ACURA PHARMACEUTICALS, INC

FORM 10-K
(Annual Report)

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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013**

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 $1.88 on June 28, 2013 (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 $36.0 million.

As of February 28, 2014, the registrant had 48,847,737 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 May 1, 2014 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, 2013

Tablet of Contents

Forward-Looking Statements

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to, the ability of our patents to protect our products from generic competition, our ability to protect and enforce our patent rights in any paragraph IV patent infringement litigation, whether private plaintiffs will challenge the Settlement Agreements we entered into with each of Par Pharmaceutical and Impax Laboratories relating to our Oxecta® patent infringement litigation , whether or not additional third parties may seek to market generic versions of Oxecta® and the results of any litigation that we have filed or may file to defend and/or assert our patents against such companies, the possible occurrence of one of the specific events that would result in Par Pharmaceutical Impax Laboratories marketing a generic Oxecta® earlier than we anticipate, the possible approval by the U.S. Food and Drug Administration ("FDA") of Sandoz Inc.'s or Ranbaxy Inc.'s generic Oxecta product prior to the expiry of our patents covering Oxecta, our and our licensee's ability to successfully launch and commercialize our products and technologies including Oxecta® Tablets and Nexafed® Tablets, the price discounting that may be offered by Pfizer for Oxecta, our and our licensee's ability to obtain necessary regulatory approvals and commercialize products utilizing our technologies and the market acceptance of and competitive environment for any of our products, the willingness of wholesalers and pharmacies to stock Nexafed Tablets, expectations regarding potential market share for our products and the timing of first sales, our ability to enter into additional license agreements for our other product candidates, our exposure to product liability and other lawsuits in connection with the commercialization of our products, the increased 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, and 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 to meet over-the-counter, or 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 product candidates, whether the FDA will agree with our analysis of our clinical and laboratory studies and how it may evaluate the results of these studies or 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, whether our product candidates will ultimately deter abuse in commercial settings and whether our Impede technology 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," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views and beliefs with respect to future events and are based on assumptions and subject to significant 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. Forward-looking statements speak only as of the date of this Report, and Acura undertakes no obligation to update or revise these 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 two proprietary technologies. 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. Pfizer Inc.'s Oxecta® (oxycodone HCl) tablets, CII is the first approved and marketed product utilizing Aversion and is commercialized under our license agreement with a subsidiary of Pfizer, or the Pfizer Agreement. We have also developed our 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 have 7 additional opioid products utilizing Aversion in various stages of development. Our product containing hydrocodone bitartrate and acetaminophen utilizing the Aversion technology, or hydrocodone/acetaminophen, is the most advanced opioid product in development and the primary focus of our opioid development efforts. Hydrocodone/acetaminophen is the most widely prescribed and often abused opioid product in the United States. We filed an Investigational New Drug Application, or IND, with the Food and Drug Administration, or FDA, on December 20, 2012, which became effective in late January 2013. On August 26, 2013, we announced the top-line results from Study AP-ADF-301 ("Study 301"), a phase II clinical study in 40 recreational drug abusers assessing the liability of snorting our hydrocodone/acetaminophen product. Study 301s primary endpoint indicated that Aversion hydrocodone/acetaminophen had slightly lower numeric mean maximum drug liking compared to an equivalent dose of a generic hydrocodone/acetaminophen tablet, however these results were not statistically significant. The Study 301 secondary endpoints demonstrated statistical significance in mean minimum drug liking, the Overall Drug Liking score and the Take Drug Again assessment. On December 5, 2013, we met with the FDA to discuss if the FDA will consider whether the results of Study 301 are acceptable for submission in a New Drug Application, or NDA. On February 7, 2014, the FDA advised us their discussion of whether the results of study AP-ADF-301 could support abuse-deterrent labeling is ongoing. We expect that the development program for our other Aversion opioid products in development will be consistent with that of Oxecta and our hydrocodone/acetaminophen product candidate.

We launched Nexafed commercially in mid-December 2012 into the $1 billion United States over the counter market, or OTC, for cold and allergy products containing a decongestant. Nexafed was demonstrated in a clinical study to meet the FDA Guideline standards for bioequivalence to the reference drug Sudafed® marketed by Johnson & Johnson Corporation. We anticipate developing line extensions for our Nexafed franchise to capitalize on the many different combination offerings in the OTC cold/allergy market and expect to launch our first line extension in 2014. We also are developing a next generation of our Impede Technology in order to further improve our Nexafed franchise.

We also have discovered an early-stage technology 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.

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 two products commercially launched containing our Aversion and Impede Technologies. We continue to invest in improvements in these technologies and to 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 Aversion Technology to Pfizer for use in Oxecta in the United States and Mexico. We are seeking licensing partners for our Aversion and Impede technologies worldwide, and marketing partners for Nexafed outside the United States.

- *Maintain an efficient internal cost structure* . We maintain an efficient internal cost structure 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 six 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.

Oxecta

Oxecta 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. Oxecta utilizes our Aversion Technology. Pfizer received FDA approval for its 505(b)(2) NDA for Oxecta on June 17, 2011 and introduced the product into the market in February 2012. Pending receipt of the FDA's advice on Pfizer's proposed Oxecta promotional materials, which were submitted to the FDA in July 2012, Pfizer did not market Oxecta to physicians. As such, Pfizer attained no meaningful sales of Oxecta in 2012 or 2013. In April 2013, Pfizer received FDA's advice on its Oxecta promotional materials and commenced a non-branded marketing campaign to raise awareness of the problem of opioid abuse in the 3 rd quarter of 2013. Pfizer expanded its commercialization of Oxecta to health care providers in late 4 th quarter of 2013 but this effort was minimal due to the holidays. We do not expect the Pfizer promotional activities will include the use of field representatives.

The safety and efficacy of Oxecta 5mg and 7.5mg tablets was established by demonstrating bioequivalence to commercially available oxycodone immediate-release tablets in the fasted state. Oxecta differs from oxycodone tablets when taken with a high fat meal though these differences are not considered clinically relevant, and Oxecta can be taken without regard to food. The FDA-approved label for Oxecta describes elements unique to our Aversion Technology, which differs from current commercially available oxycodone immediate-release tablets. The label for Oxecta includes the results from a clinical study that evaluated the effects of nasally snorting crushed Oxecta and commercially available oxycodone tablets, and limitations on exposing Oxecta 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 Oxecta responded that they would not take the drug again compared to 5% of subjects exposed to immediate-release oxycodone;
- subjects taking Oxecta reported a higher incidence of nasopharyngeal and facial adverse events compared to immediate-release oxycodone;
- a decreased ability to completely insufflate two crushed Oxecta 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 Oxecta than immediate-release oxycodone.

Although we believe these abuse deterrent characteristics differentiate Oxecta 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 Oxecta has a reduced abuse liability compared to immediate release oxycodone. Pfizer has agreed to a post-approval commitment with the FDA to perform an epidemiology study to assess the actual impact on abuse of Oxecta tablets.

Further, the Oxecta 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 Oxecta for administration via nasogastric, gastric or other feeding tubes as it may cause an obstruction. Our laboratory studies demonstrated that the Oxecta tablet characteristics may change when Oxecta is exposed to certain solvents, including water.

Aversion Technology Opioid Products in Development

We have the following multiple opioid products utilizing our Aversion Technology in various stages of development. Pursuant to a September 24, 2012 agreement with Pfizer, the license and/or option rights to these products were returned to us by Pfizer and we retain all rights to develop and commercial these products worldwide.

Aversion Technology Tablets	Comparable Brand Name [1]	Status
Hydrocodone bitartrate/acetaminophen	Vicodin®, Lortab®, Norco®	IND submitted to the FDA on December 20, 2012. Pharmacokinetic studies in progress. Awaiting feedback from the FDA on the applicability of the results of Study AP-ADF-301 for NDA submission.
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.

Development of Hydrocodone/Acetaminophen

Our hydrocodone/acetaminophen product was previously under development by Pfizer who, before returning the product to us: (1) removed niacin from the formulation, (2) conducted bioequivalence testing and (3) held a pre-IND meeting with the FDA. We expect our clinical development program for our hydrocodone/acetaminophen product to consist of:

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

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 a neither a like or 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. This effect is being further evaluated.

On December 5, 2013, we met with the FDA to discuss if the FDA will consider whether the results of Study 301 are acceptable for submission in a NDA. On February 7, 2014 the FDA advised us their discussion of whether the results of study AP-ADF-301 could support abuse-deterrent labeling is ongoing.

We have completed scale-up activities for our Aversion hydrocodone/acetaminophen product at the proposed commercial manufacturer and have manufactured our registration batches for use in subsequent clinical trials. We commenced the pharmacokinetic studies for Aversion hydrocodone/acetaminophen in the first quarter 2014.

We continue to evaluate possible partnering of our Aversion development products with alternative strategic partners.

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. In addition, 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 253 million tablet and capsule prescriptions dispensed in 2013, of which approximately 238 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 2013, sales in the IR opioid product segment were approximately $2.6 billion, of which ~97% 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. Oxecta 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 2013 is provided below:

IR Opioid Products [1]	2013 US Prescriptions (Millions) [2]	% of Total
Hydrocodone	128	54
Oxycodone	52	22
Tramadol	41	17
Codeine	11	5
3 others	6	2
Total (Average)	238	100

[1] Includes all salts and esters of the opioid and opioids in combination with other active ingredients such as acetaminophen.
[2] IMS Health, 2013

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: 2012

Source: SAMHSA, Office of Applied Studies, 2012 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 postmarketing 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 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 Oxecta contains limitations on exposing Oxecta tablets to water and other solvents and administration through feeding tubes, the FDA approved Oxecta label does not contain a description of the I.V. injection studies we performed to characterize the abuse deterrent properties of Oxecta. Pfizer has committed to the FDA to undertake epidemiological studies to assess the actual consequences of abuse of Oxecta 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 Oxecta. Further, because the FDA closely regulates promotional materials, even if the 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.

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, covering the United States, Canada and Mexico. Under the Pfizer Agreement, Pfizer will manufacture and commercialize Oxecta in the United States. As of December 31, 2013, we had received an aggregate of $78.5 million in payments from Pfizer in the form of a $30.0 million upfront cash payment, milestone payments, option fees and reimbursement for research and development expenses, including a $20.0 million milestone fee relating to the receipt of FDA approval of the NDA for Oxecta. In addition, as of December 31, 2013, we had received aggregate royalties of $10 thousand from Pfizer on net sales of Oxecta, which royalty is calculated at 5% of Oxecta net sales based on current annual net sales levels.

Pursuant to the Pfizer Agreement, we and Pfizer formed a joint steering committee to oversee development and commercialization strategies for Oxecta. Pfizer is responsible, at its own expense, for all regulatory, manufacturing and commercialization activities for Oxecta. Subject to the Pfizer Agreement, Pfizer will have final decision making authority with respect to all regulatory and commercialization activities for Oxecta.

Pfizer's royalty payment obligations for Oxecta expire on a country-by-country basis upon the later of (i) the expiration of the last valid patent claim covering Oxecta in such country, or (ii) 15 years from the first commercial sale of Oxecta in such country. No minimum annual fees are payable by either party under the Pfizer Agreement. If Pfizer, after consultation with us, enters into a license agreement with a third party to avoid or settle such third party's allegations or claims regarding freedom to operate against Oxecta, Pfizer may deduct 50% of any royalties or other license payments it pays to such third party under such license, provided that the royalties payable to us are no less than 80% of the royalties otherwise due to us under the Pfizer Agreement.

The Pfizer Agreement expires upon the expiration of Pfizer's royalty payment and other payment obligations under the Pfizer Agreement. Pfizer may terminate the Pfizer Agreement in its entirety at any time by written notice to us. We may terminate the Pfizer Agreement in its entirety if Pfizer commences any interference or opposition proceeding challenging the validity or enforceability of any of our patent rights licensed to Pfizer under the Pfizer Agreement. Either party has the right to terminate the Pfizer Agreement on a country-by-country basis if the other party is in material breach of its obligations under the Pfizer Agreement relating to such country, and to terminate the Agreement in its entirety 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, in each case subject to applicable cure periods.

In the event of termination, no payments are due except those royalties and milestones that have accrued prior to termination under the Pfizer Agreement and all licenses under the Pfizer Agreement are terminated. For all Acura terminations and termination by Pfizer where we are not in breach, the Pfizer Agreement provides for the transition of development and marketing of the licensed products from Pfizer to us, including the conveyance by Pfizer to us of the trademarks and all regulatory filings and approvals solely used in connection with the commercialization of such licensed products and, in certain cases, for Pfizer's supply of such licensed products for a transitional period at Pfizer's cost plus a mark-up.

Impede Technology Overview

Our Impede Technology, a proprietary mixture of inactive ingredients, prevents the extraction of pseudoephedrine, or PSE, from tablets 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 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 independent laboratory demonstrated our Impede 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 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.

We are developing a next generation of our Impede Technology in order to further improve our Nexafed franchise.

Separately, we are advancing in development our first line extension of Nexafed, a combination product with additional active ingredients using our current Impede Technology. We expect to launch our Nexafed first line extension in 2014.

Nexafed

Our Nexafed product is an immediate-release pseudoephedrine HCl, tablet which utilizes our patent pending Impede Technology. PSE is a widely-used nasal decongestant available in many non-prescription and prescription cold, sinus and allergy 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 Combat Methamphetamine Epidemic Act, or 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 intend to capitalize 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 launched Nexafed commercially in mid-December 2012 into the United States OTC market for cold and allergy products and have shipped Nexafed to several regional and national drug wholesalers for redistribution to pharmacies, including the three largest U.S. drug wholesalers: McKesson, Cardinal Health and AmerisourceBergen. In March 2013, we completed our first shipment of Nexafed directly to the warehouse of a regional drug chain who, we understand, would further stock all of their pharmacies with Nexafed **.** We have also gained support from other pharmacy chain customers, including Rite Aid who has made Nexafed available in the substantial majority of its 4,600 pharmacies. The support for Nexafed from these chain customers varies from providing Nexafed educational materials to their pharmacists and allowing each pharmacy to make their own purchasing decision, to the stocking of Nexafed as their only 30mg pseudoephedrine product. We estimate Nexafed is currently stocked in approximately 8,300 U.S. pharmacies, or about 12% of the 65,000 U.S. pharmacy outlets. We estimate that approximately 46% of these pharmacies, excluding Rite Aid which initiated purchasing in the 4 th quarter of 2013, are repeat customers. We continue to work to expand the wholesale and retail distribution network for Nexafed and intend to re-approach some chain customers already stocking Nexafed with programs designed to improve penetration in those chains.

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 and are currently readapting our advertising program to differentiate Nexafed from a meth-resistant competitive product that launched in August 2013. We may use consumer advertising in the future. We have shipped approximately $252 thousand and $402 thousand in Nexafed product during the quarter and year ended December 31, 2013, respectively.

We are marketing our 30mg Nexafed product under FDA's regulations applicable to OTC Monograph products. Nexafed tablets are offered in 24-count blister packaged cartons and priced comparable to other branded PSE 30mg tablets.

Impede Technology Product in Development

Given the fragmented nature of the PSE market with products containing multiple active ingredients, we are assessing our initial success with the launch of Nexafed and are considering our product development options:

Impede Technology Product	Status
Immediate-release Combination #1	In manufacturing scale-up Launch expected in 2014
Immediate-release pseudoephedrine HCl in combination with other cold and allergy active ingredients	Formulations being considered
Extended-release formulation	Development initiated

We also have been working on a next generation Impede Technology, an improvement for our Nexafed franchise, which is an enhancement on the methamphetamine resistance of our current technology in the one-pot methamphetamine conversion method.

We continue to evaluate possible licensing of our Impede Technology with commercial partners within and outside the United States.

U.S. Market Opportunity for Impede PSE Products

Methamphetamine is a highly addictive illicit drug used non-medically by an estimated 13 million people at some point in their lifetime. In 2006, the CMEA was enacted in response to an alarming increase in and widespread conversion of PSE containing products into methamphetamine. Among other things, the 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 the 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.

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 sales of non-prescription products containing either PSE or phenylephrine as a nasal decongestant, of which approximately 47% contained PSE.

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.

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.

Our 2009 survey of PSE 30mg tablet prices at these top four drug chains indicates that branded PSE products were priced, on average, to the consumer at approximately $0.25 per tablet as compared to approximately $0.12 per tablet for the corresponding store brand.

Product Labeling for Impede Technology Products

We are marketing our Nexafed product 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 methaphetamine-resistant benefits of our Nexafed product, which is supported by our 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.

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 facility is registered with U.S. Drug Enforcement Administration, or 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 volumes sufficient to meet FDA standards for NDAs. 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. Pfizer is responsible for commercial manufacture of Oxecta under the Pfizer 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 manufacture r to manufacture, package and supply our commercial quantities of Nexafed. Initially, we will source our commercial requirements of Nexafed 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 Nexafed.

In 2012, we completed initial discovery research on a new technology to address abuse and misuse of prescription pharmaceutical tablets though the intentional or accidental ingestion of multiple tablets in excess of the recommended dose. In a laboratory proof of concept study with prototype tablets, 100% of the active ingredient from 2 tablets was released in approximately 15 to 20 minutes compared with approximately 20% being released in the same timeframe when 8 tablets are tested. The synergistic effect of the ingredients in the technology retards the release of the active ingredient when multiple tablets are co-administered. The objective of this technology, if it can be optimized and it translates consistently to human use, of which no assurance can be given, will be to reduce the peak plasma concentration of drug which may be associated with adverse health consequences.

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, in collaboration with Pfizer, Purdue Pharma, Atlantic Pharmaceuticals, Egalet Corporation, KemPharm, Shionogi, Nektar Therapeutics, Signature Therapeutics, QRx Pharma, Tris Pharma, Pisgah Labs, and Collegium Pharmaceuticals, Inc. Pfizer, our partner for Oxecta, is also developing and/or marketing ER opioid products, other analgesic products and non-analgesic products, all of which will compete for development and commercialization resources with our products, which may adversely impact the sales of Oxecta.

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 directly with Johnson & Johnson's Sudafed® brand as well as generic formulations manufactured by Perrigo Company and others. A competing product from Westport Pharmaceuticals is being marketed with claims of methamphetamine-resistance.

We are aware that some large pharmaceutical companies in the past have sought to develop PSE technologies or products that resist conversion into methamphetamine, but believe those efforts have been discontinued, although there can be no assurance that this is the case.

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

Patents and Patent Applications

In April 2007, the United States Patent and Trademark Office, or USPTO, issued to us U.S. Patent No. 7,201,920 titled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms," or the 920 Patent. The 54 allowed claims in the 920 Patent encompass certain pharmaceutical compositions intended to deter the most common methods of prescription opioid analgesic product misuse and abuse. These patented pharmaceutical compositions include the mixture of functional inactive ingredients and specific opioid analgesics such as oxycodone HCl and hydrocodone bitartrate among others.

In January 2009, the USPTO issued to us U.S. Patent No. 7,476,402, or the 402 Patent, with 18 allowed claims. The 402 Patent encompasses certain combinations of kappa and mu opioid receptor agonists and other ingredients intended to deter opioid analgesic product misuse and abuse.

In March 2009, the USPTO issued to us U.S. Patent No. 7,510,726, or the 726 Patent, with 20 allowed claims. The '726 Patent encompasses a wider range of abuse deterrent compositions than our '920 Patent.

In July 2011, the USPTO issued to us U.S. Patent No. 7,981,439, or the 439 Patent, with 7 allowed claims. The 439 Patent encompasses certain compositions including any water soluble drug of abuse intended to deter the most common methods of prescription opioid analgesic product misuse and abuse.

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.

In April 2013, the USPTO issued to us U.S. Patent No. 8,409,616, or the 616 Patent, that encompasses certain immediate-release abuse deterrent dosage forms.

In January 2014, the USPTO issued to us U.S. Patent No. 8,637,540, or the 540 Patent, that encompasses certain immediate-release abuse deterrent opioid products.

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 Technology. Except for those rights conferred in the Pfizer Agreement, we have retained all intellectual property rights to our Aversion Technology, Impede Technology, and related product candidates. See below under the caption Legal Proceedings contained in Item 3 of this Report for a discussion of our pending patent infringement actions against two generic sponsors of ANDAs for generic drugs listing Oxecta as the reference drug.

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 Oxecta tablets.

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 continue after drug product approvals, and the requirements for our continued marketing of our products may change even after initial approval. We are also subject to regulation under federal, state and local laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, state, federal and foreign regulations, including possible future regulations of the pharmaceutical industry. We cannot predict the extent to which we may be affected by legislative and other regulatory developments concerning our products and the healthcare industry in general.

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

FDA approval is required before any "new drug" can be marketed. A "new drug" is one not generally recognized, by experts qualified by scientific training and experience, as safe and effective for its intended use. Our products not subject to and in compliance with an OTC Monograph are new drugs and require prior FDA approval. Such approval must be based on extensive information and data submitted in a NDA, including but not limited to adequate and well controlled laboratory and clinical investigations to demonstrate the safety and effectiveness of the drug product for its intended use(s). In addition to providing required safety and effectiveness data for FDA approval, a drug manufacturer's practices and procedures must comply with current Good Manufacturing Practices, or 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 do 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 number 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 : 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 an Abbreviated New Drug Application, or ANDA, to the FDA including the results of the preclinical and clinical testing, together with, and among other things, detailed information on the chemistry, manufacturing, quality controls, and proposed product labeling. There are two types of NDAs; a 505(b)(1) NDA and a 505(b)(2) NDA. A 505(b)(1) NDA is also known as a "full NDA" and is described by section 505(b)(1) of the FD&C Act as an application containing full reports of investigations of safety and effectiveness, in addition to other information. The data in a full NDA is either owned by the applicant or are data for which the applicant has obtained a right of reference. A 505(b)(2) application is one described under section 505(b)(2) of the FD&C Act as an application for which information, or one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted". This provision permits the FDA to rely for approval of an NDA on data not developed by the applicant, such as published literature or the FDA's finding of safety and effectiveness of a previously approved drug. 505(b)(2) applications are submitted under section 505(b)(1) of the FD&C Act and are therefore subject to the same statutory provisions that govern 505(b)(1) applications that require, among other things, "full reports" of safety and effectiveness. Pfizer’s submission for Oxecta Tablets was accepted for filing by FDA as a 505(b)(2) NDA.

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 the FDA’s fee schedule, effective on October 1, 2013, for the 2014 fiscal year, the user fee for an application fee requiring clinical data, such as a NDA, is $2,169,100. The FDA adjusts PDUFA user fees on an annual basis. PDUFA also imposes annual product and facility fees. The annual product fee for prescription drugs and biologics for the 2014 fiscal year is $104,060 and the annual facility fee for facilities used to manufacture prescription drugs and biologics for the 2014 fiscal year is $554,600. 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 a 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 a 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 the Food and Drug Administration Amendments Act, or 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 Pfizer is exempt from the pediatric studies requirement of the PREA for Oxecta.

