 98	$ 367,288	$ (362,321)	$ (13)	$ 5,052
Net loss	-	-	-	(4,989)	-	(4,989)
Other comprehensive loss	-	-	-	-	(52)	(52)
Share-based compensation	-	-	606	-	-	606
Net distribution of common stock pursuant to restricted stock unit award plan	19	-	-	-	-	-
Modification to warrants issued with promissory notes	-	-	33	-	-	33
Issuance of common stock under "at the market" offerings, net of offering costs of $8	54	-	217	-	-	217
Issuance of common stock under registered direct offering, net of offering costs of $603	1,958	20	7,013	-	-	7,033
Balance at December 31, 2015	11,801	$ 118	$ 375,157	$ (367,310)	$ (65)	$ 7,900
Net loss	-	-	-	(7,388)	-	(7,388)
Other comprehensive income	-	-	-	-	65	65
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

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2016 and 2015
(in thousands)

	2016	2015
Cash Flows from Operating Activities:		
Net loss	$ (7,388)	$ (4,989)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	138	125
Provision to reduce inventory to net realizable value	26	330
Provision for sales returns	99	267
Provision for fixed asset impairment	82	-
Share-based compensation	588	606
Amortization of debt discount and debt issuance costs	145	186
Amortization of bond premium in marketable securities	31	127
Amortization of intangible asset	207	207
Gain on sales of marketable securities	(2)	(3)
Loss on disposals of property, plant and equipment	1	19
Changes in assets and liabilities:		
Accounts receivable, net	19	(28)
Collaboration revenue receivable	(43)	(36)
Royalty receivable	(45)	(5)
Accrued investment income	37	29
Inventories	(59)	(302)
Prepaid expenses and other current assets	149	54
Other current deferred assets	-	218
Other assets	175	(175)
Accounts payable	(33)	(107)
Accrued expenses	139	(4)
Deferred revenue	-	(353)
Accrued interest – current and long term	172	127
Other current liabilities	(1)	19
Net cash used in operating activities	(5,563)	(3,688)
Cash Flows from Investing Activities:		
Purchases of marketable securities	-	(3,522)
Proceeds from sales and maturities of marketable securities	10,873	3,830
Additions to property, plant and equipment	(75)	(214)
Proceeds from disposals of property, plant and equipment	-	14
Net cash provided by investing activities	10,798	108
Cash Flows from Financing Activities:		
Proceeds from distribution of restricted stock units	1	1
Proceeds from ATM offering	-	225
Proceeds from Registered Direct offering	-	7,636
Transaction costs from ATM offering	-	(603)
Transaction costs from Registered Direct offering	-	(8)
Principal payments on debt	(2,540)	(1,960)
Net cash (used in) provided by financing activities	(2,539)	5,291
Net increase in cash and cash equivalents	2,696	1,711
Cash and cash equivalents at beginning of year	2,485	774
Cash and cash equivalents at end of year	$ 5,181	$ 2,485
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest on term loan with Oxford Finance LLC	$ 576	$ 844
Income taxes, net of refunds	$ -	$ -

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
YEAR ENDED DECEMBER 31, 2016 and 2015

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

Year ended December 31, 2016

1. There are no supplemental disclosure activities.

Year ended December 31, 2015

1. The exercise price of 60 thousand common stock purchase warrants held by our term debt lender was changed from $7.98 to $2.52 per share. The change in fair value of $33 was recorded as additional debt discount and will be amortized as interest expense over the remaining term of this debt.

See accompanying Notes to Consolidated Financial Statements.

NOTE 1 – OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principal Operations

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the "Company", "We", or "Our") is 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 product tampering associated with opioid abuse while our Impede® Technology is directed at minimizing the extraction and conversion of pseudoephedrine into methamphetamine.

- Oxaydo® Tablets (oxycodone HCl, CII), which utilizes the Aversion Technology, is the first and only 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 (collectively, "Egalet") pursuant to which we exclusively licensed to Egalet worldwide rights to manufacture and commercialize Oxaydo®. 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 4.
- Nexafed® Tablets (30mg pseudoephedrine) and Nexafed® Sinus Pressure + Pain Tablets (30/325mg pseudoephedrine and acetaminophen), utilizing the Impede Technology, were launched by us into the United States market in December 2012 and February 2015, respectively. We have multiple pseudoephedrine products in development utilizing our Impede Technology. On June 15, 2015, we and Bayer Healthcare LLC entered into a License and Development 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. 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 United States 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. See Note 4.
- 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. We have completed our first clinical study, Study AP-LTX-400, of our lead Limitx immediate release oral abuse deterrent drug candidate using the opioid hydromorphone HCI (LTX-04). Study AP-LTX-400, or Study 400, was a two cohort, open label, crossover design pharmacokinetic study in healthy adult subjects. 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. We are also developing an immediate-release hydrocodone bitartrate with acetaminophen product utilizing our Limitx Technology.

Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The going concern basis of presentation assumes that we will continue in operation for the next twelve months and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. At December 31, 2016, we had unrestricted cash and cash equivalents (after deduction of a $2.5 million compensating balance requirement under our term loan with Oxford Finance LLC) of $2.7 million, working capital deficit of $0.7 million and an accumulated deficit of $374.7 million. We had a loss from operations of $6.6 million and a net loss of $7.4 million during the year ended December 31, 2016. We have suffered recurring losses from operations and have not generated positive cash flows from operations. Our current unrestricted cash and cash equivalents will not be sufficient to fund the development of our products utilizing our Limitx and Impede Technologies, and our related operating expenses beyond mid-2017 while maintaining compliance with the $2.5 million compensating balance requirement under our term loan with Oxford Finance LLC.

