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

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012**

Or

o **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 o 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 o 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 o

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 o

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. o

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

o 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 o No ☒

Based on the last sale price on the NASDAQ Capital Market of the Common Stock of $3.14 on June 29, 2012 (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 $38.2 million.

As of February 28, 2013, the registrant had 46,369,966 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, 2013 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, 2012

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Forward-Looking Statements

Certain statements in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Forward-looking statements may include, but are not limited to, our and our licensee's ability to successfully launch and commercialize our products and technologies including 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 Aversion Technology product candidates, our exposure to product liability and other lawsuits in connection with the commercialization of our products, the increasing cost of insurance and the availability of product liability insurance coverage, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and 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, 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 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," "indicates," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in Item 1A of this Report.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on such forward-looking statements.

PART I

ITEM 1. BUSINESS

Overview

We are a specialty pharmaceutical company engaged in the research, development and commercialization of technologies and products intended to address medication abuse and misuse. We have discovered and developed 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, 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 launched in the United States Nexafed® (pseudoephedrine HC1) tablets formulated with our Impede Technology.

We have 7 additional opioid products utilizing Aversion in various stages of development. Pursuant to a September 24, 2012 letter agreement with Pfizer, all rights to these development-stage opioid products have reverted back to us. 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. Pfizer previously completed a clinical study demonstrating the hydrocodone/acetaminophen product is bioequivalent to its reference listed drug. We filed an Investigational New Drug Application, or IND, with the Food and Drug Administration, or FDA, on December 20, 2012. We expect that the development program for our hydrocodone/acetaminophen product and our other Aversion opioid products in development will be consistent with that of Oxecta. We anticipate submitting a 505(b)(2) NDA with the FDA for our hydrocodone/acetaminophen product in the first half of 2014.

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. We also have been working on the 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 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, Canada and Mexico. We are seeking licensing partners for our other Aversion technology 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. We have three issued U.S. patents covering all of our Aversion Technology opioid products, which patents 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 some of the common methods of pharmaceutical product misuse and abuse described below.

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

Intended to Deter I.V. Injection of Opioids Extracted from Dissolved Tablets

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.

Intended to Deter Nasal Snorting

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.

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. To our knowledge, Pfizer has not initiated marketing of Oxecta to physicians and is awaiting advice from the FDA on their proposed physician promotion materials which were submitted to the FDA in July 2012. As such, Pfizer's attained no meaningful sales of Oxecta in 2012.

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 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 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®	Bioequivalence to reference listed drug demonstrated. IND submitted to the FDA on December 20, 2012. NDA submission targeted for the first half of 2014.
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 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: (a) successfully removed niacin from the formulation, (2) demonstrated bioequivalence to a reference listed drug 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;
- Laboratory studies demonstrating extraction, syringing and particle size characteristics of our product; and
- An assessment of the routes of abuse of hydrocodone products.

We submitted an IND to the FDA for our hydrocodone/acetaminophen product on December 20, 2012 which became effective in late January 2013 and allows us to commence clinical trials. Based on the development program outlined above, we anticipate preparing and submitting a 505(b)(2) NDA for our hydrocodone/acetaminophen product in the first half of 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 prescription drug products in general, and opioid analgesics in particular, is a significant societal problem that has been described as epidemic in nature by Joseph A. Califano, Jr., Chairman and President, National Center for Addiction and Substance Abuse at Columbia University, July 2005. Results from the 2009 National Survey on Drug Use and Health indicate prescription drug abusers have supplanted abusers of all illicit drugs except marijuana. The survey estimated that 35 million people in the United States, or more than 10% of the population, have engaged in the non-medical use of prescription opioid analgesics at some point in their lifetime. IR Opioid Products comprise the vast majority of this abuse compared with 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 260 million tablet and capsule prescriptions dispensed in 2011 of which approximately 244 million were for IR Opioid Products and 16 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 product(s), to compete primarily in the IR Opioid Product segment of the United States opioid analgesic market. IR Opioid Product prescriptions have grown at a 3.8% compounded annual rate over the last five years. Because IR Opioid Products are used for both acute and chronic pain, a prescription, on average, contains 62 tablets or capsules. According to IMS Health, in 2011, sales in the IR Opioid Product segment were approximately $2.1 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 78% of the U.S. IR Opioid Product segment.

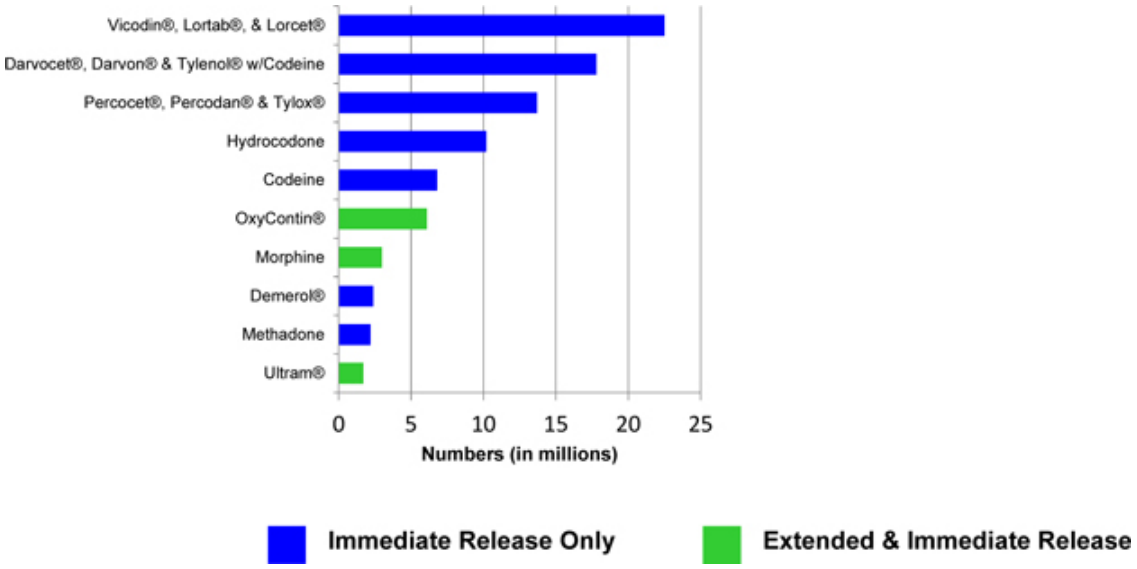
IR Opioid Products[1]	2011 US Prescriptions (Millions)[2]	% of Total
Hydrocodone	137	56
Oxycodone	54	22
Tramadol	37	15
Codeine	13	5
3 others	3	2
Total (Average)	244	100

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

[2]IMS Health, 2011

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 35 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: 2010



Source: SAMHSA, Office of Applied Studies, 2010 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 a 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, 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 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 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

On October 30, 2007, we and King Pharmaceuticals Research and Development, Inc., now a wholly-owned subsidiary of Pfizer, entered into the Pfizer Agreement to develop and commercialize in the United States, Canada and Mexico certain opioid analgesic products utilizing our proprietary Aversion Technology. The Pfizer Agreement initially provided Pfizer with an exclusive license in the United States, Canada and Mexico, or the Pfizer Territory, for Oxecta (oxycodone HCl) Tablets and oxycodone HCl/acetaminophen tablets utilizing Aversion Technology. In addition, the Pfizer Agreement provided Pfizer with an option to license in the Pfizer Territory certain future opioid analgesic products developed utilizing Aversion Technology. Pfizer exercised its option to license two additional product candidates including an undisclosed immediate-release opioid analgesic tablet product and hydrocodone bitartrate/acetaminophen tablets, each of which utilize our Aversion Technology. On September 24, 2012, we entered into a letter agreement with Pfizer which amends the Pfizer Agreement and provides for the termination of Pfizer's license to our Aversion® Technology used in the three development-stage products licensed to Pfizer and for the transfer of these products back to us. These development-stage products are hydrocodone bitartrate/acetaminophen tablets, oxycodone HCl/acetaminophen tablets and an undisclosed opioid. See the discussion above under the caption "Aversion Technology Opioid Products in Development" for further information regarding the development of these products.