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 Oxecta Tablets on Pfizer’s commitment to conduct Phase 4 epidemiological studies to assess the actual abuse levels of Oxecta 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 the 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, the FDA may require Risk Evaluation and Mitigation Strategies, or REMS, to manage known or potential serious risks associated with drugs or biological products. If the 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, the 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. The FDA has indicated Pfizer is not required to maintain a REMS for Oxecta. There can be no assurance, however, that a REMS program will not be required by the FDA in the future for Oxecta or for our Aversion IR opioid product candidates in development. We are aware that a Citizens Petition has been filed with the FDA seeking to expand the FDA’s REMS requirement for ER opioid products to include IR opioid products.

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 a FDA's 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.

DEA Regulation

Several of our products, 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 a 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, Oxecta Tablets are listed as 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 Oxecta 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.

We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Many of the Healthcare Reform Law’s most significant reforms do not take effect until 2014 and thereafter, and their details will be shaped significantly by implementing regulations, some of which have yet to be finalized. In 2012, the Supreme Court of the United States heard challenges to certain provisions of the Healthcare Reform Law. The Supreme Court’s decision upheld most of the Healthcare Reform Law; however, the Supreme Court struck down a provision in the Healthcare Reform Law that penalized states that chose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state’s current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court’s ruling, it is unclear how many states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2014 than anticipated when Congress passed the Healthcare Reform Law. For each state that does not expand its Medicaid program, there will be fewer insured patients overall. An increase in the proportion of uninsured patients who are prescribed products resulting from our proprietary or partnered programs could impact future sales of any products that are commercialized in the future 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® and Impede® 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 Oxecta

We anticipate that, for at least fiscal 2014 and 2015, our ability to generate revenues and become profitable will depend in large part on the commercial success of our only FDA approved product, Oxecta, which in turn, will depend on several factors, including our licensee Pfizer's ability to:

- obtain and increase market demand for, and sales of, Oxecta;
- obtain acceptance of Oxecta by physicians and patients;
- obtain and maintain adequate levels of coverage and reimbursement for Oxecta 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 Oxecta 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 Oxecta to meet commercial demand, including obtaining sufficient quota from the Drug Enforcement Administration; and
- maintain intellectual property protection for Oxecta and obtaining favorable drug listing treatment by the FDA to minimize generic competition.

There can be no assurance that Pfizer will devote sufficient resources to the marketing and commercialization of Oxecta. Pfizer's marketing of Oxecta may result in low market acceptance and insufficient demand for, and sales of, the product. If Pfizer fails to successfully commercialize Oxecta 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 affected.

If we are not successful in commercializing Nexafed and other Impede Technology products, our revenues and business will suffer.

We commenced the launch and commercial distribution of Nexafed in mid-December 2012. Nexafed competes 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. Nexafed 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 Nexafed, or that the pricing of Nexafed 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 Nexafed as an OTC product and generate revenue from Nexafed product sales. Our failure to successfully commercialize Nexafed and to develop and commercialize other Impede Technology products will have a material adverse effect on our business and financial condition.

If Pfizer is not successful in commercializing Oxecta, our revenues and our business will suffer.

Pursuant to our license, development and commercialization agreement with a subsidiary of Pfizer, or the Pfizer Agreement, Pfizer is responsible for manufacturing, marketing, pricing, promoting, selling, and distributing Oxecta in the United States and Mexico, or the Pfizer Territory. If such 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 Oxecta 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 Oxecta ourselves, which would substantially increase our expenses and capital requirements that we might not be able to fund, or are unable to find a suitable replacement commercialization partner, we would be unable to generate any revenue from Oxecta. Even if we are successful at replacing the commercialization capabilities of Pfizer, our revenues and/or royalties from Oxecta could be adversely impacted.

Pfizer's third party manufacturing facility is currently the sole commercial source of supply for Oxecta. If Pfizer'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 Oxecta, product revenue and our royalties could be adversely impacted.

Pfizer has a diversified product line for which Oxecta Tablets will vie for Pfizer's promotional, marketing, and selling resources. If Pfizer fails to commit sufficient promotional, marketing and selling resources to Oxecta, product revenue and our royalties could be adversely impacted. Additionally, there can be no assurance that Pfizer will commit the resources required for the successful commercialization of Oxecta Tablets.

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 Pfizer prices Oxecta inappropriately, fails to position Oxecta properly, targets inappropriate physician specialties, or otherwise does not provide sufficient promotional support, product revenue and our royalties could be materially adversely impacted.

Pfizer's promotional, marketing and sales activities in connection with Oxecta 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 Pfizer's activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, Pfizer 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 Oxecta, which could harm the commercial success of Oxecta and have a material affect on our business, financial condition and results of operations.

Our failure to continue the development of the three development stage products terminated by Pfizer under the Pfizer Agreement, 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.

In July 2012, Pfizer exercised its right to terminate the license to the three products in development, or the returned products, under the Pfizer Agreement. The termination of such license provides for the return to us of oxycodone hydrochloride with acetaminophen, hydrocodone bitartrate with acetaminophen and another undisclosed opioid product. We have the right to develop the returned products on our own or in partnership with a third party. Our plan for developing, manufacturing and commercializing the returned products includes entering into an agreement similar to the Pfizer 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 hydrocodone bitartrate with acetaminophen product on our own. Although we believe we have sufficient cash resources to fund the development of such product and submit a corresponding NDA to the FDA, there can be no assurance that this will be the case. The continued development of our hydrocodone bitartrate with acetaminophen product and the other returned products may 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 $13.9 million and $9.7 million for the years ended December 31, 2013 and 2012, respectively, net income of $10.4 million for the year ended December 31, 2011 and a net loss of $12.7 million and $15.8 million for the years ended December 31, 2010 and 2009, respectively. Our future profitability will depend on several factors, including:

- our receipt of royalties relating to Pfizer's sale of Oxecta Tablets;
- our successful marketing and sale of Nexafed and other products utilizing our Impede Technology, and market acceptance, increased demand for and sales of Nexafed;
- our receipt of milestone payments and royalties relating to our Aversion Technology products in development, including the products returned by Pfizer, 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 our Oxecta or 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.

We recognized revenues of $10 thousand in the form of royalty payments from Pfizer for the year ended December 31, 2013. Even if Pfizer succeeds in commercializing Oxecta, 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 Nexafed 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, including the three products returned to us by Pfizer under the Pfizer Agreement, maintaining and expanding the scope of our intellectual property, commercializing our Nexafed product, 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 Nexafed, if Pfizer does not successfully commercialize Oxecta, 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 the market price of our common stock.

We must rely on current cash reserves, royalty revenue from Pfizer's sale of Oxecta, revenues from Nexafed sales, the proceeds of our term loan and the net proceeds, if any, from our "at-the-market" offering of our common stock to fund operations.

Pending the receipt of milestone payments and royalties under license agreements similar to the Pfizer Agreement that we may enter into with other pharmaceutical companies in the future, of which no assurance can be given, we must rely on our current cash reserves, royalty revenue from Pfizer on its sales of Oxecta, revenues from our sales of Nexafed, the proceeds of our $10 million term loan from Oxford Finance and the net proceeds, if any, from our "at-the-market" offering of our common stock, to fund operations and product development activities. No assurance can be given that current cash reserves, royalty revenue from Pfizer on its sales of Oxecta, revenues from Nexafed product sales, the term loan from Oxford Finance or the net proceeds, if any, from our "at-the-market" offering of our common stock will be sufficient to fund continued operations and the development of our product candidates until such time as we generate additional royalty revenue from the Pfizer Agreement or any similar future license agreements. 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 product candidates utilizing our Aversion and 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 Oxecta 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 our Aversion Technology products 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 Oxecta includes the results from a clinical study which evaluated the effects of nasally snorting crushed Oxecta and commercially available oxycodone tablets and limitations on wetting or dissolving Oxecta, it does not, however, include the results of our laboratory studies intended to evaluate Oxecta's potential to limit extraction of oxycodone HCl from dissolved Oxecta 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 Oxecta may substantially limit Pfizer's ability to differentiate Oxecta from other immediate release oxycodone products, which would have a material adverse effect on market acceptance of Oxecta and on our business and results of operations.

Notwithstanding the FDA approved labeling for Oxecta, 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 Oxecta, 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 Oxecta 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 Oxecta Tablets and our marketing of Nexafed, there can be no assurance that any other product candidate utilizing our Aversion or Impede 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 Technology or Impede Technology 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, 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 Nexafed.

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 Nexafed is 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 Nexafed which are supported by our research studies. No assurance can be given, however, that the FDA will agree that Nexafed 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 Nexafed's extraction characteristics and benefits. If the FDA determines that Nexafed does not conform to the OTC monograph or if we fail to meet the general conditions, once commercialized, the product 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 has scheduled a 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 Nexafed 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 Nexafed or other Impede Technology products, this would result in substantial additional costs, suspend the commercialization of Nexafed and require FDA approval prior to sale, of which no assurance can be provided. In such case, the label for Nexafed 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 and Impede 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. Notwithstanding the receipt of FDA approval of Oxecta Tablets and the results of our numerous clinical and laboratory studies for Oxecta, Nexafed, and our Aversion and Impede Technology products in development, there can be no assurance that Oxecta, Nexafed or any other product utilizing our Aversion or Impede 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 Oxecta will show a reduction in the consequences of abuse and misuse by patients for whom Oxecta is prescribed. The failure of Oxecta, Nexafed or other products utilizing our Aversion and Impede Technologies to limit or impede actual abuse or misuse in practice will have a material adverse impact on market acceptance for such products and on our financial condition and results of operations.

Relying on third party 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 Nexafed, 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 Oxecta is conditioned on Pfizer conducting a post-approval epidemiological study to assess the actual abuse levels and consequences of Oxecta 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 Oxecta 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 or Impede 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 Pfizer Agreement grants Pfizer an exclusive license to develop and commercialize Oxecta. We believe that opportunities exist to enter into agreements similar to the Pfizer Agreement with other partners for the commercialization of Oxecta outside the Pfizer Territory, for the development and commercialization of our other opioid analgesic products (including the products returned to us by Pfizer under the Pfizer Agreement) 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 adversely affected.

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

As part of our Pfizer Agreement or other future similar license agreements (if any), we do not and 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 of the product candidate 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 product candidate that is the subject of a license agreement. Accordingly, our ability to receive any revenue from the product candidates 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 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 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 or commercializing our product candidates would be materially adversely effected. Additionally, due to the nature of the market for our product candidates, it may be necessary for us to license all or 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 Pfizer, we may have to commercialize Oxecta on our own.

Our plan for manufacturing and commercializing Oxecta Tablets currently requires us to maintain our license agreement with Pfizer. In addition to other customary termination provisions, the Pfizer Agreement provides that Pfizer may terminate the Pfizer Agreement at any time upon written notice to us. If Pfizer elects to terminate the Pfizer Agreement, or if we are otherwise unable to maintain our existing relationship with Pfizer, we would have to commercialize Oxecta 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 Oxecta 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 Impede Technology products;
- the willingness of pharmacists to recommend our Impede Technology products to their customers; and
- the willingness of consumers to pay for our products.

Oxecta 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 Impede Technology 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, beginning in 2011;
- 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, beginning in 2011;
- Extension of manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;
- 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 our agreement with Pfizer, Pfizer controls the price of Oxecta 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 the Pfizer Agreement.

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. Patent No. 7,201,920 and U.S. Patent No. 7,510,726 from the USPTO encompassing our opioid products utilizing our Aversion Technology, and U.S. Patent No. 7,981,439 encompassing certain non-opioid products utilizing our Aversion 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 affect on our operations and financial condition.

We also rely on or intend to rely on our 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 trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition and could require us 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, our licensee Pfizer has the first right to control the enforcement of certain of our patents against third party infringers. Pfizer 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 Oxecta 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 Pfizer will not be sued for infringing these patents, and if sued, there can be no assurance that we or Pfizer will prevail in any such litigation. If we or Pfizer are found to infringe either or both of these patents, we or Pfizer 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 Pfizer 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, Oxecta 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 Pfizer or its oxycodone HCl supplier will not be sued for infringing these patents. In the event of an infringement action, Pfizer and their oxycodone HCl supplier would have to either: (a) demonstrate that the manufacture of the oxycodone HCl used in Oxecta 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 Pfizer or their oxycodone HCl supplier is unable to demonstrate the foregoing, or obtain a license to these patients, Pfizer may be required or choose to withdraw Oxecta 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 less 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 affect on our operations and financial condition.

Generic manufacturers are using litigation and regulatory means to seek approval for generic versions of Oxecta, which could cause our and our licensee'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 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 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 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, 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. The above actions are referred to as the "Paragraph IV Proceedings."

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.

The Settlement Agreements with Par and Impax do not affect the status of our separate Oxecta patent litigations against Sandoz Inc. and Ranbaxy Inc. pending in the United States District Court for the District of Delaware.

Litigation is inherently uncertain and we cannot predict the outcome of the Paragraph IV Proceedings. If Sandoz and/or Ranbaxy prevails its respective lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of Oxecta prior to the expiration of our patents in 2025. Additionally, it is possible that other generic manufacturers may also seek to launch a generic version of Oxecta and challenge our patents. Any determination in the Paragraph IV Proceedings that our patents covering our Aversion Technology and Oxecta 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 affect 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 Nexafed. This coverage may not be adequate to cover any product liability claims. Product liability coverage is expensive. In the future, we may not be able to maintain such product liability insurance at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims. Any claims that are not covered by product liability insurance could have a material adverse effect on our business, financial condition and results of operations.

The pharmaceutical industry is characterized by frequent litigation. Those companies with significant financial resources will be better able to bring and defend any such litigation. No assurance can be given that we would not become involved in future litigation, in addition to the ongoing Reglan/Metoclopramide mass tort litigation discussed below under "Item 3. Legal Proceedings". 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, in collaboration with Pfizer, 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. Pfizer, our partner in commercializing Oxecta, is also developing and/or marketing ER Opioid Products, other analgesic products and non-analgesic products, all of which will compete for development and commercialization resources with our products, which may delay development or adversely impact the sales of our products.

Our Impede Technology products containing PSE, including Nexafed, 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 directly with Johnson & Johnson's Sudafed® brand as well as generic formulations manufactured by Perrigo Company and others. In addition, Highland Pharmaceuticals has recently launched 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 and issued warrants to them to purchase 297,805 shares of our common stock. Under this agreement, 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 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 between $795,000 and $995,000, 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.

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 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.

Volatility in stock prices of other companies may contribute to volatility in our stock price.

The market price of our common stock, like the market price for securities of pharmaceutical and biotechnology companies, has historically been highly volatile. The stock market from time to time experiences significant price and volume fluctuations unrelated to the operating performance of particular companies. Factors, such as fluctuations in our operating results, future sales of our common stock, announcements of the timing and amount of product sales, announcements of the status of development of our products, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements, laboratory or clinical trial results, government regulation, FDA determinations on the approval of a product candidate NDA submission, developments in patent or other proprietary rights, public concern as to the safety of drugs developed by us or others, changes in reimbursement policies, comments made by securities analysts and general market conditions may have a substantial effect on the market price of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation and shareholder derivative litigation has often been instituted. A securities class action suit or shareholder derivative suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources and result in a material adverse affect on our financial condition and results of operations.

Our stock price has been volatile and there may not be an active, liquid trading market for our common stock.

Our stock price has experienced significant price and volume fluctuations and may continue to experience volatility in the future. Factors that may have a material impact on the price of our common stock, in addition to the other issues described herein, include the launch and commercial success of Oxecta and Nexafed, results of or delays in our pre-clinical and clinical studies, any delays in, or failure to receive FDA approval of our product candidates, the entry into collaboration or license agreements relating to our products in development, announcements of technological innovations or new commercial products by us or others, developments in patents and other proprietary rights by us or others, future sales of our common stock by existing stockholders, regulatory developments or changes in regulatory guidance, the departure of our officers, directors or key employees, and period-to-period fluctuations in our financial results. Also, you may not be able to sell your shares at the best market price if trading in our stock is not active or if the volume is low. There is no assurance that an active trading market for our common stock will be maintained on the NASDAQ Capital Market.

The National Association of Securities Dealers, Inc., or NASD, and the Securities and Exchange Commission, or SEC, have adopted rules relating to the listing of publicly traded stock. If we were unable to continue to comply with such rules, we could be delisted from trading on the NASDAQ Capital Market and thereafter trading in our common stock, if any, would be conducted through the Over-the-Counter Bulletin Board of the NASD. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock from the NASDAQ Capital Market could also result in lower prices per share of our common stock than would otherwise prevail.

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.

Because our principal shareholders control a large percentage of our voting power, other stockholders' voting power may be limited

Our principal shareholders, Galen Partners III, L.P and its affiliates and Essex Woodlands Health Ventures V, beneficially own approximately 24.4% and 20.8%, respectively, of our outstanding common stock (calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended). Accordingly, these shareholders, individually or if they were to act as a group or vote in the same manner, may be able to influence the outcome of shareholder votes, including the adoption or amendment of provisions in our Certificate of Incorporation or By-Laws and the approval of mergers and other significant corporate transactions, including a sale of substantially all of our assets. These shareholders may make decisions that are adverse to other shareholders' interests. This ownership concentration may also adversely affect the market price of our common stock.

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 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 26,800,763 shares (representing approximately 48% of our shares outstanding on a fully-diluted basis – including all derivative securities, whether or not currently exercisable) remain 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 lower our value and make it more difficult for us to raise capital if needed in the future.

Future sales of our common stock in the public market by us or our significant stockholders or other insiders could lower our share price.

Sales of substantial amounts of our common stock in the public market, or the perception that the sales could occur, could cause the market price of our common stocks to decline and could materially impair our future ability to raise capital through offerings of our common stock. 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 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, 2013 we sold $3.3 million of common stock (1,940,652 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. In addition, as of December 31, 2013, our directors, executive officers, Galen Partners III, L.P. and its affiliates, and Essex Woodlands Health Ventures V, L.P. owned an aggregate of approximately 45% of our common stock, or 21,835,147 shares. They are able to sell these shares under Rule 144 of the Securities Act, subject to restrictions in the case of shares held by persons deemed to be our affiliates, or pursuant to our registration statement declared effective by the SEC on November 20, 2007.

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 2013 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, 2015. 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 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 three 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.

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.

The Settlement Agreements with Par and Impax do not affect the status of our separate Oxecta patent litigations against Sandoz Inc. and Ranbaxy Inc. pending in the United States District Court for the District of Delaware.

Litigation is inherently uncertain and we cannot predict the outcome of these infringement actions. If Sandoz and/or Ranbaxy prevails its respective lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of Oxecta prior to the expiration of our patents in 2025. Additionally, it is possible that other generic manufacturers may also seek to launch a generic version of Oxecta and challenge our patents. Any determination in these infringement actions that our patents covering our Aversion Technology and Oxecta 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 affect on our operations and financial condition.

By designating Oxecta as an RLD, we believe the FDA has acknowledged that Oxecta 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 Oxecta 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 Oxecta. 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 Acura, 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. In this product liability litigation against numerous pharmaceutical product manufacturers and distributors, including Acura, plaintiffs claim injuries from their use of the Reglan brand of metoclopramide and generic metoclopramide.

In the Pennsylvania state court mass tort proceeding, over 200 lawsuits have been filed against Acura and Halsey Drug Company alleging that plaintiffs developed neurological disorders as a result of their use of the Reglan brand and/or generic metoclopramide. Plaintiffs have filed approximately 150 lawsuits against Acura, but have served less than 50 individual lawsuits upon Acura in the New Jersey action. In the California action, Acura was not served with any complaints until the spring of 2011 when a single complaint including over 400 plaintiffs was served.

In the lawsuits filed to date, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by Acura. Acura discontinued manufacture and distribution of generic metoclopramide more than 15 years ago. In addition, Acura believes 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 Acura in favorably resolving these cases. Acura has 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. In June 2012, the New Jersey trial court dismissed Acura with prejudice.

In Philadelphia and California, Generic Defendants, including Acura, also filed dispositive motions based on the Mensing decision.

On November 18, 2011, the Philadelphia trial court denied Generic Defendants' dispositive motion. In December 2011, the Generic Defendants appealed this ruling. On April 13, 2012, all trial court proceedings were stayed pending decisions by the Pennsylvania appellate courts. An adverse decision by the Pennsylvania Superior Court was issued in July 2013. Further appeal proceedings are pending. This appeal process eventually could result in dismissal of all of the Philadelphia cases against all generic defendants including Acura, although there can be no assurance in this regard. Legal fees related to this matter are currently covered by Acura's 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." Nonetheless, plaintiffs have not confirmed they ingested any of the generic metoclopramide manufactured by Acura. Therefore, Acura expects 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.

In Nebraska, the litigation against Acura has been stayed and will be dismissed if plaintiffs present no evidence of ingestion of generic metoclopramide manufactured by Acura. Legal fees related to this matter are currently covered by Acura's insurance carrier.

As any potential loss is neither probable nor estimable, Acura has not accrued for any potential loss related to these matters as of December 31, 2013 and Acura is presently unable to determine if any potential loss would be covered by its 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
2012 Fiscal Year		
First Quarter	$ 4.23	$ 3.12
Second Quarter	3.56	2.50
Third Quarter	3.26	1.40
Fourth Quarter	4.50	1.06
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 (through January 31, 2014)	$ 1.91	$ 1.62

Holders

There were approximately 325 holders of record of our common stock on February 28, 2014. 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, 2013, 2012, 2011, 2010 and 2009 are derived from our audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2013 and 2012 and for each of the years in the three-year period ended December 31, 2013, and the reports thereon, are included elsewhere in this Report. The selected financial information presented for our 2010 and 2009 operations and for our 2011, 2010 and 2009 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	2013	2012	2011	2010	2009
Revenues, net	$ 123	$ —	$ 20,466	$ 3,311	$ 3,835
Operating expenses:					
Cost of sales	364	—	—	—	—
Research and development [1]	4,923	3,726	4,037	7,177	5,673
Selling, marketing, general and administrative [2]	8,926	6,013	5,895	8,858	11,662
Interest expense	(9)	—	—	—	—
Investment income	194	79	32	42	147
Other (expense) income	4	(8)	(34)	(14)	(3)
(Loss) income before income tax	(13,901)	(9,668)	10,532	(12,696)	(13,356)
Provision for income taxes	—	—	147	11	2,479
Net (loss) income applicable to common stockholders	$ (13,901)	(9,668)	$ 10,385	$ (12,707)	$ (15,835)
(Loss) earnings per share: Basic	$ (0.29)	$ (0.20)	$ 0.22	$ (0.27)	$ (0.35)
(Loss) earnings per share: Diluted	$ (0.29)	$ (0.20)	$ 0.22	$ (0.27)	$ (0.35)
Weighted average shares used in computing net earnings (loss) per share: Basic	47,764	47,521	47,496	47,029	45,932
Weighted average shares used in computing net earnings (loss) per share: Diluted	47,764	47,521	48,007	47,029	45,932

(1) Includes stock-based compensation expense of approximately $500, $400, $500, $1,700 and $1,900 for years 2013, 2012, 2011, 2010 and 2009, respectively.
(2) Includes stock-based compensation expense of approximately $1,900, $1,300, $1,900, $5,100 and $7,300 for years 2013, 2012, 2011, 2010 and 2009, respectively.