In addition to our $2.5 million cash reserve requirement, 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.

However, these factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. To fund further operations and product development activities beyond mid-2017, we must raise additional financing or enter into license or collaboration agreements with third parties relating to our technologies. The Company intends to explore a variety of capital raising and other transactions to provide additional funding to continue operations. These include a registered public offering of the Company's common stock, for which the Company filed a registration statement on Form S-1 with the SEC on February 3, 2017, and 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 and Bayer Agreements. 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 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 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.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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. The equity amounts and all share and per share data of the Company have been retroactively adjusted to reflect a one-for-five reverse stock split effected by us on August 28, 2015.

Reclassifications

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

Management 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.

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.

Marketable Securities

The Company did not have marketable securities at December 31, 2016. The Company's marketable securities at December 31, 2015 primarily consisted of corporate debt securities and exchange-traded funds. Our marketable securities are governed by our investment policy as approved by our Board of Directors. The Company's marketable securities are classified as available-for-sale and are recorded at fair value, based upon quoted market prices or net asset value. Unrealized temporary adjustments to fair value are included in a separate component of stockholders' equity as unrealized gains and losses and reported as a component of accumulated other comprehensive income (loss). No gains or losses on marketable securities are realized until shares are sold or a decline in fair value is determined to be other-than-temporary. If a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established.

Fair Value of Other Financial Instruments

The Company's financial instruments consist primarily of cash and cash equivalents, marketable securities, accounts and other receivables, trade accounts payable, and our long-term debt. The carrying amounts of these financial instruments, other than marketable securities and our long-term debt, are representative of their respective fair values due to their relatively short maturities. The Company has not been able to measure the fair value of long-term debt due to a very limited marketplace having little or no market activity for this debt placement but given the change in the Company's credit risk, the Company believes the fair value of long-term debt is below its carrying value. As discussed above, marketable securities are recorded at fair value.

Concentration of Credit Risk

Credit Risk: Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash and cash equivalents, marketable securities and accounts receivable. The Company maintains deposits in federally insured financial institutions 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. Additionally, the Company's excess cash is invested in accordance with the investment policy approved by our Board of Directors that seeks a combination of both liquidity and safety of principal using diversification of investments, through investments such as investment grade corporate debt securities with varying maturities. To date, the Company has not experienced any material realized losses on its cash, cash equivalents, and marketable securities.

Customers: We launched our first Impede Technology product, Nexafed®, in the United States in December 2012 and our Nexafed Sinus Pressure + Pain product in the United States in February 2015. Our accounts receivable arise 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 may maintain an allowance for potentially uncollectable accounts. We have not experienced any losses on uncollectable accounts in 2016 or 2015.

Sales to certain of our customers during 2016 and 2015 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. Sales to customers designated with an ” * ” accounted for less than 10% of our annual product sales.

Customer	2016	2015
Rite Aid Corporation	55%	54%
Cardinal Health, Inc.	13%	14%
McKesson Corporation	10%	*

Trade accounts receivable from certain of our customers at December 31, 2016 and 2015 accounting for 10% or more of our gross accounts receivable is presented below. Trade accounts receivable from customers designated with an ” ** ” accounted for less than 10% of our gross trade accounts receivable.

Customer	2016	2015
AmerisourceBergen Corporation	35%	**
McKesson Corporation	24%	11%
Cardinal Health, Inc.	19%	**
The Kroger Co.	18%	**
Rite Aid Corporation	**	68%

Inventories

Inventories at December 31, 2016 consist of raw materials to be used in the manufacture to integrate Impede 2.0 technology into our commercially available Nexafed 30mg tablets, and finished goods held for distribution and sale on our Nexafed® product line. Inventories at December 31, 2015 consisted of finished goods held for distribution and sale on our Nexafed® product line. Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value). The Company writes down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results.

Our purchases of active pharmaceutical ingredients and raw materials required for our development and clinical trial manufacture of product candidates utilizing our Aversion®, Impede® or Limitx Technologies are expensed as incurred.

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

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. See *Recent Accounting Pronouncements* for discussion on the presentation of deferred debt issuance costs as a direct reduction against long-term debt.

License Fee Revenue

In December 2014, the Company entered into an agreement with Purdue Pharma to settle a patent interference action regarding certain intellectual property held by Acura (U.S. Patent No. 8,101,630). The dispute centered on 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 into an agreement whereby Acura conceded Purdue's claim of priority in exchange for certain financial consideration to Acura including an immediate non-refundable payment of $500 thousand. In June 2015, the Company received an additional $250 thousand payment from Purdue relating to the December 2014 agreement. These amounts were recognized as revenue when received.

In January 2015, the Company entered into a Collaboration and License Agreement to commercialize Oxaydo tablets (formerly known as Oxecta) utilizing our Aversion® Technology with Egalet US, Inc. and Egalet Ltd., each a subsidiary of Egalet Corporation (collectively, "Egalet"). Egalet paid us $5.0 million upon signing the Egalet 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 4).

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 4).

Milestone Revenue

Milestone revenue is contingent upon the achievement of certain pre-defined events in the development agreements. Milestone payments are recognized as revenue upon achievement of the "at risk" milestone events, which represent the culmination of the earnings process related to that milestone. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones are substantially at risk at the inception of an agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment. Each milestone payment is non-refundable and non-creditable when made and is recognized as revenue when received. In October 2015, Egalet paid us a $2.5 million milestone payment in connection with the event of the first commercial sale of Oxaydo.

