ACURA PHARMACEUTICALS, INC

FORM 10-K
(Annual Report)

Filed 03/02/15 for the Period Ending 12/31/14

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CIK	0000786947
Symbol	ACUR
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2014**

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:**
Common Stock, par value $0.01 per share	NASDAQ Capital Market

Securities registered pursuant to section 12(g) of the Act:
(Title of Class)
None

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 $1.09 on June 30, 2014 (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 $29.0 million.

As of February 27, 2015, the registrant had 48,947,247 shares of Common Stock, par value $0.01, outstanding.
DOCUMENTS INCORPORATED BY REFERENCE **:** Portions of the Proxy Statement for the registrant’s Annual Meeting of Shareholders to be held on or about **April 30, 2015** are incorporated by reference into Part III of this Annual Report on Form 10-K.

Acura Pharmaceuticals, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2014

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Forward-Looking Statements

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

- our and our licensee's ability to successfully launch and commercialize our products and technologies, including Oxaydo Tablets and our Nexafed products;
- the pricing and price discounting that may be offered by Egalet for Oxaydo;
- the results of our development of our Limitx™ technology;
- our ability to fund, or obtain funding for, products developed utilizing our Aversion®, Impede® and Limitx™ technologies;
- the results of our meetings or discussions with the U.S. Food and Drug Administration ("FDA"), or any appeals of prior FDA determinations, relating to our Aversion hydrocodone/acetaminophen product;
- whether the results of studies AP-ADF-302, AP-ADF-303, and AP-ADF-304 relating to our Aversion hydrocodone/acetaminophen product will be acceptable to the FDA;
- whether we will conduct an additional intranasal abuse liability study on our Aversion hydrocodone/acetaminophen product and, if conducted, whether the results of such study will support the filing of a New Drug Application and/or a claim of intranasal abuse deterrence;
- our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies;
- the market acceptance of and competitive environment for any of our products;
- the willingness of wholesalers and pharmacies to stock our Nexafed products;
- expectations regarding potential market share for our products and the timing of first sales;
- our ability to enter into additional license agreements for our Aversion Technology product candidates;
- 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;
- 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 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® Technology is a mixture of inactive ingredients incorporated into pharmaceutical tablets and capsules intended to address some common methods of product tampering associated with opioid abuse. Oxaydo™ Tablets (formerly known as Oxecta®)(oxycodone HCl, CII), is the first approved product utilizing Aversion in the United States and we have 7 additional opioid products utilizing Aversion in various stages of development. 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 7.5 mg strengths. We are advised that Egalet plans to launch Oxaydo in the United States in the third quarter of 2015. We have also developed Impede® Technology which is a combination of inactive ingredients that prevent the extraction of pseudoephedrine from tablets and disrupt the direct conversion of pseudoephedrine from tablets into methamphetamine. We launched our first Impede Technology product, Nexafed®, into the United States market in December 2012 and launch our Nexafed Sinus Pressure + Pain product in the United States in February 2015. We have multiple pseudoephedrine products in development utilizing our Impede Technology. In August 2014, we received a grant from the National Institute on Drug Abuse to advance early stage development of our third abuse deterrent technology, Limitx™. Limitx is designed to retard the release of active drug ingredients when too many tablets are accidently or purposefully ingested.

Opioid analgesics are one of the largest prescription drug markets in the United States with 250 million prescriptions dispensed in 2014. Prescription opioids are also the most widely abused drugs with 12 million people abusing or misusing these products annually. We expect our Aversion Technology opioid products to compete primarily 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 65 tablets or capsules. According to IMS Health, in 2014, sales in the immediate-release opioid product segment were approximately 235 million prescriptions and $3.0 billion, of which ~98% was attributable to generic products. Immediate-release oxycodone tablets represent 14.8 million of these prescriptions or almost 1.6 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.

Hydrocodone bitartrate with acetaminophen, or hydrocodone/acetaminophen, is the most widely prescribed and often abused opioid product in the United States. Our Aversion hydrocodone/acetaminophen product is our most advanced opioid product in development and the primary focus of our opioid development efforts. On December 5, 2013, we met with the FDA to discuss the results of Study AP-ADF-301, or Study 301, a key abuse liability study for our Aversion hydrocodone/acetaminophen product and whether the results from Study 301 are acceptable for submission in a New Drug Application, or NDA. On May 27, 2014, we announced that the FDA advised us that the data from our Study 301 was insufficient to support an intranasal abuse deterrence description in our product labeling. The FDA indicated that a product will have to have an impact on "drug liking" to support a description of abuse-deterrence through a relevant route of abuse. The FDA's advice also questioned whether the intranasal route is a relevant route of abuse for hydrocodone/ acetaminophen products. We met with the FDA on August 14, 2014 to discuss the development pathway for our Aversion hydrocodone/acetaminophen tablet development candidate, which is intended to provide abuse-deterrent features to address abuse by nasal snorting and injection. The FDA continues to question the relevance of abuse of hydrocodone with acetaminophen products by the intranasal route of administration.

On September 11, 2014, we submitted a formal dispute resolution request with the FDA. The dispute pertains to the FDA's determination that nasal snorting abuse of hydrocodone with acetaminophen products lacks relevance. On October 16, 2014, we announced that the FDA denied on procedural grounds our appeal of the position taken by the Division of Anesthesia, Analgesia and Addiction Products ("DAAAP") that abuse by snorting hydrocodone with acetaminophen products lacks relevance. In a letter decision from the Office of Drug Evaluation II, the FDA indicated that DAAAP's comments and correspondence with us to date, as well as the FDA's Draft Guidance on abuse deterrent opioids, should be viewed only as recommendations and opinions, and do not preclude us from completing clinical development of our hydrocodone with acetaminophen product and submitting an NDA for consideration by the FDA. We are currently assessing our development strategy for our Aversion hydrocodone with acetaminophen product, including the merits of appealing the FDA's decision. Even if we were to file an appeal and succeed in such proceeding, in order to continue the development of our hydrocodone/acetaminophen product we will be required to conduct an additional abuse liability study that will need to demonstrate a statistically significant reduction in Drug Liking, of which no assurance can be provided. We are currently in the process of designing this next study and will make a decision on commencing this study in 2015.

We expect that the development program for all our Aversion opioid products in development will be consistent with that of Oxaydo and our hydrocodone/acetaminophen product candidate.

In 2009, the United States market for over-the-counter market, or OTC, cold and allergy products containing an oral nasal decongestant was approximately $1 billion. In 2012, the DEA reported 11,210 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. Nexafed, our 30mg pseudoephedrine hydrochloride immediate-release tablet, is stocked in approximately 19% 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 launched our first line extension, Nexafed Sinus Pressure + Pain, a 30/325mg pseudoephedrine HCl and acetaminophen tablet using our Impede technology in February 2015. The category for meth-resistant pseudoephedrine products has also been the focus of some, as yet unsuccessful, state legislation seeking to incentivize consumers and pharmacists to utilize these meth-resistant technologies.

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.

We also have discovered an early-stage technology, Limitx™, which, in proof of concept laboratory tests, demonstrates the ability to limit the release of the active ingredient from tablets when multiple tablets are consumed simultaneously. We are currently undertaking formulation optimization work for a hydromorphone HCl product using our Limitx technology.

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 that is expected to be launched in the United States by our licensee in the third quarter of 2015, and two products commercially launched containing our Impede Technology. We continue to invest in improvements in these technologies and innovate new technologies 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.

- *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 and we are seeking licensing partners for our products in development utilizing our 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.

Aversion Technology Overview

Aversion Technology is a unique composition of inactive pharmaceutical ingredients utilized with an opioid or other drug susceptible of abuse to provide abuse deterrent functionality. All of our Aversion Technology opioid products 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, while simultaneously discouraging the following common methods of pharmaceutical product misuse and abuse:

- Drug abusers may dissolve pharmaceutical tablets or capsules in water, alcohol, or other common solvents, filter the dissolved solution into a syringe, and inject the resulting fluid intravenously to obtain euphoric effects. Aversion Technology tablets dissolved in generally available solvents, including water or alcohol, into a volume and form suitable for intravenous injection, converts the tablet into a viscous gel mixture. We believe this gel will limit or impede drug abusers from extracting and injecting the active ingredients from our tablets.

- Drug abusers may crush pharmaceutical tablets or capsules and intranasally snort the resulting powder to absorb active ingredient through the nasal passages to obtain euphoric effects. The combination of Aversion Technology inactive ingredients is intended to induce nasal passage discomfort if the tablets are snorted. We believe products which utilize Aversion Technology may be disliked and will discourage prospective nasal drug abusers from snorting crushed tablets or capsules.

The extent and manner in which any of the features described above 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.

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. Oxaydo was FDA approved on June 17, 2011 and introduced, by our former licensee, Pfizer Inc., into the U.S. market in February 2012. Pfizer strategically deprioritized their efforts in immediate-release opioids commencing in summer of 2012 and we reacquired the rights to Oxaydo in April 2014, shortly after Pfizer initiated minimal, non-sales representative promotion in late 2013. 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. We are advised that Egalet plans to launch Oxaydo in the United States in the third quarter of 2015.

The 2014 market for immediate-release oxycodone products was 14.8 million dispensed prescription or 1.6 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. Because the target audience for promoting our opioid products is so large, we will seek marketing partners to best capitalize on our opioid opportunities.

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 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.

Aversion Technology Opioid Products in Development

We have the following opioid products utilizing our Aversion Technology in various stages of development:

Aversion Technology Tablets	Comparable Brand Name [1]	Status
Hydrocodone bitartrate/acetaminophen	Vicodin®, Lortab®, Norco®	All clinical work is complete except a repeat nasal snorting abuse liability study will be required. We are assessing FDA's view that abuse by nasal snorting lacks relevance before continuing the development program.
Hydromorphone HCl	Dilaudid®	Proof of Concept [2]
Methadone HCl	Methadose	Proof of Concept [2]
Morphine Sulfate	MSIR®	Proof of Concept [2]
Oxycodone HCl/acetaminophen	Percocet®	Proof of Concept [2]
Oxymorphone HCl	Opana®	Proof of Concept [2]
Tramadol HCl	Ultram®	Proof of Concept [2]

[1] Comparable Brand Name refers to currently marketed prescription products in the United States containing the same active analgesic ingredient (s) as in the corresponding Aversion Technology product.

[2] Proof of Concept is attained upon demonstration of product stability and bioavailability parameters. All proof of concept formulations contain niacin (derived from the initial Aversion formulation) and will require reformulation.

We anticipate the development program for each of our Aversion opioid products will be consistent with that of Oxaydo. Because our products use known active ingredients in approved dosage strengths, the safety and efficacy of the Aversion opioid will 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.

The abuse deterrent studies of the Aversion products will be consistent with FDA's draft guidance for the development of abuse deterrent opioids with the objective to obtain a description of our studies and/or abuse deterrent features in the product's label. 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. We also may conduct human abuse liability studies comparing the abuse liability of Aversion products to currently marketed products.

We may have to perform additional safety and/or efficacy assessment as may be identified by the FDA for each specific formulation during the IND or NDA phase of development. In accordance with the FDA draft 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.

We believe that the time to develop each Aversion opioid product from IND to NDA submission can be as short as 18 months to 24 months, provided all studies meet their primary study objectives. There can be no assurance, however, that such development timeline will be achieved.

Aversion Hydrocodone/Acetaminophen Development

Our most advanced opioid development product is Aversion hydrocodone/acetaminophen. Our clinical development program for our hydrocodone/acetaminophen product is expected to consist of:

- A nasal abuse liability liking study in about 40 recreational drug users against a reference drug, or Study AP-ADF-301 (*complete*);
- A pharmacokinetic study (Study AP-ADF-302) in about 36 fasted subjects to establish bioequivalence to the FDA's reference listed drug and determine the food effect on our drug (*complete*);
- A pharmacokinetic study (Study AP-ADF-303) in about 24 subjects demonstrating dose proportionality of our formulation (*complete*);
- A pharmacokinetic study (Study AP-ADF-304) in about 24 subjects to establish safety compared to the reference listed drugs tramadol/acetaminophen (for acetaminophen) and hydrocodone bitartrate/ibuprofen (for hydrocodone) (*complete*);
- Laboratory studies demonstrating extraction, syringing, swelling and particle size characteristics of our product (*in progress*);
- An assessment of the routes of abuse of hydrocodone products (*complete*); and
- An additional nasal abuse liability study in recreational drug users against a reference drug (*under strategic review*).

On August 26, 2013, we announced top-line results from Study AP-ADF-301 (Study 301), a phase II clinical study in 40 recreational drug abusers assessing the abuse liability of snorting of our crushed hydrocodone/acetaminophen product. Study 301's primary endpoint indicated Aversion hydrocodone/acetaminophen had slightly lower numeric mean maximum drug liking (Emax: 72.1) compared to an equivalent dose of a generic hydrocodone/acetaminophen tablet (Emax: 75.6) currently on the market, however these results were not statistically significant (p=0.22). The secondary endpoints demonstrated the effects of the Aversion ingredients on drug snorting. Aversion hydrocodone/acetaminophen's mean minimum liking (Emin: 40.2) was less than the comparator (Emin: 50.4) (the difference being statistically significant at p=0.0003). The mean minimum drug liking for Aversion hydrocodone/acetaminophen and the placebo control were 40.2 and 48.8, respectively (the difference being statistically significant at p=0.0042). A score below 50 indicates a subject disliked the drug they were taking at some point during the treatment (a score of 50 means neither like or dislike), and a score greater than 50 indicates they liked the drug they were taking.

The mean minimum liking results correlated closely the Overall Drug Liking score (ODL) and Take Drug Again assessment (TDA). ODL assessed the subject like or dislike for the drug experience 12 hours after taking the dose. The ODL for Aversion hydrocodone/acetaminophen (52.7) was lower than the generic comparator (71.0) (the difference being statistically significant at p=0.0001) with a score of 50 indicating neither a like nor dislike. TDA assessed a subject's willingness to take the drug again assessed 12 hours after taking the dose. The TDA for Aversion hydrocodone/acetaminophen (45.1) was lower than the generic comparator (71.0) (the difference being statistically significant at p=0.0001) with the Aversion hydrocodone/acetaminophen score below 50 indicating an unwillingness to take the drug again.

There were no serious adverse events reported for Aversion hydrocodone/acetaminophen. There was no sequence effect identified in the study but a carryover effect between the 5 study crossover periods was identified for the Emax measure but not the Emin measure. Due to this observed carryover effect, the FDA may review the results of our study differently than we have and/or limit the amount of data we collected in the label for our product if approved by the FDA. As such, we are strategically considering the need to complete an additional nasal abuse liability study.

On December 5, 2013, we met with FDA to discuss if the FDA will consider whether the results of Study 301 are acceptable for submission in a NDA. On May 27, 2014, we announced that the FDA advised us that the data from our Study 301 was insufficient to support an intranasal abuse deterrence claim. The FDA indicated that a product will have to have an impact on "drug liking" to support a claim of abuse-deterrence through a relevant route of abuse. The FDA's advice also questioned whether the intranasal route is a relevant route of abuse for hydrocodone/ acetaminophen products and recommended that we identify variables that could have impacted the findings from Study 301 before considering or conducting an additional intranasal abuse liability study on our Aversion hydrocodone/ acetaminophen product. We have previously submitted a report to the FDA on the prevalence of abusing hydrocodone products by intranasal administration. We met with the FDA on August 14, 2014 to discuss the development pathway for our Aversion hydrocodone/acetaminophen tablet development candidate, which is intended to provide abuse-deterrent features to address abuse by nasal snorting and injection. The FDA continues to question the relevance of abuse of hydrocodone with acetaminophen products by the intranasal route of administration. The FDA indicated that we may conduct an additional nasal abuse liability study for our Aversion hydrocodone/acetaminophen product candidate.

On September 11, 2014, we submitted a formal dispute resolution request with the FDA. The dispute pertains to the FDA's determination that nasal snorting abuse of hydrocodone with acetaminophen products lacks relevance. We believe the available data, as contained in the multiple sources provided to the FDA, strongly supports the conclusion that hydrocodone containing products are known to be abused through snorting, a standard explicitly identified in FDA's January 2013 "Guidance for Industry Abuse-Deterrent Opioids — Evaluation and Labeling". On October 16, 2014, we announced that the FDA denied on procedural grounds our appeal of the position taken by the Division of Anesthesia, Analgesia and Addiction Products ("DAAAP") that abuse by snorting hydrocodone with acetaminophen products lacks relevance. In a letter decision from the Office of Drug Evaluation II, the FDA indicated that DAAAP's comments and correspondence with us to date, as well as the FDA's Draft Guidance on abuse deterrent opioids, should be viewed only as recommendations and opinions, and do not preclude us from completing clinical development of our hydrocodone with acetaminophen product and submitting an NDA for consideration by the FDA. The FDA noted that an Advisory Committee meeting may greatly inform their considerations. The FDA letter ruling also advised us that we may appeal the decision of the Office of Drug Evaluation II to the next level within the FDA. We are currently assessing our development strategy for our Aversion hydrocodone with acetaminophen product, including the merits of appealing the FDA's decision. Even if we were to file an appeal and succeed in such proceeding, in order to continue the development of our hydrocodone/acetaminophen product we will be required to conduct an additional abuse liability study that will need to demonstrate a statistically significant reduction in Drug Liking, of which no assurance can be provided. We are currently in the process of designing this next study and will make a decision on commencing this study in 2015.

We have completed scale-up activities for our Aversion hydrocodone/acetaminophen product at the proposed commercial manufacturer and have manufactured our registration batches. We have also completed the pharmacokinetic studies (302, 303 and 304) for Aversion hydrocodone/acetaminophen, the results of which have demonstrated conformance with the FDA's standard for bioequivalence when compared to the reference drug, and demonstrated dose proportionality, or relatively consistent blood exposure, across all three dosage strengths. Such studies also evaluated blood levels of each of hydrocodone and acetaminophen compared to their respective comparator drugs, and demonstrated that our Aversion hydrocodone/acetaminophen blood levels of hydrocodone were consistent with the comparator product, while acetaminophen peak blood levels were 23% higher than the comparator product based on the geometric mean. A large variability in acetaminophen results was observed in the study. We believe the results of Studies 302, 303 and 304 satisfy the requirement for a NDA to establish the safety and pain efficacy of our Aversion hydrocodone/acetaminophen product, however, the interpretation of these results will be subject to FDA's review and acceptance of our conclusions. Before submitting and NDA, we will need to complete an additional nasal abuse liability study which is currently undergoing an internal strategic review.

U.S. Market Opportunity for Opioid Analgesic Products Utilizing Aversion Technology

The misuse and abuse of controlled prescription drugs (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 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 250 million tablet and capsule prescriptions dispensed in 2014 of which approximately 235 million were for IR opioid products and 15 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 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 65 tablets or capsules. According to IMS Health, in 2014, sales in the IR opioid product segment were approximately $3.0 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 Technology. Aversion oxycodone and our Aversion Technology products in development include the active opioid ingredients representing approximately 76% of the U.S. IR Opioid Product segment. A summary of the IR opioid product prescription data for 2014 is provided below:

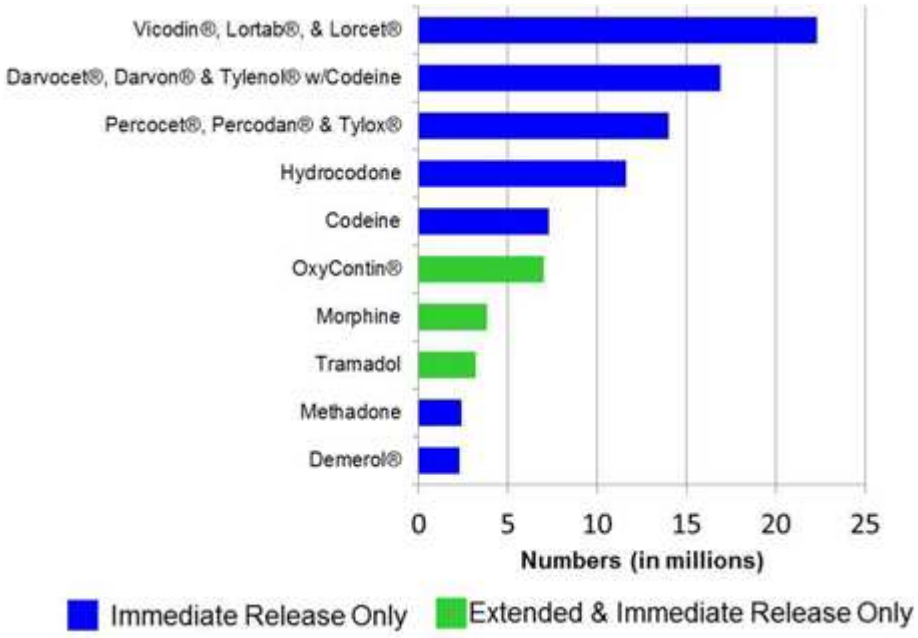
IR Opioid Products [1]	**2014** US Prescriptions (Millions) [2]	% of Total
Hydrocodone	119	50%
Oxycodone	54	23
Tramadol	45	19
Codeine	12	5
3 Others	5	3
Total	235	100%

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

[2] IMS Health, 2014

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®. We estimate 60-95% of the 37 million lifetime U.S. opioid abusers have engaged in the non-medical use of the active ingredients in our IR opioid product candidates. As indicated in the following chart, the top five abused opioid products are available only as IR opioid products.

Lifetime Non-Medical Use of Selected Pain Relievers, Age 12 or Older: 2013



Source: SAMHSA, Office of Applied Studies, 2013 National Survey on Drug Use and Health.

In a 2011 survey of 400 opioid prescribing physicians conducted for us by an independent research firm, 39% of physicians indicated they were highly concerned with the diversion of their opioid prescriptions for non-medical purposes and 42% were highly concerned about opioid misuse by their patients. However, less than 17% of these same physicians indicated they were confident they could adequately identify patients who are diverting or misusing their opioid prescriptions. Further, 77% and 66% of the physicians indicated that abuse of their opioid prescription by injection and snorting, respectively, would likely lead to serious adverse health consequences for the abuser as compared to only 38% for abuse by oral administration.

A majority of pharmaceutical products in the United States are paid for by third-party payers such as insurers, pharmacy benefit managers, self-insured companies and the federal and state governments through Medicare, Medicaid and other health care programs. We believe our product candidates must demonstrate a clinical benefit to the patient and/or an economic benefit to third-party payers and/or a benefit to health care providers to receive favorable reimbursement status by the third-party payers, of which no assurance can be given.

Several independent organizations have estimated the potential cost impact of prescription opioid abuse to insurers. An analysis of health and pharmacy insurance claims between 1998 and 2002 for almost two million Americans conducted by Analysis Group, Inc. and others indicated that enrollees with a diagnosis of opioid abuse had average claims of approximately $14,000 per year higher than an age-gender matched non-opioid abuse sample. A 2007 report by the Coalition Against Insurance Fraud, after adjusting for inflation, estimated this excess cost per patient at more than $16,000 for 2007. By applying the U.S. government's estimated 4.4 million annual opioid abusers, this organization concluded that abuse of IR and ER opioid products could cost health insurers up to $72.5 billion a year.

Product Labeling for Aversion Technology Products

In January 2013, the FDA published draft guidance for industry on the evaluation and labeling of abuse-deterrent opioids. While this guidance is non-binding on the FDA, it outlines FDA's current thinking on the labeling of abuse-deterrent products. FDA encourages sponsors to seek approval of proposed product labeling that sets forth the results of physiochemical, physiologic, pharmacodynamic, pharmacokinetic, and/or formal post-marketing studies that appropriately characterizes the abuse-deterrent properties of a product. To date, FDA has limited data correlating the potentially abuse-deterrent properties of certain opioid drug products with actual reduction in abuse or adverse events associated with abuse. When the data predict or show that a product's potentially abuse-deterrent properties can be expected to, or actually do, result in a significant reduction in that product's abuse potential, these data, together with an accurate characterization of what the data mean, should be included in product labeling.

We or our licensee may seek to include descriptions of studies that characterize the abuse-deterrent properties in the label for our Aversion 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. We have committed to the FDA to undertake epidemiological studies to assess the actual consequences of abuse of Oxaydo in the market. 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.

Egalet Agreement Covering Oxaydo

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 (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 are transferring 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 (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 coordinate 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 will pay us a $2.5 million milestone on the earlier to occur of (A) the launch of Oxaydo and (B) January 1, 2016, but in no event earlier than June 30, 2015. 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 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 the Product). Royalties will be reduced upon the entry of generic equivalents, as well 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. Egalet also may terminate the Agreement prior to the launch of Oxaydo on 30 days prior written notice upon the occurrence of serious safety issues, regulatory restrictions and intellectual property issues, in each case involving 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.

Impede 1.0 Technology

Our Impede 1.0 Technology, a proprietary mixture of inactive ingredients, prevents the extraction of pseudoephedrine, or PSE, from tablets using known extraction methods and disrupts the direct conversion of PSE from tablets into methamphetamine. The chemical structure of 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 vast range of solvents are amenable to the process.

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 several next generation, or Impede 2.0, prototypes of our Impede Technology to improve the meth-resistance of our technology. We have completed one-pot, direct conversion meth testing performed by our CRO with results as follows:

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 100 PSE 30mg tablets divided by the maximum theoretical yield of 2.7 grams.

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

We are assessing two experimental formulations of Nexafed extended-release tablets in a pilot pharmacokinetic study compared to an FDA-approved 120mg PSE extended-release product. We expect this study to inform possible formulation changes before undertaking a formal bioequivalence study. We also are assessing the one-pot results of immediate-release Impede 2.0 formulations, along with manufacturability and other pertinent information to determine our strategy for introducing Impede 2.0 into our Nexafed product line.

Nexafed Products

Our Nexafed product line consists of immediate release tablets which utilize our patented Impede 1.0 Technology. Nexafed is a 30mg pseudoephedrine tablet and Nexafed Sinus Pressure + Pain is a 30/325 mg 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. 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 is bioequivalent to Johnson & Johnson's Sudafed 30mg Tablets when a single 2 tablets 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. We are capitalizing 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 are using telemarketing, direct mail, and online and journal advertising to educate pharmacists about Nexafed and encourage pharmacists to recommend Nexafed to their customers.

We launched Nexafed commercially in mid-December 2012 into the United States OTC market for cold and allergy products. We have built a distribution system of several regional and national drug wholesalers for redistribution to pharmacies which includes the three largest U.S. drug wholesalers: McKesson, Cardinal Health and AmerisourceBergen. We also ship directly to the warehouses of certain pharmacy chains. Nexafed is currently stocked in approximately 12,600 U.S. pharmacies or about 19% 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 are actively recommending 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 approximately 50% 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. We are 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.

We shipped approximately $161 thousand in Nexafed product during the quarter ended December 31, 2014 and $327 thousand during the year ended December 31, 2014. We are marketing our Nexafed product and our Nexafed Sinus Pressure + Pain product under FDA's regulations applicable to OTC Monograph products. Nexafed and Nexafed Sinus Pressure + Pain tablets are offered in 24-count blister packaged cartons.

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
Immediate-release pseudoephedrine HCl in combination with other cold and allergy active ingredients	Nexafed Sinus Pressure + Pain launched Other formulations being considered
Extended-release formulation	Initial test formulations using Impede 2.0 undergoing pharmacokinetic testing

We are undertaking pharmacokinetic testing of two different test formulations of an extended-release PSE product that have exhibit suitable in vitro release profiles against a comparator product. These test formulations contain Impede 2.0 technology. We currently expect to initiate a pre-IND meeting with the FDA to discuss the results from our pharmacokinetic and meth testing studies to determine the development path for our extended-release development product, which, we believe, will require and NDA or ANDA submission to the FDA.

Our objective is to establish our own 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. We will evaluate possible licensing of our Impede Technology with commercial partners. Within the United States, we may consider licenses with appropriate partners that can: (a) help advance our distribution network with the goal of making meth-resistant products the standard of care in all U.S. pharmacies, and/or (b) extend our internal development resources to develop difficult to formulate products, such as extended-release.

U.S. Methamphetamine Problem and the Role Meth Resistant Technologies

Methamphetamine is a highly addictive illicit drug used non-medically by an estimated 12 million people at some point in their lifetime and 1.2 million in 2013. In 2006, the Combat Methamphetamine Epidemic Act, or CMEA, was enacted in response to an alarming increase in and widespread conversion of PSE containing products into methamphetamine. Among other things, CMEA, requires retail stores to maintain their inventory of PSE containing products in a secured location and restricts the amount of PSE products a store can sell to an individual customer. Implementation of CMEA initially reduced the number of illegal methamphetamine laboratory seizures reported by the Drug Enforcement Administration, or DEA, as the then most commonly used process for conversion of PSE to methamphetamine required substantial quantities of PSE. However, a newer process for converting PSE to methamphetamine requires less PSE. Possibly as a result of this new conversion process, the DEA reported 2010 clandestine methamphetamine laboratory seizures increased 84% over the low reported in 2007. Laboratory seizures were down 12% and 5.5% in 2011 and 2012, respectively, although certain states continue to see increases. In response to the ongoing methamphetamine problem, several local jurisdictions (state, counties and/or local municipalities) have enacted or propose to enact legislation to require a physician's prescription to obtain a PSE-containing product or have tightened consumer purchase limits beyond that established by CMEA. Further, federal funding for federal meth lab clean-up has changed which may be impacting law enforcement's policing and accounting of meth labs.

In January 2014, local media in Scott County Tennessee reported that substantially all pharmacies located in such county removed single ingredient PSE products from their shelves in favor of Nexafed. We believe similar changes took place in neighboring Campbell County. Based on local media reports, authorities in these counties subsequently reported a 90% and 88%, respectively, reduction in meth labs seizures.

In late 2013, West Virginia considered legislation requiring all PSE products to have a prescription with an exemption for meth-resistant products like Nexafed. Although this bill failed to pass, by the end of 2013, many West Virginia retailers, including Fruth's and Rite Aid had voluntarily removed single-ingredient PSE products from their shelves, some in favor of using only Nexafed. In the first half of 2014, West Virginia seized 207 meth labs or a reported 25% reduction from 2013 year-to-date (there were 530 seizures in 2013). In July 2014, CVS pharmacies announced the removal of older single-ingredient PSE products from their West Virginia stores. We believe the vast majority of West Virginia pharmacies now stock either no single-ingredient PSE products or exclusively meth-resistant products. The West Virginia Gazette reported in December 2014 that authorities seized only 83 meth labs between July and November 2014, compared to 207 meth labs in the first half of 2014 and 530 for all of 2013.

The DEA may grant exemptions from the purchase requirements of PSE under the CMEA. We believe a more robust formulation along with in-market data demonstrating a reduction in meth lab incidents may qualify for this exemption, although there can be no assurance this will be the case.

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 2009, AC Nielsen reported approximately $1.0 billion in retail sales of non-prescription products containing either PSE or phenylephrine as a nasal decongestant, of which approximately 47% contained PSE. The top selling brands of OTC cold/allergy products in 2009 were:

Brand [1]	Company	Active Ingredient(s)	2009 Retail Sales ($ Millions)
Claritin-D	Merck	PSE & Loraditine [2]	$ 113.0
Mucinex-D	Rickett Benckiser	PSE & Guaifenesin [2]	$ 72.2
Zyrtec-D	Pfizer	PSE & Ceterizine [2]	$ 52.2
Advil Sinus	Pfizer	PSE & Ibuprofen	$ 30.9
Sudafed 12 Hour	J&J	PSE [2]	$ 24.9
Sudafed 30mg	J&J	PSE	$ 20.8

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

[2] Extended release PSE formulations

The 2009 market for 30mg PSE tablets, including store brands was approximately 372 million tablets or 15.5 million boxes of 24 tablets. Nexafed is currently priced at $3.99 for a box of 24 tablets and Nexafed Sinus Pressure + Pain is currently priced at $7.50 for a box of 24 tablets.

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.

Our 2010 market research study showed that 93% of the 204 pharmacists surveyed believe that PSE has superior efficacy as a nasal decongestant compared to phenylephrine. In our 2012 survey of 215 chain and independent pharmacists, 164 indicated they had influence over the pharmacies' product offerings. Of such pharmacists, 70% indicated they were likely to stock or recommend stocking Nexafed in their pharmacies. The 215 surveyed pharmacists also indicated a willingness to recommend Nexafed to over 50% of their customers who seek a pharmacist's advice for a single ingredient nasal decongestant.

Product Labeling for Impede Technology Products

We are marketing our Nexafed and Nexafed Sinus Pressure + Pain products pursuant to the FDA's OTC Monograph regulations, which require that our product have labeling as specified in the regulations. We are advertising the extraction characteristics and methamphetamine-resistant benefits of our Nexafed 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.

Limitx™ Technology

Limitx™ technology is a novel, early stage technology intended to address abuse by excess oral consumption of multiple tablets and provide a margin of safety during accidental over-ingestion of tablets. In proof of concept laboratory tests, Limitx™ tablets demonstrated the ability to limit the release of the active ingredient from tablets when multiple tablets are simultaneously introduced into simulated gastric fluid. Using .055N HCl dissolution bath, a single Limitx tablet released most of its active ingredient within 15 minutes while eight Limitx tablets in the same bath released the equivalent of one tablet's active ingredient in 15 minutes. Eight immediate-release tablets of a marketed product comparator released the most of its active ingredient in 15 minutes compared with over 2 hours for the eight Limitx tablets.

While the initial Limitx™ formulation utilizes hydromorphone as its sole active ingredient, if such development proves successful, of which no assurance can be given, it is expected that the technology could incorporate other opioids as well. The need for abuse deterrent formulations which address excess oral consumption was stressed in the January 2013 FDA draft guidance for abuse deterrent opioids. We have patent applications pending with the USPTO covering our Limitx™ technology.

Limitx™ is being developed pursuant to a $300,000 grant (the "Grant") by the National Institute On Drug Abuse ("NIDA") of the National Institutes of Health. Phase I of development is to create an optimized formulation that can be commercially manufactured and is suitable for human testing. In Phase I, we will be developing a formulation and manufacturing process that mimics, at research scale batches, commercial manufacturing scale equipment and test and evaluate the tablets in our proof of concept dissolution apparatus. We have successfully manufactured small scale batches of the key micro-particle at our Culver facility but believe the manufacturing process used will not be scalable for commercial batches. We have tested and are in the process of installing new equipment for use in this process.

In Phase II, we will perform human pharmacokinetic testing to characterize the release of drug in vivo. NIDA funding of Phase II development, for which an application has already been submitted, will be contingent upon (1) assessment by NIDA of the Phase I progress report and its determination that the Phase I milestones were achieved, (2) review and approval of other documents necessary for continuation, and (3) availability of funds. No assurance can be given that Phase II development funding will be provided by NIDA.

Phase I research on the Company's hydromorphone tablet utilizing Limitx™ technology 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.

Patents and Patent Applications

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

Patent No. (Jurisdiction)	Subject Matter	Issued	Expires
7,201,902 (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

We have the following issued patents related 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
2004294953 (AUS)	Abuse deterrent pharmaceuticals	Apr. 2010	Nov. 2024
2010200979 (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
175863 (ISR)	Abuse deterrent pharmaceuticals	Nov. 2004	Nov. 2024
221018 (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

In January 2012, the USPTO issued to us U.S. Patent No. 8,101,630, or the 630 Patent with a single claim that encompasses an extended release abuse deterrent dosage form of oxycodone or a pharmaceutically acceptable salt thereof. The 630 Patent expires in August 2024. In July 2014, we ceded priority of the '630 patent to a patent application filed by Purdue Pharma and expect this patent to be rescinded.

In addition to our issued U.S. 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, 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 an ANDA 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 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 3 – Legal Proceedings – Paragraph IV ANDA Litigation" for a discussion of the settlements relating to such patent litigation.

Reference is made to the Risk Factors contained in Item 1A of 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.

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 a contract manufacturer to manufacture, package and supply our commercial quantities of Nexafed and Nexafed Sinus Pressure + Pain products. Initially, we will source our commercial requirements of our Nexafed products from a single manufacturer and will not have a second source. Although we believe there are alternate sources of supply that can satisfy our commercial requirements, replacing or adding a contract manufacture will result in additional costs and may delay or interrupt the supply of these 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 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 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, and Collegium Pharmaceuticals, Inc. 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. In August 2014, Purdue Pharma announced the submission of an NDA for an immediate-release oxycodone HCl product with reported abuse deterrent properties.

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 Westport Pharmaceuticals 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.

We may consider licensing our Impede Technology or products utilizing such technology for commercialization.

Government Regulation

All pharmaceutical firms, including us, are subject to extensive regulation by the federal government, principally by the FDA under the Federal Food, Drug and Cosmetic Act, or the FD&C Act, and, to a lesser extent, by state and local governments. Before our prescription products and some OTC products may be marketed in the U.S., they must be approved by the FDA for commercial distribution. Other 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 current Good Manufacturing Practices, or with 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, must be obtained 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, 2014, for the 2015 fiscal year, the user fee for an application fee requiring clinical data, such as an NDA is $2,335,200. 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.

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 recall.

In March 2014, the FDA held a workshop to discuss potential changes to the OTC Monograph regulations, including the requirement for sponsor companies to determine that their innovative formulations of inactive ingredients do not interfere with the effectiveness of the product.

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 are largely dependent on the commercial success of OXAYDO

We anticipate that, for at least fiscal 2015 and 2016, our ability to generate revenues and become profitable will depend in large part on the commercial success of our only FDA approved product, OXAYDO, which in turn will depend on several 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 we are not successful in commercializing our NEXAFED Products and other IMPEDE Technology 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 us 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 we will succeed in commercializing our NEXAFED products, or that the pricing of our NEXAFED products will allow us to generate significant revenues or profit. 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 our ability to market our NEXAFED products as OTC products and generate revenue from NEXAFED products sales. Our failure to successfully commercialize our NEXAFED® products and to develop and commercialize other IMPEDE Technology 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 will be 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 AVERSION opioid products, including hydrocodone/acetaminophen, , or to successfully establish a license agreement with a pharmaceutical company for the development and commercialization of such products, will adversely impact our ability to develop, market and sell such products and our revenues and business will suffer.

We have developed to various stages additional AVERSION opioid products. Our plan for developing, manufacturing and commercializing the AVERSION opioid products includes entering into an agreement similar to the Egalet Agreement with a strategically focused pharmaceutical company. However, there can be no assurance that we will be successful in entering into such an agreement. Pending any such agreement, we expect to continue the development of our AVERSION hydrocodone bitartrate with acetaminophen product on our own. The continued development of our hydrocodone bitartrate with acetaminophen product and the other opioid products 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 the returned products, we may have to limit the size or scope of, or delay or abandon, the development of some or all of the returned products, which would adversely impact our financial condition and results of operations.

We have a history of operating losses and may not achieve profitability sufficient to generate a positive return on shareholders' investment.

We had a net loss of $13.2, $13.9 million and $9.7 million for the years ended December 31, 2014, 2013 and 2012, respectively. Our future profitability will depend on several factors, including:

- our receipt of royalties relating to Egalet's sale of OXAYDO;
- our 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 AVERSION 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 AVERSION Technology and our ability to commercialize our IMPEDE Technology without infringing the patents and other intellectual property rights of third parties.

We cannot assure you that OXAYDO or our NEXAFED products will be successfully commercialized or our AVERSION 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, or if we or a licensee succeed in developing and commercializing one or more of our pipeline AVERSION Technology products, or if we are successful in commercializing our NEXAFED products or other 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, commercializing our NEXAFED products, and hiring of additional research and development staff.

We will need to generate revenues from direct product sales or indirectly from royalties on sales to achieve and maintain profitability. If we cannot successfully commercialize our NEXAFED products, if Egalet does not successfully commercialize OXAYDO, or if we or our licensee (if any) cannot successfully develop, obtain regulatory approval and commercialize our products in development, 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 must rely on current cash reserves, milestones payable by Egalet under the Egalet Agreement, royalties from Egalet on Egalet's sale of OXAYDO, and revenues from our NEXAFED product sales to fund operations.