BALANCE SHEET DATA (in thousands)	2013	2012	2011	2010	2009
Working capital	$ 26,346	$ 26,572	$ 35,599	$ 23,289	$ 28,750
Total assets	28,630	29,054	37,173	25,493	31,917
Total liabilities	10,707	1,424	530	1,152	2,007
Accumulated deficit	(349,112)	(335,211)	(325,543)	(335,928)	(323,221)
Stockholders' equity	$ 17,923	$ 27,630	$ 36,643	$ 24,341	$ 29,910

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 two proprietary technologies. 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. Pfizer Inc.'s Oxecta® (oxycodone HCl) tablets, CII is the first approved and marketed product utilizing Aversion and is commercialized under our license agreement with a subsidiary of Pfizer, or the Pfizer Agreement. We have also developed our 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 have 7 additional opioid products utilizing Aversion in various stages of development. Our product containing hydrocodone bitartrate and acetaminophen utilizing the Aversion technology, or hydrocodone/acetaminophen, is the most advanced opioid product in development and the primary focus of our opioid development efforts. Hydrocodone/acetaminophen is the most widely prescribed and often abused opioid product in the United States. We filed an Investigational New Drug Application, or IND, with the Food and Drug Administration, or FDA, on December 20, 2012, which became effective in late January 2013. On August 26, 2013, we announced the top-line results from Study AP-ADF-301 ("Study 301"), a phase II clinical study in 40 recreational drug abusers assessing the liability of snorting our hydrocodone/acetaminophen product. Study 301s primary endpoint indicated that Aversion hydrocodone/acetaminophen had slightly lower numeric mean maximum drug liking compared to an equivalent dose of a generic hydrocodone/acetaminophen tablet, however these results were not statistically significant. The Study 301 secondary endpoints demonstrated statistical significance in mean minimum drug liking, including the Overall Drug Liking score and the Take Drug Again assessment. On December 5, 2013, we met with the FDA to discuss if the FDA will consider whether the results of Study 301 are acceptable for submission in a New Drug Application, or NDA. On February 7, 2014, the FDA advised us their discussion of whether the results of study AP-ADF-301 could support abuse-deterrent labeling is ongoing. We expect that the development program for our other Aversion opioid products in development will be consistent with that of Oxecta and our hydrocodone/acetaminophen product candidate.

We launched Nexafed commercially in mid-December 2012 into the $1 billion United States over the counter market, or OTC, for cold and allergy products containing a decongestant. Nexafed was demonstrated in a clinical study to meet the FDA Guideline standards for bioequivalence to the reference drug Sudafed® marketed by Johnson & Johnson Corporation. We anticipate developing line extensions for our Nexafed franchise to capitalize on the many different combination offerings in the OTC cold/allergy market and expect to launch our first line extension in 2014. We also are developing a next generation of our Impede Technology in order to further improve our Nexafed franchise.

We also have discovered an early-stage technology 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, 2013, we had cash, cash equivalents and marketable securities of $26.1 million compared to $27.4 million of cash, cash equivalents and marketable securities at December 31, 2012. We had working capital of $26.3 million at December 31, 2013, compared to working capital of $26.6 million at December 31, 2012. We had an accumulated deficit of approximately $349.0 million and $335.2 million at December 31, 2013 and December 31, 2012, respectively. We had a loss from operations of $14.1 million and a net loss of $13.9 million for the year ended December 31, 2013, compared to a loss from operation of $9.7 million and a net loss of $9.7 million for the year ended December 31, 2012. As of January 31, 2014, we had cash, cash equivalents and marketable securities of approximately $24.8 million.

During the year ended December 31, 2013, we recognized $113 thousand of product sales on gross shipments of Nexafed which totaled $402 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. Our royalty revenue from Pfizer's sale of Oxecta Tablets began in February 2013 and we are accruing royalties based on the estimate of net product sales of Oxecta Tablets provided by Pfizer to us.

To fund our continued operations, we expect to rely on our current cash resources, the proceeds of our $10 million term loan from Oxford Finance, net proceeds, if any, from our "at-the-market" offering of our common stock pursuant to our Sales Agreement with MLV & Co., royalty payments that may be made under Pfizer 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 Tablets. 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, including the litigation of the Paragraph IV Proceedings, hire additional personnel, commercialize our Nexafed Tablets, 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, 2013 and 2012

	December 31		Change	
	2013	2012		
	$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 (expense), net	189	71	118	166
Income (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., we began to earn royalties on Oxecta net sales starting in February 2013. Pfizer will pay us a royalty at one of six rates ranging from 5% to 25% based on the level of annual net sales for Oxecta across all Pfizer Territories, with the highest applicable royalty rate applied to such annual sales. These royalties are based on net sales of Oxecta reported to us by Pfizer being paid to us within 45 days after the end of each calendar quarter. 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 G&A 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.

Results of Operations for the Years Ended December 31, 2012 and 2011

	December 31		Change	
	2012	2011		
	$000's		$000's	Percent
Revenues:				
Program fee revenue	—	466	(466)	(100)
Milestone revenue	—	20,000	(20,000)	(100)
Total revenues	—	20,466	(20,466)	(100)
Operating expenses:				
Research and development	3,726	4,037	(311)	(8)
Selling, marketing, general and administrative	6,013	5,895	118	2
Total operating expenses	9,739	9,932	(193)	(2)
Income (loss) from operations	(9,739)	10,534	(20,273)	(192)
Non-Operating income (expense):				
Investment income	79	32	47	147
Other expense, net	(8)	(34)	26	76
Total other income (expense), net	71	(2)	73	3,650
Income (loss) before income taxes	(9,668)	10,532	(20,200)	(192)
Provision for income taxes	—	147	(147)	(100)
Net income (loss)	$ (9,668)	$ 10,385	$ (20,053)	(193)

Revenue

In 2012, we recorded $6.0 thousand from gross product sales of Nexafed from two regional wholesalers, which we completely offset with a returned goods reserve. This compares to revenues in 2011 of $20.5 million, all from the Pfizer Agreement comprised of a $20.0 million milestone payment for achieving the FDA approval of Oxecta and the amortization of the final amount of the initial upfront fee received back in 2007.

Operating Expenses

Research and development expense during 2012 and 2011 were primarily for product candidates utilizing our Aversion and Impede Technologies, including costs of preclinical studies, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2012 and 2011 results are non-cash stock-based compensation charges of $0.4 million and $0.5 million, respectively, associated with the grant of stock options and restricted stock units. Excluding the stock-based compensation expense, there was a $0.2 million decrease in development expenses in 2012 compared to 2011.

Marketing expenses during 2012 and 2011 consisted of market research studies on our Impede Technology. Our general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll. Included in the 2012 and 2011 results are non-cash stock-based compensation charges of $1.3 million and $1.9 million, respectively, associated with the grant of stock options and restricted stock units. Excluding the stock-based compensation expense, there was an increase of $0.7 million in marketing, general and administrative expenses in 2012 compared to 2011, primarily attributable to Nexafed development and promotion.

Non-Operating Income

In the fourth quarter of 2012, the Company amended its investment policy allowing greater flexibility in investment selections. As such, some investments were shifted from lower yielding money market funds to high grade corporate bonds resulting in significant improvement in interest income over the prior year.

Income Taxes

The net loss of $9.7 million for 2012 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization. In 2011, the Company was able to utilize existing net operating loss carryforwards to offset the majority of its 2011 federal and state income taxes. The income tax expense for 2011 is comprised of federal alternative minimum taxes as well as state income taxes totaling $0.1 million. The Company has maintained a full valuation allowance on its deferred tax asset due to the uncertainty of future utilization of the Company's net operating losses.

Liquidity and Capital Resources

At December 31, 2013, we had cash, cash equivalents and marketable securities of $26.1 million compared to $27.4 million in cash and cash equivalents at December 31, 2012. We had working capital of $26.3 million at December 31, 2013 compared to $26.6 million at December 31, 2012. Our investing activities for capital expenditures were $23,000 in 2013 and $147,000 in 2012.

Pending the receipt of milestone and royalty payments under license agreements similar to the Pfizer Agreement anticipated to be negotiated and executed with other pharmaceutical company partners, of which no assurance can be given, we must rely on royalty payments from Pfizer for its sales of Oxecta, revenues for our Nexafed sales, the net proceeds, if any, from our "at-the-market" offering of our common stock pursuant to our Sales Agreement with MLV & Co., the proceeds of our $10.0 million loan from Oxford Finance completed in December 2013 (as described below), and our current cash reserves, including interest income from the investment of our cash reserves, to fund the development of our Aversion Technology, Impede Technology and related administrative and operating expenses. Our future sources of revenue, if any, will be derived from milestone payments and royalties under license agreements similar to the Pfizer Agreement with other pharmaceutical company partners, for which there can be no assurance, and from the commercialization of our Nexafed tablets and other Impede Technology products that we expect to develop.

At January 31, 2014, we had cash, cash equivalents and marketable securities of approximately $24.8 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, 2013:

	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	243	243	—	—	—
Clinical studies	675	675	—	—	—
Marketing and advertising	658	658	—	—	—
Employment agreements	667	667	—	—	—
Debt principal	10,000	—	4,280	5,720	—
Debt interest	3,451	765	1,380	1,306	—
Total	$ 15,754	$ 3,061	$ 5,667	$ 7,026	$ —

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 will use 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 the Amortization Date and starting on the Amortization Date, 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. The "Amortization Date" is April 1, 2015, but shall automatically become April 1, 2016 if we achieve 75% of our projected Nexafed® cash receipts and 75% of our projected Oxecta® cash receipts for the fiscal year ending December 31, 2014 (collectively, the "First Revenue Event"). The Amortization Date will be further deferred until April 1, 2017 if the First Revenue Event occurs and in addition, we achieve 75% of our projected Nexafed cash receipts and 75% of our projected Oxecta cash receipts for the fiscal year ending December 31, 2015 (collectively, the "Second Revenue Event"). 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.

We may voluntarily prepay the Term Loan in full, but not in part, and any prepayment is subject to a prepayment premium equal to 3% of the principal prepaid if prepaid on or prior to December 27, 2014, 2% of the principal prepaid, if prepaid after December 27, 2014 but on or 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 (A) $795,000 if the First Revenue Event does not occur, (B) $895,000 if the First Revenue Event occurs but the Second Revenue Event does not occur, or (C) $995,000 if both the First Revenue Event and the Second Revenue Event occur.

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.

Simultaneous with the funding of the Term Loan, pursuant to the terms and conditions of the Loan Agreement, we issued to the Oxford warrants to purchase an aggregate of up to 297,805 shares of our common stock at an exercise price equal to $1.595 per share (the "Warrants"). The Warrants 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 $0.3 million 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.

Commencing in February 2013, we began earning royalties based on net sales of Oxecta by Pfizer pursuant to the Pfizer Agreement. Such royalties are paid to us within 45 days after the end of each calendar quarter. We have recorded royalties of approximately $10 thousand for the year ended December 31, 2013 on Oxecta's net sales of approximately $0.2 million.

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 $0.7 million and $1.5 million at December 31, 2013 and 2012, 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, 2013, 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 2013, 2012 and 2011 were $23,000, $147,000 and $132,000, 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, 2013, 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, 2013. 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. Based on our assessment, our Chief Executive Officer and our Chief Financial Officer both believe that, as of December 31, 2013, 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 2013 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 2014 Proxy Statement to be filed with the SEC on or about March13, 2014 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 2014 Proxy Statement to be filed with the SEC on or about March 13, 2014 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 2014 Proxy Statement to be filed with the SEC on or about March 13, 2014 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 2014 Proxy Statement to be filed with the SEC on or about March 13, 2014 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 2014 Proxy Statement to be filed with the SEC on or about March 13, 2014 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, 2014

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, 2014
/s/Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2014
/s/William G. Skelly William G. Skelly	Director	February 27, 2014
/s/Bruce F. Wesson Bruce F. Wesson	Director	February 27, 2014
/s/Immanuel Thangaraj Immanuel Thangaraj	Director	February 27, 2014
/s/George K. Ross George K. Ross	Director	February 27, 2014

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, 2013 and 2012 and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 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 financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall 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, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013 **,** in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP
Chicago, Illinois
March 3, 2014

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2013 and 2012
(in thousands except par value)

	2013	2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,340	$ 7,476
Marketable securities	13,733	19,946
Accounts receivable, net of allowances of $28 and $0	194	5
Accrued investment income	120	36
Finished good inventories, net	251	219
Income taxes refundable	-	43
Prepaid expenses and other current assets	629	271
Other current deferred assets	186	-
Total current assets	27,453	27,996
Property, plant and equipment, net	941	1,052
Deferred debt issuance costs	231	-
Other assets	5	11
Total assets	$ 28,630	$ 29,059
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 274	$ 994
Accrued expenses	541	413
Other current liabilities	5	12
Deferred revenue	287	5
Total current liabilities	1,107	1,424
Long-term debt, net of debt discount of $400	9,600	-
Other liabilities	-	5
Total liabilities	$ 10,707	$ 1,429
Commitments and contingencies (Note 12)		
Common stock: $.01 par value per shares; 100,000 shares authorized, 48,325 and 45,867 shares issued and outstanding in 2013 and 2012, respectively	483	459
Additional paid-in capital	366,533	362,422
Accumulated deficit	(349,112)	(335,211)
Accumulated other comprehensive income (loss)	19	(40)
Total stockholders' equity	$ 17,923	$ 27,630
Total liabilities and stockholders' equity	$ 28,630	$ 29,059

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
YEARS ENDED DECEMBER 31, 2013, 2012 and 2011
(in thousands except per share amounts)

	2013	2012	2011
Revenues:			
Royalty revenue	$ 10	$ -	$ -
Product sales, net	113	-	-
Program fee revenue	-	-	466
Milestone revenue	-	-	20,000
Total revenues, net	123	-	20,466
Operating expenses:			
Cost of sales (excluding inventory write-down)	114	-	-
Inventory write-down	250	-	-
Research and development	4,923	3,726	4,037
Selling, marketing, general and administrative	8,926	6,013	5,895
Total operating expenses	14,213	9,739	9,932
Operating income (loss)	(14,090)	(9,739)	10,534
Non-Operating income (expense):			
Investment income	194	79	32
Gain on sales of marketable securities	4	-	-
Interest expense – promissory note	(9)	-	-
Other expense, net	-	(8)	(34)
Total other income (expense), net	189	71	(2)
Income (loss) before income taxes	(13,901)	(9,668)	10,532
Provision for income taxes	-	-	147
Net income (loss)	$ (13,901)	$ (9,668)	$ 10,385
Other comprehensive income (loss):			
Unrealized gains (losses) on securities	59	(40)	-
Total other comprehensive income (loss)	59	(40)	-
Comprehensive income (loss)	$ (13,842)	$ (9,708)	$ 10,385
Earnings (loss) per share:			
Basic	$ (0.29)	$ (0.20)	$ 0.22
Diluted	$ (0.29)	$ (0.20)	$ 0.22
Weighted average shares outstanding:			
Basic	47,764	47,521	47,505
Diluted	47,764	47,521	48,007

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2013, 2012 and 2011
(in thousands)

	Common Stock Shares	Common Stock $ Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at Dec. 31, 2010	43,894	$ 439	$ 359,830	$ (335,928)	$ -	$ 24,341
Comprehensive income: net income for the year ended Dec. 31, 2011	-	-	-	10,385	-	10,385
Share-based compensation	-	-	2,458	-	-	2,458
Net distribution of common stock pursuant to restricted stock unit award plan	828	8	(8)	-	-	-
Common shares withheld for withholding taxes on distribution of restricted stock units	(288)	(3)	(945)	-	-	(948)
Net issuance of common stock pursuant to cashless exercise of stock options	611	6	(6)	-	-	-
Common shares withheld for withholding taxes on cashless exercise of stock options	(228)	(2)	(884)	-	-	(886)
Issuance of common stock for exercise of stock options	167	2	215	-	-	217
Issuance of common stock for exercise of warrants	336	3	1,073	-	-	1,076
Balance at Dec. 31, 2011	45,320	$ 453	$ 361,733	$ (325,543)	$ -	$ 36,643
Net loss	-	-	-	(9,668)	-	(9,668)
Other comprehensive income (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 (loss)	-	-	-	-	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

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2013, 2012, and 2011
(in thousands)

	2013	2012	2011
Cash Flows from Operating Activities:			
Net income (loss)	$ (13,901)	$ (9,668)	$ 10,385
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:			
Depreciation	134	131	131
Provision to reduce inventory to net realizable value	250	-	-
Share-based compensation	1,215	1,733	2,458
Gain on sales of marketable securities	(4)	-	-
Loss on asset disposals	-	8	8
Changes in assets and liabilities			
Accounts receivable, net	(194)	-	-
Collaboration revenue receivable	-	-	126
Accrued investment income	(84)	-	-
Inventories	(282)	(219)	-
Income taxes refundable	43	110	(141)
Prepaid expenses and other current assets	(358)	(16)	(33)
Other current deferred assets	(186)	-	-
Other assets	6	-	-
Accounts payable	(720)	941	53
Accrued expenses	128	(64)	(209)
Deferred program fee revenue	-	-	(466)
Deferred revenue	287	-	-
Other liabilities	(12)	6	-
Net cash (used in) provided by operating activities	(13,678)	(7,038)	12,312
Cash Flows from Investing Activities:			
Purchases of marketable securities	(7,611)	(20,306)	-
Proceeds from sale and maturities of marketable securities	13,887	320	-
Additions to property, plant and equipment	(23)	(147)	(131)
Net cash provided by (used in) investing activities	6,253	(20,133)	(131)
Cash Flows from Financing Activities:			
Proceeds from exercise of stock options	9	9	217
Proceeds from distribution of restricted stock units	1	1	5
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(716)	(1,048)	(1,839)
Proceeds from warrant exercise	-	-	1,076
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 provided by (used in) financing activities	12,289	(1,038)	(541)
Net increase (decrease) in cash and cash equivalents	4,864	(28,209)	11,640
Cash and cash equivalents at beginning of year	7,476	35,685	24,045
Cash and cash equivalents at end of year	$ 12,340	$ 7,476	$ 35,685
Supplemental Disclosures of Cash Flow Information:			
Cash paid (refunded) during the year for:			
Interest	$ -	$ -	$ 26
Income taxes, net of refunds	$ (42)	$ (108)	$ 284

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
YEAR ENDED DECEMBER 31, 2013, 2012, and 2011

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

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 and 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 and 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 will be 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 and 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 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.

Year ended December 31, 2011

1. 829 thousand shares of common stock were eligible for distribution pursuant to our RSU Plan utilizing various cashless exercise features of the plan and after withholding 1 thousand shares for $ 3 in exercise costs and withholding 288 thousand shares for $ 948 in statutory minimum payroll taxes; we issued 540 thousand shares of common stock.
2. Options to purchase 935 thousand shares of common stock were exercised utilizing various cashless exercise features of the stock option plan and after withholding 324 thousand shares for $ 1.3 million in exercise costs and withholding 228 thousand shares for $ 886 in statutory minimum payroll taxes, we issued 383 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 two proprietary technologies. 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. Pfizer Inc.'s Oxecta® (oxycodone HCl) tablets, CII is the first approved and marketed product utilizing Aversion ® and is commercialized under a license agreement we have with a subsidiary of Pfizer. We have also developed our 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. In mid-December 2012 we launched in the United States Nexafed® (pseudoephedrine HC1) tablets formulated with our Impede ® Technology.

N **OTE 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.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers cash and cash equivalents to include cash in banks, U.S. Treasury Bills 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.

Fair Value of Other Financial Instruments

The Company's financial instruments consist primarily of cash and cash equivalents, marketable securities, accounts and other receivables, trade accounts payable and our notes payable. The carrying amounts of these financial instruments, other than marketable securities and our promissory notes, are representative of their respective fair values due to their relatively short maturities. We estimate the fair value of our notes payable to be its carrying value due to its recent funding. As discussed below, marketable securities are recorded at fair value.

Marketable Securities

The Company's marketable securities primarily consist of corporate bonds and other instruments that invest in U.S. Treasury, U.S. agency securities and agency mortgage-backed securities. 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.

Concentration of Credit Risk

We invest our excess cash in accordance with the investment policy approved by our Board of Directors that seeks a combination of both liquidity and safety of principal, such as investments in instruments issued by the United States government and investment grade corporate bonds.

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.

Sales to certain of our customers accounted for 10% or more of our annual net revenues, whether recognized or deferred, during 2013 as illustrated below:

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

Inventories

Inventories consist of finished goods held for sale and distribution on our Nexafed® product. 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 gross inventory is valued at $ 0.5 million and $ 0.2 million at December 31, 2013 and 2012, respectively. We have recorded inventory reserves of $ 0.25 million which results in a net reported inventory value of $0.25 million at December 31, 2013. We did not have an inventory reserve at December 31, 2012.

The related cost of sales on deferred revenue of $ 0.3 million from Nexafed® shipments is excluded from the value of the December 31, 2013 inventory and is reported in our Balance Sheet in the other current deferred assets account. We will recognize 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 p urchases of active pharmaceutical ingredients and raw materials required for our development and clinical trial manufacture of product candidates utilizing our Aversion® or Impede® 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 improvements	20 - 40 years
Machinery and equipment	7 - 10 years
Scientific equipment	5 - 10 years
Computer hardware and software	3 - 10 years
Office equipment	5 - 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.

Nexafed ® was launched in mid-December 2012. The Company sells Nexafed ® in the United States to wholesale pharmaceutical distributors 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.

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 recognize program fee revenue, collaboration revenue and milestone revenue. Commencing in February 2013, we began earning royalties based on net sales of Oxecta® by Pfizer. Such royalties are paid to us within 45 days after the end of each calendar quarter. We have recorded royalties of approximately $ 10 thousand for the year ended December 31, 2013 on net sales of Oxecta® by Pfizer of approximately $ 0.2 million.