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 $392 thousand and $170 thousand of collaboration revenue during the years 2016 and 2015, respectively.

Royalty Revenue

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 $149 thousand and $5 thousand on net sales for the years 2016 and 2015, respectively. (see Note 4).

Product Sales

Nexafed was launched in mid-December 2012 and Nexafed Sinus Pressure + Pain was launched in February 2015. We sell our Nexafed products in the United States to wholesale pharmaceutical distributors as well as directly to chain drug stores. Our Nexafed products are 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 has been extended to thirty-six months for Nexafed product supplied to us during 2016 from one of the Company's contract manufacturers. Given the limited sales history of our Nexafed products, we could not reliably estimate expected returns of the product at the time of shipment to certain customers. During 2014, we continued deferring the recognition of revenue. During the first quarter of 2015, we determined we had obtained sufficient sales returns history to reasonably estimate future product returns from those customers. We recorded a one-time adjustment in the first quarter of 2015 to recognize revenue that had previously been deferred, resulting in additional net revenues of $314 thousand after recording a liability for sales returns of $120 thousand, and recorded cost of sales of $255 thousand. We currently recognize revenue from our Nexafed product line when the price is fixed and determinable at the date of sale, title and risk of ownership have been transferred to the customer, and returns can be reasonably estimated, which generally occurs at the time of product shipment. At December 31, 2016 and 2015, we have a $304 thousand and $205 thousand sales returns liability, respectively. We review our sales return liability against sales returns activity each calendar quarter.

Advertising Costs

The Company records the cost of its advertising efforts when services are performed or goods are delivered.

Shipping and Handling Costs

The Company records shipping and handling costs in selling expenses. The amounts recorded from the sales of Nexafed® were not material.

Impairment of 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 in fourth quarter 2016 on equipment having a net book value of a like amount. We had no impairment charges for the year ended 2015.

Research and Development Activities

Research and Development ("R&D") expenses include internal R&D activities, external Contract Research Organization ("CRO") services and their clinical research sites, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and share-based compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include regulatory consulting, and regulatory legal counsel. Internal R&D activities and other activity expenses are charged to operations 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. We review and accrue CRO expenses and clinical trial study expenses 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. Accrued CRO costs are subject to revisions as such studies progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. During 2015, we entered into a cancelable arrangement for contract manufacturing services on a project to integrate Impede 2.0 technology into our commercially available Nexafed 30mg tablet while moving supply to an alternate contract manufacturer. Approximately $50 thousand was remaining under this agreement at December 31, 2016. At December 31, 2016 our remaining obligations under cancelable CRO arrangements were approximately $0.2 million, for services to be incurred as subjects are enrolled and progress through the studies. We did not have prepaid CRO costs and clinical trial study expenses at either December 31, 2016 or 2015.

Share-based Compensation

We have several share-based compensation plans covering stock options and RSUs for our employees and directors, which are described more fully in Note 12.

We measure our compensation cost related to share-based payment transactions based on fair value of the equity or liability 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 instruments issued comprised the following (in thousands):

	Year ended December 31,	
	2016	2015
Research and development:		
Stock option awards	$ 167	$ 158
RSU awards	-	-
	$ 167	$ 158
Selling, general and administrative:		
Stock option awards	301	384
RSU awards	143	95
	$ 444	$ 479
Total share-based compensation expense	$ 611	$ 637

Comprehensive Income (Loss)

Comprehensive income (loss) includes all changes in equity during a period except those that resulted from investments by or distributions to the Company's stockholders. Other comprehensive income (loss) refers to revenues, expenses, gains and losses that, under GAAP, are included in comprehensive income (loss), but excluded from net income (loss) as these amounts are recorded directly as an adjustment to stockholders' equity. The Company's other comprehensive income (loss) is composed of unrealized gains (losses) on certain holdings of marketable securities, net of any realized gains (losses) included in net income (loss).

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, 2016 and 2015, 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.

Earnings Per Share ("EPS")

Basic EPS 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 EPS is based on the treasury stock method and computed based on the same number of shares used in the basic share calculation and includes the effect from potential issuance of common stock, such as shares issuable pursuant to the exercise of stock options and stock warrants, assuming the exercise of all in-the-money stock options and warrants. Common stock equivalents are excluded from the computation where their inclusion would be anti-dilutive. No such adjustments were made for 2016 or 2015 as the Company reported a net loss for the years and including the effects of common stock equivalents in the diluted EPS calculation would have been antidilutive.

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

	Years ended December 31,	
	2016	2015
EPS – basic		
Numerator: net loss	$ (7,388)	$ (4,989)
Denominator (weighted):		
Common shares	11,834	10,777
Vested RSUs	36	19
Basic weighted average shares outstanding	11,870	10,796
EPS - basic	$ (0.62)	$ (0.46)
EPS – assuming dilution		
Numerator: net loss	$ (7,388)	$ (4,989)
Denominator (weighted):		
Common shares	11,834	10,777
Vested RSUs	36	19
Stock options	-	-
Common stock warrants	-	-
Diluted weighted average shares outstanding	11,870	10,796
EPS - diluted	$ (0.62)	$ (0.46)
Excluded dilutive securities:		
Common stock issuable (non weighted):		
Stock options	1,397	1,198
Common stock warrants	60	60
Total excluded potentially dilutive shares	1,457	1,258

NOTE 3 – RECENT ACCOUNTING PRONOUNCEMENTS

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

In August 2014, the FASB issued ASU No. 2014-15, "*Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*". ASU 2014-15 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, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The adoption of this standard did not have a material impact on the Company's financial statement disclosures.