Pending the receipt of the milestone payments and royalties under the Egalet Agreement relating to OXAYDO, and milestone payments and royalties under license agreements similar to the Egalet Agreement that we may enter into with other pharmaceutical companies relating to our products in development, in each case of which no assurance can be given, we must rely on our current cash reserves and revenues from our sales of our NEXAFED products to fund operations and product development activities. No assurance can be given that current cash reserves and revenues from our NEXAFED product sales will be sufficient to fund continued operations and the development of our product candidates until such time as we generate revenues from Egalet's commercialization of OXAYDO or from any of our products in development. Moreover, no assurance can be given that we will be successful in raising additional financing or, if funding is obtained, that such funding will be sufficient to fund operations until we generate sufficient revenues from OXAYDO, or until product candidates utilizing our AVERSION 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 other AVERSION 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 AVERSION 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 substantiality limit our and our licensees' advertising and promotion of such abuse deterrent features in order to differentiate AVERSION Technology 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. The FDA's January 2013 draft guidance, while not binding on the FDA, outlines the FDA's current views on the labeling of abuse deterrent products. The FDA encourages sponsors to seek approval of proposed product labeling that sets forth the results of physiochemical, physiologic, pharmacodynamic, pharmacokinetic, and/or formal post-marketing studies that appropriately characterizes the abuse-deterrent properties of a product. To date, the FDA has limited data correlating the potentially abuse-deterrent properties of certain opioid drug products with actual reduction in abuse or adverse events associated with abuse. When the data predict or show a product's potential abuse-deterrent properties can be expected to, or actually do, result in a significant reduction in that product's abuse potential, those data, together with an accurate characterization of what the data mean, should be included in product labeling. We intend to utilize certain clinical and laboratory studies for our opioid products in development to support a label describing the abuse-deterrent features of such products. However, the extent to which such information is included in the FDA approved product label is the subject of our and our licensees' discussions with, and agreement by, the FDA as part of the 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 AVERSION 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.

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 may object to our or our licensee's marketing claims and product advertising campaigns. 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 AVERSION 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 other product candidate utilizing our AVERSION, 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 AVERSION, IMPEDE or LIMITX 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 effect on our financial condition.

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

Drugs that have been deemed safe and effective by the FDA for use by the general public without a prescription are classified as OTC drug products. Certain OTC drug products may be commercialized without premarket review by the FDA if the standards set forth in the applicable regulatory monograph are met. An OTC monograph provides the marketing conditions for the applicable OTC drug product, including active ingredients, labeling, and other general requirements, such as compliance with cGMP and establishment registration. Any product which fails to conform to each of the general conditions and 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 are classified for OTC sale under an FDA OTC monograph, which will allow us to commercialize them without submitting an NDA or ANDA to the FDA. We have also determined that, provided we adhere 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 our 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 we fail to meet the general conditions, once commercialized, the products may be removed from the market and we 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 hearing in late March 2014 for public comment. Changes to the existing OTC regulations could result in a requirement that Acura file an NDA or ANDA for our NEXAFED products or other IMPEDE Technology products in order to commercialize such products. If the FDA requires that we submit 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 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 are unable to advertise and promote the extraction characteristics of NEXAFED or other IMPEDE Technology products, we may be unable to compete with national brands and pharmacy chain store brands.

Our AVERSION, IMPEDE, and LIMITX 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 AVERSION and IMPEDE Technologies, as well as LIMITX. 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 AVERSION, IMPEDE, and LIMITX Technology products in development, there can be no assurance that OXAYDO, our NEXAFED products or any other product utilizing our AVERSION, IMPEDE, or LIMITX 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 AVERSION, IMPEDE, and LIMITX 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 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 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 AVERSION 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 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, 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.

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 NDA's. 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 other AVERSION 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 AVERSION 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 AVERSION, 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. We believe that opportunities exist to enter into license agreements similar to the Egalet Agreement with other pharmaceutical company partners for the development and commercialization of our AVERSION product candidates in development in the United States and worldwide, and for the development and commercialization of additional AVERSION Technology and IMPEDE Technology product candidates for other abused and misused drugs, such as tranquilizers, stimulants, sedatives and nasal decongestants 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 our Egalet Agreement or any license agreement we may enter into relating to any of our AVERSION or IMPEDE Technology products in development, 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 AVERSION 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 Eaglet, 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 conditions prior to the launch OXAYDO, or following launch, 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 or IMPEDE 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 or IMPEDE 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 NEXAFED 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 our NEXAFED products and pharmacists may not recommend such 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 Technology. 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 products 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 AVERSION Technology, 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 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.

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 the Egalet Agreement, Egalet controls the price of OXAYDO, 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.

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 Technology and IMPEDE Technology, 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 or IMPEDE 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;
- 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 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 licensee(s), 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 AVERSION products in development. While we do not expect the claims contained in such pending patent applications will issue in their present form, there can be no assurance that such patent applications will not issue as patents with claims encompassing one or more of our product candidates. 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 in a controlled release pharmaceutical preparation. 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.

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 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'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 three 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 in "Item 3. Legal Proceedings – Reglan/Metoclopramide Litigation" 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 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 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, and Collegium Pharmaceuticals, Inc. These companies appear to be focusing their development efforts on ER Opioid Products, except for Atlantic Pharmaceuticals, while the majority of our AVERSION Technology opioid analgesic product candidates under development are IR Opioid Products.

Our IMPEDE Technology products containing PSE, including our 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. In addition, Highland Pharmaceuticals is commercializing a PSE product that is stated to resist PSE extraction in aqueous solutions.

We are concentrating a substantial majority of our efforts and resources on developing product candidates utilizing our AVERSION 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 AVERSION 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 AVERSION and IMPEDE Technologies may be substantially decreased, thus reducing our ability to generate future revenues and adversely affecting our ability to generate a profit.

If we fail to comply with the covenants and other obligations under our term loan, the lender may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.

In December 2013, we (including our wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc. ("APT")) entered into a loan and security agreement with Oxford Finance LLC ("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. Under the Oxford loan agreement, as amended, we are subject to a variety of affirmative and negative covenants, including required financial reporting, limitations on certain dispositions and licensing of assets, limitations on the incurrence of additional debt, the requirement to maintain at least $2.5 million in cash reserves until the principal amount of the Oxford loan is reduced below $5.0 million, and other requirements. To secure our performance of our obligations under this loan and security agreement, we granted Oxford a security interest in substantially all of our assets, other than intellectual property assets, and pledged to Oxford the stock of APT. Our failure to comply with the terms of the loan and security agreement, 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.

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 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 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 the year ended December 31, 2014, our stock traded as high as $2.12 per share and as low as $0.41 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 clinical development programs, including the data from our ongoing Phase 3 clinical trial evaluating our AVERSION® hydrocodone/acetaminophen product;
- FDA actions related to our products in development;
- FDA actions related to any of our potential products;

- announcements regarding the launch and sales of OXAYDO;
- announcements regarding the progress of sales of OXAYDO;
- announcements regarding the progress of our preclinical programs;
- our success in the commercialization of our NEXAFED products;
- announcements regarding the sales of our NEXAFED products;
- 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 mark new and enhanced products on a timely basis;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies;
- additions or departures of key personnel;
- commencement of, or our involvement in, litigation;
- the inability of our contract manufacturers to provide us with adequate commercial supplies of our products;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board or management;
- general economic conditions and slow or negative growth of our market; and
- political instability, natural disasters, war and/or events of terrorism.

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

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

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

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

Any future sale of a substantial number of shares 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.

In accordance with the terms of the Securities Purchase Agreement dated August 20, 2007 between us and the investors named therein, we filed a registration statement with and declared effective by the SEC, to register the shares included in our Units issued pursuant to the Securities Purchase Agreement, including shares underlying warrants included in the Units. In addition, pursuant to the exercise of previously granted piggyback registration rights, each of Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP and Essex Woodlands Health Ventures V, L.P. have exercised their piggyback registration rights to include an aggregate of 26,584,016 shares in such registration statement. As a result, approximately 26,278,000 shares (representing approximately 48% of our shares outstanding on a fully-diluted basis, including all derivative securities, whether or not currently exercisable) are available for resale by selling stockholders under the registration statement. If some or all of the shares included in such registration statement are sold by our affiliates and others 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.

In April 2013, we entered into an at-the-market equity facility, or ATM, with MLV & Co. LLC, or MLV, as sales agent under which we may sell up to approximately $13.0 million of our common stock under our prospectus supplement by any method deemed to be an "at-the-market" offering under SEC rules. As of December 31, 2014 we sold cumulatively approximately $3.3 million of common stock and issued 1,339,275 shares under the ATM. If we continue to sell shares under the ATM, such sales will dilute our existing shareholders and could cause the market price of our common stock to decline significantly. The availability of the ATM to us, as well as any sales of our common stock under the ATM, should we elect to continue to use it, could encourage short sales by third parties, which could contribute to the further decline of our stock price.

If we do not meet the continued listing standards of the NASDAQ Capital Market, our common stock could be delisted from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.

Our common stock is listed on the NASDAQ Capital Market, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If we fail to satisfy its continued listing standards, such as, for example, NASDAQ Listing Rule 5450(a)(1), which requires that the closing bid price of our common stock shall not fall below $1.00 for thirty consecutive business days. Failure to comply with NASDAQ's continued listing standards will result in the issuance of a non-compliance letter and/or initiation of delisting proceedings by NASDAQ.

On September 18, 2014, we received a letter from the Listing Qualifications Staff of the NASDAQ Stock Market notifying us that because the closing bid price of our common stock has been below $1.00 for 30 consecutive business days, it no longer complies with the requirements for continued listing on the NASDAQ Capital Market. The NASDAQ notice does not impact our current listing on the NASDAQ Capital Market at this time and our common stock will continue to trade under the symbol "ACUR". In accordance with NASDAQ rules, we have been provided a period of 180 calendar days, or until March 17, 2015, in which to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days during this 180 day period. If we do not satisfy this requirement by March 17, 2015, NASDAQ will determine whether the Company meets the applicable market value of publicly held shares requirement for continued listing and all other applicable standards for initial listing on the NASDAQ Capital Market (except the bid price requirement). If we meet such criteria, of which no assurance can be given, we may be eligible for an additional 180 day compliance period. As part of NASDAQ's determination of whether to grant us an additional 180 day compliance period, we will likely be required to commit to undertake a reverse stock split (including seeking shareholder approval for the reverse split) during such compliance period in order to meet NASDAQ's minimum bid price requirement. If we do not regain compliance, our common stock will be subject to delisting.

We intend to monitor the bid price of our common stock between now and March 17, 2015, and will consider available options to regain compliance with the listing requirements, including seeking an additional 180 day compliance period, if needed. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with other listing requirements.

If our securities are delisted from trading on the NASDAQ Capital Market and we are not able to list our securities on another exchange, such as the NYSE, our securities could then be quoted on the OTC Bulletin Board or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

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 2014 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, 2016. 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.

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

Paragraph IV ANDA Litigation

On or about September 17, 2012, we believe the FDA internally changed the status of OXAYDO (then known as OXECTA) to be considered a Reference Listed Drug, or RLD. An RLD is the standard to which all generic versions must be shown to be bioequivalent and a drug company seeking approval to market a generic equivalent must refer to the RLD. By designating Oxaydo as an RLD, the FDA was allowed to accept ANDAs referencing OXAYDO.

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 as the reference listed drug. Since such date, we have received similar Paragraph IV Notices from three 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.

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.

By designating OXAYDO as an RLD, we believe the FDA has acknowledged that OXAYDO contains unique properties and/or a unique label that is different from other FDA approved immediate-release oxycodone HCl tablets that do not contain abuse resistant characteristics. As required by the Food and Drug Administration Safety and Innovation Act of July 2012, the FDA published for comment draft guidance on the development of abuse-deterrent drug products in January 2013. We believe the ANDA applicants that refer to OXAYDO as an RLD will have to have substantially equivalent, if not identical, abuse deterrent characteristics to be considered by the FDA as therapeutically equivalent to OXAYDO. There can be no assurance, however, that FDA will rely on such guidance for ANDA applicants.

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, Acura was 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 us, plaintiffs claim injuries from their use of the Reglan brand of metoclopramide and generic metoclopramide.

In the Pennsylvania action, over 200 lawsuits have been filed against us 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 18 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. We have consistently maintained the position that these claims are without merit and intend to vigorously defend these actions.

In New Jersey, Generic Defendants, including Acura, filed dispositive motions based on the *Mensing* decision, which the Court granted with a limited exception. As of September 2012, the New Jersey trial court dismissed Acura with prejudice. In Pennsylvania, and California, Generic Defendants, including Acura, also filed dispositive motions based on the *Mensing* decision.

In Pennsylvania, on November 18, 2011, the trial court denied Generic Defendants' dispositive preemption motions. On appeal, the Pennsylvania Superior Court held in a July 29, 2013 decision that federal preemption applied, but that *Mensing* did not completely bar all claims and refused to dismiss these cases. On September 17, 2014, the Pennsylvania Supreme Court declined to hear a further appeal. On December 16, 2014, Generic Defendants filed a Petition for a Writ of Certiorari requesting that the United States Supreme Court agree to hear a further appeal on the grounds that federal preemption under *Mensing* should completely bar all of these claims. All trial court proceedings have been stayed pending resolution of this lengthy appeal process. To the extent that plaintiffs intend to pursue their claims in the future, if the appeal is denied, Acura nonetheless remains optimistic that most, if not all, of these Philadelphia cases will eventually be dismissed against us based upon the favorable aspects of the Superior Court's narrow preemption ruling and lack of product identification, although there can be no assurance in this regard. 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. Therefore, subject to further developments, plaintiffs may be permitted to proceed with these lawsuits including state law claims based on (1) failing to communicate warnings to physicians through "Dear Doctor" letters; and (2) failure to update labeling to adopt brand labeling changes. The California trial court also has acknowledged the preemptive effect of *Mensing* so that any claim "that would render the generic defendants in violation of federal law if they are found responsible under a state law cause of action, would not be permissible." To date, however, none of these plaintiffs have confirmed they ingested any of the generic metoclopramide manufactured by us. Therefore, we expect the number of plaintiffs with possible claims to be reduced voluntarily or by motion practice. Action will be taken in an effort to dismiss Acura from these cases, although there can be no assurance in this regard. 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, 2014 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

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
2013 Fiscal Year		
First Quarter	$ 3.62	$ 1.81
Second Quarter	3.78	1.85
Third Quarter	2.59	1.36
Fourth Quarter	2.23	1.50
2014 Fiscal Year		
First Quarter	2.12	1.44
Second Quarter	1.55	0.98
Third Quarter	1.13	0.68
Fourth Quarter	0.78	0.41
2015 Fiscal Year		
First Quarter (through January 31, 2015)	$ 0.70	$ 0.45

On September 18, 2014, we received a letter from the Listing Qualifications Staff of the NASDAQ Stock Market notifying us that because the closing bid price of our common stock has been below $1.00 for 30 consecutive business days, it no longer complies with the requirements for continued listing on the NASDAQ Capital Market. The NASDAQ notice does not impact our current listing on the NASDAQ Capital Market at this time and our common stock will continue to trade under the symbol “ACUR”. In accordance with NASDAQ rules, we have been provided a period of 180 calendar days, or until March 17, 2015, in which to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days during this 180 day period. If we do not satisfy this requirement by March 17, 2015, NASDAQ will determine whether the Company meets the applicable market value of publicly held shares requirement for continued listing and all other applicable standards for initial listing on the NASDAQ Capital Market (except the bid price requirement). If we meet such criteria, of which no assurance can be given, we may be eligible for an additional 180 day compliance period. As part of NASDAQ’s determination of whether to grant us an additional 180 day compliance period, we will likely be required to commit to undertake a reverse stock split (including seeking shareholder approval for the reverse split) during such compliance period in order to meet NASDAQ’s minimum bid price requirement. If we do not regain compliance, our common stock will be subject to delisting.

We intend to monitor the bid price of our common stock between now and March 17, 2015, and will consider available options to regain compliance with the listing requirements, including seeking an additional 180 day compliance period, if needed. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with other listing requirements.

Holders

There were approximately 750 holders of record of our common stock on February 27, 2015. 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.

Securities Authorized for Issuance under Equity Compensation Plans

Reference is made to the Company's Proxy Statement for its 2014 Annual Meeting of Shareholders under the caption "Compensation of Executive Officers and Directors - Restricted Stock Unit Award Plan; and Securities Authorized for Issuance under Equity Compensation Plans".

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data presented below for the years ended December 31, 2014, 2013, 2012, 2011 and 2010 are derived from our audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2014 and 2013 and for each of the years in the three-year period ended December 31, 2014, and the reports thereon, are included elsewhere in this Report. The selected financial information presented for our 2011 and 2010 operations and for our 2012, 2011 and 2010 balance sheets are derived from our audited Consolidated Financial Statements not presented in this Report.

The information set forth below 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	2014	2013	2012	2011	2010
Revenues, net	$ 751	$ 123	$ —	$ 20,466	$ 3,311
Operating expenses:					
Cost of sales	428	364	—	—	—
Research and development [1]	4,582	4,923	3,726	4,037	7,177
Selling, marketing, general and administrative [2]	7,940	8,926	6,013	5,895	8,858
Interest expense	(1,212)	(9)	—	—	—
Investment income	198	194	79	32	42
Other (expense) income	4	4	(8)	(34)	(14)
(Loss) income before income tax	(13,209)	(13,901)	(9,668)	10,532	(12,696)
Provision for income taxes	-	—	—	147	11
Net (loss) income applicable to common stockholders	$ (13,209)	$ (13,901)	(9,668)	$ 10,385	$ (12,707)
(Loss) earnings per share: Basic	$ (0.27)	$ (0.29)	$ (0.20)	$ 0.22	$ (0.27)
(Loss) earnings per share: Diluted	$ (0.27)	$ (0.29)	$ (0.20)	$ 0.22	$ (0.27)
Weighted average shares used in computing net earnings (loss) per share: Basic	48,893	47,764	47,521	47,496	47,029
Weighted average shares used in computing net earnings (loss) per share: Diluted	48,893	47,764	47,521	48,007	47,029

(1) Includes stock-based compensation expense of approximately $220, $300, $375, $500 and $1,700 for years 2014, 2013, 2012, 2011, and 2010, respectively.
(2) Includes stock-based compensation expense of approximately $700, $900, $1,360, $1,900, and $5,100 for years 2014, 2013, 2012, 2011 and 2010, respectively.

BALANCE SHEET DATA (in thousands)	2014	2013	2012	2011	2010
Working capital	$ 10,239	$ 26,346	$ 26,572	$ 35,599	$ 23,289
Total assets	16,195	28,630	29,054	37,173	25,493
Total liabilities	11,143	10,707	1,424	530	1,152
Accumulated deficit	(362,321)	(349,112)	(335,211)	(325,543)	(335,928)
Stockholders' equity	$ 5,052	$ 17,923	$ 27,630	$ 36,643	$ 24,341

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® Technology is a mixture of inactive ingredients incorporated into pharmaceutical tablets and capsules intended to address some common methods of product tampering associated with opioid abuse. Oxaydo Tablets (formerly known as Oxecta)(oxycodone HCl CII), is the first FDA approved product utilizing Aversion in the United States and is exclusively licensed to Egalet for commercialization. We have 7 additional opioid products utilizing Aversion in various stages of development. 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 have also developed Impede® Technology which is a combination of inactive ingredients that prevent the extraction of pseudoephedrine from tablets and disrupt the direct conversion of pseudoephedrine from tablets into methamphetamine. 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 February 2015. We have multiple pseudoephedrine products in development utilizing Impede. In August 2014, we received a grant from the National Institute on Drug Abuse to advance early stage development of our third abuse deterrent technology, Limitx™. Limitx is designed to retard the release of active drug ingredients when too many tablets are accidently or purposefully ingested.

Hydrocodone bitartrate with acetaminophen, or hydrocodone/acetaminophen, is the most widely prescribed and often abused opioid product in the United States. Our Aversion hydrocodone/acetaminophen product is the most advanced opioid product in development and the primary focus of our opioid development efforts. On December 5, 2013, we met with the FDA to discuss the results of Study AP-ADF-301, or Study 301, a key abuse liability study for our Aversion hydrocodone/acetaminophen product and whether the results from Study 301 are acceptable for submission in a New Drug Application, or NDA. On May 27, 2014, we announced that the FDA advised us that the data from our Study 301 was insufficient to support an intranasal abuse deterrence description in our product labeling. The FDA indicated that a product will have to have an impact on “drug liking” to support a description of abuse-deterrence through a relevant route of abuse. The FDA’s advice also questioned whether the intranasal route is a relevant route of abuse for hydrocodone/ acetaminophen products.

On September 11, 2014, we submitted a formal dispute resolution request with the FDA. The dispute pertains to the FDA's determination that nasal snorting abuse of hydrocodone with acetaminophen products lacks relevance. On October 16, 2014, we announced that the FDA denied on procedural grounds our appeal of the position taken by the Division of Anesthesia, Analgesia and Addiction Products ("DAAAP") that abuse by snorting hydrocodone with acetaminophen products lacks relevance. We are currently assessing our development strategy for our Aversion hydrocodone with acetaminophen product, including the merits of appealing the FDA's decision. Even if we were to file an appeal and succeed in such proceeding, in order to continue the development of our hydrocodone/acetaminophen product we will be required to conduct an additional abuse liability study that will need to demonstrate a statistically significant reduction in Drug Liking, of which no assurance can be provided. We are currently in the process of designing this next study and will make a decision on commencing this study in 2015.

We expect that the development program for all our Aversion opioid products in development will be consistent with that of Aversion Oxycodone and our hydrocodone/acetaminophen product candidate.

In 2009, the United States market for over-the-counter market, or OTC, cold and allergy products containing an oral nasal decongestant was approximately $1 billion. In 2012, the DEA reported 11,210 laboratory incidents involving the illegal use of OTC pseudoephedrine products to manufacture the highly addictive drug methamphetamine, or meth. Nexafed, our 30mg pseudoephedrine hydrochloride immediate-release tablet is stocked in approximately 19% of the estimated 65,000 U.S. pharmacies. Nexafed Sinus Pressure + Pain, our 30/325 mg pseudoephedrine and acetaminophen immediate–release tablet was launched in February 2015. Both Nexafed products utilizing our Impede 1.0 Technology. Many of these pharmacies are either actively recommending Nexafed to their patients or carry Nexafed as their only 30mg pseudoephedrine product. The category for meth-resistant pseudoephedrine products has also been the focus of some, as yet unsuccessful, state legislation seeking to incentivize consumers and pharmacists to utilize these meth-resistant technologies.

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

We also have discovered an early-stage technology, Limitx™, which, in proof of concept laboratory tests, demonstrates the ability to limit the release of the active ingredient from tablets when multiple tablets are consumed simultaneously.

Company's Present Financial Condition

At December 31, 2014, we had cash, cash equivalents and marketable securities of $12.1 million compared to $26.1 million of cash, cash equivalents and marketable securities at December 31, 2013. We had working capital of $10.2 million at December 31, 2014, compared to working capital of $26.3 million at December 31, 2013. We had an accumulated deficit of approximately $362.3 million and $349.0 million at December 31, 2014 and December 31, 2013, respectively. We had a loss from operations of $12.2 million and a net loss of $13.2 million for the year ended December 31, 2014, compared to a loss from operation of $14.1 million and a net loss of $13.9 million for the year ended December 31, 2013. As of January 31, 2015, we had cash, cash equivalents and marketable securities of approximately $15.9 million.

During the year ended December 31, 2014, we recognized $247 thousand of product sales on gross shipments of Nexafed which totaled $327 thousand. Certain of our customers have accepted a pricing allowance in exchange for forfeiting the right to return Nexafed and therefore we are recognizing revenue upon product shipment to them. Additionally, we are recognizing revenue from certain of our other customers based on a pharmacy's Nexafed reorder activity with their own drug wholesaler supplier. For all other customers, given the limited sales history of Nexafed, the Company currently cannot reliably estimate expected returns of the product from these customers at the time of shipment. Accordingly, the Company is deferring recognition of revenue on these product shipments of Nexafed until the right of return no longer exists or adequate history and information is available to estimate product returns.

To fund our continued operations, we expect to rely on our current cash resources, net proceeds, if any, from our "at-the-market" offering of our common stock pursuant to our Sales Agreement with MLV & Co., milestone and royalty payments, if any, that may be made under Egalet Agreement, milestones and royalty payments that may be made under future license agreements with other pharmaceutical company partners, of which there can be no assurance of obtaining, and revenues from our commercialization of our Nexafed products. Our cash requirements for operating activities may increase in the future as we continue to conduct pre-clinical studies and clinical trials for our product candidates, maintain, defend, and expand the scope of our intellectual property, hire additional personnel, commercialize our Nexafed products, or invest in other areas.

Our losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs 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. Salaries and other personnel-related costs include the non-cash 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, 2014 and 2013.

	December 31			
	2014	2013	Change	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$ 4	$ 10	$ (6)	60
Product sales, net	247	113	134	118
License fee	500	—	500	100
Total revenues, net	751	123	628	510
Operating expenses:				
Cost of sales	428	364	64	17
Research and development	4,582	4,923	(341)	(7)
Selling, marketing, general and administrative	7,940	8,926	(986)	(11)
Total operating expenses	12,950	14,213	(1,263)	(9)
Operating loss	(12,199)	(14,090)	(1,895)	(13)
Non-Operating income (expense):				
Investment income	198	194	4	2
Other expense, net	(1,208)	(5)	(1,203)	24,060
Total other income (expense), net	(1,010)	189	(1,199)	(634)
Loss before income taxes	(13,209)	(13,901)	692	5
Provision for income taxes	—	—	—	—
Net loss	$ (13,209)	$ (13,901)	$ 692	5

Revenue

Product Sales

Nexafed® was launched in mid-December 2012. The Company sells Nexafed® in the United States to wholesale pharmaceutical distributors and as well as directly to chain drug stores. Nexafed® is sold subject to the right of return for a period of up to twelve months after the product expiration. Nexafed® currently has a shelf life of twenty-four months from the date of manufacture. Given the limited sales history of Nexafed®, the Company currently cannot reliably estimate expected returns of the product at the time of shipment to certain customers. Accordingly, the Company has deferred the recognition of revenue on Nexafed® shipments to these customers until the right of return no longer exists or adequate history and information becomes available to estimate product returns. We have recognized revenue of $247 thousand in 2014 for shipments to customers where the right of return no longer existed either because a pricing allowance was accepted in exchange for forfeiting the right of return or because information became available on pharmacy's reorder activity with their drug wholesaler. We will continue to analyze information to assess the recognition of our 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.

Royalty Revenue

In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer Inc., (which agreement has since been terminated effective April 2014) we began to earn royalties on Oxecta net sales starting in February 2013. We recorded royalties of approximately $4 thousand for 2014 (January 1 to April 2014) on Pfizer's net sales of Oxecta of approximately $80 thousand.

License Fee

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 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 Acura conceded Purdue's claim of priority in exchange for certain financial consideration including an immediate non-refundable payment of $500,000.

Cost of Sales

Cost of sales includes third-party acquisition costs, third-party warehousing and product distribution charges and inventory reserve charges for the Nexafed product line.

Operating Expenses

Research and development expense (R&D) during 2014 and 2013 was primarily for our Aversion or our Impede Technologies development including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in each of the 2014 and 2013 results are non-cash share-based compensation expenses of $0.2 million and $0.3 million, respectively. Excluding the share-based compensation expense, our R&D expenses decreased approximately $0.2 million between reporting periods primarily from a reduction in Aversion development expenses on our hydrocodone/acetaminophen product candidate as we awaited response from the FDA to clinical results before continuing with additional development.

Selling and marketing expenses during 2014 and 2013 primarily consisted of advertising and marketing activities on Nexafed which was launched in December 2012. Our Nexafed advertising and marketing activities will continue in 2015. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in the 2014 and 2013 results are non-cash share-based compensation expenses of $0.7 million and $0.9 million, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses decreased approximately $0.8 million between reporting periods, resulting primarily from a reduction in legal services on our paragraph IV litigation, the majority of which was settled in 2013.

Non-Operating Income (Expense)

During 2014 non-operating expense consisted principally of interest expense on the $10.0 million promissory note entered into in December 2013 less investment income derived from our investments. During 2013 non-operating income consisted principally of investment income derived from our investments.

Income Taxes

The net loss for 2014 and 2013 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization. The Company did record $4 thousand of state tax expense in 2014.

Results of Operations for the Years Ended December 31, 2013 and 2012

	December 31			
	2013	2012	Change	
	$000's		$000's	Percent
Revenues:				
Royalty revenue	$ 10	$ -	$ 10	100
Product sales, net	113	-	113	100
Total revenues, net	123	—	123	100
Operating expenses:				
Cost of sales	364	—	364	100
Research and development	4,923	3,726	1,197	32
Selling, marketing, general and administrative	8,926	6,013	2,913	48
Total operating expenses	14,213	9,739	4,474	46
Operating loss	(14,090)	(9,739)	4,351	45
Non-Operating income (expense):				
Investment income	194	79	115	146
Other expense, net	(5)	(8)	(3)	(3)
Total other income, net	189	71	118	166
Loss before income taxes	(13,901)	(9,668)	4,233	44
Provision for income taxes	—	—	—	—
Net loss	$ (13,901)	$ (9,668)	$ 4,233	44

Revenue

Product Sales

Nexafed® was launched in mid-December 2012. The Company sells Nexafed® in the United States to wholesale pharmaceutical distributors and as well as directly to chain drug stores. Nexafed® is sold subject to the right of return for a period of up to twelve months after the product expiration. Nexafed® currently has a shelf life of twenty-four months from the date of manufacture. Given the limited sales history of Nexafed®, the Company currently cannot reliably estimate expected returns of the product at the time of shipment to certain customers. Accordingly, the Company has deferred the recognition of revenue on $0.3 million of Nexafed® shipments to these customers until the right of return no longer exists or adequate history and information becomes available to estimate product returns. We have recognized revenue of $113 thousand in 2013 for shipments to customers where the right of return no longer existed either because a pricing allowance was accepted in exchange for forfeiting the right of return or because information became available on pharmacy's reorder activity with their drug wholesaler. We will continue to analyze information to assess the recognition of our revenue but also expect to continue the deferral of some revenue in the foreseeable future. As of December 31, 2013, we had $0.3 million in deferred revenue on our balance sheet related to Nexafed shipments which occurred since its commercial launch. We had no net product sales during 2012.

Royalty Revenue

In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer Inc., (which agreement has since been terminated effective April 2014) we began to earn royalties on Oxecta net sales starting in February 2013. We recorded royalties of approximately $10 thousand for 2013 on Pfizer's net sales of Oxecta of approximately $0.2 million.

Cost of Sales

Cost of sales includes third-party acquisition costs, third-party warehousing and product distribution charges and inventory reserve charges for the Nexafed product line. During 2013, we established an inventory reserve of $0.25 million.

Operating Expenses

Research and development expense (R&D) during 2013 were primarily for our Aversion development expenses and during 2012 were for product candidates utilizing either our Aversion or our Impede® Technologies, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in each of the 2013 and 2012 results are non-cash share-based compensation expenses of $0.3 million and $0.4 million, respectively. Excluding the share-based compensation expense, our R&D expenses increased approximately $1.3 million between reporting periods primarily from our Aversion development expenses on our hydrocodone/acetaminophen product candidate.

Selling and marketing expenses during 2013 primarily consisted of advertising and marketing activities on Nexafed which was launched in December 2012. Selling and marketing expenses during 2012 primarily consisted of market research studies on our Aversion and Impede® Technologies. Our Nexafed advertising and marketing activities will continue in 2014. Our general and administrative expenses primarily consisted of legal, audit and other professional services, corporate insurance, and payroll. Included in the 2013 and 2012 results are non-cash share-based compensation expenses of $0.9 million and $1.3 million, respectively. Excluding the share-based compensation expense our selling, marketing, general and administrative expenses increased approximately $3.4 million between reporting periods, primarily for the marketing, advertising and promotional programs on Nexafed of $1.1 million, compensation costs of $0.2 million, legal services on our paragraph IV litigation of $1.7 million, patent and trademark services of $0.3 million and general corporate legal matters of $0.1 million.

Non-Operating Income

During 2013 and 2012, non-operating income consisted principally of investment income derived from our cash reserves being invested in accordance with a Board of Director approved investment policy.

Income Taxes

The net loss for 2013 and 2012 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization.

Liquidity and Capital Resources

At December 31, 2014, we had cash, cash equivalents and marketable securities of $12.1 million compared to $26.1 million in cash and cash equivalents at December 31, 2013. We had working capital of $10.2 million at December 31, 2014 compared to $26.3 million at December 31, 2013. Our investing activities for capital expenditures were $135 thousand in 2014 and $23 thousand in 2013.

Pending the receipt of milestone and royalty payments under the Egalet Agreement and similar agreements for our products in development anticipated to be negotiated and executed with other pharmaceutical company partners, of which no assurance can be given, we must rely on revenues from our Nexafed products sales, the net proceeds, if any, from our “at-the-market” offering of our common stock pursuant to our Sales Agreement with MLV & Co., and our current investments, including interest income from investments, to fund the development of our Aversion Technology, Impede Technology, Limitx Technology and related administrative and operating expenses. Our future sources of revenue, if any, will be derived from milestone payments and royalties under the Egalet Agreement and similar agreements for our products in development with other pharmaceutical company partners, for which there can be no assurance, and from the commercialization of our Nexafed products and other Impede Technology products that we expect to develop.

At January 31, 2015, we had cash, cash equivalents and marketable securities of approximately $15.9 million. We estimate that such cash reserves will be sufficient to fund the development of Aversion Technology and Impede Technology product candidates, and related operating expenses at least through the next 12 months.

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, 2014:

	Payments due by period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	$ 33	$ 26	$ 7	$ —	$ —
Contract manufacturing	492	492	—	—	—
Clinical studies	104	104	—	—	—
Marketing and advertising	—	—	—	—	—
Employment agreements	677	677	—	—	—
Debt principal	10,000	1,758	5,263	2,979	—
Debt interest	2,686	787	967	932	—
Total	$ 14,497	$ 4,349	$ 6,237	$ 3,911	$ —

Term Loan with Oxford Finance

On December 27, 2013, we and our subsidiary, Acura Pharmaceutical Technologies, Inc. entered into a Loan and Security Agreement (the "Loan Agreement") with Oxford Finance LLC ("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 (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 are 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. 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 (the "Amendment") to the Loan Agreement. Pursuant to the Amendment, (i) the exercise price of the warrant previously issued to the Lender to purchase 297,805 shares of our Common Stock was lowered from $1.59 to $0.504 per share (the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the Amendment), (ii) we agreed to maintain a $2.5 million cash balance until such time as we have repaid $5 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.

We may voluntarily prepay the Term Loan in full, but not in part, and any prepayment is subject to a prepayment premium equal to 2% of the principal prepaid, if prepaid prior to December 27, 2015, and 1% of the principal prepaid if prepaid after December 27, 2015. 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 $795,000.

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, it contains customary events of default that entitles Oxford to cause any or all of our 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 affecting us or our operations, bankruptcy and insolvency defaults and material judgment defaults.

The warrants to purchase 297,805 shares of our common stock we issued to Oxford in connection with the Term Loan, having an exercise price of $0.504 per share (as adjusted pursuant to the Amendment) 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:

Revenue Recognition

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 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. The Company sells Nexafed in the United States to wholesale pharmaceutical distributors and as well as directly to chain drug stores. Nexafed is sold subject to the right of return for a period of up to twelve months after the product expiration. Nexafed currently has a shelf life of twenty-four months from the date of manufacture. Given the limited sales history of Nexafed, the Company currently cannot reliably estimate expected returns of the product at the time of shipment to certain customers. Accordingly, the Company has deferred revenue recognition on Nexafed shipments of $353 thousand since the product’s launch to these customers until the right of return no longer exists or adequate history and information is available to estimate product returns.

Research and Development

Research and Development, or R&D, expenses include internal R&D activities, external 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 the study starting date. We review and accrue CRO expenses and clinical trial study expenses based on services performed and rely upon 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. We have entered into several cancelable CRO arrangements and our obligations under these arrangements were approximately $0.1 million and $0.7 million at December 31, 2014 and 2013, respectively, for services to be incurred as subjects are enrolled and progress through the studies.

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, 2014, 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 2014, 2013 and 2012 were $135,000, $23,000 and $147,000, respectively. Capital expenditures in each such year were primarily attributable to the purchase of scientific equipment and improvements to the Culver, Indiana facility.

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 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, 2014, our investments consisted of corporate bonds and exchange-traded funds.

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, 2014. 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 (1992). Based on our assessment, our Chief Executive Officer and our Chief Financial Officer both believe that, as of December 31, 2014, 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 2014 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Reference is made to 2015 Proxy Statement to be filed with the SEC on or about March 17, 2015 with respect to Directors, Executive Officers and Corporate Governance, which is incorporated herein by reference and made a part hereof in response to the information required by Item 10.

ITEM 11. EXECUTIVE COMPENSATION

Reference is made to our 2015 Proxy Statement to be filed with the SEC on or about March 17, 2015 with respect to Executive Compensation, which is incorporated herein by reference and made a part hereof in response to the information required by Item 11.

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

Reference is made to our 2015 Proxy Statement to be filed with the SEC on or about March 17, 2015 with respect to the to the security ownership of certain beneficial owners and management and related stockholder matters, which is incorporated herein by reference and made a part hereof in response to the information required by Item 12.