Program fee revenue is derived from amortized upfront payments, such as the $ 30.0 million upfront payment from Pfizer received in December 2007, and license fees, such as the $ 3.0 million option exercise fee paid by Pfizer to us in each of May 2008 and December 2008 upon the exercise of its option to license a third and fourth opioid analgesic product candidate under the Pfizer Agreement. We assigned an equal portion of Pfizer’s $ 30.0 million upfront payment to each of three product candidates identified in the Pfizer Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. We recognized no program fee revenue in either 2013 or 2012, and recognized $ 0.5 million of program fee revenue in 2011.

Collaboration revenue is derived from reimbursement of development expenses, which are invoiced quarterly in arrears, and are recognized when costs are incurred pursuant to the Pfizer Agreement. The research and development services provided to Pfizer under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with Pfizer. There are no ongoing research and development services being provided to Pfizer and we had no collaboration revenue in 2013, 2012 or 2011.

Milestone revenue is contingent upon the achievement of certain pre-defined events in the development of Oxecta® Tablets and other product candidates licensed to Pfizer under the Pfizer Agreement. Milestone payments from Pfizer are recognized as revenue upon achievement of the “at risk” milestone events, which represent the culmination of the earnings process related to that milestone. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product. As such, the milestones are substantially at risk at the inception of the Pfizer Agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment. Each milestone payment is non-refundable and non-creditable when made. In June 2011, Pfizer paid us a $ 20.0 million milestone relating to the receipt of FDA approval of the NDA for Oxecta®.

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.

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, 2013 or 2012. At December 31, 2013 we had $ 0.36 million in prepaid CRO costs and clinical trial study expenses. We had no prepaid CRO costs and clinical trial study expenses at December 31, 2012.

Share-based Compensation

We have three share-based compensation plans covering stock options and RSUs for our employees and directors, which are described more fully in Note 10.

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,		
	2013	2012	2011
	(in thousands)		
Research and development:			
Stock option awards	$ 315	$ 375	$ 457
RSU awards	-	-	75
	315	375	532
Selling, general and administrative:			
Stock option awards	900	1,358	1,698
RSU awards	-	-	228
	900	1,358	1,926
Total	$ 1,215	$ 1,733	$ 2,458

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, 2013 and 2012, 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 10). 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 either 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. In 2011, stock awards to purchase 2.8 million common shares were outstanding but not included in the computation of diluted EPS as the awards were anti-dilutive.

A reconciliation of the numerators and denominators of basic and diluted EPS consisted of the following:

	Years ended December 31,		
	2013	2012	2011
	(in thousands except per share data)		
EPS - basic			
Numerator: net income (loss)	$ (13,901)	$ (9,668)	$ 10,385
Denominator:			
Common shares	46,935	45,863	45,016
Vested RSUs	829	1,658	2,489
Basic weighted average shares outstanding	47,764	47,521	47,505
EPS - basic	$ (0.29)	$ (0.20)	$ 0.22
EPS – assuming dilution			
Numerator: net income (loss)	$ (13,901)	$ (9,668)	$ 10,385
Denominator:			
Common shares	46,935	45,863	45,016
Vested RSUs	829	1,658	2,489
Stock options	-	-	366
Common stock warrants	-	-	136
Diluted weighted average shares outstanding	47,764	47,521	48,007
EPS - diluted	$ (0.29)	$ (0.20)	$ 0.22
Excluded dilutive securities:			
Common stock issuable:			
Stock options	3,738	3,296	2,805
Common stock warrants	2,154	1,856	-
Total excluded potentially dilutive shares	5,892	5,152	2,805

NOTE 3 – LICENSE, DEVELOPMENT, AND COMMERCIALIZATION 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, covering the United States, Canada and Mexico. Under the Pfizer Agreement, Pfizer will manufacture and commercialize Oxecta ® in the United States. As of December 31, 2013, we had received an aggregate of $ 78.5 million in payments from Pfizer in the form of a $ 30.0 million upfront cash payment, milestone payments, option fees and reimbursement for research and development expenses, including a $ 20.0 million milestone fee relating to the receipt of FDA approval of the NDA for Oxecta ® . In addition, as of December 31, 2013, we have received $ 9 thousand of royalties from Pfizer, which royalty payments were calculated using a 5 % royalty rate based on the current annual Oxecta® net sales levels.

Pursuant to the Pfizer Agreement, we and Pfizer formed a joint steering committee to oversee development and commercialization strategies for Oxecta®. Pfizer is responsible, at its own expense, for all regulatory, manufacturing and commercialization activities for Oxecta®. Subject to the Pfizer Agreement, Pfizer will have final decision making authority with respect to all regulatory and commercialization activities for Oxecta®.

Pfizer's royalty payment obligations for Oxecta® expire on a country-by-country basis upon the later of (i) the expiration of the last valid patent claim covering Oxecta® in such country, or (ii) 15 years from the first commercial sale of Oxecta® in such country. No minimum annual fees are payable by either party under the Pfizer Agreement. If Pfizer, after consultation with us, enters into a license agreement with a third party to avoid or settle such third party's allegations or claims regarding freedom to operate against Oxecta®, Pfizer may deduct 50 % of any royalties or other license payments it pays to such third party under such license, provided that the royalties payable to us are no less than 80 % of the royalties otherwise due to us under the Pfizer Agreement.

The Pfizer Agreement expires upon the expiration of Pfizer's royalty payment and other payment obligations under the Pfizer Agreement. Pfizer may terminate the Pfizer Agreement in its entirety at any time by written notice to us. We may terminate the Pfizer Agreement in its entirety if Pfizer commences any interference or opposition proceeding challenging the validity or enforceability of any of our patent rights licensed to Pfizer under the Pfizer Agreement. Either party has the right to terminate the Pfizer Agreement on a country-by-country basis if the other party is in material breach of its obligations under the Pfizer Agreement relating to such country, and to terminate the Agreement in its entirety 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, in each case subject to applicable cure periods.

In the event of termination, no payments are due except those royalties and milestones that have accrued prior to termination under the Pfizer Agreement and all licenses under the Pfizer Agreement are terminated. For all Acura terminations and termination by Pfizer where we are not in breach, the Pfizer Agreement provides for the transition of development and marketing of the licensed products from Pfizer to us, including the conveyance by Pfizer to us of the trademarks and all regulatory filings and approvals solely used in connection with the commercialization of such licensed products and, in certain cases, for Pfizer's supply of such licensed products for a transitional period at Pfizer's cost plus a mark-up.

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 three 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.

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.

The Settlement Agreements with Par and Impax do not affect the status of our separate Oxecta® patent litigations against Sandoz Inc. and Ranbaxy Inc. pending in the United States District Court for the District of Delaware.

Litigation is inherently uncertain and we cannot predict the outcome of these infringement actions. If Sandoz and/or Ranbaxy prevails in its respective lawsuit and is able to obtain FDA approval of its product, it may be able to launch its generic version of Oxecta® prior to the expiration of our patents in 2025. Additionally, it is possible that other generic manufacturers may also seek to launch a generic version of Oxecta® and challenge our patents. Any determination in these infringement actions that our patents covering our Aversion® Technology and Oxecta® 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 affect on our operations and financial condition.

NOTE 4 – INVESTMENTS IN MARKETABLE SECURITIES

Investments in marketable securities consisted of the following:

	December 31, 2013 (in millions)	December 31, 2012 (in millions)
Marketable securities:		
Corporate bonds — maturing within 1 year	$ 3.1	$ 1.2
Corporate bonds — maturing after 1 through 4 years	6.8	6.3
Pooled investment fund	-	8.0
Exchange-traded funds	3.8	4.4
Total marketable securities	$ 13.7	$ 19.9

The Company's marketable securities are classified as available-for-sale and are recorded at fair value based on quoted market prices 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 Sheet 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, 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

	December 31, 2012 (in millions)			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale:				
Corporate bonds	$ 7.6	$ -	$ (0.1)	$ 7.5
Pooled investment fund	8.0	-	-	8.0
Exchange-traded funds	4.4	-	-	4.4
Total - Current	$ 20.0	$ -	$ (0.1)	$ 19.9

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. We had no liabilities at December 31, 2013 meeting fair value measurement.

Our assets measured at fair value or disclosed at fair value on a recurring basis as at December 31, 2013 and 2012 consisted of the following (in millions):

	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	$ 13.7	$ -	$ -

	December 31, 2012 (in millions)			
	Total	Level 1	Level 2	Level 3
Assets:				
Corporate bonds	7.5	7.5	-	-
Pooled investment fund	8.0	-	8.0	-
Exchange-traded funds	4.4	4.4	-	-
Total	$ 19.9	$ 11.9	$ 8.0	$ -

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, 2013 consisted of unrealized gains on securities of $ 19 thousand. Accumulated other comprehensive income (loss) at December 31, 2012 consisted of unrealized losses on securities of $ 40 thousand.

NOTE 5 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows:

	December 31,	
	2013	2012
	(in thousands)	
Building and improvements	$ 1,259	$ 1,259
Scientific equipment	595	595
Computer hardware and software	252	255
Machinery and equipment	252	229
Land and improvements	162	162
Other personal property	70	70
Office equipment	27	27
	2,617	2,597
Less accumulated depreciation and amortization	(1,676)	(1,545)
Total property, plant and equipment, net	$ 941	$ 1,052

Depreciation and amortization expense was approximately $ 0.1 million for each of the years ended December 31, 2013, 2012, and 2011.

NOTE 6 – ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	December 31, 2013	2012
	(in thousands)	
Professional services	$ 293	$ 216
Other fees and services	140	75
Payroll, payroll taxes and benefits	78	55
Clinical and regulatory services	-	21
Contract manufacture services	14	21
Property taxes	15	20
Franchise taxes	1	5
	$ 541	$ 413

NOTE 7 – LONG-TERM 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. The Company may use the proceeds of the Loan Agreement for general working capital and to fund its 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 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 . The "Amortization Date" is April 1, 2015, but shall automatically become April 1, 2016 if the Company achieves 75% of its projected Nexafed® cash receipts and 75% of its projected Oxecta® cash receipts for the fiscal year ending December 31, 2014 (collectively, the "First Revenue Event"). The Amortization Date will be further deferred until April 1, 2017 if the First Revenue Event occurs and in addition the Company achieves 75% of its projected Nexafed® cash receipts and 75% of its projected Oxecta® cash receipts for the fiscal year ending December 31, 2015 (collectively, the "Second Revenue Event"). 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 3 % of the principal prepaid if prepaid on or prior to December 27, 2014, 2 % of the principal prepaid, if prepaid after December 27, 2014 but on or 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 (A) $ 795 thousand if the First Revenue Event does not occur, (B) $ 895 thousand if the First Revenue Event occurs but the Second Revenue Event does not occur, or (C) $ 995 thousand if both the First Revenue Event and the Second Revenue Event occur. 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 will amortize those costs into operating 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.

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 will amortize it to non-operating 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

The annual principal payments of the Long-term debt at December 31, 2013 are as follows:

	Annual Principal Payments (in thousands)
2014	$ -
2015	1,758
2016	2,522
2017	2,741
2018	2,979
2019 and subsequent	-
Total	$ 10,000

NOTE 8 – 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, 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 will be used for general corporate purposes, which may include working capital, capital expenditures, research, development and marketing expenditures and clinical trial expenditures.

NOTE 9 – COMMON STOCK WARRANTS

The Company had outstanding common stock purchase warrants at December 31, 2012 exercisable for 1.9 million shares of our common stock at an exercise price of $ 3.40 per share and an expiration date in August 2014 . In connection with the issuance of the $ 10.0 million secured promissory notes in December 2013, we issued common stock purchase warrants to acquire approximately 298 thousand shares of our common stock at an exercise price of $ 1.595 per share with an expiration date of December 2020. The Company has outstanding common stock purchase warrants at December 31, 2013 exercisable for 2.2 million shares of our common stock at a weighted average exercise price of $ 3.15 per share. All of our outstanding common stock purchase warrants contain a cashless exercise feature.

NOTE 10 – 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 2013, 2012, and 2011.

Stock Option Plans

We maintain various stock option plans. A summary of our stock option plans as of December 31, 2013, 2012, and 2011 and for the years then ended consisted of the following:

	Years Ended December 31,					
	2013		2012		2011	
	(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	3,296	$ 5.50	3,556	$ 6.41	4,243	$ 5.40
Granted	548	1.66	475	2.80	491	3.63
Exercised	(31)	1.30	(31)	1.30	(1,102)	1.33
Forfeited or expired	(75)	5.02	(704)	8.43	(76)	3.15
Outstanding, ending	3,738	$ 4.99	3,296	$ 5.50	3,556	$ 6.41
Options exercisable	3,115	$ 5.61	2,763	$ 5.99	2,962	$ 7.01

The following table summarizes information about nonvested stock options outstanding at December 31, 2013:

	Number of Options Not Exercisable	Weighted Average Fair Value
	(in thousands except per price data)	
Outstanding at December 31, 2012	533	$ 2.77
Granted	548	1.54
Vested	(443)	2.75
Forfeited	(15)	2.17
Outstanding at December 31, 2013	623	$ 1.71

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 2013, 2012 and 2011 stock option grants were:

	2013	2012	2011
Expected dividend yield	0.0%	0.0%	0.0%
Risk-free interest rates	1.9% to 2.9%	1.7% to 2.0%	1.9% to 3.4%
Average expected volatility	111%	114%	114%
Expected term (years)	10	10	10
Weighted average grant date fair value	$ 1.54	$ 2.60	$ 3.39

As of December 31, 2013, 2012 and 2011 the aggregate intrinsic value of the option awards which were vested and outstanding was $ 13 thousand, $ 0.1 million, and $ 0.3 million, respectively. In addition, the aggregate intrinsic value of option awards exercised during the year ended December 31, 2013, 2012 and 2011 was $ 28 thousand, $ 0.1 million and $ 2.7 million, respectively. The total remaining unrecognized compensation cost on unvested option awards outstanding at December 31, 2013 was $ 1.1 million and is expected to be recognized in operating expense in varying amounts over the twenty-three months remaining in the requisite service period.

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. During 2011 options to purchase 935 thousand shares of common stock were exercised utilizing various cashless exercise features of the stock option plan and after withholding 324 thousand shares for $ 1.3 million in exercise costs and withholding 228 thousand shares for $ 886 in statutory minimum payroll taxes, we issued 383 thousand shares of common stock.

Restricted Stock Unit Award Plan

We have a Restricted Stock Unit Award Plan (“2005 RSU Plan”) for our employees and non-employee directors. Vesting of an RSU entitles the holder to receive a share of common stock of the Company on a distribution date. A summary of the RSU Plan as of December 31, 2013, 2012, and 2011, and for the years then ended consisted of the following:

	Years Ended December 31,					
	2013		2012		2011	
	(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	1,658	1,658	2,487	2,487	3,316	3,267
Granted	-	-	-	-	-	-
Distributed	(829)	(829)	(829)	(829)	(829)	(829)
Vested	-	-	-	-	-	49
Forfeited or expired	-	-	-	-	-	-
Outstanding, ending	829	829	1,658	1,658	2,487	2,487

The share-based compensation cost to be incurred on a granted RSU is the RSU’s fair value, which is the market price of the Company’s 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.

The 2005 RSU Plan provides that upon a change in control of the Company or upon termination of an employee’s employment with the Company without cause, vesting will accelerate and the RSUs will fully vest. If a change in control occurs, the vested shares underlying the RSU award will be distributed at or about the time of the change in control. Absent a change of control, one-fourth of vested shares of common stock underlying an RSU award will be distributed (after payment of $ 0.01 par value per share) on January 1 of each of 2011 thru 2014. The distribution dates of January 1, 2011 thru 2014 each consisting of 0.83 million shares and occurred as follows:

- On January 1, 2011, 0.54 million shares were distributed to the holders while 0.29 million shares were withheld by the Company upon elections made to exchange RSUs in satisfaction of $ 1.0 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;

- On January 1, 2013, 0.50 million shares were distributed to the holders while 0.33 million shares were withheld by the Company upon elections made to exchange RSUs in satisfaction of $ 0.7 million withholding tax obligations; and
- On January 1, 2014, 0.50 million shares were distributed to the holders while 0.33 million shares were withheld by the Company upon elections made to exchange RSUs in satisfaction of $ 0.5 million withholding tax obligations.

NOTE 11 – INCOME TAXES

Provision for Income Taxes

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

	December 31,		
	2013	2012	2011
	(in thousands)		
Tax (benefit) at U.S. statutory 34% tax rate	$ (4,690)	$ (3,287)	$ 3,510
State taxes (benefit), net of federal effect	(238)	-	6
Research and development tax credits	(185)	-	(77)
Share-based compensation	369	473	626
Other	2	2	(55)
Change in valuation allowance	4,742	2,812	(3,863)
Provision for income taxes	$ -	$ -	$ 147

The tax expense 2011 is federal alternative minimum taxes (“AMT”) and current state 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 $46.8 million federal income tax benefits at December 31, 2013 derived from $137.6 million Federal NOLs at the U.S. statutory tax rate of 34% and $ 2.8 million state NOLs , available to offset future taxable income, some of which have limitations for use as prescribed under IRC Section 382. Our NOLs will expire in varying amounts between 2014 and 2033 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 2013, 2012, and 2011 was approximately $ 18.0 million, $ 2.8 million, and $ 2.8 million, respectively.

As of December 31, 2013 we had federal research and development tax credits of approximately $ 1.1 million, which expire in the years 2024 through 2033 ; and we had approximately $ 0.4 million of Indiana state research and development tax credits, which expire in the years 2014 through 2017 . The components of our deferred tax assets are as follows:

	December 31,	
	2013	2012
	(in thousands)	
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	$ 46,830	$ 26,674
- State	2,843	4,434
Research and development tax credits	1,433	887
Share-based compensation	2,261	3,486
Other, net	119	(20)
Total deferred taxes	53,486	35,461
Valuation allowance	(53,486)	(35,461)
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, 2013 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, 2013, 2012 and 2011 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, 2013, the Company's tax years 2010, 2011 and 2012 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 2010. As of December 31, 2012 the Company's tax year of 2009 was included in the tax years subject to examination.

NOTE 12 – COMMITMENTS AND CONTINGENCIES

Facility Lease

The Company leases administrative office space in Palatine, Illinois under a lease expiring March 31, 2015 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. 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 state court mass tort proceeding, 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. Plaintiffs have filed approximately 150 lawsuits against us, but have served less than 50 individual lawsuits upon us in the New Jersey action. In the California action, we were not served with any complaints until the spring of 2011 when a single complaint including over 400 plaintiffs was served.

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 15 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. In June 2012, the New Jersey trial court dismissed Acura with prejudice.

In Philadelphia, and California, Generic Defendants, including Acura, also filed dispositive motions based on the *Mensing* decision.

On November 18, 2011, the Philadelphia trial court denied Generic Defendants' dispositive motion. In December 2011, the Generic Defendants appealed this ruling. On April 13, 2012, all trial court proceedings were stayed pending decisions by the Pennsylvania appellate courts. An adverse decision by t he Pennsylvania Superior Court was issued in July 2013. Further appeal proceedings are pending. This appeal process eventually could result in dismissal of all of the Philadelphia cases against all generic defendants including Acura, 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." Nonetheless, plaintiffs have not 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.

In Nebraska, the litigation against Acura has been stayed and will be dismissed if plaintiffs present no evidence of ingestion of generic metoclopramide manufactured by us. 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, 2013 and we are presently unable to determine if any potential loss would be covered by our insurance carrier.

Financial Advisor Agreement

In connection with our August 2007 Unit Offering, we are obligated to pay a fee to our then financial advisor upon each exercise of the warrants issued in the Unit Offering, in proportion to the number of warrants exercised. The amount of the fee assuming 100 % exercise of the remaining 1.9 million warrants is $ 0.38 million. The expiration date of these warrants is in August 2014 . We have not reflected this obligation as a liability in our consolidated financial statements as the payment is contingent upon the timing and exercise of the warrants by each of the warrant holders. Such fee, if any, will be paid to the financial advisor and be offset against the equity proceeds as the warrants are exercised.

SUPPLEMENTARY DATA (UNAUDITED)

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

	For Three Month Periods Ended			
	Mar. 31, 2013	June 30, 2013	Sept. 30, 2013	Dec. 31, 2013
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)

	For Three Month Periods Ended			
	Mar. 31, 2012	June 30, 2012	Sept. 30, 2012	Dec. 31, 2012
Revenues (i)	$ -	$ -	$ -	$ -
Operating expenses	2,344	2,189	2,149	3,057
Operating loss	(2,344)	(2,189)	(2,149)	(3,057)
Net loss	$ (2,333)	$ (2,179)	$ (2,140)	$ (3,016)
Basic loss per share	$ (0.05)	$ (0.05)	$ (0.04)	$ (0.06)
Diluted loss per share	$ (0.05)	$ (0.05)	$ (0.04)	$ (0.06)

(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	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)
10.4	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).
10.5	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).
*10.6	Loan and Security Agreement dated as of December 27, 2013 between Acura Pharmaceuticals, Inc. Acura Pharmaceutical Technologies, Inc. and Oxford Finance LLC
*10.7	Form of Warrant issued to Oxford Finance LLC dated December 27, 2013
*10.8	Form of Mortgage dated December 27, 2013
10.9	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")).

Exhibit Number	Exhibit Description
10.10	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).
10.11	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).
10.12	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).
†10.13	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).
†10.14	Registrant's 1998 Stock Option Plan, as amended (incorporated by reference to Appendix C to the Registrant's Proxy Statement filed on May 12, 2009).
†10.15	Registrant's 2005 Restricted Stock Unit Award Plan, as amended (incorporated by reference to Appendix B to the Registrant's Proxy Statement filed on April 2, 2008).
†10.16	Registrant's 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).
†10.17	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).
†10.18	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).
†10.19	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).
†10.20	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).
†10.21	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).

Exhibit Number	Exhibit Description
†10.22	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).
†10.23	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).
*†10.24	Seventh Amendment to Executive Employment Agreement executed December 12, 2013 between the Registrant and Clemens.
†10.25	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).
†10.26	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)
†10.27	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).
†10.28	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)
†10.29	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).
10.30	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.

Exhibit Number	Exhibit Description
* 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

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may from time to time be amended, modified, supplemented or restated, this " **Agreement** ") dated as of December 27, 2013 (the " **Effective Date** ") among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 (" **Oxford** "), as collateral agent (in such capacity, " **Collateral Agent** "), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto 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 individually and collectively, jointly and severally, " **Borrower** "), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

1. ACCOUNTING AND OTHER TERMS

1.1 Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations must be made in accordance with GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to " **Dollars** " or " **$** " are United States Dollars, unless otherwise noted.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loan .

