ACURA PHARMACEUTICALS, INC
Form 10-K
March 02, 2010

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, 2009

Or

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

For the transition period from _____ to _____

Commission file number 1-10113

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

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

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

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

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 x

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 o 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. x

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, x 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 x

Based on the last sale price on the NASDAQ Capital Market of the Common Stock on June 30, 2009 ($5.98) (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 $57,306,507.

As of February 28, 2010, the registrant had 43,728,626 shares of Common Stock, par value $0.01, outstanding.

Documents incorporated by reference: None

Acura Pharmaceuticals, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2009

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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. The most significant of such factors include, but are not limited to, our ability and the ability of King Pharmaceuticals Research and Development, Inc. (“King”) (to whom we have licensed our Aversion® Technology for certain opioid analgesic products in the United States, Canada and Mexico) and the ability other pharmaceutical companies, if any, to whom we may license our Aversion® Technology, to obtain necessary regulatory approvals and commercialize products utilizing our Aversion® and Impede™ Technologies, the ability to avoid infringement of patents, trademarks and other proprietary rights of third parties, and the ability to fulfill the U.S. Food and Drug Administration’s (“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 and the results of laboratory and clinical studies we may complete in the future, to support FDA approval of our product candidates, 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, the risk that the FDA may not agree with our analysis of our clinical studies and may evaluate the results of these studies by different methods or conclude that the results of the studies are not statistically significant, clinically meaningful or that there were human errors in the conduct of the studies or the risk that further studies of our product candidates are not positive or otherwise do not support FDA approval, whether or when we are able to obtain FDA approval of labeling for our product candidates for the proposed indications or for abuse deterrent features, whether our product candidates will ultimately deter abuse in commercial settings, and the uncertainties inherent in scientific research, drug development, laboratory and clinical trials and the regulatory approval process. Other important factors that may also affect future results include, but are not limited to: our ability to attract and retain skilled personnel; our ability to secure and protect our patents, trademarks and other proprietary rights; litigation or regulatory action that could require us to pay significant damages or change the way we conduct our business; our ability to compete successfully against current and future competitors; our dependence on third-party suppliers of raw materials; our ability to secure U.S. Drug Enforcement Administration ("DEA") quotas and source the active ingredients for our products in development; difficulties or delays in conducting clinical trials for our product candidates or in the commercial manufacture and supply of our products; and other risks and uncertainties detailed in this Report. When used in this Report, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions identify forward-looking statements.

PART I

ITEM 1. BUSINESS

Overview

We are a specialty pharmaceutical company engaged in research, development and manufacture of product candidates intended to provide abuse deterrent features and benefits utilizing our proprietary Aversion® and Impede™ Technologies. Our Aversion® Technology opioid analgesic product candidates are intended to effectively relieve pain while simultaneously discouraging common methods of opioid product misuse and abuse, including the:

- intravenous injection of dissolved tablets or capsules;
- nasal snorting of crushed tablets or capsules; and
- intentional swallowing of excess quantities of tablets or capsules.

All of our opioid product candidates utilize Aversion® Technology and are covered by two issued U.S. patents, which in combination with our anticipated product labeling and drug product listing strategies are anticipated to provide our opioid products with protection from generic competition through the expiration of our patents in 2025.

In addition to Acurox®, our lead product candidate, we (and/or our licensee, King) are developing Vycavert® (hydrocodone bitartrate/niacin/APAP), Acuracet® (oxycodone HCl/niacin/ APAP) and additional undisclosed opioid product candidates utilizing our Aversion® Technology. Four opioid product candidates are licensed to King under our License, Development and Commercialization Agreement dated October 30, 2007. We are also developing an undisclosed benzodiazepine tablet product candidate utilizing Aversion® Technology.

In addition to our Aversion® Technology, as part of our continuing research efforts we are investigating and developing novel mechanisms to incorporate abuse deterrent characteristics into abused and misused pharmaceutical products. In this regard we are engaged in initial laboratory testing of a new product candidate developed with our novel Impede™ Technology. Impede™ Technology is primarily intended to inhibit the conversion of pseudoephedrine HCl (a legally available nasal decongestant) into methamphetamine (an illicit and frequently abused drug).

Acurox® Tablets, our lead product candidates, is an orally administered immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient. On December 30, 2008, we submitted a 505(b)(2) New Drug Application ("NDA") for Acurox® Tablets to the FDA and on June 30, 2009 we received from the FDA a Complete Response Letter ("CRL"). The CRL raised issues regarding the potential abuse deterrent benefits of Acurox®. On September 2, 2009 we and King met with the FDA and agreed that the data and evidence supporting the Acurox® Tablets NDA would be presented to an FDA Advisory Committee. The FDA has not yet scheduled the Advisory Committee meeting to review the NDA for Acurox® Although the FDA stated that no new Acurox® clinical trials are required at this time, we and King are conducting an additional clinical study (see "Acurox® Tablets Development Program" below) to further support the abuse deterrent features of Acurox®.

The misuse and abuse of pharmaceutical products in general, and opioid analgesics in particular, is a significant societal problem described as epidemic in nature. It is estimated that 75 million people in the U.S. suffer from pain, and, according to U.S. government surveys, 34.9 million people, or more than 10% of the U.S. population, have used prescription opioid analgesics non-medically at some point in their lifetime. We expect our Aversion® Technology opioid product candidates to compete primarily in the market for immediate release opioid products ("IR Opioid Products") which are commonly prescribed for relief of pain for durations generally less than 30 days. In 2009, IMS Health reported 252 million prescriptions dispensed for opioid analgesic tablets and capsules, of which approximately 236 million were for IR Opioid Products and 16 million were for extended release opioid tablet and capsule products ("ER Opioid Products") which are commonly prescribed for relief of chronic pain for durations ranging from several weeks to several months or longer. We have contracted, through an independent market research firm, numerous market research studies including two which surveyed 401 and 435 opioid analgesic prescribing U.S. based physicians, respectively. These studies revealed that physicians are keenly aware of opioid analgesic abuse and are personally concerned with the potential impact of drug abuse on their respective medical practices. Our study of 401 physicians indicated that of the prescriptions likely to be written for our product candidates that utilize the analgesic oxycodone, 59% will be switched from immediate release products containing either hydrocodone or oxycodone, with the remaining 41% being switched from other currently marketed opioid analgesic products such as codeine, propoxyphene, morphine, and tramadol. Ninety-four percent (94%) of 401 physicians surveyed indicated they would either prescribe one of the Aversion® Technology products profiled in the market research questionnaire for one of their last five patients receiving an opioid prescription or they are aware of a patient in their practice for whom Aversion® Technology opioid analgesic products would be an appropriate choice.

We have established and intend to pursue future strategic alliances and licensing agreements with pharmaceutical companies to enhance our ability to develop and commercialize our product candidates. In October 2007, we entered into a License, Development and Commercialization Agreement with King to develop and commercialize certain opioid analgesic products utilizing our proprietary Aversion® Technology, including Acurox® Tablets. The King Agreement initially provided King with an exclusive license in the United States, Canada and Mexico (the "King Territory") to Acurox® Tablets and Acuracet® (oxycodone HCl/niacin/acetaminophen) Tablets, and an option to license future opioid analgesic product candidates utilizing our Aversion® Technology in the King Territory. In May and December 2008, King exercised its option and licensed an undisclosed opioid analgesic tablet product and Vycavert® (hydrocodone bitartrate/niacin/acetaminophen) Tablets, respectively. Under the terms of the King Agreement, King made an upfront cash payment to us of $30 million. As of February 28, 2010, we had received an additional $26.2 million from King in the form of milestone payments, option fees and reimbursement for research and development expenses. In addition, we are eligible for future regulatory and sales milestone payments,

reimbursement for certain research and development expenses and royalties on combined annual net sales of all products commercialized under the King Agreement.

We conduct research, development, laboratory, manufacturing, and warehousing activities at our operations facility in Culver, Indiana and lease an administrative office in Palatine, Illinois. In addition to internal capabilities and activities, we engage numerous clinical research organizations ("CROs") with expertise in regulatory affairs, clinical trial design and monitoring, clinical data management, biostatistics, medical writing, laboratory testing and related services. Such CROs perform, under our direction, development and regulatory services relating to our Aversion® and Impede™ Technology product candidates.

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 Pharmaceutical Products with Abuse Deterrent Features and Benefits. Our strategy is to facilitate rapid product development and minimize risk by utilizing active pharmaceutical ingredients with proven safety and efficacy profiles with known potential for abuse, and develop new products utilizing our proprietary Aversion® and Impede™ Technologies using the FDA's 505(b)(2) and other regulatory processes.

- Emerge as a Leader in Developing and Commercializing Products with Abuse Deterrent Features and Benefits Able to Uniquely Address the Growing Problem of Abuse of Prescription Drugs. We believe that Acurox® and our other opioid product candidates in development have demonstrated that Aversion® Technology allows products to provide the analgesic benefit they were intended to deliver, while simultaneously having features that are intended to deter misuse and abuse. We believe these benefits will be attractive to physicians, third party payers, and public advocacy groups sensitive to the problem of prescription drug abuse.

- Optimize Shareholder Value and Temper Risk by Licensing our Product Candidates to Strategically Focused Pharmaceutical Companies in the U.S. and Other Geographic Territories. On October 30, 2007, we and King entered into the King Agreement to develop and commercialize in the United States, Canada and Mexico opioid analgesic products utilizing Aversion® Technology, including Acurox ® Tablets and Acuracet® Tablets. We believe opportunities exist to enter into similar agreements with other partners for these same opioid products outside the King Territory, and in the United States and worldwide for developing additional Aversion® Technology and Impede™ Technology product candidates for other abusable drugs such as tranquilizers, stimulants, sedatives and decongestants. By licensing our product candidates to strategically focused companies with expertise and infrastructure in commercialization of pharmaceuticals, we are able to leverage our expertise, intellectual property rights and Aversion® and Impede™ Technologies without the need to build costly sales and manufacturing infrastructure. We anticipate that our future revenue, if any, will be derived from milestone and royalty payments related to the commercialization of products utilizing our Aversion® and Impede™ Technologies.

- Apply our Aversion® and Impede™ Technologies to Non-Opioid Drugs that are Subject to Abuse. We intend to first develop a portfolio of opioid analgesic products, and thereafter we intend to expand to other pharmaceutical product categories containing potentially abusable active ingredients such as tranquillizers (brand products such as Valium®, Xanax®, Klonopin® and Ativan®), stimulants (brand products such as Dexedrine®, Adderall®, Ritalin® and Concerta®), sedatives (brand products such as Nembutal®, Butisol®, and Seconal®) and decongestants (brand products such as Sudafed®, Zyrtec-D®, Allegra-D®, and Clarinex-D®). These products, like the opioid analgesics on which we are currently focused, may also be prone to misuse and abuse.

- Maintain our Efficient Internal Cost Structure. We maintain a streamlined and highly efficient cost structure focused on: (i) selection, formulation development, laboratory evaluation, manufacture, quality assurance and

stability testing of certain finished dosage form product candidates; (ii) development and prosecution of our patent applications; and (iii) negotiation and execution of license and development agreements with strategically focused pharmaceutical companies. By outsourcing the high cost elements of our product development and commercialization process, we believe that we substantially reduce required fixed overhead and capital investment and thereby reduce our business risk. We currently do not intend to use a physician focused sales force to commercialize products on our own.

Aversion® Technology Opioid Product Candidates in Development

Aversion® Technology opioid analgesic product candidates which have demonstrated Proof of Concept1 are set forth in the table below.

Our Product Candidates	Stage of Development
Acurox® (oxycodone HCl/niacin) Tablets	NDA submitted to FDA on 12/30/08; Complete Response Letter received 6/30/09; FDA Advisory Committee meeting pending scheduling.
Acuracet® (oxycodone HCl/niacin/APAP) Tablets	Investigational New Drug Application ("IND") filed with FDA and active beginning 6-1-08. Testing for NDA submission in progress
Vycavert® (hydrocodone bitartrate/niacin/APAP) Tablets	Proof of Concept complete. Testing for IND filing in progress
4th (undisclosed opioid analgesic) Tablets	Proof of Concept complete.
5th (undisclosed opioid analgesic) Tablets	Proof of Concept complete
6th (undisclosed opioid analgesic) Tablets	Proof of Concept complete
7th (undisclosed opioid analgesic) Tablets	Proof of Concept complete
8th (undisclosed opioid analgesic) Tablets	Proof of Concept complete

1 Proof of concept is attained upon demonstration of certain product stability and bioavailability parameters defined in the King Agreement. Refer to description of the King Agreement in this Report. With one exception, King has either licensed or has an option to license all opioid product candidates listed above in the U.S., Canada and Mexico.

Aversion® Technology Overview

Aversion® Technology is a proprietary platform technology providing abuse deterrent features and benefits to orally administered pharmaceutical drug products containing potentially abusable active ingredients. Our focus has been to utilize our Aversion® Technology with opioid analgesics administered in tablet form. In addition, we believe Aversion® Technology is a versatile technology which may be applicable to non-opioid active ingredients subject to abuse and administered in tablet or capsule form, including tranquilizers, sedatives and stimulants (See “Aversion® Technology Non-Opioid Product Candidates in Development” below).

Aversion® Technology opioid analgesic product candidates include a unique composition of active and inactive pharmaceutical ingredients. The opioid active ingredients are intended to provide effective relief from pain while the proprietary mixture of inactive ingredients provide non-therapeutic functionality. When dissolved in water or other solvents, the functional inactive ingredients quickly form a viscous gel, which increases the difficulty of extracting the opioid active ingredient in a form and volume suitable for injection. In addition, the combination of functional inactive ingredients is intended to induce nasal passage discomfort and disliking effects if the tablets are pulverized and snorted. Aversion® Technology opioid product candidates may also include niacin, an active ingredient in vitamins, cholesterol reducers and nutritional supplements, in amounts determined by us to be well tolerated when our product candidates are administered at recommended doses but which are intended to induce temporary disliking effects as increasing numbers of tablets are swallowed in excess of the recommended analgesic dose. When Aversion® Technology is utilized, it is intended that the resulting product provides the same therapeutic benefits as the non Aversion® Technology product, while simultaneously discouraging the most common methods of pharmaceutical product misuse and abuse.

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

Prospective drug abusers may attempt to dissolve currently marketed opioid-containing tablets or capsules in water, alcohol, or other common solvents, filter the dissolved solution, and then inject the resulting fluid intravenously to obtain euphoric effects. In product candidates utilizing Aversion® Technology, extracting the active ingredient using generally available solvents, including water or alcohol, into a volume and form suitable for intravenous ("I.V.") injection, converts the tablet into a viscous gel mixture and traps the active ingredient in the gel. Additionally, it is not possible, without difficulty, to draw this viscous gel through a needle into a syringe for I.V. injection. We believe that this gel forming feature will inhibit prospective I.V. drug abusers from extracting and injecting opioid active ingredients from product candidates developed utilizing Aversion® Technology.

Intended to Deter Nasal Snorting

Prospective drug abusers may crush or grind currently marketed pharmaceutical opioid-containing tablets or capsules and snort the resulting powder. The abused active ingredient in the powder is absorbed through the lining of the nasal passages providing the abuser with a rapid onset of euphoric effects. Aversion® Technology products are intended to discourage nasal snorting by burning and irritating the nasal passages of a prospective drug abuser who crushes and snorts such products. We believe products which utilize Aversion® Technology will inhibit prospective nasal drug abusers from snorting crushed tablets.

Intended to Deter Swallowing Excess Quantities of Tablets

Niacin, an active ingredient in vitamins, cholesterol reducers and nutritional supplements, is included in the majority of our opioid analgesic product candidates utilizing Aversion® Technology. We believe that should a person swallow excess quantities of tablets utilizing Aversion® Technology with niacin they will experience disliking symptoms, including intense flushing, itching, sweating and/or chills, headache and a general feeling of discomfort as a result of the increasing dose of niacin. It is expected that these niacin-induced disliking symptoms will begin approximately 10 to 15 minutes after the excess dose is swallowed and will dissipate approximately 75 to 90 minutes later. In addition, we believe it is generally recognized by physicians, nurses, and other health care providers that niacin has a well established safety profile in long term administration at doses far exceeding the amounts in each product candidate utilizing Aversion® Technology with niacin. We believe the undesirable niacin effects at escalating doses will not prevent, but are expected to deter, swallowing excess quantities of product candidates utilizing Aversion® Technology with niacin.

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 2008 National Survey on Drug Use and Health, estimated that 34.9 million people, or more than 10% of the population, have used prescription opioid analgesics non-medically at some point in their lifetime. In addition, it is estimated that more than 75 million people in the U.S. suffer from pain, which is more than the number of people with diabetes, heart disease and cancer combined. 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 U.S. with over 252 million tablet and capsule prescriptions dispensed in 2009 of which approximately 236 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 candidates to compete primarily in the IR Opioid Product segment of the US opioid analgesic market, a segment which has grown at a 4% compounded annual rate over the last five years. On average, an IR Opioid Product prescription contains approximately 57 tablets or capsules. According to the 2008 National Survey on Drug Use and Health, prescription drug abusers have supplanted abusers of all illicit drugs except marijuana. Of these abused prescription products, IR Opioid Products, which typically provide rapid onset of analgesia and require dosing every 4 to 6 hours, comprise the vast majority of this abuse compared with ER Opioid Products, which release their opioids gradually, generally over a 12 to 24 hour period. 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 Aversion® Technology.

According to IMS Health, in 2009, sales in the IR Opioid Product segment, comprised of 97% generic products, were $1.9 billion. Assuming the FDA approves differentiated label claims of the abuse deterrent features and benefits of

our product candidates, of which no assurance can be given, we anticipate that our Aversion® Technology IR Opioid Products will be premium priced compared to generic products resulting in rapid growth of sales in the IR Opioid Product market segment.

Despite considerable publicity regarding the abuse of OxyContin® 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 5 times as many people have misused the IR Opioid Products Vicodin®, Lortab® and Lorcet® (hydrocodone bitartrate/APAP) as have ever abused OxyContin®. We estimate 60-95% of the 34.9 million lifetime US opioid abusers have non-medically used 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: 2008

Source: SAMHSA, Office of Applied Studies, 2008 National Survey on Drug Use and Health.

We have commissioned, through an independent market research firm, three physician market research studies with 282, 401 and 435 opioid prescribing U.S. based physicians, respectively. A sampling of key findings from these approximately 1,100 physicians includes:

Physicians are keenly aware of opioid analgesic abuse

- The 282 physicians surveyed estimated on average that about one out of six prescriptions for oxycodone and hydrocodone containing products are abused.

- 94% of the 435 physicians surveyed experienced at least one suspicious incident regarding opioid abuse in the past month, while nearly 64% experienced four or more discretely different incidents regarding opioid abuse in the past month.

Physicians are personally concerned with opioid abusers impact to their respective practices

- Following the survey of 282 physicians, the researchers concluded, “abuse [of opioid analgesics] is a particular problem for physicians because many are not fully sure who is abusing these opioids, and they view such abuse as a legal threat to their practice.” “More than half [of the physicians surveyed] believe their physician colleagues are more concerned about avoiding state review [of their opioid prescribing habits] than meeting [professional association] pain guidelines [for their patients]”.

- After the survey of 435 physicians the researchers concluded “the primary motive for prescribing the Aversion® Technology product[s] is the concern physicians have about opioid abuse and the threat it represents to their practice.”

Physicians are favorably inclined toward prescribing opioids with abuse deterrent features and benefits

- 94% of the 401 physicians surveyed indicated that they would either prescribe one of the Aversion® Technology products profiled in the market research questionnaire for one of their last five patients receiving an opioid prescription or they are aware of a patient in their practice for whom Aversion® Technology products would be an appropriate choice.

- 57% of the 435 physicians indicated that their opioid analgesic prescribing would increase if they were more certain they were not aiding abusers.

- Following the survey of 401 physicians, the researchers concluded "these [Aversion® Technology oxycodone products] would disproportionately replace current immediate release oxycodone [and oxycodone/acetaminophen] prescriptions, but would also draw substantial volume from hydrocodone/acetaminophen products."

Overall, we believe the availability of opioid analgesics with abuse deterrent features, including products using our Aversion® Technology, will greatly impact the selection of products used for relief of pain. Our market research survey of the 401 physicians indicated that of the prescriptions likely to be written for our product candidates that utilize oxycodone, 59% will be switched from immediate release products containing either oxycodone or hydrocodone, with the remaining 41% being switched from other currently marketed opioid analgesic products such as codeine, propoxyphene, morphine and tramadol.

A majority of pharmaceutical products in the U.S. 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 programs. We believe our product candidates will have to 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 favored reimbursement status by the payers.

Independent estimates have been made assessing the potentially significant cost impact of prescription opioid abuse to insurers. An analysis of health and pharmacy insurance claims between 1998 and 2002 for almost 2 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 inflated this excess cost per patient to more than $16,000 for 2007, and by applying the U.S. government's estimated 4.4 million annual opioid abusers, concluded that opioid abuse could costs health insurers up to $72.5 billion a year.

Acurox® Tablets Development Program

We submitted a 505(b)(2) NDA for Acurox® Tablets to the FDA on December 30, 2008 and received a Complete Response Letter ("CRL") on June 30, 2009. On September 2, 2009 we and King met with the FDA and agreed that the data and evidence supporting the Acurox® Tablets NDA would be presented to an FDA Advisory Committee. The FDA has not yet scheduled the Advisory Committee meeting to review the NDA for Acurox®.

The NDA for Acurox® Tablets includes results from numerous clinical and laboratory studies assessing the efficacy and safety of Acurox® Tablets and to demonstrate abuse deterrent features and benefits, including the data and results from studies set forth in the table below.

Studies in the Acurox® Tablets 505(b)(2) NDA Submission		Summary of Results
AP-ADF-101 Phase I	Niacin dose-response (0-75mg)	Identified appropriate niacin dose in each Acurox® Tablet
AP-ADF-104 Phase I	Bioequivalence to non Aversion® Technology Reference Listed Drug	Acurox® Tablets are bioequivalent to the Reference Listed Drug
AP-ADF-108 Phase I	Single dose linearity and food effect	Acurox® Tablets demonstrate single dose linearity. Absorption is delayed by food.
AP-ADF-109 Phase I	Multi-dose linearity	Acurox® Tablets demonstrate multi-dose linearity
AP-ADF-106 Phase I	Evaluate effects of nasal snorting in subjects with a history of snorting and nasal drug abuse	Refer to summary in this Report
AP-ADF-103 Phase II	Repeat dose safety and tolerability	Confirmed appropriate niacin dose in each Acurox® Tablet
AP-ADF-107 Phase II	Niacin dose-response (0-600mg)	Confirmed appropriate niacin dose in each Acurox® Tablet
AP-ADF-102 Phase II	Evaluate relative dislike of oxycodone HCl/niacin versus oxycodone HCl alone	Refer to summary in this Report
AP-ADF-111 Phase II	Evaluate abuse liability of oxycodone HCl/niacin versus oxycodone HCl alone	Refer to summary in this Report
AP-ADF-105 Phase III	Evaluate safety and efficacy in relief of moderate to severe pain	Refer to summary in this Report
Extraction Test	Laboratory test quantifying I.V. abuse deterrent properties	Refer to summary in this Report
Syringe Test	Laboratory test quantifying I.V. abuse deterrent properties	Refer to summary in this Report

Although the FDA stated that no new Acurox® clinical trials are required at this time, we and King are performing an additional clinical study (Refer to Study AP-ADF-114 below) to further support the abuse deterrent features of Acurox®.

Study AP-ADF-114 or Study 114: Study 114 is a randomized, double-blind, placebo- and active-controlled study designed to assess the relative abuse potential of Acurox® Tablets. In Study 114, approximately 47 fasted recreational drug abuse subjects received single oral doses in five test treatments including (a) two potentially abused excess doses of Acurox® (oxycodone/niacin) Tablets, (b) two potentially abused excess oral doses of oxycodone HCl alone, and (c) placebo. Dosing occurred every 48 hours. Prior to the first test treatment, each subject first demonstrated, through naloxone challenge, that they were not dependent on opioids. Also, each subject demonstrated their ability to distinguish, on a 100-point VAS like/dislike scale, between placebo and oxycodone doses randomly administered on a blinded basis. Endpoints assessing abuse potential include subjective assessments on a 100-point VAS of drug liking/disliking, take drug again, and global overall drug liking/disliking. Study 114 has completed enrollment and we are awaiting results of the statistical analysis.

Study AP-ADF-106 or Study 106: Study 106 was a two part, Phase I, single-center, single-blind, clinical study in non-dependent subjects with a history of recreational intranasal opioid use to assess the safety, tolerability and pharmacodynamic effects of intranasally administered crushed Acurox® Tablets, crushed generic oxycodone HCl tablets and pure oxycodone HCl powder. The primary objective of Part 1 (15 subjects enrolled, 13 subjects completed, 14 subjects analyzed) was to determine the maximum tolerated dose of crushed Acurox® Tablets that subjects could snort in a single administration. Subjects were administered escalating doses of crushed Acurox®

Tablets (7.5/30 mg) starting at one half tablet and increasing in half tablet increments on successive days. Part 1 also assessed (over 8 hours after administration) vital signs, subjective ratings of liking and somatic (bodily) discomfort, and objective assessments of the nasal cavity determined by endoscopy and intranasal photography. Part 2 (15 subjects enrolled, 12 subjects completed, 10 subjects analyzed) assessed the relative abuse liability of intranasally administered crushed Acurox® Tablets (7.5/30 mg), crushed generic oxycodone HCl immediate release tablets and pure oxycodone HCl powder, all with a quantity of oxycodone HCl equivalent to the group median highest tolerated dose of Acurox® Tablets determined in Part 1. Part 2 measurements were made over 12 hours and included vital signs, subjective measures of liking and somatic (bodily) discomfort, objective assessments of the nasal cavity and the pharmacokinetics of oxycodone after intranasal administration.

Part 1 of the study determined the maximum tolerated intranasal dose of crushed Acurox® Tablets was 15 mg oxycodone HCl/60 mg niacin (i.e. 2 × 7.5/30 mg Acurox® Tablets).

In Part 2 of the study, nasal administration of 2 crushed Acurox® Tablets (7.5/30 mg) resulted in disliking and low positive drug effect on the Overall Drug Experience and Overall Drug Liking scales. In comparison, crushed generic oxycodone HCl tablets and oxycodone HCl powder resulted in high drug liking and positive drug effects with the mean difference being statistically significant at $p \leq 0.0035$. Furthermore, subjects were much less willing to take crushed Acurox® Tablets again compared to crushed oxycodone tablets and oxycodone powder ($p \leq 0.0007$). Intranasal administration of crushed Acurox® Tablets caused significantly greater negative objective effects for nasal congestion and discharge ($p \leq 0.0223$) and negative subjective effects for nasal burning, congestion and need to blow nose ($p \leq 0.0038$). The results were not statistically significant for the objective assessment of nasal irritation.

Examination of endoscopy and external photography revealed visible differences between the treatments as only the crushed Acurox® treatment was associated with white foamy substance in the interior and middle turbinate of the nose and visible facial flushing. Oxycodone bioavailability was similar between all three treatments. In both Parts of the study, no serious adverse events were reported. All adverse events were classified as mild or moderate with the most prevalent adverse events being nasal symptoms (congestion, discomfort, discharge), flushing, tearing and euphoria.

The principal investigator's overall conclusion was that, based on Study 106 results, intranasal administration of crushed Acurox® Tablets has a distinctively lower abuse potential than the same oxycodone HCl dose administered as crushed generic oxycodone HCl tablets or pure oxycodone HCl powder.

Study AP-ADF-102 or Study 102: Study 102 was a Phase II, single center, randomized, double blind crossover design clinical trial in 24 subjects with a history of opioid abuse with a primary endpoint to assess, whether the subjects disliked the drug effect they were feeling when varying levels of niacin were administered in combination with 40 mg of oxycodone HCl compared to 40 mg oxycodone HCl (alone) and a placebo. Each subject was randomized to a dosing sequence that included doses of niacin (0, 240, 480 , and 600 mg) administered in combination with 40 mg oxycodone HCl, while the subjects were fasted and 600 mg niacin in combination with 40 mg oxycodone HCl administered following a standardized high-fat meal. Each dosing day, vital sign measures and subjective and behavioral effects were assessed before dosing (baseline) and at 0.5, 1, 1.5, 2, 3, 4, 5, 6, and 12 hours after dosing. After completion of the study, subjects responded to a Treatment Enjoyment Assessment Questionnaire to select which of the treatments they would take again. The maximum scale response to the question "Do you dislike the drug effect you are feeling now?" (i.e., the "Disliking Score"), was designated as the primary efficacy variable. Study results were as follows:

- In the fasting state, all three doses of niacin in combination with oxycodone HCl 40mg produced significant ($p \leq .05$) Disliking Scores compared to oxycodone HCl 40mg alone. No other subjective measure was significantly affected by the niacin addition to oxycodone.
    - The high fat meal eliminated the niacin effect and also delayed the time to oxycodone peak blood levels.
        - The addition of niacin to oxycodone HCl alters the subjective response to oxycodone HCl as indicated by the significant responses on the Disliking Score. This observation in conjunction with the results from the Treatment Enjoyment Questionnaire indicates that the addition of niacin reduces the attractiveness of oxycodone to opiate abusers.
- There were no serious adverse events. Niacin produced a dose related attenuation of pupillary constriction, diastolic blood pressure increase and probably systolic blood pressure increase produced by oxycodone HCl. The alterations by niacin on the vital sign responses to oxycodone 40 mg were minimal, were seen primarily with the 600 mg niacin dose and were not clinically significant.