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

Reference is made to our 2015 Proxy Statement to be filed with the SEC on or about March 17, 2015 with respect to certain relationships and related transactions and direct independence, which is incorporated herein by reference and made a part hereof in response to the information required by Item 13.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Reference is made to our 2015 Proxy Statement to be filed with the SEC on or about March 17, 2015 with respect to auditor fees, which is incorporated herein by reference and made a part in response to the information required by Item 14.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. All Financial Statements: See Index to Financial Statements
2. Financial Statement Schedules: None
3. Exhibits: See Index to Exhibits

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: February 27, 2015

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)	February 27, 2015
/s/Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2015
/s/William G. Skelly William G. Skelly	Director	February 27, 2015
/s/Bruce F Wesson Bruce F. Wesson	Director	February 27, 2015
/s/Immanuel Thangaraj Immanuel Thangaraj	Director	February 27, 2015
/s/George K. Ross George K. Ross	Director	February 27, 2015

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, 2014 and 2013 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014. 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, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014 **,** in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP
Chicago, Illinois
March 2, 2015

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2014 and 2013
(in thousands, except par value)

	2014	2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 774	$ 12,340
Marketable securities (Note 4)	11,322	13,733
Accounts receivable, net of allowances of $5 and $28	76	194
Accrued investment income	66	120
Inventories, net (Note 5)	304	251
Prepaid expenses and other current assets	471	629
Other current deferred assets	218	186
Total current assets	13,231	27,453
Property, plant and equipment, net (Note 6)	957	941
Deferred debt issuance costs, net of accumulated amortization of $69 and $- (Note 8)	162	231
Other assets	-	5
Intangible asset, net of accumulated amortization of $155	1,845	-
Total assets	$ 16,195	$ 28,630
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 217	$ 274
Accrued expenses (Note 7)	568	541
Accrued interest	70	-
Other current liabilities	26	5
Deferred revenue	353	287
Current maturities of long-term debt (Note 8)	1,758	-
Total current liabilities	2,992	1,107
Long-term debt, net of discount of $281 and $400 (Note 8)	7,961	9,600
Long-term portion of accrued interest	190	-
Total liabilities	11,143	10,707
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock: $.01 par value per share; 100,000 shares authorized, 48,848 and 48,325 shares issued and outstanding at 2014 and 2013, respectively	488	483
Additional paid-in capital	366,898	366,533
Accumulated deficit	(362,321)	(349,112)
Accumulated other comprehensive income (loss)	(13)	19
Total stockholders' equity	5,052	17,923
Total liabilities and stockholders' equity	$ 16,195	$ 28,630

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
YEARS ENDED DECEMBER 31, 2014, 2013 and 2012
(in thousands, except per share amounts)

	2014	2013	2012
Revenues:			
Royalty revenue	$ 4	$ 10	$ -
Product sales, net	247	113	-
License fee revenue	500	-	-
Total revenues, net	751	123	-
Operating expenses:			
Cost of sales (excluding inventory write-down)	227	114	-
Inventory write-down (Note 5)	201	250	-
Research and development	4,582	4,923	3,726
Selling, marketing, general and administrative	7,940	8,926	6,013
Total operating expenses	12,950	14,213	9,739
Operating loss	(12,199)	(14,090)	(9,739)
Non-Operating income (expense):			
Investment income	198	194	79
Gain on sales of marketable securities	4	4	-
Interest expense (Note 8)	(1,212)	(9)	-
Other expense, net	-	-	(8)
Total other income (expense), net	(1,010)	189	71
Loss before income taxes	(13,209)	(13,901)	(9,668)
Provision for income taxes	-	-	-
Net loss	$ (13,209)	$ (13,901)	$ (9,668)
Other comprehensive income (loss):			
Unrealized gains (losses) on securities	(32)	59	(40)
Total other comprehensive income (loss)	(32)	59	(40)
Comprehensive loss	$ (13,241)	$ (13,842)	$ (9,708)
Loss per share:			
Basic	$ (0.27)	$ (0.29)	$ (0.20)
Diluted	$ (0.27)	$ (0.29)	$ (0.20)
Weighted average shares outstanding:			
Basic	48,893	47,764	47,521
Diluted	48,893	47,764	47,521

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2014, 2013 and 2012
(in thousands)

	Common Stock		Additional Paid-in		Accumulated Other Comprehensive	
	Shares	$ Amount	Capital	Accumulated Deficit	Income (Loss)	Total
Balance at Dec. 31, 2011	45,320	$ 453	$ 361,733	$ (325,543)	$ -	$ 36,643
Net loss	-	-	-	(9,668)	-	(9,668)
Other comprehensive loss	-	-	-	-	(40)	(40)
Share-based compensation	-	-	1,733	-	-	1,733
Net distribution of common stock pursuant to restricted stock unit award plan	827	8	(7)	-	-	1
Common shares withheld for withholding taxes on distribution of restricted stock units	(296)	(2)	(1,031)	-	-	(1,033)
Net issuance of common stock pursuant to cashless exercise of stock options	14	-	-	-	-	-
Common shares withheld for withholding taxes on cashless exercise of stock options	(5)	-	(15)	-	-	(15)
Issuance of common stock for exercise of stock options	7	-	9	-	-	9
Balance at Dec. 31, 2012	45,867	$ 459	$ 362,422	$ (335,211)	$ (40)	$ 27,630
Net loss	-	-	-	(13,901)	-	(13,901)
Other comprehensive income	-	-	-	-	59	59
Share-based compensation	-	-	1,215	-	-	1,215
Warrants issued with promissory notes	-	-	400	-	-	400
Net distribution of common stock pursuant to restricted stock unit award plan	826	8	(7)	-	-	1
Common shares withheld for withholding taxes on distribution of restricted stock units	(321)	(3)	(709)	-	-	(712)
Net issuance of common stock pursuant to cashless exercise of stock options	7	-	-	-	-	-
Common shares withheld for withholding taxes on cashless exercise of stock options	(1)	-	(4)	-	-	(4)
Issuance of common stock under “at the market” offerings, net of offering costs of $102	1,940	19	3,207	-	-	3,226
Issuance of common stock for exercise of stock options	7	-	9	-	-	9
Balance at Dec. 31, 2013	48,325	$ 483	$ 366,533	$ (349,112)	$ 19	$ 17,923
Net loss	-	-	-	(13,209)	-	(13,209)
Other comprehensive loss	-	-	-	-	(32)	(32)
Share-based compensation	-	-	890	-	-	890
Net distribution of common stock pursuant to restricted stock unit award plan	825	8	(7)	-	-	1
Common shares withheld for withholding taxes on distribution of restricted stock units	(315)	(3)	(522)	-	-	(525)
Net issuance of common stock pursuant to cashless exercise of stock options	8	-	-	-	-	-
Common shares withheld for withholding taxes on						

cashless exercise of stock options	(2)	-	(4)	-	-	(4)
Issuance of common stock for exercise of stock options	7	-	8	-	-	8
Balance at Dec. 31, 2014	48,848	$ 488	$ 366,898	$ (362,321)	$ (13)	$ 5,052

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2014, 2013, and 2012
(in thousands)

	2014	2013	2012
Cash Flows from Operating Activities:			
Net loss	$ (13,209)	$ (13,901)	$ (9,668)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	119	134	131
Provision to reduce inventory to net realizable value	201	250	-
Share-based compensation	890	1,215	1,733
Amortization of debt discount and deferred debt issue costs	188	-	-
Amortization of bond premium in marketable securities	250	-	-
Amortization of intangible asset	155	-	-
Gain on sales of marketable securities	(4)	(4)	-
Loss on disposal of property, plant and equipment	-	-	8
Changes in assets and liabilities:			
Accounts receivable	118	(194)	-
Accrued investment income	54	(84)	-
Inventories	(254)	(282)	(219)
Income taxes refundable	-	43	110
Prepaid expenses and other current assets	158	(358)	(16)
Other current deferred assets	(32)	(186)	-
Other assets	5	6	-
Accounts payable	(57)	(720)	941
Accrued expenses	27	128	(64)
Deferred revenue	66	287	-
Accrued interest – current and long term	260	-	-
Other current and non-current liabilities	21	(12)	6
Net cash used in operating activities	(11,044)	(13,678)	(7,038)
Cash Flows from Investing Activities:			
Purchases of marketable securities	(2,203)	(7,611)	(20,306)
Proceeds from sale and maturities of marketable securities	4,336	13,887	320
Acquisition of product rights	(2,000)	-	-
Additions to property, plant and equipment	(135)	(23)	(147)
Net cash (used in) provided by investing activities	(2)	6,253	(20,133)
Cash Flows from Financing Activities:			
Proceeds from exercise of stock options	8	9	9
Proceeds from distribution of restricted stock units	1	1	1
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(529)	(716)	(1,048)
Long-term debt borrowings	-	10,000	-
Capitalized debt issuance costs	-	(231)	-
Proceeds from “at the market offering”	-	3,328	-
“At the market offering” transaction costs	-	(102)	-
Net cash (used in) provided by financing activities	(520)	12,289	(1,038)
Net (decrease) increase in cash and cash equivalents	(11,566)	4,864	(28,209)
Cash and cash equivalents at beginning of year	12,340	7,476	35,685
Cash and cash equivalents at end of year	$ 774	$ 12,340	$ 7,476
Supplemental Disclosures of Cash Flow Information:			
Cash paid (refunded) during the year for:			
Interest	$ 765	$ 9	$ -
Income taxes, net of refunds	$ 14	$ (42)	$ (108)

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
YEAR ENDED DECEMBER 31, 2014, 2013, and 2012

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

Year ended December 31, 2014

1. 829 thousand shares of common stock were eligible for distribution pursuant to our 2005 Restricted Stock Unit (RSU) Plan utilizing various cashless exercise features of the plan. After withholding 4 thousand shares for $7 in exercise costs and withholding 315 thousand shares for $525 in statutory minimum payroll taxes, we issued 510 thousand shares of common stock.
2. Options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features of our stock option plan. After withholding 16 thousand shares for $32 in exercise costs and withholding 2 thousand shares for $4 in statutory minimum payroll taxes, we issued 6 thousand shares of common stock.

Year ended December 31, 2013

1. 829 thousand shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan. After withholding 3 thousand shares for $7 in exercise costs and withholding 321 thousand shares for $712 in statutory minimum payroll taxes, we issued 505 thousand shares of common stock.
2. Options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features of the stock option plan. After withholding 17 thousand shares for $32 in exercise costs and withholding 1 thousand shares for $4 in statutory minimum payroll taxes, we issued 6 thousand shares of common stock.
3. In connection with a debt issuance of $10 million, we issued the lender 298 thousand warrants with an exercise price of $1.595. The fair value of these warrants of $400 was recorded as a debt discount and is being amortized as interest expense over the term of this debt.

Year ended December 31, 2012

1. 829 thousand shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan. After withholding 2 thousand shares for $7 in exercise costs and withholding 296 thousand shares for $1.0 million in statutory minimum payroll taxes, we issued 531 thousand shares of common stock.
2. Options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features of the stock option plan. After withholding 10 thousand shares for $31 in exercise costs and withholding 5 thousand shares for $15 in statutory minimum payroll taxes, we issued 9 thousand shares of common stock.

See accompanying Notes to Consolidated Financial Statements.

NOTE 1 - DESCRIPTION OF BUSINESS

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® Technology is a mixture of inactive ingredients incorporated into pharmaceutical tablets and capsules intended to address some common methods of product tampering associated with opioid abuse. Oxaydo™ Tablets (formerly known as Oxecta®) (oxycodone HCl, CII), is the first approved product utilizing Aversion in the United States and we have 7 additional opioid products utilizing Aversion in various stages of development. 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 7.5 mg strengths. We are advised that Egalet plans to launch Oxaydo in the United States in the third quarter of 2015. We have also developed Impede® Technology which is a combination of inactive ingredients that prevent the extraction of pseudoephedrine from tablets and disrupt the direct conversion of pseudoephedrine from tablets into methamphetamine. We launched our first Impede Technology product, Nexafed®, into the United States market in December 2012 and our Nexafed Sinus Pressure + Pain product in the United States in February 2015. We have multiple pseudoephedrine products in development utilizing our Impede Technology. In August 2014, we received a grant from the National Institute on Drug Abuse to advance early stage development of our third abuse deterrent technology, Limitx™. Limitx is designed to retard the release of active drug ingredients when too many tablets are accidently or purposefully ingested.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The consolidated financial statements include the accounts of our wholly-owned subsidiary, Acura Pharmaceutical Technologies Inc., after elimination of intercompany accounts and transactions.

Reclassifications

Certain reclassifications have been made to the prior years' 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. The Company 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's marketable securities at December 31, 2014 and 2013 primarily consist 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, accrued expenses 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 believes the fair value of long-term debt approximates its carrying value based upon the borrowing rates currently available to the Company for loans with similar terms. As discussed below, 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®, into the United States market in December 2012. Our accounts receivable arise from our product sales of Nexafed and represents 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 from launch through December 31, 2014.

Sales to certain of our customers during 2014 and 2013 accounting for 10% or more of our annual product sales, whether the product shipment was recognized or deferred, are presented below:

Customer	2014
Rite Aid Corporation	28%
Cardinal Health, Inc.	24%
AmerisourceBergen Corporation	13%
McKesson Corporation	13%
Kroger Foods	11%

	2013
Rite Aid Corporation	52%
Cardinal Health, Inc.	15%

Accounts receivable from certain of our customers at December 31, 2014 and 2013 accounting for 10% or more of our gross accounts receivable are presented below:

Customer	2014
Kroger Foods	13%
Rite Aid Corporation	83%
	2013
Rite Aid Corporation	95%

Inventories

Inventories consist of both raw and packaging materials on our Oxaydo product and finished goods held for distribution and sale on our Nexafed® product. During 2014 we purchased raw and packaging material inventories for $260 thousand from Pfizer on the Oxaydo product we reacquired from them. 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

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.

Revenue Recognition

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 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.

Royalty Revenue

In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer Inc. (the “Pfizer Agreement”), we began earning royalties on Oxecta starting in February 2013. We recorded royalties of approximately $4 thousand and $10 thousand for the years ended December 31, 2014 and 2013, respectively. Effective April 9, 2014, the Pfizer Agreement was terminated and the rights to Oxecta were returned to us after making a one-time payment of $2.0 million to Pfizer.

On January 7, 2015, we, Egalet US, Inc., Egalet Ltd., and Egalet Corporation (collectively, “Egalet”) entered into a Collaboration and License Agreement to commercialize Oxaydo™ tablets (formerly known as Oxecta) containing our Aversion® Technology. We will 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) (see Note 3).

Product Sales

Nexafed® was launched in December 2012. The Company sells Nexafed® in the United States to wholesale pharmaceutical distributors as well as directly to chain drug stores. Nexafed® is generally sold subject to the right of return beginning six months prior to and ending twelve months following the product expiration. Nexafed® currently has a shelf life of twenty-four months from the date of manufacture. Given the limited sales history of Nexafed®, the Company currently cannot reliably estimate expected returns of the product at the time of shipment to certain customers. Accordingly, the Company has deferred the recognition of revenue on $0.4 million of Nexafed® shipments to these customers until the right of return no longer exists or adequate history and information becomes available to estimate product returns.

License Fees

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 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 Acura conceded Purdue's claim of priority in exchange for certain financial consideration to us including an immediate non-refundable payment of $500 thousand.

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) containing our Aversion® Technology. Egalet paid us an upfront payment of $5 million upon signing of the Egalet Agreement (see Note 3).

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 had no impairment charges for years ended 2014, 2013 and 2012.

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. We did not have any accrued CRO costs and clinical trial study expenses at either December 31, 2014 or 2013. We had no prepaid CRO costs and clinical trial study expenses at either December 31, 2014 or 2013.

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 11.

We measure our compensation cost related to share-based payment transactions based on fair value of the equity or liability instrument issued. For purposes of estimating the fair value of each stock option unit on the date of grant, we utilize the Black-Scholes option-pricing model. 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 our historical public market closing prices). Our accounting for share-based compensation for 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.
Our share-based compensation expense recognized in the Company's results of operations comprised the following:

	Year ended December 31,		
	2014	2013	2012
	(in thousands)		
Research and development:			
Stock option awards	$ 220	$ 315	$ 375
RSU awards	-	-	-
	$ 220	$ 315	$ 375
Selling, general and administrative:			
Stock option awards	550	900	1,358
RSU awards	146	-	-
	$ 696	$ 900	$ 1,358
Total share-based compensation expense	$ 916	$ 1,215	$ 1,733

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. Acura'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 both December 31, 2014 and 2013, 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 11). 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 2014, 2013 or 2012 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:

	Years ended December 31,		
	2014	2013	2012
	(in thousands except per share data)		
EPS - basic			
Numerator: net loss	$ (13,209)	$ (13,901)	$ (9,668)
Denominator:			
Common shares	48,847	46,935	45,863
Vested RSUs	46	829	1,658
Basic weighted average shares outstanding	48,893	47,764	47,521
EPS - basic	$ (0.27)	$ (0.29)	$ (0.20)
EPS – assuming dilution			
Numerator: net loss	$ (13,209)	$ (13,901)	$ (9,668)
Denominator:			
Common shares	48,847	46,935	45,863
Vested RSUs	46	829	1,658
Stock options	-	-	-
Common stock warrants	-	-	-
Diluted weighted average shares outstanding	48,893	47,764	47,521
EPS - diluted	$ (0.27)	$ (0.29)	$ (0.20)
Excluded dilutive securities:			
Common stock issuable:			
Stock options	4,556	3,738	3,296
Common stock warrants	298	2,154	1,856
Total excluded potentially dilutive shares	4,854	5,892	5,152

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update 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, 2016, 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 method by which we will adopt the standard in 2017.

NOTE 3 – LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENTS

Pfizer Agreement

In October 2007, we entered into a License, Development and Commercialization Agreement, or the Pfizer Agreement, with King Pharmaceuticals Research and Development, Inc., now a subsidiary of Pfizer, to develop and commercialize in the United States, Canada and Mexico certain opioid analgesic products utilizing our Aversion Technology. Aversion Oxycodone was approved by the U.S. Food and Drug Administration, or FDA, on June 17, 2011 and sales of Aversion Oxycodone, under Pfizer's brand name Oxecta, commenced in February 2012. For sales of Aversion Oxycodone occurring on and following February 2, 2013 (the one year anniversary of first commercial sale), Pfizer paid us a royalty of 5% of net sales of Aversion Oxycodone.

On September 24, 2012, we entered into a letter agreement with Pfizer which provided for the termination of Pfizer's license to our Aversion Technology used in three development-stage products licensed to Pfizer and for the return of these products to us. On April 9, 2014, we entered into a second letter agreement with Pfizer providing for the termination of the Pfizer Agreement and the return of Aversion Oxycodone to us effective April 9, 2014. The letter agreement further provides that (i) Pfizer will cease the development, marketing and sale of any product using our technologies effective April 9, 2014, (ii) Pfizer will retain its Oxecta® trademark, (iii) Pfizer transferred to us all studies, data, regulatory filings (including the NDA) and all other information relating to Aversion
Oxycodone pursuant to a transition process described in the letter agreement, (iv) we will remit to Pfizer a one-time termination payment of $2.0 million, and (v) each party waives all claims against the other relating to the Pfizer Agreement. Pfizer's royalty payment obligations relating to Aversion Oxycodone ceased effective April 9, 2014 and all royalty payments due to us have been received. Our termination payment of $2.0 million has been recorded on our financial statements as an intangible asset and will be amortized over the remaining useful life of the patent for Aversion Oxycodone. The recorded value of the intangible asset will be periodically assessed for impairment. We also purchased raw and packaging material inventories for $260 thousand from Pfizer on the Aversion Oxycodone product.

Egalet Agreement

On January 7, 2015, we and Egalet entered into a Collaboration and License Agreement (the "Egalet Agreement") to commercialize Aversion Oxycodone under the 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 are transferring 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 (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 coordinate 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 will pay us a $2.5 million milestone on the earlier to occur of (A) the launch of Oxaydo and (B) January 1, 2016, but in no event earlier than June 30, 2015. 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. 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 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 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. Egalet also may terminate the Agreement prior to the launch of Oxaydo on 30 days prior written notice upon the occurrence of serious safety issues, regulatory restrictions and intellectual property issues, in each case involving 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.

Paragraph IV ANDA Litigation

On or about September 17, 2012, we believe the FDA internally changed the status of Oxecta® to be considered a Reference Listed Drug, or RLD. An RLD is the standard to which all generic versions must be shown to be bioequivalent and a drug company seeking approval to market a generic equivalent must refer to the RLD. By designating Oxecta® as an RLD, the FDA was allowed to accept ANDAs referencing Oxecta®.

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 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 Oxecta® 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 Oxecta®. 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 Certification III, which indicated its intent not to market its generic Oxaydo product in advance of our patent expiry.

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 Oxecta® 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 Oxecta® 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 Oxecta® 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 Oxecta® product.

Under the Settlement Agreement with Impax, Impax may launch its generic Oxecta® 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 Oxecta® 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 Oxecta® 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.

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.

NOTE 4 – INVESTMENTS IN MARKETABLE SECURITIES

Investments in marketable securities consisted of the following:

	December 31, 2014 (in millions)	December 31, 2013 (in millions)
Marketable securities:		
Corporate bonds — maturing within 1 year	$ 3.5	$ 3.1
Corporate bonds — maturing after 1 year and through March 2017	2.8	6.8
Exchange-traded funds	5.0	3.8
Total marketable securities	$ 11.3	$ 13.7

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 investments 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, 2014 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 6.3	$ -	$ -	$ 6.3
Exchange-traded funds	5.0	-	-	5.0
Total - Current	$ 11.3	$ -	$ -	$ 11.3

	December 31, 2013 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 9.9	$ -	$ -	$ 9.9
Exchange-traded funds	3.8	-	-	3.8
Total - Current	$ 13.7	$ -	$ -	$ 13.7

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 prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined based on Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. Fair values determined based on Level 3 inputs utilize unobservable inputs and include valuations of assets or liabilities for which there is little, if any, market activity. 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, 2014 and 2013 consisted of the following (in millions):

	December 31, 2014 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	6.3		6.3	-
Exchange-traded funds	5.0	5.0	-	-
Total	$ 11.3	$ 5.0	$ 6.3	$ -

	December 31, 2013 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	9.9	-	9.9	-
Exchange-traded funds	3.8	$ 3.8	$ -	$ -
Total	$ 13.7	3.8	9.9	-

Accumulated Other Comprehensive Income (Loss)

Unrealized gains or losses on marketable securities are recorded in accumulated other comprehensive income (loss). Accumulated other comprehensive income (loss) at December 31, 2014 consisted of unrealized losses on securities of $13 thousand. Accumulated other comprehensive income (loss) at December 31, 2013 consisted of unrealized gains on securities of $19 thousand.

NOTE 5 – INVENTORIES

Inventories consist of both raw and packaging materials on our Oxaydo product and finished goods held for distribution and sale on our Nexafed product. During 2014 we purchased raw and packaging material inventories for $260 thousand from Pfizer on the Oxaydo product we reacquired from them. 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.

We have recorded Nexafed deferred revenue of $0.35 million and $0.29 million at December 31, 2014 and 2013, respectively. The related cost of sales of $0.22 million and $0.19 million at December 31, 2014 and 2013, respectively, is reported in our balance sheet in the other current deferred assets account and excluded from the reported year end inventories. We will recognize both the revenue and cost of sales on these Nexafed shipments once the right of return no longer exists or adequate history and information becomes available to estimate product returns.

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

Inventories are summarized as follows:

	December 31,	
	2014	2013
	(in thousands)	
Raw and packaging materials	$ 260	$ -
Finished goods	44	501
Total inventory	304	501
Less: inventory reserve for finished goods	(-)	(250)
Net inventory	$ 304	$ 251

Our inventory reserve activity during the year ended December 31, 2014 and 2013 was as follows:

Inventory reserve		
	2014	2013
	(in thousands)	
Beginning of year	$ 250	$ -
Reserve expense for finished goods	201	250
	451	250
Inventory write-offs	(451)	(-)
End of year	$ -	$ 250

NOTE 6 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows:

	December 31,	
	2014	2013
	(in thousands)	
Building and improvements	$ 1,259	$ 1,259
Scientific equipment	595	595
Computer hardware and software	252	252
Machinery and equipment	386	252
Land and improvements	162	162
Other personal property	70	70
Office equipment	27	27
	2,751	2,617
Less: accumulated depreciation	(1,794)	(1,676)
Total property, plant and equipment, net	$ 957	$ 941

Depreciation and amortization expense was approximately $0.1 million for each of the years ended December 31, 2014, 2013, and 2012.

NOTE 7 – ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	December 31, 2014	2013
	(in thousands)	
Professional services	$ 253	$ 293
Other fees and services	110	140
Payroll, payroll taxes and benefits	94	78
Clinical and regulatory services	83	-
Contract manufacture services	-	14
Property taxes	15	15
Franchise taxes	13	1
	$ 568	$ 541

NOTE 8 – 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 is required to make monthly interest−only payments until the April 1, 2015 ("Amortization Date") and starting on the Amortization Date, the Company is 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. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on December 1, 2018. As security for its obligations under the 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.

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 2% of the principal prepaid, if prepaid prior to December 27, 2015, and 1% of the principal prepaid if prepaid after December 27, 2015. 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 will incur and accrue 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.

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 into interest expense over the term of the loan using the loan's effective interest rate.

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 is summarized below:

2014 (in thousands)			
Debt	Current	Long-term	Total
Beginning of year	$ -	$ 10,000	$ 10,000
Principal payments	-	-	-
Classification	1,758	(1,758)	-
End of year	$ 1,758	$ 8,242	$ 10,000
Debt Discount	Current	Long-term	Total
Beginning of year	$ -	$ (400)	$ (400)
Amortization expense	-	119	119
End of year	$ -	$ (281)	$ (281)
Debt, net	$ 1,758	$ 7,961	$ 9,719

Upon the execution of the Loan Agreement on December 27, 2013, we issued to the Lender warrants to purchase an aggregate of up to 298 thousand shares of our common stock at an exercise price equal to $1.595 per share (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 (the "Amendment") to the Loan Agreement. Pursuant to the Amendment, (i) the exercise price of the warrant previously issued to the Lender to purchase 297,805 shares of our Common Stock was lowered from $1.595 to $0.504 per share (the average closing price of our common stock on Nasdaq for the 10 trading days preceding the date of the Amendment), (ii) we agreed to maintain a $2.5 million cash balance until such time as we have repaid $5 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.
Our interest expense consisted of the following:

	2014	2013
	(in thousands)	
Interest expense:		
Secured Promissory notes	$ 1,024	$ 9
Debt discount	119	-
Debt issue costs	69	-
Total interest expense	$ 1,212	$ 9

The annual principal payments of the debt at December 31, 2014 are as follows:

	Annual Principal Payments (in thousands)
2015	$ 1,758
2016	2,522
2017	2,741
2018	2,979
Total	$ 10,000

NOTE 9 – EQUITY FINANCING

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 may 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. During the year ended December 31, 2014, we did not sell any shares of our common stock pursuant to our prospectus supplement. During the year ended December 31, 2013, we sold approximately 1.94 million shares of our common stock under a Sales Agreement with MLV & Co., our sales agent, through an "at the market" offering, for gross proceeds of approximately $3.3 million. Transaction costs were approximately $0.1 million. The net proceeds of these transactions for year ended ending December 31, 2013 were approximately $3.2 million and were used for general corporate purposes, including working capital, capital expenditures, research, development and marketing expenditures and clinical trial expenditures.

NOTE 10 – COMMON STOCK WARRANTS

In connection with the issuance of the $10.0 million secured promissory notes in December 2013, we issued common stock purchase warrants ("warrants") to acquire approximately 298 thousand shares of our common stock having an exercise price of $1.595 per share with an expiration date in December 2020. In August 2014, warrants exercisable for 1.9 million shares of our common stock with an exercise price of $3.40 per share expired unexercised. At December 31, 2014, we have total outstanding warrants exercisable for 298 thousand shares of our common stock having a weighted average exercise price of $1.595 per share with an expiration date in December 2020. In January 2015, the exercise price of these warrants was reduced to $0.504 per share. The warrants contain a cashless exercise feature.

Our warrant activity during the years ended December 31, 2014 and 2013 is shown below:

	December 31,			
	2014		2013	
	Number (000's)	Weighted Average Exercise Price	Number (000's)	Weighted Average Exercise Price
Outstanding, beginning	2,154	$ 3.15	1,856	$ 3.40
Issued	-	-	298	1.60
Exercised	-	-	-	-
Expired	(1,856)	3.40	-	-
Outstanding, ending	298	$ 1.60	2,154	$ 3.15

NOTE 11 – 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 matching or profit sharing contributions for the Plan in years 2014, 2013, and 2012.

Stock Option Plans

We maintain various stock option plans. A summary of our stock option plans as of December 31, 2014, 2013, and 2012 and for the years then ended consisted of the following:

	Years Ended December 31,					
	2014		2013		2012	
	(in thousands except price data)					
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price	Number of Options)	Weighted Average Exercise Price
Outstanding, beginning	3,738	$ 4.99	3,296	$ 5.50	3,556	$ 6.41
Granted	900	0.52	548	1.66	475	2.80
Exercised	(31)	1.30	(31)	1.30	(31)	1.30
Forfeited or expired	(51)	3.50	(75)	5.02	(704)	8.43
Outstanding, ending	4,556	$ 4.14	3,738	$ 4.99	3,296	$ 5.50
Options exercisable	3,476	$ 5.21	3,115	$ 5.61	2,763	$ 5.99

The following table summarizes information about nonvested stock options outstanding at December 31, 2014:

	Number of Options Not Exercisable	Weighted Average Fair Value
	(in thousands except per price data)	
Outstanding at December 31, 2013	623	$ 1.71
Granted	900	0.46
Vested	(443)	1.73
Forfeited	-	-
Outstanding at December 31, 2014	1,080	$ 0.66

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 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 2014, 2013 and 2012 stock option grants were:

	2014	2013	2012
Expected dividend yield	0.0%	0.0%	0.0%
Risk-free interest rates	2.2%	1.9% to 2.9%	1.7% to 2.0%
Average expected volatility	97%	111%	114%
Expected term (years)	10	10	10
Weighted average grant date fair value	$ 0.46	$ 1.54	$ 2.60

As of December 31, 2014, there was no intrinsic value of the option awards which were vested and outstanding. As of December 31, 2013 and 2012 the aggregate intrinsic value of the option awards which were vested and outstanding was $13 thousand and $0.1 million, respectively. In addition, the aggregate intrinsic value of option awards exercised during the year ended December 31, 2014, 2013 and 2012 was $0.00, $28 thousand and $0.1 million, respectively. The total remaining unrecognized compensation cost on unvested option awards outstanding at December 31, 2014 was $0.8 million and is expected to be recognized in operating expense in varying amounts over the twenty-three months remaining in the requisite service period.

Information about the cashless stock option exercises during the last three years is as follows:

- During 2014, options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features of our stock option plan and after withholding 16 thousand shares for $32 in exercise costs and withholding 2 thousand shares for $4 in statutory minimum withholding payroll taxes, we issued 6 thousand shares of common stock.
- During 2013, options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features of our stock option plan and after withholding 17 thousand shares for $32 in exercise costs and withholding 1 thousand shares for $4 in statutory minimum withholding payroll taxes, we issued 6 thousand shares of common stock.
- During 2012, options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features of the stock option plan and after withholding 10 thousand shares for $31 in exercise costs and withholding 5 thousand shares for $15 in statutory minimum payroll taxes, we issued 9 thousand shares of common stock.

Restricted Stock Unit Award Plan

We have two Restricted Stock Unit Award Plans for our employees and non-employee directors, a 2005 Restricted Stock Unit Award Plan (the "2005 RSU Plan") and a 2014 Restricted Stock Unit Award Plan (the "2014 RSU Plan"). Vesting of an RSU entitles the holder to receive a share of our common stock on a distribution date. 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, 2014, 2013, and 2012, and for the years then ended consisted of the following (in thousands):

	Years Ended December 31,					
	2014		2013		2012	
	(in thousands)					
	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs	Number of RSUs	Number of Vested RSUs
Outstanding, beginning	829	829	1,658	1,658	2,487	2,487
Granted	147	147	-	-	-	-
Distributed	(829)	(829)	(829)	(829)	(829)	(829)
Vested	-	-	-	-	-	-
Forfeited or expired	-	-	-	-	-	-
Outstanding, ending	147	147	829	829	1,658	1,658

2005 Restricted Stock Unit Award Plan

Under our 2005 RSU Plan, one-fourth of vested shares of common stock underlying RSU awards of 3.3 million shares were distributed (after payment of exercise costs of $0.01 par value per share) on January 1 of each of years 2011 thru 2014. All RSUs granted under the 2005 RSU Plan had been distributed effective January 1, 2014.

Information about the distribution of 0.83 million shares under the 2005 RSU Plan during each of the last three years are as follows:

- On January 1, 2014, 0.51 million shares were distributed to the holders while 0.32 million shares were withheld by the Company upon elections made to exchange RSUs in satisfaction of $0.5 million withholding tax obligations; and
- On January 1, 2013, 0.51 million shares were distributed to the holders while 0.32 million shares were withheld by the Company upon elections made to exchange RSUs in satisfaction of $0.7 million withholding tax obligations.
- On January 1, 2012, 0.53 million shares were distributed to the holders while 0.30 million shares were withheld by the Company upon elections made to exchange RSUs in satisfaction of $1.0 million withholding tax obligations.

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 2.0 million shares of our common stock pursuant to awards under the 2014 RSU Plan.

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

- On May 1, 2014, we awarded 37 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 are 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 52 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. Distributions of stock under the January 2, 2015 award cannot be deferred until a later date and the stock under such awards will be distributed on January 4, 2016.

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

- On January 2, 2015, 129 thousand RSUs from the May 1, 2014 award were distributed and 18 thousand RSUs were deferred until a future distribution date. Of the 129 thousand RSUs distributed, 99 thousand RSUs were distributed in common stock and 30 thousand RSUs were settled in cash.

NOTE 12 – 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:

	December 31,		
	2014	2013	2012
	(in thousands)		
Benefit at U.S. statutory 34% tax rate	$ (4,491)	$ (4,690)	$ (3,287)
State taxes (benefit), net of federal effect	65	(238)	-
Research and development tax credits	(30)	(185)	-
Share-based compensation	262	369	473
Other	2	2	2
Change in valuation allowance	4,192	4,742	2,812
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 $51.5 million federal income tax benefits at December 31, 2014 derived from $151.4 million Federal NOLs at the U.S. statutory tax rate of 34% and $2.9 million state NOLs, available to offset future taxable income, some of which have limitations for use as prescribed under IRC Section 382. Our Federal and state NOLs will expire in varying amounts between 2016 and 2034 if not used, and those expirations will cause fluctuations in our valuation allowances. In 2013 we adjusted the estimated future value of NOLs under IRC Section 382 resulting in increasing those NOLs by $15.5 million with an equally offsetting valuation allowance. The net change in the valuation allowance in 2014, 2013, and 2012 was approximately $2.4 million, $18.0 million, and $2.8 million, respectively.

As of December 31, 2014 we had federal research and development tax credits of approximately $1.1 million, which expire in the years 2024 through 2034. We also had approximately $0.3 million of Indiana state research and development tax credits, which expire in the years 2015 through 2017. The components of our deferred tax assets are as follows:

	December 31,	
	2014	2013
	(in thousands)	
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	$ 51,503	$ 46,830
- State	2,898	2,843
Research and development tax credits	1,398	1,433
Share-based compensation	45	2,261
Other, net	151	119
Total deferred taxes	55,995	53,486
Valuation allowance	(55,995)	(53,486)
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, 2014 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 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, 2014, 2013 and 2012 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, 2014, the Company's tax years 2011, 2012 and 2013 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 2011. As of December 31, 2013 the Company's tax year of 2010 was included in the tax years subject to examination.

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Facility Lease

The Company leases administrative office space in Palatine, Illinois under a lease expiring March 31, 2016 for approximately $25 thousand annually.

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, Acura was 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 us, plaintiffs claim injuries from their use of the Reglan brand of metoclopramide and generic metoclopramide.

In the Pennsylvania action, over 200 lawsuits have been filed against us 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. We have consistently maintained the position that these claims are without merit and intend to vigorously defend these actions.

In New Jersey, Generic Defendants, including Acura, filed dispositive motions based on the *Mensing* decision, which the Court granted with a limited exception. As of September 2012, the New Jersey trial court dismissed Acura with prejudice. In Pennsylvania, and California, Generic Defendants, including Acura, also filed dispositive motions based on the *Mensing* decision.

In Pennsylvania, on November 18, 2011, the trial court denied Generic Defendants' dispositive preemption motions. On appeal, the Pennsylvania Superior Court held in a July 29, 2013 decision that federal preemption applied, but that *Mensing* did not completely bar all claims and refused to dismiss these cases. On September 17, 2014, the Pennsylvania Supreme Court declined to hear a further appeal. On December 16, 2014, Generic Defendants filed a Petition for a Writ of Certiorari requesting that the United States Supreme Court agree to hear a further appeal on the grounds that federal preemption under *Mensing* should completely bar all of these claims. All trial court proceedings have been stayed pending resolution of this lengthy appeal process. To the extent that plaintiffs intend to pursue their claims in the future, if the appeal is denied, Acura nonetheless remains optimistic that most, if not all, of these Philadelphia cases will eventually be dismissed against us based upon the favorable aspects of the Superior Court's narrow preemption ruling and lack of product identification, although there can be no assurance in this regard. 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 Generics Defendants' appeals from this order were denied by the California appellate courts. Therefore, subject to further developments, plaintiffs may be permitted to proceed with these lawsuits including state law claims based on (1) failing to communicate warnings to physicians through "Dear Doctor" letters; and (2) failure to update labeling to adopt brand labeling changes. California trial court also has acknowledged the preemptive effect of *Mensing* so that any claim "that would render the generic defendants in violation of federal law if they are found responsible under a state law cause of action, would not be permissible." To date, however, none of these plaintiffs have confirmed they ingested any of the generic metoclopramide manufactured by us. Therefore, we expect the number of plaintiffs with possible claims to be reduced voluntarily or by motion practice. Action will be taken in an effort to dismiss Acura from these cases, although there can be no assurance in this regard. 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, 2014 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

SUPPLEMENTARY DATA (UNAUDITED)

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

	For Three Month Periods Ended			
	Mar. 31, 2014	June 30, 2014	Sept. 30, 2014	Dec. 31, 2014
Net revenues (i)	$ 42	$ 35	$ 145	$ 529
Operating expenses	3,868	3,307	2,791	2,984
Operating loss	(3,826)	(3,272)	(2,646)	(2,455)
Net loss	$ (4,088)	$ (3,521)	$ (2,904)	$ (2,696)
Basic loss per share	$ (0.08)	$ (0.07)	$ (0.06)	$ (0.06)
Diluted loss per share	$ (0.08)	$ (0.07)	$ (0.06)	$ (0.06)

	For Three Month Periods Ended			
	Mar. 31, 2013	June 30, 2013	Sept. 30, 2013	Dec. 31, 2013
Net revenues (i)	$ 4	$ 1	$ 83	$ 35
Operating expenses	4,248	3,141	3,308	3,516
Operating loss	(4,244)	(3,140)	(3,225)	(3,481)
Net loss	$ (4,218)	$ (3,076)	$ (3,190)	$ (3,417)
Basic loss per share	$ (0.09)	$ (0.07)	$ (0.07)	$ (0.07)
Diluted loss per share	$ (0.09)	$ (0.07)	$ (0.07)	$ (0.07)

(i) See Note 2 for revenue recognition.

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	At Market Issuance Sales Agreement dated April 18, 2013 between Acura Pharmaceuticals, Inc. and MLV & Co. LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Form 8-K filed on April 18, 2013)
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	Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on March 3, 2009).
10.1	License, Development and Commercialization Agreement dated October 30, 2007 by and between the Registrant and King Pharmaceuticals Research and Development, Inc. (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on November 2, 2007)
10.2	Letter Agreement dated as of September 24, 2012 by and between the Registrant and King Pharmaceuticals Research and Development, Inc. (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on September 26, 2012) (confidential treatment has been granted for portions of this Exhibit).
10.3	Letter Agreement dated April 9, 2014 between King Pharmaceuticals Research and Development Inc. and Registrant terminating License, Development and Commercialization Agreement dated October 30, 2007 (Incorporated by Reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ending June 30, 2014 filed on August 4, 2014) (confidential treatment has been granted for portions of this Exhibit).
10.4	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)
10.5	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).
10.6	Form of Warrant dated as of August 20, 2007 issued pursuant to the PIPE SPA (incorporated by reference to Exhibit 4.1 to the Form 8-K filed on August 21, 2007)(These warrants expired in 2014).
10.7	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)

Exhibit Number	Exhibit Description
*10.8	First Amendment to Loan and Security Agreement entered into as of January 7, 2015 between Oxford Finance LLC , the Registrant and APT
*10.9	Amended and Restated Warrant A-1 issued to Oxford Finance LLC on January 7, 2015
*10.10	Amended and Restated Warrant A-2 issued to Oxford Finance LLC on January 7, 2015
*10.11	Amended and Restated Warrant A-3 issued to Oxford Finance LLC on January 7, 2015
10.12	Form of Mortgage dated December 27, 2013(incorporated by reference to Exhibit 10.8 to the Form 10-K filed March 3, 2014)
*10.13	Collaboration and License Agreement 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 requested with respect to the omitted portion).
10.14	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")).
10.15	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).
10.16	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).
10.17	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).
†10.18	Registrant's 1995 Stock Option and Restricted Stock Purchase Plan (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8, File No. 33-98396).
†10.19	Registrant's 1998 Stock Option Plan, as amended (incorporated by reference to Appendix C to the Registrant's Proxy Statement filed on May 12, 2009).
†10.20	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).
†10.21	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).

Exhibit Number	Exhibit Description
†10.22	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).
†10.23	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).
†10.24	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 2005 Form 10-K).
†10.25	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).
†10.26	Third Amendment to Executive Employment Agreement dated December 22, 2005 between Registrant and Clemens (incorporated by reference to Exhibit 10.3 to the December 2005 Form 8-K).
†10.27	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).
†10.28	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).
†10.29	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).
†10.30	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)
†10.31	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).
†10.32	Amendment to Executive Employment Agreement dated as of April 28, 2011 between the Registrant and Robert B. Jones (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed July 28, 2011)
†10.33	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).
†10.34	Strategic Transaction Bonus Grant Agreement dated February 28, 2013 between the Registrant and Robert B. Jones (incorporated by reference to Exhibit 10.1 of our Form 10-Q for the quarter ending March 31, 2013, filed May 2, 2013)

Exhibit Number	Exhibit Description
†10.35	Strategic Transaction Bonus Grant Agreement dated February 28, 2013 between the Registrant and Peter A. Clemens (incorporated by reference to Exhibit 10.2 of our Form 10-Q filed for the quarter ending March 31, 2013, filed May 2, 2013).
10.36	Stipulation of Settlement dated October 31, 2011 re: Class Action Litigation (incorporated by reference to Exhibit 10.1 to our Form 8-K filed November 4, 2011)
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 BDO USA, LLP, 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 10.8

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT to Loan and Security Agreement (this " **Amendment** ") is entered into as of January 7, 2015 (the " **Amendment Date** "), by and among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 (in its individual capacity, " **Oxford** "; and in its capacity as Collateral Agent, " **Collateral Agent** "), the Lenders listed on Schedule 1.1 thereof from time to time including Oxford in its capacity as a Lender (each a " **Lender** " and collectively, the " **Lenders** ") and ACURA PHARMACEUTICALS, INC., a New York corporation with offices located at 616 N. North Court, Suite 120, Palatine, Illinois (" **Parent** ") and ACURA PHARMACEUTICAL TECHNOLOGIES, INC., an Indiana corporation with offices locates at 16235 State Road 17, Culver, IN 46511 (" **APT** ", and along with Parent, individually and collectively, jointly and severally, " **Borrower** ").