(a) Availability . (i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate amount of Ten Million Dollars ($10,000,000) according to each Lender's Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a " **Term Loan** ", and collectively as the " **Term Loans** "). After repayment, no Term Loan may be re-borrowed.

(b) Repayment . Borrower shall make monthly payments of interest only commencing on the first (1 st) Payment Date following the Funding Date of the Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of the Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of the Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal and interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (A) forty-five (45) months if the First Revenue Event does not occur, (B) thirty-three (33) months if the First Revenue Event occurs but the Second Revenue Event does not occur and (C) twenty-one (21) months if both the First Revenue Event and the Second Revenue Event occur. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on the Maturity Date. The Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) Mandatory Prepayments . If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loan(s).

(d) Permitted Prepayment of Term Loans . Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least thirty (30) days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.

2.3 Payment of Interest on the Credit Extensions .

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a fixed per annum rate (which rate shall be fixed for the duration of the applicable Term Loan) equal to the Basic Rate, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) Default Rate . Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a fixed per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the " **Default Rate** "). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360-Day Year . Interest shall be computed on the basis of a three hundred sixty (360) day year consisting of twelve (12) months of thirty (30) days.

(d) Debit of Accounts . Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower or any of its Subsidiaries, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.

(e) Payments . Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 12:00 noon Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

2.4 Secured Promissory Notes. The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a " **Secured Promissory Note** "), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender's Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note **,** Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

2.5 Fees. Borrower shall pay to Collateral Agent:

(a) Facility Fee . A fully earned, non-refundable facility fee of Fifty Thousand Dollars ($50,000) to be shared between the Lenders pursuant to their respective Commitment Percentages payable, the entire amount of which has already been paid on or about November 15, 2013;

(b) Final Payment . The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(c) Prepayment Fee . The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares; and

(d) Lenders' Expenses . All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

2.6 Withholding. Payments received by the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Initial Credit Extension. Each Lender's obligation to make a Term Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

(a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;

(b) Borrower shall have recorded the Mortgage in Marshall County, Indiana providing for first priority mortgage lien in respect of the Mortgaged Premises in favor of Collateral Agent and such other documents which are customary in commercial mortgage transactions in Indiana, each in form and substance satisfactory to Collateral Agent.

(c) duly executed original Control Agreements with respect to any Collateral Accounts maintained by Borrower or any of its Subsidiaries;

(d) duly executed original Secured Promissory Notes and Warrants, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Term Loan Commitment Percentage;

(e) the certificate(s) for the Shares, together with Assignment(s) Separate from Certificate, duly executed in blank;

(f) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date **;**

(g) a completed Perfection Certificate for Borrower and each of its Subsidiaries;

(h) the Annual Projections, for the current calendar year;

(i) duly executed original officer's certificate for Borrower and each Subsidiary that is a party to the Loan Documents, in a form acceptable to Collateral Agent and the Lenders;

(j) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;

(k) a landlord's consent executed in favor of Collateral Agent in respect of all of Borrower's and each Subsidiaries' leased locations;

(l) a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Subsidiary maintains Collateral having a book value in excess of One Hundred Thousand Dollars ($100,000.00);

(m) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;

(n) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders; and

(o) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

3.2 Conditions Precedent to all Credit Extensions. The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of an executed Disbursement Letter in the form of Exhibit B attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(c) in such Lender's sole discretion, there has not been any Material Adverse Change or any material adverse deviation by Borrower from the Annual Projections of Borrower presented to and accepted by Collateral Agent and each Lender;

(d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes and Warrants, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

3.3 Covenant to Deliver. Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.

3.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon Eastern time three (3) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code), Borrower, shall promptly notify Collateral Agent in a writing signed by Borrower, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

4.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

4.3 Pledge of Collateral. Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) days of the certification of any Shares, the certificate or certificates for the Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

5.1 Due Organization, Authorization: Power and Authority. Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each a " **Perfection Certificate** " and collectively, the " **Perfection Certificates** "). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower's and each of its Subsidiaries' place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); such updated Perfection Certificates subject to the review and approval of Collateral Agent. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

5.2 Collateral.

(a) Borrower and each its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee (such as a warehouse) and (ii) no such third party bailee possesses components of the Collateral in excess of One Hundred Thousand Dollars ($100,000.00). None of the components of the Collateral shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to Section 6.11.

(c) All Inventory is in all material respects of good and marketable quality, free from material defects.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiary is the licensee that (i) prohibits or otherwise restricts Borrower or its Subsidiaries from granting a security interest in Borrower's or such Subsidiaries' interest in such material license or material agreement or any other property, or (ii) for which a default under or termination of could interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender within ten (10) days of Borrower or any of its Subsidiaries entering into or becoming bound by any license or agreement with respect to which Borrower or any Subsidiary is the licensee (other than over-the-counter software that is commercially available to the public).

5.3 Litigation. Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than One Hundred Thousand Dollars ($100,000.00).

5.4 No Material Deterioration in Financial Condition; Financial Statements. All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries. There has not been any material deterioration in the consolidated financial condition of Borrower and its Subsidiaries since the date of the most recent financial statements submitted to any Lender.

5.5 Solvency. Borrower and each of its Subsidiaries is Solvent.

5.6 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates, or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

5.7 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the following sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a " **Permitted Lien** ." Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower's or such Subsidiaries', prior tax years which could result in additional taxes (in an aggregate amount exceeding $25,000) becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

5.10 Shares. Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

5.11 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.12 Definition of " Knowledge. " For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance.

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries; provided, however, that if such Governmental Approval necessarily includes a filing with a Governmental Authority of an Investigational New Drug Application or New Drug Application (or similar filing with the U.S. Food and Drug Administration or foreign equivalent), Borrower shall provide Collateral Agent with written notice within five (5) days after such filing and promptly make available to Collateral Agent electronically a copy of such New Drug Application (or similar filing with the U.S. Food and Drug Administration or foreign equivalent) upon Collateral Agent's request.

6.2 Financial Statements, Reports, Certificates.

(a) Deliver to each Lender:

(i) as soon as available, but no later than forty five (45) days after the last day of each calendar month, a company prepared consolidated and consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) as soon as available, but no later than one hundred twenty (120) days after the last day of Borrower's fiscal year or within five (5) days of filing with the SEC, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion **;**

(iii) as soon as available after approval thereof by Borrower's Board of Directors, but not less than annually and no later than ten (10) days after approval thereof by Borrower's Board of Directors, Borrower's annual financial projections for the entire current fiscal year as approved by Borrower's Board of Directors, which such annual financial projections shall be set forth in a month-by-month format (such annual financial projections as originally delivered to Collateral Agent and the Lenders are referred to herein as the " **Annual Projections** "; provided that, any revisions of the Annual Projections approved by Borrower's Board of Directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(iv) within five (5) days of delivery, copies of all statements, reports and notices made available to Borrower's security holders or holders of Subordinated Debt;

(v) in the event that Borrower becomes subject to the reporting requirements under the Securities Exchange Act of 1934, as amended, within five (5) days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission,

(vi) prompt notice of any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) prompt notice of (A) any material change in the composition of the Intellectual Property, (B) the registration in the United States of any copyright, including any subsequent ownership right of Borrower or any of its Subsidiaries in or to any copyright, patent or trademark, including a copy of any such registration, and (C) any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property;

(viii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s), and

(ix) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.

(c) Keep proper books of record and account in accordance with GAAP in all material respects, in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than twice every year unless (and more frequently if) an Event of Default has occurred and is continuing.

6.3 Inventory; Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices. Borrower must promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve more than One Hundred Thousand Dollars ($100,000.00) individually or more than $250,000 in the aggregate in any calendar year.

6.4 Taxes; Pensions. Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to Lenders, promptly on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

6.5 Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies (other than Directors and Officers Insurance, Fiduciary Liability, Employment Practices Liability, Workers Compensation and Automobile insurance) shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider or responsible broker of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days (10 days for non-payment) prior written notice before any such policy or policies are canceled and in the case of the aforementioned liability policies if policy limits are reduced. Lender will receive a certificate and applicable endorsements of any renewal of any such liability policy. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to One Hundred Thousand Dollars ($100,000.00) with respect to any loss, but not exceeding Two Hundred Fifty Thousand Dollars ($250,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

6.6 Operating Accounts.

(a) Subject to the provisions of subsection (d) below, maintain all of Borrower's and its Subsidiaries' Collateral Accounts with one or more banking institutions in accounts that are subject to Control Agreement(s) in favor of Collateral Agent.

(b) Borrower shall provide Collateral Agent five (5) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account at or with any Person other than with a bank or financial institution with which one or more Control Agreement(s) in favor of Collateral Agent that are satisfactory to Collateral Agent are then in place (it being understood Bank of America is not such a bank). In addition, for each Collateral Account that Borrower or any of its Subsidiaries, at any time maintains, Borrower or such Subsidiary shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder prior to the establishment of such Collateral Account, which Control Agreement may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to deposit accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates.

(c) Neither Borrower nor any of its Subsidiaries shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).

(d) Notwithstanding the provisions of subsections (a) - (c) above,

(i) Borrower may continue to maintain Collateral Accounts with Charles Schwab (that are identified in the Perfection Certificate delivered to the Collateral Agent) for a period of up to ninety (90) days from the Effective Date, by the end of which period, Borrower must either deliver evidence of closure of all such Collateral Accounts to the Collateral Agent in form and substance satisfactory to the Collateral Agent or the Collateral Agent must have entered into Control Agreement(s) with respect to such Collateral Accounts with Borrower and Charles Schwab in form and substance satisfactory to the Collateral Agent.

(ii) Borrower must, within ninety (90) days from the Effective Date, (A) deliver evidence of closure of all such Collateral Accounts maintained by Borrower at Bank of America (that are identified in the Perfection Certificate delivered to the Collateral Agent), and (B) establish Collateral Account(s) at a bank or financial institution which Collateral Account(s) shall be subject to one or more Control Agreement(s) between the Borrower, Collateral Agent and such bank or financial institution in form and substance satisfactory to Collateral Agent.

(iii) Prior to the fulfillment of Borrower's covenants set forth in Section 6.6(d)(ii) above, the aggregate cash balance (which shall not be deemed to include the value of any securities but shall include "cash equivalents") in the Collateral Accounts maintained at Merrill Lynch, Pierce, Fenner & Smith Incorporated (that are subject to Control Agreement(s) in favor of the Collateral Agent) shall at all times be not less than the aggregate amount of the Term Loans made under this Agreement.

6.7 Protection of Intellectual Property Rights. Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower's business; (b) promptly advise Collateral Agent in writing of material infringement by a third party of its Intellectual Property; and (c) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

6.8 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

6.9 Notices of Litigation and Default. Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Two Hundred Fifty Thousand Dollars ($250,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

6.10 Intentionally Omitted.

6.11 Landlord Waivers; Bailee Waivers. In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Subsidiary will first provide thirty (30) days' prior written notice to Collateral Agent and, in the event that the Collateral at any new location is valued in excess of One Hundred Thousand ($100,000.00) in the aggregate, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

6.12 Creation/Acquisition of Subsidiaries. In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary, Borrower shall provide prior written notice to Collateral Agent and each Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the stock, units or other evidence of ownership of each such newly created Subsidiary.

6.13 Further Assurances.

(a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

(b) Deliver to Collateral Agent and Lenders, within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change; provided, however, that if such filing with a Governmental Authority is an Investigational New Drug Application or New Drug Application (or similar filing with the U.S. Food and Drug Administration or foreign equivalent), Borrower shall provide Collateral Agent with written notice within five (5) days after such filing and promptly make available to Collateral Agent electronically a copy of such New Drug Application (or similar filing with the U.S. Food and Drug Administration or foreign equivalent) upon Collateral Agent's request.

7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, " **Transfer** "), or permit any of its Subsidiaries to Transfer, all or any part of its business or property (excluding any equity securities of Parent or instruments or securities convertible into equity securities of Parent, so long as such securities are not debt securities and so long as transfer, assignment, conveyance, sale or other disposition thereof is not used to effect a merger or consolidation in violation of the provisions of Section 7.3 or other provisions of this Agreement), except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out or obsolete Equipment; and (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses.

7.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within 5 days of such change, or (ii) enter into any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower's equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Collateral Agent the venture capital investors prior to the closing of the transaction). Borrower shall not, without at least thirty (30) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than One Hundred Thousand Dollars ($100,000.00) in assets or property of Borrower or any of its Subsidiaries); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person. A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom. Without limiting the foregoing, Borrower shall not, without Collateral Agent's prior written consent, enter into any binding contractual arrangement with any Person to attempt to facilitate a merger or acquisition of Borrower, unless (i) no Event of Default exists when such agreement is entered into by Borrower, and (ii) such agreement does not give such Person the right to claim any fees, payments or damages from Borrower in excess of Two Hundred Fifty Thousand Dollars ($250,000), and (iii) Borrower notifies Collateral Agent in advance of entering into such an agreement.

7.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent's Lien), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of " **Permitted Liens** " herein.

7.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

7.7 Distributions; Investments. (a) Pay any dividends (other than dividends payable solely in capital stock or dividends payable to Parent from APT) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock (other than repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or restricted stock unit plans or similar plans, provided such repurchases do not exceed, in the aggregate, One Million Dollars ($1 million) for the fiscal year 2014 and Three Hundred Fifty Thousand Dollars ($350,000) for any other fiscal year during the term of this Agreement), or (b) directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so.

7.8 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries and (c) the Voting Agreement.

7.9 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

7.10 Compliance. Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

7.11 Compliance with Anti-Terrorism Laws. Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent's policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an " **Event of Default** ") under this Agreement:

8.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

8.2 Covenant Default.

(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), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to financial covenants or any other covenants set forth in subsection (a) above;

8.3 Material Adverse Change. A Material Adverse Change occurs;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender's Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of One Hundred Thousand Dollars ($100,000.00) or that could reasonably be expected to have a Material Adverse Change;

8.7 Judgments. One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Two Hundred Fifty Thousand Dollars ($250,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree), including but not limited to any judgment, order, decree, or arbitration award relating to any litigation, arbitration, or other dispute disclosed by Borrower to Collateral Agent prior to the Effective Date and set forth on the Perfection Certificate delivered as of the Effective Date;

8.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

8.9 **Subordinated Debt.** A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

8.10 **Mortgage.** An event of default occurs under the Mortgage;

8.11 **Governmental Approvals.** Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change;

8.12 **Lien Priority** . Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement; or

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right at the written direction of the Required Lenders **,** without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, " **Exigent Circumstance** " means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.

9.3 Protective Payments. If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

9.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable and customary banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Except to the extent of any loss, damage or destruction of the Collateral caused by Collateral Agent's or the Lenders' failure to comply with reasonable and customary banking practices regarding the safekeeping of the Collateral in the possession or control of the Collateral Agent or the Lenders, as applicable, Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

10. NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, " **Communication** ") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:

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

ACURA PHARMACEUTICAL TECHNOLOGIES, INC.
c/o 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
If to Collateral Agent:	OXFORD FINANCE LLC 133 North Fairfax Street Alexandria, Virginia 22314 Attention: Legal Department Fax: (703) 519-5225 Email: LegalDepartment@oxfordfinance.com
with a copy (which shall not constitute notice) to:	Greenberg Traurig, LLP One International Place Boston, MA 02110 Attn: Jonathan Bell, Esq. Fax: (617) 310-6001 Email: bellj@gtlaw.com

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

New York law governs the Loan Documents without regard to principles of conflicts of law. Borrower, Lenders and Collateral Agent each submit to the exclusive jurisdiction of the State and Federal courts in the City of New York, Borough of Manhattan. NOTWITHSTANDING THE FOREGOING, COLLATERAL AGENT AND THE LENDERS SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST BORROWER OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH COLLATERAL AGENT AND THE LENDERS (IN ACCORDANCE WITH THE PROVISIONS OF SECTION 9.1) DEEM NECESSARY OR APPROPRIATE TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE COLLATERAL AGENT'S AND THE LENDERS' RIGHTS AGAINST BORROWER OR ITS PROPERTY. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, first class, registered or certified mail return receipt requested, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT, AND THE LENDERS EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in **(any** such sale, transfer, assignment, negotiation **,** or grant of a participation, a **"Lender Transfer")** all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; *provided* , *however* , that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an " **Approved Lender** ") **.** Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer (i) in respect of the Warrants or (ii) in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.

12.2 Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an " **Indemnified Person** ") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, " **Claims** ") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct.

12.3 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

12.4 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.5 Correction of Loan Documents. Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties **.**

12.6 Amendments in Writing; Integration. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature;

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term " **Required Lenders** " or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;

(iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

(b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

12.8 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.9 Confidentiality. In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms at least as protective as this Section 12.9); (c) as required by law, regulation, subpoena, or other order, upon reasonable prior written notice to Borrower if providing such notice is practicable and legally feasible; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms at least as protective as those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose related to this Agreement and (to the extent any of the following purposes shall not be deemed to be related to this Agreement) may also: (i) use confidential information for any of their internal record keeping, due diligence, risk analysis, market analysis, maintenance and development of client databases, statistical and reporting purposes; (ii) use Borrower's name and the principal terms of the Loans for customary client reference purposes; and (iii) use masked confidential information for regulatory reporting purposes to the extent required by or advisable under applicable law. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.

12.10 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

12.11 Cooperation of Borrower. If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Loan to an assignee in accordance with Section 12.1, (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

13. DEFINITIONS

13.1 Definitions. As used in this Agreement, the following terms have the following meanings:

" **Account** " is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

" **Account Debtor** " is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

" **Affiliate** " of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

" **Agreement** " is defined in the preamble hereof.

" **Amortization Date** " is April 1, 2015, but shall automatically become April 1, 2016 if the First Revenue Event occurs. Furthermore, if after the occurrence of the First Revenue Event, the Second Revenue Event occurs, Amortization Date shall automatically become April 1, 2017.

" **Annual Projections** " is defined in Section 6.2(a).

" **Anti-Terrorism Laws** " are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

" **Approved Fund** " is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.

" **Approved Lender** " is defined in Section 12.1.

" **Basic Rate** " is, with respect to a Term Loan, the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to Eight and Thirty-Five Hundredths percent (8.35%).

" **Blocked Person** " is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

" **Borrower** " is defined in the preamble hereof.

" **Borrower's Books** " are Borrower's or any of its Subsidiaries' books and records including ledgers, federal, and state tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

" **Business Day** " is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

" **Cash Equivalents** " are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an " **Auction Rate Security** ").

" **Claims** " are defined in Section 12.2.

" **Code** " is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

" **Collateral** " is any and all properties, rights and assets of Borrower described on Exhibit A .

" **Collateral Account** " is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

" **Collateral Agent** " is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

" **Commitment Percentage** " is set forth in Schedule 1.1 , as amended from time to time.

" **Commodity Account** " is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

" **Communication** " is defined in Section 10.

" **Compliance Certificate** " is that certain certificate in the form attached hereto as Exhibit C .

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

" **Control Agreement** " is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control (within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

" **Copyrights** " are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

" **Credit Extension** " is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower's benefit.

" **Default Rate** " is defined in Section 2.3(b).

" **Deposit Account** " is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

" **Designated Deposit Account** " is Borrower's deposit account, account number 5800103177, maintained with Bank of America Merrill Lynch.

" **Disbursement Letter** " is that certain form attached hereto as Exhibit B .

" **Dollars** , " " **dollars** " and "$" each mean lawful money of the United States.

" **Effective Date** " is defined in the preamble of this Agreement.

" **Eligible Assignee** " is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an "accredited investor" (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor's Rating Group and a rating of Baa2 or higher from Moody's Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars ($5,000,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, "Eligible Assignee" shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower's Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

“ **Equipment** ” is all “equipment” as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

“ **ERISA** ” is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

“ **Event of Default** ” is defined in Section 8.

“ **Final Payment** ” is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such Term Loan multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares.

“ **Final Payment Percentage** ” is: (A) Seven and Ninety-Five Hundredths percent (7.95%) if the First Revenue Event does not occur, (B) Eight and Ninety-Five Hundredths percent (8.95%) if the First Revenue Event occurs but the Second Revenue Event does not occur and (C) Nine and Ninety-Five Hundredths percent (9.95%) if both the First Revenue Event and the Second Revenue Event occur.

“ **First Revenue Event** ” is the achievement by Borrower, for the fiscal year 2014, of (i) seventy-five percent (75%) of its projected net Nexafed cash receipts set forth in the Projected Receipts and (ii) seventy-five percent (75%) of its projected Oxecta royalty receipts set forth in the Projected Receipts, and delivery of evidence of such achievement by Borrower to Collateral Agent, on or before February 15, 2015, in such form and substance as is acceptable to Collateral Agent in its discretion.

“ **Foreign Subsidiary** ” is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

“ **Funding Date** ” is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

“ **GAAP** ” is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

“ **General Intangibles** ” are all “general intangibles” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

" **Governmental Approval** " is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

" **Governmental Authority** " is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

" **Guarantor** " is any Person providing a Guaranty in favor of Collateral Agent.

" **Guaranty** " is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

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

" **Indemnified Person** " is defined in Section 12.2.

" **Insolvency Proceeding** " is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

" **Insolvent** " means not Solvent.

" **Intellectual Property** " means all of Borrower's or any Subsidiary's right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any Investigational New Drug Application, New Drug Application, Abbreviated New Drug Application or similar application (or foreign equivalent) filed with the U.S. Food and Drug Administration (or foreign equivalent) or licensed to Borrower or any of its Subsidiaries;

(c) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals, preclinical and clinical studies, abuse liability studies, bioequivalence studies, pseudoephedrine conversion and extraction studies, and the results of such studies;

(d) any and all source code;

(e) any and all design rights which may be available to Borrower;

(f) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(g) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

" **Inventory** " is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, product samples, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

" **Investment** " is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, payment or capital contribution to any Person.

" **Key Person** " is each of Borrower's (i) Chief Executive Officer, who is Robert B. Jones as of the Effective Date, (ii) Chief Financial Officer, who is Peter A. Clemens as of the Effective Date and (iii) Vice President of Technical Affairs, who is Albert W. Brzeczko as of the Effective Date.

" **Lender** " is any one of the Lenders.