The principal study investigator's overall conclusion was that the results of Study 102 supported the hypothesis that the addition of niacin to oxycodone HCl in a minimal ratio of 30 mg niacin to 5 mg oxycodone HCl is aversive compared to oxycodone HCl alone. The addition of niacin did not alter the safety profile of oxycodone HCl alone.

Study AP-ADF-111 or Study 111: Study 111 is entitled "A Phase II, Single-Center, Randomized, Double-Blind, Assessment of the Abuse Liability of Acurox® (oxycodone HCl and niacin) Tablets in Subjects with a History of Opioid Abuse". In Study 111, 30 fasted subjects with a history of opioid abuse received a single dose of study drugs every 48 hours for 9 days and were enrolled in two dosing sequences. The first dosing sequence (Sequence 1) included randomized doses of (i) niacin 240mg alone; (ii) a combination of oxycodone HCl 40mg with niacin 240mg (4 times the expected recommended dose of Acurox® Tablets 5/30mg); and (iii) placebo tablets. The objective of Sequence 1 was to assess the effects of oxycodone HCl on the effects of niacin. The second dosing sequence (Sequence 2) included randomized doses of (i) a combination of oxycodone HCl 40mg with niacin 240mg (4 times the expected recommended dose of Acurox® Tablets 5/30mg) and (ii) oxycodone HCl 40mg alone. Sequence 2 was designed to assess the abuse liability and abuse deterrence potential of Acurox® Tablets versus oxycodone HCl alone. On each dosing day, vital sign measures and subjective and behavioral effects were assessed before dosing (baseline) and at 0.5, 1, 1.5, 2, 3, 4, 5, 6, and 12 hours after dosing. Vital signs included measurement of pupil size, blood pressure, heart rate, oral temperature and respiratory rate. For both Sequence 1 and Sequence 2, subjective changes were measured with a two item Drug Rating Questionnaire-Subject (DRQS) and a 40 item short form of the Addiction Research Center Inventory (ARCI). The ARCI was comprised of three scale scores including the Morphine Benzedrine Group scale (MBG) measuring euphoria, the LSD/dysphoria scale measuring somatic/bodily discomfort and dysphoria and the Pentobarbital Chlorpromazine Alcohol Group scale (PCAG) measuring apathetic sedation. For Sequence 2 only, in addition to the DRQS and ARCI, subjects also completed a Street Value Assessment Questionnaire and a Treatment Enjoyment Assessment Questionnaire.

Sequence 1 results demonstrated that response to niacin 240 mg alone compared to placebo causes significant dislike scores ($p = .03$), and significant LSD/dysphoria scores ($p < .001$) with these negative niacin induced effects manifesting rapidly, reaching peak at 0.5-1.5 hours and thereafter diminishing. At 0.5 hours after drug administration, oxycodone HCl 40 mg has limited effect on niacin-induced disliking and dysphoric effects. At the one hour observation and afterward, oxycodone may attenuate niacin-induced disliking and dysphoric effects.

Sequence 2 demonstrated that the combination of oxycodone HCl 40mg and niacin 240mg (4 times the expected recommended dose of Acurox® Tablets 5/30mg) had the potential to be aversive when compared to oxycodone HCl 40mg alone as shown by statistically significant and clinically meaningful results in the dislike/like scores ($p = .033$), the Treatment Enjoyment Assessment scores ($p = .005$) and the LSD/dysphoria scores ($p<.001$). The dislike/like score at 0.5 hours was designated the primary measure of abuse liability and abuse deterrence potential for Acurox® Tablets 5/30mg and the Treatment Enjoyment Assessment scores and LSD/dysphoria scores at 0.5 hours were additional measures of the abuse deterrence potential of Acurox® Tablets. Subjective measures not achieving statistical significance included the MBG scores measuring euphoria, the PCAG score measuring apathetic sedation and the Street Value Assessment Questionnaire score, in which subjects indicated they would pay more for oxycodone HCl alone compared to Acurox® Tablets ($p=.097$).

In this study of 30 subjects with a history of opioid abuse there were no serious adverse events reported. Alterations by niacin compared to placebo on vital signs were minimal and not clinically meaningful. The differences in vital signs between oxycodone HCl/niacin and niacin alone at 4 times the expected recommended dose of Acurox® Tablets were minimal and not clinically meaningful.

Study AP-ADF-105 or Study 105: Study 105 is entitled “A Phase III, Randomized, Double-blind, Placebo-controlled, Multicenter, Repeat-dose Study of the Safety and Efficacy of Acurox® (oxycodone HCl and niacin) Tablets versus Placebo for the Treatment of Acute, Moderate to Severe Postoperative Pain Following Bunionectomy Surgery in Adult Patients.” A total of 405 patients were randomized to one of three treatment arms of approximately 135 patients per arm. One treatment arm received a dose of two Acurox® Tablets 5/30 mg, a second treatment arm received a dose of two Acurox® Tablets 7.5/30 mg, and the third treatment arm received a dose of two placebo tablets. Study drugs were administered every 6 hours for 48 hours. The primary endpoint was the sum of the difference in pain

intensity, measured on a 100mm visual analog scale (VAS), compared to baseline over a 48 hour period ("SPID48"). Prior to initiating Study 105, the study design, endpoints and statistical analysis plan were submitted to and agreed by the FDA under a Special Protocol Assessment and the study was conducted accordingly. Results of Study 105 demonstrate that compared to placebo, Acurox® Tablets 5/30 mg and 7.5/30 mg both met the primary pain relief endpoint with p=.0001 and p<.0001, respectively. Acurox® Tablets were generally well tolerated with the most prevalent reported adverse events in patients receiving Acurox® Tablets being nausea, vomiting, dizziness, pruritus and flushing; side effects known to be consistent with opioid and niacin therapies. Most adverse events were mild or moderate and there were no serious adverse events. Six patients (2.2%) receiving Acurox® Tablets withdrew from the study due to treatment–emergent adverse events compared with no withdrawals due to treatment-emergent adverse events for the placebo group.

Extraction Test - In consultation with experts in the field, a laboratory protocol for evaluating the relative IV abuse liability of Acurox® Tablets was designed. To provide unbiased, scientifically derived and documented study results, we engaged a laboratory CRO specializing in pharmaceutical product analysis to execute the protocol. The protocol was intended to mimic the uncontrolled "real world" environment, except that professional chemists with access to a wide range of laboratory equipment and supplies would pose as potential IV drug abusers. As would be the case with a potential IV drug abuser, these chemists were allowed unrestricted access to information in developing oxycodone extraction methods and techniques. The CRO was provided with a list of ingredients (active and inactive) contained in each test product, allotted up to 80 hours total time to complete the evaluations and allowed to use any methodology and/or solvents desired to attempt to extract oxycodone HCl from the tablets in a form suitable for I.V. injection. The test products were: OxyContin® (oxycodone HCl) Tablets 1 x 40 mg (Purdue Pharma), Oxycodone HCl Tabs 8 x 5 mg (Mallinckrodt), Percocet® (oxycodone HCl/APAP) Tablets 8 x 5/325 mg (Endo) and -Acurox® (oxycodone HCl/niacin) Tablets 8 x 5/30 mg (Acura). The results of the Extraction Test suggest that currently marketed oxycodone HCl containing tablets may be easily dissolved in water in as little as 3 - 10 minutes for potential abuse via IV injection. By contrast, the Extraction Test simulation suggests that preparing an injectable form of Acurox® Tablets is difficult and not practical due to the time required (almost 6 hours) and the inability to obtain a sufficient oxycodone yield that would provide any degree of euphoric effect to the prospective drug abuser.

Syringe Test - The Syringe Test was developed to simulate the relative difficulty of abusing dissolved opioid tablets and capsules via IV injection. The test was designed as a scientifically reproducible method to quantitatively measure the difficulty of drawing into a syringe a solution made from tablets or capsules dissolved in varying types and volumes of solvent. The test utilizes seven (7) solvents available to potential abusers, the largest syringe barrel available without a prescription and the largest bore needle in the subcutaneous syringe set family. The needle and barrel are much larger than typically used by abusers and represent a worst case scenario (e.g. easier to prepare an IV injection). The Syringe Test results suggest that preparing an injectable form of Acurox® Tablets using a variety of available solvents is impractical due to high solvent volume requirements and the viscous/gelatinous mixture formed when dissolving Acurox® Tablets in lower volumes of the solvents tested. Even if a "Theoretically Injectable" solution of crushed Acurox® Tablets is achieved it would require further processing by the prospective abuser to separate oxycodone from other tablet ingredients (including niacin and numerous excipients) and a reduction in total volume to provide a solution in a volume and form that is practically suitable for IV injection.

Expectations for Acurox® Tablets Product Labeling

The FDA has publicly stated that an explicit indication or claims of abuse deterrence will not be permitted in product labeling unless such indication or claims are supported by double blind controlled clinical studies demonstrating an actual reduction in product abuse by patients or drug abusers. We believe the cost, time and practicality of designing and implementing clinical studies adequate to support explicit labeling claims of abuse deterrence are prohibitive. The FDA has stated that scientifically derived data and information describing the physical characteristics of a product candidate and/or the results of laboratory and clinical studies simulating product abuse may be acceptable to include in the product label. We intend to include in the labels of our Aversion® Technology product candidates both a physical description of the abuse deterrent characteristics and information from our numerous laboratory and clinical studies designed to simulate the relative difficulty of abusing our product candidates. The extent to which such information will be included in the FDA approved product label will be the subject of our discussions with and agreement by the FDA as part of the NDA review process for each of our product candidates. Further, because FDA closely regulates promotional materials, even if FDA initially approves labeling that includes a description of the abuse deterrent characteristics of the product, the FDA will continue to review the acceptability of promotional labeling claims and product advertising campaigns for our product candidates.

King Agreement

On October 30, 2007, we and King Pharmaceuticals Research and Development, Inc. (“King”), a wholly-owned subsidiary of King Pharmaceuticals, Inc., entered into a License, Development and Commercialization Agreement (the “King Agreement”) to develop and commercialize in the United States, Canada and Mexico (the "King Territory") certain opioid analgesic products utilizing our proprietary Aversion® Technology. The King Agreement initially provided King with an exclusive license in the King Territory for Acurox® (oxycodone HCl/niacin) Tablets and Acuracet® (oxycodone HCl/niacin/APAP) Tablets, utilizing Aversion® Technology. In addition, the King Agreement provides King with an option to license in the King Territory all future opioid analgesic products developed utilizing Aversion® Technology. At December 31, 2009, King had exercised its option to license two additional product candidates including an undisclosed opioid analgesic tablet product and Vycavert® (hydrocodone bitartrate/niacin/APAP) Tablets, each of which utilize our Aversion® Technology. We are responsible for using commercially reasonable efforts to develop Acurox® Tablets through regulatory approval by the FDA. The King Agreement provides that we or King may develop additional opioid analgesic product candidates utilizing our Aversion® Technology and, if King exercises its option to license such additional product candidates, they will be subject to the milestone and royalty payments and other terms of the King Agreement.

Pursuant to the King Agreement, we and King formed a joint steering committee to oversee development and commercialization strategies for Aversion® opioid analgesic products licensed to King. We are responsible for all Acurox® Tablet development activities, the expenses for which we are reimbursed by King, through FDA approval of a 505(b)(2) NDA. After NDA approval King will be responsible for commercializing Acurox® Tablets in the U.S. With respect to all other products licensed by King pursuant to the Agreement in all King Territories, King will be responsible, at its own expense, for development, regulatory, and commercialization activities. All products developed pursuant to the King Agreement will be manufactured by King or a third party contract manufacturer under the direction of King. Subject to the King Agreement, King will have final decision making authority with respect to all development and commercialization activities for all licensed products. We have reviewed our participation in the King-Acura joint steering committee in light of the requirements of Emerging Issues Task Force, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21") and concluded that this activity has no standalone value therefore it does not meet the criteria to be considered a separate unit of accounting.

At December 31, 2009, we had received aggregate payments of $56.2 million from King, consisting of a $30.0 million non-refundable upfront cash payment, $15.2 million in reimbursed research and development expenses relating to Acurox® Tablets, $6.0 million in fees relating to King's exercise of its option to license an undisclosed opioid analgesic tablet product and Vycavert® Tablets, and a $5.0 million milestone fee relating to our successful achievement of the primary endpoints for our pivotal Phase III clinical study for Acurox® Tablets. The King Agreement also provides for King's payment to us of a $3.0 million fee upon King's exercise of its option for each future opioid product candidate. In the event that King does not exercise its option for a future opioid product candidate, King may be required to reimburse us for certain of our expenses relating to such future opioid product candidate. Further, we may receive up to $23 million in additional non-refundable milestone payments for each product candidate licensed to King, including Acurox® Tablets, which achieve certain regulatory milestones in specific countries in the King Territory. We can also receive a one-time $50 million sales milestone payment upon the first attainment of $750 million in net sales of all of our licensed products across all King Territories. In addition, for sales occurring following the one year anniversary of the first commercial sale of the first licensed product sold, King will pay us a royalty at one of 6 rates ranging from 5% to 25% based on the level of combined annual net sales for all products licensed by us to King across all King Territories, with the highest applicable royalty rate applied to such combined annual sales. King's royalty payment obligations expire on a product by product and country-by-country basis upon the later of (i) the expiration of the last valid patent claim covering such product in such country, or (ii) fifteen (15) years from the first commercial sale of such product in such country. No minimum annual fees are payable by either party under the King Agreement. Reference is made to Item 9 of Note A of the Notes to Consolidated Financial Statements included as a part of this Report, entitled "Revenue Recognition and Deferred Program Fee Revenue" for a description of the revenue recognition method employed by the Company under the King Agreement.

The King Agreement expires upon the expiration of King's royalty payment and other payment obligations under the King Agreement. King may terminate the King Agreement in its entirety or with respect to any product at any time after March 31, 2010, upon the provision of not less than 12 months' prior written notice, and in its entirety if regulatory approval of the NDA for Acurox® Tablets is not received prior to March 31, 2010 and with respect to a particular product with respect to a country in which regulatory approval for such product is withdrawn by a regulatory authority in such country. We do not expect to receive FDA approval of the NDA for Acurox® Tablets prior to March 31, 2010. As a result, King may terminate the King Agreement at any time following such date upon written notice to us. We may terminate the King Agreement with respect to a product in the United States in the event such product is not commercially launched by King within 120 days after receipt of regulatory approval of such product or in its entirety if King commences any interference or opposition proceeding challenging the validity or enforceability any of our patent rights licensed to King under the King Agreement. Either party has the right to terminate the King Agreement on a product by product and country-by-country basis if the other party is in material breach of its obligations under the King Agreement relating to such product and 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 King Agreement and all licenses under the King Agreement are terminated. For all Acura terminations and termination by King where we are not in breach, the King Agreement provides for the transition of development and marketing of the licensed products from King to us, including the conveyance by King 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 King's supply of such licensed products for a transitional period at King's cost plus a mark-up.

The foregoing description of the King Agreement contains forward-looking statements about Acurox® Tablets, and other product candidates being developed pursuant to the King Agreement. As with any pharmaceutical products under development or proposed to be developed, substantial risks and uncertainties exist in development, regulatory review and commercialization process. There can be no assurance that the King Agreement will not be terminated by its terms prior to receipt of regulatory approval for any product developed pursuant to the King Agreement. Further, there can be no assurance that any product developed, in whole or in part, pursuant to the King Agreement will receive regulatory approval or prove to be commercially successful. Accordingly, investors in the Company should recognize that there is no assurance that the Company will receive the milestone payments or royalty revenues described in the King Agreement or even if such milestones are achieved, that the related products will be successfully commercialized and that any royalty revenues payable to us by King will materialize. For further discussion of other risks and uncertainties associated with the Company, see Item 1A in this Report under the heading "Risks Factors".

Patents and Patent Applications

In April 2007, the United States Patent and Trademark Office ("USPTO"), issued to us a patent titled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms" (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 specific opioid analgesics such as oxycodone HCl and hydrocodone bitartrate among others.

In January 2009, the USPTO issued to us a patent (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 a patent (the "726 Patent") with 20 allowed claims. The 726 Patent encompasses a wider range of abuse deterrent compositions than our 920 Patent.

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. Except for those rights conferred in the King Agreement, we have retained all intellectual property rights to our Aversion® Technology, Impede™ Technology, and related product candidates.

Reference is made to Item 1A, "Risk Factors" for a discussion, among other things, of pending patent applications owned by third parties including claims that may encompass our Acurox® Tablets and other product candidates. If such third party patent applications result in valid and enforceable issued patents containing claims in their current form, we or our licensees could be required to obtain a license to such patents, should one be available, or alternatively, to alter our product candidates to avoid infringing such third-party patents.

Competition in the Opioid Product Market

We compete to varying degrees with numerous companies in the pharmaceutical research, development, manufacturing and commercialization fields. Many of our competitors have substantially greater financial and other resources and are able to expend more funds and effort than us in research and development of their competitive technologies and products. Although a larger company with greater resources than us will not necessarily have a higher likelihood of receiving regulatory approval for a particular product or technology as compared to a smaller competitor, the company with a larger research and development expenditure will be in a position to support more development projects simultaneously, thereby potentially improving the likelihood of obtaining regulatory approval of a commercially viable product or technology than its smaller rivals.

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 of South San Francisco, CA, (in collaboration with King Pharmaceuticals Inc.), Purdue Pharma of Stamford, CT, Atlantic Pharmaceuticals, of Atlanta, GA, Egalet a/s, of Verlose, Denmark and Collegium Pharmaceuticals, Inc., of Cumberland, RI. These companies appear to be focusing their development efforts on ER Opioid Products while our lead product candidate, Acurox® Tablets, and the majority of our other Aversion® Technology opioid analgesic product candidates under development, are IR Opioid Products.

Aversion® Technology Non-Opioid Product Candidates in Development

We are developing a benzodiazepine product candidate utilizing our Aversion® Technology intended for the treatment of anxiety disorders. According to Drugs of Abuse, published by the US Drug Enforcement Administration, tranquilizers are abused in manners similar to opioid analgesics. The 2008 National Survey on Drug Use and Health estimates that 21.5 million people have abused prescription tranquilizers (including benzodiazepines) at some point in their lifetime and 5.1 million have abused tranquilizers in the past year.

We have completed a 2-way pilot crossover pharmacokinetic study in 9 healthy adult subjects of a single oral dose of the Aversion® Technology benzodiazepine product candidate compared to the reference listed drug. While the Aversion® Technology product candidate did not achieve bioequivalence to the reference listed drug in this pilot study, the Aversion® Technology product candidate demonstrated suitable bioavailability of the active benzodiazepine ingredient and we believe such product candidate may demonstrate bioequivalence to the reference listed drug in a larger pivotal scale study.

The Aversion® Technology benzodiazepine product candidate is intended to be encompassed by numerous pending patent applications filed with the USPTO by the Company. However, at this stage, there can be no assurances that such pending patent applications will result in issued patent claims encompassing our benzodiazepine product candidate.

Impede™ Technology Product Candidates in Development

We are engaged in laboratory testing of a pseudoephedrine HC1 product candidate utilizing our novel Impede™ Technology. Impede™ Technology is primarily intended to inhibit the conversion of pseudoephedrine HC1 into methamphetamine, an illicit and frequently abused drug.

Most pseudoephedrine containing products are classified by the FDA for sale Over-The-Counter (without a doctor's prescription) and most product formulations do not require the approval of a New Drug Application by the FDA to initiate commercial distribution and marketing. In 2006 regulations relating to over-the counter sale of pseudoephedrine HCl products were amended with the enactment of the federal Combat Methamphetamine Abuse Act (CMAA). The CMAA was enacted in response to an alarming increase in and widespread conversion of pseudoephedrine containing products into methamphetamine. Among other things, the CMAA requires retail stores to maintain their inventory of pseudoephedrine containing products in a secured location and restricts the amount of pseudoephedrine products a store can sell to an individual customer. Implementation of the CMAA initially reduced the number of illegal methamphetamine laboratories as, the most commonly used process for conversion of pseudoephedrine to methamphetamine requires substantial quantities of pseudoephedrine. However, a newer, more efficient process for converting pseudoephedrine to methamphetamine requires less pseudoephedrine. Possibly as a result of the more efficient process, the DEA reported a 15% increase in clandestine methamphetamine laboratory seizures in 2008. Impede™ Technology is designed to deter a wide range of processes of methamphetamine production including both the older and newer processes.

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 (the "FD&C Act"), and, to a lesser extent, by state and local governments. Before our products may be marketed in the U.S., they must be approved by the FDA for commercial distribution. Additionally, we are subject to extensive regulation by the DEA under the Controlled Substances Act for research, development and manufacturing of controlled substances. 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.

However, because of recent developments in the legislative and regulatory framework within which drug products are reviewed and approved by FDA, approval of drug products by FDA may be subject to continuing obligations intended to assure safe use of the products. Specifically, effective March 25, 2008, under Title IX of Subtitle A of the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), FDA may require a Risk Evaluation and Mitigation Strategy ("REMS") to manage known or potential serious risks associated with drugs or biological products. If FDA finds 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, a marketing and sales communication plan, elements to assure safe product use, a REMS implementation system, and a timetable for FDA's assessment of the effectiveness of the REMS.

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.

The Federal Controlled Substances Act imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products. Establishments may not handle controlled drug substances until they have been inspected and registered by the DEA. Facilities must be equipped to meet DEA security requirements. A principal factor in determining the particular requirements, if any, applicable to a product is its actual or potential abuse profile. A pharmaceutical product may be "scheduled" as a C-I, C-II, C-III, C-IV or C-V controlled substance, with C-I substances considered to present the highest risk of substance abuse and C-V substances the lowest. Because of the potential for abuse, opioid analgesic active pharmaceutical ingredients and finished drug products, including all of our Aversion® Technology product candidates, are regulated, or scheduled, under the Controlled Substances Act. Because it contains oxycodone HCl, we believe that Acurox® Tablets will be a DEA C-II product.

FDA approval is required before any "new drug," can be marketed. A "new drug" is one not generally recognized as safe and effective for its intended use. Our products are new drugs. Such approval must be based on adequate and well controlled laboratory and clinical investigations. In addition to providing required safety and effectiveness data for FDA approval, a drug manufacturer's practices and procedures must comply with current Good Manufacturing Practices ("cGMPs"), which apply to the 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.

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 IND, which must become active before human clinical trials 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 the both the active ingredients and finished drug product are produced to assess compliance with 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, and analytical data are then submitted to the FDA as a part of an IND. An IND must become effective 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. 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. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. Once an IND is in effect, the protocol for each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed.

Human clinical trials are typically conducted in three phases that often overlap:

Phase I: 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 II: Once the preliminary safety and tolerability of the drug in humans is confirmed during phase I, phase II involves studies in a somewhat larger group of study subjects. Unlike phase I studies, which typically involve healthy subjects, participants in phase II studies maybe affected by the disease or condition for which the product candidate is being developed. Phase II 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 III: Phase III trials typically involve a large numbers of patients affected by the disease or condition for which the product candidate is being developed.. Phase III 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 III trials are typically the most costly and time-consuming of the clinical phases.

Phase IV: Phase IV 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 IV 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, the sponsor must submit an NDA 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) and a 505(b)(2). 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. The FDA provided written guidance to us stating that Acurox® Tablets is a suitable product candidate for submission as a 505(b)(2) NDA and in February 2009 accepted our Acurox® Tablets

NDA for filing.

Each NDA requires a user fee, pursuant to the requirements of the Prescription Drug User Fee Act ("PDUFA"), as amended. According to FDA's fee schedule, effective on October 1, 2009, for the 2010 fiscal year, the user fee for an application fee requiring clinical data (such as an NDA) is $1,247,200. The FDA adjusts PDUFA user fees on an annual basis. PDUFA also imposes an annual product and facility fees. The annual product fee for prescription drugs and biologics for the 2010 fiscal year is $71,250 and the annual facility fee for facilities used to manufacture prescription drugs and biologics for the 2010 fiscal year is $425,600. A written request can be submitted for a waiver of the application fee for the first human drug application that is filed by a small business, but no waivers for product or establishment fees are available. Where we are subject to these fees, they are significant expenditures that may be incurred in the future and must be paid at the time of submission of each application to FDA. The King Agreement provides that King will reimburse us for the NDA application fee for Acurox® Tablets and pay user fees for all products licensed by the Company to King pursuant to the King Agreement.

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 product candidates 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 product candidates are approved with labeling that includes descriptions of the abuse deterrent characteristics 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 supplement, for further FDA review and approval. 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 patent protection 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 Pediatric Research Equity Act ("PREA"), became law in 2003, and was also subsequently reauthorized and amended by FDAAA. The reauthorization of 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. We have requested a deferral of the pediatric assessment in our Acurox® Tablets NDA submission.

The terms of approval of any Acurox® Tablet NDA, including the indication and product labeling (and, consequently advertising and promotion) may be more restrictive than what is sought in the NDA or what is desired by us. Additionally, FDA may condition approval of abuse deterrence statements and claims for Acurox® Tablets on phase IV clinical studies for continued assessment of such statements or claims. The Acurox® Tablet testing and FDA approval process 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, as a condition of approval of any NDA, FDA may require a REMS to ensure the safe use and monitoring of any of our products. If required, a REMS may include, but may not be limited to, use of an FDA-approved Medication Guide and/or Patient Package Insert, a communication plan for patients or healthcare providers concerning the drug, a description of elements to assure safe use of the product, and a timetable for FDA's assessment of the effectiveness of the REMS.

In addition, we, our suppliers and our licensees are required to comply with extensive FDA requirements both before and after approval. For example, we or our licensees are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotion for 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 commercial activities 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.

Facilities for Research, Development, and Manufacturing

We conduct research, development, laboratory, manufacturing and related activities for product candidates utilizing Aversion® and Impede™ Technologies at our Culver, Indiana facility. The 28,000 square foot facility is registered with the DEA to perform research, development and manufacture of certain DEA Scheduled active pharmaceutical ingredients and finished dosage form products. We obtain quotas for supply of DEA-scheduled active pharmaceutical ingredients from the DEA and develop finished drug product candidate dosage forms in our Culver laboratories. We manufacture clinical trial supplies of drug products in our Culver facility in volumes sufficient to meet FDA standards for NDAs. King is responsible for commercial manufacture of the product candidates licensed under the King Agreement. We expect that all future product candidates developed by us will be commercially manufactured by our licensees or other qualified third party contract manufacturers.

Segment Reporting

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

Legal Proceedings

We are not involved in any material legal proceedings.

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.

Raw Materials

To purchase certain active ingredients required for our development and manufacture of product candidates utilizing our Aversion® Technology, we are required to file for and obtain supply quotas from the DEA. No assurance can be given that we will be successful in obtaining adequate DEA quotas in a timely manner. Even assuming adequate and timely DEA quotas, there can be no assurances that the approved manufacturers of raw materials for our product candidates will supply us with our requirements for the active or inactive ingredients required for the development and manufacture of our product candidates.

Subsidiaries

Our Culver, Indiana research, development, and manufacturing operations are conducted by Acura Pharmaceutical Technologies, Inc., an Indiana corporation and our wholly-owned subsidiary.

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.

Risks Relating to Our Business and Industry

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

We had a net loss of $15.8 million for the year ended December 31, 2009, net income of $14.5 million for the year ended December 31, 2008 and a net loss of $4.3 million the year ended December 31, 2007. Our future profitability will depend on several factors, including:

- our receipt of milestone payments and royalties relating to products developed and commercialized under our license agreement with King (as more fully described under the caption "Item 1. Business — King Agreement"); and

- the receipt of FDA approval and the successful commercialization by King and other future licensees (if any) of products utilizing our Aversion® and Impede™ Technologies without infringing the patents and other intellectual property rights of third parties.

We cannot assure you that we will ever have a product approved for commercialization by the FDA or that we or our licensees will bring any product to market.

We recognized revenues of $3.8 million and $44.4 million in the years ended December 31, 2009 and 2008, respectively, from payments received under the King Agreement. However, we have not yet generated any revenues from Aversion® Technology product sales. Even if we succeed in commercializing one or more of our Aversion® Technology product candidates, 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 additional product candidates, maintaining and expanding the scope of our intellectual property, and hiring of additional research and development staff.

We will need to generate royalty revenues from product sales to achieve and maintain profitability. If we cannot successfully develop, obtain regulatory approval for and commercialize our product candidates licensed to King under the King Agreement or other product candidates under similar license agreements anticipated to be negotiated and executed with other pharmaceutical companies, of which no assurance can be given, 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 milestone payments and royalties, if any, under the King Agreement or under similar license agreements anticipated to be negotiated and executed with other pharmaceutical companies, of which no assurance can be given, we must rely on our current cash reserves and third-party financing to fund operations and product development activities. No assurance can be given that current cash reserves will be sufficient to fund the continued operations and development of our product candidates until such time as we generate additional revenue from the King Agreement or similar license agreements anticipated to be negotiated and executed with the other pharmaceutical companies. 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 product candidates are unproven and may not be approved by the FDA.

We are committing a majority of our resources to the development of Acurox® Tablets and other product candidates utilizing our Aversion® Technology. In December 2008 we submitted a 505(b)(2) NDA for Acurox® Tablets to the FDA and on June 30, 2009 we received the FDA's CRL. The FDA intends to have an Advisory Committee review the NDA for Acurox®. There can be no assurance that the FDA will ultimately approve Acurox® Tablets or any other product candidate utilizing Aversion® Technology for commercial distribution. Further there can be no assurance that other product candidates developed using Aversion® 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 a NDA submission. Our failure to successfully develop and achieve final FDA approval of a product candidate utilizing Aversion® Technology will have a material adverse effect on our financial condition.