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 in all Pfizer Territories. Subject to the Pfizer Agreement, Pfizer will have final decision making authority with respect to all regulatory and commercialization activities for Oxecta.

As of December 31, 2012, we had received aggregate payments of $78.5 million from Pfizer, consisting of a $30.0 million non-refundable upfront cash payment, $17.5 million in reimbursed research and development expenses relating to licensed products, $6.0 million in fees relating to Pfizer's exercise of its option to license an undisclosed immediate-release opioid analgesic tablet product and hydrocodone bitartrate/acetaminophen tablets, a $5.0 million milestone fee relating to our successful achievement of the primary endpoints for our pivotal Phase III clinical study for Aversion oxycodone HCl with niacin tablets and a $20.0 million milestone fee relating to the FDA's approval of the Oxecta Tablets NDA. We can also receive a one-time $50 million sales milestone payment upon the first attainment of $750 million in net sales of Oxecta across all Pfizer Territories. In addition, for Oxecta sales occurring on and following February 2, 2013 (the one year anniversary of the first commercial sale of Oxecta), 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.

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 and confirmed by a law enforcement agency, 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 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.

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 following the demonstration in a clinical study that Nexafed met the FDA Guideline standards for bioequivalence to the reference drug Sudafed® marketed by Johnson & Johnson Corporation.

We have shipped Nexafed to several regional and national drug wholesalers for redistribution to pharmacies. We continue to work to expand the wholesaler distribution network for Nexafed. Many of these stocking wholesalers have placed multiple orders with us as pharmacies have begun stocking Nexafed and are depleting the wholesaler inventory.

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. Due to the influence of pharmacists in stocking decisions and pharmacy operations in independent (non-chain) pharmacies, we believe that most of our pharmacy distribution, at this time, is in independent pharmacies, however, we believe that some chain pharmacy stores are stocking Nexafed purchased directly by the store from wholesalers. Transshipment reports provided to us from one wholesaler shows some pharmacies have placed multiple orders with the wholesaler, potentially indicating we are generating some pharmacist recommendations and consumer demand. Through January, 2013 we have shipped approximately $20 thousand in Nexafed sales.

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 pseudoephedrine HCl in combination with other cold and allergy active ingredients	Formulation developed and stability testing ongoing

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 products with commercial partners for distribution 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% in 2011. 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, laboratory, manufacturing, 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 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 manufacturer 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 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 release 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 a/s, KemPharm 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 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 delay development or adversely impact the sales of our products.

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.

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. Highland Pharmaceuticals has recently launched in certain test markets a PSE product that is stated to resist PSE extraction in aqueous solutions.

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. We believe our stimulant product candidate currently in development is encompassed by the 439 Patent.

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

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

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

The FDA Drug Approval Process

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

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

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

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

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

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

Phase 4: 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 ANDA to the FDA including the results of the preclinical and clinical testing, together with, among other things, detailed information on the chemistry, manufacturing, quality controls, and proposed product labeling. There are two types of NDAs; a 505(b)(1) NDA and a 505(b)(2) NDA. A 505(b)(1) NDA is also known as a "full NDA" and is described by section 505(b)(1) of the FD&C Act as an application containing full reports of investigations of safety and effectiveness, in addition to other information. The data in a full NDA is either owned by the applicant or are data for which the applicant has obtained a right of reference. A 505(b)(2) application is one described under section 505(b)(2) of the FD&C Act as an application for which information, or one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted". This provision permits the FDA to rely for approval of an NDA on data not developed by the applicant, such as published literature or the FDA's finding of safety and effectiveness of a previously approved drug. 505(b)(2) applications are submitted under section 505(b)(1) of the FD&C Act and are therefore subject to the same statutory provisions that govern 505(b)(1) applications that require among other things, "full reports" of safety and effectiveness. 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 FDA’s fee schedule, effective on October 1, 2012, for the 2013 fiscal year, the user fee for an application fee requiring clinical data, such as an NDA is $1,958,800. 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 2013 fiscal year is $98,380 and the annual facility fee for facilities used to manufacture prescription drugs and biologics for the 2013 fiscal year is $526,500. A written request can be submitted for a waiver of the application fee for the first human drug application that is filed by a small business, but no waivers for product or establishment fees are available. Where we are subject to these fees, they are significant expenditures that may be incurred in the future and must be paid at the time of submission of each application to FDA.

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

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

The Best Pharmaceuticals for Children Act, or BPCA, became law in 2002 and was subsequently reauthorized and amended by FDAAA. The reauthorization of BPCA provides an additional six months of market exclusivity beyond the expiration date of existing market exclusivities or eligible patents to NDA applicants that conduct acceptable pediatric studies of new and currently-marketed drug products for which pediatric information would be beneficial, as identified by FDA in a Pediatric Written Request. The FD&C Act, as amended by the Pediatric Research Equity Act, or PREA, requires that most applications for drugs and biologics include a pediatric assessment (unless waived or deferred) to ensure the drugs' and biologics' safety and effectiveness in children. Such pediatric assessment must contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective. The pediatric assessments can only be deferred provided there is a timeline for the completion of such studies. FDA may waive (partially or fully) the pediatric assessment requirement for several reasons, including if the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed. The FDA has indicated 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 by FDA may be subject to continuing obligations intended to assure safe use of the products. Specifically, under the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007, or FDAAA, FDA may require Risk Evaluation and Mitigation Strategies, or REMS, to manage known or potential serious risks associated with drugs or biological products. If FDA finds, at the time of approval or afterward, that a REMS is necessary to ensure that the benefits of our products outweigh the risks associated with the products, FDA will require a REMS and, consequently, that we take additional measures to ensure safe use of the product. Components of a REMS may include, but are not limited to, a Medication Guide and/or Patient Package Insert, a marketing and sales communication plan for patients or healthcare providers concerning the drug, Elements To Assure Safe Use, or ETASUs such as, but not limited to, patient, prescriber, and pharmacy registries, and restrictions on the extent or methods of distribution, a REMS implementation system, and a timetable for assessment of the effectiveness of the REMS. The FDA has indicated Pfizer is not required to maintain a REMS for Oxecta.

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

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

FDA’s OTC Monograph Process

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

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

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

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

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

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 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 a Schedule II controlled substances under the CSA, the same as all other oxycodone HCl products. Consequently, their manufacture, shipment, storage, sale and use will be subject to a high degree of regulation. For example, generally, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

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

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

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II and List I Chemicals. Distributions of any Schedule I or II controlled substance must also be accomplished using special order forms, with copies provided to the DEA. Because 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. 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. 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, nine 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 is 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 and we have not generated any revenue from sales of Oxecta.