" **Lenders** " are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

" **Lenders' Expenses** " are all audit fees and expenses, costs, and expenses (including reasonable attorneys' fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

" **Lien** " is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

" **Loan Documents** " are, collectively, this Agreement, the Warrants, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, Mortgage, the Post Closing Letter and any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

" **Material Adverse Change** " is (a) a material impairment in the perfection or priority of Collateral Agent's Lien in the Collateral or in the value of such Collateral; (b) a material impairment in the perfection or priority of Collateral Agent's Lien in the Mortgaged Premises or in the value of the Mortgaged Premises; (c) a material adverse change in the business, operations or condition (financial or otherwise) or prospects of Borrower or any Subsidiary; or (d) a material impairment of the prospect of repayment of any portion of the Obligations.

" **Maturity Date** " is December 1, 2018.

" **Mortgage** " is a first lien Mortgage, Assignment, Security Agreement, and Fixture Filing in respect of the Mortgaged Premises in favor of Collateral Agent to secure the Obligations.

" **Mortgaged Premises** " is the real property owned by Borrower located at 16235 State Road 17, Culver, Indiana 46511.

" **Obligations** " are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents (other than the Warrants), or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower's duties under the Loan Documents (other than the Warrants).

" **OFAC** " is the U.S. Department of Treasury Office of Foreign Assets Control.

" **OFAC Lists** " are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

" **Operating Documents** " are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

" **Patents** " means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

" **Payment Date** " is the first (1 st) calendar day of each calendar month, commencing on February 1, 2014.

" **Perfection Certificate** " and " **Perfection Certificates** " is defined in Section 5.1.

" **Permitted Indebtedness** " is:

(a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Two Hundred Fifty Thousand Dollars ($250,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business; and

(g) Indebtedness relating to loans from Parent to APT; and

(h) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (e) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

" **Permitted Investments** " are:

(a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, (ii) any Investments permitted by Borrower's investment policy as of Effective Date, and (iii) any Investments permitted by Borrower's investment policy and added by amendment following the Effective Date, provided that such amendment to the investment policy has been approved in writing by Collateral Agent;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of Deposit Accounts in which Collateral Agent has a perfected security interest;

(e) Investments in connection with Transfers permitted by Section 7.1;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors; not to exceed One Hundred Thousand Dollars ($100,000) in the aggregate for (i) and (ii) in any fiscal year;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;

(i) Investments by Parent in APT; and

(j) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the licensing of technology, the development of technology or the providing of technical support, provided that if such license is exclusive, it shall be 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.

" **Permitted Licenses** " are (A) licenses of over-the-counter software that is commercially available to the public, and (B) 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.

" **Permitted Liens** " are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) liens securing Indebtedness permitted under clause (e) of the definition of " **Permitted Indebtedness** ," provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Twenty Five Thousand Dollars ($25,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(j) easements, reservations, rights-of-way, restrictions, minor defects or irregularities in title and similar charges or encumbrances affecting real property not constituting a material adverse effect on the business or condition (financial or otherwise) of Borrower;

(k) easements, zoning restrictions, rights-of-way and similar encumbrances on real property imposed by law or arising in the ordinary course of business that do not secure any monetary obligations and do not materially detract from the value of the Mortgaged Premises or interfere with the ordinary conduct of business of Borrower; and

(l) Liens consisting of Permitted Licenses.

" **Person** " is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

" **Post Closing Letter** " is that certain Post Closing Letter dated as of the Effective Date by and among Collateral Agent, the Lenders and Borrower.

" **Prepayment Fee** " is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Funding Date of such Term Loan through and including the first anniversary of the Funding Date of such Term Loan, three percent (3.00%) of the principal amount of such Term Loan prepaid;

(ii) for a prepayment made after the date which is after the first anniversary of the Funding Date of such Term Loan through and including the second anniversary of the Funding Date of such Term Loan, two percent (2.00%) of the principal amount of the Term Loans prepaid; and

(iii) for a prepayment made after the date which is after the second anniversary of the Funding Date of such Term Loan and before the Maturity Date of such Term Loan, one percent (1.00%) of the principal amount of the Term Loans prepaid.

" **Pro Rata Share** " is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

" **Projected Receipts** " means the projected net cash receipts and royalty receipts for Nexafed and Oxecta, as provided by Borrower to Collateral Agent and Lenders (and acknowledged thereby) on the Effective Date.

" **Registered Organization** " is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

" **Required Lenders** " means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an " **Original Lender** ") have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

" **Requirement of Law** " is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

" **Responsible Officer** " is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

" **Second Revenue Event** " is the achievement by Borrower, for the fiscal year 2015, of (i) seventy-five percent (75%) of its projected net Nexafed cash receipts set forth in the Projected Receipts and (ii) seventy-five percent (75%) of its projected Oxecta royalty receipts set forth in the Projected Receipts, and delivery of evidence of such achievement by Borrower to Collateral Agent, on or before February 15, 2016, in such form and substance as is acceptable to Collateral Agent in its discretion. The occurrence of the First Revenue Event is a precondition for the occurrence of the Second Revenue Event.

" **Secured Promissory Note** " is defined in Section 2.4.

" **Secured Promissory Note Record** " is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

" **Securities Account** " is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

" **Shares** " is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower's Subsidiary, in any Subsidiary; provided that, in the event Borrower, demonstrates to Collateral Agent's reasonable satisfaction, that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary which is a Foreign Subsidiary, creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code, "Shares" shall mean sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary.

" **Solvent** " is, with respect to any Person: the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

" **Subordinated Debt** " is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

" **Subsidiary** " is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

" **Term Loan** " is defined in Section 2.2(a)(ii) hereof.

" **Term Loan Commitment** " is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1 **.** " **Term Loan Commitments** " means the aggregate amount of such commitments of all Lenders.

" **Trademarks** " means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

" **Transfer** " is defined in Section 7.1.

" **Voting Agreement** " means the Voting Agreement dated as of February 6, 2004, as amended to date, between Parent, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., Essex Woodlands Health Ventures V, L.P., Care Capital investments II, LP and Care Capital Offshore Investments II, LP.

" **Warrants** " are those certain Warrants to Purchase Stock dated as of the Effective Date, or any date thereafter, issued by Parent in favor of each Lender or such Lender's Affiliates.

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IN WITNESS WHEREOF , the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

ACURA PHARMACEUTICALS, INC.

By /s/ Peter A. Clemens
Name: Peter A. Clemens
Title: Sr. V.P. & C.F.O.

BORROWER:

ACURA PHARMACEUTICAL TECHNOLOGIES, INC.

By /s/ Peter A. Clemens
Name: Peter A. Clemens
Title: Sr. V.P. & C.F.O.

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

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

SCHEDULE 1.1

Lenders and Commitments

Lender	Term Loans Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$ 10,000,000	100.00%
TOTAL	**$ 10,000,000**	**100.00%**

EXHIBIT A

Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights, rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; and (ii) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral."

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property (excluding Permitted Licenses).

EXHIBIT B

Form of Disbursement Letter

[see attached]

DISBURSEMENT LETTER

[DATE]

The undersigned, being the duly elected and acting _____ of ACURA PHARMACEUTICALS, INC., a New York corporation with offices located at 616 N. North Court, Suite 120, Palatine, Illinois for and on behalf of each Borrower under the Loan Agreement (as defined below) (collectively, " **Borrower** "), does hereby certify to **OXFORD FINANCE LLC** (" **Oxford** " and " **Lender** "), as collateral agent (the " **Collateral Agent** ") in connection with that certain Loan and Security Agreement dated as of December [_], 2013, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the " **Loan Agreement** "; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof.

2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.

3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.

4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.

5. No Material Adverse Change has occurred.

6. The undersigned is a Responsible Officer.

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7. The proceeds of the Term Loan shall be disbursed as follows:

Disbursement from Oxford:		
Loan Amount	$	_____
Plus:		
—Deposit Received	$	50,000
Less:		
—Facility Fee	$	(50,000)
[—Interim Interest	$	(_____)]
—Lender's Legal Fees	$	(_____)*
Net Proceeds due from Oxford:	**$**	_____
TOTAL TERM LOAN NET PROCEEDS FROM LENDERS	**$**	_____

8. The Term Loan shall amortize in accordance with the Amortization Table attached hereto.

9. The aggregate net proceeds of the Term Loans shall be transferred to the Designated Deposit Account as follows:

Account Name:	ACURA PHARMACEUTICALS INC.
Bank Name:	Bank of America, N.A.
Bank Address:	135 S. LaSalle Street, Chicago, IL 60603
Account Number:	5800103177
ABA Number:	0260-0959-3

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* Legal fees and costs are through the Effective Date. Post-closing legal fees and costs, payable after the Effective Date, to be invoiced and paid post-closing.

Dated as of the date first set forth above.

BORROWER:

ACURA PHARMACEUTICALS, INC. for
itself and on behalf of all Borrowers

By _____
Name: _____
Title: _____

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: _____
Name: _____
Title: _____

AMORTIZATION TABLE
(Term Loan)

[see attached]

EXHIBIT C

Compliance Certificate

TO: OXFORD FINANCE LLC, as Collateral Agent and Lender

FROM: ACURA PHARMACEUTICALS, INC., for itself and on behalf of all Borrowers

The undersigned authorized officer (" **Officer** ") of ACURA PHARMACEUTICALS, INC., a New York corporation with offices located at 616 N. North Court, Suite 120, Palatine, Illinois for and on behalf of each Borrower under the Loan Agreement (as defined below) (collectively, " **Borrower** "), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the " **Loan Agreement** ;" capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below;

(b) There are no Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower's Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower's Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	Actual	Complies		
1)	Financial statements	Monthly within 45 days		Yes	No	N/A
2)	Annual (CPA Audited) statements	Within 120 days after FYE		Yes	No	N/A
3)	Annual Financial Projections/Budget (prepared on a monthly basis)	Annually (within 10 days of Board Approval), and when revised		Yes	No	N/A
4)	A/R & A/P agings	If applicable		Yes	No	N/A
5)	8-K, 10-K and 10-Q Filings	If applicable, within 5 days of filing		Yes	No	N/A
6)	Compliance Certificate	Monthly within 30 days		Yes	No	N/A
7)	IP Report	When required		Yes	No	N/A
8)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		$_____	Yes	No	N/A
9)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period		$_____	Yes	No	N/A

Deposit and Securities Accounts
(Please list all accounts; attach separate sheet if additional space needed)

	Institution Name	Account Number	New Account?		Account Control Agreement in place?	
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No

Other Matters

1)	Have there been any changes in management since the last Compliance Certificate?	Yes	No
2)	Have there been any transfers/sales/disposals/retirement of Collateral or Intellectual Property prohibited by the Loan Agreement?	Yes	No
3)	Have there been any new or pending claims or causes of action against Borrower that involve more than One Hundred Thousand Dollars ($100,000.00)?	Yes	No
4)	Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

ACURA PHARMACEUTICALS, INC., for itself and on behalf of all Borrowers

By: _____
Name: _____
Title: _____

Date:

LENDER USE ONLY

Received by: _____ Date: _____

Verified by: _____ Date: _____

Compliance Status: Yes No

EXHIBIT D

Form of Secured Promissory Note

[see attached]

SECURED PROMISSORY NOTE
(Term Loan)

$_____ Dated: December [_], 2013

FOR VALUE RECEIVED, the undersigned, ACURA PHARMACEUTICALS, INC., a New York corporation with offices located at 616 N. North Court, Suite 120, Palatine, Illinois and ACURA PHARMACEUTICAL TECHNOLOGIES, INC., an Indiana corporation with offices locates at 16235 State Road 17, Culver, IN 46511 (individually and collectively, jointly and severally, " **Borrower** ") HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC (" **Lender** ") the principal amount of TEN MILLION DOLLARS ($10,000,000) or such lesser amount as shall equal the outstanding principal balance of the Term Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated December [_], 2013 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the " **Loan Agreement** "). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this " **Note** "). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term Loan, interest on the Term Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

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IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

ACURA PHARMACEUTICALS, INC.

By _____
Name: _____
Title: _____

BORROWER:

ACURA PHARMACEUTICAL TECHNOLOGIES, INC.

By _____
Name: _____
Title: _____

LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

Date	Principal Amount	Interest Rate	Scheduled Payment Amount	Notation By

CORPORATE BORROWING CERTIFICATE

BORROWER : [ACURA PHARMACEUTICALS, INC.][ACURA PHARMACEUTICAL TECHNOLOGIES, INC.] **DATE** : [DATE]

LENDER: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a [ACURA PHARMACEUTICALS, INC.][ACURA PHARMACEUTICAL TECHNOLOGIES, INC.] existing under the laws of the State of [New York][Indiana].

3. Attached hereto as Exhibit A and Exhibit B , respectively, are true, correct and complete copies of (i) Borrower's Articles/Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Articles/Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Articles/Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

[*Balance of Page Intentionally Left Blank*]

RESOLVED , that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature	Authorized to Add or Remove Signatories
			☐
			☐
			☐
			☐

RESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER , that such individuals may, on behalf of Borrower:

Borrow Money . Borrow money from the Lenders.
Execute Loan Documents . Execute any loan documents any Lender requires.
Grant Security . Grant Collateral Agent a security interest in any of Borrower's assets.
Negotiate Items . Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.
Issue Warrants . Issue warrants for Borrower's capital stock.
Further Acts . Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER , that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[*Balance of Page Intentionally Left Blank*]

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By: _____

Name: _____

Title: _____

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as
[print title]
of the date set forth above.

By: _____

Name: _____

Title: _____

[*Signature Page to Corporate Borrowing Certificate*]

EXHIBIT A

Articles/Certificate of Incorporation (including amendments)

[see attached]

EXHIBIT B

Bylaws

[see attached]

DEBTOR: **[ACURA PHARMACEUTICALS, INC.][ACURA PHARMACEUTICAL TECHNOLOGIES, INC.]**
SECURED PARTY: **OXFORD FINANCE LLC,**
as Collateral Agent

EXHIBIT A TO UCC FINANCING STATEMENT

Description of Collateral

The Collateral consists of all of Debtor's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights, rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; and (ii) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral."

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Debtor has agreed not to encumber any of its Intellectual Property (excluding Permitted Licenses).

Capitalized terms used but not defined herein have the meanings ascribed in the Uniform Commercial Code in effect in the State of New York as in effect from time to time (the "Code") or, if not defined in the Code, then in the Loan and Security Agreement by and between Debtor, Secured Party and the other Lenders party thereto (as modified, amended and/or restated from time to time).

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.

FORM [1] OF WARRANT TO PURCHASE STOCK (A__)

Company:	ACURA PHARMACEUTICALS, INC., a New York corporation
Number of Shares:	[_____] [1] (this Warrant and any other Warrants issued on the date of issuance of this Warrant pursuant to the Loan Agreement (as defined herein below), together, shall be exercisable for a total number of shares of Common Stock equal to: (i) four and seventy-five hundredths percent (4.75%) of the aggregate principal amount of the term loans funded under the Loan Agreement on the date of issuance of this Warrant divided by (ii) the Warrant Price set forth below)
Type/Series of Stock:	Common Stock
Warrant Price:	$1.595 per share (which represents the average 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:	December 27, 2013
Expiration Date:	December 27, 2020. See also Section 5.1(b).
Credit Facility:	This 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.

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:

[1] Three warrants were issued with respect to 178,683, 74,451 and 44,671 underlying shares, respectively.

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 DECEMBER 27, 2013, 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 December 27, 2013 (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

Acura Pharmaceuticals, Inc.
Capitalization at December 27, 2013

Beneficial Owner	Comon Stock Outstanding	Restricted Stock Units	Common Stock Warrants	Common Stock Options	Fully Diluted Shares
Galen Partners III, L.P.	10,535,082	-	459,400	-	10,994,482
Galen Partners International III, L.P.	950,122	-	41,562	-	991,684
Galen Employee Fund III, L.P.	43,394	-	1,939	-	45,333
Essex Woodlands Health Ventures V	9,781,985	-	502,901	-	10,284,886
Care Capital Investments II	4,032,885	-	730,559	-	4,763,444
Care Capital Offshore Investment II	276,656	-	50,120	-	326,776
Andy Reddick	-	227,500	-	-	227,500
Robert Jones	51,095	23,750	-	907,500	982,345
Peter A. Clemens	214,021	117,500	-	429,375	760,896
Robert Seiser	86,340	47,250	-	326,725	460,315
James Emigh	138,204	38,875	-	294,725	471,804
Albert Brzeczko	18,000	6,000	-	308,000	332,000
William Skelly	-	25,000	-	100,000	125,000
William Sumner	94,852	25,000	-	15,000	134,852
Bruce Wesson	14,904	-	-	100,000	114,904
Richard Markham	-	-	-	75,000	75,000
George Ross	3,000	-	-	100,000	103,000
Immanuel Thangaraj	-	-	-	90,000	90,000
David Azad	-	-	-	21,250	21,250
Brad Rivet	-	-	-	185,000	185,000
Other employees	258,437	150,625	-	784,947	1,194,009
Ron Spivey (no longer insider)	-	167,500	-	-	167,500
Non-insiders	**21,826,109**		**69,548**	**-**	**21,895,657**
Totals	**48,325,086**	**829,000**	**1,856,029**	**3,737,522**	**54,747,637**
Percent of Total	**88.3%**	**1.5%**	**3.4%**	**6.8%**	**100.0%**

Notes:
Information for specified persons in Column entitled "Common Stock" is based on their public filings
Information in column entitled "Common Stock" with respect to "Other Employees" is an estimate
Not all Stock Options are Currently Exercisable
Restricted Stock Units will be exchanged for stock on or about January 1, 2014

MORTGAGE, ASSIGNMENT
OF RENTS AND LEASES, SECURITY AGREEMENT AND FIXTURE FILING
by and from

ACURA PHARMACEUTICAL TECHNOLOGIES, INC.,

an Indiana corporation, "Mortgagor"

to

OXFORD FINANCE LLC, a Delaware limited liability company, "Mortgagee"

Dated as of December 27, 2013

Location: 16235 State Road 17, Culver, Indiana 46511

MORTGAGE, ASSIGNMENT OF
RENTS AND LEASES, SECURITY AGREEMENT AND FIXTURE FILING
(Marshall County, Indiana)

THIS MORTGAGE, ASSIGNMENT OF RENTS AND LEASES, SECURITY AGREEMENT AND FIXTURE FILING (this " **Mortgage** ") is dated as of this 27th day of December, 2013, by and from **ACURA PHARMACEUTICAL TECHNOLOGIES, INC.** , an Indiana corporation with offices locates at 16235 State Road 17, Culver, IN 46511 (" **Mortgagor** " or " **Term Borrower** "), to **OXFORD FINANCE LLC** , a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 (" **Oxford** "), as collateral agent (in such capacity, " **Collateral Agent** ") (together with its successors and assigns, " **Mortgagee** ").

RECITALS:

WHEREAS, Mortgagor is the fee owner of the real property described in Exhibit A attached hereto.

WHEREAS, Mortgagor and ACURA PHARMACEUTICALS, INC., a New York corporation with offices located at 616 N. North Court, Suite 120, Palatine, Illinois (" **Parent** ") (Mortgagor and Parent being sometimes referred to collectively herein as the " **Borrowers** " and each as a " **Borrower** "), and Mortgagee have entered into that certain Loan and Security Agreement, of even date herewith (as the same may be amended, amended and restated, supplemented or otherwise modified from time to time, the " **Loan Agreement** ") providing for a term loan from certain Lenders (as therein defined) in the maximum principal amount of TEN MILLION DOLLARS ($10,000,000.00).

WHEREAS, Mortgagee is acting as Collateral Agent for the Lenders pursuant to the terms of the Loan Agreement;

WHEREAS, as a condition to the Lenders' agreement to enter into the Loan Agreement, and to make available to Borrowers the financial accommodations provided therein, Mortgagee has required that Mortgagor, among other things, secure the "Obligations" of Borrowers under the Loan Agreement and the other Loan Documents by delivery and recordatoin of this Mortgage.

WHEREAS, Mortgagor is receiving a good and valuable benefit, the sufficiency and receipt of which is hereby acknowledged, from the Lenders for entering into, and agreeing to extend credit and provide financial accommodations under, the Loan Agreement and the other Loan Documents with the Borrowers.

ARTICLE 1
DEFINITIONS

Section 1.1. **Definitions** . All capitalized terms used herein without definition shall have the respective meanings ascribed to them in the Loan Agreement. As used herein, the following terms shall have the following meanings:

(a) " **Event of Default** ": shall have the meaning ascribed to such term in Article 4 hereof.

(b) " **Mortgaged Property** ": All of Mortgagor's interest in (1) the fee interest in the real property described in Exhibit A attached hereto and incorporated herein by this reference, together with any greater estate therein as hereafter may be acquired by Mortgagor (the " **Land** "), (2) all improvements now owned or hereafter acquired by Mortgagor, now or at any time situated, placed or constructed upon the Land (the " **Improvements** "; the Land and Improvements are collectively referred to herein as the " **Premises** "), (3) all materials, supplies, equipment, apparatus and other items of personal property now owned or hereafter acquired by Mortgagor and now or hereafter attached to or installed in any of the Improvements or the Land, fixtures and goods that are or are to become fixtures, and water, gas, electrical, telephone, storm and sanitary sewer facilities and all other utilities whether or not situated in easements (the " **Fixtures** "), (4) all deposit accounts maintained by Mortgagor with respect to the Mortgaged Property (the " **Deposit Accounts** "), (5) all existing and future leases, subleases, licenses, concessions, occupancy agreements or other agreements (written or oral, now or at any time in effect) which grant to any Person a possessory interest in, or the right to use or occupy, all or any part of the Mortgaged Property, whether made before or after the filing by or against Mortgagor of any petition for relief under the Bankruptcy Code, together with any extension, renewal or replacement of the same and together with all related security and other deposits (the " **Leases** "), (6) all of the rents, additional rents, revenues, royalties, income, proceeds, profits, early termination fees or payments, security and other types of deposits, and other benefits paid or payable by tenants under the Leases for using, leasing, licensing, possessing, operating from, residing in, selling or otherwise enjoying the Mortgaged Property or any part thereof, whether paid or accruing before or after the filing by or against Mortgagor of any petition for relief under the Bankruptcy Code (the " **Rents** "), (7) all other agreements, such as construction contracts, architects' agreements, engineers' contracts, utility contracts, maintenance agreements, management agreements, service contracts, listing agreements, guaranties, warranties, permits, licenses, certificates and entitlements in any way relating to the construction, use, occupancy, operation, maintenance, enjoyment or ownership of the Mortgaged Property, in each case only to the extent Borrower is permitted under the terms thereof to grant a Lien hereunder (the " **Property Agreements** "), (8) all rights, privileges, tenements, hereditaments, rights-of-way, easements, appendages and appurtenances appertaining to the foregoing, (9) all property tax refunds, utility refunds and rebates, earned or received at any time (the " **Tax Refunds** "), (10) all accessions, replacements and substitutions for any of the foregoing and all proceeds thereof (the " **Proceeds** "), (11) all insurance policies, unearned premiums therefor and proceeds from such policies covering any of the above property now or hereafter acquired by Mortgagor (the " **Insurance** "), (12) all of Mortgagor's right, title and interest in and to any awards, damages, remunerations, reimbursements, settlements or compensation heretofore made or hereafter to be made by any governmental authority pertaining to the Land, Improvements or Fixtures (the " **Condemnation Awards** "), (13) all of Mortgagor's rights to appear and defend any action or proceeding brought with respect to the Mortgaged Property and to commence any action or proceeding to protect the interest of Mortgagor in the Mortgaged Property, and (14) all rights, powers, privileges, options and other benefits of Mortgagor as lessor under the Leases, including, without limitation, the immediate and continuing right to claim for, receive, collect and receive all Rents payable or receivable under the Leases or pursuant thereto (and to apply the same to the payment of the Obligations), and to do all other things which Mortgagor or any lessor is or may become entitled to do under the Leases. As used in this Mortgage, the term "Mortgaged Property" shall mean all or, where the context permits or requires, any portion of the above or any interest therein but in no event shall include Intellectual Property (as defined in the Loan Agreement).