Even if the FDA Approves Acurox® Tablets for commercial distribution, if Acurox® Tablets are not approved with labeling describing its abuse deterrent features, we will be unable to refer to the abuse deterrent characteristics of Acurox® to promote the product.

Our strategy for Acurox® Tablets depends upon our ability to distinguish Acurox® from other immediate release oxycodone HCl containing products based primarily on abuse deterrent features. As with all of our product candidates utilizing Aversion® Technology, even if Acurox® Tablets are approved by the FDA, our failure to achieve approval of product labeling that sufficiently differentiates Acurox® Tablets from other immediate release oxycodone HCl containing tablets may adversely affect 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 are not pursuing and have not conducted the clinical trials necessary to include an explicit product label claim of abuse deterrence. Instead, we intend to rely on certain clinical and laboratory studies to support the inclusion of information about the abuse deterrent characteristics of Acurox® Tablets to support promotion by our licensee(s) of the product. We intend to include in the product labels of our product candidates both a physical description of the abuse deterrent characteristics and information from our multiple laboratory and clinical studies designed to simulate the relative difficulty of abusing our product candidates. However, the extent to which such information will be included in the FDA approved product label will be the subject of our 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 will be able to market our product candidates with labeling that sufficiently differentiates them from other products that have comparable therapeutic profiles. If the FDA does not approve the Acurox® Tablet labeling with such information, we will not be able to promote Acurox® Tablets based on its abuse deterrent features, may not be able to differentiate Acurox® from other oxycodone HCl containing immediate release products, 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 FDA closely regulates promotional materials and other promotional activities, even if FDA initially approves product labeling that includes a description of the abuse deterrent characteristics of our product, FDA may object to our marketing claims and product advertising campaigns.

Relying on third party contract research organizations ("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 U.S. 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. This demonstration requires significant testing. 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 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, 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 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, or a 505(b)(2) 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. The FDA commonly takes more than a year to grant final approval for an NDA, or 505(b)(2) NDA. The Prescription Drug User Fee Act (“PDUFA”) sets time standards for 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. If we or our licensees fail to obtain regulatory approval for any of our product candidates, we will have fewer commercialized products and correspondingly lower revenues. Even if regulatory approval of our products 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. Such events would have a material adverse effect on our operations and financial condition.

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 Good Manufacturing Practices ("cGMP") and to stop shipments of allegedly violative products. In the event the FDA takes any such action relating to our products (if any are approved by FDA), 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 do not have the facilities, equipment or personnel to manufacture commercial quantities of our product candidates and therefore must rely on our licensees or other qualified third party companies with appropriate facilities and equipment to contract manufacture commercial quantities of products utilizing our Aversion® and Impede™ Technologies. These licensees are also subject to cGMP regulations.

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 while repairs were being made. 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.

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

On October 30, 2007, we entered into an Agreement with King (as more fully described under the caption "Item 1. Business – King Agreement"). At December 31, 2009 we had received aggregate payments of $56.2 million from King, consisting of a $30.0 million non-refundable upfront cash payment, $15.2 million in reimbursed research and development expenses relating to our licensed product candidates, $6.0 million in option exercise fees relating to King's exercise of its option to license an undisclosed opioid analgesic tablet product and Vycavert® Tablets, and a $5.0 million milestone fee relating to our successful achievement of the primary end points for our pivotal Phase III clinical study for Acurox® Tablets. Our future revenue, if any, will be derived from milestone payments and royalties under the King Agreement and under similar license agreements anticipated to be potentially negotiated and executed with other pharmaceutical companies. No assurance can be given that we will receive the milestone and royalty payments provided for in the King Agreement, or that we will be successful in entering into similar agreements with other pharmaceutical companies to develop and commercialize products utilizing our Aversion® or Impede™ Technologies.

As part of such license agreements, we will not have day-to-day control over the activities of our licensees with respect to any product candidate. If a licensee fails to fulfill its obligations under an agreement with us, we may be unable to assume the development 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 King, we may have to reduce or delay our product candidate development.

Our plan for developing, manufacturing and commercializing Acurox® Tablets and other opioid analgesic product candidates utilizing our Aversion® Technology currently requires us to successfully maintain our license agreement with King to advance our programs and provide funding to support our expenditures on Acurox® Tablets and other opioid analgesic product candidates. In addition to other customary termination provisions, the King Agreement provides that King may terminate the King Agreement in its entirety if FDA approval of the Acurox® Tablets NDA is not received prior to March 31, 2010. We anticipate FDA approval of the NDA for Acurox® Tablets will not occur prior to March 31, 2010 as the Advisory Committee remains unscheduled. As a result, King may terminate the King Agreement following such date upon written notice to us. If King elects to terminate the King Agreement, or if we are otherwise unable to maintain our existing relationship with King, we may have to limit the size or scope of, or delay or abandon the development of, Acurox® Tablets and other opioid analgesic product candidates or undertake and fund development of these product candidates ourselves. If we were required to fund development and commercialization efforts with respect to Acurox® Tablets and other opioid analgesic product candidates on our own, we may need to obtain additional financing, which may not be available on acceptable terms, or at all.

If King is not successful in commercializing Acurox® Tablets and other licensed product candidates incorporating the Aversion® Technology our revenues and our business will suffer.

Pursuant to the King Agreement, King is responsible for manufacturing, marketing, pricing, promoting, selling, and distributing certain of our product candidates in the US, Canada and Mexico. 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 the products 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. In this event our revenues and/or royalties for these products could be adversely impacted.

King's manufacturing facility is currently the sole commercial source of supply for Acurox® and our other product candidates licensed to King. If King's manufacturing facility fails to obtain sufficient DEA quotas for the opioid active ingredients contained in such product candidates, fails to source adequate quantities of active and inactive ingredients, fails to comply with regulatory requirements, or otherwise experiences disruptions in commercial supply of our product candidates, product revenue and our royalties could be adversely impacted.

King has a diversified product line for which Acurox® and our other product candidates licensed to King will vie for King's promotional, marketing, and selling resources. If King fails to commit sufficient promotional, marketing and selling resources to our products, product revenue and our royalties could be adversely impacted.

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

The market may not be receptive to products incorporating our Aversion® Technology.

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 willingness of third party payers to reimburse for our prescription products; and
- the willingness of consumers to pay for our products.

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 products unless our products demonstrate commercially viable advantages over other products currently marketed for the same indications. Consumers may not be willing to purchase our products. If our products do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

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

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

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In the event that we or our licensees are successful in bringing any products to market, 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.

Consolidation in the healthcare industry could lead to demands for price concessions or to 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.

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. 7,476,402 from the United States Patent and Trademark Office (“USPTO”) encompassing our opioid product candidates 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 such patent claims will be 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 the 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, potential investors, 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 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 may initiate against third parties to enforce our patent rights or other intellectual property rights;
- litigation or other proceedings we 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 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 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 and other intellectual property proceedings may also consume significant management time.

Our technologies may be found to infringe claims of patents owned by others. If we determine or if we are found to be infringing a patent held by another party, we or our licensees might have to seek a license to make, use, and sell the patented technologies. In that case, we 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 technology that may be required would materially harm our business, financial condition and results of operations. If a legal action is brought against us, 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 a competitor who has suggested to the USPTO that the USPTO should declare an interference between that competitor's pending patent application and one of our U.S. patents for the Aversion® Technology. We believe that there is no valid basis for declaring such an interference and that even if such an interference were

declared, that we would prevail. There can be no assurance, however, that such an interference will not be declared or if declared, that we will ultimately succeed such that this competitor would not obtain patent claims which could encompass our lead product candidate and other product candidates in development.

We are aware of certain United States and international pending patent applications owned by third parties with claims potentially encompassing our product candidates. 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 cannot assure you that our 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.

We may be exposed to product liability claims and may not be able to obtain 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. 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 or obtain 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 such litigation. 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.

The pharmaceutical industry is highly competitive and is affected by new technologies, governmental regulations, health care legislation, availability of financing, litigation and other factors. If our product candidates receive FDA approval, they will compete with a number of existing and future drug products and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience, clinical or other benefits for a specific indication than our products, or may offer comparable performance at lower 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 or our licensees will compete for market share against fully integrated pharmaceutical companies or other companies that collaborate with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have products already approved, marketed or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs, have substantially greater financial resources, experience in developing products, obtaining FDA and other regulatory approvals, formulating and manufacturing drugs, and commercializing products than we do.

We are concentrating a substantial majority of our efforts and resources on developing product candidates utilizing our Aversion® Technology. The commercial success of products utilizing Aversion® Technology 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 Aversion® Technology. 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® Technology 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 Andrew D. Reddick, our President and Chief Executive Officer, Ron J. Spivey, Ph.D., our Senior Scientific Advisor, Robert Jones, our Senior Vice President and Chief Operating 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 intense 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.

The U.S. Drug Enforcement Administration ("DEA") limits the availability of the active ingredients used in our product candidates and, as a result, our quota may not be sufficient to complete clinical trials or may result in development delays.

The DEA regulates certain finished drug products and active pharmaceutical ingredients, including certain opioid active pharmaceutical ingredients and pseudoephedrine HCl in our current product candidates. 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.

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

Significant equity restructuring often results in an Internal Revenue Section 382 ownership change that limits the future use of Net Operating Loss ("NOL") carryforwards and other tax attributes. 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. If we establish a contingent tax liability reserve, interest and penalties related to uncertain tax positions would be classified as general and administrative expenses.

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 the research, development and regulatory submissions of our product candidates that could cause our operating results to fluctuate. The forecasting of the timing of sales of our product candidates is difficult due to 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 technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements, laboratory or clinical trial results, government regulation, 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 has often been instituted. A securities class action 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 have a material impact on the price of our common stock, in addition to the other issues described herein, include 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 success of our license agreement with King, 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 in 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.

GCE Holdings LLC can control all matters requiring approval by shareholders.

GCE Holdings LLC beneficially owns approximately 75.9% of our outstanding common stock as of December 31, 2009 (calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended). As a result, GCE Holdings LLC, in view of its ownership percentage of our common stock, will be able to control all matters requiring approval by our shareholders, including the approval or rejection of mergers, sales or licenses of all or substantially all of our assets, or other business combination transactions. The interests of GCE Holdings LLC may not always coincide with the interests of our other shareholders and as such we may take action in advance of its interests to the detriment of our other shareholders. Accordingly, you may not be able to influence any action we take or consider taking, even if it requires a shareholder vote.

We are currently a “Controlled Company” within the meaning of the NASDAQ Capital Market Listing Requirements and, as a result, are exempt from certain corporate governance requirements.

Because GCE Holdings LLC controls more than 50% of the voting power of our common stock, we are currently considered to be a “controlled company” for purposes of a NASDAQ Capital Market listing requirements. As such, we are permitted, and have elected, to opt out of the NASDAQ Capital Market listing requirements that would otherwise require our board of directors to have a majority of independent directors, our board nominations to be selected, or recommended for the board’s selection either by a nominating committee comprised entirely of independent directors or by a majority of independent directors, and our compensation committee to be comprised entirely of independent directors. Accordingly, you may not have the same protections afforded to stockholders of companies that are subject to all of the NASDAQ Capital Market corporate governance requirements.

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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 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 GCE Holdings, LLC, 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 64% of our shares outstanding on a fully-diluted basis – including all derivative securities, whether or not currently exercisable on a pre-reverse stock basis) were included in the registration statement for resale by selling stockholders. Such registration statement was declared effective by the SEC on November 20, 2007. If some or all of such 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.

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 2009 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, 2011. The lease agreement provides for rent, property taxes, common area maintenance, and janitorial services on an annualized basis of approximately $29,200 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 our facility located at 16235 State Road 17, Culver, Indiana. At this location, our wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc., owns a 28,000 square foot facility with 7,000 square feet of warehouse, 10,000 square feet of manufacturing space, 6,000 square feet of research and development labs and 5,000 square feet of administrative and storage space. The facility is located on 30 acres of land.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. (RESERVED)

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

Until February 1, 2008, our common stock was traded on the Over-the-Counter ("OTC") Bulletin Board. Commencing February 4, 2008, our common stock was admitted for trading on the NASDAQ Capital Market under the symbol "ACUR".

Set forth below for the period January 1, 2008 through February 1, 2008 are the high and low bid prices for our common stock for trading in our common stock on the OTC Bulletin Board as reported by the OTC Bulletin Board. Such over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	Bid Prices	
Period	High $	Low $
2008 Fiscal Year		
First Quarter (through February 1, 2008)	8.60	5.90

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.

	Sale Prices	
Period	High $	Low $
2008 Fiscal Year		
First Quarter (commencing February 4, 2008)	10.50	6.75
Second Quarter	10.00	7.49
Third Quarter	8.97	5.79
Fourth Quarter	7.89	3.43
2009 Fiscal Year		
First Quarter	7.69	4.07
Second Quarter	9.00	4.85
Third Quarter	6.51	4.85
Fourth Quarter	5.79	4.00
2010 Fiscal Year		
First Quarter (through January 31, 2010)	5.54	4.85

Holders

There were approximately 600 holders of record of our common stock on February 28, 2010. 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 “Item 11 - Executive Compensation - 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, 2009, 2008, 2007, 2006 and 2005 are derived from our audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2009 and 2008 and for each of the years in the three-year period ended December 31, 2009, and the reports thereon, are included elsewhere in this Report. The selected financial information as of December 31, 2007, 2006, and 2005 and for the years ended December 31, 2006 and 2005 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". All share data gives effect to the 1 for 10 reverse stock split implemented December 5, 2007.

OPERATING DATA (in thousands) except per share data	2009	2008	2007	2006	2005
Revenues	$ 3,835	$ 44,437	$ 6,404	$ —	$ —
Operating expenses:					
Research and development(1)	5,673	14,322	7,169	5,172	6,265
Marketing, general and administrative expenses(2)	11,662	9,133	4,141	5,654	5,296
Interest expense	—	—	(1,207)	(1,140)	(636)
Interest income	147	780	268	18	36
Amortization of debt discount & deferred private debt offering costs	—	—	(2,700)	(183)	—
(Loss) gain on fair value change of conversion features	—	—	(3,483)	4,235	—
(Loss) gain on fair value change of common stock warrants	—	—	(1,905)	2,164	—
(Loss) gain on asset disposals	(3)	(2)	22	(22)	81
Other (expense) income	—	(1)	(3)	(213)	5
(Loss) income before income tax	(13,356)	21,759	(13,914)	(5,967)	(12,075)
Income tax expense (benefit)	2,479	7,285	(9,600)	—	—
Net (loss) income	$ (15,835)	$ 14,474	$ (4,314)	$ (5,967)	$ (12,075)
Net (loss) income per share: Basic	$ (0.35)	$ 0.32	$ (0.11)	$ (0.75)	$ (1.81)
Net (loss) income per share: Diluted	$ (0.35)	$ 0.29	$ (0.11)	$ (0.75)	$ (1.81)
Weighted average shares used in computing net income (loss) per share: Basic	45,932	45,675	39,157	34,496	6,680
Weighted average shares used in computing net income (loss) per share: Diluted	45,932	49,416	39,157	34,496	6,680

(1) Includes stock-based compensation expense of $1,904, $560, $371, $2,067, and $3,325 for years 2009, 2008, 2007, 2006 and 2005, respectively.
(2) Includes stock-based compensation expense of $7,300, $3,290, $544, $3,517, and $3,133 for years 2009, 2008, 2007, 2006 and 2005, respectively.

BALANCE SHEET DATA(3) (in thousands)	2009	2008	2007	2006	2005
Working capital (deficiency)	$ 28,750	$ 35,991	$ 22,306	$ (28,641)	$ (2,478)
Total assets	31,917	42,961	45,628	1,619	1,792
Total debt, net (4)	—	—	—	28,787	7,613
Total liabilities	2,007	5,897	26,908	39,899	7,954

Accumulated deficit	(323,221)	(307,386)	(321,860)	(317,543)	(291,616)
Stockholders' equity (deficit)	$ 29,910	$ 37,064	$ 18,720	$ (38,280)	$ (6,162)

(3) Reflects impact of $30 million received from King in December, 2007.

(4) Includes estimated fair value of conversion features of convertible debt outstanding as of December 31, 2006.

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 3 of this Report for a description of the most significant of such factors.

Company Overview

We are a specialty pharmaceutical company engaged in research, development and manufacture of product candidates intended to provide abuse deterrent features and benefits utilizing our proprietary Aversion® and Impede™ Technologies. Our Aversion® Technology opioid analgesic product candidates are intended to effectively relieve pain while simultaneously discouraging common methods of opioid product misuse and abuse, including:

- intravenous injection of dissolved tablets or capsules;
- nasal snorting of crushed tablets or capsules; and
- intentional swallowing of excess quantities of tablets or capsules.

In addition to Acurox®, our lead product candidate, we (and/or our licensee, King Pharmaceuticals Research and Development, Inc.) are developing Vycavert® (hydrocodone bitartrate/niacin/APAP), Acuracet® (oxycodone HCl/niacin/APAP) and additional undisclosed opioid product candidates utilizing Aversion® Technology. Four opioid product candidates are licensed to King under the King Agreement. We are also developing a benzodiazepine tablet product candidate utilizing our Aversion® Technology.

Our research efforts continue to investigate and develop novel mechanisms to incorporate abuse deterrent characteristics into abused and misused pharmaceutical products. In this regard we are engaged in laboratory testing of a new product candidate developed with our novel Impede™ Technology. Impede™ Technology is primarily intended to inhibit the conversion of pseudoephedrine HCl (a legally available nasal decongestant) into methamphetamine (an illicit and frequently abused drug).

Company’s Present Financial Condition

At December 31, 2009, we had cash and cash equivalents of $30.2 million compared to $35.4 million of cash, cash equivalents, and short-term investments at December 31, 2008. We had working capital of $28.8 million at December 31, 2009 compared to working capital of $36.0 million at December 31, 2008. We had an accumulated deficit of approximately $323.2 million and $307.4 million at December 31, 2009 and December 31, 2008, respectively. We had a loss from operations of approximately $13.5 million and a net loss of $15.8 million for the year ended December 31, 2009, compared to income from operations of $21.0 million and net income of $14.5 million for the year ended December 21, 2008. As of February 28, 2010 we had cash and cash equivalents of approximately $28.4 million.

During the year ended December 31, 2009, we recognized revenues of $3.8 million derived from the $3.0 million amortized portion of the $30.0 million upfront cash payment received from King in December 2007 and $0.8 million for reimbursement of research and development expenses for Acurox® Tablets licensed to King under the King Agreement. During the year ended December 31, 2008, we recognized revenues of $44.4 million derived from the $21.9 million amortized portion of the $30.0 million upfront cash payment received from King in December 2007, $6.0 million in option exercise fees paid to us by King for licenses to the third and fourth opioid analgesic product candidates, $5.0 million in an Acurox® Tablet development milestone payment received from King, and $11.5 million paid to us by King for reimbursement of research and development expenses for Acurox® Tablets. We have yet to generate any royalty revenues from product sales. To fund our continued operations, we expect to rely on our current cash resources and additional payments that may be made under the King Agreement and under future license agreements with other pharmaceutical company partners, of which there can be no assurance of obtaining. 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, if necessary and expand the scope of our intellectual property, hire additional personnel, or invest in other areas.

In 2007, we recognized revenue of $6.4 million derived from $3.4 million which was the amortized portion of the $30.0 million non-refundable cash payment received from King in December 2007 and $3.0 million received from King in reimbursement of our Acurox® Tablet development expenses incurred under the King Agreement. 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, 2009 and 2008

	December 31			
	2009	2008	Change	
	$000's		$000's	Percent
Revenues				
Program fee revenue	3,077	27,941	(24,864)	(89)%
Collaboration fee revenue	758	11,496	(10,738)	(93)%
Milestone revenue	—	5,000	(5,000)	(100)%
Total revenue	3,835	44,437	(40,702)	(92)%
Operating expenses				
Research and development expense	5,673	14,322	(8,649)	(60)%
Marketing, general and administrative expense	11,662	9,133	2,529	28%
Total operating expenses	17,335	23,455	(6,120)	(26)%
(Loss) income from operations	(13,500)	20,982	(34,482)	(164)%
Other income (expense)				
Interest income	147	780	(633)	(81)%
Loss on asset disposals	(3)	(2)	(1)	50%
Other expense	—	(1)	1	100%
Total other income	144	777	(633)	(81)%
(Loss) income before income tax	(13,356)	21,759	(35,115)	(161)%
Income tax expense	2,479	7,285	(4,806)	(66)%
Net (loss) income	(15,835)	14,474	(30,309)	(209)%

Revenue

In December 2007, King paid us a $30.0 million upfront fee in connection with the closing of the King Agreement. Program fee revenue recognized during 2009 from amortizing this upfront fee was $3.0 million compared to $21.9 million in 2008. We have assigned an equal portion of the program fee revenue to each of three product candidates identified under the King Agreement. We have completed our development activities on 2 of the 3 product candidates and have fully amortized the portion of the upfront fee for those two product candidates in 2008. We currently estimate the development period for the third product candidate to end in December, 2010. Also, included in program fee revenue in 2008 are two $3.0 million option exercise fees paid by King to us in May and December 2008, respectively, upon the exercise of its option to license a third and fourth opioid analgesic product candidate under the King Agreement. In June 2008, King paid us a $5.0 million milestone payment for successfully achieving the primary end points in our pivotal Phase III study, AP-ADF-105 for Acurox® Tablets. We had no milestone revenue in 2009.

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Collaboration revenue recognized in 2009 was $0.8 million for reimbursement, pursuant to the King Agreement, of our Acurox® Tablets development and regulatory expenses incurred during 2009. We invoice King in arrears on a calendar quarter basis for our reimbursable development and regulatory expenses under the King Agreement. We expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying research and development expenses. The Company had collaboration revenue of $11.5 million for 2008.

Operating Expenses

Research and development expense during 2009 and 2008 were primarily for product candidates utilizing our Aversion® Technology, including costs of preclinical, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2009 and 2008 results are non-cash stock-based compensation charges of $1.9 million and $0.6 million, respectively, associated with the grant of stock options and restricted stock units. Excluding the stock-based compensation expense, there is a $10.0 million decrease in development expenses primarily attributable to a reduction of our clinical study costs. During 2008, we conducted and completed our pivotal Phase III clinical trial for Acurox®.

Marketing expenses during 2009 and 2008 consisted of Aversion® Technology customized market data research studies. Our general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll.. Included in the 2009 and 2008 results are non-cash stock-based compensation charges of $7.3 million and $3.3 million, respectively, associated with the grant of stock options and restricted stock units. Excluding the stock-based compensation expense, there is a decrease of $1.5 million in marketing, general and administrative expenses including reductions of $0.9 million in payroll, $0.3 million legal and accounting professional services, and $0.3 million state franchise taxes.

Other Income (Expense)

During 2009 and 2008, we had no debt and cash proceeds received pursuant to the King Agreement were primarily invested in money market funds, U.S. Treasury Bills, bank commercial paper, and overnight sweep investments, resulting in interest income of $0.1 million and $0.8 million, respectively.

Income Tax Expense (Benefit)

Deferred income taxes have been recognized in prior years for temporary differences between financial statement and income tax bases of assets and liabilities and loss carry-forwards for which income tax benefits are expected to be realized in future years. During 2009 we recorded a valuation allowance to reduce our net deferred income tax assets to the amount that is more likely than not to be realized. Net loss for 2009 includes a provision for income tax expense of $2.5 million for such adjustment to our valuation allowance as we determined that the utilization of certain deferred tax assets recorded in prior years cannot be reasonably predicted based upon financial forecast for succeeding years.

Net income for 2008 includes a provision for income tax expense of $8.5 million which has been partially offset by $1.2 million of income tax benefits recorded from the anticipated utilization of some of our deferred tax assets arising from net operating loss carryforwards.

Results of Operations for the Years Ended December 31, 2008 and 2007

	December 31,			
	2008	2007	Change	
	$000's		$000's	Percent
Revenues				
Program fee revenue	27,941	3,427	24,514	715%
Collaboration fee revenue	11,496	2,977	8,519	286
Milestone revenue	5,000	—	5,000	100%
Total revenue	44,437	6,404	38,033	594%
Operating expenses				
Research and development expenses	14,322	7,169	7,153	100%
Marketing, general and administrative expenses	9,133	4,141	4,922	121%
Total operating expenses	23,455	11,310	12,145	107%
Income (loss) from operations	20,982	(4,906)	25,888	528%
Other income (expense)				
Interest income (expense) net	780	(939)	1,719	183%
Amortization of debt discount	—	(2,700)	2,700	100%
Loss on fair value change of conversion features	—	(3,483)	3,483	100%
Loss on fair value change of common stock warrants	—	(1,905)	1,905	100%
(Loss) gain on asset disposals	(2)	22	(24)	(109)%
Other expense	(1)	(3)	2	67%
Total other income	777	(9,008)	9,785	109%
Income (loss) before income tax	21,759	(13,914)	35,673	256%
Income tax expense (benefit)	7,285	(9,600)	(16,885)	232%
Net income (loss)	14,474	(4,314)	18,788	436%

Revenue

In December 2007, King paid us a $30.0 million upfront fee in connection with the closing of the King Agreement. Program fee revenue recognized during 2008 from amortizing this upfront fee was $21.9 million compared to $3.4 million in 2007. We have assigned an equal portion of the program fee revenue to each of three product candidates identified under the King Agreement. We have completed our development activities on 2 of the 3 product candidates and have fully amortized the portion of the upfront fee for those two product candidates in 2008. We currently estimate the development period for the third product candidate to end in December, 2010. Also, included in program fee revenue are two $3.0 million option exercise fees paid by King to us in May and December 2008, respectively, upon the exercise of its option to license a third and fourth opioid analgesic product candidate under the King Agreement. In June 2008, King paid us a $5.0 million milestone payment for successfully achieving the primary end points in our pivotal Phase III study, AP-ADF-105 for Acurox® Tablets. We had no milestone revenue in 2007.

Collaboration revenue recognized in 2008 was $11.5 million for reimbursement, pursuant to the King Agreement, of our Acurox® Tablets development and regulatory expenses incurred during 2008. We invoice King in arrears on a calendar quarter basis for our reimbursable development and regulatory expenses under the King Agreement. We

expect the amount and timing of collaboration revenue to fluctuate in relation to the amount and timing of the underlying research and development expenses. The Company had collaboration revenue of $3.0 million for 2007 representing such reimbursable expenses from September 19, 2007, the commencement date for reimbursement purposes set forth in the King Agreement, to December 31, 2007.

Operating Expenses

Research and development expense during 2008 and 2007 were primarily for product candidates utilizing our Aversion® Technology, including costs of preclinical, clinical trials, clinical trial supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2008 and 2007 results are non-cash stock-based compensation charges of $0.6 million and $0.4 million, respectively. Excluding the stock-based compensation expense, in 2008 there was a $7.0 million increase in development expenses primarily attributable to increasing clinical study costs, including our pivotal Phase III clinical trial for Acurox®.

Marketing expenses during 2008 and 2007 consisted of Aversion® Technology customized market data research studies. Our general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll costs. Included in the 2008 and 2007 results are non-cash stock-based compensation charges of $3.3 million and $0.5 million, respectively, associated with the grant of stock options and restricted stock units. Excluding the stock-based compensation expense, there is an increase of $2.2 million in marketing, general and administrative expenses including $0.8 million of payroll costs, $0.3 million of legal services, $0.5 million of state franchise taxes, $0.2 million of tax reserves and $0.1 million of audit and tax services.

Other Income (Expense)

During 2008, we had no debt and cash proceeds received pursuant to the King Agreement were primarily invested in bank commercial paper with maturity dates less than 12 months, money market funds, U.S. Treasury Bills and in overnight sweep investments, resulting in interest income of $0.8 million.

During 2007 we incurred interest on our $5.0 million Secured Term Note at the variable rate of prime plus 4.5% through August 19, 2007 and thereafter at the fixed rate of 10% per annum. Upon the closing of the King Agreement on December 7, 2007, we repaid this Secured Term Note in full. We also incurred interest on our $10.544 million Senior Secured Convertible Bridge Notes (collectively, the “Bridge Loans”) at the fixed rate of 10%. On August 20, 2007, the entire $10.544 million principal amount of the Bridge Loans was converted into Units consisting of our common stock and warrants in accordance with our Unit Offering.

Other expense for 2007 includes a) debt discount amortization expense of $2.7 million arising from values assigned to conversion features on issuances of bridge loans, b) $3.5 million loss on fair value changes to amended conversion features on bridge loans being accounted for as mark-to-market liabilities and c) $1.9 million loss on fair value changes to common stock warrants being accounted for as mark-to-market liabilities.

Income Tax Expense (Benefit)

Deferred income taxes have been recognized in prior years for temporary differences between financial statement and income tax bases of assets and liabilities and loss carry-forwards for which income tax benefits are expected to be realized in future years. At the same time, we recorded a valuation allowance to reduce net deferred income tax assets to the amount that is more likely than not to be realized. Net income for 2008 includes a provision for income tax expense of $8.5 million which has been offset by $1.2 million of income tax benefits recorded from the anticipated utilization of some of our deferred tax assets arising from net operating loss carryforwards.

In 2007, based upon the receipt of the $30 million under the King Agreement we determined that we will be able to realize deferred income tax assets in the future and therefore we adjusted the valuation allowance by $9.6 million which is reflected as a tax benefit in the 2007 statement of operations.