We anticipate that, for at least the next several years, 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:

- successfully launch of Oxecta in the United States;
- 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 Adminstration; 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 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, Canada 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 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, in view of Pfizer's recent acquisition of King Pharmaceuticals in February 2011, 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 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 our products, which could harm the commercial success of Oxecta and materially affect 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. Pursuant to a letter agreement between us and Pfizer dated September 24, 2012, the effective date of such termination was accelerated from the 12-month period provided in the Pfizer Agreement to the date of the letter agreement. As of such date, 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 commercialize 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 $9.7 million for the year ended December 31, 2012, 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 our FDA approved Oxecta Tablets, for which we only receive royalties on sales occurring on and following February 2, 2013, the one year anniversary of the first commercial sale of Oxecta Tablets;

- 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;

- 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; and

- our successful launch and marketing of Nexafed and other products utilizing our Impede Technology, and market acceptance, increased demand for and sales of Nexafed.

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

We recognized revenues of $0, $20.5 million, $3.3 million and $3.8 million in the years ended December 31, 2012, 2011, 2010 and 2009, respectively, from payments received under the Pfizer Agreement. However, we have not yet generated any royalty revenues from Oxecta product sales. 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 our 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, technology licensing fees and third party financing to fund operations.

Pending the receipt of royalties, if any, under the Pfizer Agreement or milestone payments and royalties under similar license agreements 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, revenues from sales of Nexafed and third-party financing to fund operations and product development activities. No assurance can be given that current cash reserves or revenues from Nexafed product sales will be sufficient to fund the continued operations and development of our product candidates until such time as we generate additional 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.

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 has publicly stated that explicit indications or claims of abuse deterrence will not be permitted unless such indications or claims are supported by double blind controlled clinical studies demonstrating an actual reduction in product abuse by patients or drug abusers. Because the cost, time and practicality of designing and implementing clinical studies adequate to support explicit claims of abuse deterrence are prohibitive, we and Pfizer are not pursuing and have not conducted the clinical trials necessary to include an explicit product label claim of abuse deterrence. Instead, we will rely on certain clinical and laboratory studies to support product labeling describing the relative difficulty of abusing or misusing our products and such products' abuse deterrent features. 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. If the FDA requires that we submit a NDA or ANDA to obtain marketing approval for Nexafed, 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 would be subject to FDA review and approval and there can be no assurance that we will be able to market Nexafed 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, 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 an 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 current good manufacturing practice or 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 may 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 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 an 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 never obtain regulatory approval for any of our product candidates in development. For example, we previously submitted an 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; 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 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 will compete in the highly competitive market for cold, sinus and allergy products generally available to the consumer without a prescription. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in marketing their competing products. Category leading brands are often supported by regional and national advertising and promotional efforts. 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 even if commercialized, 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.

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; and

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

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.

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, if any, 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. Pfizer has advised us that it will not exercise its first right under our license agreement to control the enforcement of our patents licensed to Pfizer for Oxecta against these generic sponsors. As a result, on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. - Florida, Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc. 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*."

Litigation is inherently uncertain and we cannot predict the outcome of the Paragraph IV Proceedings. If any of these generic companies 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, or 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 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. 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 a/s, KemPharm 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.

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 profits.

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 certain employees, 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, Care Capital Investments II, LP and its affiliate and Essex Woodlands Health Ventures V, beneficially own approximately 29.8%, 23.0% and 22.2%, 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, 34,243,273 shares (representing approximately 65% of our shares outstanding on a fully-diluted basis – including all derivative securities, whether or not currently exercisable) are available for resale by selling stockholders under the registration statement. If some or all of the shares included in such registration statement are sold by our affiliates and others it may have the effect of depressing the trading price of our common stock. In addition, such sales could 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 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. As of December 31, 2012, our directors, executive officers, Galen Partners III, L.P. and its affiliates, Care Capital Investments II, LP and its affiliate, and Essex Woodlands Health Ventures V, L.P. owned an aggregate of approximately 73% of our common stock, or 33,507,053 shares. They will be 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 2012 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, 2014. 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. Pfizer has advised us that they will not exercise their first right under the Pfizer Agreement to control the enforcement of our patents licensed to Pfizer for Oxecta against these generic sponsors. As a result, on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. – Florida (Watson), Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc. 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 January 2, 2013, our motion to dismiss the suit against Watson on the grounds that Watson had amended its ANDA from a Paragraph IV certification to Paragraph III, which indicated its intent not to market its product in advance of our patents expiring, was accepted by the Court.

Litigation is inherently uncertain and we cannot predict the outcome of these infringement actions. If any of these generic companies 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.

Citizen's Petition filing with FDA

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 a 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.

On September 21, 2012, Pfizer, as licensee of our Aversion Technology used in Oxecta under the Pfizer Agreement, filed a Citizen's Petition with the FDA requesting that the FDA: (1) refrain from permitting an ANDA applicant to rely on Oxecta as a reference listed drug unless the ANDA applicant demonstrates that its product uses the same inactive ingredients as those in Oxecta; (ii) require an ANDA applicant seeking approval of a product that relies on Oxecta as the reference listed drug and uses inactive ingredients different from those in Oxecta to submit an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetics Act; and (iii) refrain from rating a product as therapeutically equivalent to Oxecta unless it has the same inactive ingredients as Oxecta. On February 15, 2013 the FDA denied without comment this Citizen's Petition.

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 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. To date, Acura has not been served with any metoclopramide lawsuits in jurisdictions other than Philadelphia, New Jersey and California state courts.

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. On November 28, 2012, the Pennsylvania Superior Court heard the appellate oral argument. A decision on this appeal should be issued later this year and a further appeal to the Pennsylvania Supreme Court likely will follow. 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 issued an April 17, 2012 ruling (confirmed in 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, plaintiffs are now permitted to proceed with their lawsuits including state law claims based on (1) failing to communicate warnings to physicians through "Dear Doctor" letters; (2) failure to update labeling to adopt brand labeling changes; and (3) failure to withdraw generic products from the market. Despite its refusal to grant the demurrer or motion to strike, the California trial court 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. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to this matter as of December 31, 2012. Legal fees related to this matter are currently covered by our insurance carrier.

ITEM 4. MINE SAFETY DISLCOSURES

Not Applicable.

PART II

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

Market and Market Prices of Common Stock

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

Period	Sale Prices	
	High	Low
2011 Fiscal Year		
First Quarter	$ 3.62	$ 2.91
Second Quarter	6.80	3.16
Third Quarter	4.10	2.28
Fourth Quarter	5.49	2.97
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 (through January 31, 2013)	$ 2.77	$ 1.81

Holders

There were approximately 600 holders of record of our common stock on February 28, 2013. 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 2013 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, 2012, 2011, 2010, 2009 and 2008 are derived from our audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2012 and 2011 and for each of the years in the three-year period ended December 31, 2012, and the reports thereon, are included elsewhere in this Report. The selected financial information presented for our 2009 and 2008 operations and for our 2010, 2009 and 2008 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	2012	2011	2010	2009	2008
Revenues	$ —	$ 20,466	$ 3,311	$ 3,835	$ 44,437
Operating expenses:					
Research and development[1]	3,726	4,037	7,177	5,673	14,322
Selling, general and administrative[2]	6,013	5,895	8,858	11,662	9,133
Interest expense	—	—	—	—	—
Interest income	79	32	42	147	780
Other (expense) income	(8)	(34)	(14)	(3)	(3)
(Loss) income before income tax	(9,668)	10,532	(12,696)	(13,356)	21,759
Income tax expense (benefit)	—	147	11	2,479	7,285
Net (loss) income applicable to common stockholders	(9,668)	$ 10,385	$ (12,707)	$ (15,835)	$ 14,474
(Loss) earnings per share: Basic	$ (0.20)	$ 0.22	$ (0.27)	$ (0.35)	$ 0.32
(Loss) earnings per share: Diluted	$ (0.20)	$ 0.22	$ (0.27)	$ (0.35)	$ 0.29
Weighted average shares used in computing net earnings (loss) per share: Basic	47,521	47,496	47,029	45,932	45,675
Weighted average shares used in computing net earnings (loss) per share: Diluted	47,521	48,007	47,029	45,932	49,416

(1) Includes stock-based compensation expense of approximately $400, $500, $1,700, $1,900 and $600 for years 2012, 2011, 2010, 2009 and 2008, respectively.
(2) Includes stock-based compensation expense of approximately $1,300, $1,900, $5,100, $7,300 and $3,300 for years 2012, 2011, 2010, 2009 and 2008, respectively.