Revenue from Contracts with Customers

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the transition method we will utilize to adopt the standard for use in 2018.

Presentation of Debt Issuance Costs

In April 2015, the FASB issued ASU No. 2015-03, *"Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs."* The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The amendments are effective for financial statements issued for fiscal years beginning after December 15, 2015. Early adoption of the amendments is permitted and the Company elected to adopt this guidance effective April 1, 2015. The Company adopted the guidance to implement the simplified presentation prescribed as the purpose of the amendment.

Leases

In February 2016, the FASB issued ASU 2016-02, Leases, which will require most leases (with the exception of leases with terms of less than one year) to be recognized on the balance sheet as an asset and a lease liability. 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 method beginning with the earliest comparative period presented. The Company is currently evaluating the effect of the new standard on its consolidated financial statements and related disclosures.

NOTE 4 – LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENTS

KemPharm Agreement

On October 13, 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.

Bayer Agreement

On June 15, 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. The Bayer Agreement also grants Bayer first right to negotiate a license to the Impede Technology for certain other products.

We and Bayer have formed a joint development committee to coordinate development of the Bayer Licensed Product. We are eligible to receive reimbursement of certain of our development costs, success-based development and regulatory milestones payments, and low mid-single digit royalties on net sales of the Bayer Licensed Product in countries with patent coverage and a reduced royalty elsewhere.

The term of the Bayer Agreement with respect to each country expires when royalties are no longer payable with respect to such country. After expiration of the term Bayer retains a license to sell the Bayer Licensed Product on a royalty free basis. Either party may terminate the Bayer Agreement in its entirety if the other party materially breaches the Bayer Agreement, subject to an applicable cure period, 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. Bayer may terminate the Bayer Agreement immediately prior to completion of our development obligations or at any time upon six (6) months prior written notice thereafter. We may terminate the Bayer Agreement with respect to the U.S. if Bayer ceases or suspends development or commercialization of the Bayer Licensed Product for a certain period of time.

Egalet Agreement

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 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.

MainPointe Agreement

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 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 $425,000 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 million, $500,000 and $250,000, 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 $500,000 per product (for all 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.

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.

Terminated Pfizer Agreement

In 2007, we entered into License, Development and Commercialization Agreement for Oxaydo (named Oxecta™ under a Pfizer trademark) and other Aversion opioid development products with King Pharmaceuticals Research and Development, Inc., which became a subsidiary of Pfizer in 2011 (the "Pfizer Agreement"). In April 2014, we entered into two letter agreements with Pfizer providing for the termination of the Pfizer Agreement and the return to us of Oxaydo 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 Oxaydo, which is 9.7 years. During each of the years ended December 31, 2016 and 2015, we recorded amortization expense of $207 thousand. Annual amortization of the patent for years 2017 thru 2021 is expected to approximate $207 thousand. We also purchased from Pfizer selected raw and packaging material inventories for $260 thousand relating to Oxaydo. In 2015, we wrote off and disposed of these inventories in the same amounts as the purchase costs.

NOTE 5 – INVESTMENTS IN MARKETABLE SECURITIES

The Company did not have investments in marketable securities at December 31, 2016. Investments in marketable securities at December 31, 2015 consisted of the following (in millions):

	December 31, 2015
Marketable securities:	
Corporate bonds — maturing within 1 year	$ 3.1
Corporate bonds — maturing after 1 year and through March 2017	0.4
Exchange-traded funds	7.3
Total marketable securities	$ 10.8

The Company's marketable securities are classified as available-for-sale and are recorded at fair value based on quoted market prices or net asset value using the specific identification method. The purchase cost of corporate bonds may include a purchase price premium or discount which will be amortized or accreted against earned interest income to the maturity date of the bond. Our marketable securities are classified as current in the Company's Consolidated Balance Sheets as they may be sold within one year in response to changes in market prices or interest rates, to realign our investment concentrations or to meet our working capital needs.

The following tables provide a summary of the fair value and unrealized gains (losses) related to the Company's available-for-sale securities (in millions):

	December 31, 2015			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 3.6	$ -	$ (0.1)	$ 3.5
Exchange-traded funds	7.3	-	-	7.3
Total - Current	$ 10.9	$ -	$ (0.1)	$ 10.8

Fair Value Measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants. Fair values determined based on Level 1 inputs utilize quoted market prices in active markets for identical assets or liabilities. Fair values determined based on Level 2 inputs utilize observable market-based inputs or unobservable inputs that are corroborated by market data. Fair values determined based on Level 3 inputs utilize unobservable inputs reflecting the reporting entity's own assumptions. A financial asset or liability's classification within the above hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

Our assets measured at fair value or disclosed at fair value on a recurring basis as at December 31, 2015 consisted of the following (in millions):

	December 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	3.5	-	3.5	-
Exchange-traded funds	7.3	7.3	-	-
Total	$ 10.8	$ 7.3	$ 3.5	$ -

Accumulated Other Comprehensive Income (Loss)

Unrealized gains or losses on marketable securities are recorded in accumulated other comprehensive income (loss). The Company did not have investments in marketable securities at December 31, 2016. Accumulated other comprehensive income (loss) at December 31, 2015 consisted of unrealized losses on securities of $65 thousand.