Liquidity and Capital Resources

At December 31, 2009, we had cash and cash equivalents of $30.2 million compared to $35.4 million in cash, cash equivalents, and short-term investments at December 31, 2008. We had working capital of $28.8 million at December 31, 2009 compared to $36.0 million at December 31, 2008. The decrease in our cash position of $5.2 million and cash flows used in operating activities of $5.0 million for the year ended December 31, 2009, are primarily due to expenses incurred in developing product candidates not covered by the King Agreement. The decrease in working capital of $7.2 million is primarily due to reductions in collaboration revenue receivable from King of $3.2 million and deferred income taxes of $2.5 million. Cash flows generated from operating activities were $4.2 million for the year ended December 31, 2008, primarily representing net income for the period recognizing certain non-cash items such as deferred program fee revenue, net deferred tax assets, and charges for stock compensation. Our investing activities in 2009 included capital expenditures of $0.2 million and net maturities of short-term investments of $5.0 million.

At February 28, 2010, we had cash and cash equivalents of approximately $28.4 million. We estimate that such cash reserves will be sufficient to fund the development of Aversion® Technology product candidates, Impede™ Technology product candidates, and related operating expenses at least through the next 12 months.

Pending our receipt of milestone payments and royalties from King related to product candidates developed under the King Agreement, and other milestone and royalty payments under similar license agreements anticipated to be negotiated and executed with other pharmaceutical company partners, of which no assurance can be given, 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 ongoing administrative and operating expenses. Our future sources of revenue, if any, will be derived from milestone payments and royalties under the King Agreement and under similar license agreements with other pharmaceutical company partners, for which there can be no assurance.

The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our product candidates and the resources we devote to the development and commercialization of our product candidates.

The following table presents our expected cash payments on contractual obligations outstanding as of December 31, 2009 (in thousands):

	Payments due by period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	$ 36	$ 29	$ 7	$ —	$ —
Clinical studies(1)	1,440	1,440	—	—	—
Employment agreements	1,009	1,009	—	—	—
Total	$ 2,485	$ 2,478	$ 7	$ —	$ —

(1) Approximately $1,197 is expected to be reimbursed to us by King under the provisions of the King Agreement.

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

We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. In connection with King 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 King received in December 2007, and license fees, such as the $3.0 million option exercise fee paid by King to us in each of May and December 2008 upon the exercise of its option to license a third and fourth opioid analgesic product candidate under the King Agreement. We have assigned an equal portion of King's $30.0 million upfront payment to each of three product candidates identified in the King 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 $3.1 million, $21.9 million, and $3.4 million of this program fee revenue in 2009, 2008 and 2007, 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 King Agreement. The ongoing research and development services being provided to King under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with King. We recognized $0.8 million, $11.5 million and $3.0 million of collaboration revenue in 2009, 2008 and 2007, respectively of which $0.4 million and $3.5 million were current receivables at December 31, 2009 and 2008, respectively

Milestone revenue is contingent upon the achievement of certain pre-defined events in the development of Acurox® Tablets and other product candidates licensed to King under the King Agreement. Milestone payments from King 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 King 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, King paid us a $5.0 million milestone payment for successfully achieving the primary endpoints in our pivotal Phase III study, AP-ADF-105 for Acurox® Tablets.

Research and Development

Research and Development ("R&D") expenses include internal R&D activities, external CRO activities, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, depreciation, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and incentive compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include clinical trial studies and regulatory consulting, and regulatory 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 work 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 trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Advance payments are amortized to expense based on work performed. We have entered into several CRO clinical trial agreements for which the unfunded CRO commitments were $1.4 million and $1.0 million at December 31, 2009 and 2008, respectively, and are expected to be incurred as subjects are enrolled into the clinical 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. We recorded adjustments of $2.5 million increase and $1.2 million decrease to the deferred income tax asset valuation allowance during 2009 and 2008, respectively. These adjustments recognized a $2.5 million tax expense and a $1.2 million tax benefit from income taxes in our income for 2009 and 2008, respectively. At December 31, 2009, 100% of the deferred income tax assets are offset by a valuation allowance due to uncertainties with respect to future utilization of net operating loss carryforwards. If in the future it is determined that amounts of our deferred income tax assets would likely be realized, the valuation allowance would be

reduced in the period in which such determination is made and a benefit from income taxes in such period would be recognized.

Stock Compensation

On January 1, 2006, we adopted the Financial Accounting Standards Board ("FASB") statement on share-based payments. This change in accounting replaces existing requirements under FASB and eliminates the ability to account for share-based compensation transaction using the intrinsic value method. The compensation cost related to share-based payment transactions is now 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). Because our employee stock options have characteristics significantly different from those of trade options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable measure of the fair value of its employee stock options.

We had previously accounted for stock-based compensation using the intrinsic value method when the exercise price of our employee stock options equaled the market price of the underlying common stock on the date of grant, no compensation expense was recognized. Accordingly, no compensation expense had been recognized in the consolidated financial statements in connection with these types of grants for 2005 and earlier. When the exercise price of our employee stock options was less than the market price of the underlying common stock on the date of grant, compensation expense was recognized. Equity instruments issued to nonemployees in exchange for goods, fees and services are accounted for under the fair value-based method.

Our accounting for stock-based compensation for restricted stock units ("RSUs") has been 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.

Debt Discount

For years 2007 and prior, debt discount resulting from the issuance of common stock warrants in connection with subordinated debt and other notes payable as well as from beneficial conversion features contained in convertible debt was recorded as a reduction of the related obligations and was amortized over the remaining life of the related obligations. Debt discount related to the common stock warrants issued was determined by a calculation based on the relative fair values ascribed to such warrants determined by management's use of the Black-Scholes valuation model.

Conversion Features and Common Stock Warrants

For year 2007 certain provisions of the amended conversion features contained in our Bridge Loan Agreements required us to separate the value of the conversion feature from the debt and record such value as a separate liability which was marked-to-market at each balance sheet date. We used the Black-Scholes option-pricing model to compute the estimated fair value of the conversion features. Marked-to-market adjustments resulted in the recording of further gains and losses.

As a result of the amendment to the Bridge Loan Agreements, all outstanding common stock purchase warrants were fair valued using the Black - Scholes option-pricing model and recorded as a liability with a corresponding reduction in additional paid-in capital. This warrant liability was marked-to-market each balance sheet date which resulted in the recording of further gains and losses.

Capital Expenditures

Our capital expenditures during 2009, 2008, and 2007 were $220,000, $143,000 and $31,000, respectively. Capital expenditures in each such year were 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, 2009, our investments consisted primarily of investments in U.S. Treasury Bills or in money market accounts and checking funds with variable, market rates of interest.

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

None.

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-14. 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. No significant changes were made in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

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, 2009. 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, 2009, our internal control over financial reporting is effective based on those criteria.

The attestation report concerning the effectiveness of our internal control over financial reporting as of December 31, 2009 issued by BDO Seidman, LLP, an independent registered public accounting firm, appears at the end of this Item 9A.

Changes in Internal Control Over Financial Reporting. There was no change in our internal control over financial reporting that occurred during the Fourth Quarter 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

We have audited Acura Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Acura Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's 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. 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.

In our opinion, Acura Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Acura Pharmaceuticals, Inc. as of December 31, 2009 and December 31, 2008, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2009 and our report dated March 2, 2010 expressed an unqualified opinion on those consolidated financial statements.

/s/ BDO Seidman, LLP

Chicago, Illinois
March 2, 2010

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Item 8B. OTHER INFORMATION

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

Name	Age	Position
Andrew D. Reddick	57	President, Chief Executive Officer and Director
Robert B. Jones	51	Senior Vice President and Chief Operating Officer
Peter A. Clemens	57	Senior Vice President, Chief Financial Officer and Secretary
Albert W. Brzeczko	53	Vice President, Technical Affairs
Robert A. Seiser	46	Vice President, Treasurer and Corporate Controller
James F. Emigh	54	Vice President of Marketing and Administration
Bruce F. Wesson	67	Director
William A. Sumner	72	Director
Richard J. Markham	59	Director
William G. Skelly	59	Director
Immanuel Thangaraj	39	Director
George K. Ross	68	Director

Andrew D. Reddick has been President and Chief Executive Officer since August, 2003 and a member of our Board of Directors since August, 2004. From April, 2000 to September, 2002 Mr. Reddick was Chief Operating Officer and Sr. Vice President Commercial Operations for Adolor Corporation and from June, 1999 to March, 2000 he served as President of Faulding Laboratories, Inc. Mr. Reddick holds a Bachelor of Arts degree in Biology from the University of California and a Masters of Business Administration degree from Duke University.

Robert B. Jones has been our Senior Vice President and Chief Operating Officer since April 2008. From May, 2003 to March, 2008, Mr. Jones served first as the Vice President, Finance and then as Vice President, Strategy and Business Analysis of Adolor Corporation. From November 2000 to May, 2003 he served as Vice President, Finance and then as Chief Operating Officer of Opt-E-Script, Inc., a privately held personalized medicine company where Mr. Jones was responsible for all commercialization activities. Prior to that, Mr. Jones was Vice President, Sales and Marketing for Purepac Pharmaceutical Company. Mr. Jones received his M.B.A. from the University of North Carolina and a B.S. from Cornell University.

Peter A. Clemens has been Senior Vice President, Chief Financial Officer and Secretary since April 2004. Mr. Clemens was our Vice President, Chief Financial Officer and Secretary from February 1998 to March 2004 and a member of our Board of Directors from June, 1998 to August, 2004. Mr. Clemens is a Certified Public Accountant and earned a Bachelor of Business Administration degree from the University of Notre Dame and a Masters of Business Administration from Indiana University.

Albert W. Brzeczko, Ph.D., has been Vice President, Technical Affairs since February 2009. From 1999 through 2009, Dr. Brzeczko was Vice President, Global Pharma New Product Development and Pharma Technologies for International Specialty Products, Inc., a contract services group specializing in the development of technologies for the bioenhancement of poorly soluble drugs. Prior to 1999, Dr. Brzeczko held various positions of increasing responsibility in pharmaceutical product development with UPM Pharmaceuticals, Banner Pharmacaps, Mylan Laboratories, and DuPont Merck. Dr. Brzeczko received a Bachelor of Science degree in biochemistry and a Ph.D. in pharmaceutical sciences from the University of Maryland.

Robert A. Seiser has been a Vice President, Treasurer and Corporate Controller since April 2004. Mr. Seiser joined us in March 1998 as our Treasurer and Corporate Controller. Mr. Seiser is a Certified Public Accountant and earned a Bachelor of Business Administration degree from Loyola University of Chicago.

James F. Emigh has been Vice President of Marketing and Administration since April 2004. Prior to such time, Mr. Emigh was our Vice President of Sales and Marketing. Mr. Emigh joined us in May, 1998, serving first as Executive Director of Customer Relations and then as Vice President of Operations until November, 2002. Mr. Emigh holds a Bachelor of Pharmacy degree from Washington State University and a Masters of Business Administration from George Mason University.

Bruce F. Wesson has been a member of our Board of Directors since March, 1998. Mr. Wesson has been a Partner of Galen Associates, a health care venture firm, and a General Partner of Galen Partners III, L.P. since January 1991. Prior to January, 1991, he was Senior Vice President and Managing Director of Smith Barney, Harris Upham & Co. Inc., an investment banking firm. He currently serves on the Boards of Derma Sciences, Inc., Chemtura Corporation, and as Vice Chairman of the Board of MedAssets, Inc., each a publicly traded company. Mr. Wesson earned a Bachelor of Arts degree from Colgate University and a Masters of Business Administration from Columbia University.

William A. Sumner has been a member of our Board of Directors since August, 1997. From 1974 until his retirement in 1995, Mr. Sumner held various positions within Hoechst-Roussel Pharmaceuticals, Inc., including Vice President and General Manager, Dermatology Division from 1991 through 1995, Vice President, Strategic Business Development, from 1989 to 1991 and Vice President, Marketing from 1985 to 1989. Since his retirement from Hoechst-Roussel Pharmaceuticals, Inc. in 1995, Mr. Sumner has served as a consultant in the pharmaceutical industry. He currently serves on the Board of 3I, Ingredient Innovations International, a privately held company. Mr. Sumner earned a Bachelor of Arts degree from Montclair State University and a Master of Arts degree from the University of Virginia.

Richard J. Markham has been a member of our Board of Directors since May, 2006. Since November, 2004 Mr. Markham has served as a partner at Care Capital, LLC, a venture capital firm that primarily invests in life sciences companies. From May 2002 until August 2004, Mr. Markham was the Vice Chairman of the Management Board and Chief Operating Officer of Aventis SA. From December, 1999 until May, 2002 he was the Chief Executive Officer of Aventis Pharma AG. Previously he was the Chief Executive Officer of Hoechst Marion Roussel, the President and Chief Operating Officer of Marion Merrell Dow, Inc. and a member of its board of directors. From 1973 to 1993 Mr. Markham was associated with Merck & Co. Inc., culminating in his position as President and Chief Operating Officer. Mr. Markham received a B.S. in Pharmacy and Pharmaceutical Sciences from Purdue University.

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

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

George K. Ross has been a member of our Board of Directors since January, 2008. Since April 2002, Mr. Ross has been a consultant to early stage businesses and a financial investor. Since July 2005 he has served as Executive Director, Foundations and Partnerships for World Vision U.S. in New York City. His business career has included senior financial officer and board member positions with both public and private companies in diverse industries. Mr. Ross was Executive Vice President and Chief Financial Officer and a board member of Tier Technologies Inc. from

February 1997 to January 2000, which became a public company during this period. Mr. Ross is a Certified Public Accountant and earned a Bachelor of Arts degree from Ohio Wesleyan University and a Masters of Business Administration from Ohio State University.

Ron J. Spivey, Ph.D., serves on a part-time (non-executive officer) basis as our Senior Scientific Advisor since January 1, 2009. From April 2004 through December 31, 2008 Dr. Spivey was our Senior Vice President and Chief Scientific Officer. From June, 2003 to March, 2004 Dr. Spivey was President of Gibraltar Associates, a private consulting services company for the pharmaceutical industry. From March, 1998 to May, 2002 he served as Vice President, Scientific Affairs for Alpharma/Purepac Pharmaceuticals. Dr. Spivey holds a Bachelor of Arts degree from Indiana University and a Ph.D. degree in pharmaceutics from the University of Iowa.

As of the date of this Report, the Company had 15 full-time employees, nine of whom are engaged in the research, development and manufacture of product candidates utilizing the Aversion® Technology. The remaining employees are engaged in administrative, legal, accounting, finance, 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.

Corporate Governance

Audit Committee

The Audit Committee is composed of George K. Ross, Chairman, William A. Sumner and William G. Skelly. The Audit Committee is responsible for selecting the Company's registered independent public accounting firm, approving the audit fee payable to the auditors, working with independent auditors and other corporate officials, reviewing the scope and results of the audit by, and the recommendations of, our independent auditors, approving the services provided by the auditors, reviewing our financial statements and reporting on the results of the audits to the Board, reviewing our insurance coverage, financial controls and filings with the SEC, including, meeting quarterly prior to the filing of our quarterly and annual reports containing financial statements filed with the SEC, and submitting to the Board its recommendations relating to our financial reporting, accounting practices and policies and financial, accounting and operational controls.

In assessing the independence of the Audit Committee in 2009, our Board reviewed and analyzed the standards for independence provided in NASDAQ Marketplace Rule 4200(a)(15) and applicable SEC regulations. Based on this analysis, our Board has determined that each of Messrs. Ross, Sumner and Skelly satisfies such standards for independence. Our Board also determined that Mr. Ross is a "financial expert" as provided in NASDAQ Marketplace Rule 4350(d)(2)(A) and SEC regulations.

The Charter of our Audit Committee is available on our website, www.acurapharm.com, under the menu item "Audit Committee Charter" appearing under the "Corporate" tab.

Compensation Committee

The Compensation Committee is composed of Richard J. Markham, Chairman, Bruce F. Wesson and Immanuel Thangaraj. This committee is responsible for consulting with and making recommendations to the Board of Directors about executive compensation and compensation of employees. See "Item 11. Executive Compensation –Board Process" for a summary of the procedures for approving compensation for our senior management and employees. The Charter of our Compensation Committee is available on our website, www.acurapharm.com, under the menu item "Compensation Committee Charter" appearing under the "Corporate" tab.

Although the listing standards of the NASDAQ Capital Market specify that the compensation of our executive officers must be determined, or recommended to the Board, either by a majority of independent directors or a compensation committee comprised solely of independent directors, we are relying on the "controlled company" exemption provided in the listing standards of the NASDAQ Capital Market in having each of Messrs. Markham, Wesson and Thangaraj as members of the Compensation Committee.

Nominating Committee

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

The experience, qualifications, attributes or skills that led the Board to conclude that the current board members, should serve are (i) their pharmaceutical industry and senior level management experience in the case of Messrs. Reddick, Skelly, Sumner, Wesson and Markham; (ii) financial and senior level management expertise in the case of Mr. Ross, and (iii) their experience in overseeing management as principals of private equity firms in the case of Messrs. Wesson, Thangaraj and Markham. In addition we are required to elect the three designees of GCE Holdings LLC– Messrs. Markham, Thangaraj, and Wesson - to our Board pursuant to the Voting Agreement described in “Item 13. Certain Relationships and Related Transactions, and Director Independence”. See also “Item 10. Directors, Executive Officers and Corporate Governance” for a further description of the experience of our directors.

Separation of Roles of Chairman and CEO

Mr. Markham serves as the Chairman of our Board of Directors and Mr. Reddick serves as Chief Executive Officer. We believe the separation of offices is beneficial because a separate chairman (i) can provide the Chief Executive Officer with guidance and feedback on his performance, (ii) provides a more effective channel for the Board to express its views on management, (iii) allows the chairman to focus on shareholder interests and corporate governance while the Chief Executive Officer manages the Company’s operations. As Mr. Markham has significant senior level pharmaceutical industry experience, he is particularly well suited to serve as Chairman.

Board’s Role in Risk Assessment

The Board as a whole engages in risk oversight as part of its functions. As an emerging pharmaceutical development company we face numerous risks identified under Item 1A-Risk Factors”, many of which are outside of our control. In addition, the Audit Committee reviews our insurance coverage and the Board and Audit Committee regularly monitors our liquidity position and operating expenses and reviews our capital funding needs. The Company believes the Board leadership structure effectively enables it to oversee risk management.

Shareholder Communications to the Board

Shareholders who wish to send communications to our Board of Directors may do so by sending them in care of our Secretary at the address on the cover page of this Report. The envelope containing such communication must contain a clear notation indicating that the enclosed letter is a "Shareholder-Board Communication" or "Shareholder-Director Communication" or similar statement that clearly and unmistakably indicates the communication is intended for the Board. All such communications must clearly indicate the author as a shareholder and state whether the intended recipients are all members of the Board or just certain specified directors. Our Secretary will have the discretion to screen and not forward to Directors communications which the Secretary determines in his or her discretion are communications unrelated to our business or our governance, commercial solicitations, or communications that are offensive, obscene, or otherwise inappropriate. The Secretary will, however, compile all shareholder communications which are not forwarded and such communications will be available to any Director.

Code of Ethics

Our Code of Ethics applicable to our principal executive officer, principal financial officer, principal accounting officer and all of our other employees is available on our website, www.acurapharm.com, under the menu item "Code of Ethics" appearing under the "Corporate" tab.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our Directors and executive officers, and persons who own beneficially more than ten percent (10%) of our Common Stock, to file reports of ownership and changes of ownership with the SEC. Copies of all filed reports are required to be furnished to us pursuant to Section 16(a). Based solely on the reports received by us and on written representations from reporting persons, we believe that our Directors, executive officers and greater than ten percent (10%) beneficial owners of our Common Stock complied with all Section 16(a) filing requirements during the year ended December 31, 2009.

ITEM 11. EXECUTIVE COMPENSATION

Unless otherwise noted all share and share price information with respect to our common stock give effect to a 1 for 10 reverse stock split implemented December 5, 2007.

Compensation Discussion and Analysis

Our executive compensation program consists of (i) an annual salary and bonus compensation and (ii) equity incentives represented by the issuance of stock options and restricted stock units ("RSUs"). The salary, bonuses, and equity incentives serve to link executive pay to corporate performance.

Policies for Allocating Between Various Forms of Compensation

For a number of years prior to 2007, because we had insufficient cash reserves, our ability to pay cash bonuses and increase salaries was limited. As a result, we did not grant cash bonuses or increase salaries to our principal executives in the three years ended December 31, 2006. Instead we sought to incentivize our senior management with equity compensation in the form of stock options and RSUs.

In 2004 and 2005 we issued stock options to our employees with an exercise price at a discount to the then current trading price for our common stock. Because our stock price is based on relatively low trading volume and a small public float, it can fluctuate widely at times. As a result, we determined that the issuance of RSUs presented a number of advantages. First, it allows us to reduce the dilutive effect of this equity-based compensation, as there are fewer shares underlying a restricted stock award than an equivalent value issued in a stock option award. Second, the vesting schedule of the RSUs was structured to minimize the potential excise tax under Section 280G of the Internal Revenue Code upon a change of control. Third, it is difficult to set an exercise price for options that accurately reflects the value of the Company due to the low trading volume and small public float for our common stock.

As a result, in 2005 we established a restricted stock unit plan (the "2005 RSU Plan") and issued RSUs aggregating 2,750,000 shares to employees. In addition, RSUs with respect to 100,000 shares were issued to each of our two independent directors in 2006. In each case, the number of RSUs we issued was influenced by the closing price of the stock underlying the RSUs on the date of grant. As a result of an amendment to our RSU Plan approved by our Board in March 2008, and ratified by our shareholders in April 2008, we increased the number of RSUs available for issuance under the 2005 RSU Plan from 3 million to 3.5 million. After giving effect to RSU awards since the adoption of the 2005 RSU Plan, as of the date of this Report, 184,000 shares remain available for RSU grants under

such plan.

Following the completion of our Unit Offering in August 2007 and the consummation of the King Agreement in December 2007, our cash position improved and we were able to increase salaries and grant bonuses to our employees as discussed below under the caption “Salary and Bonus”. In addition to periodic awards of equity-based compensation (see “Stock Options” below), our objective is to award merit based cash bonuses and salary increases on an annual basis going forward. The amounts and timing of any such awards will be subject to available cash reserves and the satisfaction of employee performance objectives established by our Chief Executive Officer and the Compensation Committee. Our equity-based compensation going forward is targeted to allow senior management as a group to own between 5% and 10% of our outstanding common stock, so as to align their interests with shareholders’ interests.

In 2007, no stock options or RSU awards were made to senior management. In view of our improved cash reserves following the closing of the King Agreement, and recognizing that no salary increases or bonuses had been awarded to senior management over the prior four years, the Compensation Committee and the Board determined that salary increases and bonuses for each executive officer was appropriate. As part of its analysis the Compensation Committee and the Board considered the stock option and RSU awards previously made to the executive officers in 2004 and 2005 and determined that additional equity incentive compensation was not warranted in 2007.

As discussed below under the caption "Stock Options", in 2008 and 2009, we awarded stock options to employees with such options having an exercise price equal to the fair market value of our Common Stock on the date of grant. In 2009 we also awarded RSUs to employees. These stock options and RSUs were awarded in recognition that no equity-based compensation awards had been granted since 2005 and in an effort to retain valued employees. We have also issued RSUs and options to executives upon commencement of employment. For example, in 2009 we awarded 24,000 RSUs and options to purchase 96,000 shares of Common Stock to Dr. Brzeczko upon commencement of employment and in 2008 we awarded 50,000 RSUs and 30,000 options to purchase Common Stock to Mr. Jones upon commencement of employment.

Salary and Bonus

Each of Andrew Reddick, Robert Jones and Peter Clemens are parties to employment agreements, described under the caption "Employment Agreements" below, which provide the minimum annual base salary to be payable to such officers, subject to increase at the discretion of the Board. For 2009, the annual salaries of Messrs. Reddick, Jones and Clemens were $365,000, $290,000 and $205,000, respectively. In addition, the Reddick, Jones and Clemens employment agreements provide for annual bonus payments, in the discretion of the Compensation Committee or the Board, subject to the satisfaction of such targets, conditions or parameters as may be agreed upon from time to time by the employee and the Compensation Committee.

The bonus performance targets for Messrs. Reddick, Spivey, Jones and Clemens for 2008 included advancing Acurox® to NDA submission, and other product candidates using our Aversion® Technology to proof of concept, implementing the King Agreement, licensing of additional products to King through the exercise of King's options under the King Agreement and licensing products utilizing our Aversion® Technology outside of North America. Such performance targets are both organization and individual goals. In 2008 we advanced several products using our Aversion® Technology, licensed two additional products to King, and advanced Acurox® by submitting a 505(b)(2) NDA to the FDA. Considering these achievements, we awarded bonuses of $328,500, $315,000, $130,500 and $102,500 to Messrs. Reddick, Spivey, Jones and Clemens. In addition, to induce Dr. Spivey to remain as a full time employee through December 31, 2008, we paid him an additional $315,000 retention bonus on December 31, 2008. Although salaries were increased for 2009 for non-executive officer employees, no salary increases were granted to Messrs. Reddick, Jones or Clemens for 2009. Dr. Spivey became a part-time employee in 2009, at an annual salary of $120,000 per year.

The material bonus performance targets for 2009 consisted of achieving FDA approval of the Acurox® Tablet NDA, advancement of additional product candidates (both opioid and non-opioid) utilizing Aversion® Technology, and expansion of our intellectual property portfolio relative to abuse deterrent technologies. Such performance targets were both organization and individual goals. We met most but not all of our 2009 performance targets. We did not receive FDA approval of the Acurox® Tablet NDA in 2009, although we did advance additional product candidates through development and expanded our intellectual property portfolio with the addition of two issued patents and the filing of new patent applications. Considering these circumstances we granted bonuses of $140,000, $112,000 and $74,000, respectively, to Messrs. Reddick, Jones, and Clemens, which amounts represented substantially less than their 2008 bonus awards. Recognizing that our executives did not receive a salary increase for 2009, for 2010 we modestly increased their salaries in the range of 3.2% and 3.6%. As a result, Messrs. Reddick, Jones and Clemens

now receive annual salaries of $377,000, $300,000 and $211,500, respectively.

The material bonus performance targets for 2010 are similar to the 2009 goals and include the gaining of FDA agreement to accept resubmission of the Acurox® Tablets NDA, subsequent FDA approval of such NDA resubmission, advancement of additional product candidates (both opioid and non-opioid) utilizing our Aversion® and Impede™ Technologies and enhancement of our intellectual property portfolio for abuse deterrent technologies. Such performance targets are both organizational and individual goals for Messrs. Reddick and Jones. Mr. Clemens' bonus is weighted 50% to the achievement of the foregoing organizational goals and 50% to the achievement of goals unique to his position as Chief Financial Officer.

No compensation will be earned with respect to a performance measure unless a performance "floor" for that measure is exceeded; the incentive opportunity with respect to a measure will be earned if the target is achieved; achievement between the floor and the target results in a lower amount of award with respect to that performance measure. An amount larger than the incentive opportunity for each performance measure can be earned, up to and possibly exceeding a specified limit, for exceeding the target for that measure. Depending on market conditions and other circumstances, performance criteria may be modified during the course of the year, and other performance criteria reweighted. In setting compensation levels, the Compensation Committee compares our Company to companies of comparable business focus, market capitalization, technological capabilities and market in which we compete for executives. As part of this process, the Compensation Committee and the Board does not use the compensation levels of comparable companies as benchmarks, rather as a factor in evaluating the compensation levels of the named, executive officer. To date, compensation consultants have not been retained by the Compensation Committee or the Board as part of this process.

In ascertaining the achieved level of performance against the targets, the effects of certain extraordinary events, as determined by the Compensation Committee, such as (i) major acquisitions and divestitures, (ii) significant one-time charges, and (iii) changes in accounting principles required by the Financial Accounting Standards Board, are "compensation neutral" for the year in which they occurred; that is, they are not taken into account in determining the degree to which the targets are met in that year.

The Compensation Committee may, after a review of an executive’s performance, recommend to the Board that a bonus award be made to such executives based upon other non-enumerated performance targets (whether or not they are parties to employment agreements). This could result in the award of salary increases or bonuses above a targeted range amount.

For our other executive officers not subject to an employment contract (Messrs. Brzeczko, Seiser and Emigh), the Compensation Committee will set the annual salary for such executive officers between December and March and establish potential bonus compensation that such executives may earn based upon quantitative and, if applicable, qualitative performance goals established by the Compensation Committee. For 2008 and 2009 each of Messrs. Seiser’s and Emigh’s salaries was $160,000. Dr. Brzeczko commenced employment in February, 2009 at an annual salary of $265,000.

The salary and bonus performance targets for both Messrs. Emigh and Seiser for 2008 consisted of advancing our Acurox® Tablets to NDA submission and other product candidates utilizing our Aversion® Technology through proof of concept, implementing the King Agreement, licensing of additional products to King through the exercise of King’s options under the King Agreement, and licensing products utilizing our Aversion® Technology outside of North America. Such performance targets were both organization and individual goals. For the reasons stated above in the case of Messrs. Reddick, Spivey, Jones and Clemens, we paid bonuses of $56,000 and $40,000 to Messrs. Seiser and Emigh, respectively, for 2008. Although salaries were increased for 2009 for non-executive officer employees, no salary increases were granted to Messrs. Seiser or Emigh for 2009.