(c) " **Obligations** ": Collectively, all of the present and future obligations of Mortgagor and each other Borrower arising from, or owing under or pursuant to, this Mortgage, the Loan Agreement, or any of the other Loan Documents, including all Loans made under the Loan Agreement (including any interest, fees (including reasonable attorneys' fees), or expenses that accrue after the filing of an Insolvency Proceeding, regardless of whether allowed or allowable in whole or in part as a claim in any insolvency proceeding).

(d) " **Permitted Real Property Encumbrances** ": shall mean (i) the lien of ad valorem taxes not yet due, and (ii) zoning restrictions, easements, licenses, restrictions on the use of real property or minor irregularities in title thereto, which do not materially impair the use of the Mortgaged Property in the operation of the business of Mortgagor or Borrowers or the value of the Mortgaged Property for the purpose of such business, and (iii) Permitted Liens under the Loan Agreement that are inherently liens on Mortgaged Property.

(e) " **UCC** ": The Uniform Commercial Code of the state in which the Land is located or, if the creation, perfection and enforcement of any security interest herein granted is governed by the laws of a state other than the state in which the Land is located, then, as to the matter in question, the Uniform Commercial Code in effect in that state.

ARTICLE 2
GRANT

Section 2.1. **Grant** . For and in consideration of good and valuable consideration, the receipt and sufficiency whereof are hereby acknowledged, and in order to secure the indebtedness and other obligations of Mortgagor herein set forth, to secure the full and timely payment and performance of the Obligations, Mortgagor MORTGAGES, GRANTS A SECURITY INTEREST IN, BARGAINS, ASSIGNS, SELLS AND WARRANTS, to Mortgagee the Mortgaged Property, subject, however, to the Permitted Real Property Encumbrances, TO HAVE AND TO HOLD the Mortgaged Property and all parts, rights and appurtenances thereof, to Mortgagee, and Mortgagor does hereby bind itself, its successors and assigns to WARRANT AND FOREVER DEFEND the title to the Mortgaged Property unto Mortgagee.

TO HAVE AND TO HOLD, the Mortgaged Property, together with all and singular the parts, rights, privileges, hereditaments, and appurtenances thereto in any ways belonging or appertaining, to the use, benefit, and behoof of Mortgagee, its successors and assigns.

ARTICLE 3
WARRANTIES, REPRESENTATIONS AND COVENANTS

Mortgagor warrants, represents and covenants to Mortgagee as follows:

Section 3.1. **Title to Mortgaged Property and Lien of this Instrument** . Mortgagor (i) has good and indefeasible title to the Mortgaged Property, in fee simple (to the extent that the Mortgaged Property constitutes real property), free and clear of any Liens, claims or interests, except the Permitted Real Property Encumbrances and (ii) has full power and lawful authority to encumber the Mortgaged Property in the manner and form set forth in this Mortgage. This Mortgage creates valid, enforceable first priority liens and security interests against the Mortgaged Property.

Section 3.2. **First Lien Status**. Mortgagor shall preserve and protect the first Lien status of this Mortgage. If any Lien other than the Permitted Real Property Encumbrances is asserted against the Mortgaged Property, Mortgagor shall promptly, and at its expense, (a) give Mortgagee a detailed written notice of such Lien (including origin, amount and other terms), and (b) pay the underlying claim in full or take such other action so as to cause it to be released or contest the same in compliance with the requirements of the Loan Agreement (including the requirement of providing a bond or other security satisfactory to Mortgagee).

Section 3.3. **Payment and Performance**. Mortgagor shall pay the Obligations when due under the Loan Documents and shall perform the Obligations in full when they are required to be performed.

Section 3.4. **Replacement of Fixtures**. Except as otherwise permitted under the Loan Agreement or any other Loan Document, Mortgagor shall not, without the prior written consent of Mortgagee, permit any of the Fixtures to be removed at any time from the Land or Improvements, unless the removed item is removed temporarily for maintenance and repair or replacement or, if removed permanently, is obsolete or is of minimal value, owned by Mortgagor subject to the Lien of this Mortgage and the other Loan Documents, and free and clear of any other Lien except such as may be permitted under the Loan Agreement or any other Loan Document, or approved in writing by Mortgagee.

Section 3.5. **Inspection**. Mortgagor shall permit Mortgagee and its agents, representatives and employees to inspect the Mortgaged Property and all books and records of Mortgagor located thereon, and to conduct such environmental and engineering studies as Mortgagee may require.

Section 3.6. **Other Covenants**. All of the covenants in the Loan Agreement are incorporated herein by reference and, together with covenants in this Article 3, shall, to the extent applicable, be covenants running with the land.

Section 3.7. Condemnation Awards and Insurance Proceeds.

(a) Condemnation Awards . Mortgagor, promptly upon obtaining knowledge of the institution of any proceedings for the condemnation of the Premises or any portion thereof, will notify Mortgagee of the pendency of such proceedings. Mortgagee may participate in any such proceedings and Mortgagor from time to time will deliver to Mortgagee all instruments requested by it to permit such participation. Mortgagor assigns all awards and compensation to which it is entitled for any condemnation or other taking, or any purchase in lieu thereof, to Mortgagee and authorizes Mortgagee to collect and receive such awards and compensation and to give proper receipts and acquittances therefor, subject to the terms of the Loan Agreement. Mortgagor, upon request by Mortgagee, shall make, execute and deliver any and all instruments requested for the purpose of confirming the assignment of the aforesaid awards and compensation to Mortgagee free and clear of any Liens, charges or encumbrances of any kind or nature whatsoever. Notwithstanding the foregoing, provided no Event of Default then exists, with the prior written consent of the Mortgagee, Mortgagor may receive such proceeds and apply the same to such repair or restoration.

(b) Insurance Proceeds . Mortgagor assigns to Mortgagee all proceeds of any insurance policies insuring against loss or damage to the Mortgaged Property. Mortgagor authorizes Mortgagee to collect and receive such proceeds and authorizes and directs the issuer of each of such insurance policies to make payment for all such losses directly to Mortgagee, instead of to Mortgagor and Mortgagee jointly, as more specifically described in the Loan Agreement. In the event that the issuer of such insurance policy fails to disburse directly or solely to Mortgagee but disburses instead either solely to Mortgagor or to Mortgagor and Mortgagee, jointly, Mortgagor shall immediately endorse and transfer such proceeds to Mortgagee. Upon Mortgagor's failure to do so, Mortgagee may execute such endorsements or transfers from and in the name of Mortgagor, and Mortgagor hereby irrevocably appoints Mortgagee as Mortgagor's agent and attorney-in-fact so to do. Notwithstanding the foregoing, provided no Event of Default then exists, with the prior written consent of the Mortgagee, Mortgagor may receive such proceeds and apply the same to such repair or restoration

Section 3.8. Costs of Defending and Upholding the Lien . If any action or proceeding is commenced to which action or proceeding Mortgagee is made a party or in which it becomes necessary for Mortgagee to defend or uphold the Lien of this Mortgage including any extensions, renewals, amendments or modifications thereof, Mortgagor shall, on demand, reimburse Mortgagee for all expenses (including, without limitation, reasonable attorneys' fees and reasonable appellate attorneys' fees) incurred by Mortgagee in any such action or proceeding and all such expenses shall be secured by this Mortgage. In any action or proceeding to foreclose this Mortgage or to recover or collect the Obligations, the provisions of law relating to the recovering of costs, disbursements and allowances shall prevail unaffected by this covenant.

Section 3.9. **TRANSFER OF THE MORTGAGED PROPERTY**. EXCEPT AS EXPRESSLY PERMITTED PURSUANT TO THE TERMS OF THE LOAN AGREEMENT, MORTGAGOR SHALL NOT SELL, TRANSFER, PLEDGE, ENCUMBER, CREATE A SECURITY INTEREST IN, GROUND LEASE, OR OTHERWISE HYPOTHECATE, ALL OR ANY PORTION OF THE MORTGAGED PROPERTY WITHOUT THE PRIOR WRITTEN CONSENT OF MORTGAGEE. THE CONSENT BY MORTGAGEE TO ANY SALE, TRANSFER, PLEDGE, ENCUMBRANCE, CREATION OF A SECURITY INTEREST IN, GROUND LEASE OR OTHER HYPOTHECATION OF, ANY PORTION OF THE MORTGAGED PROPERTY SHALL NOT BE DEEMED TO CONSTITUTE A NOVATION OR A CONSENT TO ANY FURTHER SALE, TRANSFER, PLEDGE, ENCUMBRANCE, CREATION OF A SECURITY INTEREST IN, GROUND LEASE, OR OTHER HYPOTHECATION, OR TO WAIVE THE RIGHT OF MORTGAGEE, AT ITS OPTION, TO DECLARE THE OBLIGATIONS SECURED HEREBY IMMEDIATELY DUE AND PAYABLE, WITHOUT NOTICE TO MORTGAGOR OR ANY OTHER PERSON OR ENTITY, UPON ANY SUCH SALE, TRANSFER, PLEDGE, ENCUMBRANCE, CREATION OF A SECURITY INTEREST, GROUND LEASE, OR OTHER HYPOTHECATION TO WHICH MORTGAGEE SHALL NOT HAVE CONSENTED.

Section 3.10. **Security Deposits**. To the extent required by law, or after an Event of Default has occurred and during its continuance, if required by Mortgagee, all security deposits of tenants of the Mortgaged Property shall be treated as trust funds not to be commingled with any other funds of Mortgagor. Within twenty (20) days after request by Mortgagee, Mortgagor shall furnish satisfactory evidence of compliance with this Section 3.10, as necessary, together with a statement of all security deposits deposited by the tenants and copies of all Leases not theretofore delivered to Mortgagee, as requested thereby, certified by Mortgagor.

ARTICLE 4
DEFAULT

Section 4.1. **Events of Default**. The occurrence of any of the following events shall constitute an event of default under this Mortgage (each an "**Event of Default**"):

(a) an "Event of Default" (as such term is defined in the Loan Agreement) shall have occurred;

(b) the breach or violation of any of the terms contained in Article 3 of this Mortgage (other than 3.4 and 3.6), except that with respect to Section 3.3, the following shall constitute an Event of Default: failure to make any payment of principal or interest on any Credit Extension on its due date, failure to make payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1(a) of the Loan Agreement, and failure to pay any other Obligations within three (3) Business Days after such Obligations are due and payable.

(c) Mortgagor's breach of any of the covenants set forth in this Mortgage other than those set forth in Article 3 hereof (other than in Sections 3.3, 3.4 and 3.6) , which breach or failure to comply continues for a period of fifteen (15) days or more, provided, however, that if the default cannot by its nature be cured within the fifteen (15) day period or cannot after diligent attempts by Mortgagor be cured within such fifteen (15) day period, and such default is likely to be cured within a reasonable time, then Mortgagor shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and prior to the expiration of such reasonable time period the failure to cure the default shall not be deemed an Event of Default; provided, however, if such breach or failure to comply would otherwise result in an Event of Default under the Loan Agreement or any other Loan Document, such breach or failure to comply shall result in an Event of Default hereunder concurrently with the occurrence of an Event of Default under the Loan Agreement or such other Loan Document; or

(d) if any statement or representation in any warranty or representation set forth in Article 3 hereof shall now or hereafter prove to be false or misleading in any material respect.

ARTICLE 5
REMEDIES AND FORECLOSURE

Section 5.1. **Remedies** . If an Event of Default exists, Mortgagee may, at Mortgagee's election, exercise any or all of the following rights, remedies and recourses:

(a) Declare the Obligations to be immediately due and payable, without further notice, presentment, protest, notice of intent to accelerate, notice of acceleration, demand or action of any nature whatsoever (each of which hereby is expressly waived by Mortgagor), whereupon the same shall become immediately due and payable.

(b) Notify all tenants of the Premises and all others obligated on leases of any part of the Premises that all rents and other sums owing on leases have been assigned to Mortgagee and are to be paid directly to Mortgagee, and to enforce payment of all obligations owing on leases, by suit, ejectment, cancellation, releasing, reletting or otherwise, whether or not Mortgagee has taken possession of the Premises, and to exercise whatever rights and remedies Mortgagee may have under any assignment of rents and leases.

(c) As and to the extent permitted by law, enter the Mortgaged Property, either personally or by its agents, nominees or attorneys, and take exclusive possession thereof and thereupon, Mortgagee may (i) use, operate, manage, control, insure, maintain, repair, restore and otherwise deal with all and every part of the Premises and conduct business thereat; (ii) complete any construction on the Premises in such manner and form as Mortgagee deems advisable in the reasonable exercise of its judgment; (iii) exercise all rights and power of Mortgagor with respect to the Premises, whether in the name of Mortgagor, or otherwise, including, without limitation, the right to make, cancel, enforce or modify leases, obtain and evict tenants, and demand, sue for, collect and receive all earnings, revenues, rents, issues, profits and other income of the Premises and every part thereof, which rights shall not be in limitation of Mortgagee's rights under any assignment of rents and leases securing the Obligations; and (iv) pursuant to the provisions of the Loan Agreement, apply the receipts from the Premises to the payment of the Obligations, after deducting therefrom all expenses (including attorneys' fees) incurred in connection with the aforesaid operations and all amounts necessary to pay the taxes, assessments, insurance and other charges in connection with the Mortgaged Property, as well as just and reasonable compensation for the services of Mortgagee, its counsel, agents and employees.

(d) Hold, lease, develop, manage, operate or otherwise use the Mortgaged Property upon such terms and conditions as Mortgagee may deem reasonable under the circumstances (making such repairs, alterations, additions and improvements and taking other actions, from time to time, as Mortgagee deems necessary or desirable), and apply all Rents and other amounts collected by Mortgagee in connection therewith in accordance with the provisions of Section 5.7 hereof.

(e) Require Mortgagor to assemble any collateral under the UCC and make it available to Mortgagee, at Mortgagor’s sole risk and expense, at a place or places to be designated by Mortgagee, in its sole discretion.

(f) Institute proceedings for the complete foreclosure of this Mortgage, either by judicial action or, to the extent permitted by law, by power of sale, in which case the Mortgaged Property may be sold for cash or credit in accordance with applicable law in one or more parcels as Mortgagee may determine. Except as otherwise required by applicable law, with respect to any notices required or permitted under the UCC, Mortgagor agrees that twenty (20) days' prior written notice shall be deemed commercially reasonable. At any such sale by virtue of any judicial proceedings, power of sale (to the extent permitted by law), or any other legal right, remedy or recourse, the title to and right of possession of any such property shall pass to the purchaser thereof, and to the fullest extent permitted by law, Mortgagor shall be completely and irrevocably divested of all of its right, title, interest, claim, equity, equity of redemption, and demand whatsoever, either at law or in equity, in and to the property sold and such sale shall be a perpetual bar both at law and in equity against Mortgagor, and against all other Persons claiming or to claim the property sold or any part thereof, by, through or under Mortgagor. Mortgagee may be a purchaser at such sale. If Mortgagee is the highest bidder, Mortgagee may credit the portion of the purchase price that would be distributed to Mortgagee against the Obligations in lieu of paying cash. In the event this Mortgage is foreclosed by judicial action, appraisement and valuation of the Mortgaged Property is waived. In the event of any sale made under or by virtue of this Article 5 (whether made by virtue of judicial proceedings or of a judgment or decree of foreclosure and sale) all of the Obligations, if not previously due and payable, immediately thereupon shall become due and payable. The failure to make any such tenants of the Premises party to any such foreclosure proceedings and to foreclose their rights will not be, nor be asserted to be by Mortgagor, a defense to any proceedings instituted by Mortgagee to collect the sums secured hereby.

(g) With or without entry, to the extent permitted and pursuant to the procedures provided by applicable law, institute proceedings for the partial foreclosure of this Mortgage for the portion of the Obligations then due and payable (if Mortgagee shall have elected not to declare the entire Obligations to be immediately due and owing), subject to the continuing Lien of this Mortgage for the balance of the Obligations not then due; or (1) as and to the extent permitted by law, sell for cash or upon credit the Mortgaged Property or any part thereof and all estate, claim, demand, right, title and interest of Mortgagor therein, pursuant to power of sale (to the extent permitted by law) or otherwise, at one or more sales, as an entity or in parcels, at such time and place, upon such terms and after such notice thereof as may be required or permitted by law, and in the event of a sale, by foreclosure or otherwise, of less than all of the Mortgaged Property, this Mortgage shall continue as a Lien on the remaining portion of the Mortgaged Property; or (2) institute an action, suit or proceeding in equity for the specific performance of any covenant, condition or agreement contained herein or in any Credit Document; or (3) to the extent permitted by applicable law, recover judgment on the Loan Agreement or any other Loan Document either before, during or after any proceedings for the enforcement of this Mortgage.

(h) Make application to a court of competent jurisdiction for, and obtain from such court as a matter of strict right and without notice to Mortgagor or regard to the adequacy of the Mortgaged Property for the repayment of the Obligations, the appointment of a receiver of the Mortgaged Property, and Mortgagor irrevocably consents to such appointment. Any such receiver shall have all the usual powers and duties of receivers in similar cases, including the full power to rent, maintain and otherwise operate the Mortgaged Property upon such terms as may be approved by the court, and shall apply such Rents in accordance with the provisions of Section 5.7 hereof.

(i) Exercise all other rights, remedies and recourses granted under the Loan Documents or otherwise available at law or in equity.

Section 5.2. **Separate Sales**. The Mortgaged Property may be sold in one or more parcels and in such manner and order as Mortgagee in its sole discretion may direct; the right of sale arising out of any Event of Default shall not be exhausted by any one or more sales.

Section 5.3. **Remedies Cumulative, Concurrent and Nonexclusive**. Mortgagee shall have all rights, remedies and recourses granted in the Loan Documents and available at law or equity (including the UCC), which rights (a) shall be cumulated and concurrent, (b) may be pursued separately, successively or concurrently against Mortgagor or others obligated under the Loan Documents, or against the Mortgaged Property, or against any one or more of them, at the sole discretion of Mortgagee, as the case may be, (c) may be exercised as often as occasion therefor shall arise, and the exercise or failure to exercise any of them shall not be construed as a waiver or release thereof or of any other right, remedy or recourse, and (d) are intended to be, and shall be, nonexclusive. No action by Mortgagee in the enforcement of any rights, remedies or recourses under the Loan Documents or otherwise at law or equity shall be deemed to cure any Event of Default.

Section 5.4. **Release of and Resort to Collateral**. Mortgagee may release, regardless of consideration and without the necessity for any notice to or consent by the holder of any subordinate Lien on the Mortgaged Property, any part of the Mortgaged Property without, as to the remainder, in any way impairing, affecting, subordinating or releasing the Lien created in or evidenced by the Loan Documents or their status as a first and prior Lien in and to the Mortgaged Property. For payment of the Obligations, Mortgagee may resort to any other security in such order and manner as Mortgagee may elect.

Section 5.5. **Waiver of Redemption, Notice and Marshalling of Assets**. To the fullest extent permitted by law, Mortgagor hereby irrevocably and unconditionally waives and releases (a) all benefit that might accrue to Mortgagor by virtue of any present or future statute of limitations or law or judicial decision exempting the Mortgaged Property from attachment, levy or sale on execution or providing for any stay of execution, exemption from civil process, redemption or extension of time for payment, (b) all notices of any Event of Default or of any election by Mortgagee to exercise or the actual exercise of any right, remedy or recourse provided for under the Loan Documents, except as otherwise specifically set forth in Section 4.1 hereof or elsewhere in this Mortgage or any other Loan Document, and (c) any right to a marshalling of assets or a sale in inverse order of alienation.

Section 5.6. **Discontinuance of Proceedings**. If Mortgagee shall have proceeded to invoke any right, remedy or recourse permitted under the Loan Documents and shall thereafter elect to discontinue or abandon it for any reason, Mortgagee shall have the unqualified right to do so and, in such an event, Mortgagor and Mortgagee shall be restored to their former positions with respect to the Obligations, the Loan Documents, the Mortgaged Property and otherwise, and the rights, remedies, recourses and powers of Mortgagee shall continue as if the right, remedy or recourse had never been invoked, but no such discontinuance or abandonment shall waive any Event of Default which may then exist or the right of Mortgagee thereafter to exercise any right, remedy or recourse under the Loan Documents for such Event of Default.

Section 5.7. **Application of Proceeds**. The proceeds of any sale made under or by virtue of this Article 5, together with any Rents and other amounts generated by the holding, leasing, management, operation or other use of the Mortgaged Property, shall be applied by Mortgagee (or the receiver, if one is appointed) in the following order unless otherwise required by applicable law:

(a) to the payment of the costs and expenses of taking possession of the Mortgaged Property and of holding, using, leasing, repairing, improving and selling the same, including, without limitation (1) trustee's and receiver's fees and expenses, including the repayment of the amounts evidenced by any receiver's certificates, (2) court costs, (3) attorneys' and accountants' fees and expenses, (4) costs of advertisement, (5) all costs and expenses incurred by Mortgagee to cure defaults of Mortgagor under this Mortgage and the other Loan Documents, and (6) all costs and expenses incurred by Mortgagee to protect or preserve the Mortgaged Property;

(b) to the payment of the Obligations in such manner and order of preference as set forth in the Loan Agreement and the other Loan Documents; and

(c) the balance, if any, to the payment of the Persons legally entitled thereto.