BALANCE SHEET DATA (in thousands)	2012	2011	2010	2009	2008
Working capital	$ 26,572	$ 35,599	$ 23,289	$ 28,750	$ 35,991
Total assets	29,054	37,173	25,493	31,917	42,961
Total liabilities	1,424	530	1,152	2,007	5,897
Accumulated deficit	(335,211)	(325,543)	(335,928)	(323,221)	(307,386)
Stockholders' equity	$ 27,630	$ 36,643	$ 24,341	$ 29,910	$ 37,064

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 an October 2007 license agreement, or Pfizer Agreement, 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. We have launched Nexafed® (pseudoephedrine HC1) tablets formulated with our Impede Technology.

We have 7 additional opioid products utilizing Aversion in various stages of development. Pursuant to a September 24, 2012 letter agreement with Pfizer, all rights to these development-stage opioid products have reverted back to us. Hydrocodone bitartrate with acetaminophen, 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. Pfizer previously completed a clinical study demonstrating the hydrocodone/acetaminophen product is bioequivalent to its reference listed drug. We filed an Investigation New Drug application, or IND, with the Food and Drug Administration, or FDA, on December 20, 2012. We expect that the development program for our hydrocodone/acetaminophen product and our other Aversion opioid products in development will be consistent with that of Oxecta. We anticipate submitting a 505(b)(2) New Drug Application, or NDA, with the FDA for our hydrocodone/acetaminophen product in the first half of 2014.

We launched Nexafed commercially in mid-December 2012 into the $1 billion United States over the counter, or OTC, market for cold and allergy products. 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. We also have been working on the 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, 2012, we had cash, cash equivalents and marketable securities of $27.4 million compared to $35.7 million of cash and cash equivalents at December 31, 2011. We had working capital of $26.6 million at December 31, 2012 compared to working capital of $35.6 million at December 31, 2011. We had an accumulated deficit of approximately $335.2 million and $325.5 million at December 31, 2012 and December 31, 2011, respectively. We had a loss from operations of $9.7 million and a net loss of $9.7 million for the year ended December 31, 2012, compared to income from operations of $10.5 million and net income of $10.4 million for the year ended December 31, 2011. As of January 31, 2013 we had cash, cash equivalents and marketable securities of approximately $25.5 million.

During the year ended December 31, 2012, we recognized gross product sales of $6 thousand derived from the sale of our Nexafed Tablets to two regional wholesalers which were completely offset by a return goods reserve until demand for Nexafed is established. During the year ended December 31, 2011, we recognized revenues of $0.5 million derived from the amortized portion of the $30.0 million upfront cash payment received from Pfizer's King Pharmaceuticals subsidiary in December 2007, and a $20.0 million milestone fee paid by Pfizer under the Pfizer Agreement relating to FDA approval of the NDA for Oxecta. During the year ended December 31, 2010, we recognized revenues of $3.3 million derived from the $1.1 million amortized portion of the $30.0 million upfront cash payment received from Pfizer's King Pharmaceutical subsidiary in December 2007 and $2.2 million for reimbursement of research and development expenses for Oxecta Tablets. We have yet to generate any royalty revenues from Pfizer's sale of Oxecta Tablets. To fund our continued operations, we expect to rely on our current cash resources, additional payments that may be made under Pfizer Agreement and 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 prosecution 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 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, 2012 and 2011

	December 31			
	2012	2011	Change	
	$000's		$000's	Percent
Revenues				
Program fee revenue	—	466	(466)	(100)
Milestone revenue	—	20,000	(20,000)	(100)
Total revenue	—	20,466	(20,466)	(100)
Operating expenses				
Research and development	3,726	4,037	(311)	(8)
Selling, 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)
Other income (expense)				
Interest income	79	32	47	147
Other expense	(8)	(34)	26	76
Total other income (expense)	71	(2)	73	3,650
Income (loss) before income tax	(9,668)	10,532	(20,200)	(192)
Income tax expense	—	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, in 2012 there was a $0.2 million decrease in development expenses 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, in 2012 there was an increase of $0.7 million in marketing, general and administrative expenses compared to 2011 primarily attributable to Nexafed development and promotion.

Other Income (Expense)

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.

Net Income (Loss)

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.

Results of Operations for the Years Ended December 31, 2011 and 2010

	December 31		Change	
	2011	2010		
	$000's		$000's	Percent
Revenues				
Program fee revenue	466	1,088	(622)	(57)
Collaboration fee revenue	—	2,233	(2,233)	(100)
Milestone revenue	20,000	—	20,000	—
Total revenue	20,466	3,311	17,155	518
Operating expenses				
Research and development	4,037	7,177	(3,140)	(44)
Selling, general and administrative	5,895	8,858	(2,963)	(33)
Total operating expenses	9,932	16,035	(6,103)	(38)
Income (loss) from operations	10,534	(12,724)	23,258	183
Other income (expense)				
Interest income	32	12	20	167
Other expense	(34)	(14)	(20)	(142)
Total other income (expense)	(2)	28	(30)	(107)
Income (loss) before income tax	10,532	(12,696)	23,228	183
Income tax expense	147	11	136	1,236
Net income (loss)	10,385	(12,707)	23,092	182

Revenue

In December 2007, Pfizer paid us a $30.0 million upfront fee in connection with the closing of the Pfizer Agreement. Program fee revenue recognized during 2011 from amortizing this upfront fee was $0.5 million compared to $1.1 million in 2010. We have assigned an equal portion of the program fee revenue to each of three product candidates identified under the Pfizer Agreement. We have completed our development activities on all 3 product candidates, fully amortized the portion of the upfront fee for two product candidates in 2008, and fully amortized the portion of the upfront fee for the third product candidate in 2011. We had milestone revenue of $20.0 million and $0 in 2011 and 2010, respectively.

In 2011 we incurred no development or regulatory expenses relating to the licensed products pursuant to the Pfizer Agreement, and therefore recognized no collaboration revenue for such year. We do not expect collaboration revenue from Pfizer in 2012. The Company had collaboration revenue of $2.2 million for 2010.

Operating Expenses

Research and development expense during 2011 and 2010 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 2011 and 2010 results are non-cash stock-based compensation charges of $0.5 million and $1.7 million, respectively, associated with the grant of stock options and restricted stock units. Excluding the stock-based compensation expense, in 2011 there was a $2.0 million decrease in development expenses compared to 2010 primarily attributable to a reduction in development activities for our Aversion Technology product candidates.