WHEREAS, Collateral Agent, Borrower and Lenders party thereto from time to time have entered into that certain Loan and Security Agreement, dated as of December 27, 2013 (as amended, supplemented or otherwise modified from time to time, the " **Loan Agreement** ") pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

WHEREAS, Borrower, Lenders and Collateral Agent desire to amend certain provisions of the Loan Agreement as provided herein and subject to the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, Lenders and Collateral Agent hereby agree as follows:

1. Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Loan Agreement.

2. In exchange for each Warrant issued to the Lenders or their Affiliates by Parent on the Effective Date, on the date hereof, Parent will issue to the holder thereof an Amended and Restated Warrant, exercisable for the same number of shares in such form and substance as agreed to by the parties.

3. Section 6.10 of the Loan Agreement is hereby amended and restated in its entirety as follows:

   "6.10 **Financial Covenant** . For so long as the aggregate outstanding principal amount of all Term Loans made hereunder is Five Million Dollars ($5,000,000.00) or more, Borrower shall maintain total cash reserves of at least Two Million Five Hundred Thousand Dollars ($2,500,000.00) in Collateral Accounts which are subject to a Control Agreement in favor of Collateral Agent and maintained in accordance with the terms of Section 6.6."

4. Section 8.2(a) of the Loan Agreement is hereby amended and restated in its entirety as follows:

   "(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.10 (Financial Covenant), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or"

5. Section 13.1 of the Loan Agreement is hereby amended by adding the following definition thereto in alphabetical order:

""Egalet License" is that certain Collaboration and License Agreement, made and entered into as of January 7, 2015, by and between the Parent and Egalet US Inc., a corporation organized and existing under the laws of the State of Delaware, having offices at 460 East Swedesford Road, Suite 19087, Wayne, PA, Egalet Limited., a company organized under the laws of England and Wales with its principal place of business at 33 St. James' Square, London SW1Y 4JS, United Kingdom and guaranteed by Egalet Corporation, a corporation organized and existing under the laws of the State of Delaware, having offices located at 60 East Swedesford Road, Suite 1050, Wayne, PA, an executed, true and complete copy of which has been provided by Borrower to Collateral Agent on or before the Amendment Date; provided, however, that the Egalet License for the purposes of this Agreement shall not include any amendment to the licenses granted by Borrower thereunder unless any new or modified license granted by Borrower in such amendment is a Permitted License and the consent, if any, of Collateral Agent or the Lenders required under the definition of Permitted License is obtained by Borrower in advance of such amendment; provided further that Egalet License for the purposes of this Agreement shall not include any amendment which would lower the milestone payments, co-promotion rates, or royalty rates thereof or any amendment to Sections 4.3, 8.2, 11.1.3, 11.2.2 or 17.2 thereof unless such amendment is consented to by the Collateral Agent."

6. Section 13.1 of the Loan Agreement is hereby amended by amending and restating the definition of " **Permitted Licenses** " therein as follows:

"" **Permitted Licenses** " are (A) licenses of over-the-counter software that is commercially available to the public, (B) the Egalet License and non-exclusive and exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), (i) no Event of Default has occurred and is continuing at the time of such license; (ii) the license constitutes an arms length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers to Collateral Agent and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof and (y) any such license could not result in a legal transfer of title of the licensed property, but may be exclusive as to geographic areas outside the United States, and may be exclusive in the United States (and its territories and possessions) subject to the prior written consent of Required Lenders, and the Required Lenders shall be obligated to respond to Borrower within ten (10) calendar days regarding their decision to grant or withhold such consent after receipt of a request for such consent from Borrower in writing; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement; provided that the parties acknowledge and agree that notwithstanding clauses (ii) and (iii), the Egalet License includes an assignment of the Product NDA (as defined in the Egalet License) and associated IND (as defined in the Egalet License), the other documents and items specified in Sections 4.3, 8.2, 11.1.3 and 11.2.2 of the Egalet License and the provisions of Section 17.2 of the Egalet License, and the restrictions of clauses (ii) and (iii) shall not apply to same; provided further that the parties acknowledge and agree that the Egalet License has been consented to by the Collateral Agent and the Required Lenders."

7. Limitation of Amendment.

   a. The amendments set forth in Sections 2 through 5 above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

   b. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

8. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

    a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

    b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

    c. The organizational documents of Borrower delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by the Borrower to the Collateral Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

    d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (i) any law or regulation binding on or affecting Borrower, (ii) any contractual restriction with a Person binding on Borrower, (iii) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

    e. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

    f. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

9. Collateral Agent represents and warrants to Borrower that all Required Lenders have executed this Amendment.

10. Except as expressly set forth herein, the Loan Agreement shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

11. This Amendment shall be deemed effective as of the Amendment Date upon (a) the due execution and delivery to Collateral Agent of this Amendment by each party hereto and (b) Borrower's payment of all Lenders' Expenses incurred through the date hereof, which may be debited from any of Borrower's accounts with Lenders *provided however* , that Lender's Expenses in connection with this Amendment shall not exceed $ **7,500** .

12. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument.

13. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of New York.

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IN WITNESS WHEREOF , the parties hereto have caused this First Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

ACURA PHARMACEUTICALS, INC.

By: /s/ Peter A. Clemens
Name: Peter A. Clemens
Title: Sr. VP & CFO

BORROWER:

ACURA PHARMACEUTICAL TECHNOLOGIES, INC.

By: /s/ Peter A. Clemens
Name: Peter A. Clemens
Title: Sr. VP & CFO

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: /s/Mark Davis
Name: Mark Davis
Title: Vice President-Finance, Secretary & Treasurer

EXHIBIT A
Form of Warrant

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE " **ACT** "), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 5.3 AND 5.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

AMENDED AND RESTATED WARRANT TO PURCHASE STOCK (A3)

Company:	ACURA PHARMACEUTICALS, INC., a New York corporation
Number of Shares:	[____]
Type/Series of Stock:	Common Stock
Warrant Price:	$[___] per share (which represents the average closing price of the Company's common stock for the previous ten days of trading, calculated on the day before the issuance of this Warrant)
Issue Date:	[_____]
Expiration Date:	[_____] See also Section 5.1(b).
Credit Facility:	This Amended and Restated Warrant to Purchase Stock (" **Warrant** ") is issued in connection with that certain Loan and Security Agreement of even date herewith among Oxford Finance LLC, as Lender and Collateral Agent, the Lenders from time to time party thereto, and the Company and (as modified, amended and/or restated from time to time, the " **Loan Agreement** ").

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, OXFORD FINANCE LLC (" **Oxford** " and, together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, " **Holder** ") is entitled to purchase the number of fully paid and non-assessable shares (the " **Shares** ") of the above-stated Type/Series of Stock (the " **Class** ") of the above-named company (the " **Company** ") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant. This Warrant amends and restates in its entirety that certain warrant numbered [__], issued by the Company on December 27, 2013.

1. EXERCISE.

1.1 Method of Exercise . Holder may at any time and from time to time exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Cashless Exercise . On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

X = Y(A-B)/A

where:

X = the number of Shares to be issued to the Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);

A = the Fair Market Value (as determined pursuant to Section 1.3 below) of one Share; and

B = the Warrant Price.

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

1.4 Delivery of Certificate and New Warrant . Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.

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

1.6 Treatment of Warrant Upon Acquisition of Company .

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

(b) Treatment of Warrant at Acquisition . In the event of an Acquisition in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a " **Cash/Public Acquisition** "), either (i) Holder shall exercise this Warrant pursuant to Section 1.1 and/or 1.2 and such exercise will be deemed effective immediately prior to and contingent upon the consummation of such Acquisition or (ii) if Holder elects not to exercise the Warrant, this Warrant will expire immediately prior to the consummation of such Acquisition.

(c) The Company shall provide Holder with written notice of its request relating to the Cash/Public Acquisition (together with such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such contemplated Cash/Public Acquisition giving rise to such notice), which is to be delivered to Holder not less than seven (7) Business Days prior to the closing of the proposed Cash/Public Acquisition. In the event the Company does not provide such notice, then if, immediately prior to the Cash/Public Acquisition, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon such exercise to the Holder and Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as the date thereof.

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

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

2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

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

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

2.3 Intentionally Left Blank .

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

2.5 No Fractional Share . No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.

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

3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 Representations and Warranties . The Company represents and warrants to, and agrees with, the Holder as follows:

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

(b) The Company's capitalization table attached hereto as Schedule 1 is true and complete, in all material respects, as of the Issue Date.

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

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

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

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

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

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

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

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

Reference is made to Section 1.6(c) whereby this Warrant will be deemed to be exercised pursuant to Section 1.2 hereof if the Company does not give written notice to Holder of an Acquisition as required by the terms hereof. Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

4. REPRESENTATIONS, WARRANTIES OF THE HOLDER.

The Holder represents and warrants to the Company as follows:

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

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

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

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

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

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

5. MISCELLANEOUS.

5.1 Term; Automatic Cashless Exercise Upon Expiration .

(a) Term . Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Eastern time, on the Expiration Date and shall be void thereafter.

(b) Automatic Cashless Exercise upon Expiration . In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall, within a reasonable time, deliver a certificate representing the Shares (or such other securities) issued upon such exercise to Holder.

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

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

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

5.4 Intentionally Left Blank.

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

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

Oxford Finance LLC
133 N. Fairfax Street
Alexandria, VA 22314
Attn: Legal Department
Telephone: (703) 519-4900
Facsimile: (703) 519-5225
Email: LegalDepartment@oxfordfinance.com

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

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

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

LeClairRyan
One Riverfront Plaza
1037 Raymond Boulevard
Sixteenth Floor
Newark, New Jersey 07102
Attn: John P. Reilly
Fax: (973) 491-3511
Email: John.Reilly@leclairryan.com

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

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

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

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

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

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

[Remainder of page left blank intentionally]

[Signature page follows]

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

"COMPANY"

ACURA PHARMACEUTICALS, INC.

By: _____

Name: _____
(Print)
Title: _____

"HOLDER"

OXFORD FINANCE LLC

By: _____

Name: _____
(Print)
Title: _____

APPENDIX 1

NOTICE OF EXERCISE

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

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

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

☐ Cashless Exercise pursuant to Section 1.2 of the Warrant

☐ Other [Describe] _____

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

_____

Holder's Name

_____

_____

(Address)

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

HOLDER:

_____

By: _____

Name: _____

Title: _____

Date: _____

APPENDIX 2

ASSIGNMENT

For value received, Oxford Finance LLC hereby sells, assigns and transfers unto

Name: [OXFORD TRANSFEREE]

Address:_ _____

Tax ID: _____]

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

OXFORD FINANCE LLC

By: _____

Name: _____

Title: _____

Date: _____

By its execution below, and for the benefit of the Company, [OXFORD TRANSFEREE] makes each of the representations and warranties set forth in Article 4 of the Warrant and agrees to all other provisions of the Warrant as of the date hereof.

[OXFORD TRANSFEREE]

By: _____

Name: _____

Title: _____]

SCHEDULE 1

Company Capitalization Table

See attached

Exhibit 10.9

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE " **ACT** "), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 5.3 AND 5.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

AMENDED AND RESTATED WARRANT TO PURCHASE STOCK (A1)

Company:	ACURA PHARMACEUTICALS, INC., a New York corporation
Number of Shares:	178,683
Type/Series of Stock:	Common Stock
Warrant Price:	$0.504 per share (which represents the average closing price of the Company's common stock for the previous ten days of trading, calculated on the day before the issuance of this Warrant)
Issue Date:	January 7, 2015
Expiration Date:	December 27, 2020. See also Section 5.1(b).
Credit Facility:	This Amended and Restated Warrant to Purchase Stock (" **Warrant** ") is issued in connection with that certain Loan and Security Agreement of even date herewith among Oxford Finance LLC, as Lender and Collateral Agent, the Lenders from time to time party thereto, and the Company and (as modified, amended and/or restated from time to time, the " **Loan Agreement** ").

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, OXFORD FINANCE LLC (" **Oxford** " and, together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, " **Holder** ") is entitled to purchase the number of fully paid and non-assessable shares (the " **Shares** ") of the above-stated Type/Series of Stock (the " **Class** ") of the above-named company (the " **Company** ") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant. This Warrant amends and restates in its entirety that certain warrant numbered A1, issued by the Company on December 27, 2013.

SECTION 1. EXERCISE.

1.1 Method of Exercise . Holder may at any time and from time to time exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Cashless Exercise . On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

X = Y(A-B)/A

where:

X = the number of Shares to be issued to the Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);

A = the Fair Market Value (as determined pursuant to Section 1.3 below) of one Share; and

B = the Warrant Price.

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

1.4 Delivery of Certificate and New Warrant . Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.

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

1.6 Treatment of Warrant Upon Acquisition of Company .

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

(b) Treatment of Warrant at Acquisition . In the event of an Acquisition in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a " **Cash/Public Acquisition** "), either (i) Holder shall exercise this Warrant pursuant to Section 1.1 and/or 1.2 and such exercise will be deemed effective immediately prior to and contingent upon the consummation of such Acquisition or (ii) if Holder elects not to exercise the Warrant, this Warrant will expire immediately prior to the consummation of such Acquisition.

(c) The Company shall provide Holder with written notice of its request relating to the Cash/Public Acquisition (together with such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such contemplated Cash/Public Acquisition giving rise to such notice), which is to be delivered to Holder not less than seven (7) Business Days prior to the closing of the proposed Cash/Public Acquisition. In the event the Company does not provide such notice, then if, immediately prior to the Cash/Public Acquisition, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon such exercise to the Holder and Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as the date thereof.

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

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

SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

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

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

2.3 Intentionally Left Blank .

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

2.5 No Fractional Share . No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.

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

SECTION 3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 Representations and Warranties . The Company represents and warrants to, and agrees with, the Holder as follows:

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

(b) The Company's capitalization table attached hereto as Schedule 1 is true and complete, in all material respects, as of the Issue Date.

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

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

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

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

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

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

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

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

Reference is made to Section 1.6(c) whereby this Warrant will be deemed to be exercised pursuant to Section 1.2 hereof if the Company does not give written notice to Holder of an Acquisition as required by the terms hereof. Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

SECTION 4. REPRESENTATIONS, WARRANTIES OF THE HOLDER.

The Holder represents and warrants to the Company as follows:

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

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

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

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

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

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

SECTION 5. MISCELLANEOUS.

5.1 Term; Automatic Cashless Exercise Upon Expiration .

(a) Term . Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Eastern time, on the Expiration Date and shall be void thereafter.

(b) Automatic Cashless Exercise upon Expiration . In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall, within a reasonable time, deliver a certificate representing the Shares (or such other securities) issued upon such exercise to Holder.

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

> THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE " **ACT** "), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO OXFORD FINANCE LLC DATED JANUARY 7, 2015, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

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

5.4 Intentionally Left Blank.

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

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

Oxford Finance LLC
133 N. Fairfax Street
Alexandria, VA 22314
Attn: Legal Department
Telephone: (703) 519-4900
Facsimile: (703) 519-5225
Email: LegalDepartment@oxfordfinance.com

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

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

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

LeClairRyan
One Riverfront Plaza
1037 Raymond Boulevard
Sixteenth Floor
Newark, New Jersey 07102
Attn: John P. Reilly
Fax: (973) 491-3511
Email: John.Reilly@leclairryan.com

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

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

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

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

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

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

[Remainder of page left blank intentionally]

[Signature page follows]

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

"COMPANY"

ACURA PHARMACEUTICALS, INC.

By: /s/Peter A. Clemens

Name: Peter A. Clemens
(Print)
Title: Sr. VP & CFO

"HOLDER"

OXFORD FINANCE LLC

By: /s/Mark Davis

Name: Mark Davis
(Print)
Title: Vice President-Finance, Secretary & Treasurer

APPENDIX 1

NOTICE OF EXERCISE

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

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

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

☐ Cashless Exercise pursuant to Section 1.2 of the Warrant

☐ Other [Describe] _____

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

_____
Holder's Name

_____

_____
(Address)

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

HOLDER:

_____

By: _____

Name: _____

Title: _____

Date: _____

APPENDIX 2

ASSIGNMENT

For value received, Oxford Finance LLC hereby sells, assigns and transfers unto

Name: [OXFORD TRANSFEREE]

Address: _____

Tax ID: _____]

that certain Warrant to Purchase Stock issued by ACURA PHARMACEUTICALS, INC. (the " **Company** "), on January 7, 2015 (the " **Warrant** ") together with all rights, title and interest therein.

OXFORD FINANCE LLC

By: _____

Name: _____

Title: _____

Date: _____

By its execution below, and for the benefit of the Company, [OXFORD TRANSFEREE] makes each of the representations and warranties set forth in Article 4 of the Warrant and agrees to all other provisions of the Warrant as of the date hereof.

[OXFORD TRANSFEREE]

By: _____

Name: _____

Title: _____]

SCHEDULE 1

Company Capitalization Table

Beneficial Owner	Comon Stock Outstanding	Restricted Stock Units	Common Stock Warrants	Common Stock Options	Fully Diluted Shares	Percent of Total
Galen Partners III, L.P.	10,284,671		-	-	10,284,671	19.09%
Galen Partners International III, L.P.	927,460		-	-	927,460	1.72%
Galen Employee Fund III, L.P.	42,367		-	-	42,367	0.08%
Essex Woodlands Health Ventures V	9,781,985		-	-	9,781,985	18.16%
Robert Jones	62,778		-	1,159,500	1,222,278	2.27%
Peter A. Clemens	279,518		-	600,000	879,518	1.63%
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James Emigh	198,304		-	342,500	540,804	1.00%
Albert Brzeczko	26,000		-	452,000	478,000	0.89%
William Skelly	5,000	36,764	-	90,000	131,764	0.24%
Bruce Wesson	94,904	36,764	-	90,000	221,668	0.41%
George Ross	3,000	36,764	-	90,000	129,764	0.24%
Immanuel Thangaraj	-	36,764	-	90,000	126,764	0.24%
Brad Rivet	2,000		-	266,000	268,000	0.50%
Other employees	437,383		-	910,667	1,348,050	2.50%
Non-insiders	**26,591,887**		**297,805**	**111,250**	**27,000,942**	**50.12%**
Totals	**48,847,982**	**147,056**	**297,805**	**4,576,417**	**53,869,260**	**100.0%**
Percent of Total	**90.7%**	**0.3%**	**0.6%**	**8.5%**	**100.0%**	

Does Not Include 51,546 RSUs (206,184) being issued to each of 4 Non-Employee Directors on 1/2/2015 or exchange of existing RSUs on 1/2//2015

Exhibit 10.10

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE " **ACT** "), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 5.3 AND 5.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

AMENDED AND RESTATED WARRANT TO PURCHASE STOCK (A2)

Company:	ACURA PHARMACEUTICALS, INC., a New York corporation
Number of Shares:	74,451
Type/Series of Stock:	Common Stock
Warrant Price:	$0.504 per share (which represents the average closing price of the Company's common stock for the previous ten days of trading, calculated on the day before the issuance of this Warrant)
Issue Date:	January 7, 2015
Expiration Date:	December 27, 2020. See also Section 5.1(b).
Credit Facility:	This Amended and Restated Warrant to Purchase Stock (" **Warrant** ") is issued in connection with that certain Loan and Security Agreement of even date herewith among Oxford Finance LLC, as Lender and Collateral Agent, the Lenders from time to time party thereto, and the Company and (as modified, amended and/or restated from time to time, the " **Loan Agreement** ").

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, OXFORD FINANCE LLC (" **Oxford** " and, together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, " **Holder** ") is entitled to purchase the number of fully paid and non-assessable shares (the " **Shares** ") of the above-stated Type/Series of Stock (the " **Class** ") of the above-named company (the " **Company** ") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant. This Warrant amends and restates in its entirety that certain warrant numbered A2, issued by the Company on December 27, 2013.

SECTION 1. EXERCISE.

1.1 Method of Exercise . Holder may at any time and from time to time exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Cashless Exercise . On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

X = Y(A-B)/A

where:

X = the number of Shares to be issued to the Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);

A = the Fair Market Value (as determined pursuant to Section 1.3 below) of one Share; and

B = the Warrant Price.

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

1.4 Delivery of Certificate and New Warrant . Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.

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

1.6 Treatment of Warrant Upon Acquisition of Company .

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

(b) Treatment of Warrant at Acquisition . In the event of an Acquisition in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a " **Cash/Public Acquisition** "), either (i) Holder shall exercise this Warrant pursuant to Section 1.1 and/or 1.2 and such exercise will be deemed effective immediately prior to and contingent upon the consummation of such Acquisition or (ii) if Holder elects not to exercise the Warrant, this Warrant will expire immediately prior to the consummation of such Acquisition.

(c) The Company shall provide Holder with written notice of its request relating to the Cash/Public Acquisition (together with such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such contemplated Cash/Public Acquisition giving rise to such notice), which is to be delivered to Holder not less than seven (7) Business Days prior to the closing of the proposed Cash/Public Acquisition. In the event the Company does not provide such notice, then if, immediately prior to the Cash/Public Acquisition, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon such exercise to the Holder and Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as the date thereof.

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

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

SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

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

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

2.3 Intentionally Left Blank .

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

2.5 No Fractional Share . No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.

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

SECTION 3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 Representations and Warranties . The Company represents and warrants to, and agrees with, the Holder as follows:

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

(b) The Company's capitalization table attached hereto as Schedule 1 is true and complete, in all material respects, as of the Issue Date.

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

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

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

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

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

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

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

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

Reference is made to Section 1.6(c) whereby this Warrant will be deemed to be exercised pursuant to Section 1.2 hereof if the Company does not give written notice to Holder of an Acquisition as required by the terms hereof. Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

SECTION 4. REPRESENTATIONS, WARRANTIES OF THE HOLDER.

The Holder represents and warrants to the Company as follows:

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

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

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

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

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

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

SECTION 5. MISCELLANEOUS.

5.1 Term; Automatic Cashless Exercise Upon Expiration .

(a) Term . Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Eastern time, on the Expiration Date and shall be void thereafter.

(b) Automatic Cashless Exercise upon Expiration . In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall, within a reasonable time, deliver a certificate representing the Shares (or such other securities) issued upon such exercise to Holder.

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

> THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE " **ACT** "), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO OXFORD FINANCE LLC DATED JANUARY 7, 2015, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

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

5.4 Intentionally Left Blank.

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

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

Oxford Finance LLC
133 N. Fairfax Street
Alexandria, VA 22314
Attn: Legal Department
Telephone: (703) 519-4900
Facsimile: (703) 519-5225
Email: LegalDepartment@oxfordfinance.com

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

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

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

LeClairRyan
One Riverfront Plaza
1037 Raymond Boulevard
Sixteenth Floor
Newark, New Jersey 07102
Attn: John P. Reilly
Fax: (973) 491-3511
Email: John.Reilly@leclairryan.com

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

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

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

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

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

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

[Remainder of page left blank intentionally]

[Signature page follows]

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

"COMPANY"

ACURA PHARMACEUTICALS, INC.

By: /s/Peter A. Clemens

Name: Peter A. Clemens
(Print)
Title: Sr. VP & CFO

"HOLDER"

OXFORD FINANCE LLC

By: /s/Mark Davis

Name: Mark Davis
(Print)
Title: Vice President-Finance, Secretary & Treasurer

[Signature Page to Warrant to Purchase Stock-A2]

APPENDIX 1

NOTICE OF EXERCISE

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

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

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

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☐ Other [Describe] _____

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

_____
Holder's Name

_____

_____
(Address)

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

HOLDER:

_____

By: _____

Name: _____

Title: _____

Date: _____

APPENDIX 2

ASSIGNMENT

For value received, Oxford Finance LLC hereby sells, assigns and transfers unto

Name: [OXFORD TRANSFEREE]

Address: _____

Tax ID: _____]

that certain Warrant to Purchase Stock issued by ACURA PHARMACEUTICALS, INC. (the " **Company** "), on January 7, 2015 (the " **Warrant** ") together with all rights, title and interest therein.

OXFORD FINANCE LLC

By: _____

Name: _____

Title: _____

Date: _____

By its execution below, and for the benefit of the Company, [OXFORD TRANSFEREE] makes each of the representations and warranties set forth in Article 4 of the Warrant and agrees to all other provisions of the Warrant as of the date hereof.

[OXFORD TRANSFEREE]

By: _____

Name: _____

Title: _____]

SCHEDULE 1

Company Capitalization Table

Beneficial Owner	Comon Stock Outstanding	Restricted Stock Units	Common Stock Warrants	Common Stock Options	Fully Diluted Shares	Percent of Total
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Brad Rivet	2,000		-	266,000	268,000	0.50%
Other employees	437,383		-	910,667	1,348,050	2.50%
Non-insiders	**26,591,887**		**297,805**	**111,250**	**27,000,942**	**50.12%**
Totals	**48,847,982**	**147,056**	**297,805**	**4,576,417**	**53,869,260**	**100.0%**
Percent of Total	**90.7%**	**0.3%**	**0.6%**	**8.5%**	**100.0%**	

Does Not Include 51,546 RSUs (206,184) being issued to each of 4 Non-Employee Directors on 1/2/2015 or exchange of existing RSUs on 1/2//2015

Exhibit 10.11

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE " **ACT** "), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 5.3 AND 5.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

AMENDED AND RESTATED WARRANT TO PURCHASE STOCK (A3)

Company:	ACURA PHARMACEUTICALS, INC., a New York corporation
Number of Shares:	44,671
Type/Series of Stock:	Common Stock
Warrant Price:	$0.504 per share (which represents the average closing price of the Company's common stock for the previous ten days of trading, calculated on the day before the issuance of this Warrant)
Issue Date:	January7, 2015
Expiration Date:	December 27, 2020. See also Section 5.1(b).
Credit Facility:	This Amended and Restated Warrant to Purchase Stock (" **Warrant** ") is issued in connection with that certain Loan and Security Agreement of even date herewith among Oxford Finance LLC, as Lender and Collateral Agent, the Lenders from time to time party thereto, and the Company and (as modified, amended and/or restated from time to time, the " **Loan Agreement** ").

THIS WARRANT CERTIFIES THAT, for good and valuable consideration, OXFORD FINANCE LLC (" **Oxford** " and, together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, " **Holder** ") is entitled to purchase the number of fully paid and non-assessable shares (the " **Shares** ") of the above-stated Type/Series of Stock (the " **Class** ") of the above-named company (the " **Company** ") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant. This Warrant amends and restates in its entirety that certain warrant numbered A3, issued by the Company on December 27, 2013.

SECTION 1. EXERCISE.

1.1 Method of Exercise . Holder may at any time and from time to time exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Cashless Exercise . On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

X = Y(A-B)/A

where:

X = the number of Shares to be issued to the Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);

A = the Fair Market Value (as determined pursuant to Section 1.3 below) of one Share; and

B = the Warrant Price.

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

1.4 Delivery of Certificate and New Warrant . Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired.

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

1.6 Treatment of Warrant Upon Acquisition of Company .

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

(b) Treatment of Warrant at Acquisition . In the event of an Acquisition in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a " **Cash/Public Acquisition** "), either (i) Holder shall exercise this Warrant pursuant to Section 1.1 and/or 1.2 and such exercise will be deemed effective immediately prior to and contingent upon the consummation of such Acquisition or (ii) if Holder elects not to exercise the Warrant, this Warrant will expire immediately prior to the consummation of such Acquisition.

(c) The Company shall provide Holder with written notice of its request relating to the Cash/Public Acquisition (together with such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such contemplated Cash/Public Acquisition giving rise to such notice), which is to be delivered to Holder not less than seven (7) Business Days prior to the closing of the proposed Cash/Public Acquisition. In the event the Company does not provide such notice, then if, immediately prior to the Cash/Public Acquisition, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon such exercise to the Holder and Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as the date thereof.

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

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

SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

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

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

2.3 Intentionally Left Blank .

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

2.5 No Fractional Share . No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.

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

SECTION 3. REPRESENTATIONS AND COVENANTS OF THE COMPANY.

3.1 Representations and Warranties . The Company represents and warrants to, and agrees with, the Holder as follows:

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

(b) The Company's capitalization table attached hereto as Schedule 1 is true and complete, in all material respects, as of the Issue Date.

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

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

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

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

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

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

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

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

Reference is made to Section 1.6(c) whereby this Warrant will be deemed to be exercised pursuant to Section 1.2 hereof if the Company does not give written notice to Holder of an Acquisition as required by the terms hereof. Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

SECTION 4. REPRESENTATIONS, WARRANTIES OF THE HOLDER.

The Holder represents and warrants to the Company as follows:

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

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

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

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

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

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

SECTION 5. MISCELLANEOUS.

5.1 Term; Automatic Cashless Exercise Upon Expiration .

(a) Term . Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Eastern time, on the Expiration Date and shall be void thereafter.

(b) Automatic Cashless Exercise upon Expiration . In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall, within a reasonable time, deliver a certificate representing the Shares (or such other securities) issued upon such exercise to Holder.

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

> THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE " **ACT** "), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO OXFORD FINANCE LLC DATED JANUARY 7, 2015, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

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

5.4 Intentionally Left Blank.

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

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

Oxford Finance LLC
133 N. Fairfax Street
Alexandria, VA 22314
Attn: Legal Department
Telephone: (703) 519-4900
Facsimile: (703) 519-5225
Email: LegalDepartment@oxfordfinance.com

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

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

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

LeClairRyan
One Riverfront Plaza
1037 Raymond Boulevard
Sixteenth Floor
Newark, New Jersey 07102
Attn: John P. Reilly
Fax: (973) 491-3511
Email: John.Reilly@leclairryan.com

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

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

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

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

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

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

[Remainder of page left blank intentionally]

[Signature page follows]

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

"COMPANY"

ACURA PHARMACEUTICALS, INC.

By: /s/Peter A. Clemens

Name: Peter A. Clemens
(Print)
Title: Sr. VP & CFO

"HOLDER"

OXFORD FINANCE LLC

By: /s/Mark Davis

Name: Mark Davis
(Print)
Title: Vice President-Finance, Secretary & Treasurer

APPENDIX 1

NOTICE OF EXERCISE

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

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

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

☐ Cashless Exercise pursuant to Section 1.2 of the Warrant

☐ Other [Describe] _____

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

_____
Holder's Name

_____

_____
(Address)

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

HOLDER:

_____

By: _____

Name: _____

Title: _____

Date: _____

APPENDIX 2

ASSIGNMENT

For value received, Oxford Finance LLC hereby sells, assigns and transfers unto

Name: [OXFORD TRANSFEREE]

Address: _____

Tax ID: _____]

that certain Warrant to Purchase Stock issued by ACURA PHARMACEUTICALS, INC. (the " **Company** "), on January 7, 2015 (the " **Warrant** ") together with all rights, title and interest therein.

OXFORD FINANCE LLC

By: _____

Name: _____

Title: _____

Date: _____

By its execution below, and for the benefit of the Company, [OXFORD TRANSFEREE] makes each of the representations and warranties set forth in Article 4 of the Warrant and agrees to all other provisions of the Warrant as of the date hereof.

[OXFORD TRANSFEREE]

By: _____

Name: _____

Title: _____]

SCHEDULE 1

Company Capitalization Table

Beneficial Owner	Comon Stock Outstanding	Restricted Stock Units	Common Stock Warrants	Common Stock Options	Fully Diluted Shares	Percent of Total
Galen Partners III, L.P.	10,284,671		-	-	10,284,671	19.09%
Galen Partners International III, L.P.	927,460		-	-	927,460	1.72%
Galen Employee Fund III, L.P.	42,367		-	-	42,367	0.08%
Essex Woodlands Health Ventures V	9,781,985		-	-	9,781,985	18.16%
Robert Jones	62,778		-	1,159,500	1,222,278	2.27%
Peter A. Clemens	279,518		-	600,000	879,518	1.63%
Robert Seiser	110,725		-	374,500	485,225	0.90%
James Emigh	198,304		-	342,500	540,804	1.00%
Albert Brzeczko	26,000		-	452,000	478,000	0.89%
William Skelly	5,000	36,764	-	90,000	131,764	0.24%
Bruce Wesson	94,904	36,764	-	90,000	221,668	0.41%
George Ross	3,000	36,764	-	90,000	129,764	0.24%
Immanuel Thangaraj	-	36,764	-	90,000	126,764	0.24%
Brad Rivet	2,000		-	266,000	268,000	0.50%
Other employees	437,383		-	910,667	1,348,050	2.50%
Non-insiders	**26,591,887**		**297,805**	**111,250**	**27,000,942**	**50.12%**
Totals	**48,847,982**	**147,056**	**297,805**	**4,576,417**	**53,869,260**	**100.0%**
Percent of Total	**90.7%**	**0.3%**	**0.6%**	**8.5%**	**100.0%**	

Does Not Include 51,546 RSUs (206,184) being issued to each of 4 Non-Employee Directors on 1/2/2015 or exchange of existing RSUs on 1/2//2015

Exhibit 10.13

EXECUTION COPY

COLLABORATION AND LICENSE AGREEMENT

BETWEEN

ACURA PHARMACEUTICALS, INC.

EGALET US, INC.

AND

EGALET LIMITED

DATED

JANUARY 7, 2015

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (this " *Agreement* ") is made and entered into as of January 7, 2015 (the "Effective Date"), by and between Acura Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of New York, having offices located at 616 N. North Court, Suite 120, Palatine, IL 60067 (" *Acura* "), Egalet US, Inc., a corporation organized under the laws of the State of Delaware, having offices at 460 East Swedesford Road, Suite 19087, Wayne, PA (" *Egalet US* "), with respect to all rights and obligations under this Agreement in the United States (subject to Section 17.19), Egalet Limited, a company organized under the laws of England and Wales with its principal place of business at 33 St. James' Square, London SW1Y 4JS, United Kingdom (" *Egalet UK* "), with respect to all rights and obligations under this Agreement outside of the United States (subject to Section 17.19) (Egalet US and Egalet UK individually, a " *Egalet Entity* ," and together, " *Egalet* "), and for purposes of Section 17.21 Egalet Corporation, a corporation organized under the laws of the State of Delaware, having offices at 460 East Swedesford Road, Wayne, PA.

PRELIMINARY STATEMENTS

The Parties wish to collaborate on the commercialization of the Product pursuant to which Egalet will license the Product from Acura and be responsible for the manufacture and commercialization of the Product, subject to Acura's Co-Promotion Rights. Egalet will make an upfront payment and an additional payment to Acura and pay Acura a Sales Milestone Payment and royalties, in accordance with this Agreement.

NOW, THEREFORE, in consideration of the foregoing preliminary statements and the mutual agreements and covenants set forth herein, the Parties hereby agree as follows:

1. DEFINITIONS

1.1 "*AAA*" shall have the meaning assigned to such term in Section 16.2.

1.2 "*Acura*" shall have the meaning assigned to such term in the preamble.

1.3 "*Acura Expense Recovery Amount*" has the meaning assigned to such term in Exhibit 10.8 .

1.4 "*Acura License Agreements*" shall have the meaning assigned to such term in Section 2.2.2 .

1.5 "*Affiliate*" means, with respect to a Party, any entity controlling, controlled by, or under common control with, such Party, for only so long as such control exists. For these purposes, "control" shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of an entity. Notwithstanding the foregoing, a private equity or venture capital firm with an ownership interest in an entity shall not be an Affiliate by reason of such ownership .

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1.6 "*Agreement"* means this Collaboration and License Agreement together with all exhibits, schedules and attachments hereto .

1.7 "*AMP"* shall have the meaning assigned to such term in Section 5.3.5 .

1.8 "*Anti-Kickback Statute"* means the Federal Health Care Programs Anti-Kickback Law, Title 42 of the U.S. Code Section 1320a-7b(b) .

1.9 *"API"* means oxycodone (free base) or any pharmaceutically acceptable salt thereof (e.g., oxycodone hydrochloride), and any solvates, hydrates, anhydrides, and polymorphs of oxycodone and pharmaceutically acceptable salts of oxycodone. For avoidance of doubt, API shall not include any opioid other than oxycodone .

1.10 "*APT"* means Acura Pharmaceutical Technologies, Inc., an Indiana corporation and wholly-owned subsidiary of Acura .

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

1.12 "*Audited Party"* shall have the meaning assigned to such term in Section 6.11 .

1.13 "*Auditing Party"* shall have the meaning assigned to such term in Section 6.11 .

1.14 "*Authorized Generic"* means a Product commercialized by Egalet, its Affiliates or a permitted sublicensee as a non-branded generic product under or pursuant to the Product NDA.

1.15 "*Aversion Composition"* means a composition that includes **[*****]** .

1.16 "*Aversion Mark"* shall have the meaning assigned to such term in Section 7.3.

1.17 *"Aversion Patent Rights"* means the patents and patent applications set forth on Exhibit 1.17 and any patents and patent applications disclosing or claiming the Aversion Composition or the Product owned or Controlled by Acura or its Affiliates during the Term, including issued patents resulting from such applications, and all divisions, continuations, continuations-in-part, substitutions, reissues, reexaminations, extensions, registrations, patent term extensions and renewals of the foregoing.

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1.18 *"Aversion® Technology"* means the technology reflected in the Aversion Patent Rights, and all Know-How developed, owned or Controlled by Acura or its Affiliates on the Effective Date or any time during the Term relating to the Aversion Composition and/or the Product.

1.19 "*Bankruptcy Code"* shall have the meaning assigned to such term in Section 14.3 .

1.20 "*Bioequivalence Study"* means an in vivo pharmacokinetic study to demonstrate Bioequivalence.

1.21 "*Bioequivalent" or "BE"* means a product that meets the FDA's requirements for bioequivalence provided in 21 CFR 320.1 and Bioequivalence shall have a corresponding meaning .

1.22 "*Calendar Quarter"* means a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively .

1.23 "*cGCP"* means current Good Clinical Practices (a) as promulgated under 21 C.F.R. Parts 11, 50, 54, 56, 312, and 314, as the same may be amended or re-enacted from time to time and (b) required by law in countries other than the United States where clinical studies are conducted .

1.24 "*cGLP"* means current Good Laboratory Practices (a) as promulgated under 21 C.F.R. Part 58, as the same may be amended or re-enacted from time to time and (b) as required by law in countries other than the United States where non-clinical laboratory studies are conducted .

1.25 *"cGMP"* means current Good Manufacturing Practices (a) as promulgated under 21 C.F.R. Parts 210 and 211, as the same may be amended or re-enacted from time to time and (b) as required by law in countries other than the United States where pharmaceutical product Manufacturing is conducted .

1.26 *"CMC"* means the Chemistry, Manufacturing and Control activities, data and information necessary to support any regulatory filing with respect to any Product, including without limitation, the CMC section of a Regulatory Approval Application or Regulatory Approval in the Territory .

1.27 *"Change of Control"* means (i) a Third Party (or group of Third Parties acting in concert) acquires, directly or indirectly, beneficial ownership or a right to acquire beneficial ownership of shares of Acura representing fifty percent (50%) or more of the voting shares (where voting includes being entitled to vote for the election directors) then outstanding of Acura; (ii) a Third Party purchases all or substantially all of Acura's and APT's assets; or (iii) a merger or consolidation of Acura with or into any Third Party, as a result of which the holders of voting stock of Acura immediately prior to such merger or consolidation hold less than fifty percent (50%) of the outstanding voting shares of the surviving entity or parent of the surviving entity .

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1.28 "*Charges"* shall have the meaning assigned to such term in Section 6.12 .

1.29 "*Commercialization Condition"* shall have the meaning assigned to such term in Section 5.2.2 .

1.30 "*Commercialization Program"* shall have the meaning assigned to such term in Section 5.1.

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

1.32 *"Commercial Year"* means any period beginning (A) with the First Commercial Sale of the Product by Egalet or (B) immediately after the end of the prior Commercial Year; and ending the earlier of (A) twelve months thereafter or (B) the end of the Term.

1.33 "*Contract Manufacturer"* means **[*****]** or such other manufacturer appointed by Egalet after consultation with Acura.

1.34 *"Confidential Information"* means, with respect to either Party, all confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which are disclosed by or on behalf of such Party to the other Party pursuant to, and in contemplation of, this Agreement, including, without limitation, information relating to the Aversion Technology or the Product or any proprietary commercial information developed by Egalet for the Product.

1.35 *"Control"* means, with respect to an item of information, Know-How or Patent Right, the possession of the ability by ownership, license or otherwise (other than by operation of the license and other rights pursuant to this Agreement) to assign or grant a license or sublicense or disclose as provided for herein under such item or right without violating the terms of any agreement or other arrangement, express or implied, with any Third Party.

1.36 *"Controlled Substances Act" or "CSA"* means the law enacted by the United States Congress as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended and updated.