Messrs. Brzeczko's, Seiser's and Emigh's performance targets for 2009 were the same as those for Reddick, Jones and Clemens as stated above. Because only some of these targets were met we paid lower bonuses to Messrs. Seiser and Emigh in 2009 than in 2008. In 2009, Messrs. Seiser and Emigh received bonuses of $21,500 and $20,000 respectively. Similarly Dr. Brzeczko's 2009 year-end bonus was $33,000, which was less than the maximum bonus target included in his February 2009 employment offer letter. Messrs. Brzeczko's, Seiser's and Emigh's organizational bonus performance targets for 2010 are consistent with those for Messrs. Reddick, Jones and Clemens as outlined above. Such officers' bonuses are weighted 50% to the organizational performance targets and 50% to the achievement of performance targets unique to their respective positions. After receiving no salary increases in 2009, in 2010 we awarded salary increases to Messrs. Brzeczko, Seiser and Emigh generally consistent with inflation. As a result, for 2010 Messrs. Brzeczko, Seiser and Emigh will receive annual salaries of $273,000, $165,000 and $165,000, respectively.

Stock Options

A long-term component of our executive compensation program consists of stock option grants. The options generally permit the option holder to buy the number of shares of our Common Stock covered by the option (an "option exercise") at a price fixed at the time of grant. While we have historically granted stock options having an exercise price equal to the fair market value of our Common Stock on the date of grant and continued this practice in 2009, during 2004 and 2005, we issued stock options to our employees at a discount to the trading price of our common stock. It is our expectation that discounted stock option grants will occur, if at all, only on an isolated basis in the future where circumstances warrant. With respect to stock options grants having an exercise price equal to the market price of our Common Stock on the date of grant, such options generally gain value only to the extent our stock price exceeds the option exercise price during the life of the option. Generally, a portion of the options vest over a period of time if the option holder remains an employee and expire no later than 10 years after grant. Executives will generally be subject to limitations in selling the vested option stock due to securities law considerations, and therefore will have an incentive to increase shareholder value. In 2007 no option grants were made to our executive officers as the Compensation Committee and the Board elected to grant salary increases and bonuses instead based on our improved cash position and the absence of the award of such cash incentives during the prior four years.

It is the Company's practice to grant stock options to executives upon commencement of employment. On April 7, 2008, the date Mr. Jones joined us as Senior Vice President and Chief Operating Officer, he was granted stock options exercisable for 30,000 shares. See "—Summary Compensation Table and Discussion of Employment and Incentive Arrangements-Employment Agreements". In 2009, we granted stock options to purchase 96,000 shares to Dr. Brzeczko upon his commencement of employment as Vice President of Technical Affairs. See "—Summary Compensation Table and Discussion of Employment and Incentive Arrangements. In addition, in May 2008 and April 2009 we granted options for an aggregate of 1,040,000 and 1,030,000 shares, respectively, to our employees, generally, exercisable at fair market value on the date of grant, which options vest in equal installments over 24 months. The May 2008 option grants included options with respect to 250,000, 160,000, 160,000, 100,000, 80,000, and 80,000 underlying shares, to Messrs. Reddick, Spivey, Jones, Clemens, Seiser and Emigh, respectively, which represented 24%, 15%, 15%, 10%, 8% and 8% of the options granted to all employees, generally. The April 2009 option grants included options with respect to 250,000, 160,000, 120,000, 96,000, and 72,000 underlying shares, to Messrs. Reddick, Jones, Clemens, Seiser and Emigh, respectively, which represented 24%, 16%, 12%, 9% and 7%, respectively, of the options granted to all employees, generally. Dr. Brzeczko was not included in the April 2009 option grants, as he had received an option grant in February 2009 upon commencement of his employment. It is likely we will maintain similar but not necessarily identical ratios of distribution of option awards in the future as we made in 2008 and 2009 to those persons and/or persons in similar management positions.

Timing Policies with Respect to Options

We have no plan or practice to time option grants in coordination with the release of non-public information and we do not time the release of non-public information to affect the value of executive compensation. Option grant dates for options issued to any new executive officers will likely be the starting date of their employment.

Restricted Stock Units

Another component of our executive compensation program is the grant of RSUs under our 2005 RSU Plan. A RSU represents a contingent obligation to deliver a share of our common stock to the holder of the RSU on a distribution date. Each RSU award made to our executives in 2005 vested one-third (1/3) upon grant and the balance in equal monthly increments on the first day of each month beginning January 1, 2006 and ending December 1, 2007. We will issue the vested shares underlying the RSU awards on the earlier of (i) a Change of Control (as defined in our 2005 RSU Plan), or (ii) in four annual installments starting on January 1, 2011. In the event of a Change of Control, our issuance of the vested shares shall be made in a lump sum distribution. In the absence of a Change of Control, the issuance of the vested shares shall be made in four (4) equal installments on each of January 1, 2011, January 1, 2012, January 1, 2013 and January 1, 2014. Upon our distribution of the vested shares underlying the RSU awards, the recipients must submit to us the par value of $0.01 per share. In 2005, we granted Messrs. Reddick, Spivey, Clemens, Seiser and Emigh RSU awards with respect to 825,000, 660,000, 440,000, 165,000 and 137,500 underlying shares, respectively. Of the RSU awards to employees noted above in 2005, 30%, 24%, 16%, 6% and 5% were issued to Messrs. Reddick, Spivey, Clemens, Seiser and Emigh, respectively. In the case of Messrs. Reddick, Spivey and Clemens, such awards were reflected in their employment agreements. We may also grant RSUs in connection with commencement of employment. In April 2008, upon commencement of his employment, Mr. Jones was granted an RSU award for 50,000 shares, which vested monthly in 2,500 share installments commencing May 31, 2008. Dr. Brzeczko and another executive were also awarded RSUs upon commencement of employment in 2009. No additional RSUs were granted to our executive officers in 2007 or 2008 as the Compensation Committee and the Board elected to grant salary increases in 2007, option awards in 2008 and bonuses in 2007 and 2008. In April 2009 we granted an aggregate of 285,000 RSUs to all of our employees (other than those who had already received awards earlier in the year upon commencement of employment), including 85,000, 45,000, 30,000, 24,000 and 18,000 to Messrs. Reddick, Jones, Clemens, Seiser and Emigh, respectively, representing 30%, 16%, 11%, 8% and 6% of RSUs granted to employees generally. It is likely we will maintain similar but not necessarily identical ratios of distribution of RSU awards in the future as we made in 2005 and 2009 to those persons and/or persons in similar management positions. Equity awards granted to executive upon commencing employment are considered in and serve to reduce, the annual equity awards that may be made to such executive in later in such year.

Termination/Severance Benefits

The employment agreement of each of Messrs. Reddick, Jones and Clemens provide severance benefits under certain circumstances. The severance benefits provided to each such executive differ, but include payments of a pro rata bonus or non equity incentive compensation, one to two years of salary and one to two years of benefits. See “Employment Agreements” and “Quantifying Termination/Change of Control Payments” in this Item 11. We believe severance arrangements for the highest level officers help them to focus on their respective job functions and give them comfort that we will not lightly terminate their employment. We believe these severance benefits were necessary to be able to initially hire and to retain these executives. In turn Messrs. Reddick, Jones and Clemens have agreed after their employment with us ends under certain circumstances not to compete or solicit our employees for hire for a limited period of time. We believe that such non-compete and non-solicit provisions are important to protect our business. The severance benefits are standard in employment contracts and were the results of negotiations between us and our executives.

The other executive officers named in the Summary Compensation Table have no contractual severance benefits if terminated by us other than acceleration of vesting of their RSUs.

Retirement Plans

Beginning in 1998, we have maintained a 401(k) plan that allows us to make both discretionary and matching contributions, but we have not done so since inception. We have no pension plans or non-qualified deferred

compensation plans and, as a result, the columns relating to such plans in the Summary Compensation Table are blank.

Change in Control

Currently unexercisable options vest with respect to all underlying shares upon a change of control (as defined in employment agreements, in the case of Messrs. Reddick, Jones and Clemens, and in stock option agreements, in the case of Messrs. Brzeczko, Emigh and Seiser) for all executive officers. In addition, discounted options that are subject to Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A), become exercisable upon a change of control that qualifies as a change of control under Section 409A. In addition, RSUs vest with respect to all underlying shares upon a change of control and are distributed upon a change of control (provided the requirements of Section 409A are met). In addition, Messrs. Reddick, Jones and Clemens receive severance and bonuses if they terminate their employment after a change of control (as defined in their employment agreements), or we terminate their employment after a change of control. We believe our change of control provisions incentivize our executives to seek opportunities for us and realize benefits from a change of control transaction even though such change of control may lead to the termination of their positions.

Tax Reimbursements

Because of the excise tax imposed by Internal Revenue Code Section 280G, our executive officers may be subject to such tax upon the exercise of options and distributions under RSUs upon a change of control. We currently have no agreements to reimburse our executive officers for any taxes imposed as a result of these additional excise taxes. We will pay taxes incurred by Mr. Reddick on a lump sum distribution of the value of twelve months of benefits, which he may elect in lieu of continued benefits, in the event his employment terminates under certain circumstances. We also allow our employees to elect to have shares withheld upon exercise of options and upon the exchange of RSUs in satisfaction of the statutory minimum withholding tax obligations of such employees relating to such option exercises or RSU exchanges.

Perquisites and Other Benefits

Our executive officers receive no perquisites. We have not made either discretionary or matching contributions to their 401(k) plans, although our plan provides that we may do so. Our executive officers are not provided auto allowances and they receive no country club or golf club memberships. We may, however, consider such perquisites in the future.

Board Process

The Compensation Committee of the Board of Directors approves all compensation and awards to our executive officers and other employees and thereafter submits its recommendation to the full Board for approval. All such decisions are made with the consultation of the Chief Executive Officer, except those relating to the compensation of the Chief Executive Officer. Except for salary adjustments and cash bonus and equity awards to the Chief Executive Officer, these items are generally based upon the recommendation of the Chief Executive Officer. For example, in 2009, the Chief Executive Officer made recommendations with respect to bonuses and salary increases for all other employees (other than himself) and the Compensation Committee and Board adopted such recommendations. With respect to salary adjustments and cash bonus and equity items to the Chief Executive Officer, the Compensation Committee establishes such awards for the Chief Executive Officer subject to review and approval of the Board.

Summary Compensation Table and Discussion of Employment and Incentive Arrangements

The following table sets forth a summary of the compensation paid by us for services rendered in all capacities to us during each of the three fiscal years ended December 31, 2009, to our Chief Executive Officer, Chief Financial Officer and our next three most highly compensated executive officers (collectively, the "2009 named executive officers") whose total annual compensation for 2009 exceeded $100,000:

Summary Compensation Table

Name and Principal Position	Year	Base Salary ($)	Bonus ($)	Stock Awards1 ($)	Option Awards2 ($)	Total ($)
Andrew D. Reddick	2007	300,000	850,000	—	—	1,040,000
President & CEO	2008	365,000	328,500	—	2,369,600	3,063,100
	2009	365,000	140,000	533,800	1,504,725	2,543,525
Peter A. Clemens	2007	180,000	180,000	—	—	360,000
SVP & CFO	2008	205,000	102,500	—	947,840	1,255,340
	2009	205,000	74,000	188,400	722,268	1,189,668
Robert B. Jones,	2008	211,923	130,500	282,600	685,466	1,310,489
SVP & COO (commenced employment April 7, 2008)	2009	290,000	112,000	431,500	963,024	1,796,524
Albert W. Brzeczko VP, Technical Affairs (commenced employment February 9, 2009)	2009	234,423	73,000	136,580	523,978	967,981
Robert A. Seiser	2007	133,000	140,000	—	—	273,000
VP, Treasurer & Corporate	2008	160,000	56,000	—	758,272	974,272
Controller	2009	160,000	21,500	150,720	577,814	910,034

(1) The 2008 entries reflect the grant date fair value of RSUs awarded with respect to 50,000 underlying shares in 2008 to Mr. Jones. The 2009 entries reflect the grant date fair value of RSUs with respect to 85,000, 45,000, 30,000, 24,000 and 24,000 underlying shares issued in 2009 to Messrs. Reddick, Jones, Clemens, Brzeczko, and Seiser, respectively. Grant date fair values are computed in accordance with FASB ASC Topic 718, which are the closing value of the price of our Common Stock on the business day preceding the date of grant reduced by the $.01 par value payable by a holder upon exchange of an RSU. In all cases we exclude the possibility of forfeiture. See Note I to our Financial Statements for a general discussion of assumptions used in calculating grant date fair-value.

(2) The 2008 entries reflect the grant date fair value of options with respect to 250,000, 100,000, 190,000, and 80,000 underlying shares issued in 2008 to Messrs. Reddick, Clemens, Jones, and Seiser, respectively. The 2009 entries reflect the grant date fair value of options with respect to 250,000, 120,000, 160,000, 96,000, and 96,000 underlying shares issued in 2009 to Messrs. Reddick, Clemens, Jones, Brzeczko and Seiser, respectively. Grant date fair values are computed in accordance with FASB ASC Topic 718. To calculate grant date fair value, we consider an assumed risk free interest rate and a historical volatility percentage for our Common Stock. For the option with respect to 30,000 shares issued to Mr. Jones in April 2008 we used a risk free interest rate of 3.57% and historical volatility of 142.47%. For other options issued in 2008 we used a risk free interest rate of 3.85% and historical volatility of 124.84%. For options issued to Dr, Brzeczko in February 2009 we used a risk free interest rate of 3.07% and historical volatility of 124.19%. For other options issued in 2009 we used a risk free interest rate of 2.96% and historical volatility of 123.92%. In all cases we excluded the possibility of forfeiture and calculated values based on 10 year option terms. See Note I to our Financial Statements for a general discussion of assumptions used in calculating grant date fair value.

Other Compensatory Arrangements

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

Employment Agreements

Andrew D. Reddick is employed pursuant to an Employment Agreement effective as of August 26, 2003, as amended, which provides that Mr. Reddick will serve as our Chief Executive Officer and President for a term currently scheduled to expire December 31, 2010. The term of the Employment Agreement provides for automatic one (1) year renewals in the absence of written notice to the contrary from us or Mr. Reddick at least ninety (90) days prior to the expiration of the initial term or any subsequent renewal period. Pursuant to an amendment to the Employment Agreement executed on July 9, 2008, our non-renewal of the Employment Agreement is considered a termination without Cause for all purposes under the Employment Agreement. Mr. Reddick's base salary under the Employment Agreement is $377,000 (increased by the Board from $365,000 effective January 1, 2010). Pursuant to the Employment Agreement, Mr. Reddick is entitled to an annual bonus based on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. For our 2009 fiscal year, Mr. Reddick was awarded a bonus of $140,000 due to, among other reasons, the achievement of certain of the items discussed above under the caption "Salary and Bonus". The Employment Agreement also provides for our grant in August, 2004 to Mr. Reddick of stock options exercisable for up to 875,000 shares of Common Stock at an exercise price of $1.30 per share. Such stock options provide for vesting of 300,000 shares on the date of grant of the option, with the balance vesting in monthly increments of 25,000 shares at the expiration of each monthly period thereafter commencing with the month ending August 31, 2004. The exercise price of $1.30 per share represents a discount to the fair market value of our Common Stock on the date of grant. On August 12, 2004, the date of grant of the stock options, the average of the closing bid and asked prices for our Common Stock was $4.35. Because 450,000 of the discounted options are subject to Section 409A, in 2007, we established an exercise schedule to comply with Section 409A for such 450,000 options so that the options are exercisable (subject to earlier exercisability as set forth in the table below entitled "Events Affecting Option Vesting and Exercise") in four equal installments on January 1 of each of 2011, 2012, 2013 and 2014, provided that such options may be exercised only in the calendar year in which they first become exercisable, and in no event later than August 11, 2014. The Employment Agreement also acknowledges our grant in December, 2005 to Mr. Reddick of a Restricted Stock Unit Award providing for our issuance of up to 825,000 shares of our Common Stock. The Restricted Stock Unit vested one-third (1/3) upon grant and the balance in equal monthly increments on the first day of each month beginning January 1, 2006 and ending December 1, 2007. The vested shares underlying the Restricted Stock Unit Award will be issued by us on the earlier of (i) a Change in Control (as defined in our 2005 RSU Plan), or (ii) January 1, 2011. In the event of a Change in Control, we will issue the vested shares in a lump sum distribution. In the absence of a Change of Control, the issuance of the vested shares shall be made in four (4) equal installments on each of January 1, 2011, January 1, 2012, January 1, 2013 and January 1, 2014. Upon issuance of the shares underlying the Restricted Stock Unit Award, Mr. Reddick must remit to us the par value of $0.01 per share or have us withhold shares to satisfy such payment obligation. On December 22, 2005, the date of grant of the Restricted Stock Unit Award, the average of the closing bid and asked prices of our Common Stock was $3.33, as reported by the OTCBB. Mr. Reddick has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the Restricted Stock Unit Award until we issue the underlying shares. The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause. In the event the Employment Agreement is terminated due to death or disability, we are required to pay Mr. Reddick, or his designee, a pro rata portion of the annual bonus that would have been payable to Mr. Reddick during such year assuming full achievement of the bonus criteria established for such bonus.

In the event that the Employment Agreement is terminated by us without Cause, or by Mr. Reddick for Good Reason, we are required to pay Mr. Reddick an amount equal to the bonus for such year, calculated on a pro rata basis assuming full achievement of the bonus criteria for such year (to the extent it has not already been paid), as well as Mr. Reddick's base salary for one year (such salary amount being the "Severance Pay"). In case of termination without Cause, such severance is payable in equal monthly installments over a period of twelve (12) months, and in the case of termination by Mr. Reddick for Good Reason, one-half of such severance is payable six months after termination, and the remaining half of such severance is payable thereafter in six monthly installments. In addition, Mr. Reddick is at his option entitled to continued coverage under our then existing benefit plans, including medical and life insurance, for twelve (12) months from the date of termination or the value of such benefits payable in a lump sum thirty days of termination together with amount needed to pay income tax on such lump sum. The Employment Agreement permits Mr. Reddick to terminate the Employment Agreement in the event of a Change in Control (as defined in the Employment Agreement), in which case such termination is considered to be made without Cause, entitling Mr. Reddick to the benefits described above, except that (i) the Severance Pay is payable in a lump sum within six months after the date of termination, and (ii) with options being treated as set forth in the table below entitled, “Events Affecting Option Vesting and Exercise.” The Employment Agreement restricts Mr. Reddick from disclosing, disseminating or using for his personal benefit or for the benefit of others, confidential or proprietary information (as defined in the Employment Agreement) and, provided we have not breached the terms of the Employment Agreement, from competing with us at any time prior to one year after the termination of his employment with us. In addition he has agreed not to (and not to cause or direct any person to) hire or solicit for employment any of our employees or those of our subsidiaries or affiliates (i) for six (6) months following the termination of his employment by us without Cause or by him for Good Reason, prior to a Change of Control, (ii) for twelve (12) months following the termination of his employment for Cause, prior to a Change of Control, or (iii) twenty-four (24) months following a Change of Control. On each of May 23, 2008 and April 24, 2009, we granted Mr. Reddick options to purchase 250,000 shares of our Common Stock exercisable at the fair market value of our Common Stock at the date of grant and vesting in equal installments over 24 months. On April 24, 2009 we also granted Mr. Reddick RSUs with respect to an additional 85,000 underlying shares that vest in equal installments over 24 months and are exercisable on the same schedule as the RSUs granted to Mr. Reddick in 2005. The table entitled “Events Affecting Option Vesting and Exercise,” below summarizes the vesting and exercisability of Mr. Reddick’s options following a number of termination scenarios or a Change of Control.

Robert B. Jones commenced employment with us on April 7, 2008 pursuant to an Employment Agreement dated March 18, 2008, which provides that Mr. Jones will serve as our Senior Vice President and Chief Operating Officer for a term currently scheduled to expire December 31, 2010. The term of the Employment Agreement provides for automatic one (1) year renewals in the absence of written notice to the contrary from us (which would give Mr. Jones the right to terminate his employment for Good Reason) or Mr. Jones at least ninety (90) days prior to the expiration of the initial term or any subsequent renewal period. Mr. Jones’ base salary under the Employment Agreement is $300,000 (increased from $290,000 effective January 1, 2010). Pursuant to the Employment Agreement Mr. Jones is eligible for annual bonuses of up to thirty percent (30%) of his base salary on the achievement of such targets, conditions, or parameters as may be set from time to time by the Board of Directors or the Compensation Committee of the Board of Directors. In 2009, Mr. Jones was awarded a bonus of $112,000 due to, among other reasons, the achievement of certain of the items discussed above under the caption “Salary and Bonus”. The Employment Agreement provides for our grant in April 2008 to Mr. Jones of stock options exercisable for up to 30,000 shares of Common Stock at an exercise price equal to the last sale price of our Common Stock on the last trading day prior to his April 7, 2008 commencement date. The stock option provides for vesting of 1,500 shares on the last day of each month commencing May 31, 2008 and as of December 31, 2009 the stock option was fully vested. In addition, on each of May 23, 2008 and April 24, 2009, we granted Mr. Jones stock options to purchase 160,000 shares of our Common Stock exercisable at the fair market value of our Common Stock at the date of grant and vesting in equal installments over 24 months (subject to earlier exercisability as set forth in the table below entitled “Events Affecting Option Vesting and Exercise”). The Employment Agreement also provides for our grant in April 2008 to Mr. Jones of a Restricted Stock Unit Award providing for our issuance of up to 50,000 shares of our Common Stock. The

Restricted Stock Units granted to Mr. Jones in 2008 vested 2,500 shares on the last day of each month commencing May 31, 2008 and as of December 31, 2009 are fully vested. The vested shares underlying the Restricted Stock Unit Award will be issued by us on the earlier of (i) a Change in Control (as defined in our 2005 RSU Plan), or (ii) January 1, 2011. In the event of a Change in Control, we will issue the vested shares in a lump sum distribution. In the absence of a Change in Control, the issuance of the vested shares shall be made in four (4) equal installments on each of January 1, 2011, January 1, 2012, January 1, 2013 and January 1, 2014. Upon issuance of the shares underlying the Restricted Stock Unit Award, Mr. Jones must remit to us the par value of $0.01 per share or have us withhold shares to satisfy such payment obligation. Mr. Jones has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the Restricted Stock Unit Award until we issue the shares. The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause. In the event that we terminate the Employment Agreement without Cause or Mr. Jones terminates the Employment Agreement for Good Reason, we are required to pay Mr. Jones an amount equal to the bonus for such year, calculated on a pro rata basis assuming full achievement of the bonus criteria for such year (to the extent it has not already been paid), as well as Mr. Jones' base salary for one year (such salary amount being the "Severance Pay"). In case of termination without Cause and for Good Reason, such Severance Pay is payable in equal monthly installments over a period of twelve (12) months, with a six month payment delay for the that portion of the Severance Pay that would cause the payments to fall outside an exception to the deferred compensation rules requiring certain severance payments to certain officers of a public company to be made commencing six months after termination However, if such termination without Cause or for Good Reason follows within two years of a qualifying Change of Control then the Severance Pay is payable in a lump sum 31 days after termination, otherwise if such termination follows a Change of Control by more than two years then the Severance Pay is payable six months and one day following termination. In addition, upon a termination without Cause or for Good Reason any shares remaining unvested under stock options and restricted stock units granted to Mr. Jones will vest in full and Mr. Jones will be entitled to continued coverage under our then existing benefit plans, including medical and life insurance, for twelve (12) months from the date of termination. The Employment Agreement restricts Mr. Jones from disclosing, disseminating or using for his personal benefit or for the benefit of others, confidential or proprietary information (as defined in the Employment Agreement) and, provided we have not breached the terms of the Employment Agreement, from competing with us at any time prior to one year after the termination of his employment with us. In addition, Mr. Jones has agreed not to (and not to cause or direct any person to) hire or solicit for employment any of our employees or those of our subsidiaries or affiliates (i) for six (6) months following the termination of his employment by us without Cause or by him for Good Reason, prior to a Change of Control, (ii) for twelve (12) months following the termination of his employment for Cause, prior to a Change of Control, or (iii) twenty-four (24) months following a Change of Control. On April 24, 2009 we granted Mr. Jones RSUs with respect to an additional 40,000 underlying shares that vest in equal installments over 24 months and are exercisable on the same schedule as the RSUs granted to Mr. Jones in 2008 The table entitled “Events Affecting Option Vesting and Exercise,” below, summarizes the vesting and exercisability of Mr. Jones’ options following a number of termination scenarios or a Change of Control.

Peter A. Clemens is employed pursuant to an Employment Agreement effective as of March 10, 1998, as amended, which provides that Mr. Clemens will serve as our Senior Vice President and Chief Financial Officer for a term currently scheduled to expire December 31, 2010. The term of the Employment Agreement provides for automatic one (1) year renewals in the absence of written notice to the contrary from the Company or Mr. Clemens at least ninety (90) days prior to the expiration of any renewal period. Pursuant to a 2008 amendment to the Employment Agreement, our non-renewal of the Employment Agreement is considered as a termination without Cause for all purposes under the Employment Agreement. Mr. Clemens current base salary under the Employment Agreement is $211,500 (increased from $205,000 effective January 1, 2010). Under the Employment Agreement, he may also receive an annual bonus to be determined based on the satisfaction of such targets, conditions or parameters as may be determined from time to time by the Compensation Committee of the Board of Directors. In 2009, Mr. Clemens was awarded a bonus of $74,000 due to, among other reasons, the achievement of certain of the items discussed above under the caption "Salary and Bonus." The Employment Agreement also provides for the grant of stock options on March 10, 1998 to purchase 30,000 shares of our Common Stock at an exercise price of $23.75 per share, which options vest in equal increments of 2,500 option shares at the end of each quarterly period during the term of the Employment Agreement (as such vesting schedule may be amended by mutual agreement of Mr. Clemens and the Board of Directors) In addition, in August 2004, the Company granted stock options to Mr. Clemens to purchase 37,500 shares of Common Stock at an exercise price of $1.30 per share, which exercise price represents a discount to the fair market value of our Common Stock on the date of grant. Such stock options vest in four equal portions at the end of each annual period commencing March 9, 2005. Such stock options are exercisable (subject to earlier exercisability as set forth in the table below entitled "Events Affecting Option Vesting and Exercise") in four equal installments on January 1 of each of 2011, 2012, 2013 and 2014, provided that such options may be exercised only in the calendar year in which they first become exercisable, and in any event no later than their respective expiration dates. In addition, on May 23, 2008, we granted Mr. Clemens options to purchase 100,000 shares of our Common Stock and on April 24, 2009 we granted Mr. Clemens options to purchase 120,000 shares of our Common Stock, in each case at an exercise price equal to the fair market value of our Common Stock at the date of grant and vesting in equal installments over 24 months (subject to earlier exercisability as set forth in the table below entitled "Events Affecting Option Vesting and Exercise"). The Employment Agreement also acknowledges the grant to Mr. Clemens of a Restricted Stock Unit Award providing for our issuance of up to 440,000 shares of our Common Stock. The Restricted Stock Unit vests one-third (1/3) upon grant and the balance in equal monthly increments on the first day of each month beginning January 1, 2006 and ending December 1, 2007. We will issue the vested shares underlying the Restricted Stock Unit Award on the earlier of (i) a Change in Control (as defined in our 2005 RSU Plan), or (ii) January 1, 2011. In the event of a Change in Control, we will issue the vested shares in a lump sum distribution. In the absence of a Change in Control, our issuance of the vested shares shall be made in four (4) equal installments on each of January 1, 2011, January 1, 2012, January 1, 2013 and January 1, 2014. Upon issuance of the shares underlying the Restricted Stock Unit Award, Mr. Clemens must remit to us the par value of $0.01 per share or have us withhold shares to satisfy such payment obligation. On December 22, 2005, the date of grant of the Restricted Stock Unit Award, the average of the closing bid and asked prices of our Common Stock was $3.33, as reported by the OTCBB. Mr. Clemens has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the Restricted Stock Unit Award until we issue the shares. On April 24, 2009 we granted Mr. Clemens RSUs with respect to an additional 30,000 underlying shares that vest in equal installments over 24 months and are exercisable on the same schedule as the RSUs granted to Mr. Clemens in 2005. The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause. In the event the Employment Agreement is terminated by us without Cause or by Mr. Clemens for Good Reason, we are required to pay Mr. Clemens an amount equal to $410,000 or twice his then base salary, whichever is greater, payable in the case of termination without Cause in a lump sum within 30 days following termination and in the case of termination for Good Reason, six months after termination and to continue to provide Mr. Clemens coverage under our then existing benefit plans, including medical and life insurance, for a term of 24 months. The Employment Agreement permits Mr. Clemens to terminate the Employment Agreement in the event of a Change in Control (as defined in the Employment Agreement), in which case he would receive the same payments as on a termination for Good Reason. The Employment Agreement also restricts Mr. Clemens from disclosing, disseminating

or using for his personal benefit or for the benefit of others confidential or proprietary information (as defined in the Employment Agreement) and, provided we have not breached the terms of the Employment Agreement, from competing with us at any time prior to two years after the earlier to occur of the expiration of the term and the termination of his employment. In addition, for a period of two (2) years from and after the effective date of the termination of his employment with us (for any reason whatsoever), (i) induce or attempt to influence any employee of the Corporation or any of its subsidiaries or affiliates to leave its employ, or (ii) aid any person, business, or firm, including a supplier, a competitor, licensor or customer of or our manufacturer for the Corporation, in any attempt to hire any person who shall have been employed by us or any of our subsidiaries or affiliates within the period of one (1) year of the date of any such requested aid. The table entitled "Events Affecting Option Vesting and Exercise," below, summarizes the vesting and exercisability of Mr. Clemens' options following a number of termination scenarios or a Change of Control.