Marketing expenses during 2011 and 2010 consisted of market research studies on our Aversion and Impede Technologies. Our general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll. Included in the 2011 and 2010 results are non-cash stock-based compensation charges of $1.9 million and $5.1 million, respectively, associated with the grant of stock options and restricted stock units. Excluding the stock-based compensation expense, in 2011 there was an increase of $0.2 million in marketing, general and administrative expenses compared to 2010.

Other Income (Expense)

During 2011 and 2010, we had no debt and cash proceeds received pursuant to the Pfizer Agreement were invested in U.S. Treasury Bills and money market funds in accordance with the investment policy approved by our Board of Directors, resulting in minimal interest income in 2011 and 2010 due to the prevailing low variable, market rates of interest.

Net Income (Loss)

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 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. The net loss of $12.7 million for 2010 includes no federal or state income tax benefit provisions due to uncertainty of their future utilization. A state tax expense was recorded for the Company’s subsidiary operations apportioned to one state jurisdiction.

Liquidity and Capital Resources

At December 31, 2012, we had cash, cash equivalents and marketable securities of $27.4 million compared to $35.7 million in cash and cash equivalents at December 31, 2011. We had working capital of $26.6 million at December 31, 2012 compared to $35.6 million at December 31, 2011. Our investing activities in 2012 and 2011 were less than $0.2 million due to capital expenditures.

At January 31, 2013, we had cash, cash equivalents and marketable securities of approximately $25.5 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.

Pending our receipt of royalty payments from Pfizer related to Oxecta, other milestone and royalty payments under similar license agreements anticipated to be negotiated and executed with other pharmaceutical company partners, and revenues from the commercialization of our Nexafed tablets, we must rely on 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 royalties under the Pfizer Agreement and milestone payments and royalties under similar license agreements with other pharmaceutical company partners, for which there can be no assurance, and from the commercialization of our Nexafed tablets.

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, 2012:

	Payments due by period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	$ 31	$ 25	$ 6	$ —	$ —
Contract manufacturing	179	179	—	—	—
Clinical studies	1,527	1,527	—	—	—
Employment agreements	602	602	—	—	—
Total	$ 2,339	$ 2,333	$ 6	$ —	$ —

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, Deferred Program Fee Revenue and Collaboration Revenue

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 the fourth quarter of 2012. The Company sells Nexafed in the United States to wholesale pharmaceutical distributors subject to the right of return for a period of up to six 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. Accordingly, the Company defers recognition of revenue on the product shipments of Nexafed until the right of return no longer exists or adequate history and information is available to estimate product returns.

In connection with Pfizer Agreement, we recognize program fee revenue, collaboration revenue and milestone revenue.

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's King subsidiary 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 have 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 $0, $0.5, $1.1 million, $3.1 million and $21.9 million of this program fee revenue in 2012, 2011, 2010, 2009 and 2008, respectively. We do not expect any further program fee revenue from Pfizer.

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 ongoing research and development services being provided to Pfizer under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with Pfizer. We recognized $0, $0, $2.2 million, $0.8 million and $11.5 million of collaboration revenue in 2012, 2011, 2010, 2009 and 2008, respectively. We do not expect any further collaboration revenue from Pfizer.

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 2008, Pfizer paid us a $5.0 million milestone payment for successfully achieving the primary endpoints in our pivotal Phase III study, AP-ADF-105 for Aversion oxycodone HCl with Niacin Tablets. In June 2011, Pfizer paid us a $20.0 million milestone fee relating to the receipt of FDA approval of the NDA for Oxecta. Under the Pfizer Agreement, we remain eligible to receive milestone payments for the achievement of certain net sales level of Oxecta and a regulatory milestone for the approval of Oxecta in another territory. There can be no assurance, however, that Pfizer will achieve these milestones.

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 $1,527,000 and $133,000 at December 31, 2012 and 2011, 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, 2012, 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. We recorded adjustments by way of increase of $2.5 million to the deferred income tax asset valuation allowance during 2009. This adjustment recognized a $2.5 million tax expense from income taxes in our income for 2009. 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 2012, 2011 and 2010 were $147,000, $132,000 and $41,000, 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, 2012, our investments consisted of corporate bonds, exchange-traded funds and another security instrument investing in U.S. Treasuries, U.S. agency securities and agency mortgage backed securities.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

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

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. 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, management believes that, as of December 31, 2012, 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 2012 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 2013 Proxy Statement to be filed with the SEC on or about March 11, 2013 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 2013 Proxy Statement to be filed with the SEC on or about March 11, 2013 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 2013 Proxy Statement to be filed with the SEC on or about March11, 2013 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 2013 Proxy Statement to be filed with the SEC on or about March 11, 2013 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 2013 Proxy Statement to be filed with the SEC on or about March 11, 2013 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 28, 2013

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 28, 2013
/s/Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2013
/s/William G. Skelly William G. Skelly	Director	February 28, 2013
/s/Bruce F Wesson Bruce F. Wesson	Director	February 28, 2013
/s/Richard J. Markham Richard J. Markham	Director	February 28, 2013
/s/Immanuel Thangaraj Immanuel Thangaraj	Director	February 28, 2013
/s/George K. Ross George K. Ross	Director	February 28, 2013

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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, 2012 and 2011 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, 2012. 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, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012**,** in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP
Chicago, Illinois
March 4, 2013

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2012 and 2011
(in thousands except par value)

	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	$ 7,476	$ 35,685
Marketable securities	19,946	-
Finished goods inventory, net	219	-
Income taxes refundable	43	153
Prepaid expenses and other current assets	307	291
Total current assets	27,991	36,129
Property, plant and equipment, net	1,052	1,044
Other assets	11	-
Total assets	$ 29,054	$ 37,173
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 994	$ 53
Accrued expenses	413	477
Other current liabilities	12	-
Total current liabilities	1,419	530
Other liabilities	5	-
Total liabilities	1,424	530
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Common stock: $.01 par value per shares; 100,000 shares authorized, 45,867 and 45,320 shares issued and outstanding in 2012 and 2011, respectively	459	453
Additional paid-in capital	362,422	361,733
Accumulated deficit	(335,211)	(325,543)
Accumulated other comprehensive income (loss)	(40)	-
Total stockholders' equity	27,630	36,643
Total liabilities and stockholders' equity	$ 29,054	$ 37,173

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPRENESIVE INCOME (LOSS)
YEARS ENDED DECEMBER 31, 2012, 2011 and 2010
(in thousands except per share amounts)

	2012	2011	2010
Revenues:			
Program fee revenue	$ -	$ 466	$ 1,088
Collaboration revenue	-	-	2,223
Milestone revenue	-	20,000	-
Total revenues	-	20,466	3,311
Operating expenses:			
Research and development	3,726	4,037	7,177
Selling, general and administrative	6,013	5,895	8,858
Total operating expenses	9,739	9,932	16,035
Operating income (loss)	(9,739)	10,534	(12,724)
Non-operating income (expense):			
Interest income	79	32	42
Other expense, net	(8)	(34)	(14)
Total other income (expense), net	71	(2)	28
Income (loss) before income taxes	(9,668)	10,532	(12,696)
Provision for income taxes	-	147	11
Net income (loss)	$ (9,668)	$ 10,385	$ (12,707)
Other comprehensive income (loss):			
Unrealized gains (losses) on securities	(40)	-	-
Total other comprehensive income (loss)	(40)	-	-
Comprehensive income (loss)	$ (9,708)	$ 10,385	$ (12,707)
Earnings (loss) per share:			
Basic	$ (0.20)	$ 0.22	$ (0.27)
Diluted	$ (0.20)	$ 0.22	$ (0.27)
Weighted average shares outstanding:			
Basic	47,521	47,496	47,029
Diluted	47,521	48,007	47,029