1.37 *"Cost of Goods Sold"* means the cost of goods sold as determined under GAAP, consistent with the Egalet's accounting practices for other Egalet products.

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1.38 "*Co-Promote Notice*" shall have the meaning assigned to such term in Section 5.3.3.

1.39 "*Co-Promotion Payment*" shall have the meaning assigned to such term in Section 5.3.5.

1.40 "*Co-Promotion Right*" shall have the meaning assigned to such term in Section 5.3.1.

1.41 "*CSO*" means a contract sales organization.

1.42 "*DEA*" means the United States Drug Enforcement Administration, or any successor thereto.

1.43 "*Defend*" shall have the meaning assigned to such term in Section 10.5.1.

1.44 "*Detail*" shall mean to engage in a Product Detail.

1.45 "*Disclosing Party*" shall have the meaning assigned to such term in Section 12.1.

1.46 *"Dose Proportionality Study"* means a pharmacokinetic study to determine the correlation between increase in doses of a drug and its bioavailability.

1.47 "*Effective Date*" shall have the meaning assigned to such term in the preamble of this Agreement.

1.48 "*Egalet*" shall have the meaning assigned to such term in the preamble of this Agreement.

1.49 "*Egalet Entity*" shall have the meaning assigned to such term in the preamble to this Agreement.

1.50 "*Egalet UK*" shall have the meaning assigned to such term in the preamble of this Agreement.

1.51 "*Egalet US*" shall have the meaning assigned to such term in the preamble of this Agreement.

1.52 **[*****]** has the meaning assigned to such term in Exhibit 10.8.

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1.55 **[*****]** shall have the meaning assigned to such term in Exhibit 10.8.

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1.56 **[*****]** shall have the meaning assigned to such term in Exhibit 10.8.

1.57 *"Executive Officers"* shall have the meaning assigned to such term in Section 3.4 .

1.58 *" Expense Split Percentage "* means **[*****]** .

1.59 *"Expert"* shall have the meaning assigned to such term in Section 16.3.1.

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

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

1.62 *"Field"* means all present and future indications for the Product as a human therapeutic.

1.63 *"First Commercial Sale"* means (i) with respect to the United States, the first sale of the Product by Egalet in an arm's length sale for use or consumption by the general public of such Product in the United States and (ii) with respect to other countries in the Territory, the first sale of such Product in such country in an arm's length sale after the application or submission required to market the Product in such country has received the relevant Regulatory Approvals, provided however that the following shall not constitute a First Commercial Sale:

(a) any sale to an Affiliate or sublicensee unless the Affiliate or sublicensee is the last entity in the distribution chain of the Product;

(b) any use of such Product in clinical trials (including post-Regulatory Approval clinical trials), non-clinical development activities or other development activities with respect to such Product, or disposal or transfer of Products for a bona fide charitable purpose; and

(c) compassionate use.

1.64 *"Force Majeure"* shall have the meaning assigned to such term in Section 16.5 .

1.65 *"Forecast"* means Egalet's forecast requirements for the Product provided to any manufacturer of the Product, including the Contract Manufacturer.

1.66 *"GAAP"* means generally accepted accounting principles in the United States, consistently applied by the Party at issue.

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1.67 "*Generic Equivalent"* means, with respect to the Product, a generic pharmaceutical product that is therapeutically equivalent to the Product, where "therapeutically equivalent" means: (i) for purposes of the United States, an AB rating is assigned to the product's entry in the list of drug products with effective approvals published in the then-current edition of FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and any current supplement to the publication (also known as the "Orange Book") referred to in 21 C.F.R. 314.3 and such product is covered by an Abbreviated New Drug Application (as defined in the FD&C Act) or an application under Section 505 (b)(2) of the FD&C Act which primarily relies on the Product's NDA as the reference listed drug; and (ii) for purposes of other countries in the Territory, a rating equivalent to the FDA's AB rating is assigned to the product by that country's Regulatory Authority and such product relies primarily on the Regulatory Approval of the Product in that country for approval.

1.68 "*Generic Licenses"* shall have the meaning assigned to such term in Section 9.2.

1.69 "*Generic Parties"* means Par Pharmaceutical Inc., Sandoz, Inc. and Impax Laboratories, Inc., and their successors in interest and assigns and any, subject to Section 10.4, Person with whom Egalet or Acura enters into an agreement with respect to a Generic Equivalent following a Paragraph IV Certification filed by such Person or its Affiliates.

1.70 "*Gross Margin"* shall have the meaning assigned to such term in Section 5.3.5.

1.71 "*Incremental Net Sales"* shall have the meaning assigned to such term in Section 5.3.5.

1.72 *"IND"* means an Investigational New Drug Application and any amendments thereto submitted to the FDA or the foreign equivalent thereof.

1.73 "*Infringement Action"* shall have the meaning assigned to such term in Section 10.5.1.

1.74 "*Joint Steering Committee" or "JSC"* shall have the meaning assigned to such term in Section 3.1.

1.75 *"Know-How"* means all commercial, technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and know-how, including Regulatory Data, study designs and protocols), in all cases, whether or not confidential, proprietary, patented or patentable, in written, electronic or any other form now known or hereafter developed.

1.76 "*Knowledge"* means, when used with respect to a Party, the actual knowledge of the representatives of such Party listed on Exhibit 1.74, as of the Effective Date.

1.77 "*Launch"* means the First Commercial Sale of the Product by Egalet.

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1.78 "*Launch Date*" with respect to the United States means the date of Launch of the Product in such country.

1.79 *"Launch Quantities"* means (i) for the United States and the 5mg and 7.5mg dosages, a minimum of **[*****]** and (ii) for other dosages and jurisdictions, a sufficient amount of tablets to supply wholesalers and/or retail chains with **[*****]** .

1.80 "*Lien*" means any lien, mortgage, deed of trust, pledge, security interest, charge or encumbrance of any kind (including any conditional sale or other title retention agreement, any lease in the nature of a security interest, and any agreement to give any security interest).

1.81 "*Limitx™ Technology*" means an abuse-deterrent technology in development or discovered by Acura during the Term which is designed to address oral abuse of immediate-release tablets when an excess number of tablets are accidently or purposefully ingested, where such product may also impact abuse by snorting.

1.82 "*Losses*" means any and all damages, fines, fees, settlements, payments, obligations, penalties, deficiencies, losses, costs and expenses.

1.83 "*Manufacture*" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of the Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

1.84 *"Manufacture and Supply Agreement"* means a manufacturing agreement entered into by Egalet for the Product with a Contract Manufacturer.

1.85 "*Marketing Plan*" shall have the meaning assigned to such term in Section 5.2.4.

1.86 *"Medical Affairs"* means the provision to hospital consultants, key opinion leaders, Regulatory Authorities and healthcare professionals of scientific and medical information relating to the value and correct usage of the Product.

1.87 "*NDA*" means a New Drug Application filed with the FDA pursuant to and under 21 U.S.C. Section 355(b) of the FD&C Act or the equivalent in any jurisdiction which must be approved by the Regulatory Authority in such jurisdiction prior to marketing the Product in such jurisdiction.

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1.88 "*Net Sales"* means, with respect to the Product, the gross amount invoiced for sales of such Product in arm's length sales by Egalet, its Affiliates and permitted sublicensees, if any, to non-sublicensee Third Parties, commencing with the First Commercial Sale of such Product, less the following deductions from such gross amounts which are actually incurred, allowed, accrued or specifically allocated: (i) credits, price adjustments or allowances for damaged products (to the extent not covered by insurance), defective goods, returns or rejections of Product; (ii) normal and customary trade, cash and quantity discounts, allowances and credits (other than price discounts granted at the time of invoicing which have been already been reflected in the gross amount invoiced); (iii) chargeback payments, rebates and similar allowances (or the equivalent thereof) granted to group purchasing organizations, managed health care organizations, distributors or wholesalers or to federal, state/provincial, local and other governments, including their agencies, or to trade customers; (iv) any fees paid to any Third Party logistics providers, wholesalers and distributors; (v) any freight, postage, shipping, insurance and other transportation charges incurred by the selling Person in connection with shipping the Product to Third Party logistics providers, wholesalers and distributors and to customers; (v) adjustments for billing errors or recalls; (vi) sales, value-added (to the extent not refundable in accordance with Applicable Law), and excise taxes, tariffs and duties, and other taxes (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and other comparable laws), levied on, absorbed, determined and/or imposed with respect to such sale (but not including taxes assessed against the income derived from such sale); and (vii) amounts written off by reason of uncollectible debt, provided that if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid. Net Sales, as set forth in this definition, shall be calculated applying, in accordance with GAAP, the standard accounting practices the selling Person customarily applies to other branded products sold by it or its Affiliates under similar trade terms and conditions.

1.89 "*Offensive Infringement Action"* shall have the meaning assigned to such term in Section 10.4.1.

1.90 "*Other Countries"* means countries or any portion or portions thereof located in the Territory outside the United States.

1.91 *"PDUFA"* means the Prescription Drug User Fee Act, as amended and supplemented and as the same may be further amended and supplemented, and rules and regulations of the FDA promulgated thereunder.

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

1.93 "*Paragraph IV Proceeding"* means an action brought in response to a Paragraph IV Certification under 21 U.S.C. § 355(c)(3)(C) or 21 U.S.C. 355(j)(5)(B)(iii).

1.94 "*Party"* means, as applicable, Acura or Egalet and, when used in the plural, shall mean Acura and Egalet. "Parties" shall not refer to the relationship among the Egalet Entities but rather to the relationship between Egalet and Acura or any Egalet Entity and Acura. By way of example, in Section 17.1 where it states that no Party shall make any commitments for the other, it is referring to Egalet or an Egalet Entity on the one hand and Acura on the other hand, it being the intention that each Egalet Entity shall bind the other.

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1.95 "*Patent Challenge*" shall have the meaning assigned to such term given in Section 14.4.

1.96 "*Patent Rights*" means any patents and patent applications, issued patents resulting from such applications, and all divisions, continuations, continuations-in-part, substitutions, reissues, reexaminations, extensions, registrations, patent term extensions and renewals of the foregoing.

1.97 "*Payment Default*" shall have the meaning set forth in Section 14.2.1.

1.98 "*PDMA*" means the Prescription Drug Marketing Act of 1987, Title 21 of the U.S. Code of Federal Regulations, Parts 203 and 205, as amended, and any final regulations or guidances promulgated, from time-to-time, thereunder.

1.99 "*Person*" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.100 "*Pfizer Termination Agreement*" means the letter agreement between Acura and King Pharmaceuticals Research and Development Inc. ("King Pharma") dated April 9, 2014 terminating the License, Development and Commercialization Agreement dated October 30, 2007 between Acura and King Pharmaceuticals Research and Development Inc.

1.101 "*Phase III Clinical Trial*" means, with respect to a drug candidate, a clinical trial of a drug candidate in patients for the purpose of establishing safety and efficacy of one or more particular doses in patients being studied, and which will (or is intended to) satisfy the requirements of a pivotal trial for purposes of obtaining approval of a product in a country by the health Regulatory Authority in such country to market such product, as more fully described in 21 C.F.R. § 312.21(c), or its successor regulation, or the equivalent in any foreign country.

1.102 "*Phase IV Clinical Trial*" *or* "*Post-Marketing Study*" means a post-marketing human clinical trial for the Product commenced after receipt of a Regulatory Approval in the country for which such trial is being conducted and that is conducted within the parameters of the Regulatory Approval for the Product. Phase IV Clinical Trials may include, without limitation, epidemiological studies, modeling and pharmacoeconomic studies, investigator-sponsored clinical trials of Product and post-marketing surveillance studies.

1.103 "*Product*" means each of the 5 mg and 7.5 mg strengths of immediate release tablets or capsules containing the API as its sole active analgesic pharmaceutical ingredient incorporating the Aversion Composition, and approved in the United States pursuant the Product NDA, and as the same may be approved in Other Countries (using the Aversion Composition), any Product Line Extensions and any Authorized Generic.

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1.104 "*Product Detail(s)*" means a face-to-face meeting, between (A) a professional field sales representative having demonstrated proficiency in (i) pharmaceutical selling and related regulations and (ii) the Product's attributes and (B) a health care professional with prescribing authority, during which a presentation of at least one of the Product's attributes is orally presented in a manner consistent with the quality of, and made in a manner consistent with, those presentations customarily conducted by professional field sales representatives in the pharmaceutical industry; it being understood and agreed that a Product Detail does not include a reminder or sample drop (or other comparable activity).

1.105 "*Product Fees*" means the product fees assessed by the FDA pursuant to PDUFA, as codified in Sections 735 and 736 of the FD&C Act, or any successor thereto, and similar fees imposed by statute, regulation or Regulatory Authorities in other jurisdictions in the Territory.

1.106 " *Product Line Extensions* " means any dosages of immediate release tablets or capsules (containing the API as its sole active analgesic pharmaceutical ingredient) incorporating the Aversion Composition (in whole or in part), in **[*****]** for which Regulatory Approval is received during the Term.

1.107 "*Product Line Extension Studies*" means **[*****]** .

1.108 "*Product NDA*" means NDA number N202080, including any supplement or amendment thereto.

1.109 "*Product-specific Intellectual Property*" means Aversion Patent Rights and the Aversion Technology that solely relate to the Product or any Product Line Extension.

1.110 "*Product-specific Offensive Infringement Action*" means an Offensive Infringement Action relating to a Third Party's actual, potential or suspected unauthorized use, misappropriation or infringement of the Aversion Technology or the Aversion Patent Rights arising from such Third Party's development, manufacture and/or commercialization of an immediate release product having the API as its sole active analgesic pharmaceutical ingredient.

1.111 "*Product-specific Infringement Action*" means an Infringement Action commenced or threatened by a Third Party against Acura, Egalet on their Affiliates for infringement of any Patent Rights of a Third Party or for misappropriation of any Third Party know-how, relating to the development, manufacture and/or commercialization of the Product.

1.112 "*Product Mark*" shall have the meaning assigned to such term in Section 7.3.1.

1.113 "*Prosecute*" shall have the meaning assigned to such term in Section 10.4.2.

1.114 "*Quota*" means the manufacturing quota quantity of API for the Product allotted by the DEA to the Contract Manufacturer.

1.115 "*Receiving Party*" shall have the meaning assigned to such term in Section 12.1.

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1.116 *"Regulatory Approval"* means all approvals (including pricing and reimbursement approval and schedule classifications), product and/or establishment licenses, registrations or authorizations of any Regulatory Authority, necessary for the commercialization, use, storage, import, export, transport, offer for sale, or sale of the Product in a regulatory jurisdiction within the Territory.

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

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

1.119 *"Required Post-Marketing Studies"* shall have the meaning assigned to such term in Section 4.1.1.

1.120 *"Required Launch Date"* shall have the meaning assigned to such term in Section 5.4.1.

1.121 *"Royalty Term"* shall have the meaning assigned to such term in Section 14.1.1.

1.122 *"Royalty True-up"* shall have the meaning assigned to such term in Section 6.4.1.

1.123 *"Rx"* shall have the meaning assigned to such term in Section 5.3.5.

1.124 *"Sales Milestone Payment"* shall have the meaning assigned to such term in Section 6.3.

1.125 *"Second Submission Date"* shall have the meaning assigned to such term in Section 16.3.2.

1.126 *"Specifications"* means the specifications for the Product, including the Manufacturing, testing, packaging, labeling, storage and quality control specifications for the Product, as set forth in the Product NDA, plus any additional specifications mutually agreed upon in writing by the Parties, as the same may be modified, in writing, from time to time.

1.127 *"Term"* shall have the meaning assigned to such term in Section 14.1.2.

1.128 *"Terminated Country(ies)"* shall have the meaning assigned to such term in Section 14.7.2.

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1.129 *"Territory"* means worldwide.

1.130 *"Third Party"* means any Person who or which is neither a Party nor an Affiliate of a Party.

1.131 *"Third Party Infringement"* shall have the meaning assigned to such term in Section 10.4.1.

1.132 *"Trademarks"* shall have the meaning assigned to such term in Section 7.3.

1.133 *"Upfront Payment"* shall have the meaning assigned to such term in Section 6.1.

1.134 *"United States" or "U.S."* means The United States of America, including its possessions and territories.

1.135 *"U.S. Sublicensee"* shall have the meaning assigned to such term in Section 7.2.

2. REPRESENTATIONS, WARRANTIES AND COVENANTS

2.1 *By Both Parties* . Each Party hereby represents, warrants and covenants to the other Party, as of the Effective Date, that:

2.1.1 such Party: (A) is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized; (B) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted; and (C) is in compliance with all requirements of Applicable Law, except to the extent that any noncompliance would not have a material adverse effect on the properties, business, financial or other condition of such Party and would not materially adversely affect such Party's ability to perform its obligations under this Agreement;

2.1.2 such Party: (A) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and (B) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. The Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms except to the extent that enforceability may be limited by applicable bankruptcy, insolvency or other laws affecting the enforcement of creditors' rights generally and subject to the general principles of equity (regardless of whether enforcement is sought in a court of law or equity);

2.1.3 such Party has obtained all necessary consents, approvals and authorizations of all governmental authorities and Third Parties required to be obtained by such Party in connection with this Agreement, other than any approvals required of applicable Regulatory Authorities as may be required under this Agreement from time to time;

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2.1.4 the execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (A) do not, to the best of such Party's Knowledge, conflict with or violate any requirement of Applicable Law; and (B) do not conflict with, or constitute a default under, any contractual obligation of such Party;

2.1.5 neither it nor any of its Affiliates has been debarred under Section 306 of the FD&C Act or any equivalent local law or regulation and, to its Knowledge, no member of its staff has been charged with or convicted under federal law or foreign equivalent for conduct relating to the development or approval of any Regulatory Approval Application or Regulatory Approvals, or otherwise relating to the regulation of any drug product under any relevant statute, law, or regulation, and if at any time such Party or any of its Affiliates or any member of its staff is debarred or charged with or convicted under federal law or foreign equivalent for conduct relating to the development or approval of any Regulatory Approval Application or Regulatory Approvals, or otherwise relating to the regulation of any drug product under any relevant statute, law, or regulation, it will provide prompt written notice of same to the other Party; and

2.1.6 it follows, and will continue to follow during the Term, reasonable commercial practices to protect its proprietary and Confidential Information, including requiring its employees, consultants and agents to be bound in writing by obligations of confidentiality and non-disclosure, and requiring its employees and using commercially reasonable efforts to require its consultants and agents to assign to it any and all inventions and discoveries discovered by such employees, consultants and/or agents made within the scope of and during their employment or engagement to the extent relating to the subject matter of this Agreement, and only disclosing Confidential Information to Third Parties pursuant to written agreements containing appropriate confidentiality and non-disclosure obligations.

2.2 By Acura. Acura represents, warrants and covenants to Egalet that:

2.2.1 As of the Effective Date, (A) except for the rights granted to Egalet under this Agreement and the Generic Licenses, Acura owns or has exclusive rights to all of the Aversion Technology and the Aversion Patent Rights in existence on the Effective Date and the exclusive right to grant licenses (except for the Generic Licenses) with respect thereto, free of any Lien; and (B) Acura has the legal right and authority, and has all rights, authorizations and consents necessary, to grant to Egalet the licenses granted under this Agreement, including under Section 7.1 and 7.3;

2.2.2 Exhibit 2.2.2 sets forth a complete and correct list of all agreements relating to the licensing, sublicensing or other granting of rights with respect to the Aversion Technology or Aversion Patent Rights or the Product to which Acura or any of its Affiliates is a party (the " *Acura License Agreements* "), and Acura has provided complete and accurate copies of all such agreements to Egalet. Acura and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this Agreement. Acura and its Affiliates are not in material breach of any Acura License Agreement pursuant to which Acura and/or its Affiliates receive a license or sublicense to Acura Technology or Aversion Patent Rights. As between the Parties, Acura shall be solely responsible for any payment obligations to Third Parties pursuant to any Acura License Agreement. Except for the Acura License Agreements, there are no settlement agreements between Acura or its Affiliates and any Third Party relating to the Product or the Aversion Patent Rights;

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2.2.3 Acura has exercised, and continues to exercise Commercially Reasonable Efforts in the prosecution of the Aversion Patent Rights set forth in Exhibit 1.17 in all material respects accordance with all Applicable Laws. Such Aversion Patent Rights have been filed and maintained and all applicable fees due on or prior to the Effective Date have been paid on or before the due date for payment. To Acura's Knowledge, the issued patents included in the Aversion Patent Rights are valid and enforceable.

2.2.4 None of the Aversion Technology in existence on the Effective Date was obtained by Acura or its Affiliates in violation of any contractual or fiduciary obligation to which Acura or its Affiliates or any of their respective employees or staff members are or were bound, or by the misappropriation of the trade secrets of any Third Party;

2.2.5 Except for the Acura License Agreements, Acura and its Affiliates have not entered into, and will not enter into, any agreement with any Third Party which is or would be in conflict with the rights granted to Egalet under this Agreement;

2.2.6 Acura has complied and shall continue to comply with in all material respects with Applicable Laws in the United States in connection with its performance of any development activities relating to the Product and all such activities shall be in compliance with cGLP, cGCP and cGMP, and will conduct such activities in accordance with this Agreement;

2.2.7 As of the Effective Date, there are no claims, judgments, litigations, suits, actions, disputes, arbitration, judicial or legal, administrative or other proceedings or governmental investigations pending or, to Acura's Knowledge, threatened against Acura or any of its Affiliates in connection with the Product (including that the manufacture, use or sale of the Product infringes, misappropriates or violates the intellectual property rights of any third party), the Aversion Patent Rights (including that any of the issued patents included in the Aversion Patent Rights are invalid or unenforceable) or Aversion Technology or which would be reasonably expected to materially affect or restrict the ability of Acura to consummate the transactions contemplated under this Agreement and to perform its obligations under this Agreement;

2.2.8 Neither Acura nor any of its Affiliates has received any written notice of any claim that any Patent or trade secret right owned or controlled by a Third Party has been or would be infringed or misappropriated by the research, development, manufacture, or commercialization of the Aversion Technology or the Product;

2.2.9 Information provided by Acura in response to any of Egalet's due diligence requests prior to the Effective Date was in all material respects complete, truthful and accurate;

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2.2.10 Acura has complied and will continue to comply with the terms of the Pfizer Termination Agreement, and after the transfer of obligations regarding the Required Post-Marketing Study, pharmacovigilance and Medical Affairs to Egalet pursuant to this Agreement, will have no material obligations under such agreement; and

2.2.11 Acura shall comply with all Applicable Laws in the United States in connection with the performance of its Co-Promotion Rights, including, without limitation, the FD&C Act, the PDMA, the Anti-Kickback Statute and all U.S. federal and state health care fraud and abuse statutes and regulations.

2.2.12 To Acura's Knowledge, the manufacture, use and commercialization of the Product does not infringe any valid claim in a granted patent owned by a Third Party or misappropriate any trade secret owned by a Third Party.

2.2.13 The licenses and rights granted to Egalet under this Agreement do not constitute the sale, license or other disposition of all or substantially all of Acura's assets.

2.2.14 As of the Effective Date, Acura does not have total assets or annual net sales (as the terms "assets" and "net sales" are defined and measured under 15 U.S.C. §18a and the regulations promulgated thereunder) of $151.7 million or more.

2.3 By Egalet . Egalet represents, warrants and covenants to Acura that:

2.3.1 Egalet shall comply with all Applicable Laws in connection with the performance of its development activities and the Commercialization Program, including, without limitation, the FD&C Act, the PDMA, the Anti-Kickback Statute and all federal, state and foreign health care fraud and abuse statutes and regulations;

2.3.2 Neither Egalet nor its Affiliates has entered into, and will not enter into, any agreement with any Third Party that is in conflict with its obligations under this Agreement;

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

2.3.4 Information provided by Egalet in response to any of Acura's due diligence requests prior to the Effective Date was in all material respects complete, truthful and accurate;

2.3.5 Egalet shall comply with all Applicable Laws in connection with its performance of any development activities and all such activities and shall be in compliance with cGLP, cGCP and cGMP and all Applicable Laws, as applicable, and will conduct such activities in accordance with this Agreement;

2.3.6 Except pursuant to Section 17.2, Egalet shall not transfer, convey, assign or otherwise dispose of, or create or suffer to exist any Lien on, the Product NDA, the IND relating to the Product or any other Regulatory Approval or Regulatory Approval Application during the Term, *provided, however* , nothing shall prohibit Egalet and/or its Affiliates from obtaining debt financing for Egalet or its Affiliates secured by substantially all of their assets, except as provided in this Section 2.3.6;

2.3.7 Egalet shall not request, solicit or cause the FDA to (i) delist any Aversion Patent Rights from the FDA's Orange Book, (ii) withdraw or suspend the Product NDA (or any supplement or amendment thereto), or (iii) omit or exclude the Product from a list of marketed drugs filed in accordance with 21 U.S.C. §360 (as may be amended or replaced); and

2.3.8 Egalet shall provide Acura with not less than **[*****]** days' prior written notice of Egalet's intended launch of an Authorized Generic of the Product in the United States.

2.3.9 As of the Effective Date, Egalet does not have total assets or annual net sales (as the terms "assets" and "net sales" are defined and measured under 15 U.S.C. §18a and the regulations promulgated thereunder) of $151.7 million or more.

2.4 *Disclaimers.*

2.4.1 Except to the extent provided in Sections 2.2.3 and 2.2.12, Acura hereby expressly disclaims any representation or warranty as to the validity or enforceability of any Aversion Patent Rights, the non-infringement of any Third Party patent or other intellectual property right or the prospects or likelihood of development or commercial success of the Product.

2.4.2 EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 2 AND EXPRESSLY AS SET FORTH ELSEWHERE IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE, OR NON-INFRINGEMENT.

3. JOINT STEERING COMMITTEE

3.1 *Members; Officers.* Promptly after the Effective Date, the Parties shall establish a joint steering committee (the "Joint Steering Committee" or "JSC") as more fully described in this Section 3. The JSC shall be comprised of three (3) representatives from each Party. Such representatives shall include individual representatives with expertise to fulfill each Parties obligations under this Agreement. Any member of the JSC may designate a substitute to attend and perform the functions of that member at any meeting of the Joint Steering Committee. Each Party may, in its discretion, invite non-member representatives of such Party to attend meetings of the JSC. A chairperson and secretary shall be selected by Egalet .

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3.2 Responsibilities of the Joint Steering Committee. The JSC shall be responsible for reviewing and providing input on and, if expressly specified in this Agreement, approving the overall strategy of the Parties under this Agreement, including development plans and strategies, and for reviewing the Commercialization Program. Specifically, the JSC shall perform the following functions:

3.2.1 recommend a date not to be more than three (3) months from the Effective Date, to transfer to Egalet (i) pharmacovigilance reporting and related activities, including preparation and submission of 15-day reports and preparation of periodic adverse drug event reports (PADER); and (ii) Medical Affairs;

3.2.2 review, at least annually, the Commercialization Program, the Marketing Plan, Manufacturing operations, DEA Quotas, Product development plans and the Product sales forecast (including projected royalties payable to Acura) for the collaboration;

3.2.3 review all material Product development, marketing, Manufacturing (including Product inventory levels and requirements) and regulatory activities, milestones and accomplishments and progress to forecast, in summary fashion on a Calendar Quarter basis and in a reasonably detailed manner on a semi-annual basis;

3.2.4 review the Launch Date for the Product in the United States;

3.2.5 if Acura exercises its Co-Promotion Right, review and approve target health care provider lists, as applicable, and data and reports relating to Product Details undertaken during the prior Calendar Quarter, including the relative priority of such Details;

3.2.6 determine and approve the allocation of overlapping target healthcare providers pursuant to Section 5.3.13;

3.2.7 discuss strategies, plans and updates relating to pending or threatened Infringement Actions and Offensive Infringement Actions;

3.2.8 evaluate the progress of development of the Product in Other Countries and the timing of Launch in such Other Countries following receipt of Regulatory Approval in such Other Countries;

3.2.9 review and provide comment on the protocols and plans for the Required Post-Marketing Studies;

3.2.10 review and approve any Product Line Extension proposed to be conducted by Acura pursuant to Section 4.4.1;

3.2.11 review and approve (by unanimous consent of the JSC members) the proposed budget relating to each of the Product Line Extension Studies and the Required Post-Marketing Studies within ten (10) business days after submission of such proposed budget to the JSC, *provided* that neither Party shall withhold approval for a proposed budget for the Product Line Extension Studies (determined as a group) or a Required Post-Marketing Studies (determined as a group) that is **[*****]** or less, and *provided further* that this Section 3.2.11 is subject to Section 6.14;

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3.2.12 identify regular reports and channels of communications for the provision of periodic updates of progress relating to the Commercialization of the Product and the development and filing for Regulatory Approval of Product Line Extensions; and

3.2.13 perform such other responsibilities as may be agreed upon by the Parties in writing from time to time.

Egalet will report regularly and no less than semi-annually on any material changes to or material variances from the Commercialization Program and the aforementioned plans and budgets, whether such changes have actually occurred or are expected. Notwithstanding the foregoing, the JSC shall not have the authority to make any determination that either Party is in breach of this Agreement or has complied with its obligations under this Agreement, or to assess any charges or expenses in excess of the amounts allocated to a Party pursuant to the budgets agreed to by the Parties in accordance with Sections 3.2.11 and 6.14, except as provided in Section 6.14.

3.3 *Meetings* . During the Term, the Joint Steering Committee shall meet at least once each Calendar Quarter, and more frequently as the Parties deem appropriate, on such dates, and at such places and times, as provided herein or as the Parties shall agree. Meetings of the JSC that are held in person shall alternate between the offices of the Parties, or such other place as the Parties may agree. Either Party may cause a meeting to be held by teleconference or videoconference or other similar means. The members of the JSC also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate by either Party. Each Party shall provide to the JSC such information in its possession relating to its activities under the Agreement as reasonably needed by the JSC to perform its functions and exercise its responsibilities as above.

3.4 *Decision-making* . Except as otherwise provided in this Agreement, decisions of the JSC shall be made by consensus, with each Party having collectively one (1) vote in all decisions. In the event that the JSC is unable to reach a consensus decision within fifteen (15) days after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to the Chief Executive Officer of Acura, or such other person holding a similar position designated by Acura from time to time, and the Chief Executive Officer of Egalet, or such other person holding a similar position designated by Egalet from time to time (collectively, the " *Executive Officers* ") for resolution. The Executive Officers shall meet promptly to discuss the matter submitted and to determine a resolution. If the Executive Officers are unable to determine a resolution within ten business (10) days after the matter was referred to them, then, with respect to all development, commercialization, financial or budgetary matters, Egalet shall, subject to Sections 3.2.6 and 3.2.11, have final-decision making authority, provided that Egalet may not unilaterally decide any dispute, or waive any obligation or covenant, in a manner or result that is contrary to the express terms of this Agreement. Notwithstanding the foregoing, (i) any dispute relating to Sections 3.2.6, 5.2.4 and/or 5.3.13, and any dispute relating to Section 3.2.11 if a proposed budget for an activity described in such Section exceeds **[*****]** , shall be settled in accordance with the Special Arbitration Provisions of Section 16.3 and (ii) no decision by the Joint Steering Committee shall require Acura or Egalet to undertake additional development obligations or expenses, or incur any out-of-pocket expense, without such Party's express written consent.

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3.5 *Minutes* . With the sole exception of specific items of the JSC meeting minutes to which the chairperson and the secretary cannot agree and which are escalated as provided in Section 3.4, definitive minutes of all meetings of the JSC shall be finalized no later than thirty (30) days after the meeting to which the minutes pertain. If at any time during the preparation and finalization of JSC meeting minutes, the secretary and the chairperson do not agree on any issue with respect to the minutes, such issue shall be escalated to the Executive Officers. The decision resulting from the escalation process shall be recorded by such secretary in amended finalized minutes for said meeting.

3.6 *Term* . The JSC shall exist throughout the Term.

3.7 *Expenses* . Each Party shall be responsible for all travel and related costs and expenses for its members and approved invitees to attend meetings of, and otherwise participate on, the JSC or any subcommittee.

4. PRODUCT LINE EXTENSIONS, DEVELOPMENT FOR OTHER COUNTRIES AND POST-MARKETING STUDIES

4.1 *Required Post-Marketing Studies.*

4.1.1 Egalet will conduct all Post-Marketing Studies required by the FDA with respect to the Product (the " *Required Post-Marketing Studies* "). Egalet will bear its own internal expenses and the Parties shall share out-of-pocket expenses for the Required Post-Marketing Studies based on the Expense Split Percentage.

4.1.2 Egalet will prepare and deliver to the JSC a detailed plan and budget for the Required Post-Marketing Studies.

4.1.3 Egalet shall keep complete and accurate scientific records relating to Post-Marketing Studies and will make such records reasonably available to Acura for review and/or copying. Such scientific records shall be maintained in accordance with good scientific practices. Each Party shall also keep detailed records of costs it incurs in connection with the Required Post-Marketing Studies, including all supporting documentation for such expenses, and will keep such records for at least three (3) years after the date that such expense was incurred.

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4.2 *Development for Use in Other Countries* . Egalet, in its sole discretion and at its sole cost and expense, may, at any time during the Term, develop the Product for use in one or more Other Countries (including Product Line Extensions). If Egalet elects to develop the Product for use in one or more Other Countries, Egalet shall prepare and deliver to the JSC for review and comment, its development plan for the Product for Other Countries in the Territory, including the estimated timing of commencement and completion of such development activities. Acura will cooperate with Egalet in such development activities, *provided* the Parties shall agree in writing in advance the services that Acura will provide and the fees and expenses to be paid by Egalet in connection therewith (including fees for Acura's internal cost at a full-time equivalent rate to be mutually agreed), as well as a related payment schedule. In the event that Egalet conducts development, in and with respect to such Other Countries, the Parties agree that such development shall be planned in such a manner as not to impair or otherwise adversely affect the Regulatory Approval of the Product in the United States.

4.3 *Regulatory Approval in Other Countries* Egalet, in its sole discretion and at its sole cost and expense, may apply for Regulatory Approval for the Product (including Product Line Extensions) in one or more Other Countries. Egalet shall own all such Regulatory Approvals, subject to Acura's right to require the transfer of same to Acura as provided in Section 14.7, and shall pay any and all expenses in connection therewith. Acura shall provide Egalet access and a right of reference to the protocols, data, documents, reports and analyses included in regulatory filings for the Product in existence at the Effective Date for Egalet's use in obtaining Regulatory Approvals in Other Countries. At Egalet's request, Acura shall cooperate and assist Egalet in connection with the preparation and filing of Regulatory Approvals for the Product in Other Countries, subject to the Parties written agreement on the fees and expenses payable by Egalet to Acura for such assistance. In the event Egalet elects to develop and materially develops the Product in an Other Country and does not pursue Regulatory Approval in such Other Country within **[*****]** , Acura, in its sole discretion and upon written notice to Egalet, may terminate this Agreement solely with respect to such Other Country.

4.4 *Development and Regulatory Approval of Product Line Extensions* .

4.4.1 Subject to Section 4.4.2, Egalet, at its sole discretion and at its sole cost and expense, may undertake the development and seek Regulatory Approval of Product Line Extensions. Acura shall negotiate in good faith with Egalet a development agreement if Egalet desires for Acura to develop or assist in the development of Product Line Extensions. Acura, may, in its sole discretion, develop Product Line Extensions at its own cost and expense (subject to Section 4.4.2) by notifying the Joint Steering Committee of its intention and obtaining the consent of the Joint Steering Committee, not to be unreasonably withheld or delayed. Any such Product Line Extensions shall be included in the licenses granted by Acura to Egalet under this Agreement without any additional cost or charge to Egalet except as provided in Section 4.4.2. Each Party shall provide to the JSC written Calendar Quarter updates of its development efforts relating to Product Line Extensions, including the status of filing for Regulatory Approval. Egalet shall own and maintain all Regulatory Approvals relating to Product Line Extensions, subject to Acura's right to require the transfer of same to Acura as provided in Section 14.7.

4.4.2 The Parties shall share any out-of-pocket costs relating to Product Line Extension Studies in the United States according to the Expense Split Percentage.

4.5 *Standards of Conduct* . Each Party conducting any development work (whether relating to Post-Marketing Studies, the development of the Product for Other Countries or the development of Product Line Extensions) shall:

4.5.1 conduct its activities in good scientific manner, and in compliance in all material respects with all requirements of Applicable Laws, rules and regulations, and all other requirements of any applicable cGMP, cGLP and cGCP, to attempt to achieve the objectives of the development program efficiently and expeditiously;

4.5.2 maintain records, in sufficient detail and in good scientific manner, which shall be complete and accurate and shall fully and properly reflect all work done and results achieved in the form required under all Applicable Laws; and

4.5.3 allow representatives of the other Party, upon reasonable prior written notice and during normal business hours, to visit such Party's facilities where any development activities with respect to the Product are being conducted, and consult, during such visits and by telephone, with personnel performing work on the Product, and so long as such visits and consultations are not unreasonably disruptive; *provided , however ,* that a visiting Party shall be required to provide the other Party a list of any consultants and/or representatives of such visiting Party at least three (3) business days in advance of such consultant/representatives' first visit to the other Party, and the other Party shall not be required to permit visits from any consultant/representative of the visiting Party also engaged by any Third Party reasonably determined by the other Party to be a competitor of such Party. Each Party, its representatives and consultants shall maintain any information received (whether by observation or otherwise) during such visit in confidence in accordance with Section 12 and shall not use such information except to the extent otherwise permitted by this Agreement.

5. COMMERCIALIZATION PROGRAM

5.1 *Generally* . The commercialization program shall begin on the Effective Date, and shall include Egalet's activities to manufacture, sell, offer for sale, advertise, market, promote, launch (including pre-launch marketing) and commercialize the Product in the United States (the " *Commercialization Program* "), as the same may be modified, from time to time, as set forth in this Agreement. Egalet shall exercise Commercially Reasonable Efforts in implementing and carrying out the Commercialization Program. All marketing, distribution and other expenses of the Commercialization Program shall be solely borne by Egalet.

5.2 *Egalet Responsibilities; Rights* . Subject to Section 5.3 and the Generic Licenses, Egalet, either itself or through its Affiliates or permitted sublicensees shall be responsible for, and shall have the exclusive right to engage in, all marketing, advertising, promotion, launch and sales activities in connection with the marketing of the Products in the Territory. Egalet (and/or its Affiliates and/or permitted sublicensees, as applicable) shall have the authority to determine the specific activities and actions taken in all marketing, advertising, promotion, launch and sales activities in connection with the marketing of the Products in the Territory, subject to compliance with the this Agreement. As part of the Commercialization Program, Egalet shall:

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5.2.1 As of the later to occur of **[*****]** Egalet shall provide for a minimum of **[*****]** full-time field sales representatives within **[*****]** to Detail the Product until such sales representative shall have used good faith efforts to Detail the Product at least once to at least **[*****]** of the health care providers on such field sales representative's list of target health care providers (comprising a subset of Egalet's target health care provider list existing as of such date as described in Section 5.3.13 (such target list to include a number of health care providers per sales representative consistent with pharmaceutical industry practice)). For clarity, such sales representatives shall be permitted to detail any other products (other than a product that would violate the provisions of Section 9.1) during a Product Detail. Egalet will be solely responsible for recruiting, hiring and maintaining its sales force of sales representatives for the promotion of the Product in accordance with its standard procedures and the requirements of this Agreement, and Egalet may utilize a contract sales force to fulfill all or any portion of its obligations under this Section 5.2.1. Egalet agrees any of its sales representatives involved in the promotion of the Product will not have any legal or regulatory disqualifications, bars or sanctions. Egalet will be responsible for the activities of its sales representatives, including compliance by its sales representatives with training and Detailing requirements. For the avoidance of doubt, failure to achieve the required number of sales representatives as required by this Section 5.2.1 shall be deemed to be a material breach of a material obligation by Egalet, and Acura shall have its rights under Section 14.2 with respect to such breach;

5.2.2 Without limiting Sections 5.4.1 and 5.4.2, use Commercially Reasonable Efforts to Launch the Product in the United States, and in each Other Country in the Territory as soon as commercially practical after Regulatory Approval in such country, and to perform such obligations by using personnel with sufficient skills and experience, together with sufficient equipment and facilities. Notwithstanding the foregoing, Egalet shall not be deemed to have failed to perform the foregoing obligations, if it is using Commercially Reasonably Efforts, in the event one or more of the following events or circumstances (the " *Commercialization Conditions* ") occurs and such event or circumstance, or the material effect thereof, is continuing: **[*****]** ;

5.2.3 Egalet shall exercise Commercially Reasonable Efforts to commercialize the Product following Launch in the U.S. and such Other Countries;

5.2.4 not later than **[*****]** prior to the anticipated Launch of the Product in the United States, prepare an overview-marketing plan for the Product, which shall include plans related to the prelaunch, Launch, promotion and sale of the Product in the United States and which shall include forecasts for the number of sales representatives, and a reasonably descriptive overview of the marketing and advertising campaigns, including related budgets, proposed to be conducted (each, a " *Marketing Plan* "). Thereafter, each Marketing Plan shall be updated by Egalet, in accordance with Egalet's usual marketing operations planning cycles, but in no case less than once each Commercial Year during the Term. Egalet shall provide copies of the Marketing Plan to the JSC for review and comment as soon as practicable following preparation. If Acura exercises its Co-Promotion Right pursuant to Section 5.3, Egalet promptly shall update, through the JSC, the Marketing Plan to reflect Acura's Co-Promotion Right in a manner that is consistent with Section 5.3 and which does not materially disadvantage Acura in relation to the exercise of its Co-Promotion Right. If Acura should dispute whether the Marketing Plan complies with the requirements of the immediately preceding sentence, such dispute shall be settled in accordance with the Special Arbitration Provisions of Section 16.3; and

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5.2.5 maintain records in accordance with Egalet's usual business practices of the work done and results achieved in connection with the Commercialization Program and as may be required under all Applicable Laws.