NOTE 6 – INVENTORIES

Inventories at December 31, 2016 consist of raw materials to be used in the manufacture to integrate Impede 2.0 technology into our commercially available Nexafed 30mg tablets, and finished goods held for distribution and sale on our Nexafed product line. Inventories at December 31, 2015 consist of finished goods held for distribution and sale on our Nexafed product line. During 2014, we purchased selected raw and packaging material inventories for $260 thousand from Pfizer related to the Oxaydo product we reacquired from them (see Note 4). During 2015, we entirely wrote off and disposed of these inventories. Inventories are stated at the lower of cost (first-in, first-out method) or market (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 are summarized as follows (in thousands):

	December 31,	
	2016	2015
Raw materials	$ 98	$ -
Finished goods	243	346
Total inventory	341	346
Less: inventory reserve - finished goods	(32)	(70)
Net inventory	$ 309	$ 276

Inventory reserve activity during the years ended December 31, 2016 and 2015 was as follows (in thousands):

	2016	2015
Beginning of year	$ 70	$ -
Reserve expense - raw and packaging	-	260
Reserve expense - finished goods	26	70
	96	330
Inventory write-offs - raw and packaging	-	(260)
Inventory write-offs - finished goods	(64)	-
End of year	$ 32	$ 70

NOTE 7 – PROPERTY, PLANT AND EQUIPMENT

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

	December 31, 2016	2015
Building and improvements	$ 1,273	$ 1,265
Scientific equipment	598	598
Computer hardware and software	109	124
Machinery and equipment	568	508
Land and improvements	162	162
Other personal property	70	70
Office equipment	27	27
	2,807	2,754
Less: impairment reserve	(82)	(-)
Less: accumulated depreciation	(1,858)	(1,741)
Total property, plant and equipment, net	$ 867	$ 1,013

Depreciation expense was approximately $0.1 million for each of the years ended December 31, 2016 and 2015.

NOTE 8 – ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	December 31, 2016	2015
Professional services	$ 232	$ 171
Other fees and services	95	64
Payroll, payroll taxes and benefits	116	101
Clinical and regulatory services	233	92
Marketing, advertising, and promotion	10	115
Property taxes	16	15
Franchise taxes	1	6
	$ 703	$ 564

NOTE 9 – DEBT

On December 27, 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 full principal amount of the Term Loan was funded on December 27, 2013. We are using the proceeds of the Loan Agreement for general working capital and to fund our business requirements. 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 of December 31, 2016, we have made $4.5 million in aggregate principal payments. As security for its obligations under the Loan Agreement, the Company granted Lender a security interest in substantially all of its existing and after−acquired assets, exclusive of its intellectual property assets. Pursuant to the Loan Agreement, the Company is not allowed to pledge its intellectual property assets 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) (the “Warrants”). We recorded $400 thousand as debt discount associated with the 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.

The fair value of the warrants was determined using the Black-Scholes option-pricing model. Significant assumptions used in the Black-Scholes model were:

Expected dividend yield	0.0%
Risk-free interest rate	2.4%
Expected volatility	92%
Expected term (years)	7

On January 7, 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.

On October 13, 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, has been modified so that the $2.5 million cash balance reserve remains in place until we raised 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.

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. Per the term 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.

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, 2016 and 2015, we have accumulated and accrued $559 thousand and $387 thousand, respectively, of 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, a material adverse change in the Company, bankruptcy and insolvency defaults and material judgment defaults.

Our debt at December 31, 2016 is summarized below (in thousands):

Current Debt	Current	Long-term	Total
Balance at Dec 31, 2015	$ 2,320	$ 5,720	$ 8,040
Principal payments	(2,540)	-	(2,540)
Classification	2,741	(2,741)	-
Balance at Dec 31, 2016	$ 2,521	$ 2,979	$ 5,500

Debt Discount	Current	Long-term	Total
Balance at Dec 31, 2015	$ -	$ (193)	$ (193)
Amortization expense	-	95	95
Classification	(98)	98	-
Balance at Dec 31, 2016	$ (98)	$ -	$ (98)

Deferred Debt Issuance Costs	Current	Long-term	Total
Balance at Dec 31, 2015	$ -	$ (97)	$ (97)
Amortization expense	-	50	50
Classification	(47)	47	-
Balance at Dec 31, 2016	$ (47)	$ -	$ (47)
Current Debt, net at Dec 31, 2016	$ 2,376	$ 2,979	$ 5,355

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

	2016	2015
Interest expense:		
Term Loan	$ 748	$ 971
Debt discount	95	121
Debt issue costs	50	65
Total interest expense	$ 893	$ 1,157

The annual principal payments of the debt at December 31, 2016 are as follows:

Year	Annual Principal Payments (in thousands)
2017	$ 2,521
2018	2,979
Total	$ 5,500

NOTE 10 – EQUITY FINANCINGS

Our universal shelf registration statement on Form S-3 was declared effective by the Securities and Exchange Commission (“SEC”) on March 15, 2013. On April 18, 2013, we filed a prospectus supplement with the SEC pursuant to which we could sell shares of our common stock from time to time in “at the market” offerings and certain other transactions, having sales proceeds of up to $13 million. We did not sell any shares of our common stock pursuant to our prospectus supplement during the year ended December 31, 2014. During the year ended December 31, 2015, we sold approximately 54 thousand shares of our common stock (after giving effect to our one-for-five reverse stock split) for gross proceeds of $225 thousand. Transaction costs were approximately $8 thousand. The net proceeds of $217 thousand were used for general corporate purposes. In order to allow for the sale of our shares of common stock under our shelf registration statement pursuant to the Placement Agency Agreement and Securities Purchase Agreement described below, on June 30, 2015, we and MLV & Co., LLC, as sales agent, terminated the at-market issuance sales agreement dated April 18, 2013, thereby terminating any further “at the market offerings” under our prospectus supplement filed with the SEC on April 18, 2013.