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2012, 2011 and 2010
(in thousands)

	Common Stock Shares	Common Stock $ Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
Balance at Dec. 31, 2009	43,728	$ 437	$ 352,694	$ (323,221)	$ -	$ 29,910
Comprehensive loss: net loss for the year ended Dec. 31, 2010	-	-	-	(12,707)	-	(12,707)
Share-based compensation	-	-	6,746	-	-	6,746
Issuance of common stock for cashless exercise of warrants	43	1	(1)	-	-	-
Issuance of common stock for exercise of warrant	123	1	391	-	-	392
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

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2012, 2011, and 2010
(in thousands)

	2012	2011	2010
Cash Flows from Operating Activities:			
Net income (loss)	$ (9,668)	$ 10,385	$ (12,707)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:			
Depreciation and amortization	131	131	135
Share-based compensation	1,733	2,458	6,746
Loss on asset disposals	8	8	14
Changes in assets and liabilities			
Inventories, net	(219)	-	-
Collaboration revenue receivable	-	126	231
Income taxes refundable	110	(141)	
Prepaid expenses and other current assets	(16)	(33)	(37)
Accounts payable	941	53	-
Accrued expenses	(64)	(209)	226
Deferred program fee revenue	-	(466)	(1,088)
Other assets and liabilities	6	-	-
Net cash (used in) provided by operating activities	(7,038)	12,312	(6,480)
Cash Flows from Investing Activities:			
Purchases of marketable securities	(20,306)	-	-
Proceeds from sale of marketable securities	320	-	-
Additions to property, plant and equipment	(147)	(131)	(41)
Net cash used in investing activities	(20,133)	(131)	(41)
Cash Flows from Financing Activities:			
Proceeds from exercise of stock options	9	217	-
Proceeds from distribution of restricted stock units	1	5	-
Proceeds from warrant exercise	-	1,076	392
Statutory minimum withholding taxes paid on the distribution of common stock pursuant to restricted stock unit plan and exercise of stock options	(1,048)	(1,839)	-
Net cash (used in) provided by financing activities	(1,038)	(541)	392
Net (decrease) increase in cash and cash equivalents	(28,209)	11,640	(6,129)
Cash and cash equivalents at beginning of period	35,685	24,045	30,174
Cash and cash equivalents at end of period	$ 7,476	$ 35,685	$ 24,045
Supplemental Disclosures of Cash Flow Information:			
Cash paid during the year for:			
Interest	$ -	$ 26	$ -
Income taxes, net of refunds	$ (108)	$ 284	$ 20

See accompanying Notes to Consolidated Financial Statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
YEAR ENDED DECEMBER 31, 2012, 2011, and 2010

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

Year ended December 31, 2012

1. 829 shares of common stock were distributed pursuant to our Restricted Stock Unit Plan utilizing various cashless exercise features of the plan and after withholding 2 shares for $7 in exercise costs and withholding 296 shares for $1.0 million in statutory minimum payroll taxes, 531 shares of common stock were issued.
2. Options to purchase 24 shares of common stock were exercised utilizing various cashless exercise features of the plan and after withholding 10 shares for $31 in exercise costs and withholding 5 shares for $15 in statutory minimum payroll taxes, 9 shares of common stock were issued.

Year ended December 31, 2011

1. 829 shares of common stock were distributed pursuant to our RSU Plan utilizing various cashless exercise features of the plan and after withholding 1 shares for $3 in exercise costs and withholding 288 shares for $948 in statutory minimum payroll taxes, 540 shares of common stock were issued.
2. Options to purchase 935 shares of common stock were exercised utilizing various cashless exercise features of the plan and after withholding 324 shares for $1.3 million in exercise costs and withholding 228 shares for $886 in statutory minimum payroll taxes, 383 shares of common stock were issued.

Year ended December 31, 2010

1. Warrants to purchase 65 shares of common stock were exercised in cashless exercise transactions resulting in the net issuance of 43 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, 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. In late December 2012 we launched in the United States Nexafed® (pseudoephedrine HC1) tablets formulated with our Impede Technology.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The consolidated financial statements include the accounts of its 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, and trade accounts payable. The carrying amounts of these financial instruments, other than marketable securities, are representative of their respective fair values due to their relatively short maturities. 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 high 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. 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 due to the recent market launch of Nexafed® late in December 2012.

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. We had inventory valued at $0.2 million at December 31, 2012. We had no inventory at December 31, 2011. Purchases 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

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 the fourth quarter of 2012. The Company sells Nexafed in the United States to wholesale pharmaceutical distributors subject to the right of return for a period of up to six 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. Accordingly, the Company defers recognition of revenue on the product shipments of Nexafed until the right of return no longer exists or adequate history and information is 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.

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 2012 and $0.5 million and $1.1 million of program fee revenue in 2011 and 2010, respectively.

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. We recognized $2.2 million of collaboration revenue in 2010. There are no ongoing research and development services being provided to Pfizer and we had no collaboration revenue in 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 launch of Nexafed in the fourth quarter of 2012 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 had no accrued CRO costs at December 31, 2012 and had accrued $28 thousand of CRO and clinical trial study expenses at December 31, 2011.

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, 2012 and 2011, 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.

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).

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 RSUs (See Note 9). 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 2012 or 2010 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,		
	2012	2011	2010
	(in thousands except per share data)		
EPS - basic			
Numerator: net income (loss)	$ (9,668)	$ 10,385	$ (12,707)
Denominator:			
Common shares	45,863	45,016	43,842
Vested RSUs	1,658	2,480	3,187
Basic weighted average shares outstanding	47,521	47,496	47,029
EPS - basic	$ (0.20)	$ 0.22	$ (0.27)
EPS – assuming dilution			
Numerator: net income (loss)	$ (9,668)	$ 10,385	$ (12,707)
Denominator:			
Common shares	45,863	45,016	43,842
Vested RSUs	1,658	2,489	3,187
Stock options	-	366	-
Common stock warrants	-	136	-
Diluted weighted average shares outstanding	47,521	48,007	47,029
EPS - diluted	$ (0.20)	$ 0.22	$ (0.27)
Excluded dilutive securities:			
Common stock issuable:			
Stock options	3,296	2,805	4,243
Common stock warrants	1,856	-	2,193
RSUs	-	-	49
Total excluded potentially dilutive shares	5,152	2,805	6,485

Share-based Compensation

We have three share-based compensation plans covering stock options and Restricted Stock Units ("RSU") for our employees and directors, which are described more fully in Note 9.

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,		
	2012	2011	2010
	(in thousands)		
Research and development:			
Stock option awards	$ 375	$ 457	$ 1,419
RSU awards	-	75	278
	375	532	1,697
Selling, general and administrative:			
Stock option awards	1,358	1,698	4,365
RSU awards	-	228	684
	1,358	1,926	5,049
Total	$ 1,733	$ 2,458	$ 6,746

Recent Accounting Pronouncements

In June 2011, the FASB issued a final standard requiring entities to present net income and other comprehensive income in either a single continuous statement or in two separate, but consecutive, statements of net income and other comprehensive income. The new standard eliminates the option to present items of other comprehensive income in the statement of changes in equity. The new requirements do not change which components of comprehensive income are recognized in net income or other comprehensive income, or when an item of other comprehensive income must be reclassified to net income. Also, earnings per share computations do not change. The new requirements are effective for interim and annual periods beginning after December 15, 2011, with early adoption permitted. Full retrospective application is required. The Company adopted this standard for the annual period ended December 31, 2011 but because we had no other comprehensive income, there was no change in our financial statement presentations. During 2012 we had other comprehensive income and had applied retroactive application to the annual periods ended December 31, 2011 and 2010. The Company elected to present net income and other comprehensive income in a single continuous statement of net income and other comprehensive income. As this standard related only to the presentation of other comprehensive income, the adoption of this accounting standard did not have an impact on the Company's consolidated financial statements.