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

Event	Vesting of All Options (Options not subject to Section 409A(1) are exercisable upon vesting)	Exercisability of Options not subject to section 409A(1)	Exercisability of Options Subject to Section 409A(1)
Termination due to Death	No additional vesting	Vested options immediately exercisable for one year following termination	Vested options immediately exercisable for the lesser of (a) one year following termination or (b) the last day of the year in which they become exercisable
Termination by Company Without Cause or by Employee for Good Reason or following Change of Control (not qualifying under Section 409A)	All options fully vest for Messrs. Reddick and Jones. Mr. Clemens's options vest upon termination after Change of Control.	Vested options immediately exercisable for one year following termination	Vested options exercisable commencing six months after termination for the lesser of (a) one year following termination or (b) the last day of the year in which they become exercisable
Termination due to Disability	No additional vesting	Vested options immediately exercisable for one year following termination	Vested options exercisable commencing six months after termination for the lesser of (a) one year following termination or (b) the last day of the year in which they become exercisable
Termination by the Company for Cause or by executive other than for Good Reason	No additional vesting	Vested options immediately exercisable for 40 days following termination	Vested options exercisable commencing six months after termination for the lesser of (a) 40 days thereafter or (b) the last day of the calendar year in which they first become exercisable
Change of Control	Options fully vest	Vested options immediately exercisable	Vested options exercisable upon Change of Control qualifying under Section 409A during the year in which the Change of Control occurs

(1) See Footnote 2 to table entitled "Outstanding Equity Awards at 2009 Year-End" and corresponding text for identification of options subject to Section 409A. Mr. Jones does not hold any such options.

Mr. Seiser and Dr. Brzeczko are not parties to an employment agreement. Dr. Brzeczko was hired pursuant to an offer letter. He received a $40,000 signing bonus and is eligible for an additional annual bonus of up to 35% of his base salary. In 2009 he received an additional bonus of $33,000. Upon commencement of his employment on February 9, 2009, he received 24,000 RSUs vesting in equal installments over 24 months, and stock options exercisable for 96,000 shares of Common Stock vesting in equal installments over 24 months. Effective January 1, 2010, Dr. Brzeczko's annual salary is $273,000 (increased from $265,000).

Mr. Seiser is employed at an annual salary of $165,000 (increased from $160,000 effective January 1, 2010). In 2009 he was granted 24,000 RSUs vesting in equal installments over 24 months, and stock options exercisable for 96,000 shares of Common Stock vesting in equal installments over 24 months.

Stock Option Plans

We maintain three stock option plans adopted in 1995, 1998 and 2008, respectively. In the past we used, and may continue to use, stock options to attract and retain key employees in the belief that employee stock ownership and stock-related compensation devices encourage a community of interest between employees and shareholders.

The 1995 Stock Option Plan

The 1995 Stock Option Plan was approved by our shareholders in September, 1995. As of December 31, 2009 incentive stock options ("ISO's") to purchase 19,000 shares and non-qualified options to purchase 6,500 shares were outstanding under the 1995 Stock Option Plan. In May, 2005 the 1995 Stock Option Plan expired and the remaining unissued shares allocated to the Plan were terminated. The average per share exercise price for all outstanding options under the 1995 Stock Option Plan is $12.27.

The 1998 Stock Option Plan

The 1998 Stock Option Plan was adopted by the Board of Directors in April, 1998 and approved by our shareholders in June, 1998. The 1998 Stock Option Plan permits the grant of ISO's and non-qualified stock options to purchase shares of our Common Stock. The 1998 Stock Option Plan was amended by the Board of Directors in April, 1999 to increase the number of shares available for the grant of options under the Plan from 260,000 to 360,000 shares. Our shareholders ratified the Plan amendment on August 19, 1999. The 1998 Stock Option Plan was further amended by Board of Directors in April, 2001 to increase the number of shares available for grant of options under the Plan from 360,000 to 810,000 shares. Our shareholders ratified the Plan amendment on June 14, 2001. The 1998 Stock Option Plan was further amended by the Board of Directors on May 5, 2004 to increase the number of shares available for grant of options under the Plan from 810,000 to 2,000,000 shares. Our shareholders ratified the Plan amendment on August 12, 2004. The 1998 Stock Option Plan was further amended on February 8, 2006 to make such plan compliant with Section 409A of the Internal Revenue Code, as amended. Our shareholders ratified the amendment on December 14, 2006. On June 25, 2009, the 1998 Stock Option Plan was further amended by our shareholders to allow participants to require us to withhold Common Stock upon exercise of options for payment of exercise price and statutory minimum withholding taxes. As of December 31, 2009, stock options to purchase 1,361,514 shares of Common Stock had been granted under the 1998 Stock Option Plan. Of such option grants, 54,750 are ISO's and 1,306,764 are non-qualified options. No exercise price of an ISO was set at less than 100% of the fair market value of the underlying Common Stock. The exercise price of non-qualified options exercisable for 1,174,414 shares of Common Stock has been set at less than the fair market value on the date of grant of the underlying Common Stock. Subject to the terms of the 1998 Stock Option Plan, the Board of Directors, or a Committee appointed by the Board determines the persons to whom grants are made and the vesting, timing, amounts and other terms of such grant. An employee may not receive ISO's exercisable in any one calendar year for shares with a fair market value on the date of grant in excess of $100,000. No quantity limitations apply to the grant of non-qualified stock options.

Options issued to date at a discount under the 1998 Stock Option Plan, which had not vested as of December 31, 2004, are exercisable (subject to earlier exercise as described below) in four equal installments on January 1 of each of 2011, 2012, 2013 and 2014. These options are exercisable earlier than stated above upon a qualifying change of control and upon termination of employment (generally for a period of 90 days), subject in the case of termination, to a 6 month waiting period prior to exercise for Messrs. Reddick, Clemens, Jones and Seiser. In no event are these options exercisable outside the calendar year in which they first become exercisable.

In April, 2008 the 1998 Stock Option Plan expired and the remaining unissued shares allocated to the Plan were terminated. The average per share exercise price for all outstanding options under the 1998 Stock Option Plan is $2.35.

The 2008 Stock Option Plan

The 2008 Stock Option Plan was adopted by the Board of Directors on March 14, 2008 and approved by our shareholders on April 30, 2008. On June 25, 2009, the 1998 Stock Option Plan was amended to allow participants to require us to withhold Common Stock upon exercise of options for payment of exercise price and statutory minimum withholding taxes. The 2008 Stock Option Plan permits the grant of ISO's and non-qualified stock options to purchase

in the aggregate up to 6,000,000 shares of our Common Stock. As of December 31, 2009, stock options to purchase 2,284,000 shares of Common Stock had been granted under the 2008 Stock Option Plan. Of such option grants, 1,005,246 are ISOs and 1,278,754 are non-qualified options. No exercise price of an ISO or a non-qualified stock option was set at less than 100% of the fair market value of the underlying Common Stock. Subject to the terms of the 2008 Stock Option Plan, the Board of Directors, or a Committee appointed by the Board determines the persons to whom grants are made and the vesting, timing, amounts and other terms of such grant. An employee may not receive ISO's exercisable in any one calendar year for shares with a fair market value on the date of grant in excess of $100,000. No quantity limitations apply to the grant of non-qualified stock options. The average per share exercise price for all outstanding options under the 2008 Stock Option Plan is $7.95.

Restricted Stock Unit Award Plan

On December 22, 2005, the Board of Directors approved our 2005 Restricted Stock Unit Award Plan (the "2005 RSU Plan") for our employees and non-employee directors. The RSU Plan was amended by the Board of Directors on October 26, 2006 to allow transfer of RSUs under limited circumstances. We believe that the 2005 RSU Plan did not require shareholder approval. Nevertheless, on December 14, 2006, our shareholders ratified the 2005 RSU Plan, as amended, at our 2006 Annual Shareholders' Meeting. A RSU represents the contingent obligation of the Company to deliver a share of our Common Stock to the holder of the RSU on a distribution date. On March 14, 2008 the Board of Directors adopted and on April 30, 2008 our shareholders ratified an amendment to the 2005 RSU Plan increasing the number of shares available under the 2005 RSU Plan from 3 million to 3.5 million.

The purpose of the 2005 RSU Plan is to attract, motivate and retain experienced and knowledgeable employees by offering additional stock-based compensation and incentives to defer and potentially enhance their compensation and to encourage stock ownership in the Company and to attract and retain qualified non-employee directors. The 2005 RSU Plan is intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended and is designed to confirm that compensation deferred under the Plan which is subject to Code Section 409A is not included in the gross income of 2005 RSU Plan participants until such time as the shares of Common Stock underlying RSUs are distributed as set forth in the Plan and Code Section 409A.

The RSU Plan is administered by our Board of Directors or a Committee appointed by the Board of Directors. However, with respect to non-employee directors, the Board administers the Plan, and the Committee has no discretion with respect to any grants to non-employee directors. RSUs granted under the RSU plan vest on a schedule determined by the Board of Directors or such Committee as set forth in a restricted stock unit award agreement. Unless otherwise set forth in such award agreement, the RSUs fully vest upon a change in control (as defined in the 2005 RSU Plan) of the Company or upon termination of an employee's employment without cause or due to death or disability, and in the case of a non-employee director, such person's death or disability or if such person is not renominated as a director (other than for "cause" or refusal to stand for re-election) or is not elected by our stockholders, if nominated. Vesting of an RSU entitles the holder thereof to receive a share of Common Stock of the Company on a distribution date (after payment of the $0.01 par value per share).

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 (whether prior to or after 2011), the vested shares underlying the RSU award will be distributed at or about the time of the change in control. No dividends accrue on the shares underlying the RSUs prior to issuance. The recipients of RSU awards need not be employees or directors of the Company on a distribution date.

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

Recipients of RSUs generally will not recognize income when they are awarded RSUs (unless they elect to recognize income by making a Section 83(b) election). RSU recipients will recognize ordinary income in an amount equal to the fair market value of the shares of our Common Stock issued pursuant to a distribution under the RSU. We will generally be entitled to a tax deduction in the same amount.

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As of December 31, 2009 we had granted RSUs providing for our issuance of up to an aggregate of 3,333,000 shares of our Common Stock. Of such RSU awards 17,000 were forfeited in 2009 upon an employee's termination of employment. 2,750,000 of such RSU awards vest one-third (1/3) on grant and the balance vest in equal monthly increments on the first day of each month beginning January 1, 2006 and ending December 1, 2007. 200,000 of such RSU awards vested 77,778 shares on grant and the balance vested in equal monthly increments on the first day of March 1, 2006 and ending December 1, 2007. 50,000 of such RSU awards vest at a rate of 2,500 on the last day of each month commencing May 31, 2008, and as of December 31, 2009, all of such RSU awards had vested. 24,000 of such RSU awards vest in 24 equal monthly installments on the 9th day of each month commencing March 9, 2009 and as of December 31, 2009, 10,000 of such RSU awards had vested. 24,000 of such RSU awards vested in equal monthly installments on the last day of each month commencing June 11, 2009, and as of December 31, 2009, 7,000 of such RSU awards vested and 17,000 were forfeited. 285,000 of such RSU awards vest in equal installments on the 24th day of each month commencing May 24, 2009 and as of December 31, 2009, 95,000 of such RSU awards had vested.

Outstanding Equity Awards at 2009 Year End

The following table presents information regarding outstanding stock and stock option awards at December 31, 2009 for each of the 2009 named executive officers:

Outstanding Equity Awards at 2009 Year-End

	Stock Option Awards				Restricted Stock Unit Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested ($)(1)
Andrew D. Reddick	450,000(2)	—	$ 1.30	08/12/2014	56,667	$ 301,468
	197,917	52,083	$ 9.87	05/23/2018		
	83,333	166,667	$ 6.29	04/23/2019		
Robert B. Jones	30,000	—	$ 8.64	04/06/2018	30,000	$ 159,600
	126,667	33,333	$ 9.87	05/23/2018		
	53,333	106,667	$ 6.29	04/23/2019		
Peter A. Clemens	12,500	—	$ 18.75	02/17/2010	20,000	$ 106,400
	10,000	—	$ 11.125	06/29/2010		
	37,500(2)	—	$ 1.30	03/09/2014		
	79,167	20,833	$ 9.87	05/23/2018		
	40,000	80,000	$ 6.29	04/23/2019		
Albert W. Brzeczko	40,000	56,000	$ 5.70	02/08/2019	14,000	$ 74,480
Robert A. Seiser	3,000	—	$ 18.75	02/17/2010	16,000	$ 85,120
	4,000	—	$ 11.125	06/29/2010		
	2,500	—	$ 24.60	11/15/2011		
	24,900(2)	—	$ 1.30	03/09/2014		
	63,334	16,666	$ 9.87	05/23/2018		
	32,000	64,000	$ 6.29	04/23/2019		

(1) Based on the closing price of $5.33 reported on the Nasdaq Capital Market on December 31, 2009 reduced by the $.01 par value per share that must be paid on the distribution of shares underlying the RSUs.

(2) See “Stock Option Plans –1998 Stock Option Plan” for information regarding these options which were issued at a discount to fair market vale and also see table entitled “Events Affecting Stock Option Vesting And Exercise” (column labeled “Exercisability of Options Subject to Section 409A”) with respect to Messrs. Reddick and Clemens and “Potential Payments Potential Payments Upon Termination or Change in Control - Messrs. Brzeczko and Seiser”, with respect to Mr. Seiser.

Grants of Plan Based Awards in 2009

The following table presents information regarding the grant of awards made to our 2009 named executive officers in the last completed fiscal year under our 2005 RSU Plan and 2008 Stock Option Plan:

		Grants of Plan-Based Awards			
Name	Grant Date	Stock awards under the 2005 Restricted Stock Unit Award Plan - Number of shares of stock (#)	Option awards under the 2008 Stock Option Plan- Number of securities underlying options (#)	Exercise or base price of option awards ($/Sh)	Grant date fair value of stock and option awards (2)
Andrew D. Reddick	4/24/2009	85,000	—	(1)	$ 534,000
	4/24/2009	—	250,000	$ 6.29	$ 1,505,000
Robert B. Jones	4/24/2009	45,000	—	(1)	$ 188,000
	4/24/2009	—	160,000	$ 6.29	$ 963,000
Peter A. Clemens	4/24/2009	30,000	—	(1)	$ 126,000
	4/24/2009	—	120,000	$ 6.29	$ 722,000
Albert W. Brzeczko	2/9/2009	24,000	—	(1)	137,000
	2/9/2009	—	96,000	$ 5.70	$ 524,000
Robert A. Seiser	4/24/2009	24,000	—	(1)	$ 151,000
	4/24/2009	—	96,000	$ 6.29	$ 578,000

(1) RSUs require the payment of $0.01 par value per share upon the distribution of the shares underlying the RSUs.

(2) See Notes 1 and 2 to Summary Compensation Table for methodology used in computing grant date fair value. See also Note I to our Financial Statements.

Option Exercises and Stock Vested in 2009

The following table presents information regarding the exercise of options by our 2009 named executive officers and vesting of awards made to a 2009 named executive officer under our 2005 RSU Plan that occurred in our last completed fiscal year.

Option Exercise and Stock Vested In Fiscal Year 2009

	Option Awards		Stock Awards	
Name	Number of Shares acquired on exercise	Value Realized on exercise	Number of Shares Vested (#)(1)	Value Realized on Vesting ($)(2)
Andrew D. Reddick	425,000(3)	$ 1,258,000(4)	28,333	$ 156,895
Robert B. Jones	—	—	35,000	$ 251,587
Peter A. Clemens	—	—	10,000	$ 55,375
Albert W. Brzeczko	—	—	10,000	$ 58,010
Robert A. Seiser	—	—	8,000	$ 44,300

(1) The vested shares underlying the RSUs will be issued by us on the earlier of (i) a Change of Control (as defined in our 2005 Restricted Stock Unit Award Plan), or (ii) in four annual installments starting on January 1, 2011. In the event of a Change of Control, our issuance of the vested shares shall be made in a lump sum distribution. In the absence of a Change of Control, the issuance of the vested shares shall be issued in four (4) equal installments on each of January 1, 2011, January 1, 2012, January 1, 2013 and January 1, 2014. Upon our distribution of the vested shares underlying the RSUs, the recipients must submit to us the par value of $0.01 per share. The recipients of the RSUs have no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying such awards until the shares are issued by us.

(2) Value is determined by subtracting the $.01 par value required to be paid on exchange of each share for RSUs from the closing price of our Common Stock on the Nasdaq Capital Market on each vesting date (or the preceding closing price if the vesting date is not a trading date) and multiplying the result by the number of shares underlying the RSUs that vested on such date and then aggregating those results.

(3) Of the 425,000 options exercised, 249,353 shares were withheld by the Company for payment of the exercise price and statutory minimum withholding taxes leaving Mr. Reddick with a net total of 175,647 common shares. As of the date of this Report, Mr. Reddick continues to own all 175,647 of such common shares.

(4) Computed by multiplying the 425,000 shares acquired on exercise by the sum of the $4.26 closing price of our stock on the Nasdaq Capital Market on November 23, 2009, the trading day immediately preceding the date of Mr. Reddick's option exercise less the $1.30 exercise price per share.

Securities Authorized For Issuance under Equity Compensation Plans

The following table includes information as of December 31, 2009 relating to our 1995, 1998 and 2008 Stock Option Plans and our 2005 Restricted Stock Unit Award Plan, which comprise all of our equity compensation plans. The table provides the number of securities to be issued upon the exercise of outstanding options and distributions under outstanding Restricted Stock Unit Awards under such plans, the weighted-average exercise price of outstanding options and the number of securities remaining available for future issuance under such equity compensation plans:

Equity Compensation Plan Information

Plan Category	Number Of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (Column a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (Column b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column a (Column c)
Stock Option Equity Compensation Plans Approved by Security Holders	3,671,014	$ 5.90	3,716,000
Stock Option Equity Compensation Plans Not Approved by Security Holders	—	—	—
Restricted Stock Unit Equity Compensation Plans Approved by Security Holders	3,316,000	$ 0.01	184,000
Restricted Stock Unit Equity Compensation Plans Not Approved by Security Holders	—	—	—
TOTAL	6,987,014	$ 3.10	3,900,000

Potential Payments Upon Termination or Change in Control

Messrs. Brzeczko and Seiser

Options. If a change of control occurs (which constitutes a change of control under the stock option agreements) previously unvested options vest and become exercisable with respect to all underlying shares (relating to 52,000 and 64,000 shares for Messrs. Brzeczko and Mr. Seiser, respectively, as of December 31, 2009). Messrs. Brzeczko and Seiser would realize a benefit of $284,000 and $385,000 from such option vesting if such change of control had occurred on December 31, 2009. Upon the occurrence of a change of control that meets the requirements of Section 409A of the Internal Revenue Code or upon termination of employment, stock options granted to Mr. Seiser to purchase 24,900 shares of Common Stock become exercisable in full.

RSUs. If a change of control occurs (which constitutes a change of control under the 2005 RSU Plan) then Messrs. Brzeczko's and Seiser's previously unvested RSUs vest respect to all underlying shares. Messrs. Brzeczko and Seiser would realize a benefit of $80,000 and $100,000 from such vesting if such change of control had occurred on December 31, 2009. Upon the occurrence of a change of control that meets the requirements of Section 409A of the Internal Revenue Code, the RSUs are fully distributable for shares upon payment of the $.01 par value per share, instead of under their normal distribution schedule.

The dollar benefits described above are the compensation cost for such awards that would have been recognized in 2009 in our financial statements in accordance with FASB ASC TOPIC 718, had such accelerated vesting/distribution

occurred.

Messrs. Reddick, Jones and Clemens

Based upon a hypothetical triggering date of December 31, 2009, the quantifiable benefits for Messrs. Andrew Reddick, Robert Jones and Peter Clemens upon a termination/change of control would have been as set forth the table below:

Triggering Event	Executive	Severance	Bonus	Value of Options Vesting (4)	Value of RSUs Vesting (5)	Medical, Dental, Health, Disability and Life Insurance Benefits	Total (7)
Termination by Company without Cause or by Employee for Good Reason or after a Change of Control	Andrew D. Reddick	$ 365,000(1)(8)	—(3)	$ 469,000 (with respect to Change of Control, only payable upon termination after Change of Control)	$ 356,000	$ 26,270(6)	$ 1,216,270
	Robert B. Jones	290,000(1)(8)	—(3)	312,000	188,415	26,270(6)	$ 816,685
	Peter A. Clemens	410,000(2)(9)	—(3)	188,000	126,000	52,540(10)	$ 776,540
Termination for Death	Andrew D. Reddick	—	—(3)	—	356,000	$ 50,000	$ 406,000
	Robert B. Jones	—	—	—	188,000	$ 50,000	$ 238,000
	Peter A. Clemens	—	—	—	126,000	$ 50,000	$ 176,000
Termination for Disability	Andrew D. Reddick	—	—(3)	—	356,000	—	$ 356,000
	Robert B. Jones	—	—	—	188,000		$ 188,000
	Peter A. Clemens	—	—	—	126,000	—	$ 126,000
Termination with Cause	Andrew D. Reddick	—	—	—	—	—	—
	Robert B. Jones	—	—	—	—	—	—
	Peter A. Clemens	—	—	—	—	—	—
Change of Control Without Termination	Andrew D. Reddick	—	—	469,000	356,000	—	$ 825,000
	Robert B. Jones	—	—	312,000	188,000	—	$ 500,000

Peter A. Clemens	—	—	188,000	126,000	—	$	314,000

The terms "Change of Control", "Cause", and "Good Reason" have the meanings in the listed executive's employment agreements.

(1) In the case of termination without Cause, payable in 12 monthly installments. In the case of termination for Good Reason, one half of amount is payable six months and one day after termination, and remaining amount is payable thereafter in six monthly installments. In the case of termination after a Change of Control, amount is payable in a lump sum six months and one day after termination.

(2) In the case of termination without Cause, payable in a lump sum within 30 days after termination. In the case of termination for Good Reason and termination after Change of Control, amount is payable in a lump sum six months and one day after termination.

(3) Payable in a lump sum within 30 days after termination. Because bonuses were paid prior to December 31, 2009, named executives would not have been entitled to any additional bonuses upon termination at December 31, 2009.

(4) The dollar amount reported is the compensation cost for such awards that would have been recognized in 2009 in our financial statements in accordance with FASB ASC TOPIC 718 had the unvested stock options at December 31, 2009 vested at such date. See "Employment Agreements" for a description of the exercise periods following termination.

(5) The dollar amount reported is the compensation cost for such awards that would have been recognized in 2009 in our financial statements in accordance with FASB ASC TOPIC 718, had the unvested RSUs at December 31, 2009 vested at such date

(6) Represents the value of medical, dental, disability and life insurance for the twelve months following termination and a tax gross up for such amounts. Payable in lump sum within 30 days after termination. Assumes executive has selected lump sum payment option, in lieu of continued benefits. This amount is estimated.

(7) Excludes accrued vacation.

(8) Represents one year of salary, at the rate in effect on December 31, 2009.

(9) Represents two years of base salary, at the rate in effect on December 31, 2009.

(10) Represents the estimated value of medical, dental, disability and life insurance for the twenty-four months following termination. Payable in lump sum within thirty days after termination.

Director Compensation

The following table sets forth a summary of the compensation paid by us to our Directors (other than Andrew Reddick, whose compensation, is reflected in the Summary Compensation Table) for services rendered in all capacities to us during the fiscal year ended December 31, 2009:

2009 DIRECTOR COMPENSATION

Director	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($)(2)	Total ($)
William G. Skelly	27,500	—	107,283	134,783
William A. Sumner	26,500	—	107,283	133,783
Bruce F. Wesson	24,000	—	107,283	131,283
Richard J. Markham	28,500	—	107,283	110,133
Immanuel Thangaraj	20,000(3)	—	107,283	127,283
George K. Ross	32,000	—	107,283	139,283

(1) Messrs. Skelly and Sumner each held fully vested RSUs with respect to 100,000 underlying shares, as of December 31, 2009. Messrs. Wesson, Markham, Thangaraj and Ross held no RSUs.

(2) Messrs. Skelly, Sumner, Wesson, Markham, Thangaraj and Ross, held vested options with respect to, 47,500, 34,000, 30,000, 30,000, 30,000 and 30,000 underlying shares, respectively, as of December 31, 2009. Each was awarded options to purchase 15,000 shares of our Common Stock on January 2, 2009 at an exercise price of $7.48. The dollar amounts represent the grant date fair value of such options awarded in 2009 in accordance with FASB ASC Topic 718 and exclude the possibility of forfeiture. In computing the grant date fair value under a Black-Scholes model and used a risk free interest rate of 2.46%, historical volatility of 124.16% and an option term of 10 years. See Note I to our Financial Statements for a general discussion of our assumptions.

(3) Committee and board meeting attendance fees waived.

Our Director compensation program provides for a $20,000 annual retainer for each non-employee Director (and an additional annual retainer of $5,000 for the chairperson of the Audit Committee and $2,500 for each other Committee chairperson), a $1,000 fee for each Board meeting attended in person ($500 if attended telephonically), and a $500 fee for each Committee meeting attended ($250 if attended telephonically). The annual retainer fees are payable in four equal installments at the end of each calendar quarter during the year. In addition, non-employee Directors will receive an annual grant of options to purchase 15,000 shares of our Common Stock. The stock options have a term of 10 years and have an exercise price equal to the closing price of our Common Stock on the first trading day of the year of grant as reported by the NASDAQ Capital Market. The stock options vest in equal installments at the end of each calendar quarter during the year of grant. Directors who are also our employees receive no additional or special remuneration for their services as Directors. We also reimburse Directors for travel and lodging expenses, if any, incurred in connection with attendance at Board meetings.

Compensation Committee Interlocks and Insider Participation

During 2009 there were no Compensation Committee interlocks or insider participation in compensation decisions.

Compensation Committee Report

The following report of the Compensation Committee is not deemed to be “soliciting material” or to be “filed” with the Commission or subject to Regulation 14A or 14C [17 CFR 240.14a-1 et seq. or 240.14c-1 et seq.], other than as specified, or to the liabilities of Section 18 of the Exchange Act [15 U.S.C. 78r].

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis in this Report with Company management. Based on such review and discussions, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this Report.

Richard J. Markham, Bruce Wesson and Immanuel Thangaraj.

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

The following table sets forth information regarding the beneficial ownership of the Common Stock, as of February 1, 2010, for individuals or entities in the following categories: (i) each of the Company's Directors and nominees for Directors; (ii) the Company's principal executive officer, the Company's principal financial officer and the next three highest paid executive officers of the Company whose total annual compensation for 2009 exceeded $100,000 (the "2009 named executive officers"); (iii) all Directors and executive officers as a group; and (iv) each person known by the Company to be a beneficial owner of more than 5% of the Common Stock. Unless indicated otherwise, each of the shareholders has sole voting and investment power with respect to the shares beneficially owned.

Name of Beneficial Owner	Amount Owned	Percent of Class (1)
GCE Holdings LLC, c/o Galen Partners III, L.P. 680 Washington Boulevard, Stamford, CT 06901	34,564,956(2)	75.9%
Vivo Ventures Fund VI, L.P. 575 High St, Suite 201 Palo Alto, CA 9430131	2,450,000(3)	5.5%
Andrew D. Reddick	969,397(4)	2.2%
Robert B. Jones	250,000(5)	*
William G. Skelly	52,250(6)	*
Bruce F. Wesson	47,750(2)(7)	*
William A. Sumner	56,750(8)	*
Peter A. Clemens	211,747(9)	*
Richard J. Markham	33,750(2)(10)	*
Immanuel Thangaraj	43,750(2)(11)	*
Robert A. Seiser	151,733(12)	*
Albert W. Brzeczko	52,000(13)	*
George K. Ross	33,750(14)	*
All Officers and Directors as a Group (12 persons)	2,045,610(15)	4.5%

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

(1) Shows percentage ownership assuming (i) such party converts all of its currently convertible securities or securities convertible within 60 days of February 1, 2010 into the Company's common stock, and (ii) no other Company security holder converts any of its convertible securities. No shares held by any Director or 2009 named executive officer has been pledged as collateral security.

(2) GCE Holdings LLC, a Delaware limited liability company, was the assignee of all of the our preferred stock (prior to its conversion into common stock) and bridge loans entered into in 2005, 2006 and 2007 (prior to their conversion into common stock and warrants) formerly held by each of Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen"), Care Capital Investments II, LP, Care Capital Offshore Investments II, LP (collectively, "Care Capital") and Essex Woodlands Health Ventures Fund V, L.P. ("Essex"). Galen, Care Capital and Essex own approximately 39.8%, 30.6% and 29.6%, respectively, of the membership interests in GCE Holdings LLC. The following natural persons exercise voting, investment and dispositive rights over our securities held of record by GCE Holdings LLC: (i) Galen Partners III, L.P., Galen Partners International III, L.P. and Galen Employee Fund III, L.P.: Bruce F. Wesson, L. John Wilkerson, David W. Jahns, and

Zubeen Shroff; (ii) Care Capital Investments II, LP and Care Capital Offshore Investments II, LP: Jan Leschly, Richard Markham, Argeris Karabelas and David Ramsay; and (iii) Essex Woodlands Health Ventures Fund V, L.P.: Immanuel Thangaraj, James L. Currie and Martin P. Sutter. Pursuant to a Voting Agreement among us, GCE Holdings LLC and certain other shareholders, GCE Holdings LLC has the right to designate three of the seven members of the Company's Board of Directors. The Board designees of GCE Holdings LLC are Immanuel Thangaraj, Richard Markham and Bruce Wesson. Amounts for GCE Holdings, LLC include 1,786,481 shares underlying warrants, exercisable at $3.40 per share. Excludes 381,381 shares and warrants to purchase 14,999 shares held by Galen, 136,178 shares and warrants to purchase 34,500 shares held by Essex; and 10,923 shares, options to purchase 40,000 shares and warrants to purchase 15,000 shares held by Care Capital.