On June 30, 2015, we entered into a Placement Agency Agreement (the “Placement Agency Agreement”) with Roth Capital Partners, LLC (“Roth”), pursuant to which we engaged Roth to act as sole placement agent in a registered direct offering (the “Offering”) of 1.958 million shares of our common stock, par value $.01 (after giving effect to our one-for-five reverse stock split). On June 30, 2015, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain institutional investors (the “Purchasers”), pursuant to which we agreed to sell 1.958 million shares of our common stock at a price of $3.90 per share (after giving effect to our one-for-five reverse stock split) to the Purchasers in the Offering, for gross proceeds to the Company of $7.64 million, before expenses. The Offering was made pursuant to a prospectus supplement dated June 30, 2015 filed with the Securities and Exchange Commission in connection with a takedown from the Company’s shelf registration statement on Form S-3 (File No. 333-187075), which became effective on March 15, 2013, and the related base prospectus included in the Registration Statement, as supplemented by the prospectus supplement. The transactions contemplated by the Placement Agency Agreement and the Purchase Agreement closed on July 7, 2015.

Pursuant to the terms of the Placement Agency Agreement, we paid Roth a cash placement fee equal to 6.5% of the gross proceeds in the Offering or $496 thousand, and reimbursed Roth $35 thousand for its expenses. The net proceeds from the Offering, after these and other legal expenses, was $7.0 million.

NOTE 11 – COMMON STOCK WARRANTS

We have outstanding 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 9 for a discussion of the reduction of the exercise price of these warrants to $2.52 per share which were originally issued in connection with the issuance of the $10.0 million secured promissory notes in December 2013. These warrants contain a cashless exercise feature.

Our warrant activity during the years ended December 31, 2016 and 2015 is shown below (in thousands except price data):

	December 31,			
	2016		2015	
	Number	WAvg Exercise Price	Number	WAvg Exercise Price
Outstanding, beginning	60	$ 2.52	60	$ 7.98
Issued	-	-	-	-
Exercised	-	-	-	-
Expired	-	-	-	-
Modification	-	-	-	(5.46)
Outstanding, ending	60	$ 2.52	60	$ 2.52

NOTE 12 – EMPLOYEE BENEFIT PLANS

401(k) and Profit-Sharing 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 in years 2016 or 2015.

Stock Option Plans

We maintain various stock option plans. A summary of our stock option plans as of December 31, 2016 and 2015 and for the years then ended consisted of the following (in thousands except exercise price):

	Years Ended December 31,			
	2016		2015	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, beginning	1,198	$ 15.67	911	$ 20.70
Granted	199	0.92	315	2.01
Exercised	-	-	-	-
Forfeited or expired	-	-	(28)	26.75
Outstanding, ending	1,397	$ 15.67	1,198	$ 15.67
Exercisable, ending	1,062	$ 17.41	814	$ 22.04

The following table summarizes information about nonvested stock options outstanding at December 31, 2016 (in thousands except price data):

	Number of Options Not Exercisable	Weighted Average Fair Value
Outstanding at December 31, 2015	384	$ 1.85
Granted	199	0.92
Vested	(248)	1.89
Forfeited	-	-
Outstanding at December 31, 2016	335	$ 1.18

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 2016 and 2015 stock option grants were:

	2016	2015
Expected dividend yield	0.0%	0.0%
Risk-free interest rates	2.3%	2.2%
Average expected volatility	85%	89%
Expected term (years)	10	10
Weighted average grant date fair value	$ 0.77	$ 1.72

The intrinsic value of the option awards which were vested and outstanding at December 31, 2015 was $6 thousand. The option awards vested and outstanding at December 31, 2016 did not have intrinsic value. The total remaining unrecognized compensation cost on unvested option awards outstanding at December 31, 2016 was approximately $400 thousand, and is expected to be recognized in operating expense in varying amounts over the 23 months remaining in the requisite service period. There were no option award exercise activity during 2016 or 2015.

Restricted Stock Unit Award Plan

We have two Restricted Stock Unit Award Plans for our employees and non-employee directors, a 2014 Restricted Stock Unit Award Plan (the "2014 RSU Plan") and a 2005 Restricted Stock Unit Award Plan (the "2005 RSU Plan"). Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. The share-based compensation cost to be incurred on a granted RSU 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 over the vesting period of the RSU award.

A summary of the grants under the RSU Plans as of December 31, 2016 and 2015, and for the years then ended consisted of the following (in thousands):

	Years Ended December 31,			
	2016		2015	
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	45	45	29	29
Granted	88	-	42	-
Distributed	(42)	(42)	(26)	(26)
Vested	-	88	-	42
Forfeited or expired	-	-	-	-
Outstanding, ending	91	91	45	45

2014 Restricted Stock Unit Award Plan

Our 2014 RSU Plan was approved by shareholders on May 1, 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, 2016, approximately 241 thousand shares are available for award under the 2014 RSU Plan.