NOTE 3 – LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

On October 30, 2007, we and King Pharmaceuticals Research and Development, Inc., now a wholly-owned subsidiary of Pfizer, entered into the Pfizer Agreement to develop and commercialize in the United States, Canada and Mexico certain opioid analgesic products utilizing our proprietary Aversion Technology. The Pfizer Agreement initially provided Pfizer with an exclusive license in the United States, Canada and Mexico, or the Pfizer Territory, for Oxecta (oxycodone HCl) Tablets and oxycodone HCl/acetaminophen tablets utilizing Aversion Technology. In addition, the Pfizer Agreement provided Pfizer with an option to license in the Pfizer Territory certain future opioid analgesic products developed utilizing Aversion Technology. Pfizer exercised its option to license two additional product candidates including an undisclosed immediate-release opioid analgesic tablet product and hydrocodone bitartrate/acetaminophen tablets, each of which utilize our Aversion Technology. On September 24, 2012, we entered into a letter agreement with Pfizer which amends the Pfizer Agreement and provides for the termination of Pfizer's license to our Aversion® Technology used in the three development-stage products licensed to Pfizer and for the transfer of these products back to us. These development-stage products are hydrocodone bitartrate/acetaminophen tablets, oxycodone HCl/acetaminophen tablets and an undisclosed opioid.

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 in all Pfizer Territories. Subject to the Pfizer Agreement, Pfizer will have final decision making authority with respect to all regulatory and commercialization activities for Oxecta.

As of December 31, 2012, we had received aggregate payments of $78.5 million from Pfizer, consisting of a $30.0 million non-refundable upfront cash payment, $17.5 million in reimbursed research and development expenses relating to licensed products, $6.0 million in fees relating to Pfizer's exercise of its option to license an undisclosed immediate-release opioid analgesic tablet product and hydrocodone bitartrate/acetaminophen tablets, a $5.0 million milestone fee relating to our successful achievement of the primary endpoints for our pivotal Phase III clinical study for Aversion oxycodone HCl with niacin tablets and a $20.0 million milestone fee relating to the FDA's approval of the Oxecta Tablets NDA. We received none of these payments from Pfizer during 2012. We can also receive a one-time $50 million sales milestone payment upon the first attainment of $750 million in net sales of Oxecta across all Pfizer Territories. In addition, for Oxecta sales occurring on and following February 2, 2013 (the one year anniversary of the first commercial sale of Oxecta), 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.

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. Pfizer has advised us that they will not exercise their first right under the Pfizer Agreement to control the enforcement of our patents licensed to Pfizer for Oxecta against these generic sponsors. As a result, on October 31, 2012, we initiated suit against each of Watson Laboratories, Inc. – Florida ("Watson"), Par Pharmaceutical, Inc., Impax Laboratories, Inc. and Sandoz Inc. 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 January 2, 2013, our motion to dismiss the suit against Watson on the grounds that Watson had amended its ANDA from a Paragraph IV certification to Paragraph III, which indicated its intent not to market its product in advance of our patents expiring, was accepted by the Court.

Litigation is inherently uncertain and we cannot predict the outcome of these infringement actions. If any of these generic companies 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 materially adversely affect the Company's operations and financial condition.

NOTE 4 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows:

	December 31,	
	2012	2011
	(in thousands)	
Building and improvements	$ 1,259	$ 1,252
Scientific equipment	595	583
Computer hardware and software	255	270
Machinery and equipment	229	117
Land and improvements	162	162
Other personal property	70	70
Office equipment	27	27
	2,597	2,481
Less accumulated depreciation and amortization	(1,545)	(1,437)
Total property, plant and equipment, net	$ 1,052	$ 1,044

Depreciation and amortization expense was approximately $0.1 million for each of the years ended December 31, 2012, 2011, and 2010.

NOTE 5 – ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	December 31, 2012	December 31, 2011
	(in thousands)	
Professional services	$ 216	$ 191
Other fees and services	75	42
Payroll, payroll taxes and benefits	55	104
Clinical and regulatory services	21	59
Contract manufacture services	21	-
Property taxes	20	21
Franchise taxes	5	60
	$ 413	$ 477

NOTE 6 – INVESTMENTS IN MARKETABLE SECURITIES

Investments in marketable securities consisted of the following:

	December 31, 2012 (in millions)
Marketable securities:	
Corporate bonds — maturing within one year	$ 1.2
Corporate bonds — maturing after one through four years	6.3
Pooled investment fund	8.0
Exchange-traded funds	4.4
Total marketable securities	$ 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 table provides a summary of the fair value and unrealized gains (losses) related to the Company's available-for-sale securities:

	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, 2012 meeting fair value measurement.

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

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

NOTE 7 – COMMON STOCK WARRANTS

The Company has outstanding common stock purchase warrants at December 31, 2012 exercisable for 1.9 million shares of common stock, all of which contain a cashless exercise feature. These warrants have an exercise price of $3.40 per share and expiration date of August 2014.

NOTE 8 – 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,		
	2012	2011	2010
	(in thousands)		
Tax (benefit) at U.S. statutory 34% tax rate	$ (3,287)	$ 3,510	$ (4,320)
State taxes (benefit), net of federal effect	-	6	(56)
Research and development tax credits	-	(77)	(45)
Share-based compensation	473	626	-
Other	2	(55)	(316)
Change in valuation allowance	2,812	(3,863)	4,748
Provision for income taxes	$ -	$ 147	$ 11

The tax expense 2011 is federal alternative minimum taxes (“AMT”) and current state taxes, and for 2010 it is 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 $26.7 million federal income tax benefits at December 31, 2012 derived from $78.5 million Federal NOLs at the U.S. statutory tax rate of 34%, 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 2013 and 2031 if not used, and those expirations will cause fluctuations in our valuation allowances. The components of our deferred tax assets are as follows:

	December 31,	
	2012	2011
	(in thousands)	
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	$ 26,674	$ 22,963
- State	4,434	4,179
Research and development tax credits	887	887
Deferred program fee revenue	-	-
Share-based compensation	3,486	4,628
Other, net	(20)	(8)
Total deferred taxes	35,461	32,649
Valuation allowance	(35,461)	(32,649)
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. In 2011 we decreased our valuation allowance to utilize the NOLs to offset our taxable income from our 2011 operating results; however we still incurred an AMT liability. We continue to maintain full valuation allowance against all of our deferred tax assets at December 31, 2012 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, 2012, 2011, and 2010 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, 2012, the Company's tax years 2009, 2010 and 2011 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 tax authorities for years before 2009. Tax year 2008 was open as of December 31, 2011.

NOTE 9 – 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 15% of their annual earnings. The Plan provides that the Company can make discretionary matching contributions equal to 25% of the first 6% of employee contributions for an aggregate employee contribution of 1.5%, along with a discretionary profit-sharing contribution. We did not contribute matching or profit sharing contributions for the Plan in years 2012, 2011, and 2010.