5.3 *Acura's Co-Promotion Rights.*

5.3.1 Subject to the terms of this Section 5.3, Acura shall have the non-sublicensable, non-transferable (except in connection with an assignment of this Agreement pursuant to Section 17.2) right to co-promote the Product (including Product Line Extensions) in the United States (the " *Co-Promotion Right* ").

5.3.2 If Acura wishes, in good faith to evaluate the exercise of the Co-Promotion Right, Egalet shall provide Acura, at Acura's reasonable request (which in any event shall not be made more than once per Calendar Quarter) and on thirty (30) days' prior written notice, (a) a list of target heath care providers to which Egalet (and its Affiliates and sublicensees) is then Detailing the Product or to which it then intends to Detail the Product, (b) after the First Commercial Sale of the Product in the Territory, a written report for the then most recent Calendar Quarter containing, by dosage strength, the number of units of Product sold, the gross sales, the Net Sales and the AMP for each dosage strength of the Product, including details of all necessary calculations of the same, including (i) the calculations which detail the differences between Net Sales and gross sales; (ii) the total number of prescriptions filled in such Calendar Quarter for the Product; (iii) a statement of amount of inventory of the Product held by Egalet as of the last day of such Calendar Quarter; (iv) the average number of tablets per Rx; and (v) the average Cost of Goods Sold for each dosage strength of the Product; and (c) such other information reasonably requested by Acura to evaluate the exercise of its Co-Promotion Right.

5.3.3 Acura may exercise the Co-Promotion Right by providing Egalet sixty (60) days' prior written notice thereof at any time after one (1) year after the Launch of the Product in the United States (the " *Co-Promote Notice* "). From and after the sixtieth (60th) day after the Co-Promote Notice, Acura shall commence co-promotion of the Product in accordance with this Section 5.3.

5.3.4 Acura may cease the co-promotion of the Product at any time on sixty (60) days' written notice to Egalet, and the Co-Promotion Right shall terminate on the sixtieth (60 th) day after such notice; provided, however, that if (i) Egalet exercises its right under Section 5.3.13 to add Acura target health care providers to Egalet's list of target health care providers, and (ii) Acura's notice of cessation of its Co-Promotion Right specifies Egalet's exercise of its right under Section 5.3.13 as the cause of Acura's cessation, which notice of cessation must be provided within thirty (30) days after the later of (i) Egalet's exercise of such right under Section 5.3.13, and (ii) the resolution of any dispute relating to Egalet's exercise of such right under Section 5.3.13 as provided for in such section and Section 16.3, then Acura may, at any time upon sixty (60) days' prior written notice to Egalet resume the co-promotion of the Product, including establishing its list of target health care providers in accordance with Section 5.3.13. Except as provided in this Section 5.3.4, after termination of the Co-Promotion Right, Acura shall not have any further rights to co-promote the Product nor to subsequently exercise the Co-Promotion Right.

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5.3.5 Following Acura's exercise of the Co-Promotion Right, Acura will be entitled to receive, and Egalet shall remit to Acura within forty five (45) days (or if later, within thirty (30) days following Acura's provision to Egalet of Acura's Detail report described in Section 5.3.9) after each Calendar Quarter commencing with the Calendar Quarter following the Co-Promote Notice, **[*****]** . " *Incremental Net Sales* " shall mean **[*****]** . " *Gross Margin* " shall mean **[*****]** . Acura's receipt of the Gross Margin payment described above (" *Co-Promotion Payment* ") will be in lieu of the royalty payments otherwise payable to Acura under the Agreement calculated based on Incremental Net Sales resulting from prescriptions written by the health care providers contained in Acura's list provided to Egalet pursuant to Section 5.3.13. Co-Promotion Payments in respect of a Calendar Quarter shall be paid within forty-five (45) days; (or if later, within thirty (30) days following Acura's provision to Egalet of Acura's Detail report described in Section 5.3.9) after the end of such Calendar Quarter. For clarity, Acura will not be entitled to a Co-Promotion Payment in respect of any prescriptions written by health care providers that are not Acura's list provided to Egalet pursuant to Section 5.3.13, even if Acura has Detailed such providers. Notwithstanding the foregoing, Egalet shall be responsible for all distribution activities relating to the Product.

5.3.6 Acura may perform some or all of its co-promotion through a CSO reasonably acceptable to Egalet, at Acura's sole cost and expense. Acura will be solely responsible for recruiting, hiring and maintaining its sales force of sales representatives for promotion of the Product in accordance with its standard procedures and the requirements of this Agreement. Acura agrees that any of its sales representatives involved in the promotion of the Product will not have any legal or regulatory disqualifications, bars or sanctions. Acura will be responsible for the activities of its sales representatives, including compliance by its sales representatives with training and Detailing requirements. In particular, Acura will provide its sales representatives assigned to promote the Product with the level of oversight, management, direction and sales support with respect to the promotion of Product reasonably necessary to effectively and efficiently promote the Product in accordance with the terms of this Agreement and Applicable Law. If Egalet raises any concern with Acura regarding the performance or fitness of any Acura sales representative, Acura will consider Egalet's comments and recommendations in good faith. For clarity, Acura's implementation or non-implementation of Egalet's comments and recommendations shall not relieve Acura of any responsibility for breach of any of its obligations hereunder with respect to the performance or fitness of any Acura sales representative.

5.3.7 Acura will train its sales force consistent with Egalet training requirements and Egalet sales force policies. In connection therewith, within thirty (30) days after receipt of the Co-Promote Notice, Egalet, upon Acura's request shall provide training materials to, and hold in-person meetings or webcasts for, each member of Acura's sales force prior to his or her commencement of promotion of the Product to ensure that he or she is appropriately trained in proper detailing and sales techniques. On an ongoing basis **[*****]** , at Acura's request and upon reasonable prior notice, Egalet shall provide training materials to, and hold in-person meetings or webcasts for, each member of Acura's sales force as necessary to provide training (in the case of new hires), refresher training and training updates. The Parties shall use good faith efforts to coordinate the timing of, and attendance at, any such trainings so that such training is provided to reasonably sized groups consistent with industry standards. Acura shall bear (i) the costs of training materials, (ii) Egalet's out-of-pocket costs relating to such training, and (iii) Egalet's internal costs for salaries and benefits for its personnel who provide training, refresher training and training updates to Acura; provided that Acura shall not be responsible for Egalet's costs pursuant to this subsection (iii) where such training also includes Egalet's sales representatives.

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5.3.8 Acura will adhere to the Marketing Plan, *provided* such Marketing Plan conforms to the requirements of this Agreement.

5.3.9 Acura will, at its cost and expense, maintain records and otherwise establish procedures to ensure compliance with all Applicable Laws and professional requirements that apply to its promotion and marketing of the Product, including compliance with the PhRMA Code on Interactions with Healthcare Professionals. Acura will provide Egalet with copies of any such records promptly upon Egalet's request. Further, Acura will prepare and provide to Egalet, at no cost or expense to Egalet, such reports regarding its activities under this Section 5.3 as Egalet may reasonably require, including in order to comply with reporting requirement under the Sunshine Act (5 U.S.C. § 552b). In addition, Acura will provide Egalet with a report, as soon as practicable and with a target delivery date of **[*****]** following the end of each Calendar Quarter, setting forth in reasonable detail the Details made by its sales representatives of the Product during such Calendar Quarter.

5.3.10 Acura will only use promotional materials and detailing scripts provided and approved by Egalet, and Egalet shall provide copies requested by Acura of all such sales material and detailing scripts to Acura for promotion of the Product at Acura's expense for such copies, *provided* that all other production costs (such as developing such marketing materials and detailing scripts) shall be borne by Egalet. For clarity, Egalet shall not be required to develop any promotional materials or detailing scripts specifically for Acura. Acura will instruct its sales representatives to make only those statements and claims regarding the Product, including as to efficacy and safety, that are consistent with the Product labeling and accompanying inserts and the approved promotional materials and detailing scripts.

5.3.11 Acura's sales force must be at least **[*****]** or full-time equivalents thereof within **[*****]** , *provided* that such sales representatives may also market any other products (other than a product that would violate the provisions of Section 9.2). Such sales force will provide **[*****]** co-promotion of the Product as agreed to by the Parties, *provided* that in the absence of such agreement the Acura sales force will co-promote the Product **[*****]** .

5.3.12 Egalet will be solely responsible for the execution of Medical Affairs, after the transfer of such responsibility as set forth in Section 11.5.

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5.3.13 At the time provided in Section 5.3.2, and within **[*****]** following each Calendar Quarter during the period Acura is co-promoting the Product pursuant to Section 5.3, Egalet will provide Acura a list of target health care providers to which Egalet (and its Affiliates and sublicensees) is then Detailing the Product or to which it then intends to Detail the Product. In its Co-Promote Notice, Acura shall provide to Egalet a list of health care providers to which it intends to Detail the Product, which shall not (i) overlap with those health care providers on Egalet's then-current list (including any health care providers within the same group or department practice at the same location as a health care provider on Egalet's then-current list) and (ii) include any managed care organizations or pharmacies.

5.3.13.1 Thereafter, Acura may, from time-to-time, change its list of target health care providers, *provided* any such target health care provider is not (i) on Egalet's then-current list (including any health care providers within the same group or department practice at the same location as a health care provider on Egalet's then-current list) and (ii) a managed care organization or pharmacy. Acura shall provide Egalet with **[*****]** prior written notice of any addition of health care providers to its then-current list, and in any event will provide within **[*****]** days following each Calendar Quarter during the period Acura is co-promoting the Product pursuant to Section 5.3, a then-current list of target health care providers to which Acura is then Detailing the Product or to which it then intends to Detail the Product, *provided* any such target health care provider is not (x) on Egalet's then-current list (including any health care providers within the same group or department practice at the same location as a health care provider on Egalet's then-current list) and (y) a managed care organization or pharmacy. Acura shall not Detail the Product to a health care provider not on its then-current list, without the consent of Egalet.

5.3.13.2 Egalet (and its Affiliates and sublicensees) may Detail any health care providers that are not on Acura's then-current list (other than health care providers within the same group practice at the same location as a health care provider on Acura's then-current list), even if such health care providers are not on Egalet's then-current list.

5.3.13.3 Neither Party shall Detail the Product to a health care provider on the other Party's list, without the consent of the other Party. Notwithstanding the foregoing, Egalet may, **[*****]** , request the JSC to approve territory realignment by submitting to the JSC a new list of Egalet target health care providers, which list may contain overlapping target health care providers on Acura's then-current list, not to exceed an amount equal to **[*****]** of those health care providers contained on Acura's then-current list of targeted health care providers, provided that if at such time Acura's sales force Detailing the Product exceeds **[*****]** sales representatives, then Egalet's new list of target health care providers may contain overlapping target health care providers on Acura's then-current list in an amount up to and including **[*****]** of those health care providers contained on Acura's then-current list of targeted health care providers. For such overlapping target health care providers, the JSC will determine in good faith whether it reasonably believes the Egalet field sales representatives can materially improve Product prescribing from an overlapping target health care provider and, if so, Egalet shall be entitled to have such target health care provider on its list; *provided however* , that if Acura files a notice of dispute with the JSC within ten (10) days of its determination, Acura will be entitled to receive the Co-Promotion Payment (as calculated pursuant to Section 5.3.5) derived from such overlapping health care provider that are contested in Acura's dispute notice for **[*****]** following the date of Acura's notice of dispute, provided that with respect to those health care providers that Acura has not detailed within the **[*****]** , Acura will be entitled to receive the Co-Promotion Payment (as calculated pursuant to Section 5.3.5) derived from such overlapping health care provider for only the **[*****]** following the date of Acura's notice of dispute, and *provided further* that in the case where Acura's sales force Detailing the Product exceeds **[*****]** sales representatives, no such determination from the JSC will be required in order for Egalet to include such overlapping health care providers (capped at **[*****]**) on its list but Acura will automatically be entitled to receive the Co-Promotion Payment for the **[*****]** as provided in the immediately preceding proviso. No Party shall include a health care provider on its respective list unless it has Detailed the Product to such health care provider **[*****]** or in good faith intends to Detail the Product to such heath care provider **[*****]** following the provision of the list.

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5.3.14 Acura's Co-Promotion Right shall terminate thirty (30) days after the first commercial sale of a Generic Equivalent in the United States.

5.3.15 Egalet may terminate Acura's Co-Promotion Right, without prejudice to any other remedies available to it at law or in equity, in the event Acura shall have materially breached or defaulted in the performance of any of its material obligations under this Section 5.3 and such breach or default shall have continued for sixty (60) days after written notice thereof was provided to Acura by Egalet. Any such termination under this Section 5.3.15 shall become effective at the end of such sixty (60) day period unless Acura has cured any such noticed breach(es) or default(s) prior to the expiration of such sixty (60) day period.

5.3.16 Acura's Co-Promotion Rights under this Section 5 shall remain in full force and effect regardless of a Change of Control of Acura or any assignment or transfer of this Agreement to a Third Party, *provided , however ,* they shall be suspended **[*****]** following a Change of Control transaction or any assignment or transfer of this Agreement to a Third Party, if the acquiror in such Change of Control transaction, or the assignee or transferee of this Agreement, as applicable, is marketing a pharmaceutical product in, or is conducting or has conducted **[*****]** , the United States which is or would be in direct competition with a pharmaceutical product being marketed by Egalet in the United States at the time of such Change of Control transaction or assignment or transfer of this Agreement, as applicable, until such acquiror or assignee or transferee, as applicable, divests such competing product. If such acquiror, assignee or transferee does not divest such competing product within **[*****]** of the closing of such Change of Control transaction or assignment or transfer of this Agreement, as applicable, Acura's Co-Promotion Right shall terminate. For purposes of this Section 5.3.16, a pharmaceutical product shall be deemed in direct competition with a pharmaceutical product being marketed by Egalet or its Affiliates in the United States if it is **[*****]** .

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5.4 *Product Launch Diligence.*

5.4.1 Egalet shall use Commercially Reasonable Efforts to Launch the Product in the United States as soon as commercially practical following the Effective Date and with respect to Other Countries, as provided in Section 5.4.2. Notwithstanding the foregoing, Egalet shall not be deemed to have failed to perform the foregoing obligations, if it is using its Commercially Reasonably Efforts, in the event one or more Commercialization Conditions have occurred and is continuing or the material effect of such Commercialization Condition is continuing. In any event, Egalet must Launch the Product in the United States by **[*****]** , *provided* that if one or more Commercialization Conditions has occurred and the material effect of such Commercialization Condition(s) is continuing and has an adverse effect on Egalet's ability to Launch by such date, Egalet may delay the Launch beyond such date; and if the Launch does not occur by **[*****]** due to any Commercialization Condition, then Egalet shall Launch the Product not later than **[*****]** following the date such Commercialization Condition or material effect shall have been substantially remedied or abated (the " *Required Launch Date* "). Egalet shall order Launch Quantities from the Contract Manufacturer with sufficient lead time (giving effect to any intervening Commercialization Condition and Egalet's reasonable assessment of the timing of remedy or abatement of such Commercialization Condition) so that such quantities are received in advance of the Required Launch Date.

5.4.2 Egalet shall use Commercially Reasonable Efforts to Launch the Product in any Other Country in the Territory as soon as commercially practical after receipt of Regulatory Approval for the Product in such country, *provided* that no Commercialization Condition has occurred and is continuing or the material effect of such Commercialization Condition is continuing; and if a Commercialization Condition or the material effect thereof delays such Launch, then Egalet shall Launch the Product as soon as reasonably practical following the date such Commercialization Condition or material effect shall have been remedied or abated.

5.4.3 For the avoidance of doubt, failure to satisfy its obligations pursuant to Sections 5.4.1 shall be deemed to be a material breach of a material obligation by Egalet, and Acura shall have its rights under Section 14.2 to terminate this Agreement with respect to such country with respect to such breach.

5.5 *Parties' Responsibilities in Support of Commercialization.*

5.5.1 Regulatory Filings. Each Party shall provide or otherwise make available to the other Party upon reasonable request complete copies of any material regulatory filings relating to the Product (including any Product Line Extensions) in the Territory, including Regulatory Approval Applications, material filings with the FDA, including, without limitation, material supplements or amendments thereto, all written material correspondence with the FDA regarding such regulatory filings, and all existing written minutes of material meetings and memoranda of material conversations between it (including, to the extent practicable, its investigators) and the FDA in its possession (or in the possession of any of its agents and subcontractors, such as contract research organizations used by it). The requesting Party shall reimburse the providing Party for its out-of-pocket expenses in connection with the provision of materials pursuant to this Section 5.5.1.

5.6 *Non-Solicitation.*

5.6.1 During the Term and for **[*****]** period thereafter, Acura and its Affiliates shall not hire, solicit for hire, or otherwise engage for employment (or the provisions of services under contract) any sales representative employed (whether as an employee or third party contractor) by Egalet or any of its Affiliates or any sales force representative that was employed by Egalet or any of its Affiliates at any time during the **[*****]** period preceding such hiring, solicitation, or recruitment.

5.6.2 During the Term and for **[*****]** period thereafter, Egalet and its Affiliates shall not hire, solicit for hire, or otherwise engage for employment (or the provisions of services under contract) any sales representative employed by Acura or any of its Affiliates or any sales force representative that was employed (whether as an employee or third party contractor) by Acura or any of its Affiliates at any time during the **[*****]** period preceding such hiring, solicitation, or recruitment.

6. MILESTONE AND ROYALTY PAYMENTS

As partial consideration for the rights granted to Egalet hereunder, Egalet shall make the following payments to Acura:

6.1 *Upfront Payment* . Within ten (10) days after the Effective Date, Egalet shall make a non-refundable, non-creditable payment to Acura of Five Million Dollars ($5,000,000), in immediately available funds by wire transfer (the " *Upfront Payment* "), with **[*****]** .

6.2 *Additional Payment.* Within ten (10) days after the later of (a) the First Commercial Sale of the Product by Egalet and (b) June 30, 2015, but in the case of each of subsections (a) and (b), in any event not later than January 1, 2016, Egalet shall make a non-refundable, non-creditable payment to Acura of Two and One-Half Million Dollars ($2,500,000), in immediately available funds by wire transfer, with **[*****]** .

6.3 *Sales Milestone Payment.* Within thirty (30) days after the end of the first calendar year in which worldwide Net Sales of the Product (including any Product Line Extensions and including any Incremental Net Sales generated by Acura's Co-Promotion activities (but excluding Net Sales generated in a country where the Royalty Term has expired or been terminated, after the later of (i) such expiration or termination and (ii) any inventory sell-off by Egalet under Section 14.9)) reach $150 million during such calendar year, Egalet shall make a non-refundable, non-creditable payment to Acura of twelve and one-half million dollars ($12,500,000), in immediately available funds by wire transfer (the " *Sales Milestone Payment* "), with **[*****]** .

6.4 *Royalties.*

6.4.1 As partial consideration to Acura for the license rights, and other rights granted to Egalet under this Agreement, during the Term, Egalet shall pay to Acura a royalty based on calendar year Net Sales of the Product in the Territory by Egalet, its Affiliates and permitted sublicensees during each calendar year according to the following table:

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Royalty Rate:	Portion of Worldwide Calendar Year Net Sales of the Product Greater Than:	Portion of Worldwide Calendar Year Net Sales of the Product Up to But Not Exceeding:
[***]**	**[*****]**	**[*****]**
[***]**	**[*****]**	**[*****]**
[***]**	**[*****]**	**[*****]**
[***]**	**[*****]**	**[*****]**

In calculating worldwide calendar year Net Sales, the Net Sales in a country whose Royalty Term has expired or terminated shall be excluded, but only for the period following the later of (i) such expiration or termination and (ii) any inventory sell-off by Egalet under Section 14.9. Royalties for Net Sales of the Product in a country in the Territory shall be payable only during the Royalty Term in such country.

Notwithstanding the foregoing, in a calendar year in which aggregate Net Sales of the Product in the Territory achieves or exceeds **[*****]** , the royalty rate will be **[*****]** on all Net Sales in that calendar year. Egalet shall undertake a royalty true-up during the Calendar Quarter in which calendar year Net Sales first exceed **[*****]** . Royalties shall be recalculated for all Net Sales for all prior Calendar Quarters during such calendar year, as if the **[*****]** royalty rate had been applicable from the first dollar of Net Sales for such calendar year. The difference between such recalculated royalties and those actually paid to Acura for prior Calendar Quarters is referred to as the "Royalty True-Up."

For purposes of this Section 6.4, Net Sales shall exclude the Incremental Net Sales used in the calculation of Acura's Co-Promotion Payments under Section 5.3.5.

6.4.2 If, with respect to the Product being sold in a country in the Territory in a particular Calendar Quarter, there are sales of a single Generic Equivalent of the Product (considering all strengths of such Generic Equivalent as one Generic Equivalent) in such country during such Calendar Quarter, then the Net Sales of the Product for such country in such Calendar Quarter, used for calculating the royalties owed to Acura for such Net Sales, shall be reduced by **[*****]** .

6.4.3 If, with respect to the Product being sold in a country in the Territory in a particular Calendar Quarter, there are sales of two or more Generic Equivalents of the Product (counting all strengths of a particular Generic Equivalent as one Generic Equivalent) in such country during such Calendar Quarter, then the Net Sales of the Product for such country in such Calendar Quarter, used for calculating the royalties owed to Acura for such Net Sales, shall be reduced by **[*****]** .

6.5 *Co-Promotion Payments* . Egalet shall remit to Acura the Co-Promotion Payments provided in Section 5.3.5 at the times specified in such section.

6.6 *Reduction of Payments for Royalty Stacking* . Royalties and Co-Promotion Payments payable to Acura shall be subject to reduction as set forth in Section 10.7.

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6.7 *Royalty Payments* . Within forty five (45) days following the end of each Calendar Quarter (or if later, with respect to Co-Promotion Payments, within thirty (30) days following Acura's provision to Egalet of Acura's Detail report described in Section 5.3.9), beginning with the Calendar Quarter in which the First Commercial Sale of the Product is made in the Territory, and for each Calendar Quarter thereafter, Egalet will pay to Acura the royalty payments calculated pursuant to Sections 6.4, 6.5 and 6.6 and the applicable Royalty True-Up, if any. Each royalty payment and Co-Promotion Payment shall be accompanied by a report, substantially in the form as attached hereto in Exhibit 6.7 , summarizing (a) (i) the total gross sales of the Product(s), on a dosage-by-dosage, country-by-country basis, (ii) total Net Sales for each Product (including an itemization of the deductions applied to such gross sales to derive such Net Sales) during the relevant Calendar Quarter, (iii) the calculation of royalties due thereon, and (iv) the Royalty True-up, if any, and (b) if the Co-Promotion Right has been exercised by Acura, (i) the calculation of the Co-Promotion Payment (including the AMP and an itemization of all items used to calculate the Co-Promotion Payment), (ii) the total number of prescriptions for the Product filled in such Calendar Quarter, (iii) the average number of tablets per Rx, and (iv) the average Cost of Goods Sold for each dosage strength of the Product. In the event that no royalty payments or Co-Promotion Payments are payable in respect of a given Calendar Quarter, Egalet shall submit a report so indicating.

6.8 *Mode of Payment; Currency Conversion* . All payments required under this Agreement shall be made in U.S. dollars, regardless of the country(ies) in which sales are made or expenses are incurred, via wire transfer of immediately available funds as directed by the Party entitled to such payment from time to time. Whenever, for the purpose of calculating any sums due under this Agreement, conversion from any foreign currency shall be required, such conversion shall be made as follows: the amounts shall be converted into United States dollars using the average rate of exchange for such currencies for the relevant period, such exchange rate shall be the mid-price exchange rate taken from The Wall Street Journal as published on the last day of the relevant period for which payments are due, or such other publication as may be agreed between the Parties from time to time. All amounts payable under this Agreement and not paid when due in accordance with the provisions hereof shall bear interest from the due date until paid at the rate equal to the lesser of **[*****]** , and (ii) the maximum interest rate permitted by Applicable Law.

6.9 *Inventory Purchase* . Acura shall test the items listed on Exhibit 6.9 at Acura's cost in accordance with Egalet's standard operating procedures for its viability for use in manufacturing the Product and shall provide Egalet with the results of such testing in writing. If such testing confirms that such items meet the specifications for such materials, Egalet shall purchase such API and packaging inventory, as listed on Exhibit 6.9 , from Acura at Acura's cost (as specified in such Exhibit). **[*****]** Prior to use of the API comprising a portion of the purchased inventory, Egalet shall conduct such testing as it shall determine reasonably necessary to confirm such API meets applicable specifications. If the API fails to meet applicable specifications, Egalet shall return such non-conforming API to Acura and Acura shall refund to Egalet all amounts paid therefor, including shipping costs. To the extent Egalet, its Affiliates or its Contract Manufacturer, have been unable to use the purchased inventory in the Manufacture of the Product within **[*****]** following the Launch of the Product, Egalet may return such remaining purchased inventory to Acura for a refund (determined based on the unit costs provided in Exhibit 6.9).

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6.10 *Records Retention* . Commencing with the Launch of the Product, (i) Egalet shall keep complete and accurate records pertaining to the sale of Product for a period of **[*****]** after the year in which such sales occurred, and in sufficient detail to permit Acura to confirm the accuracy of the royalties, Co-Promotion Payments and other amounts paid by Egalet hereunder, and any amounts for which Egalet has invoiced Acura and (ii) Acura shall keep complete and accurate records relating to its co-promotion of the Product (including Details performed) in sufficient detail to permit Egalet to confirm the Co-Promotion Payments paid or payable to Acura, and relating to any amounts for which it has invoiced Egalet.

6.11 *Audits* . At the request and expense of either Party (" *Auditing Party* "), the other Party (" *Audited Party* ") shall permit an independent, certified public accountant appointed by the Auditing Party and reasonably acceptable to the Audited Party, at reasonable times and upon reasonable written notice, but not more than once per calendar year, to examine such records as may be necessary for the sole purpose of verifying the calculation and reporting of Net Sales and Co-Promotion Payments and the correctness of any royalty or other payment made under this Agreement (including, without limitation, with respect to Infringement Actions, the Required Post-Marketing Study, and any expense sharing) or compliance with its commercialization requirements or co-promotion requirements for any period within the preceding **[*****]** . All results of any such examination shall be made available to the Audited Party. In the event that any audit reveals an under-payment in the amount of royalties, Co-Promotion Payments or other payment obligation that should have been paid by the Audited Party to the other, then the underpayment amount shall be paid within thirty (30) days after Auditing Party makes a demand therefore, plus interest thereon if such amount is in excess of **[*****]** of the amount that actually should have been paid. Such interest shall be calculated from the date such amount was due until the date such amount is actually paid, at the rate of **[*****]** for the date such amount was due. In addition, if the underpayment is in excess of **[*****]** of the amount that actually should have been paid **[*****]** , then the Audited Party shall reimburse the Auditing Party for the reasonable cost of such audit.

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6.12 *Taxes* . In the event that a Party is mandated under the laws of a country to withhold any tax to the tax or revenue authorities in such country in connection with any payment to the other Party, such amount shall be deducted from the payment to be made by such withholding Party, provided, however, that the withholding Party shall take reasonable and lawful actions, at the other Party's sole cost, to avoid and minimize such withholding and promptly notify the other Party so that the other Party may take lawful actions to avoid and minimize such withholding. The withholding Party shall promptly furnish the other Party with copies of any tax certificate or other documentation evidencing such withholding as necessary to satisfy the requirements of the United States Internal Revenue Service related to any application by such other Party for foreign tax credit for such payment. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect. Notwithstanding the foregoing, if Egalet is required to withhold or deduct any taxes by any government outside the United States, any subdivision thereof, or any other governmental unit within the territory of such government (such taxes collectively referred to as "Charges"), or Acura is required to pay any Charge imposed by any government outside the United States solely as a result of being a party to this Agreement, with respect to any amount payable to Acura under this Agreement, (in each case other than amounts with respect to Net Sales outside the United States) Egalet shall pay such additional amounts so that payments received by Acura net of all Charges, shall equal the amount to which Acura would have been entitled had there been no such Charges, provided, however that Egalet shall have no obligation to pay any additional amount to the extent that the Charges are imposed by reason of Acura (A) not being a resident of the United States for tax purposes or (B) failing to provide a form or similar other evidence reasonably requested by Egalet that would allow for a reduction or exemption of such Charges that Acura is legally able to provide (including, for the avoidance of doubt, Acura's qualification for the benefit of an applicable income tax convention). In addition, if Acura or its Affiliates is required to, or deems it advisable to file tax returns or make other filings with respect to Charges in any jurisdiction outside the United States by virtue of Egalet UK or another non-US Affiliate of Egalet making payments to Acura hereunder (other than with respect to royalties for Net Sales arising outside the United States), Egalet will reimburse Acura for the reasonable out-of-pocket cost of preparation and filing such tax returns or other filings. Egalet represents and warrants that no withholdings for taxes are required to be made on payments to Acura for milestones or royalties (for sales in the United States) described in this Agreement, Co-Promotion Payments or payments under Section 6.1 and 6.2 under currently applicable law so long as Acura is a resident of the United States for tax purposes.

6.13 *Bundling Prohibited* . The Product may not be sold in any bundled transaction with any other products or any service by Egalet or its Affiliates or permitted sublicensees (or by Acura or its Affiliates and sublicensees in exercising its Co-Promotion Rights) unless a reasonable pro-rated allocation of the payments received in such bundled transaction is attributable to the Products contained in the bundle.

6.14 *Invoicing and Payment of Shared Expenses*

(a) For all expenses that are to be shared by Parties pursuant to the express terms of this Agreement, the Party incurring such expense shall invoice the other Party for its Expense Split Percentage of such expense, and shall provide such other supporting details as the other Party shall reasonably request. All such invoices shall be payable within thirty (30) days from the date of receipt of such invoice and supporting materials. For the avoidance of doubt, expenses not explicitly designated as subject to the Expense Split Percentage in this Agreement shall be borne in their entirety by the responsible Party.

(b) In the event that the proposed budget for Product Line Extension Studies (determined as a group) or the proposed budget for Required Post-Marketing Studies (determined as a group) exceeds **[*****]** and Acura withholds its consent under Section 3.2.11, or does not provide its agreement within the ten (10) business day period specified in Section 3.2.11, Egalet may elect in its sole discretion to approve such budget, provided that (i) Acura shall be responsible for paying its Expense Split Percentage of such expenses only up to such **[*****]** , (ii) Egalet shall be responsible for one hundred percent (100%) of such expenses exceeding **[*****]** , and (iii) Egalet shall be entitled to apply as a credit against any royalty payments, Co-Promotion Payments and milestone payments owed to Acura an amount equal to **[*****]** percent **[*****]** of Acura's Expense Split Percentage of such expenses exceeding **[*****]** .

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7. GRANT OF RIGHTS

7.1 *License Grants to Egalet.*

7.1.1 Subject to the terms and conditions of this Agreement, Acura hereby grants to Egalet the exclusive (even as to Acura and its Affiliates, except subject to Acura's Co-Promotion Right and the Generic Licenses) royalty-bearing, license in the Field throughout the Territory, with the right to grant sublicenses, under the Aversion Patent Rights and the Aversion Technology, including the Product-specific Intellectual Property to make, develop, Manufacture, have Manufactured, import, use, sell, offer to sell and otherwise commercialize (including without limitation, marketing, advertising, promoting, detailing, and distributing) the Product in the Territory.

7.1.2 Except as expressly set forth in this Agreement, no license is granted by Acura under its rights in any intellectual property, including any Patent Rights, whatsoever for any activities by Egalet that are outside the scope of the license grant in this Section 7.1 and Section 7.3.

7.2 *Sublicensing* . Egalet may grant sublicenses of the licenses granted to Egalet under Section 7.1, subject to Acura's prior written consent for a sublicense in the United States to a Third Party to market or sell the Product (other than sublicenses granted to Third Parties acting as distributors or wholesalers or to Third Parties providing products or non-marketing/selling services to or on behalf of Egalet or its Affiliates), such consent not to be unreasonably withheld, delayed or conditioned, except in the case of **[*****]** which consent Acura may withhold in its sole discretion (a " *U.S. Sublicensee* "); *provided* , *however* , that (i) Egalet shall submit a copy of the draft of each such sublicense agreement with a U.S. Sublicensee to Acura at least **[*****]** before execution, which copy may be redacted as to financial information and Third Party confidential information not directly related to Products; (ii) Egalet shall submit a copy of each such executed sublicense agreement (other than sublicenses granted to Third Parties acting as distributors or wholesalers or to Third Parties providing products or non-marketing/selling services to or on behalf of Egalet or its Affiliates) to Acura, which copy may be redacted as to financial information and Third Party confidential information not directly related to Product; (iii) Egalet shall guarantee and be responsible for the making of all payments due, and the making of any reports under this Agreement, with respect to sales of the Product by its Affiliates or sublicensees and their compliance with all applicable terms of this Agreement; (iv) each Affiliate or sublicensee agrees in writing to maintain appropriate books and records relating to the Product and to permit Acura to review such books and records and visit such facilities for such review, pursuant to the provisions of Sections 5.2.5 and 6.11; (v) such sublicense agreement requires it to continue in full force and effect in accordance with the terms and conditions of the respective sublicense agreement upon the termination of this Agreement, and permits Egalet to assign to Acura such sublicense agreements; and (vi) such sublicense agreement requires such sublicensee to observe all other applicable terms of this Agreement. No sublicense granted by Egalet shall be valid unless it has complied with this Section 7.2.

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7.3 *Trademarks; Logos* . Egalet shall have the right to market the Products throughout the Territory under a trademark or trademarks (collectively, the " *Trademarks* ", such term excludes the Aversion Mark, Product Mark and the Corporate Trademarks) selected by Egalet at its sole discretion. Except as otherwise expressly provided in this Agreement, Egalet shall own all right, title and interest in and to such Trademarks, subject to transfer to Acura under Section 14.7. Subject to Applicable Law, all labeling and packaging for Product to be marketed and sold in the Territory shall contain a reference to Aversion® (the " *Aversion Mark* "). Except as otherwise expressly provided in this Agreement, Acura shall own all right, title and interest in and to the Aversion Mark. Egalet shall assume full responsibility, at its sole cost and expense, for prosecuting or litigating any infringement of a Trademark, the Product Mark or a Corporate Trademark by a Third Party, and shall be entitled to retain all recoveries in connection therewith and Acura shall assume full responsibility, at its sole cost and expense, for prosecuting or litigating any infringement of the Aversion Mark. In connection with this Section 7.3:

7.3.1 Acura hereby grants to Egalet a royalty-free license to use the Aversion Mark and the Oxaydo trademark (the " *Product Mark* "), in each country of the Territory, for the Term and, if the Term has expired pursuant to Section 14.1, after the Term, in connection with the marketing, promotion and sale of the Product as contemplated in this Agreement, and if this Agreement has been terminated, after the Term for the sole purpose of selling of inventory under Section 14.9. The license grant in this Section 7.3.1 shall be royalty free and shall be exclusive with respect to the Oxaydo trademark and non-exclusive with respect to the Aversion Mark. The ownership and all goodwill from the use of the Aversion Mark shall vest in and inure to the benefit of Acura. Acura reserves all rights not expressly granted herein. Acura shall maintain the Aversion Mark in all countries in which the Aversion Mark are registered as of the Effective Date, shall exercise Commercially Reasonable Efforts to file for and seek to obtain registrations of, and shall maintain once such registrations are obtained, the Aversion Mark in all countries in which Egalet commercializes the Product or, upon reasonable advance written notice, intends to commercialize the Product. If selected by Egalet as the Trademark for the Product, Acura shall use Commercially Reasonable Efforts to file for trademark protection for the Oxaydo trademark in each country in the Territory in which the Aversion Mark is registered as of the Effective Date, shall use Commercially Reasonable Efforts to obtain such trademark protection, and upon issuance, shall maintain the Oxaydo trademark in such jurisdictions, and shall exercise Commercially Reasonably Efforts to file for and seek to obtain registrations of, and shall maintain once such registrations are obtained, the Oxaydo trademark in all countries in which Egalet commercializes the Product or, upon reasonable advance written notice, intends to commercialize the Product. Acura shall not abandon or permit to lapse any of the Aversion Mark or the Oxaydo trademark without Egalet's prior written consent, not to be unreasonably withheld, delayed or conditioned.

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7.3.2 In the event that a Party exercises its rights to terminate this Agreement with respect to the Product in any or all country(ies) pursuant to Section 14.2 or in all countries pursuant to Sections 14.3, 14.4, 14.5, 14.6, or 15 without limiting Acura's rights under such sections, Egalet shall, and hereby does, grant to Acura a royalty-free, non-transferable, non-sublicensable license to use the applicable Trademark(s) consisting of the corporate name and logo of Egalet and its Affiliates (collectively, the " *Corporate Trademarks* ") used with respect to the Product in such country(ies) solely in connection with the marketing, sale, distribution and promotion of the in the applicable country of the inventory purchased by Acura under Section 14.9; *provided , however* , that, Acura shall diligently proceed to select, obtain regulatory approval for, and complete the revision of all packaging and labeling to include a corporate name, and corporate logo chosen by Acura, none of which shall be confusingly similar to the Corporate Trademarks, and in no case more than the later of **[*****]** . Egalet agrees to cooperate with Acura in all reasonable respects to enable Acura to maintain the Corporate Trademarks in such country(ies) for the permitted period, including, but not limited to, providing all required information and documentation regarding the Trademarks in such country(ies) on a timely basis and providing such other assistance as may be reasonably necessary. For the avoidance of doubt, at the end of the later of **[*****]** , Acura shall have no further rights to use the Corporate Trademarks in the Territory in connection with the marketing and promotion of the Products. The ownership and all goodwill from the use of the Corporate Trademarks shall vest in and inure to the benefit of Egalet. Egalet reserves all rights not expressly granted herein.

7.3.3 Egalet hereby acknowledges the exclusive ownership of Acura of the Aversion Mark furnished by Acura (or its Affiliates) for use in connection with the Product. Egalet shall not, during the Term or thereafter, register, use, or attempt to obtain any right in and to the Aversion Mark or in and to any name, logo or trademark confusingly similar thereto. Acura hereby acknowledges Egalet's exclusive ownership rights in the Trademarks, and accordingly agrees that at no time during or after the Term to challenge or assist others to challenge the Trademarks or the registration thereof or attempt to register any trademarks, trade names or logos confusingly similar to such Trademarks.

7.3.4 All representations of the Aversion Mark that Egalet intends to use shall first be submitted to Acura for approval (which shall not be unreasonably withheld or delayed) of design, color, and other details or shall be exact copies of those used by Acura and shall in any event comply with all usage guidelines as established by Acura from time to time. Egalet shall submit representative promotional materials using the Aversion Mark to Acura for Acura's review and comment prior to their first use and prior to any subsequent change or addition to such promotional materials.

7.3.5 Quality Control.

7.3.5.1 For the sake of clarity and with respect to this Section 7.3.5, Acura is the licensor as it pertains to the Aversion Mark and Product Marks and licensee as it pertains to the Corporate Trademarks. Egalet is the licensee as it pertains to the Aversion Mark and Product Marks and is the licensor as it pertains to the Corporate Trademarks. Each of Egalet and Acura are therefore "Licensor" and "Licensee," as applicable. For the purposes of this Section 7.3.5, "Licensed Trademarks" shall mean the Aversion Mark, Product Marks and the Corporate Trademarks, collectively.