(3) Includes shares held by an affiliated fund. Includes warrants to purchase 450,000 shares exercisable at $3.40 per share held by Vivo Ventures Fund VI, L.P. and an affiliated fund (collectively, "Vivo"). Number of shares give effect to the transfer of warrants to purchase 496,364 and 3,636 shares from Vivo Ventures Fund VI, L.P. and Vivo Ventures VI Affiliates Fund, L.P., respectively, to Warrant Strategies Fund, LLC on November 30, 2007 but are otherwise current as of November 20, 2007. The information with respect to Vivo is based solely on our knowledge of our sale of securities to them and our knowledge of the warrant transfer stated above.

(4) Includes 793,750 shares subject to stock options exercisable within 60 days of February 1, 2010, of which 450,000 shares are subject to fully vested options, exercisable commencing January 1, 2011 or upon termination of employment or a change of control of the Company. Excludes 910,000 restricted stock unit awards ("RSUs") granted to Mr. Reddick. Mr. Reddick has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the RSUs until the shares are issued by the Company pursuant to the terms of Company's 2005 Restricted Stock Unit Plan.

(5) Includes 250,000 shares subject to stock options exercisable within 60 days of February 1, 2010. Excludes 95,000 RSUs granted to Mr. Jones Mr. Jones has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the RSUs until the shares are issued by the Company pursuant to the terms of Company's 2005 Restricted Stock Unit Plan.

(6) Includes 51,250 shares subject to stock options exercisable within 60 days of February 1, 2010. Excludes 100,000 RSUs granted to Mr. Skelly. Mr. Skelly has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the RSUs until the shares are issued by the Company pursuant to the terms of the Company's 2005 Restricted Stock Unit Plan.

(7) Includes 47,750 shares subject to stock options exercisable within 60 days of February 1, 2010. Mr. Wesson's holdings do not include securities held by GCE or by Galen.

(8) Includes 36,750 shares subject to stock options exercisable within 60 days of February 1, 2010. Excludes 100,000 RSUs granted to Mr. Sumner. Mr. Sumner has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the RSUs until the shares are issued by the Company pursuant to the terms of the Company's 2005 Restricted Stock Unit Plan.

(9) Includes 206,667 shares subject to stock options exercisable with 60 days of February 1, 2010, of which 37,500 shares are subject to fully vested options, exercisable commencing January 1, 2011 or upon termination of employment or a change of control of the Company. Excludes 470,000 RSUs granted to Mr. Clemens (of which 453,750 will have vested within 60 days of February 1, 2010). Mr. Clemens has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the RSUs until the shares are issued by the Company pursuant to the terms of Company's 2005 Restricted Stock Unit Plan. Includes 5,080 shares held by minor children.

(10) Includes 33,750 shares subject to stock options exercisable within 60 days of February 1, 2010. Mr. Markham's holdings do not include amounts held by GCE or Care Capital of which Mr. Markham disclaims beneficial ownership.

(11) Includes 43,750 shares subject to stock options exercisable within 60 days of February 1, 2010. Mr. Thangaraj's holdings do not include securities held by GCE or by Essex. Mr. Thangaraj disclaims beneficial ownership in securities held by GCE and Essex except to the extent of his pecuniary interest therein.

(12) Includes 151,733 shares subject to stock options exercisable within 60 days of February 1, 2010, of which 24,900 shares are subject to fully vested options exercisable commencing January 1, 2011 or upon termination of employment or a change of control of the Company. Excludes 189,000 RSUs granted to Mr. Seiser. Mr. Seiser has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the RSUs until the shares are issued by the Company pursuant to the terms of Company's 2005 Restricted Stock Unit Plan.

(13) Includes 52,000 shares subject to stock options exercisable within 60 days of February 1, 2010. Excludes 24,000 RSUs granted to Dr. Brzeczko (13,000 of which will have vested within 60 days of February 1, 2010). Dr. Brzeczko has no rights as a stockholder, including no dividend or voting rights, with respect to the shares underlying the RSUs until the shares are issued by the Company pursuant to the terms of Company's 2005 Restricted Stock Unit Plan.

(14) Includes 33,750 shares subject to stock options exercisable within 60 days of February 1, 2010.

(15) Includes 2,045,610 shares which Directors and executive officers have the right to acquire within 60 days of February 1, 2010 through exercise of outstanding stock options, of which 512,300 shares subject to fully vested options, are exercisable commencing January 1, 2011 or upon termination of employment or a change of control of the Company. Includes securities (other than RSUs) held by James Emigh, our Vice President, Marketing and Administration, in addition to the officers and directors listed above.

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

Certain Relationships and Related Transactions

GCE Holdings LLC, our 75.9% stockholder ("GCE") was the assignee of all shares of the Company's preferred stock (prior to conversion of such preferred stock into common stock) formerly held by each of Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen"), Care Capital Investments II, LP, Care Capital Offshore Investments II, LP (collectively, "Care Capital") and Essex Woodlands Health Ventures V, L.P., ("Essex" and together with Galen and Care, the "VC Investors"). Galen, Care and Essex own 39.8%, 30.6% and 29.6%, respectively, of the membership interest in GCE. Messrs. Wesson, Markham and Thangaraj, each a Director, exercise investment control over the membership interests in GCE held by Galen, Care and Essex, respectively, and correspondingly exercise investment control over our common stock held by GCE.

As a condition to the completion of our 2004 debenture offering, we, the investors in our 2004 debentures and the holders of our outstanding 5% convertible senior secured debentures due March 31, 2006 issued by us during the period from 1998 through 2003 executed a certain Voting Agreement dated as of February 6, 2004 (the "Voting Agreement"). The Voting Agreement provided that each of Galen, Care and Essex (collectively, the "Lead 2004 Debenture Investors") had the right to designate for nomination one member of our Board of Directors, and that the Lead Debenture 2004 Investors collectively may designate one additional member of the Board (collectively, the "Designees"). In connection with the conversion of our preferred shares into common stock completed in November 2005, the Voting Agreement was amended to reflect the conveyance by each of Galen, Care and Essex of their holdings in our preferred shares (prior to their conversion into common stock) to GCE. After giving effect to a further amendment in January 2008, the Voting Agreement, as amended, provides that our Board of Directors shall be comprised of not more than seven (7) members, three (3) of whom shall be designees of GCE, one of whom shall be our CEO and three of whom shall be independent directors. The designees of GCE are Messrs. Wesson, Markham and Thangaraj.

On August 20, 2007, we entered into a Securities Purchase Agreement with GCE Holdings LLC, our controlling shareholder, and the other investors named therein (collectively, the "Unit Investors"), pursuant to which the Unit Investors purchased units consisting of four shares of common stock and a warrant to purchase one share of common stock. In accordance with the requirements of the Securities Purchase Agreement, we filed a registration statement with the SEC for purposes of registering the resale of the shares of common stock issued as part of the Units and the shares of common stock issuable upon exercise of the warrants issued as part of the Units (the "Registration Statement"). The Registration Statement was declared effective by the SEC on November 20, 2007. We must exercise best efforts to keep the Registration Statement effective until the earlier of (i) the date that all shares of common stock and shares of common stock underlying Warrants covered by the Registration Statement have been sold, or (ii) the fifth anniversary of the Registration Statement, provided that the period during which the Registration Statement must be kept effective can be shortened to not less than two years by agreement of holders of registrable securities. Shares of common stock eligible for sale under Rule 144(k) of the Securities Act of 1933, as amended, need not be included in the Registration Statement. Under certain circumstances, if shares are excluded from the Registration Statement by the SEC, we may be required to file one or more additional Registration Statements for the excluded shares. Subject to certain exceptions, for each day that we fail to keep the Registration Statement effective, we must pay each Investor 0.05% of the purchase price of securities covered by the Registration Statement and held by such Unit Investor at such time, up to a maximum of 9.9% of the amount paid by a Unit Investor for the Units.

The requirement in the Securities Purchase Agreement to file the Registration Statement triggered the piggyback registration rights granted to certain holders of shares of our common stock and warrants exercisable for common stock pursuant to an Amended and Restated Registration Rights Agreement dated as of February 6, 2004, as amended. GCE Holdings LLC, 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. exercised their piggyback registration rights under such Agreement. As a result, an aggregate of 26,584,016 shares of common stock and shares underlying warrants held by such shareholders (after giving effect to our 1 for 10 reverse stock split effected December 5, 2007) were included in the Registration Statement.

Our Board has not adopted formalized written policies and procedures for the review or approval of related party transactions. As a matter of practice, however, our Board has required that all related party transactions, including, without limitation, each of the transactions described above in this Item 13, be subject to review and approval by a committee of independent directors established by the Board. The Board's practice is to evaluate whether a related party (including a director, officer, employee, GCE Holdings, Galen, Care, Essex or other significant shareholder) will have a direct or indirect interest in a transaction in which we may be a party. Where the Board determined that such proposed transaction involves a related party, the Board formally establishes a committee comprised solely of independent directors to review and evaluate such proposed transaction (the "Independent Committee"). The Independent Committee is authorized to review any and all information it deems necessary and appropriate to evaluate the fairness of the transaction to us and our shareholders (other than the interested related party to such transaction), including meeting with management, retaining third party experts (including counsel and financial advisors if determined necessary and appropriate by the Independent Committee) and evaluating alternative transactions, if any. The Independent Committee is also empowered to negotiate the terms of such proposed related party transaction on our behalf. The proposed related party transaction may proceed only following the approval and recommendation of the Independent Committee. Following the Independent Committee's approval, the related party transaction is subject to final review and approval of the Board as a whole, with any interested director abstaining from such action.

Each of the transactions described above in this Item 13 were subject to the review, evaluation, negotiation and approval of an Independent Committee of the Board. In each of such case, the Independent Committee was comprised of Messrs. Sumner and Skelly.

Director Independence

In assessing the independence of our Board members, our Board has reviewed and analyzed the standards for independence required under the NASDAQ Capital Market, including NASDAQ Marketplace Rule 4200(a)(15), and applicable SEC regulations. Based on this analysis, our Board has determined that each of Messrs. William A. Sumner, William Skelly and George Ross meet the standards for independence provided in the listing requirements of the NASDAQ Capital Market and SEC regulations. As a result, three of our seven Board members meet such standards of independence. Although the listing standards of the NASDAQ Capital Market specify that a majority of a listed issuer's board of directors must be comprised of independent directors, we are relying upon an exemption for "controlled companies" provided in the listing standards for the NASDAQ Capital Market. A "controlled company" is a company of which more than 50% of the voting power is held by an individual, a group or another company. Based on GCE Holdings LLC's ownership of approximately 76% of our common stock, we are considered a controlled company under the rules of the NASDAQ Capital Market and are relying upon this exemption in having less than a majority of independent directors on our Board.

With respect to our Board committees, our Board has determined that the members of our Compensation committee do not meet the standards for independence described above.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our registered independent public accounting firm is BDO Seidman, LLP. The fees billed by this firm in 2009 and 2008 were as follows:

	2009	2008
Audit Fees	$ 118,100	$ 131,764
Audit-Related Fees	—	—
Total Audit and Audit-Related Fees	118,100	131,764
Tax Fees	62,255	180,677
All Other Fees	—	—
Total for BDO Seidman, LLP	$ 180,355	$ 312,441

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

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

Audit Committee's Pre-Approval Policies and Procedures

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

All of the audit-related, tax and other services provided by BDO Seidman in 2009 and 2008 and related fees (as described in the captions above) were approved in advance by the Audit Committee.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. All Financial Statements: See Index to Financial Statements

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

SIGNATURES

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

Date: March 2, 2010

ACURA PHARMACEUTICALS, INC.

By: ANDREW D. REDDICK
Andrew D. Reddick
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/Andrew D. Reddick Andrew D. Reddick	President, Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2010
/s/Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 2, 2010
/s/William G. Skelly William G. Skelly	Director	March 2, 2010
/s/Bruce F Wesson Bruce F. Wesson	Director	March 2, 2010
/s/William A. Sumner William A. Sumner	Director	March 2, 2010
/s/Richard J. Markham Richard J. Markham	Director	March 2, 2010
/s/Immanuel Thangaraj Immanuel Thangaraj	Director	March 2, 2010
/s/George K. Ross George K. Ross	Director	March 2, 2010

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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, 2009 and 2008 and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009. 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and the significant estimates made by management, as well as evaluating the overall presentation of the financial statements. 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, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Acura Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 2, 2010 expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP
Chicago, Illinois
March 2, 2010

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2009 and 2008
(in thousands except par values)

	2009	2008
Assets		
Current assets		
Cash and cash equivalents	$ 30,174	$ 30,398
Short-term investments	-	5,039
Collaboration revenue receivable	357	3,529
Prepaid insurance	193	283
Prepaid expenses and other current assets	33	148
Deferred income taxes	-	2,491
Total current assets	30,757	41,888
Property, plant and equipment, net	1,160	1,073
Total assets	$ 31,917	$ 42,961
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ -	$ 382
Deferred program fee revenue	1,555	4,632
Accrued expenses	452	883
Total current liabilities	2,007	5,897
Commitments and contingencies (Note J)		
Stockholders' equity		
Common stock - $.01 par value; 100,000 shares authorized; 43,728 and 42,723 shares issued and outstanding in 2009 and 2008, respectively	437	427
Additional paid-in capital	352,694	344,023
Accumulated deficit	(323,221)	(307,386)
Total stockholders' equity	29,910	37,064
Total liabilities and stockholders' equity	$ 31,917	$ 42,961

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2009, 2008 and 2007
(in thousands except per share data)

	2009	2008	2007
Revenues			
Program fee revenue	$ 3,077	$ 27,941	$ 3,427
Collaboration revenue	758	11,496	2,977
Milestone revenue	-	5,000	-
Total revenue	3,835	44,437	6,404
Operating expenses			
Research and development expense	5,673	14,322	7,169
Marketing, general and administrative expense	11,662	9,133	4,141
Total operating expenses	17,335	23,455	11,310
(Loss) income from operations	(13,500)	20,982	(4,906)
Other income (expense)			
Interest income	147	780	268
Interest expense	-	-	(1,207)
Amortization of debt discount	-	-	(2,700)
Loss on fair value change of conversion features	-	-	(3,483)
Loss on fair value change of common stock warrants	-	-	(1,905)
Other (expense) income	(3)	(3)	19
Total other income (expense)	144	777	(9,008)
(Loss) income before income tax	(13,356)	21,759	(13,914)
Income tax expense (benefit)	2,479	7,285	(9,600)
Net (loss) income	(15,835)	14,474	(4,314)
Deemed dividend from modification of debt	-	-	(3)
Net (loss) income applicable to common stockholders	$ (15,835)	$ 14,474	$ (4,317)
Earnings (loss) per share			
Basic	$ (0.35)	$ 0.32	$ (0.11)
Diluted	$ (0.35)	$ 0.29	$ (0.11)
Weighted average shares			
Basic	45,932	45,675	39,157
Diluted	45,932	49,416	39,157

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
YEARS ENDED DECEMBER 31, 2009, 2008 and 2007
(in thousands except par values)

	Common Stock $0.01 Par Value		Additional Paid-in	Accumulated	
	Shares	$ Amount	Capital	Deficit	Total
Balance at Dec. 31, 2006	33,099	$ 331	$ 278,932	$ (317,543)	$ (38,280)
Net loss for the year ended Dec. 31, 2007	-	-	-	(4,314)	(4,314)
Deemed dividend related to debt modification	-	-	-	(3)	(3)
Reclassification of conversion feature value	-	-	21,086	-	21,086
Reclassification of common stock warrant value	-	-	12,453	-	12,453
Conversion feature value of issued debt	-	-	1,789	-	1,789
Other stock-based compensation	-	-	915	-	915
Net proceeds from unit offering	5,556	56	14,090	-	14,146
Conversion of bridge loan notes, net	3,905	39	9,961	-	10,000
Issuance of common shares for exercise of options	31	-	116	-	116
Issuance of common shares for interest	84	1	811	-	812
Issuance of common shares for cashless exercise of warrants	32	-	-	-	-
Reverse stock split	(1)	-	-	-	-
Balance at Dec. 31, 2007	42,706	$ 427	$ 340,153	$ (321,860)	$ 18,720
Net income for the year ended Dec. 31, 2008	-	-		14,474	14,474
Other stock-based compensation	-	-	3,850	-	3,850
Issuance of common shares for exercise of warrant	17	-	20	-	20
Balance at Dec. 31, 2008	42,723	$ 427	$ 344,023	$ (307,386)	$ 37,064
Net loss for the year ended Dec. 31, 2009	-	-	-	(15,835)	(15,835)
Other stock-based compensation	-	-	9,204	-	9,204
Issuance of common shares for cashless exercise of warrants	730	7	(7)	-	-
Issuance of common shares for exercise of warrant	50	1	159	-	160
Issuance of common shares for cashless exercise of options and payroll taxes	225	2	(685)	-	(683)
Balance at Dec. 31, 2009	43,728	$ 437	$ 352,694	$ (323,221)	$ 29,910

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2009, 2008, and 2007
(in thousands, except supplemental data)

	2009	2008	2007
Cash flows from operating activities:			
Net (loss) income	$ (15,835)	$ 14,474	$ (4,314)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	130	143	130
Amortization of debt discount	-	-	2,700
Loss on the fair value change of conversion features	-	-	3,483
Loss on the fair value change of common stock warrants	-	-	1,905
Non-cash stock compensation expense	9,204	3,850	915
(Gain) loss on asset disposals	(3)	1	(22)
Common stock issued for interest	-	-	812
Deferred income taxes	2,479	7,109	(9,600)
Change in fixed asset impairment reserve	-	(29)	-
Changes in assets and liabilities			
Collaboration revenue receivable	3,172	(553)	(2,977)
Prepaid expenses and other current assets	222	207	(398)
Other assets and deposits	-	-	7
Accounts payable	(382)	382	-
Accrued expenses	(1,113)	549	5
Deferred program fee revenue	(3,077)	(21,942)	26,574
Net cash (used in) provided by operating activities	(5,203)	4,191	19,220
Cash flows from investing activities:			
Purchases of short-term investments	-	(26,039)	-
Maturities of short-term investments	5,039	21,000	-
Capital expenditures	(220)	(143)	(31)
Proceeds from asset disposals	-	1	22
Net cash provided by (used in) investing activities	4,819	(5,181)	(9)
Cash flows from financing activities:			
Common stock issued for warrant exercise	160	-	-
Proceeds from issuance of senior secured bridge term notes	-	-	2,696
Repayments on secured term note	-	-	(5,000)
Net proceeds from the unit offering	-	-	14,146
Proceeds from exercise of stock options	-	-	119
Proceeds from exercise of warrant	-	20	-
Payments on capital lease obligations	-	-	(32)
Net cash provided by financing activities	160	20	11,929
Net (decrease) increase in cash and cash equivalents	(224)	(970)	31,140
Cash and cash equivalents at beginning of period	30,398	31,368	228
Cash and cash equivalents at end of period	$ 30,174	$ 30,398	$ 31,368
Cash paid during the period:			
Interest	$ -	$ 2	$ 395
Income taxes	$ 108	$ 82	$ -

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
YEAR ENDED DECEMBER 31, 2009, 2008, and 2007

Supplemental disclosures of noncash investing and financing activities presented on a reverse stock split basis:

Year ended December 31, 2009

1. Warrants to purchase 1,479,000 shares of common stock were exercised at exercise prices of $2.70 and $3.40 per share in a cashless exercise transactions resulting in the issuance of 730,000 shares of common stock.
2. Options to purchase 525,000 shares of common stock were exercised at exercise prices of $1.30 per share in cashless exercise transactions and after withholding shares for statutory minimum payroll taxes calculated at $685,000, the transactions resulted in the issuance of 225,000 shares of common stock.

Year ended December 31, 2008

1. Impaired fixed assets with a $52,000 net book value were disposed and a $29,000 reduction in the impairment allowance was favorably recognized.
2. A $1,177,000 valuation allowance against deferred income tax assets was removed which resulted in an equal amount recorded as a benefit against current income tax expense.

Year ended December 31, 2007

1. The Company issued 47,552 shares of common stock valued at $460,000 as payment of the accrued interest due on Senior Secured Convertible Bridge Term Notes Payable.
2. The Company issued 36,150 shares of common stock valued at $352,000 as payment of accrued interest due on Secured Term Note Payable.
3. Warrants to purchase an aggregate 58,000 shares of common stock were exercised at exercise prices between $1.20 and $6.60 per share in a series of cashless exercise transactions resulting in the issuance of aggregate 31,361 shares of common stock.
4. The issuance of $896,000 Senior Secured Convertible Bridge Term Notes during the period January 1, 2007 through March 29, 2007 included conversion features measured at $849,000, which resulted in the recording of an equal amount of debt discount and conversion feature liabilities.
5. The change in all separated conversion feature’s fair value through March 30, 2007 resulted in a loss of $3,483,000. Due to a debt agreement modification on March 30, 2007, the then current conversion feature fair value of $21,086,000 was reclassified from liabilities to equity.
6. The issuance of $1,800,000 of Senior Secured Bridge Term Notes included conversion features measured at $1,552,000, which resulted in a recording of an equal amount of debt discount to equity.
7. The change in the common stock warrants’ fair value through the earlier of their exercise date or March 30, 2007 resulted in a loss of 1,668,000. Due to a debt agreement modification on March 30, 2007, the then current fair value of all 1,592,100 outstanding common stock warrants of $12,307,000 was reclassified from liabilities to equity, as was $146,000 of such value related to warrants exercised during the period.
8. Anti-dilution provisions in certain warrant grants were triggered resulting in a loss of $236,000 with an equal amount recorded against equity.
9. Senior Secured Convertible Bridge Term Notes Payable of $10,544,000, less unamortized debt discount of $544,000 was converted into 3,905,184 shares of common stock.

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2009, 2008 and 2007

NOTE A - DESCRIPTION OF BUSINESS AND SUMMARY OF ACCOUNTING POLICIES

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the "Company" or "We") is a specialty pharmaceutical company engaged in research, development and manufacture of product candidates intended to provide abuse deterrent features and benefits utilizing our proprietary Aversion® and Impede™ Technologies.

Amounts presented are rounded to the nearest thousand, where indicated, except share and per share data. The equity amounts and all share and per share data of the Company have been adjusted to reflect a one-for-ten reverse stock split on December 5, 2007.

Summary of Significant Accounting Policies

A summary of the significant accounting policies consistently applied in the preparation of the accompanying consolidated financial statements follows.

1. Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Acura Pharmaceutical Technologies, Inc. All significant intercompany accounts and transactions are eliminated in consolidation. We have evaluated subsequent events through the time of filing this Form 10-K with the SEC on March 2, 2010.

2. Cash and Cash Equivalents

The Company considers all highly liquid securities with an original maturity of three months or less to be cash equivalents. Our cash and cash equivalent balances can consist of U.S. Treasury Bills or money market accounts and checking funds with variable, market rates of interest. From time to time, amounts may exceed the Federal Reserve insurance limits however we believe our credit risk exposure is not material. We believe the financial risks associated with these instruments are minimal and we have not experienced any losses from our investments in these securities. 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.

3. Short-Term Investments

The Company's entire portfolio of short-term investments at December 31, 2008 consisted of depository bank commercial paper and was accounted for as "held to maturity securities". The investments matured and were sold in 2009.

4. Concentration of Credit Risk

The Company invests its excess cash in accordance with the investment policy approved by our Board of Directors that seeks both liquidity and safety of principal. The policy provides for investments in instruments issued by the United States government and by commercial institutions with strong investment grade credit ratings and places restrictions on maturity terms and concentrations by type and issuer.

5. Use of Estimates in Consolidated Financial Statements

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and use assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the consolidated financial statements, as well as the reported amounts of revenues and expenses during the reporting period. 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.

6. Inventories

The Company had no inventories at each of December 31, 2009 and 2008. Purchases of active pharmaceutical ingredients and raw materials required for the Company's development and clinical trial manufacture of product candidates utilizing its Aversion® or Impede™ Technologies are expensed as incurred. To purchase certain active pharmaceutical ingredients required for our development and manufacture, we are required to file for and obtain quotas annually from the U.S. Drug Enforcement Agency.

7. Property, Plant and Equipment

Property, plant and equipment are recorded at cost. Depreciation is recorded on a straight-line basis over the estimated useful lives of the related assets. Leasehold improvements are amortized on a straight-line basis over the shorter of their useful lives or the terms of their respective leases. Betterments are capitalized and maintenance and repairs are charged to operations as incurred. The estimated 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

8. Debt

Debt Discount

For years 2007 and prior, debt discount resulting from the issuance of common stock warrants in connection with subordinated debt and other notes payable as well as from beneficial conversion features contained in convertible debt was recorded as a reduction of the related obligations and was amortized over the remaining life of the related obligations. Debt discount related to the common stock warrants issued was determined by a calculation based on the relative fair values ascribed to such warrants determined by management's use of the Black-Scholes valuation model.

Debt Conversion Features and Common Stock Warrants

For years 2007 and prior, certain provisions of the amended conversion features contained in the Company's Bridge Loan Agreements required the Company to separate the value of the conversion feature from the debt and record such value as a separate liability which was marked-to-market at each balance sheet date. The Company used the Black-Scholes option-pricing model to compute the estimated fair value of the conversion features. Marked-to-market adjustments resulted in the recording of further gains and losses.

As a result of the amendment to the Bridge Loan Agreements, all outstanding common stock purchase warrants were accounted for at fair value using the Black - Scholes option-pricing model and recorded as a liability with a corresponding reduction in additional paid-in capital. This warrant liability was marked-to-market each balance sheet date which resulted in the recording of further gains and losses. This practice ceased in 2007, see Note F.

9. Revenue Recognition, Deferred Program Fee Revenue and Collaboration Revenue

We recognize revenue when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. In connection with our License, Development, and Commercialization Agreement dated October 30, 2007 (the "King Agreement") with King Pharmaceuticals Research and Development, Inc. ("King"), 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 King received in December 2007, and license fees, such as the $3.0 million option exercise fee paid by King to us in each of May and December 2008 upon the exercise of its option to license a third and fourth opioid analgesic product candidate under the King Agreement. We have assigned an equal portion of King's $30.0 million upfront payment to

each of three product candidates identified in the King Agreement and recognize the upfront payment as program fee revenue ratably over our estimate of the development period for each identified product candidate. We expect to recognize the remainder of the program fee revenue for the third product candidate ratably over its remaining development period which we currently estimate to end in December 2010. We recognized $3.1 million, $21.9 million, and $3.4 million of this program fee revenue in 2009, 2008 and 2007, 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 King Agreement. The ongoing research and development services being provided to King under the collaboration are priced at fair value based upon the reimbursement of expenses incurred pursuant to the collaboration with King. We recognized $0.8 million, $11.5 million and $3.0 million of collaboration revenue in 2009, 2008 and 2007, respectively of which $0.4 million and $3.5 million were current receivables at December 31, 2009 and 2008, respectively.

Milestone revenue is contingent upon the achievement of certain pre-defined events in the development of Acurox® Tablets and other product candidates licensed to King under the King Agreement. Milestone payments from King 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 King 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, we recognized milestone revenue when King paid us a $5.0 million payment for successfully achieving the primary endpoints in our pivotal Phase III study, AP-ADF-105 for Acurox® Tablets.

10. Research and Development

Research and Development (“R&D”) expenses include internal R&D activities, external contract research organization (“CRO”) activities, and other activities. Internal R&D activity expenses include facility overhead, equipment and facility maintenance and repairs, depreciation, laboratory supplies, pre-clinical laboratory experiments, depreciation, salaries, benefits, and incentive compensation expenses. CRO activity expenses include preclinical laboratory experiments and clinical trial studies. Other activity expenses include clinical trial studies and regulatory consulting, and regulatory counsel. Internal R&D activities and other activity expenses are charged to operations as incurred. The Company makes payments to the CRO's based on agreed upon terms and may include payments in advance of the study starting date. The Company reviews and accrues CRO expenses and clinical trial study expenses based on work performed and relies 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 trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. Advance payments are amortized to expense based on work performed. The Company has entered into several CRO clinical trial agreements pursuant to which the unfunded CRO commitments were $1.4 million at December 31, 2009 and are expected to be incurred as subjects are enrolled into the clinical studies.

11. Income Taxes

The Company accounts 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 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. During 2009 the Company determined it was more likely than not that it would not be able to realize its recorded deferred income tax assets and recorded an adjustment of $2.5 million to the deferred income tax asset valuation allowance and recognized an expense from income taxes in such period. During 2008 and 2007, the Company determined it was more likely than not that it would be able to realize some of its deferred income tax assets in the near future, and recorded adjustments of $1.2 million and $8.6 million to the deferred income tax asset valuation allowance, respectively. These adjustments recognized a benefit from income taxes in our income for such periods. At both December 31, 2009 and 2008, 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.

12. Earnings Per Share

The computation of basic earnings (loss) per share of common stock is based upon the weighted average number of common shares outstanding during the period, including shares related to vested restricted stock units (See Note I). The computation of diluted earnings (loss) per share is based on the same number of shares used in the basic share calculation adjusted for the effect of other potentially dilutive securities. No such adjustments were made for 2009 or 2007 as their effects would be antidilutive.