Stock Option Plans

We maintain various stock option plans. A summary of our stock option plans as of December 31, 2012, 2011, and 2010 and for the years then ended consisted of the following:

	Years Ended December 31,					
	2012		2011		2010	
	(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	3,556	$ 6.41	4,243	$ 5.40	3,671	$ 5.90
Granted	475	2.80	491	3.63	649	3.36
Exercised	(31)	1.30	(1,102)	1.33	-	-
Forfeited or expired	(704)	8.43	(76)	3.15	(77)	10.10
Outstanding, ending	3,296	$ 5.50	3,556	$ 6.41	4,243	$ 5.40
Options exercisable	2,763	$ 5.99	2,962	$ 7.01	3,528	$ 5.71

The following table summarizes information about nonvested stock options outstanding at December 31, 2012:

	Number of Options Not Exercisable	Weighted Average Fair Value
	(in thousands except per price data)	
Outstanding at December 31, 2011	594	$ 3.22
Granted	475	2.62
Vested	(536)	3.52
Forfeited	-	-
Outstanding at December 31, 2012	533	$ 2.77

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, our stock options have been held until their expiration date. The assumptions used in the Black-Scholes model to determine fair value for the 2012, 2011 and 2010 stock option grants were:

	2012	2011	2010
Expected dividend yield	0.0%	0.0%	0.0%
Risk-free interest rates	1.7% to 2.0%	1.9% to 3.4%	3.5% to 3.9%
Average expected volatility	114%	114%	119%
Expected term (years)	10	10	10
Weighted average grant date fair value	$ 2.60	$ 3.39	$ 3.18

As of December 31, 2012, 2011 and 2010 the aggregate intrinsic value of the option awards which were vested was $0.1 million, $0.3 million, and $2.4 million, respectively. In addition, the aggregate intrinsic value of option awards exercised during the year ended December 31, 2012 and 2011 was $0.1 million and $2.7 million, respectively. There were no options exercised in 2010. The total remaining unrecognized compensation cost related to the unvested option awards at December 31, 2012 was $1.5 million and is expected to be recognized in varying amounts over the twent-three months remaining in the requisite service period.

During 2012, options to purchase 24 thousand shares of common stock were exercised utilizing various cashless exercise features of our stock option plan and after withholding shares for $31 thousand in exercise costs and $15 thousand in statutory minimum payroll taxes, we issued 9 thousand shares of common stock. During 2011 options to purchase 0.9 million shares of common stock were exercised utilizing various cashless exercise features of our stock option plan and after withholding shares for $1.3 million in exercise costs and $0.9 million in statutory minimum payroll taxes, we issued 0.4 million 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, 2012, 2011, and 2010, and for the years then ended consisted of the following:

	Years Ended December 31,					
	2012		2011		2010	
	(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	2,487	2,487	3,316	3,267	3,316	3,112
Granted	-	-	-	-	-	-
Distributed	(829)	(829)	(829)	(829)	-	-
Vested	-	-	-	49	-	155
Forfeited or expired	-	-	-	-	-	-
Outstanding, ending	1,658	1,658	2,487	2,487	3,316	3,267

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. During 2011 all of the remaining unvested RSU awards became vested. The weighted average fair value of a RSU outstanding at December 31, 2012 is $3.75.

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. 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, 2012, 2013 and 2014. 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. Each distribution date 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.

NOTE 10 – COMMITMENTS AND CONTINGENCIES

Facility Lease

The Company leases administrative office space in Palatine Illinois under a lease expiring March 31, 2014 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 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. To date, Acura has not been served with any metoclopramide lawsuits in jurisdictions other than Philadelphia, New Jersey and California state courts.

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. On November 28, 2012, the Pennsylvania Superior Court heard the appellate oral argument. A decision on this appeal should be issued later in 2013 and a further appeal to the Pennsylvania Supreme Court likely will follow. 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 issued an April 17, 2012 ruling (confirmed in 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, plaintiffs are now permitted to proceed with their lawsuits including state law claims based on (1) failing to communicate warnings to physicians through "Dear Doctor" letters; (2) failure to update labeling to adopt brand labeling changes; and (3) failure to withdraw generic products from the market. Despite its refusal to grant the demurrer or motion to strike, the California trial court 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. As any potential loss is neither probable nor estimable, we have not accrued for any potential loss related to this matter as of December 31, 2012. Legal fees related to this matter are currently 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. 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, 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)

	For Three Month Periods Ended			
	Mar. 31, 2011	June 30, 2011	Sept. 30, 2011	Dec. 31, 2011
Revenues (i)	$ 233	$ 20,233	$ -	$ -
Operating expenses	3,067	2,871	2,147	1,847
Operating income (loss)	(2,834)	17,362	(2,147)	(1,847)
Net income (loss)	(2,857)	17,029	(2,141)	(1,646)
Basic earnings (loss) per share	$ (0.06)	$ 0.36	$ (0.05)	$ (0.03)
Diluted earnings (loss) per share	$ (0.06)	$ 0.35	$ (0.05)	$ (0.03)

(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
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	Amended and Restated Voting Agreement dated as of February 6, 2004 among the Registrant, Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P., and others (incorporated by reference to Exhibit 10.5 of the Form 8-K filed on February 10, 2004 (the "February 2004 Form 8-K")).
10.7	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).
10.8	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).

Exhibit Number	Exhibit Description
10.9	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).
10.10	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).
10.11	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).
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16	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).
10.17	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).
10.18	Fourth Amendment to Executive Employment Agreement dated December 16, 2007 between Registrant and Clemens (incorporated by reference to Exhibit 10.28 to the Form 10-K for the year ending December 31, 2007, filed on March 5, 2008).
10.19	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).
10.20	Sixth Amendment to Executive Employment Agreement executed December 14, 2012 between Registrant and Clemens (incorporated by reference to Exhibit 10.2 to our Form 8-K filed on December 17, 2012).
10.21	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).

Exhibit Number	Exhibit Description
10.22	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)
10.23	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).
10.24	Stipulation of Settlement dated October 31, 2011 re: Class Action Litigation (incorporated by reference to Exhibit 10.1 to our Form 8-K filed November 4, 2011)
14.1	Code of Ethics (incorporated by reference to Exhibit 14.1 of the Form 8-K filed on December 10, 2007).
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21 to the Form 10-K for the fiscal year ended December 31, 2006 filed on March 15, 2007).
*23.1	Consent of BDO USA LLP, Independent Registered Public Accounting Firm.
*31.1	Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
*31.2	Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
*32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*101.INS	XBRL Instance Document
*101.SCH	XBRL Taxonomy Extension Schema Document
*101.CAL	XBRL Extension Calculation Linkbase
*101.LAB	XBRL Extension Label Linkbase
*101.PRE	XBRL Extension Presentation Linkbase
*101.DEF	XBRL Taxonomy Extension Definition Linkbase

*Filed or furnished herewith.

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) of Acura Pharmaceuticals, Inc. of our report dated March 4, 2013, relating to the consolidated financial statements, which appear in this Form 10-K.

/s/ BDO USA, LLP
Chicago, Illinois
March 4, 2013

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 28, 2013

/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 28, 2013

/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, 2012 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 28, 2013 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, 2012 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 28, 2013 By: /s/Peter A. Clemens
Peter A. Clemens
Senior Vice President and Chief Financial Officer