Information about the awards under the 2014 RSU Plan is as follows:

- On May 1, 2014, we awarded approximately 7 thousand RSUs to each of our 4 non-employee directors. Such RSU awards vested 50% on June 30, 2014 and 25% on each of September 30 and December 31, 2014. Such 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 RSU awards subject to cash settlement were recorded as a liability in the Company's balance sheet. The liability was $26 thousand at December 31, 2014. Accordingly the vested portion of the awards containing the cash settlement feature are being marked-to-market each reporting period until they are distributed. Marked-to-market accounting can create fluctuations in our compensation expense including the need to record additional expense. RSU awards 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.

- On January 2, 2015, we awarded approximately 10 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 2015. The RSU awards subject to cash settlement are subject to marked-to market accounting and the liability recorded in the Company's balance sheet was $45 thousand at December 31, 2015. Distributions of stock under the January 2, 2015 award cannot be deferred until a later date and the stock under such awards were distributed on January 4, 2016.

- On January 4, 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 the January 4, 2016 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. On January 3, 2017, approximately 66 thousand RSUs under such awards were distributed.

- On January 3, 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. The portion of the RSU awards which are subject to cash settlement are also subject to marked-to market accounting. Distributions of stock under the January 3, 2017 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.

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

- On January 2, 2015, 26 thousand RSUs from the May 1, 2014 award were distributed and 4 thousand RSUs were deferred until a future distribution date. Of the 26 thousand RSUs distributed, 19 thousand RSUs were distributed in common stock and 7 thousand RSUs were settled in cash.

- On January 4, 2016, 1 thousand RSUs from the May 1, 2014 award and 42 thousand RSUs from the January 2, 2015 award were distributed. There are 2 thousand RSUs from the May 1, 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.

- On January 3, 2017, 1 thousand RSUs from the May 1, 2014 award and 66 thousand RSUs from the January 4, 2016 award were distributed. There are 1 thousand RSUs from the May 1, 2014 award and 22 thousand RSUs from the January 4, 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.

NOTE 13 – INCOME TAXES

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,	
	2016	2015
Benefit at U.S. statutory 34% tax rate	$ (2,512)	$ (1,696)
State taxes (benefit), net of federal effect	49	41
Research and development tax credits	-	-
Share-based compensation	159	184
Other	2	11
Change in valuation allowance	2,302	1,460
Provision for income taxes	$ -	$ -

Deferred Tax Assets and Valuation Allowance

Deferred tax assets reflect the tax effects of net operating losses ("NOLs"), tax credit carryovers, and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The most significant item of our deferred tax assets is derived from our Federal NOLs. We have approximately $47.2 million Federal income tax benefits at December 31, 2016 derived from $138.8 million Federal NOLs at the U.S. statutory tax rate of 34% and $2.1 million State NOLs. These NOLs are available to offset future taxable income, some of which already have limitations for future use as prescribed under IRC Section 382. We have updated our previously conducted Section 382 study through December 31, 2016 which provides no further limitations for future use of the NOLs. Our Federal and State NOLs will expire in varying amounts between 2017 and 2036 if not used, and those expirations will cause fluctuations in our valuation allowances. The net change in the valuation allowance in 2016 and 2015 was approximately $5.6 million and $0.6 million, respectively.

As of December 31, 2016 we had federal research and development tax credits of approximately $1.2 million, which expire in the years 2024 through 2034. We also had approximately $0.2 million of Indiana state research and development tax credits, which will expire in 2017.

The components of our deferred tax assets are as follows:

	December 31,	
	2016	2015
	(in thousands)	
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	$ 47,192	$ 52,772
- State	2,135	2,050
Research and development tax credits	1,320	1,394
Share-based compensation	57	38
Other, net	332	368
Total deferred taxes	51,036	56,622
Valuation allowance	(51,036)	(56,622)
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, 2016 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, 2016 and 2015, 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, 2016, the Company's tax years 2013, 2014 and 2015 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 2013.

NOTE 14 – COMMITMENTS AND CONTINGENCIES

Reglan®/Metoclopramide Litigation

Halsey Drug Company, as predecessor to us, has been 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 Pennsylvania action, over 200 lawsuits were filed against Acura and Halsey Drug Company alleging that plaintiffs developed neurological disorders as a result of their use of the Reglan brand and/or generic metoclopramide. In the New Jersey action, plaintiffs filed approximately 150 lawsuits against us, but served less than 50 individual lawsuits upon us. In the California action, there are 89 pending cases against us, with more than 445 individual plaintiffs.

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 19 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, and California, Generic Defendants, including us, also filed dispositive motions based on the *Mensing* decision.

In Pennsylvania, on November 18, 2011, the trial court denied Generic Defendants' dispositive preemption motions, without prejudice. In July 2013, the Pennsylvania Superior Court issued an adverse decision, and a subsequent appeal to the Pennsylvania Supreme Court was denied. On December 16, 2014, the Generic Defendants filed a Joint Petition for Certiorari with the United States Supreme Court captioned *Teva Pharmaceuticals USA, Inc. et al. v. Dorothy Bentley, et al.*, No. 14-711 (U.S.) seeking reversal of the Pennsylvania state court decision. On April 27, 2015, the U.S. Supreme Court denied this Petition and this matter has been returned to the trial court for further proceedings.

From July, 2015 to date, the court has taken procedural steps to narrow this litigation, including requests for plaintiffs to voluntarily discontinue cases, such as those filed against us, where there is no case-specific product identification. The trial court proceedings were stayed on January 12, 2017. We are in the process of obtaining voluntary dismissal without prejudice of all of the Pennsylvania cases pending against us. We expect that the Court will approve these dismissals during the second quarter of 2017 and should finally dismiss the Pennsylvania-based litigation against us with prejudice later this year. Legal fees related to this matter are currently covered by our insurance carrier.