	Year ended December 31,		
(in thousands except per share data)	2009	2008	2007
Basic earnings per share			
Numerator:			
Net (loss) income	$ (15,835)	$ 14,474	$ (4,314)
Deemed dividend from modification of debt	-	-	(3)
Net (loss) income applicable to common stockholders	$ (15,835)	$ 14,474	$ (4,317)
Denominator:			
Common shares (weighted)	42,912	42,719	36,656
Vested restricted stock units (weighted)	3,020	2,956	2,501
Weighted average number of shares outstanding	45,932	45,675	39,157
Basic earnings (loss) per common share	$ (0.35)	$ 0.32	$ (0.11)
Diluted earnings (loss) per share			
Denominator:			
Common shares (weighted)	42,912	42,719	36,656
Vested restricted stock units (weighted)	3,020	2,952	2,501
Stock options	-	1,443	-
Common stock warrants	-	2,302	-
Weighted average number of shares outstanding	45,932	49,416	39,157
Diluted earnings (loss) per common share	$ (0.35)	$ 0.29	$ (0.11)
Excluded potentially dilutive securities:			
Common stock issuable (1):			
Employee and director stock options	3,671	1,149	1,858
Common stock warrants	2,380	-	3,972
Non-vested restricted stock units	204	30	-
Total excluded dilutive shares	6,255	1,179	4,820

(1) Number of shares issuable represents those securities which were either i) nonvested at year end or ii) were vested but antidilutive. The number of shares is based on maximum number of shares issuable on exercise or conversion of the related securities as of year end. Such amounts have not been adjusted for the treasury stock method or weighted average outstanding calculations as required if the securities were dilutive.

13. Stock-Based Compensation

The Company has four stock-based compensation plans covering stock options and restricted stock units for its employees and directors, which are described more fully in Note I.

The Company measures its 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, the Company utilizes 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 the Company's common stock (as determined by reviewing its historical public market closing prices). Because the Company's employee stock options have characteristics significantly different from those of trade options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable measure of the fair value of its employee stock options.

The Company's accounting for stock-based compensation for restricted stock units ("RSUs") has been based on the fair-value method. The fair value of the RSUs is the market price of the Company's common stock on the date of grant, less its exercise cost.

14. Accounting Developments

In October 2009, the FASB issued an amendment to its previously released guidance on revenue arrangements with multiple deliverables. This guidance becomes effective for the Company at the beginning of its 2011 fiscal year. The pronouncement addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the arrangement consideration should be allocated among the separate units of accounting. The pronouncement may be applied retrospectively or prospectively for new or materially modified arrangements and early adoption is permitted. The Company is currently assessing the impact of adopting this guidance.

In June 2009, the FASB Accounting Standards Codification ("Codification") was issued. The Codification will become the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles. The Codification explicitly recognizes rules and interpretive releases of the Securities and Exchange Commission ("SEC") under federal securities laws as authoritative generally accepted accounting principles for SEC registrants. The Company adopted this statement on September 30, 2009 and its adoption did not have an effect on our consolidated financial statements.

In May 2009, the FASB established the general standards of accounting for and disclosure of subsequent events. In addition, this statement requires disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. The Company adopted this standard on July 1, 2009 and has provided the new disclosures as required.

In March 2008, the Financial Accounting Standards Board ("FASB") issued a statement for disclosures about derivative instruments and hedging activities intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. The Company adopted this statement on January 1, 2009 with no effect on the Company's consolidated financial statements as we had no derivative or hedging activities.

In December 2007, the FASB issued guidance on collaborative arrangements, which is effective for calendar-year companies beginning January 1, 2009. The pronouncement clarified the manner in which costs, revenues and sharing payments made to, or received by, a partner in a collaborative arrangement should be presented in the income statement and set forth certain disclosures that should be required in the partners' financial statements. The implementation of this standard did not have an impact on the Company's consolidated financial statements.

In December 2007, the FASB issued a statement to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. The Company adopted this statement on January 1, 2009 with no effect on the Company's consolidated financial statements as we did not have any noncontrolling interests in a subsidiary.

In December 2007, the FASB issued a statement on business combinations. The statement defines the acquirer as the entity that obtains control of one or more businesses in the business combination, establishes the acquisition date as the date the acquirer achieves control and requires the acquirer to recognize the assets and liabilities assumed and any non-controlling interest at their fair values as of the acquisition date. The statement requires, among other things, that the acquisition related costs be recognized separately from the acquisition. The Company adopted this guidance on January 1, 2009 for business combinations for which the acquisition date is on or after January 1, 2009.

In June 2007, FASB issued guidance on "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities" which was effective for fiscal years beginning after December 15, 2007. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense when the related goods are delivered or services are performed, or when goods or services are no longer expected to be provided. The adoption of this guidance did not have an impact on the Company's consolidated financial statements.

NOTE B – LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

On October 30, 2007, we and King Pharmaceuticals Research and Development, Inc. (“King”), a wholly-owned subsidiary of King Pharmaceuticals, Inc., entered into a License, Development and Commercialization Agreement (the “King Agreement”) to develop and commercialize in the United States, Canada and Mexico (the "King Territory") certain opioid analgesic products utilizing our proprietary Aversion® Technology. In addition, the King Agreement provides King with an option to license in the King Territory all future opioid analgesic products developed utilizing Aversion® Technology. At December 31, 2009, King had exercised its option to license two additional product candidates including an undisclosed opioid analgesic tablet product and Vycavert® (hydrocodone bitartrate/niacin/APAP) Tablets, each of which utilize our Aversion® Technology. We are responsible for using commercially reasonable efforts to develop Acurox® Tablets through regulatory approval by the FDA. The King Agreement provides that we or King may develop additional opioid analgesic product candidates utilizing our Aversion® Technology and, if King exercises its option to license such additional product candidates, they will be subject to the milestone and royalty payments and other terms of the King Agreement.

At December 31, 2009, we had received aggregate payments of $56.2 million from King, consisting of a $30.0 million non-refundable upfront cash payment, $15.2 million in reimbursed research and development expenses relating to Acurox® Tablets, $6.0 million in fees relating to King’s exercise of its option to license an undisclosed opioid analgesic tablet product and Vycavert® Tablets, and a $5.0 million milestone fee relating to our successful achievement of the primary endpoints for our pivotal Phase III clinical study for Acurox® Tablets. The King Agreement also provides for King’s payment to us of a $3.0 million fee upon King’s exercise of its option for each future opioid product candidate. In the event that King does not exercise its option for a future opioid product candidate, King may be required to reimburse us for certain of our expenses relating to such future opioid product candidate. Further, we may receive up to $23 million in additional non-refundable milestone payments for each product candidate licensed to King, including Acurox® Tablets, which achieve certain regulatory milestones in specific countries in the King Territory. We can also receive a one-time $50 million sales milestone payment upon the first attainment of $750 million in net sales of all of our licensed products across all King Territories. In addition, for sales occurring following the one year anniversary of the first commercial sale of the first licensed product sold, King will pay us a royalty at one of 6 rates ranging from 5% to 25% based on the level of combined annual net sales for all products licensed by us to King across all King Territories, with the highest applicable royalty rate applied to such combined annual sales. King’s royalty payment obligations expire on a product by product and country-by-country basis upon the later of (i) the expiration of the last valid patent claim covering such product in such country, or (ii) fifteen (15) years from the first commercial sale of such product in such country.

The King Agreement expires upon the expiration of King’s royalty payment and other payment obligations under the King Agreement. King may terminate the King Agreement in its entirety or with respect to any product at any time after March 31, 2010, upon the provision of not less than 12 months’ prior written notice, and in its entirety if regulatory approval of the NDA for Acurox® Tablets is not received prior to March 31, 2010 and with respect to a particular product with respect to a country in which regulatory approval for such product is withdrawn by a regulatory authority in such country. We do not expect to receive FDA approval of the NDA for Acurox® Tablets prior to March 31, 2010. As a result, King may terminate the King Agreement at any time following such date upon written notice to us. We may terminate the King Agreement with respect to a product in the United States in the event such product is not commercially launched by King within 120 days after receipt of regulatory approval of such

product or in its entirety if King commences any interference or opposition proceeding challenging the validity or enforceability any of our patent rights licensed to King under the King Agreement.

NOTE C – PREFERRED SHARES

As of the date of this Report, the Company has no issued or authorized preferred shares. Prior to June 2008, the Company was authorized to issue various series of convertible preferred stock. In November 2005 all of the Company's issued and outstanding preferred shares were automatically and mandatorily converted into the Company's common stock in accordance with the terms of the Company's Restated Certification of Incorporation and in June 2009, the Company amended its Restated Certificate of Incorporation to eliminate all authorized preferred stock.

NOTE D – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows:

	December 31,	
(in thousands)	2009	2008
Building and improvements	$ 1,465	$ 1,385
Land and improvements	161	161
Machinery and equipment	26	23
Scientific equipment	569	476
Computer hardware and software	251	225
Office equipment	27	52
Other personal property	60	60
	2,559	2,382
Less accumulated depreciation and amortization	(1,399)	(1,309)
Total property, plant and equipment, net	$ 1,160	$ 1,073

Depreciation and amortization expense for the years ended December 31, 2009, 2008 and 2007 was $130,000, $143,000, and $130,000, respectively.

NOTE E – ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	December 31,	
(in thousands)	2009	2008
Payroll, payroll taxes and benefits	$ 89	$ 77
Professional services	160	168
Franchise taxes	21	144
Property taxes	19	39
State income taxes	-	94
Clinical and regulatory services	75	173
Other fees and services	88	188
	$ 452	$ 883

NOTE F – NOTES PAYABLE

Convertible Bridge Term Notes

A November 2006 amendment of the conversion feature on all of the then outstanding Bridge Loans, coupled with the requirement under current accounting guidance to separate the value of the conversion feature from the debt, required the Company to record the value of the amended conversion feature on that outstanding debt as a liability. Upon revaluing the aggregate conversion features on all outstanding Bridge Loans as of March 30, 2007 (the date immediately before further amendment to the Bridge Loans), the Company recorded the resulting increase in value as

a $3.48 million loss. The increase in the Company's common stock trading price from December 31, 2006 to March 30, 2007 resulted in the increase in the value of the conversion liability. The Bridge Loan amendment on March 30, 2007 limited the conversion price of the post-October 2006 loans to no lower than $2.10 per share. With this limit in place, the outstanding conversion feature no longer had to be reflected as Company liabilities. As such, the Company recorded a $21.1 million reclassification of that liability to additional paid-in capital.

To compute the estimated value of the conversion features just prior to the reclassification described above, the Company used the Black-Scholes option-pricing model with the following assumptions on these dates:

	Mar 30, 2007
Company stock price	$ 8.50
Exercise price	(1)
Expected dividend	0.0%
Risk –free interest rate	5.07%
Expected volatility	none
Contracted term	1 day

(1) The conversion price per share used to estimate fair value of the Bridge Loan conversion rights was equal to the fixed conversion price per share set forth above for each of the specified Bridge Loan amounts. While the Bridge Loan Agreements provide for other than fixed conversion prices under certain circumstances, the Company has judged that the fixed conversion prices will most likely be the lowest price per share under any of the circumstances and the lender would therefore select such fixed price for their conversion.

The conversion features related to additional $1.8 million Bridge Note issuances in 2007 were not required to be separated and accounted for at fair value. However, based on the conversion price of those notes, the issuances did include beneficial conversion features whereby the common stock to be issued upon conversion would be worth more than the underlying debt if converted upon issuance. That incremental value, computed as $1.5 million was recorded as additional paid-in capital and as debt discount, which would be amortized over the term of the notes.

NOTE G – COMMON STOCK WARRANTS

As a result of a November 2006 amendment to the Company's then outstanding Bridge Loan Agreements, the Company's outstanding common stock purchase warrants commenced being accounted for as marked-to-market liability. Upon revaluing these warrants just before their exercise or as of March 30, 2007 (the date immediately before further amendment to the Bridge Loan Agreements), the Company recorded the resulting increase in value as a $1.7 million loss. The increase in the Company's common stock trading price from December 31, 2006 to March 30, 2007 resulted in the increase in the value of the recorded warrant liability. The Bridge Loan agreement amendment on March 30, 2007 limited the conversion price of the Bridge Loans, and with this limit in place, the outstanding common stock purchase warrants were no longer required to be accounted for as a liability. As such, the Company recorded a combined $12.5 million reclassification of that liability to additional paid-in capital during the first quarter of 2007.

The Company has outstanding common stock purchase warrants at December 31, 2009 exercisable for an aggregate 2,380,000 shares of common stock, all of which contained cashless exercise features. Warrants for 64,000 and 2,316,000 shares at an exercise price of $1.29 and $3.40 per share, respectively, will expire in May 2010 and August 2014, respectively, if unexercised. These warrants have a weighted average remaining term of 4.5 years and a weighted average exercise price of $3.34.

NOTE H – INCOME TAXES

Provision for Income Taxes

The reconciliation between the statutory federal income tax rate and the Company's effective income tax rate is as follows:

	December 31,		
(in thousands)	2009	2008	2007
Tax (benefit) at U.S. 34% statutory rate	$ (4,541)	$ 7,398	$ (4,731)
Current state tax (benefit), net of Federal effect	(416)	1,518	(413)
Research tax credits	(100)	(129)	(220)
Wage reported stock compensation	(587)	-	-
	-	-	1,184

Fair value change of conversion feature fair value			
Fair value change of warrant	-	-	648
Debt discount amortization	-	-	918
Financing costs	-	-	311
Other	(330)	(325)	(64)
	(5,974)	8,462	(2,367)
Increase (decrease) in valuation allowance	8,453	(1,177)	(7,233)
Provision (benefit) for income taxes	$ 2,479	$ 7,285	$ (9,600)

Tax expense for 2009 is deferred taxes, 2008 is comprised of $0.2 million of current state taxes and $7.1 million of deferred taxes, and for 2007 the entire $9.6 million tax benefit is deferred 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 income tax purposes. The most significant item of our deferred tax assets is derived from our Federal NOLs. We have approximately $23.1 million federal income tax benefit at December 31, 2009 derived from $68 million Federal NOLs at the 34% federal income tax rate, available to offset future taxable income, some of which have limitations for use as prescribed under internal revenue code IRC Section 382. Our NOLs will expire in varying amounts between 2010 and 2029 if not used. Income tax benefits of $3.0 million and $1.4 million from NOLs under valuation allowance expired in 2009 and 2007, respectively. The components of our deferred tax assets are as follows:

	December 31,	
(in thousands)	2009	2008
Deferred tax assets:		
Estimated future value of NOLs		
- Federal	$ 23,114	$ 22,920
- State	3,862	2,365
Research tax credits	194	754
Deferred program fee revenue	611	1,819
Share-based compensation	10,505	7,364
Other, net	41	98
Total deferred taxes	38,327	35,320
Valuation allowance	(38,327)	(32,829)
Net deferred tax assets	$ -	$ 2,491

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which may be uncertain. Valuation allowances are placed on deferred tax assets when uncertainty exist on their near term utilization. Periodic reviews are made by us on the valuation allowances and fluctuations can occur. Those fluctuations are reflected as income tax expenses or benefits in the period they occur. Prior to 2007 we were uncertain of achieving future earnings and accordingly, we offset 100% of deferred tax assets with a valuation allowance. In 2007, based upon the economics of the King Agreement, we concluded that it was likely that we would realize sufficient future earnings to enable us to utilize at least $9.6 million of these deferred tax assets and we reduced the valuation allowance by that amount. Similarly, in 2008, we concluded that it was likely that we would be able to utilize at least another $1.2 million of these deferred tax assets and we reduced the valuation allowance by that amount and $11.9 million of deferred tax assets were used to offset our 2008 federal and state tax liabilities. In 2009, we increased the valuation allowance by $2.5 million for the then available deferred tax assets and placed a valuation allowance against the current year's operating results.

Uncertainty in Income Taxes

On January 2007 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 December 31, 2009, 2008 or 2007, we had no liability for income tax associated with uncertain tax positions. The Company's practice will be to recognize interest and penalties related to uncertain tax positions in interest expense and other expense, respectively. The Company files federal and state tax returns. In the normal course of business the Company is subject to examination by taxing authorities. With few exceptions, the Company believes it is no longer subject to U.S. federal and state income tax examinations for years before 2006.

NOTE I – EMPLOYEE BENEFIT PLANS

401(k) and Profit-Sharing Plan

The Company has a 401(k) and Profit-Sharing Plan (the "Plan") for all 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. The Company did not contribute matching or profit sharing contributions for the Plan in years 2009, 2008 and 2007.

Stock Option Plans

The Company maintains various stock option plans. A summary of the Company's stock option plans as of December 31, 2009, 2008, and 2007, and for the years then ended consisted of the following:

	Years Ended December 31,					
	2009		2008		2007	
	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price	Number of Options (000's)	Weighted Average Exercise Price
Outstanding, beginning	2,968	$ 4.93	1,858	$ 2.60	1,899	$ 2.60
Granted	1,312	6.38	1,160	9.58	-	-
Exercised	(525)	1.30	-	-	(31)	3.80
Forfeited or expired	(84)	7.95	(50)	23.69	(10)	3.60
Outstanding, ending	3,671	$ 5.90	2,968	$ 4.93	1,858	$ 2.60
Options exercisable	2,712	$ 5.49	2,215	$ 3.26	1,827	$ 2.56

The following table summarizes information about nonvested stock options outstanding at December 31, 2009:

	Number of Options Not Exercisable (000)'s	Weighted Average Fair Value
Outstanding at December 31, 2008	754	$ 6.88
Granted	1,312	6.06
Vested	(1,039)	7.89
Forfeited or expired	(68)	6.02
Outstanding at December 31, 2009	959	$ 6.77

The Company estimated 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 the Company has not paid any cash dividends) and employee exercise behavior. Expected volatilities utilized in the Black-Scholes model are based on the historical volatility of the Company's 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 factors. No options were granted in 2007.

The assumptions used in the Black Scholes model to determine fair value for the 2009 and 2008 stock option grants were:

	2009	2008
Dividend yield	0.0%	0.0%
Risk-free interest rate	2.4% to 3.1%	3.63%
Average volatility	124%	141%
Forfeitures	0.0%	0.0%
Expected holding period	10 years	10 years
Weighted average grant date fair value	$ 6.06	$ 6.88

As of December 31, 2009, 2008, and 2007 the aggregate intrinsic value of the option awards vested was $4.8 million, $10.5 million, and $8.1 million, respectively. In addition, the aggregate intrinsic value of option awards exercised during the years ended December 31, 2009 and 2007 was $1.7 million and $0.5 million, respectively. The total remaining unrecognized compensation cost related to the unvested option awards at December 31, 2009 was $6.4 million and is expected to be recognized over the next seven month weighted average remaining requisite service period. The total fair value of the option awards that vested during the years ended December 31, 2009, 2008 and 2007 was $8.2 million, $3.7 million, and $0.1 million, respectively and was recognized as stock-based compensation. Stock-based compensation from option awards in the amount of $1.7 million and $0.6 million is included in research and development expense in the years ended December 31, 2009 and 2008, respectively. There was no stock-based compensation from option awards included in research and development expense during 2007. Stock-based compensation from option awards in the amount of $6.5 million, $3.1 million and $0.1 million is included in general and administrative expenses in the years ended December 31, 2009, 2008 and 2007, respectively.

Restricted Stock Unit Award Plan

The Company has a Restricted Stock Unit Award Plan ("2005 RSU Plan") for its employees and non-employee directors. Vesting of an RSU entitles the holder thereof to receive a share of common stock of the Company on a distribution date.

At December 31, 2007, an aggregate of 2.95 million RSUs were outstanding and fully vested. During 2009 and 2008, 333,000 and 50,000 RSUs were granted, respectively, and 142,000 and 20,000 RSUs vested, respectively. During 2009, 17,000 RSU awards were canceled. At December 31, 2009 and 2008, 3.32 million and 3.0 million RSUs were outstanding, respectively, and 3.11 million and 2.97 million RSUs were vested, respectively. The RSUs have a weighted average fair value of $3.75 per share at December 31, 2009.

The stock-based compensation cost to be incurred on the RSUs 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 fair value of the RSU grants made in 2009 and 2008 was $2.1 million and $0.4 million, respectively. The total remaining unrecognized compensation cost related to the unvested RSU awards amounted to $1.3 million at December 31, 2009. The Company recognized compensation cost from the RSU awards of $1.0 million, $0.2 million, and $0.8 million during the years ended December 31, 2009, 2008 and 2007, respectively. Stock-based compensation from RSU awards in the amount of $0.2 million and $0.4 million is included in research and development expense in the years ended December 31, 2009 and 2007, respectively. There was no stock-based compensation from RSU awards included in research and development expense during 2008. Stock-based compensation from RSU awards in the amount of $0.8 million, $0.2 million, and $0.4 million is included in general and administrative expense in the years ended December 31, 2009, 2008 and 2007, respectively. No related tax benefits were recorded in calendar year 2009, 2008, or 2007.

As of December 31, 2009, 2008 and 2007, the aggregate intrinsic value of the RSU awards outstanding and vested was $16.6 million, $21.8 million and $18.0 million, respectively. As defined in the 2005 RSU Plan, including 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 (whether prior to or after 2011), the vested shares underlying the RSU award will be distributed at or about the time of the change in control.

NOTE J – COMMITMENTS AND CONTINGENCIES

Employment Agreements

Each of Andrew D. Reddick, Robert B. Jones and Peter A. Clemens are parties to employment agreements containing similar terms expiring December 31, 2010, which provide annual salary of $377,000, $300,000 and $212,000, respectively, plus the payment of annual bonuses, in the discretion of the Company's Compensation Committee or Board of Directors, based on the achievement of targets, conditions, or parameters as set by the Compensation

Committee or the Board of Directors.

Statutory Minimum Withholding Tax Obligations

Under our stock option plans and our 2005 RSU plan, our employees may elect to have shares withheld upon exercise of options and upon the exchange of RSUs in satisfaction of the statutory minimum withholding tax obligations of such employees relating to such option exercises or RSU exchanges.

Financial Advisor Agreement

In connection with the Company's August 2007 Unit Offering, the Company is obligated to pay a fee to the Company's then financial advisor upon each exercise of the warrants issued in the Unit Offering, in proportion to the number of warrants exercised. The maximum amount of such remaining fee assuming 100% exercise of the remaining 1,339,000 warrants is $273,000. The Company has not reflected this obligation as a liability in its 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.

NOTE K – QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly consolidated financial data is shown below.

(in thousands except share data)	Three Month Period Ended			
	Mar. 31	Jun. 30	Sept. 30	Dec. 31
Calendar Year 2009				
Total revenue (a)	$ 1,380	$ 897	$ 808	$ 750
Loss from operations	(2,197)	(3,256)	(3,970)	(4,077)
Net loss (b)	(1,277)	(6,520)	(3,954)	(4,084)
Loss per common share				
Basic	$ (0.03)	$ (0.14)	$ (0.09)	$ (0.09)
Diluted	$ (0.03)	$ (0.14)	$ (0.09)	$ (0.09)

	Mar. 31	Jun. 30	Sept. 30	Dec. 31
Calendar Year 2008				
Total revenue (a)	$ 17,084	$ 15,685	$ 3,880	$ 7,788
Income (loss) from operations	12,132	11,227	(3,186)	809
Net income (loss) (b)	7,449	6,870	3,148	(2,993)
Income (loss) per common share				
Basic	$ 0.16	$ 0.15	$ 0.07	$ (0.07)
Diluted	$ 0.15	$ 0.13	$ 0.06	$ (0.07)

(a) See Note A(9) for revenue recognition.

(b) The Company recorded valuation adjustments on its deferred income tax assets and recorded income tax expense of $2.5 million and $3.6 million in quarters ended Jun. 30, 2009 and Dec. 31, 2008, respectively, and recorded income tax benefit of $5.0 million in the quarter ended Sept. 30, 2008.

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 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) (confidential treatment has been requested for portions of this Exhibit).
10.2	Securities Purchase Agreement dated as of August 20, 2007 ("PIPE SPA") among the Registrant, Vivo Ventures Fund VI, L.P., Vivo Ventures VI Affiliates Fund, L.P. (collectively "Vivo"), GCE Holdings LLC, and certain other signatories thereto (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 21, 2007).
10.3	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).
10.4	Form of Warrants dated May 5, 2003 issued to Galen Partners III, L.P., Galen Partners International, III, L.P., Galen Employee Fund III, L.P., Essex Woodlands Health Ventures Fund V, L.P. and Care Capital Investments II, LP and others) (incorporated by reference to Exhibit 10.6 to the October 2007 S-3).
10.5	Amended and Restated Voting Agreement dated as of February 6, 2004 among the Registrant, Care Capital Investments II, LP, Essex Woodlands Health Ventures Fund 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")).
10.6	Joinder and Amendment to Amended and Restated Voting Agreement dated November 9, 2005 between the Registrant, GCE Holdings, Essex Woodlands Health Ventures Fund 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).
10.7	Second Amendment to Amended and Restated Voting Agreement dated as of January 24, 2008 between the Registrant and GCE Holdings, LLC (incorporated by reference to Exhibit 10.1 to the Form 8-K filed January 28, 2008).
10.8	

	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).
10.9	Registrant’s 1998 Stock Option Plan, as amended (incorporated by reference to Appendix C to the Registrant’s Proxy Statement filed on May 12, 2009).

Exhibit Number	Exhibit Description
10.10	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).
10.11	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)
10.12	Executive Employment Agreement dated as of August 26, 2003 between the Registrant and Andrew D. Reddick ("Reddick") (incorporated by reference to Exhibit 10.2 to the Form 10-Q for the quarter ended June 30, 2004 (the "June 2004 10-Q")).
10.13	Amendment to Executive Employment Agreement between the Registrant and Reddick, dated May 27, 2004 (incorporated by reference to Exhibit 10.4 to the June 2004 10-Q).
10.14	Second Amendment to Executive Employment Agreement between the Registrant and Reddick, dated May 24, 2005 incorporated by reference to Exhibit 10.116 to the Form 10-K for the year ending December 31, 2005 filed on February 21, 2006 (the "2005 Form 10-K")).
10.15	Third Amendment to Executive Employment Agreement between the Registrant and Reddick, dated December 22, 2005 (incorporated by reference to Exhibit 10.1 to the Form 8-K filed December 23, 2005 (the "December 2005 Form 8-K")).
10.16	Fourth Amendment to Executive Employment Agreement between the Registrant and Reddick dated December 16, 2007 (incorporated by reference to Exhibit 10.20 to the Form 10-K for the year ending December 31, 2007, filed on March 5, 2008).
10.17	Fifth Amendment to Executive Employment Agreement between the Registrant and Reddick executed July 9, 2008 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on July 10, 2008)
10.18	Executive Employment Agreement dated as of April 5, 2004 between the Registrant and Ron J. Spivey (incorporated by reference to Exhibit 10.3 to the June 2004 10-Q).
10.19	Amendment to Executive Employment Agreement dated December 22, 2005 between Registrant and Ron J. Spivey (incorporated by reference to Exhibit 10.2 to the December 2005 Form 8-K).
10.20	Second Amendment to Executive Employment Agreement dated December 19, 2007 between the Registrant and Ron J. Spivey (incorporated by reference to Exhibit 10.23 to the Form 10-K for the year ending December 31, 2007, filed on March 5, 2008).

10.21	Third Amendment to Employment Amendment to Executive Employment Agreement executed July 9, 2008 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed on July 10, 2008).
10.22	Amended and Restate Employment Agreement effective as of January 1, 2009 between the registrant and Ron J. Spivey (incorporated by reference to Exhibit 10.3 to our Form 8-K filed on July 10, 2008)
10.23	Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens ("Clemens") (incorporated by reference to Exhibit 10.44 to the Form 10-K for the period ending December 31, 2007, filed on April 15, 1998).
10.24	First Amendment to Employment Agreement made as of June 28, 2000 between the Registrant and Clemens (incorporated by reference to Exhibit 10.44A to the Registrant's 2005 Form 10-K).

Exhibit Number	Exhibit Description
10.25	Second Amendment to Executive Employment Agreement between Registrant and Clemens, dated as of January 5, 2005 (incorporated by reference to Exhibit 99.1 to the Registrant's Form 8-K filed January 31, 2005).
10.26	Third Amendment to Executive Employment Agreement dated December 22, 2005 between Registrant and Clemens (incorporated by reference to Exhibit 10.3 to the December 2005 Form 8-K).
10.27	Fourth Amendment to Executive Employment Agreement dated December 16, 2007 between Registrant and Clemens (incorporated by reference to Exhibit 10.28 to the Form 10-K for the year ending December 31, 2007, filed on March 5, 2008).
10.28	Fifth Amendment to Executive Employment Agreement executed July 9, 2008 between Registrant and Clemens (incorporated by reference to Exhibit 10.4 to our Form 8-K filed on July 10, 2008)
10.29	Employment Agreement dated as of March 18, 2008 between the Registrant and Robert B. Jones (incorporated by reference to Exhibit 10.1 to our Form 8-K filed on March 24, 2008)
*10.30	Consulting Agreement dated as of December 10, 2009 between Registrant and Garth Boehm
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 the Form 10-K for the fiscal year ended December 31, 2006 filed on March 15, 2007).
*23.1	Consent of BDO Seidman 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.

*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 reports dated March 2, 2010, relating to the consolidated financial statements, and the effectiveness of Acura Pharmaceuticals, Inc.'s internal control over financial reporting, which appear in this Form 10-K.

/s/ BDO Seidman, LLP
Chicago, Illinois
March 2, 2010