7.3.5.2 Licensor shall have the right to exercise quality control over the Licensee's use of the Licensed Trademarks, as applicable, to a degree reasonably necessary to maintain the validity of the Licensed Trademarks, as applicable, and to protect the goodwill associated therewith.

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7.3.5.3 Licensee shall, in its packaging, sale, marketing, advertising, disposition and distribution of the Product and product packaging adhere to a level of quality regarding the maintenance of the validity of the Licensed Trademarks, as applicable, and the protection of the goodwill associated therewith consistent with the reasonable standards of quality otherwise set by Licensee.

7.3.5.4 Licensee shall comply with all Applicable Laws in the packaging, sale, distribution, advertising, disposition and marketing of the Product and product packaging, and Licensee shall use all legends, notices, and markings as required by Law.

7.3.5.5 Licensee shall, upon reasonable request by Licensor, submit to Licensor samples of Product packaging and representative samples of all publicly distributed materials bearing the Licensed Trademarks or product packaging which are then currently sold or distributed, or pending sale or distribution by Licensee.

8. MANUFACTURING AND SUPPLY

8.1 *Manufacture* . To the extent that Acura has executed any agreements with **[*****]** with respect to the Product prior to the Effective Date, Acura shall assign such agreements to Egalet within ten (10) days after the Effective Date, and the Parties shall reasonably cooperate, including by executing any assignment documentation, to effect such assignment. Within five (5) days of such assignment, Egalet shall remit to Acura the out-of-pocket costs and expenses incurred by Acura in connection with such agreements as set forth in Exhibit 8.1 . During the Term, Egalet shall have the sole obligation and responsibility, and at its sole cost and expense, for all aspects of Manufacturing, including without limitation, testing packaging and labeling the Product, and any costs associated with storage, release and Third Party logistics. Egalet may engage a Contract Manufacturer to Manufacture (including, labeling, packaging and testing) the Product. As part of such responsibilities, Egalet shall have the sole responsibility to coordinate with and provide to its Contract Manufacturer such information and materials as shall be reasonably necessary for such Contract Manufacturer to obtain sufficient Quota for the API from the DEA. Egalet covenants and agrees to use Commercially Reasonable Efforts to obtain the right under any agreement with a Third Party providing for the Manufacture or distribution of the Product (if such agreement does not also provide for the manufacture or distribution of other products of Egalet or its Affiliates) to assign such agreement to Acura upon termination of this Agreement pursuant to Sections 14.2, 14.3, 14.4, 14.5, 14.6 or 15.

8.2 *Manufacturing Technology Transfer*. Upon Egalet's request, Acura shall make available to Egalet or its designated Contract Manufacturer(s) all Aversion Technology reasonably necessary to assist with the transfer of the Aversion Technology relating to the manufacture of the Product to Egalet or Egalet's Contract Manufacturer(s) of the Product, at no charge. All reasonable out-of-pocket expenses incurred by Acura personnel in connection with activities associated with any such technology transfer will be promptly reimbursed by Egalet (other than with respect to a transfer to **[*****]**), provided that in order to be reimbursed, Acura shall have first obtained Egalet's prior written approval for (i) any individual expense exceeding **[*****]** and (ii) any and all expenses when total expenses to be reimbursed under this Section 8.2 exceed **[*****]** . Acura shall exercise Commercially Reasonable Efforts in connection with the technology transfer contemplated in this Section 8.2 .

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8.3 *Regulatory Changes*. Any costs and expenses associated with regulatory changes requested by a Regulatory Authority relating to the Product, the Product NDA or a foreign equivalent, including the costs of implementing CMC changes or additional testing not included in the Product NDA, will be borne by Egalet .

9. NON-COMPETES

9.1 *Egalet Restrictive Covenant* . During the Term, except as provided in this Agreement, Egalet shall not, and shall cause its Affiliates to not, develop, have developed, commercialize (including market, distribute and sell), have commercialized, manufacture or have manufactured, or collaborate with or license another person or entity to develop, have developed, commercialize, have commercialized, manufacture or have manufactured in the Territory an immediate-release product containing **[*****]** The restriction in this Section 9.1 shall terminate with respect to a particular country as provided in Article 14.

9.2 *Acura Restrictive Covenant* . During the Term, except as provided in this Agreement, Acura shall not, and shall cause its Affiliates to not, develop, have developed, commercialize (including market, distribute and sell), have commercialized, Manufacture or have manufactured, or collaborate with or license another Person or entity to develop, have developed, commercialize, have commercialized, manufacture or have manufactured in the Territory an immediate-release product containing **[*****]** . The restriction in this Section 9.2 shall terminate with respect to a particular country as provided in Article 14.

9.3 *Limitx Oxycodone Single Ingredient Product* . If Acura determines to license, transfer or convey to a Third Party **[*****]** it will send Egalet written notice of same, before offering such product to any Third Party. Acura's notice shall contain such information as Egalet shall reasonably require to evaluate such product (which shall be subject to the protections of Article 12 hereof). Egalet shall send Acura a written notice within thirty (30) days of receipt of Acura's notice and supporting information indicating whether or not it is elects to pursue licensing discussions with Acura for such product. If Egalet's written notice indicates that it is not interested in acquiring rights to such product or if Egalet does not respond in writing to Acura within such thirty (30) day period, then Acura and its Affiliates shall be free to negotiate with any Third Party and enter into an agreement relating to such product and Egalet shall have no rights thereto. If Egalet's written notice indicates it is interested in acquiring rights to such product from Acura, then, from the date of Egalet's notice and for a period of ninety (90) days thereafter, Acura shall negotiate in good faith with Egalet the terms and provisions of a definitive agreement providing for Acura's license to Egalet of such product and during such period neither Acura nor its Affiliates shall discuss or negotiate with any Third Party terms relating to development or commercialization of such product, or enter into an agreement with a Third Party providing for the sale, license or other conveyance of such Product. In the absence of the Parties' execution of a definitive agreement during such ninety (90) day period for development and/or commercialization for such product, Acura and its Affiliates shall be free to negotiate after the end of such ninety (90) day period with any Third Party and enter into an agreement relating to such product and Egalet shall have no rights thereto. For the avoidance of doubt, Acura shall not be required to provide any notice to Egalet under this Section 9.3 in connection with its undergoing or completing a Change of Control transaction, or sale of all or substantially all of its line of business which includes the Limitx Technology. This Section 9.3 shall not survive termination or expiration of this Agreement.

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10. INTELLECTUAL PROPERTY OWNERSHIP; PATENTS

10.1 *Ownership.* Acura shall retain all right, title and interest in and to Aversion Technology, subject to the licenses granted to Egalet pursuant to Section 7.1 .

10.2 *Inventions.* Title to all inventions and discoveries made by Acura's and its Affiliates' and their respective employees, consultants and agents resulting from development activities shall reside with Acura. Title to all inventions and discoveries made by Egalet's and its Affiliates and their respective employees, consultants and agents resulting from development activities shall reside with Egalet and title to all inventions and discoveries made by both Acura and Egalet (or Affiliates thereof) employees, consultants and agents resulting from development activities shall be jointly owned. Inventorship shall be determined in accordance with United States patent law. Notwithstanding the foregoing, if during the Term, Egalet, any employee or agent of Egalet, or any Affiliate of Egalet makes an improvement, invention, refinement, discovery, or development primarily related to the Aversion Technology or the Product as it relates to the Aversion Technology, Egalet shall, assign and cause such improvement, invention, refinement, discovery, or development to Acura and Acura shall be deemed hereby to, without further action required, grant a royalty free, perpetual, irrevocable, non-terminable, worldwide license to Egalet (including the right to sublicense through multiple tiers) to such improvement, invention, refinement, discovery or development for (i) use in developing, Manufacturing, selling, distributing, marketing and commercializing the Product and (ii) use in developing, manufacturing, selling, distributing, marketing and commercializing any other products that do not incorporate the Aversion Composition.

10.3 *Patent Prosecution and Maintenance.*

10.3.1 Acura shall have full responsibility for, and shall control the preparation and prosecution of, and the maintenance of, and subject to Section 10.3.2 shall maintain during the Term, all Aversion Patent Rights and the inventions relating to the Aversion Technology, other than Product-specific Intellectual Property. The expense of such prosecution and maintenance will be at Acura's expense with respect to Aversion Patent Rights (i) for the United States and (ii) for Other Countries if such Aversion Patent Rights have been filed as of the Effective Date. The costs and expenses of the prosecution and maintenance of Aversion Patent Rights and inventions relating to the Aversion Technology not included in 10.3.1(i) or 10.3.1(ii) will, if requested by Egalet to be filed, prosecuted and/or maintained, be solely borne by Egalet, and Egalet will remit to Acura Acura's out-of-product costs for such amounts within thirty (30) days of receipt of Acura's invoice. Egalet shall have full responsibility for, and shall control the preparation and prosecution of, and the maintenance of all Product-specific Intellectual Property and the inventions relating to the Product-specific Intellectual Property, and subject to Section 10.3.3 shall maintain all Product-specific Intellectual Property during the Term. The expense of such prosecution and maintenance of Product-specific Intellectual Property by Egalet will be at Egalet's expense. Notwithstanding which Party satisfies the prosecution and maintenance expenses relating to the Aversion Patent Rights, Acura will own all such Patent Rights.

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10.3.2 Acura shall have the sole right to determine whether any invention relating to Aversion Technology, other than Product-specific Intellectual Property, is patentable, and if so, shall, in its sole discretion, determine whether or not to proceed with the preparation and prosecution of a patent application covering any such invention. In the event Acura determines not to proceed with the preparation and prosecution of a patent application covering any such invention, or payment of maintenance fees related to a granted patent covering any such invention for which it has the right to do so pursuant to 10.3.1 above, where such invention covers the Product or such pending patent application or granted patent claims the Product, prior to discontinuing such preparation, prosecution and/or payment of maintenance fees (to the extent it is not already required to pay such fees), Acura shall offer Egalet the opportunity to maintain such preparation and prosecution, and to pay such maintenance fees (to the extent it is not already required to pay such fees), at Egalet's sole cost and expense. Egalet shall have ninety (90) days to decide whether or not to assume these costs, during which time Acura shall make Commercially Reasonable Efforts to prepare, prosecute, and maintain any such Patent Rights. In the event Egalet chooses to maintain such preparation and prosecution or pay such maintenance fees (to the extent it is not already required to pay such fees), Acura agrees to cooperate with Egalet to execute all lawful papers and instruments reasonably necessary to transfer and assign such Patent Rights to Egalet.

10.3.3 Egalet shall have the sole right to determine whether any invention within Product-specific Intellectual Property is patentable, and if so, shall, in its sole discretion, determine whether or not to proceed with the preparation and prosecution of a patent application covering any such invention. In the event Egalet determines not to proceed with the preparation and prosecution of a patent application covering any such invention, or payment of maintenance fees related to a granted patent covering any such invention, for which it has responsibility pursuant to 10.3.1 above, prior to discontinuing such preparation, prosecution and/or payment of maintenance fees, Egalet shall offer Acura the opportunity to maintain such preparation and prosecution, and to pay such maintenance fees (to the extent it is not already required to pay such fees), at Acura's sole cost and expense. Acura shall have ninety (90) days to decide whether or not to assume these costs, during which time Egalet shall make Commercially Reasonable Efforts to prepare, prosecute, and maintain any such Patent Rights.

10.3.4 Each Party having responsibility for preparation, filing, prosecution and maintenance of Patent Rights pursuant to Sections 10.3.1, 10.3.2 and 10.3.3 shall keep the other Party advised on the status of preparation, filing and prosecution of all patent applications included within such Patent Rights and the maintenance and extension of any issued patents within such Patent Rights, and shall allow the other Party a reasonable opportunity and reasonable time, but not less than 10 working days, to review and comment regarding relevant material communications and drafts of any material responses or proposed filings by the responsible Party before any applicable filings are submitted to any relevant patent office or government authority, and consider in good faith any reasonable comments offered by the other Party for inclusion in any final filings submitted by the responsible Party to any relevant patent office or government authority in the Territory.

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10.3.5 Each Party agrees with the other Party to cooperate with the other Party to execute all lawful papers and instruments, to make all rightful oaths and declarations, and to provide consultation and assistance as may be necessary in the preparation, prosecution, maintenance and enforcement of all such Patent Rights.

10.4 *Intellectual Property Enforcement.*

10.4.1 If either Party learns of an actual, potential or suspected, unauthorized use, misappropriation or infringement of the Aversion Patent Rights or Aversion Technology by a Third Party, including the receipt of a Paragraph IV Certification with respect to the Product (a *"Third Party Infringement"*), such Party shall promptly notify the other Party in writing and shall promptly provide such other Party with available evidence of such Third Party Infringement. Subject to Section 10.4.5, Section 10.4.2 sets forth the rights of the Parties to commence and prosecute an action relating to such Third Party Infringement (an " *Offensive Infringement Action "*).

10.4.2 During the Term and thereafter with respect to events arising during the Term,

(i) Acura shall have the first right, but not the obligation, to undertake control of, and manage and prosecute, including selection of counsel (collectively, "Prosecute"), such Offensive Infringement Action, except as otherwise provided in subsection (ii) below;

(ii) Egalet shall have the first right, but not the obligation, to Prosecute such Offensive Infringement Action if it is a Product-specific Offensive Infringement Action, or is in response to a Paragraph IV Certification relating to the Product;

(iii) Acura, shall have the right, but not the obligation, to Prosecute any such Offensive Infringement Action for which Egalet is not undertaking the Prosecution as provided in subsection (ii) above; and

(iv) Egalet shall have the right, but not the obligation, to Prosecute any Offensive Infringement Action for which Acura is not undertaking the Prosecution as provided in subsection (i) above.

10.4.3 A Party having the first right to prosecute an Offensive Infringement Action shall request a meeting to discuss whether it intends to Prosecute such action within (i) fifteen (15) days in the case of an Offensive Infringement Action relating to a Paragraph IV Certification for the Product, and (ii) within ninety (90) days after receiving such written request for other Offensive Infringement Actions. If the Party having the first right of Prosecution declines to Prosecute the action, the other Party may, by written notice to the declining Party, Prosecute such action.

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10.4.4 The Prosecuting Party shall control and manage such action (including without limitation, control over the settlement of such action, *provided* the other Party consents to such settlement, such consent not to be unreasonably withheld, delayed or conditioned) and the other Party shall cooperate with the Prosecuting Party and join the action as required by law for subject matter jurisdiction or as reasonably requested. If the other Party joins the action it may do so at its sole cost and expense, and the Prosecuting Party shall not oppose any attempt by the other Party to join, or otherwise intervene in such action. The Parties' shall share out-of-pocket expenses (including attorneys' fees) solely with respect to Product-specific Offensive Infringement Actions as follows: **[*****]** . Any and all amounts recovered with respect to a Product-specific Offensive Infringement Action shall be applied first to reimburse the Parties for their reasonable out-of-pocket expenses (including reasonable attorneys' fees and expenses already paid under Section 6.14(a)) in Prosecuting such Product-specific Offensive Infringement Action. If such proceeds are insufficient with respect to Product-specific Offensive Infringement Actions, then the Parties shall share such remaining out-of pocket expenses according to the sharing of such expenses for Product-specific Offensive Infringement Actions as provided above in this Section 10.4.4. Any recovery in excess of the Parties' out-of-pocket expenses with respect to a Product-specific Offensive Infringement Action will be shared as follows: **[*****]** . Notwithstanding the foregoing, Acura's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license, covenant not to sue relating to, dedication to the public, admission of non-infringement, invalidity or unenforceability or abandonment of any of Acura's intellectual property, including, without limitation, the Aversion Technology, and Egalet's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license or covenant not to sue with respect to any Third Party Infringement related to a Paragraph IV Certification with respect to the Product or other Product-specific Offensive Infringement Action, or that would otherwise grant any rights to manufacture, use, sell or otherwise commercialize **[*****]** or admission of non-infringement, invalidity or unenforceability or abandonment of any Product-specific Intellectual Property.

10.4.5 **[*****]**

10.5 *Infringement Action Brought by Third Parties.*

10.5.1 If Acura, Egalet or any of their respective Affiliates is sued or threatened with suit during the Term by a Third Party for infringement of any patent of a Third Party or for misappropriation of any Third Party know-how, proprietary, technical or confidential information in the development, Manufacture and/or commercialization of the Product in the Territory during the Term (other than infringement or misappropriation of any Trademark or trade dress arising out of the marketing and/or sale of the Product in the Territory during the Term), (each, an " *Infringement Action* "), such Party shall promptly notify the other Party in writing (whether such action was brought against Egalet or Acura). During the Term and thereafter with respect to events arising during the Term,

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(i) Acura shall have the first right, but not the obligation, to undertake control of, and manage, and defend, including selection of counsel (collectively, " *Defend* "), such Infringement Action, except as otherwise provided in subsection (ii) below;

(ii) Egalet shall have the first right, but not the obligation, to Defend such Infringement Action if it is a Product-specific Infringement Action;

(iii) Acura, shall have the right, but not the obligation, to Defend any such Infringement Action for which Egalet has the first right but is not undertaking the defense as provided in subsection (ii) above; and

(iv) Egalet shall have the right, but not the obligation, to Defend any Infringement Action for which Acura has the first right but is not undertaking the defense as provided in subsection (i) above.

10.5.2 A Party having the first right to Defend an action shall notify the other Party in writing whether it intends to defend such action within the earlier of (A) twenty (20) days prior to the date of any required court filing (as the same may have been extended) and (B) forty (40) days after receiving written notice of such action. If the Party with the first right to Defend chooses not to Defend the action then the other Party, may by written notice to the Party with the first right, undertake the defense.

10.5.3 The Defending Party shall have the right to control and manage such action (including without limitation, control over the settlement of such action), provided, however, that any such settlement shall also release the non-Defending Party from the claims relating to the Infringement Action (provided that the non-Defending party executes a mutual release in favor of the party releasing the non-Defending Party), and further provided it obtains the written consent of the non-Defending Party not to be unreasonably withheld, delayed or conditioned. Without limiting the foregoing, Acura's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license, covenant not so sue relating to, dedication to the public, admission of non-infringement, invalidity or unenforceability or abandonment of Acura's intellectual property, including without limitation, the Aversion Technology, and Egalet's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license or covenant not to sue with respect to any Third Party Infringement related to a Paragraph IV Certification with respect to the Product or that would otherwise grant any rights to manufacture, use, sell or otherwise commercialize an immediate release product containing **[*****]** or admission of invalidity or unenforceability or abandonment of any Product-specific Intellectual Property. Each Party shall, promptly upon the other Party's request, provide reasonable assistance in conducting the litigation. The non-Defending Party shall cooperate with the Defending Party and join the action as reasonably requested. If the non-Defending Party so desires, it may join such action, at its sole cost and expense, and the Defending Party shall not oppose any attempt by the other Party to join, or otherwise intervene, in such action.

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10.5.4 In any Infringement Action, each Party shall bear its own internal costs. Out-of-pocket costs (including attorneys' fees and costs), and any damages and settlement payments in any Infringement Action **[*****]** .

10.5.5 If there is any recovery or award to a Party in any Infringement Action that is a Product-specific Infringement Action, the Parties shall share any in the recovery or award (after payment of, and/or reimbursements for previously paid, out-of-pocket-expenses) according to the Expense Split Percentage, and if there is any recovery or award to a Party in any Infringement Action that is not a Product-specific Infringement Action, the Defending Party shall retain any recovery or award (after payment of, and/or reimbursements for previously paid, out-of-pocket-expenses).

10.5.6 Each Party's obligations under this Section 10.5 shall be limited solely to Infringement Actions in the Territory relating to actions taken during the Term.

10.5.7 During the pendency of any action (including appeals) under this Section 10.5, and thereafter, Egalet shall continue to make all payments due to Acura under this Agreement.

10.5.8 **[*****]**

10.6 *Cooperation.* Each Party shall execute all necessary and proper documents, take such actions as shall be appropriate to allow the Party with the right to bring such actions, as set forth in this Article 10, to institute and Prosecute Offensive Infringement Actions, **[*****]** , and Defend Infringement Actions and **[*****]** and shall otherwise cooperate with respect to such actions, including (a) by joining as a party to any Offensive Infringement Action, **[*****]** , Infringement Action or **[*****]** if requested by the Prosecuting Party or Defending Party, as applicable, at the Prosecuting Party's or Defending Party's expense, and (b) making its and its Affiliates and licensees and sublicensees and all of their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action. If a Prosecuting Party or Defending Party desires to withdraw from or cease pursuing an Offensive Infringement Action, **[*****]** , Infringement Action or **[*****]** , as applicable, it will promptly notify the other Party (in good time to enable the other Party to meet any deadlines by which any action must be taken to preserve any rights in such action) and such other Party may continue or may substitute itself for the withdrawing Party and proceed under the terms and conditions of this Article 10. If only one Party is controlling any Offensive Infringement Action, **[*****]** , Infringement Action or **[*****]** , the Party controlling any such action will, to the extent not prohibited by court order or applicable law, keep the non-controlling Party updated with respect to any such action, including providing copies of all material documents received or filed in connection with any such action.

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10.7 *License Fees to Third Parties.* In the event either Acura or Egalet learns of any Third Party Patent Rights which may cover the abuse deterrent features of the Product in the Territory, such Party will promptly notify the other Party. The Parties agree to confer in good faith regarding such potential infringement risk and to explore reasonable alternatives for avoiding such risk and to provide such information to each other as either Party may reasonably request. If Egalet or any of its Affiliates or sublicensees enters into an agreement with a Third Party to obtain a license under a Patent Right or other right that is determined by its patent counsel to be reasonably required to avoid the infringement of such Third Party Patent Rights in order to manufacture, use or sell the Product in the Territory or to practice the rights under the Aversion Patent Rights or Aversion Technology granted to Egalet hereunder (including in connection with the settlement of an Infringement Action), or shall be subject to a final court or other binding order or ruling or settlement agreement requiring any payments, including the payment of a royalty to a Third Party patent holder in respect of manufacture, use or sales of the Product or to practice of the Aversion Patent Rights or Aversion Technology granted to Egalet hereunder, then Egalet may deduct from the royalties due to Acura pursuant to Section 6.7, and Co-Promotion Payments due to Acura pursuant to Section 5.3.5 (without duplication), **[*****]** for any such license to such Patent Right or other right or payment made pursuant to such agreement or such final court or other binding order or ruling or settlement agreement, provided that in no event shall the royalties or the Co-Promote Payments due to Acura be reduced by more than **[*****]** . **[*****]** .

10.8 **[*****]**

10.9 *Exclusivity of Sections 10.4, 10.5, 10.7 and 10.8.* **[*****]**

11. REGULATORY MATTERS.

11.1 *Ownership and Maintenance of Regulatory Approvals.*

11.1.1 Promptly upon receipt from Egalet of the Upfront Payment, Acura will send the FDA any required properly executed forms (i.e., FDA Forms 356h and 1571, if applicable) and a letter transferring the Product NDA and associated IND to Egalet, and take any other actions reasonably necessary to provide for and effect the transfer of the Product NDA and IND to Egalet. Following such transfer of ownership of the Product NDA and IND, and for foreign equivalents of the NDAs for the Product in all Other Countries, Egalet shall during the Term, at its sole expense (subject to Section 11.1.2), maintain and continue in force and effect the Product NDA and IND, including the filing of all annual and other reports or filings required by the FDA or any other Regulatory Authority, the performance and completion of the Required Post-Marketing Study, the preparation and submission of stability studies on batches of the Product as may be required under Applicable Law, and the preparation and filing of any notices, amendments or supplements as may be required to change or add another source of supply of the API for such Product, if Egalet elects to change or add such other source of supply. Egalet shall not be deemed to have breached its obligations under this Section 11.1.1 if the maintenance and continuance in full force and effect of the Product NDA and IND is precluded or materially impaired by any requirement of the FDA or other Regulatory Authority or any Applicable Law.

11.1.2 During the Term, **[*****]** .

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11.1.3 In connection with the transfer of the Product NDA to Egalet, Acura shall provide or make available to Egalet a copy of the Product NDA, and other information and documents required to be transferred by Applicable Law in connection with the transfer of the Product NDA and the responsibilities associated with the ownership thereof. Notwithstanding the transfer of the Product NDA to Egalet, Egalet acknowledges that Acura is retaining copies of the Product NDA and all documents relating thereto for its use as provided in Section 11.2.1.

11.2 *Acura's Right of Reference.*

11.2.1 Egalet shall permit Acura access to, and hereby grants Acura, at no cost or fee, the perpetual right to reference and use, all development and regulatory data and reports associated with the Product (including Product Line Extensions) for Acura's, its Affiliates' and its licensee's use in the development and/or Regulatory Approval of any product of Acura or its Affiliates inside and outside the Territory (other than a product that would violate the provisions of Section 9.2). Such development and regulatory data and reports shall include, without limitation, preclinical and clinical data and reports, regulatory submissions and filings, Regulatory Approvals and any adverse event reports. In furtherance of the foregoing, Egalet shall, promptly upon the request of Acura, deliver a letter to the FDA (or the relevant Regulatory Authority) authorizing Acura, its Affiliates or sublicensees to reference and use the applicable regulatory submissions and filings related to the Product (including, without limitation, the Product NDA) in the Territory, at no cost or fee, for Acura's, its Affiliates' and its licensee's use in the development and/or regulatory approval of any product of Acura or its Affiliates inside or outside the Territory (other than a product that would violate the provisions of Section 9.2). Such right of reference attaches to the rights to the Product, and Egalet shall ensure that any transferee or assignee of rights in the Product shall also grant such rights of reference to Acura and its Affiliates and sublicensees.

11.2.2 All Regulatory Approval Applications and Regulatory Approvals for the Product for the United States and in other Countries shall be owned by Egalet, subject to transfer to Acura pursuant to Article 14.

11.3 *Adverse Reaction Reporting.*

11.3.1 Acura and Egalet shall report to the other any information of which they have knowledge concerning any Product complaints or adverse drug experience in connection with the use of the Product. Upon receipt of any such information concerning any adverse drug experience or unexpected adverse drug experience by either Acura or Egalet, the Parties shall promptly consult each other and use Commercially Reasonable Efforts to arrive at a mutually acceptable procedure for taking such possible actions as appropriate or required under the circumstances (with Egalet having primary responsibility for the taking of such action if specific to the Product, at its expense, and Acura having primary responsibility for the taking of such action if not specific to the Product, at its expense, including, without limitation, in each case with respect to the Party having primary responsibility providing information gathering and related services with respect to any such event); *provided, however,* that nothing contained herein shall be construed as restricting the right or duty of either Party to make a required report or submission to the FDA or take any other action that it deems to be required by Applicable Law.

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11.3.2 Egalet shall be responsible for investigating any Product complaints and adverse drug experiences, and for preparing reports to the FDA and foreign equivalents to be filed by Egalet for the reporting of any adverse drug experiences. Acura shall cooperate with any investigations made by Egalet relating to Product complaints or adverse drug experiences, and shall provide such information reasonably requested by Egalet to assist in Egalet's investigation of and preparation of reports relating to, such Product complaint or adverse drug experiences. Egalet shall prepare all adverse drug experience reports to be filed with the FDA pursuant to 21 C.F.R. §§ 314.80(b) and (c) and equivalent foreign reports with respect to the Product and provide copies to Acura for review prior to filing, *provided* that Acura shall prepare such reports for Egalet (to be included in Egalet's reports) for adverse events relating to Product distributed in the pre-Effective Date period until Egalet takes over such responsibility as provided in this Agreement. Egalet shall file such reports with the FDA or other applicable Regulatory Authority.

11.3.3 Acura shall keep the Joint Steering Committee reasonably advised of any serious safety issues or serious adverse events relating to its other products using Aversion Technology. At Egalet's request, Acura shall provide Egalet a copy of adverse drug experience reports filed with the FDA pursuant to 21 C.F.R. §314.80(b) and (c) and equivalent foreign reports relating to serious safety issues with respect to products using the Aversion Technology. **[*****]** .

11.4 *Recall; Withdrawal.*

Without limiting Section 13.1, Egalet shall be fully responsible and pay for any recalls or Product withdrawals. If Egalet, in its discretion, recalls, detains or retains the Products (voluntarily or by order of a Regulatory Authority), Acura agrees to reasonably cooperate in such actions, at Egalet's sole expense.

11.5 *Medical Affairs.*

Acura will be responsible for Medical Affairs for no more than three months after the Effective Date, according to a timeline established by the JSC. Thereafter, such responsibility will be assumed by Egalet.

12. CONFIDENTIAL INFORMATION

12.1 *Confidentiality* . A receiving Party (the " *Receiving Party* ") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any Confidential Information which is disclosed to it by the other Party (the " *Disclosing Party* ") or otherwise received, accessed or developed by a Receiving Party in connection with the execution, delivery and performance of this Agreement. Each Party agrees that all such Confidential Information: (i) shall not be used by the Receiving Party except in connection with the activities contemplated by this Agreement or in order to further the purposes of this Agreement; (ii) shall be maintained in confidence by the Receiving Party; and (iii) shall not be disclosed by the Receiving Party to any Third Party who is not a consultant of, or an advisor to, the Receiving Party or an Affiliate or sublicensee of the Receiving Party, and who in each case has signed a confidentiality agreement containing provisions substantially comparable to those set forth in this Agreement, without the prior written consent of the Disclosing Party.

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12.2 *Exceptions to Obligation.* The obligations of confidentiality and non-use set forth in Section 12.1 shall not apply to any such Confidential Information which:

12.2.1 either before or after the date of the disclosure to the Receiving Party becomes published or otherwise part of the public domain through no fault or omission on the part of the Receiving Party or its Affiliates;

12.2.2 either before or after the date of the disclosure to the Receiving Party is lawfully disclosed to the Receiving Party or its Affiliates by sources other than the Disclosing Party rightfully in possession of the Confidential Information and without restriction as to confidentiality or use;

12.2.3 is independently developed by or for the Receiving Party or its Affiliates without reference to or in reliance upon the Disclosing Party's Confidential Information as demonstrated by competent written records; or

12.2.4 is required to be disclosed under Applicable Laws or regulations or an order by a court or other regulatory body having competent jurisdiction; *provided , however ,* that except where impracticable, the Receiving Party shall give the Disclosing Party reasonable advance notice of such disclosure requirement (which shall include a copy of any applicable subpoena or order) and shall cooperate with the Disclosing Party to oppose, limit or secure confidential treatment for such required disclosure. In the event of any such required disclosure, the Receiving Party shall disclose only that portion of the Confidential Information of the Disclosing Party that the Receiving Party is legally required to disclose.

12.3 *Exclusions* . The restrictions set forth in this Article 12 shall not prevent either Party from (i) disclosing Confidential Information in connection with preparing, filing, prosecuting or maintaining the Aversion Patent Rights or Product-specific Aversion Intellectual Property covering the Product in accordance with Article 10, (ii) disclosing Confidential Information to governmental agencies to the extent required or desirable to obtain and maintain a Regulatory Approval, (iii) disclosing Confidential Information to potential private investors (under a confidentiality agreement at least as restrictive as the provisions of this Article 12) in connection with fundraising activities, (iv) disclosing Confidential Information to underwriters and financial advisors (under an obligation of confidentiality) in connection with the public offering of securities, or (v) disclosing Confidential Information that is reasonably determined is required to be disclosed by the Receiving Party (to comply with applicable securities or other laws) to public investors or governmental agencies in connection with the public offering of securities, *provided* that in all of the above cases, the Party disclosing Confidential Information of the Disclosing Party shall use all reasonable efforts to provide prior written notice of such disclosure to the Disclosing Party and to take reasonable and lawful actions to avoid or limit such disclosure or to assist the Disclosing Party in avoiding or limiting such disclosure. Further, either Party may also disclose the existence and terms of this Agreement to its attorneys and advisors, to potential acquirors in connection with a potential change of control or sale of assets and to existing and potential investors or lenders of such Party, as a part of their due diligence investigations, or to potential permitted assignees or sublicensees, in each case under an agreement to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially similar to the terms contained in this Agreement. Acura recognizes that by reason of Egalet's exclusive rights under this Agreement, Egalet has an interest in Acura's retention in confidence of certain information of Acura. Accordingly, until the end of the Term, and for a period of **[*****]** thereafter, Acura shall keep confidential, and not publish or otherwise disclose, and not use for any purpose other than to fulfill Acura's obligations, Aversion Technology, to the extent that the information pertains specifically to the Product, except to the extent: (a) the Product Information is in the public domain or generally available through no fault of Acura, or (b) such disclosure or use is expressly permitted by the terms and conditions of this Agreement. In addition, the restrictions contained in Section 12.1 shall not apply to Acura to the extent the Confidential Information of Acura relates to any application of Acura's intellectual property or the Aversion Technology or inventions owned by Acura to any compounds or products, other than the Product or as such Acura intellectual property, Aversion Technology or inventions relate to the Product.

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12.4 *Limitations on Use* . Each Party shall limit the use, and cause each of its Affiliates and its sublicensees to limit the use, of any Confidential Information obtained by such Party from the other Party, its Affiliates or its sublicensees, pursuant to this Agreement or otherwise, so that such use is solely in connection with the activities or transactions contemplated hereby.

12.5 *Remedies* . Each Party shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Section 12.

12.6 *Previous Confidentiality Agreement* . Nothing herein shall relieve any party of any breach of that certain Confidentiality Agreement, dated as of August 28, 2014, by and between the Parties with respect to the information disclosed between the Parties prior to the date hereof, *provided* any information disclosed under such agreement shall also be deemed disclosed under this Agreement and such agreement shall not apply to any information disclosed after the date hereof, which disclosure shall be governed by this Agreement.

12.7 *Publicity* . The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of the press release attached as Exhibit 12.7-1 with respect to Acura, and in the form of the press release attached as Exhibit 12.7-2 with respect to Egalet (the " *Press Releases* "). Neither Party may issue any other news release or make any other public announcement, written or oral, relating to the terms of this Agreement, without the prior approval of the other Party, and Acura may not issue any news release or make any public announcement, written or oral, relating to the Product (including Egalet's development, manufacturing or commercialization of the Product) without the prior approval of Egalet, except solely to the extent a Party is advised by its legal counsel that the same is required by law or as otherwise permitted pursuant to Section 12.3; *provided , however* , the consent of a Party shall not be unreasonably withheld, delayed or conditioned. The contents of any announcement or similar publicity relating to this Agreement or the Product shall be provided by the Party issuing such announcement or publicity to the other Party reasonably in advance thereof, and if previously reviewed and approved by the reviewing Party, can be re-released by either Party without a requirement for re-approval. Each Party shall limit public disclosure of the terms set forth in this Agreement to the minimum extent required by law (by, for example, requesting confidential treatment of such terms in documents required to be filed with the U.S. Securities and Exchange Commission); *provided , however* , the Parties may, after any required public disclosure for compliance with any Applicable Law, including securities laws, reference such terms in news releases or oral statements without seeking approval from the other Party.

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12.8 *Survival* . The Confidentiality provisions of this Agreement shall survive termination or expiration of this Agreement for **[*****]** , except that with respect to trade secrets they shall survive indefinitely.

13. INDEMNIFICATION; INSURANCE; LIABILITY

13.1 *By Acura* . Acura shall indemnify, defend and hold harmless Egalet and its Affiliates, and their respective directors, officers, employees and agents, from and against any and all Losses (including the reasonable fees of attorneys and other professionals) for claims of any Third Party to the extent arising out of or resulting from:

13.1.1 negligence or wrongful intentional acts or omissions of Acura or its Affiliates, and their respective directors, officers, employees and agents, in connection with the activities contemplated under this Agreement;

13.1.2 any breach of any representation, warranty or covenant made by Acura pursuant to this Agreement; or

13.1.3 any claims arising out of the manufacturing and/or commercialization of the Product or Aversion Technology by or on behalf of Acura or its Affiliates prior to the date of this Agreement;

13.1.4 any claims of personal injury (including death) or property damage relating to or arising out of the use of the Product prior to the date of this Agreement;

13.1.5 any claims arising out of or relating to the Pfizer Termination Agreement;

13.1.6 any claims arising out of Egalet's or its Contract Manufacturer's use of the API purchased by Egalet from Acura pursuant to Section 6.9 due to the failure of such API to meet the specifications for the Product (set forth in the Product NDA) in connection with the manufacture of such API, provided that Egalet shall have satisfied the requirement to test such API as provided in Section 6.9 prior to use in the Manufacture of the Product;

13.1.7 any claims for infringement relating to the Acura Trademarks; or

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13.1.8 any claims relating to the marketing of Product by Acura pursuant to its Co-Promotion Right, except as the same relates to sales and marketing materials provided by Egalet or actions directed by Egalet related to such marketing;

except in each case to the extent of Losses attributable to: (i) Egalet's or its Affiliates breach of this Agreement or negligence or wrongful intentional acts or omissions, or (ii) matters that are subject to Section 13.2.

13.2 *By Egalet* . Egalet shall indemnify, defend and hold harmless Acura, and its Affiliates, and their respective directors, officers, employees and agents, from and against any and Losses (including the reasonable fees of attorneys and other professionals) for claims of any Third Party to the extent arising out of or resulting from:

13.2.1 negligence or wrongful intentional acts or omissions of Egalet or its Affiliates or sublicensees, and their respective directors, officers, employees and agents, in connection with the activities contemplated under this Agreement;

13.2.2 any warranty claims, Product recalls or any claims of personal injury (including death) or property damage relating to or arising out of the use of the Product, or any sale or offer for sale of the Product by Egalet, its Affiliates or permitted sublicensees;

13.2.3 any claims arising out of the development, Manufacturing and/or commercialization of the Product by Egalet, its Affiliates, its sublicensees or its Contract Manufacturer;

13.2.4 any claims for infringement relating to the Trademarks or the Product Mark; or

13.2.5 any breach of any representation, warranty or covenant made by Egalet pursuant to this Agreement;

except in each case to the extent of Losses attributable to: (i) Acura's or its Affiliates breach of this Agreement or negligence or wrongful intentional acts or omissions, or (ii) matters that are subject to Section 13.1.

13.3 *Complete Indemnification* . Indemnification hereunder shall include the reasonable costs and expenses of the Parties, relating to legal fees and expenses, actually incurred by an Indemnitee in connection with enforcement of Sections 13.1 and 13.2.

13.4 *Notice* . Each Party will notify promptly the other if it becomes aware of a claim (actual or potential) by any Third Party (a " *Third Party Claim* ") for which indemnification may be sought by that Party and will give such information with respect thereto as the other Party shall reasonably request. If any proceeding (including any governmental investigation) is instituted involving any Party for which such Party may seek an indemnity under Section 13.1 or Section 13.2 (the " *Indemnified Party* "), the Indemnified Party shall not make any admission or statement concerning such Third Party Claim, but shall promptly notify the other Party (the " *Indemnifying Party* ") orally and in writing and the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any Third Party Claims that are the subject matter of such proceeding. The Indemnifying Party shall not be obligated to indemnify the Indemnified Party to the extent any admission or statement made by the Indemnified Party or any failure by such Party to notify the Indemnifying Party of the claim materially prejudices the defense of such claim.

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13.5 *Defense of Claim* . The following provisions shall apply to any claim to which a Party is entitled to indemnification from the other Party under this Article 13. If the Indemnifying Party elects to defend or, if local procedural rules or laws do not permit the same, elects to control the defense of a Third Party Claim, it shall be entitled to do so provided it gives notice to the Indemnified Party of its intention to do so within forty-five (45) days after the receipt of the written notice from the Indemnified Party of the potentially indemnifiable Third Party Claim (the " *Litigation Condition* "). Subject to compliance with the Litigation Condition, the Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld or delayed) to represent the Indemnified Party and shall pay the fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party. The Indemnified Party shall not settle any claim for which it is seeking indemnification without the prior consent of the Indemnifying Party which consent shall not be unreasonably withheld, conditioned or delayed. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in the defense of such claim that is being managed and/or controlled by the Indemnifying Party, at the Indemnifying Party's cost and expense. The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed), effect any settlement of any pending or threatened proceeding in which the Indemnified Party is, or based on the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless such settlement includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding and will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner. Notwithstanding the foregoing, Acura's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license, covenant not to sue relating to, admission of invalidity or unenforceability or abandonment of any of Acura's intellectual property, including the Aversion Technology, and Egalet's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license or covenant not to sue with respect to any Third Party Infringement related to a Paragraph IV Certification with respect to the Product or that would otherwise grant any rights to manufacture, use, sell or otherwise commercialize **[*****]** or admission of invalidity or unenforceability or abandonment of any Product-specific Intellectual Property. If the Litigation Condition is not met, then the Indemnified Party shall have the right to control the defense of such Third Party Claim, for which the Indemnifying Party shall pay the reasonable fees and costs incurred by the Indemnified Party, and the Parties shall cooperate in and be consulted on the material aspects of such defense at the Indemnifying Party's expense; *provided* that if the Indemnifying Party does not satisfy the Litigation Condition, the Indemnifying Party may at any subsequent time during the pendency of the relevant Third Party Claim irrevocably elect, if permitted by local procedural rules or laws, to defend and/or to control the defense of the relevant Third Party Claim at its sole cost and expense and so long as the Indemnifying Party also agrees to pay the reasonable fees and costs incurred by the Indemnified Party in relation to the defense of such Third Party Claim from the inception of the Third Party Claim until the date the Indemnifying Party assumes the defense or control thereof.