In California, the trial court entered a May 25, 2012 Order denying Generic Defendants' dispositive preemption motions. The Generic Defendants' appeals from this order were denied by the California appellate courts. In May 2014, the California Court denied a subsequent demurrer and motion to strike seeking dismissal of plaintiffs' manufacturing defect and defective product claims to the extent that they are barred by federal preemption based upon the June 2013 *Bartlett* decision. Thus far, we and most Generic Defendants have not been required to file answers or other responsive pleadings in each individual case in which they are named defendants. 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 within the next three to six months. 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, 2016 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

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

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, 2016, we have accrued approximately $95 thousand of cost sharing expenses of certain clinical studies for product line extensions (additional strengths) of Oxaydo for the United States under the Egalet.

Facility Lease

The Company leases administrative office space in Palatine, Illinois under a lease for $25 thousand annually expiring March 31, 2017. Effective April 1, 2017, the office space is leased on a month to month basis.

NOTE 15 – SUBSEQUENT EVENT

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 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 $425,000 for the net book value of 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 million, $500,000 and $250,000, 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 $500,000 per product (for all 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.

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.

SUPPLEMENTARY DATA - QUARTERLY FINANCIAL DATA (Unaudited)

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

	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

	For Three Month Periods Ended			
	Mar. 31, 2015	June 30, 2015	Sept. 30, 2015	Dec. 31, 2015
Net revenues	$ 5,357	$ 341	$ 210	$ 2,679
Operating expenses	3,845	2,739	2,615	3,389
Operating income (loss)	1,512	(2,398)	(2,405)	(710)
Net loss	$ 1,239	$ (2,663)	$ (2,649)	$ (916)
Basic income (loss) per share	$ 0.13	$ (0.28)	$ (0.23)	$ (0.08)
Diluted income (loss) per share	$ 0.13	$ (0.28)	$ (0.23)	$ (0.08)

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 3.1 to the Form 8-K filed on March 3, 2009).
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).
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	Registration Rights Agreement dated as of February 6, 2004 between the Registrant and certain investors (incorporated by reference to Exhibit 10.6 of the Form 8-K filed on February 10, 2004)

Exhibit Number	Exhibit Description
10.4	Loan and Security Agreement dated as of December 27, 2013 between Acura Pharmaceuticals, Inc. Acura Pharmaceutical Technologies, Inc. and Oxford Finance LLC (incorporated by reference to Exhibit 10.6 to the Form 10-K filed March 3, 2014).
10.5	First Amendment to Loan and Security Agreement entered into as of January 7, 2015 between Oxford Finance LLC, the Registrant and 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	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).

Exhibit Number	Exhibit Description
†10.15	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).
†10.16	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).
†10.17	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).
†10.18	Registrant's 2016 Stock Option Plan (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on April 28, 2016).
†10.19	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).
†10.20	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).
†10.21	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).
†10.22	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).
†10.23	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).
†10.24	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).
†10.25	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).
†10.26	Seventh Amendment to Executive Employment Agreement executed December 12, 2013 between the Registrant and Clemens (incorporated by reference to Exhibit 10.24 to the Form 10-K for the year ending December 31, 2013 filed on March 3, 2014).
†10.27	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).
†10.28	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).

Exhibit Number	Exhibit Description
†10.29	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).
10.30	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).
14.1	Code of Ethics (incorporated by reference to Exhibit 14.1 of the Form 8-K filed on December 10, 2007).
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21 to the Form 10-K for the fiscal year ended December 31, 2006 filed on March 15, 2007).
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
31.2*	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
32*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Extension Calculation Linkbase
101.LAB*	XBRL Extension Label Linkbase
101.PRE*	XBRL Extension Presentation Linkbase
101.DEF*	XBRL Taxonomy Extension Definition Linkbase

* Filed or furnished herewith.

† Management contract or compensatory plan or arrangement

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Acura Pharmaceuticals, Inc.
Palatine, Illinois

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-213017, 333-195612, 333-151653, 333-151620, 333-133172, 333-123615, 333-63288, and 33-98396), and on Form S-3 (Nos. 333-210039 and 333-146416) of Acura Pharmaceuticals, Inc. of our report dated March 31, 2017, relating to the consolidated financial statements, which appear in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
Chicago, Illinois
March 31, 2017

EXHIBIT 31.1

CERTIFICATION

I, Robert B. Jones, certify that:

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

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

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

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

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

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

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (its fourth fiscal quarter) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: March 31, 2017

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

EXHIBIT 31.2

CERTIFICATION

I, Peter A. Clemens, certify that:

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

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

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

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

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

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

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

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (its fourth fiscal quarter) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: March 31, 2017

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

EXHIBIT 32

CERTIFICATION OF

CHIEF EXECUTIVE OFFICER
AND
CHIEF FINANCIAL OFFICER

PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert B. Jones, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of Acura Pharmaceuticals, Inc. for the fiscal year ended December 31, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report of Form 10-K fairly presents, in all material respects, the financial condition Acura Pharmaceuticals, Inc. as of the dates presented and results of operations of Acura Pharmaceuticals, Inc. for the periods presented.

March 31, 2017

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

I, Peter A. Clemens, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of Acura Pharmaceuticals, Inc. for the fiscal year ended December 31, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report of Form 10-K fairly presents, in all material respects, the financial condition Acura Pharmaceuticals, Inc. as of the dates presented and results of operations of Acura Pharmaceuticals, Inc. for the periods presented.

March 31, 2017

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