Section 5.8. Occupancy After Foreclosure . Except as otherwise required by applicable law, any sale of the Mortgaged Property or any part thereof in accordance with Section 5.1(f) or Section 5.1(g) hereof will divest all right, title and interest of Mortgagor in and to the property sold. Subject to applicable law, any purchaser at a foreclosure sale will receive immediate possession of the property purchased. If Mortgagor retains possession of such property or any part thereof subsequent to such sale, Mortgagor will be considered a tenant at sufferance of the purchaser, and will, if Mortgagor remains in possession after demand to remove, be subject to eviction and removal, forcible or otherwise, with or without process of law.

Section 5.9. Additional Advances and Disbursements; Costs of Enforcement .

(a) If any Event of Default exists, Mortgagee shall have the right, but not the obligation, to cure such Event of Default in the name and on behalf of Mortgagor. All sums advanced and expenses incurred at any time by Mortgagee under this Section 5.9 , or otherwise under this Mortgage or any of the other Loan Documents or applicable law, shall bear interest from the date that such sum is advanced or expense incurred, to and including the date of reimbursement, computed at the rate or rates at which interest is then computed on the Obligations, and all such sums, together with interest thereon, shall be secured by this Mortgage.

(b) Subject to any limits set forth in the Loan Agreement, Mortgagor shall pay all expenses (including reasonable attorneys' fees and expenses and all costs and expenses related to legal work, research and litigation) of or incidental to the perfection and enforcement of this Mortgage and the other Loan Documents, or the enforcement, compromise or settlement of the Obligations or any claim under this Mortgage and the other Loan Documents, and for the curing thereof, or for defending or asserting the rights and claims of Mortgagee in respect thereof, by litigation or otherwise.

Section 5.10. **No Mortgagee in Possession**. Neither the enforcement of any of the remedies under this Article 5, the assignment of the Rents and Leases under Article 6, the security interests under Article 7, nor any other remedies afforded to Mortgagee under the Loan Documents, at law or in equity shall cause Mortgagee to be deemed or construed to be a mortgagee in possession of the Mortgaged Property, to obligate Mortgagee to lease the Mortgaged Property or attempt to do so, or to take any action, incur any expense, or perform or discharge any obligation, duty or liability whatsoever under any of the Leases or otherwise.

Section 5.11. **WAIVER OF MORTGAGOR'S RIGHTS**. BY EXECUTION OF THIS MORTGAGE, MORTGAGOR EXPRESSLY: (A) ACKNOWLEDGES THE RIGHT OF MORTGAGEE TO ACCELERATE THE APPLICABLE INDEBTEDNESS EVIDENCED BY THE LOAN AGREEMENT OR OTHER LOAN DOCUMENTS, AS THE CASE MAY BE, UPON THE OCCURRENCE OF AN EVENT OF DEFAULT; (B) TO THE EXTENT ALLOWED BY APPLICABLE LAW, AND EXCEPT AS EXPRESSLY SET FORTH IN SECTION 4.1 HEREOF OR ELSEWHERE IN THIS MORTGAGE, THE LOAN AGREEMENT, OR ANY OTHER LOAN DOCUMENT, WAIVES ANY AND ALL RIGHTS WHICH MORTGAGOR MAY HAVE BY REASON OF ANY APPLICABLE LAW, TO NOTICE AND TO JUDICIAL HEARING PRIOR TO THE EXERCISE BY MORTGAGEE OF ANY RIGHT OR REMEDY HEREIN PROVIDED TO MORTGAGEE; (C) ACKNOWLEDGES THAT MORTGAGOR HAS READ THIS MORTGAGE AND ITS PROVISIONS HAVE BEEN EXPLAINED FULLY TO MORTGAGOR AND MORTGAGOR HAS CONSULTED WITH LEGAL COUNSEL OF MORTGAGOR'S CHOICE PRIOR TO EXECUTING THIS MORTGAGE; AND (D) ACKNOWLEDGES THAT ALL WAIVERS OF THE AFORESAID RIGHTS OF MORTGAGOR HAVE BEEN MADE KNOWINGLY, INTENTIONALLY AND WILLINGLY BY MORTGAGOR AS PART OF A BARGAINED FOR LOAN TRANSACTION.

ARTICLE 6
ASSIGNMENT OF RENTS AND LEASES

Section 6.1. **Assignment**. In furtherance of and in addition to the assignment made by Mortgagor in Section 2.1 of this Mortgage, as security for the Obligations. Mortgagor hereby transfers and conveys to Mortgagee all of its right, title and interest in and to all Leases, whether now existing or hereafter entered into, and all of its right, title and interest in and to all Rents. This assignment is an assignment for additional security only. So long as no Event of Default shall have occurred and be continuing and to the extent not prohibited by the Loan Agreement, Mortgagor shall have the right from Mortgagee to exercise all rights extended to the landlord under the Leases, including the right to receive and collect all Rents and to use the same in any manner as it sees fit. The foregoing right is granted subject to the conditional limitation that no Event of Default shall have occurred and be continuing. Upon the occurrence and during the continuance of an Event of Default, whether or not legal proceedings have commenced, and without regard to waste, adequacy of security for the Obligations or solvency of Mortgagor, the rights herein granted shall automatically expire and terminate, without notice by Mortgagee (any such notice being hereby expressly waived by Mortgagor).

Section 6.2. **Perfection Upon Recordation**. Mortgagor acknowledges that Mortgagee has taken all actions necessary to obtain, and that upon recordation of this Mortgage, Mortgagee shall have, to the extent permitted under applicable law, a valid and fully perfected, first priority, present assignment of the Rents arising out of the Leases and all security for such Leases. Mortgagor acknowledges and agrees that upon recordation of this Mortgage, Mortgagee's interest in the Rents shall be deemed to be fully perfected, "choate" and enforced as to Mortgagor and all third parties, including, without limitation, any subsequently appointed trustee in any case under the Bankruptcy Code, without the necessity of commencing a foreclosure action with respect to this Mortgage, making formal demand for the Rents, obtaining the appointment of a receiver or taking any other affirmative action.

Section 6.3. **Bankruptcy Provisions**. Without limitation of the absolute nature of the assignment of the Rents hereunder, Mortgagor and Mortgagee agree that (a) this Mortgage shall constitute a "security agreement" for purposes of Section 552(b) of the Bankruptcy Code, (b) the security interest created by this Mortgage extends to property of Mortgagor acquired before the commencement of a case in bankruptcy and to all amounts paid as Rents and (c) such security interest shall extend to all Rents acquired by the estate after the commencement of any case in bankruptcy.

Section 6.4. **No Merger of Estates**. So long as part of the Obligations secured hereby remain unpaid and undischarged, the fee and leasehold estates to the Mortgaged Property shall not merge, but shall remain separate and distinct, notwithstanding the union of such estates either in Mortgagor, Mortgagee, any tenant or any third party by purchase or otherwise.

ARTICLE 7
SECURITY AGREEMENT

Section 7.1. **Security Interest**. This Mortgage constitutes a "security agreement" on personal property within the meaning of the UCC and other applicable law and with respect to the Fixtures, Leases, Rents, Deposit Accounts, Property Agreements, Tax Refunds, Proceeds, Insurance and Condemnation Awards. To this end, Mortgagor grants to Mortgagee a first and prior security interest in the Fixtures, Leases, Rents, Deposit Accounts, Property Agreements, Tax Refunds, Proceeds, Insurance and Condemnation Awards and all other Mortgaged Property which is personal property to secure the payment and performance of the Obligations, and agrees that Mortgagee shall have all the rights and remedies of a secured party under the UCC with respect to such property. Any notice of sale, disposition or other intended action by Mortgagee with respect to the Fixtures, Leases, Rents, Deposit Accounts, Property Agreements, Tax Refunds, Proceeds, Insurance and Condemnation Awards sent to Mortgagor at least ten (10) days prior to any action under the UCC shall constitute reasonable notice to Mortgagor.

Section 7.2. **Financing Statements**. Mortgagor shall deliver to Mortgagee, in form and substance satisfactory to Mortgagee, such financing statements and such further assurances as Mortgagee may, from time to time, reasonably consider necessary to create, perfect and preserve Mortgagee's security interest hereunder and Mortgagee may cause such statements and assurances to be recorded and filed, at such times and places as may be required or permitted by law to so create, perfect and preserve such security interest. Mortgagor's state of organization is the State of Florida.

Section 7.3. **Fixture Filing**. To the extent permitted under the UCC of the state in which the Land is located, this Mortgage shall also constitute a "fixture filing" for the purposes of the UCC against all of the Mortgaged Property which is or is to become fixtures. Information concerning the security interest herein granted may be obtained at the address of Debtor (Mortgagor) and Secured Party (Mortgagee) as set forth in the first paragraph of this Mortgage.

ARTICLE 8
RESERVED

ARTICLE 9
MISCELLANEOUS

Section 9.1. **Notices**. Any notice required or permitted to be given under this Mortgage shall be given in accordance with Section 11.1 of the Loan Agreement.

Section 9.2. **Covenants Running with the Land**. All Obligations contained in this Mortgage are intended by Mortgagor and Mortgagee to be, and shall be construed as, covenants running with the Mortgaged Property. As used herein, "Mortgagor" shall refer to the party named in the first paragraph of this Mortgage and to any subsequent owner of all or any portion of the Mortgaged Property. All Persons who may have or acquire an interest in the Mortgaged Property shall be deemed to have notice of, and be bound by, the terms of the Loan Agreement and the other Loan Documents; however, no such party shall be entitled to any rights thereunder without the prior written consent of Mortgagee.

Section 9.3. **Attorney-in-Fact**. Mortgagor hereby irrevocably appoints Mortgagee and its successors and assigns, as its attorney-in-fact, which agency is coupled with an interest and with full power of substitution, (a) to execute and/or record any notices of completion, cessation of labor or any other notices that Mortgagee deems appropriate to protect Mortgagee's interest, if Mortgagor shall fail to do so within ten (10) days after written request by Mortgagee, (b) upon the issuance of a deed pursuant to the foreclosure of this Mortgage or the delivery of a deed in lieu of foreclosure, to execute all instruments of assignment, conveyance or further assurance with respect to the Leases, Rents, Deposit Accounts, Property Agreements, Tax Refunds, Proceeds, Insurance and Condemnation Awards in favor of the grantee of any such deed and as may be necessary or desirable for such purpose, (c) to prepare, execute and file or record financing statements, continuation statements, applications for registration and like papers necessary to create, perfect or preserve Mortgagee's security interests and rights in or to any of the Mortgaged Property, and (d) while any Event of Default exists, to perform any obligation of Mortgagor hereunder, however: (1) Mortgagee shall not under any circumstances be obligated to perform any obligation of Mortgagor; (2) any sums advanced by Mortgagee in such performance shall be added to and included in the Obligations and shall bear interest at the rate or rates at which interest is then computed on the Obligations; (3) Mortgagee as such attorney-in-fact shall only be accountable for such funds as are actually received by Mortgagee; and (4) Mortgagee shall not be liable to Mortgagor or any other person or entity for any failure to take any action which it is empowered to take under this Section 9.3. Notwithstanding the foregoing, Mortgagee shall be liable for its gross negligence, willful misconduct, and bad faith in connection with exercising its rights hereunder to the extent determined by a court of competent jurisdiction in a final, non-appealable judgment.

Section 9.4. **Successors and Assigns**. This Mortgage shall be binding upon and inure to the benefit of Mortgagee and Mortgagor and their respective successors and assigns. Mortgagor shall not, without the prior written consent of Mortgagee, assign any rights, duties or obligations hereunder.

Section 9.5. **No Waiver**. Any failure by Mortgagee to insist upon strict performance of any of the terms, provisions or conditions of the Loan Documents shall not be deemed to be a waiver of same, and Mortgagee shall have the right at any time to insist upon strict performance of all such terms, provisions and conditions.

Section 9.6. **Loan Agreement**. If any conflict or inconsistency exists between this Mortgage and the Loan Agreement, the Loan Agreement shall govern.

Section 9.7. **Release or Reconveyance**. Upon payment and performance in full of the Obligations and termination of the Loan Agreement and the other Loan Documents, Mortgagee, at Mortgagor's expense, shall release the Liens created by this Mortgage or reconvey the Mortgaged Property to Mortgagor.

Section 9.8. **Waiver of Stay, Moratorium and Similar Rights**. Mortgagor agrees, to the full extent that it may lawfully do so, that it will not at any time insist upon or plead or in any way take advantage of any stay, marshalling of assets, extension, redemption or moratorium law now or hereafter in force and effect so as to prevent or hinder the enforcement of the provisions of this Mortgage or the Obligations secured hereby, or any agreement between Mortgagor and Mortgagee or any rights or remedies of Mortgagee.

Section 9.9. **Applicable Law**. This Mortgage shall be governed by and construed under the laws of the state in which the Mortgaged Property is located.

Section 9.10. **Headings**. The Article, Section and Subsection titles hereof are inserted for convenience of reference only and shall in no way alter, modify or define, or be used in construing, the text of such Articles, Sections or Subsections.

Section 9.11. **Entire Agreement**. This Mortgage and the other Loan Documents embody the entire agreement and understanding between Mortgagor and Mortgagee and supersede all prior agreements and understandings between such parties relating to the subject matter hereof and thereof. Accordingly, the Loan Documents may not be contradicted by evidence of prior, contemporaneous or subsequent oral agreements of the parties. There are no unwritten oral agreements between the parties.

Section 9.12. **Proceeds.** So long as no Event of Default shall have occurred and be continuing and to the extent not prohibited by the Loan Agreement, Mortgagor shall have a the right from Mortgagee to use Tax Refunds and cash Proceeds in any manner as it sees fit, including for general working capital (without the same constituting Proceeds). The foregoing right is granted subject to the conditional limitation that no Event of Default shall have occurred and be continuing. Upon the occurrence and during the continuance of an Event of Default, whether or not legal proceedings have commenced, and without regard to waste, adequacy of security for the Obligations or solvency of Mortgagor, the right herein granted shall automatically expire and terminate, without notice by Mortgagee (any such notice being hereby expressly waived by Mortgagor).

ARTICLE 10
LOCAL LAW PROVISIONS

Section 10.1. **Inconsistencies**. In the event of any inconsistency between the terms and conditions of the other articles and provisions of this Mortgage and this Article 10, the terms and conditions of this Article 10 shall control and be binding.

Section 10.2. **Costs, Expenses and Attorneys' Fees**. The terms, "expenses (including, without limitation, reasonable attorneys' fees) incurred by Mortgagee," "costs, disbursements and allowances," "costs and expenses of taking possession of the Mortgaged Property," "attorneys' fees and expenses," and similar terms and phrases as used in this Mortgage, including, without limitation, Sections 3.8, 5.7(a), 5.9(b) and 10.4 shall include, without limitation, support staff and paraprofessional costs, amounts expended in litigation preparation and computerized research, telephone and telefax expenses, mileage, depositions, postage, photocopies, process service, videotapes, and all costs associated with environmental testing, audits, reviews, inspections, remediation and clean-up.

Section 10.3. **Fixture Filing** . Mortgagor and Mortgagee agree, to the extent permitted by law, that: (i) all of the goods subject to the foregoing grant of security interest, or are to become, fixtures on the land described in Exhibit A ; (ii) this instrument, upon recording in the real estate records of the proper office, shall constitute a "fixture filing" within the meaning of Sections 9.1-313 and 9.1-402 of the UCC; (iii) Mortgagor is a record owner of the Premises; (iv) the addresses of Mortgagor and Mortgagee are as set forth on the first page of this Mortgage; (v) Mortgagor's state organizational number is 197602-119; and (vi) a carbon, photographic, or other reproduction of this instrument, or of any financing statement relating hereto, shall be sufficient for filing purposes.

Section 10.4. **Indebtedness** . This Mortgage is given to secure indebtedness in an amount not to exceed a maximum aggregate principal amount of TEN MILLION DOLLARS ($10,000,000.00), exclusive of interest thereon, fees with respect thereto and exclusive of unpaid balances of advances made with respect to the Mortgaged Property for the protection of the Mortgaged Property or the security of this Mortgage or for the payment of taxes, assessments, insurance premiums and all other costs which Mortgagee is authorized by the Mortgage to pay on Mortgagor's behalf and exclusive of attorneys fees incurred by Mortgagee in connection with any collection or enforcement action hereunder; and all amendments, extensions, renewals, modifications, replacements or substitutions to any of the foregoing.

[The remainder of this page has been intentionally left blank]

IN WITNESS WHEREOF , Mortgagor has caused this Mortgage to be duly EXECUTED AND DELIVERED by its duly authorized representative all as of the day and year first above written.

MORTGAGOR:

ACURA PHARMACEUTICAL TECHNOLOGIES, INC. , an Indiana corporation

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

STATE OF Illinois)
)ss.
COUNTY OF Cook)

On December 16, 2013, before me, the undersigned, Notary Public in and for said State and County, personally appeared [Peter A. Clemens, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.

/s/ Robert A. Seiser
Notary Public, State of Illinois

Robert A. Seiser
Printed Name of Notary Public

My Commission Expires: 8/13/2016

PREPARED BY, RECORDING REQUESTED BY,
AND WHEN RECORDED MAIL TO:

Jonathan Bell Esq.
Greenberg Traurig LLP
One International Place
20 th Floor
Boston, MA 02110

I affirm, under the penalties for perjury, that I have taken reasonable care to redact each Social Security number in this document, unless required by law.

- Jonathan Bell, Esq.

Exhibit A
Real Property Description

A part of the Northwest Quarter of Section 9, Township 32 North, Range 1 East, Union Township, Marshall County, Indiana, described as follows: Commencing at the Northeast corner of said Northwest Quarter; thence South 0°00'00" East (assumed bearing) along the East line of said Northwest Quarter a distance of 691.20 feet to a PK nail at the point of beginning; thence continuing South 0°00'00" East along said East line a distance of 691.20 feet to a PK nail; thence South 89°52'40" West a distance of 200.00 feet to a 5/8 inch rebar; thence South 0°00'00" East a distance of 346.00 feet to a 5/8 inch rebar; thence North 89°39'39" West a distance of 1092.89 feet to a 5/8 inch rebar on the West line of the East half of said Northwest Quarter; thence North 1°09'23" West along said West line a distance of 1011.77 feet to a 5/8 inch rebar; thence North 89°08'41" East a distance of 1313.44 feet to the point of beginning, containing 29.077 acres, more or less. Subject to legal highways, rights-of-way and easements of record.

EXCEPT:

A part of the Northwest Quarter of Section 9, township 32 North, Range 1 East, Union Township, Marshall County, Indiana, described as follows: Commencing at a 5/8 inch iron rod located at the Northeast corner of said Northwest Quarter; thence South 00°00'00" West (record bearing) along the East line of said Quarter 1169.13 feet to a Mag nail at the point of beginning of this description; thence continuing South 00° 00'00" West along the East line of said Quarter 213.27 feet to a PK nail at the Northeast corner of the Helen D. Fishburn parcel as recorded in Deed Record 1984, page 4258 in the Office of the Marshall County Recorder; thence South 89°52'40" West 200.00 feet to a 5/8 inch iron rod at the Northwest corner of said Fishburn parcel; thence South 00°00'00" West along the West line of said Fishburn parcel 4.77 feet to a 5/8 inch iron rod at the intersection with the Easterly extension of a chainlink fence; thence North 89°15'19" West along said fenceline 109.57 feet to a fence corner post; thence North 00°35'23" East along said fenceline 128.93 feet to a fence corner post; thence North 88°56'06" East along said fenceline 40.40 feet to a fence corner post; thence North 00°15'11" East 37.88 feet to a 5/8 inch iron rod, thence North 89°35'46" East 65.54 feet to a 5/8 inch iron rod; thence North 02°36'10" East 48.65 feet to a 5/8 inch iron rod; thence North 89°52'40" East 199.93 feet to the point of beginning, containing 1.37 acres, subject to all easements, rights-of-way and restrictions of record.

EXECUTION VERSION

SEVENTH AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS **SEVENTH AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT** (this " **Amendment** ") made this 12 th day `of December, 2013 by and between **ACURA PHARMACEUTICALS, INC.** , a New York corporation (the " **Corporation** "), with offices at 616 N. North Court, Suite 120, Palatine, Illinois 60067 and **PETER A. CLEMENS** (the " **Employee** ").

R E C I TA L S

A. The Corporation and the Employee executed an Executive Employment Agreement dated as of March 10, 1998, as amended (as amended, the " **Employment Agreement** ").

B. The Corporation [1] and the Employee now desire to further amend the Employment Agreement as provided herein.

NOW, THEREFORE , in consideration of the mutual covenants and undertakings herein contained, the parties agree as follows:

1. The first sentence of Section 3(a) of the Employment Agreement is hereby deleted in its entirety and the following is inserted in its place:

"(a) Base Salary . The Corporation shall pay the Employee an aggregate base salary at an annual rate of $280,000 payable in equal installments on the Company's regular payroll schedule, less such deductions or amounts to be withheld as required by applicable law or regulations."

2. The first sentence of Section 3(b) of the Employment Agreement is hereby deleted in its entirety and the following is inserted in its place:

"(b) Annual Bonus . During the Term, the Employee will be eligible to receive from the Corporation an annual bonus (the "Bonus") in the amount of up to seventy percent (70%) of the Employee's then current annual Base Salary during the fiscal year (or portion thereof) for which the Bonus may be awarded."

3. Except as expressly amended by this Amendment, the Employment Agreement remains in full force and effect. Capitalized terms used herein shall have the same meaning as in the Employment Agreement unless otherwise defined herein. This Amendment shall be governed and construed and enforced in accordance with the local laws of the State of New York applicable to agreements made and to be performed entirely in New York.

[1] The Board of Directors of the Corporation approved the terms of this Amendment at its December 12, 2013 meeting following the recommendation of the Compensation Committee which recommended approval at its September 20, 2013 meeting.

4. This Amendment may be executed in one or more facsimile or original counterparts, each of which shall be deemed an original, but all of which taken together will constitute one and the same instrument.

5. This Amendment shall be effective on January 1, 2014.

[SIGNATURES ON NEXT PAGE]

IN WITNESS WHEREOF , the parties have executed this Amendment as of the date first above written.

ACURA PHARMACEUTICALS, INC.

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

EMPLOYEE

By: /s/ Peter Clemens
Peter A. Clemens

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. 333-151653, 333-151620, 333-133172, 333-123615, 333-63288, and 33-98356) and on Form S-3 (No. 333-146416 and 333-187075) of Acura Pharmaceuticals, Inc. of our report dated March 3, 2014, relating to the consolidated financial statements, which appear in this Form 10-K.

/s/ BDO USA, LLP
Chicago , Illinois
March 3, 2014

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, 2014

/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, 2014

/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, 2013 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, 2014 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, 2013 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, 2014 By: /s/Peter A. Clemens
Peter A. Clemens
Senior Vice President and Chief Financial Officer