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13.6 *Assumption of Defense* . Notwithstanding anything to the contrary contained herein, an Indemnified Party shall be entitled to assume the defense of any Third Party Claim with respect to the Indemnified Party, upon written notice to the Indemnifying Party pursuant to this Section 13.7, in which case the Indemnifying Party shall be relieved of liability under Section 13.1 or Section 13.2, as applicable, solely for such Third Party Claim and related Losses.

13.7 *Insurance.* During the Term and for **[*****]** thereafter, each Party shall maintain insurance with reputable and credit worthy insurance companies, in such amounts and against such risks as are usually maintained by comparable U.S. publicly registered companies engaged in the pharmaceutical business. Each Party shall, at the request of the other Party, provide the other Party with a certificate of insurance evidencing its insurance coverage. In the event a Party desire to self insure, in whole or in part, it shall obtain the prior written consent of the other Party, not unreasonably withheld or delayed.

13.8 *No Set-off.* Except as expressly set forth in this Agreement, neither Party may set-off or recoup against a payment owed to the other Party, without the consent of the other Party, other than any amounts payable to the first Party by such other Party as determined in a final judgment.

14. TERM; TERMINATION

14.1 *Term* . This Agreement is made as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this Section 14, shall expire:

14.1.1 As to each country in the Territory upon **[*****]** (the " *Royalty Term* "); and

14.1.2 in its entirety, upon the expiration of this Agreement with respect the last Product in all countries in the Territory (the " *Term* ").

14.2 *Termination for Cause.*

14.2.1 Either Party may terminate this Agreement in its entirety, in the event the other Party shall have breached or defaulted in its payment obligation hereunder (" *Payment Default* ") and such breach or default shall have continued for thirty (30) days after written notice thereof was provided to the breaching Party by the other Party. Any such termination under this Section 14.2.1 shall become effective at the end of such thirty (30) day period unless the breaching Party has cured any such noticed breach(es) or default(s) prior to the expiration of such thirty (30) day period.

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14.2.2 Acura may terminate this Agreement, without prejudice to any other remedies available to it at law or in equity with respect to any particular country, and in its entirety if such particular country is the United States, if Egalet has materially breached its obligations to use Commercially Reasonable Efforts to commercialize the Product in such country as required by Section 5.1, 5.2 and 5.4 (" *Commercialization Default* "), and such material breach shall have continued for sixty (60) days after written notice thereof was provided to Egalet by Acura. Any such termination under this Section 14.2.2 shall become effective at the end of such sixty (60) day period unless Egalet has cured any such noticed breach(es) prior to the expiration of such sixty (60) day period.

14.2.3 Either Party may terminate this Agreement, without prejudice to any other remedies available to it at law or in equity with respect to any particular country, and in its entirety if such particular country is the United States, in the event the other Party shall have materially breached or defaulted in the performance of any of its material obligations hereunder (other than Payment Defaults and Commercialization Defaults which are governed by Sections 14.2.1 and 14.2.2 above) with respect to such country and, such breach or default shall have continued for sixty (60) days after written notice thereof was provided to the breaching Party by the other Party. Any such termination under this Section 14.2.3 shall become effective at the end of such sixty (60) day period unless the breaching Party has cured any such noticed breach(es) or default(s) prior to the expiration of such sixty (60) day period.

14.2.4 Acura may terminate this Agreement in its entirety by written notice to Egalet, effective upon receipt, without prejudice to any other remedies available to it at law or in equity, if Egalet fails to Launch the Product in the United States by the Required Launch Date.

14.2.5 Acura may terminate this Agreement in its entirety by written notice to Egalet, effective upon receipt, without prejudice to any other remedies available to it at law or in equity if Egalet fails to achieve the required number of sales representatives as provided in Section 5.2.1 at the time specified in such Section.

14.2.6 Acura may terminate this Agreement in an Other County as provided in Section 4.3.

14.2.7 The right of either Party to terminate this Agreement as provided in this Section 14.2 shall not be affected in any way by its waiver or failure to take action with respect to any previous breach or default.

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14.3 *Termination for Insolvency* . Subject to Applicable Law, either Party (i.e., the non-insolvent Party) may terminate this Agreement, if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of substantially all of its assets, or if the other Party proposes a written agreement of composition or extension of substantially all of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment of substantially all of its assets for the benefit of creditors. All rights and licenses granted under or pursuant to any section of this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, United States Code (the " *Bankruptcy Code* ") licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of, or complete access to all documents embodying, any such intellectual property or relating to obtaining protection of or maintaining same, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

14.4 *Termination for Patent Challenge* . Acura will be permitted to terminate this Agreement by written notice effective upon receipt if Egalet or its Affiliates, directly or indirectly through assistance granted to a Third Party, commence any interference or opposition proceeding, challenge in a legal or administrative proceeding the validity or enforceability of, or oppose in a legal or administrative proceeding any extension of or the grant of a supplementary protection certificate with respect to, any Aversion Patent Rights (except as a defense against a patent infringement action initiated by Acura or its Affiliates or licensees against Egalet or its Affiliates) (each such action, a " *Patent Challenge* "). Egalet will include provisions in all agreements granting sublicenses of Egalet's rights hereunder (other than agreements with manufacturers, services providers, distributors and other agents) providing that if the sublicensee or its Affiliates undertake a Patent Challenge with respect to any Aversion Patent Rights under which the sublicensee is sublicensed, Egalet will be permitted to terminate such sublicense agreement. If a sublicensee of Egalet (or an Affiliate of such sublicensee) undertakes a Patent Challenge of any such Aversion Patent Right under which such sublicensee is sublicensed (other than sublicensees that are manufacturers, services providers, distributors and other agents), then Egalet upon receipt of notice from Acura of such Patent Challenge will terminate the applicable sublicense agreement. If Egalet fails to so terminate such sublicense agreement, Acura may terminate Egalet's right to sublicense in the country(ies) covered by such sublicense agreement and any sublicenses previously granted in such country(ies) shall automatically terminate. In connection with such sublicense termination, Egalet shall cooperate with Acura's reasonable requests to cause such a terminated sublicensee to discontinue activities with respect to the Product in such country(ies).

14.5 *Termination by Egalet for Convenience* . Egalet may terminate this Agreement in its entirety upon 120 days prior written notice, provided that **[*****]** .

14.6 *Termination by Egalet for Commercialization Conditions*. If a Commercialization Condition specified in subsections (i), (ii) or (v) of Section 5.2.2 has occurred prior to the Launch of the Product and continues for at least ninety (90) days and Egalet determines in good faith that further development, manufacturing or commercialization of the Product is not Commercially Reasonable, then Egalet may terminate this Agreement upon thirty (30) days written notice to Acura.

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14.7 *Effect of Expiration or Termination.*

14.7.1 Following the expiration of the Term with respect to a country in the Territory pursuant to Section 14.1.1, Egalet's license to Manufacture, market, sell, have sold, distribute and otherwise exploit the Product in such country in the Territory shall become royalty-free, perpetual, irrevocable, non-exclusive and non-terminable.

14.7.2 If this Agreement is terminated by a Party pursuant to Section 14.2 in all or any countries of the Territory (the " *Terminated Country(ies)* "), or in its entirety pursuant to Section 14.3, 14.4, 14.5, 14.6 or 15, in addition to any other remedies available to a Party at law or in equity:

(a) Any and all licenses granted by Acura to Egalet under this Agreement (other than the license granted under Section 10.2(ii)), shall terminate in their entirety or with respect to the Terminated Country(ies), as the case may be, on the effective date of such termination, and the licenses granted by Egalet to Acura under this Agreement shall continue;

(b) Egalet shall promptly transfer to Acura, at Egalet's expense, copies of all data, reports, records and documentation that relate to Product in such Terminated Country(ies);

(c) Egalet shall assign and transfer to Acura all of its and its Affiliates' right, title and interest in and to all Regulatory Approvals and Regulatory Approval Applications prepared (whether completed or partially completed), filed and/or granted for the Product (including any Product Line Extensions) in such Terminated Country(ies), and Egalet shall promptly file with any applicable Regulatory Authority notice of such transfer and assignment;

(d) Egalet shall return to Acura all relevant records and materials in Egalet's possession or control containing Confidential Information relating to Product in such Terminated Country(ies), *provided , however* , that Egalet may keep one copy of such Confidential Information for archival purposes only;

(e) to the extent Egalet owns or holds any right, title and interest in any Trademarks, trade names, and/or logos under which only the Product has been or is being marketed or sold in the Terminated Country(ies) (excluding for avoidance of doubt the Corporate Trademarks), or internet domain registrations for any such Trademarks or tradenames (excluding for avoidance of doubt domain name registrations incorporating the Corporate Trademarks (in whole or in part)), Egalet shall assign the same to Acura;

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(f) Egalet shall assign to Acura any clinical trial agreements (to the extent assignable and not cancelled and requested by Acura) in such Terminated Country(ies), and all data, including clinical data, materials and information of any kind or nature whatsoever, in Egalet's possession or in the possession of its Affiliates or its or their respective agents, that are solely related to the Product in such Terminated Country(ies) developed or being developed under this Agreement (including any Product Line Extensions). All such filings, approvals and data transferred to Acura pursuant to this Section 14.7 shall be deemed to be Acura Confidential Information;

(g) Egalet shall assign to Acura, at Acura's request, to the extent assignable and not cancelled) all sublicense agreements granted by Egalet under this Agreement with respect to such Product in the Terminated Country(ies);

(h) Each Party's restrictive covenant in Section 9.2 shall terminate with respect to the Terminated Countries;

(i) if the Agreement is not terminated in its entirety, Egalet shall supply, or cause to be supplied, to Acura, upon Acura's written request, Acura's or its licensee's commercial requirements of Product, pursuant to a supply agreement to be negotiated in good faith by the Parties on commercially reasonable terms, *provided* that (i) any Product shall be supplied at **[*****]** ; (ii) Egalet's supply obligation shall continue after termination of the Agreement, as provided in clause (j), (iii) Egalet shall maintain the same quality and specifications for Manufacturing the Product as immediately prior to notice of termination; and (iv) Egalet shall not be liable for any acts or omissions of any such Contract Manufacturer (including with respect to the Manufacture of the Product);

(j) if the Agreement is terminated in its entirety, (i) if Egalet is having the Product Manufactured by a Contract Manufacturer, then at Acura's request the applicable Manufacture and Supply Agreement shall be assigned to Acura to the extent assignable and provided that no other products of Egalet are being manufactured by such Contract Manufacturer; and (ii) if Egalet or its Affiliates is Manufacturing the Product, or if a Contract Manufacturer is Manufacturing the Product but the applicable Manufacture and Supply Agreement is not assigned to Acura, then Egalet shall supply, or cause to be supplied, to Acura, upon Acura's written request, Acura's or its licensee's commercial requirements of Product, (A) pursuant to a supply agreement to be negotiated in good faith by the Parties on commercially reasonable terms, if Egalet or its Affiliates is Manufacturing the Product, or (B) **[*****]** ; (2) Egalet's supply obligation (including through a Contract Manufacturer) shall not continue for more than **[*****]** after the termination of this Agreement, (3) Egalet shall maintain the same quality and specifications for Manufacturing the Product as immediately prior to notice of termination; (4) Egalet shall not be liable for any acts or omissions of any such Contract Manufacturer (including with respect to the Manufacture of the Product); (5) Acura shall effect a transfer as soon as commercially practicable of the Product Manufacturing activities from Egalet to another supplier; and (6) Egalet shall also provide Acura or its designated supplier, at Acura's cost, reasonable assistance and cooperation in providing a Manufacturing transfer package with the goal of enabling Acura or such designated supplier to Manufacture the Product as soon as commercially practical; and

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(k) Any transfers under this Section 14.7.2 shall be free of any Liens and all documents and information transferred to Acura, to the extent solely related to the Product, shall be Acura's Confidential Information and not Egalet's Confidential Information.

14.7.3 If this Agreement is terminated by Egalet, either in its entirety or with respect to a particular country in the Territory, pursuant to Sections 14.2, 14.3 or 14.6, Acura shall reimburse Egalet for its reasonable costs and expenses incurred in connection with its obligations under Section 14.7.2.

14.8 *Accrued Rights; Surviving Obligations.*

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

14.8.2 All of the Parties' rights and obligations under Sections 4.1.3, 5.6, 6.10, 6.11, for the post-termination/expiration licenses – 7.3.1 and 7.3.2, 7.3.3, 7.3.5, 10.1, 10.2, 10.3.5, 11.2.1, 11.3 (to the extent needed to accomplish post-termination/expiration reporting solely with respect to commercialization of the Product prior to termination/expiration) 12, 13, 14.7, 14.8, 14.9, 16 and 17 and, with respect to payments, Net Sales, Co-Promotion Payments and milestones accrued or achieved prior to termination (or pursuant to Product inventory sell off), Sections 5.3.5, 5.3.13.3, 6.3, 6.4, 6.5, 6.7, 6.8 and 6.12, shall survive termination, relinquishment or expiration of this Agreement, and all other provisions reasonable construed to survive shall also survive termination or expiration. Where a provision specifies a survival period, such provision shall survive only during such survival period.

14.9 *Acura's Repurchase Right and Inventory Sell-Off Right* . Upon the termination of this Agreement in its entirety pursuant to Sections 14.2, 14.3, 14.4, 14.5, 14.6 or 15, Acura may, but shall not be required to, purchase all of the Product in Egalet's possession or control. Pending Acura's exercise or waiver of its right to purchase Egalet's Product inventory, or in the event Acura waives or does not exercise such right, Egalet shall continue to exercise Commercially Reasonable Efforts to commercialize the Product (except in the case of termination pursuant to Section 14.6). If Acura does not exercise such right within sixty (60) days of termination then notwithstanding termination of Egalet's licenses and other rights under this Agreement, Egalet, its sub-licensees under this Agreement and their respective Affiliates shall exercise Commercially Reasonable Efforts to sell all Product inventory then in its possession or control (or such additional quantities as Acura may approve in writing) (except in the case of termination pursuant to Section 14.6), as though this Agreement had not terminated, including, without limitation, paying the royalty payments, pursuant to Section 6.4, to Acura on such Net Sales.

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15. FORCE MAJEURE.

15.1 *Force Majeure* . Any delay in the performance of any of the duties or obligations of either Party hereto (except the payment of money due hereunder) shall not be considered a breach of this Agreement, and the time required for performance shall be extended for a period equal to the period of such delay, if such delay has been caused by or is the result of acts of God; acts of public enemy; insurrections; terrorism, riots; injunctions; embargoes; fires; explosions; earthquakes; floods; shortages of energy; governmental prohibition or restriction; or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the Party so affected (" *Force Majeure* ") . The Party so affected shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall be excused from the performance, or the punctual performance, of such obligations, as the case may be, from the date of such notice, up to a maximum of one hundred eighty (180) days, after which time the Party not affected, may terminate this Agreement upon written notice to the affected Party if the failure in performance constitutes a material breach of this Agreement. To the extent possible, each Party shall use reasonable diligent efforts to avoid or minimize the duration of any Force Majeure.

16. *DISPUTE RESOLUTION*

16.1 *Referral to Executive Officers* . The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to a Party's rights and/or obligations hereunder. If the Parties cannot resolve any such dispute within fifteen (15) calendar days after notice of a dispute from one Party to another, any Party may, by notice to the other Party, have such dispute referred to the Executive Officers. The Executive Officers shall meet promptly to negotiate in good faith the matter referred and to determine a resolution. During such period of negotiations, any applicable time periods under this Agreement shall be tolled. If the Executive Officers are unable to determine a resolution in a timely manner, which shall in no case be more than thirty (30) days after the matter was referred to them (or ten (10) days after referral if regarding a dispute arising out of or relating to Sections 3.2.6, 3.2.11, 5.2.4 or 5.3.13), the matter may be resolved through arbitration in accordance with the arbitration provisions set forth in Section 16.2 or Section 16.3, as applicable, upon notice by a Party on the other Party specifically requesting such arbitration.

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16.2 *Arbitration* . Where a Party has served a written notice upon another requesting arbitration of a dispute pursuant to this Section 16.2, any such arbitration shall be submitted to final and binding arbitration under the then current commercial arbitration rules of the American Arbitration Association (the " *AAA* ") in accordance with this Section 16.2. The place of arbitration of any dispute shall be New York, New York. Such arbitration shall be conducted by one (1) arbitrator mutually agreed by the Parties but if such agreement cannot be reached within ten (10) days of the commencement of the arbitration, then an arbitrator appointed by the AAA. The arbitrator shall be a person with relevant experience in the pharmaceutical industry. The arbitration proceeding shall be held as soon as practicable but in any event within ninety (90) days of appointment of the arbitrator. Any award rendered by the arbitrators shall be final and binding upon the Parties. Judgment upon any award rendered may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. The arbitrator shall render a formal, binding, non-appealable resolution and award as expeditiously as possible, but not more than thirty (30) days after the hearing. Each Party shall pay its own expenses of arbitration, and the expenses of the arbitrator shall be equally shared between the Parties unless the arbitrators assess as part of their award all or any part of the arbitration expenses of a Party (including reasonable attorneys' fees) against the other Party. A Party may make application to the Arbitrator for the award and recovery of its fees and expenses (including reasonable attorneys' fees). This Section 16.2, shall not prohibit a Party from seeking injunctive relief from a court of competent jurisdiction in the event of a breach or prospective breach of this Agreement by any other Party which would cause irreparable harm to the first Party.

16.3 *Special Arbitration Provisions* . In the event of a dispute arising out of or relating to Sections 3.2.6, 3.2.11, 5.2.4, or 5.3.13, which dispute remains unresolved after referral to the Executive Officers, then such dispute shall be finally settled by arbitration under the then current expedited procedures applicable to the then current commercial arbitration rules of the AAA in accordance with the following terms:

16.3.1 Upon written request by either Party to the other Party, the Parties shall promptly negotiate in good faith to appoint a mutually acceptable independent person, with scientific, technical and regulatory experience with respect to the development or commercialization of the Product necessary to resolve such dispute (an " *Expert* "). If the Parties are not able to agree within five (5) business days after the receipt by a Party of the written request in the immediately preceding sentence, the AAA shall be responsible for selecting an Expert within ten (10) business days of being approached by a Party. The fees and costs of the Expert and the American Arbitration Association, if applicable, shall be shared equally by the Parties. The place of arbitration of any dispute shall be New York, New York, unless the Parties agree otherwise or the selection of the Expert requires otherwise.

16.3.2 Within five (5) business days after the designation of the Expert, the Parties shall each simultaneously submit to the Expert and the other Party a written statement of their respective positions on such disagreement. Each Party shall have fifteen (15) business days from receipt of the other Party's submission to submit to the Expert and the other Party a written response thereto, which shall include any scientific, technical or commercialization information in support thereof (the " *Second Submission Date* "). The Expert shall have the right to meet with the Parties, either alone or together, as necessary to make a determination.

16.3.3 No later than ten (10) business days after the Second Submission Date, the Expert shall make a determination by selecting the resolution proposed by one (1) of the Parties that the Expert deems as a whole to be the most fair and reasonable to the Parties in light of the totality of the circumstances. The Expert shall provide the Parties with a written statement setting forth the basis of his/her determination in connection therewith. The decision of the Expert shall be final and conclusive.

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16.3.4 This Section 16.3 shall not prohibit a Party from seeking injunctive relief from a court of competent jurisdiction in the event of a breach or prospective breach of this Agreement by the other Party which would cause irreparable harm to the first Party.

17. MISCELLANEOUS

17.1 *Relationship of Parties* . Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.

17.2 *Assignment* . Except pursuant to a sublicense permitted under this Agreement, neither Party shall be entitled to assign its rights or delegate its obligations hereunder without the express written consent of the other Party hereto, except that either Party may assign its rights and transfer its duties hereunder to an Affiliate or in connection with the merger of the Party into a Third Party or in connection with the sale of all or substantially all of the Party's assets or stock, *provided* that in the case of any assignment by Acura, all Aversion Patent Rights and Aversion Technology licensed to Egalet under this Agreement shall be transferred to such assignee effective as of such assignment. Notwithstanding the foregoing, each Party shall remain responsible for any failure to perform on the part of any Affiliates. No assignment and transfer shall be valid or effective unless done in accordance with this Section 17.2 and unless and until the assignee/transferee shall agree in writing to be bound by the provisions of this Agreement.

17.3 *Limitation of Damages* . EXCEPT IN RESPECT OF A BREACH OF SECTIONS 9.1 OR 9.2 OR ARTICLE 12, NO PARTY AND NONE OF THEIR RESPECTIVE AFFILIATES SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING IN ANY WAY OUT OF OR BASED UPON THIS AGREEMENT, INCLUDING (a) THE DEVELOPMENT, MANUFACTURE, USE OR SALE OF PRODUCT UNDER THIS AGREEMENT, (b) THE PRACTICE OF THE PATENTS OR OTHER RIGHTS LICENSED HEREUNDER, OR (c) REFERENCE TO OR USE OF THE REGULATORY APPROVALS OR DOCUMENTATION. HOWEVER, THE FOREGOING LIMITATION SHALL NOT APPLY IN ANY WAY TO LIMIT EITHER PARTY'S OBLIGATIONS WITH RESPECT TO (1) THIRD PARTY CLAIMS UNDER SECTION 13.1 OR SECTION 13.2; OR (2) CLAIMS ARISING FROM WILLFUL MISCONDUCT.

17.4 *Books and Records* . Any books and records to be maintained under this Agreement by a Party shall be maintained in accordance with GAAP, and/or cGMP, as applicable.

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17.5 *Further Actions* . Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

17.6 *Notice* . Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

In the case of Acura, to:	Acura Pharmaceuticals, Inc. 616 N. North Court, Suite 120 Palatine, IL 60067 Attention: Robert B. Jones Facsimile No.: 847-705- 5399 Telephone No.: 847-705-7709
with a copy to:	LeClairRyan One Riverfront Plaza 1037 Raymond Boulevard Sixteenth Floor Newark, NJ 07102 Attention: John P. Reilly, Esq. Facsimile No.: 973-491-3492 Telephone No.: 973-491-3354
in the case of Egalet, to:	Egalet US, Inc. 460 East Swedesford Road Wayne, Pennsylvania Attention: Robert Radie Telephone No.: 610-833-4200
with a copy to:	Dechert LLP 1095 Avenue of the Americas New York, New York 10036 Attention: Thomas A. Rayski, Esq. Facsimile No.: 212-698-3599 Telephone No.: 212-698-3859

or to such other address for such Party as it shall have specified by like notice to the other Party, *provided, however*, that notices of a change of address shall be effective only upon receipt thereof. With respect to notices given pursuant to this Section 17.6: (i) if delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given; (ii) if sent by overnight express courier service, the date of delivery shall be deemed to be the next business day after such notice or request was deposited with such service; and (iii) if sent by certified mail, the date of delivery shall be deemed to be the fifth business day after such notice or request was deposited with the applicable national postal service.

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17.7 *Use of Name* . Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement.

17.8 *Waiver* . A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

17.9 *Compliance with Law* . Nothing in this Agreement shall be deemed to permit a Party to export, re-export or otherwise transfer any Products sold under this Agreement without compliance with Applicable Laws.

17.10 *Severability* . If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

17.11 *Amendment* . No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

17.12 *Governing Law* . This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York without regard to conflict of law principles and the Parties hereby submit and consent to the exclusive jurisdiction of the federal or state courts in New York for the resolution of disputes under this Agreement that require the involvement of a court.

17.13 *Entire Agreement* . This Agreement, together with all exhibits and schedules hereto, sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and merges all prior discussions and negotiations between them, and neither of the Parties shall be bound by any conditions, definitions, warranties, understandings or representations with respect to such subject matter other than as expressly provided herein or as duly set forth on or subsequent to the date hereof in writing and signed by a proper and duly authorized officer or representative of the Party to be bound thereby.

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17.14 *Parties in Interest* . All of the terms and provisions of this Agreement shall be binding upon, inure to the benefit of and be enforceable by the Parties hereto and their respective permitted successors and assigns.

17.15 *Descriptive Headings* . The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

17.16 *Construction of Agreement* . The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement

17.17 *Waiver of Jury Trial* . EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT. EACH PARTY HERETO (i) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THAT FOREGOING WAIVER, AND (ii) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND ANY RELATED INSTRUMENTS, AS APPLICABLE, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 17.17.

17.18 *Counterparts* . This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures, scanned signatures, and signatures in PDFs shall be treated as original signatures.

17.19 *Relationship of Egalet Parties.*

17.19.1 **[*****]**

17.20 *Service of Process.* **[*****]**

17.21 *Guaranty of Egalet Corporation* . **[***** *- one and one-half pages redacted*]**

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IN WITNESS WHEREOF , each of the Parties has caused this Agreement to be executed by its duly authorized representative as of the date first above written.

ACURA PHARMACEUTICALS, INC.

By: /s/Robert B. Jones 1/7/2015
Name: Robert B. Jones
Title: President and Chief Executive Officer

EGALET US, INC.

By: /s/ Robert Radie
Name:
Title:

EGALET LIMITED

By: /s/ Robert Radie
Name:
Title:

Solely as to Section 17.21

EGALET CORPORATION

By: /s/ Robert Radie
Name:
Title:

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

EXECUTION COPY

EXHIBIT 1.17
AVERSION PATENT RIGHTS

TABLE 1: US AVERSION PATENTS AND APPLICATIONS

MLB REF. NO.	US PATENT/ APPLICATION NO.	STATUS	FILING DATE	TITLE	REPRESENTATIVE INDEPENDENT CLAIM

[*** - THREE PAGES REDACTED]**

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TABLE 2: NON-US AVERSION PATENTS AND APPLICATIONS

MLB REF. NO.	COUNTRY	PATENT/ APPLICATION NO.	STATUS	FILING DATE	TITLE	REPRESENTATIVE INDEPENDENT CLAIM

[*** - FIVE PAGES REDACTED]**

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EXECUTION COPY

EXHIBIT 1.74
KNOWLEDGE GROUPS

Acura Knowledge Group :
[***]**

Egalet Knowledge Group :

[***]**

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

Exhibit 2.2.2
Acura License Agreements

[***]**

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

EXECUTION COPY

Exhibit 6.7

FORM OF ROYALTY AND CO-PROMOTION REPORT

PROVIDE SEPARATE REPORT FOR EACH STRENGTH AND EACH COUNTRY

[*** -** ***Three Pages Redacted*** **]**

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

Examples With Respect to Co-Promotion Payments

[*** - *Slightly over one page redacted*]**

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

EXHIBIT 6.9
INVENTORY TO BE PURCHASED BY EGALET

Acura Pharmaceuticals, Inc.
Aversion ® Oxycodone HCl Raw Materials

Description	Quantity	UOM	Unit Cost	Cost
[***]**				
Total				**[*****]**

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EXHIBIT 8.1

REIMBURSED MANUFACTURE AND SUPPLY EXPENSES

The following out-of-pocket costs will be 100% reimbursed by Egalet to Acura to the extent actually incurred by Acura:

1. Validation Services: [*****]
2. Validation Inventory: [*****]
3. Launch Inventory: [*****]

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

EXHIBIT 10.8
[***] PATENT MATTERS**

10.8 **[***** - *Six Pages Redacted*]**

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

EXHIBIT 12.7-1
ACURA PRESS RELEASE

(SEE ATTACHED)

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

Acura Pharmaceuticals Partners with Egalet Corporation to Commercialize Immediate Release Oxycodone Product Utilizing Acura's Aversion® (Abuse-Deterrent) Technology

Palatine, IL (January __, 2015) - Acura Pharmaceuticals, Inc. (NASDAQ: ACUR), today announced that the Company has entered into a Collaboration and License Agreement (the "Agreement") with Egalet US, Inc. and Egalet Ltd. (together "Egalet", subsidiaries of Egalet Corporation (NASDAQ: EGLT), which is also a party to the Agreement with obligations thereunder) granting Egalet exclusive worldwide rights to commercialize Acura's immediate release oxycodone hydrochloride tablets product which incorporates Acura's patented Aversion® (abuse-deterrent) Technology platform. The licensed product, formerly known as Oxecta, will be marketed by Egalet under the name OXAYDO™. OXAYDO is FDA approved in 5mg and 7.5mg strengths for the treatment of acute and chronic moderate to severe pain.

Acura and Egalet will form a joint steering committee to coordinate commercialization strategies and the development of product line extensions. Egalet will be responsible for all commercial, regulatory and manufacturing activities. The parties are working to transition the product to Egalet for commercial launch in the U.S. as soon as commercially practical.

The Agreement provides for an upfront cash payment of $5.0 million to Acura upon execution, with an additional $2.5 million due upon the later of (i) June 30, 2015 and (ii) the first commercial sale of the Product in the U.S.; but in no event later than January 1, 2016. Acura is to receive an additional one-time payment of $12.5 million when annual world-wide net sales of OXAYDO first reach $150 million in a calendar year. Acura is also to receive a stepped royalty at percentage rates from mid-single digits to double digits based on the level of OXAYDO world-wide net sales in a calendar year (including any product line extensions). Royalties will be payable on the first commercial sale of OXAYDO and expire, on a country-by-country basis, upon the expiration of Acura's patent in such country.

Bob Jones, President and CEO said, "We are excited to partner with Egalet who, like us, is committed to address the problem of prescription opioid abuse. We believe Egalet shares our objective of aggressively bringing OXAYDO to the market and introducing the product to the healthcare community. Egalet is developing complementary extended-release abuse-deterrent technologies that could create, long term, an exciting portfolio of products to treat pain".

The Company will host a conference to discuss the Agreement with Egalet on **[*****]** January __, 2015 at 8:30 a.m. ET. To participate in the live conference call, please dial xxx-xxx-xxxx (U.S. and Canada) five to ten minutes prior to the start of the call. The participant passcode is yyyyy.

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About Acura Pharmaceuticals
Acura Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development and commercialization of product candidates intended to address medication abuse and misuse, utilizing its proprietary LIMITX™, AVERSION® and IMPEDE® Technologies. LIMITX contains ingredients that are intended to reduce or limit the rate or extent of opioid release when multiple tablets are ingested. AVERSION contains polymers that cause the drug to gel when dissolved; it also contains compounds that irritate the nasal passages if the product is snorted. IMPEDE is designed to disrupt the processing of pseudoephedrine from tablets into methamphetamine.

In June 2011, the U.S. Food and Drug Administration approved our oxycodone HCl immediate-release tablets which incorporate the AVERSION Technology. The Company has a development pipeline of additional AVERSION Technology products containing other opioids.

In December 2012, the Company commenced commercialization of NEXAFED® (pseudoephedrine HCl), a 30 mg immediate-release abuse-deterrent decongestant. This next generation pseudoephedrine tablet combines effective nasal congestion relief with IMPEDE Technology, a unique polymer matrix that disrupts the conversion of pseudoephedrine into the dangerous drug, methamphetamine.

Forward-Looking Statements
This release contains forwarding-looking statements which reflect management's current view of future events and operations, including, but not limitation to; statements pertaining to the potential of OXAYDO™ to reduce prescription opioid abuse; statements pertaining to the expected timetable for launch of OXAYDO™; and statements pertaining to the potential success of the Company's collaboration with Egalet, including the payments to be received under the Agreement. These forward-looking statements involve certain significant risks and uncertainties and constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Some important factors that may cause actual results to differ materially from the forward-looking statements include dependence on the successful launch and commercialization of OXAYDO™; dependence on Egalet's ability to successfully manufacture or have manufactured OXAYDO™ for commercial sale; dependence on Acura's and Egalet's compliance with FDA and other government regulations that relate to their respective businesses; dependence on the successful development and commercialization of product line extensions to OXAYDO™; and dependence on unexpected changes in technologies and technological advances. Other important factors that may cause actual results to differ materially from the forward-looking statements are discussed in the "Risk Factors" section and other sections of Acura's Form 10-K for the year end December 31, 2013 and Acura's Form 10-Q for the quarter ended September 30, 2014, each of which are on file with the U.S. Securities and Exchange Commission. Acura does not undertake to publicly update or revise any of its forward-looking statements even if experience or future changes show that the indicated results or events will not be realized.

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

Contact:

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

for Acura Media Relations
pr@acurapharm.com
847-705-7709

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

EXHIBIT 12.7-2
EGALET PRESS RELEASE

Egalet Announces Agreement to License Marketed Pain Treatment

Wayne, PA (January __, 2015) - Egalet Corporation (Nasdaq: EGLT) ("Egalet") today announced that it has agreed to license from Acura Pharmaceuticals, Inc. (Nasdaq: ACUR) worldwide rights to OXAYDO™ (oxycodone HCI, USP) tablets for oral use only -CII, the first and only approved immediate-release oxycodone product formulated to deter abuse via snorting. OXAYDO is indicated in the United States for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate.

"With OXAYDO, physicians now have an immediate-release opioid product designed to discourage abuse via snorting," said Jeffrey Dayno, MD, chief medical officer of Egalet. "This is an important addition to extended-release opioids with abuse-deterrent properties to help address the broader public health challenge of opioid misuse and abuse. In addition, marketing of OXAYDO will help us build relationships with future prescribers of our Guardian™ Technology products."

Under the terms of the agreement with Acura Pharmaceuticals, Egalet has licensed worldwide rights to OXAYDO for an upfront payment of $5 million, a milestone payment of $2.5 million upon first commercial sale, a payment of $12.5 million when the product has achieved $150 million in net sales in a calendar year and a tiered royalty of single-digit to double-digit percent based on sales thresholds.

OXAYDO™ (previously known as OXECTA™) is the first immediate-release opioid analgesic formulated with Aversion Technology® intended to discourage abuse associated with snorting. This single-agent product has no acetaminophen and therefore does not carry the liver toxicity associated with APAP products. The most common adverse reactions with OXAYDO are nausea, constipation, vomiting, headache, pruritus, insomnia, dizziness, asthenia and somnolence.

Egalet plans to launch OXAYDO in the third quarter of 2015. Egalet will provide updates on commercial activities in the first quarter of 2015.

About Acute Pain
Acute pain is pain that comes on quickly, can be severe, but lasts a relatively short time. [i] Acute pain has many different causes including surgery, broken bones and dental work, among others. Acute pain can be mild and last for just seconds or it might be severe and come and go over weeks or months. In most cases, acute pain does not last longer than six months, and it resolves when the underlying cause of pain has been treated or has healed. Unrelieved acute pain, however, might lead to chronic pain. [ii]

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About Chronic Pain
There are approximately 100 million Americans—more than those affected by heart disease, cancer, and diabetes combined—who suffer from chronic pain that is often undertreated according to the Institute of Medicine. It is also the most common reason patients seek medical care, resulting in $635 billion annually in both medical costs and decreased work productivity. Chronic pain is typically defined as pain that lasts beyond the healing of an injury or that persists beyond three months. Common types of chronic pain include low back pain, arthritis, headache and face and jaw pain. Severe pain typically stops an individual from participating in activities and causes patients to change their behavior to avoid such activities. According to an article in the *New England Journal of Medicine* , chronic pain is associated with functional loss and disability, reduced quality of life, high health care costs, and premature death. Chronic pain also can result in isolation, depression, sleep disorders and other issues that have a negative impact not only on patients but family members as well.

It is important that these patients whose chronic pain often interrupts their daily lives gain and maintain access to adequate pain relief. Opioids analgesics play an important role in the management of moderate to severe pain and are the most widely prescribed products for pain, with prescriptions exceeding 200 million in 2013.

Important Safety Information for OXAYDO ™ (oxycodone HCl, USP) Tablets for oral use only - CII
OXAYDO is an immediate-release oral formulation of oxycodone HCl indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate.

OXAYDO is contraindicated in patients with respiratory depression, paralytic ileus, acute or severe bronchial asthma or hypercarbia, or known hypersensitivity to oxycodone or any components of the product.

Respiratory depression is the primary risk of OXAYDO and it must be used with extreme caution in patients with chronic obstructive pulmonary disease or cor pulmonale, in patients with decreased respiratory reserve, hypoxia, hypercapnia or pre-existing respiratory depression.

OXAYDO contains oxycodone HCl, an opioid agonist and a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. OXAYDO can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing in situations where there is concern about an increased risk of misuse or abuse. OXAYDO may be abused by crushing, chewing, snorting or injecting the product and these practices pose a significant risk to the abuser that could result in overdose and death.

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Patients receiving central nervous system depressants concomitantly with OXAYDO may exhibit an additive central nervous system depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced. Patients should not consume alcoholic beverages, or any medications containing alcohol while taking OXAYDO.

OXAYDO may cause severe hypotension in patients whose ability to maintain blood pressure has been compromised. OXAYDO may produce orthostatic hypotension in ambulatory patients. OXAYDO must be administered with caution in patients in circulatory shock.

Serious adverse reactions that may be associated with OXAYDO include: respiratory depression, respiratory arrest, circulatory depression, cardiac arrest, hypotension and/or shock. The most common adverse reactions are nausea, constipation, vomiting, headache, pruritus, insomnia, dizziness, asthenia and somnolence.

In opioid naïve patients, start dosing OXAYDO with five to 15 mg every four to six hours as needed for pain. OXAYDO should not be given to anyone other than the individual for whom it was prescribed. Keep OXAYDO in a locked cabinet, drawer or medicine safe so that it will not be stolen.

Please see full prescribing information for OXAYDO at www.oxaydo.com.

Conference Call Information

Egalet's management will host a conference call to discuss the commercial update:

Date:	Monday, January __, 2015
Time:	8:00 a.m. EDT
Webcast (live and archive):	http://egalet.investorroom.com/eventsandwebcasts
Dial-in numbers:	1-877-870-4263 (domestic)
Replay dial-in numbers:	1-412-317-0790 (international)
	1-877-344-7529 (domestic)
	1-412-317-0088 (international)
	Conference Number: 10050459

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

About Egalet
Egalet, a fully integrated commercial pharmaceutical company, is focused on developing, manufacturing and marketing innovative pain treatments. The Company is marketing OXAYDO®, an abuse-deterrent immediate-release oxycodone product for the management of acute and chronic moderate to severe pain where an opioid is appropriate. In addition, using Egalet's proprietary Guardian™ Technology, the Company is developing a pipeline of clinical-stage, opioid-based product candidates that are specifically designed to deter abuse by physical and chemical manipulation. The lead programs, Egalet-001, an abuse-deterrent, extended-release, oral morphine formulation, and Eglaet-002, an abuse-deterrent, extended-release, oral oxycodone formulation, are in late-stage clinical development for the management of pain severe enough to require daily, around-the-clock opioid treatment and for which alternative treatments are inadequate. Egalet's Guardian Technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include multiple active pharmaceutical ingredients with similar or different release profiles. For more information please visit www.egalet.com.

Investor and Media Contact:
BiotechComm
E. Blair Clark-Schoeb
Tel: 917-432-9275
Email: blair@biotechcomm.com

[i] http://www.theacpa.org/search.aspx?term=acute%20pain
[ii] http://my.clevelandclinic.org/services/anesthesiology/pain-management/diseases-conditions/hic-acute-vs-chronic-pain

******* Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

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. 333-195612, 333-151653, 333-151620, 333-133172, 333-123615, 333-63288, and 33-98356) and on Form S-3 (Nos. 333-187075 and 333-146416) of Acura Pharmaceuticals, Inc. of our report dated March 2, 2015, relating to the consolidated financial statements, which appear in this Form 10-K.

/s/ BDO USA, LLP
Chicago, Illinois
March 2, 2015

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: February 27, 2015

/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: February 27, 2015

/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, 2014 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.

February 27, 2015

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, 2014 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.

February 27, 2015

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