

ACURA PHARMACEUTICALS, INC  
Form 10-K  
March 05, 2008

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

**FORM 10-K**

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO  
SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE  
ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31,  
2007**

**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**  
(State or other jurisdiction of Incorporation or  
organization)

**11-0853640**  
(I.R.S. Employer Identification No.)

**616 N. North Court, Suite 120, Palatine, Illinois**  
(Address of principal executive office)

**60067**  
(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 ☒

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 ☒

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

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

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

☐ Large Accelerated Filer, ☐ Accelerated Filer, ☒ Non-Accelerated Filer.

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

Based on the average closing bid and asked prices of the Common Stock on June 29, 2007 (\$11.10) (the last business day of the registrant's most recently completed second fiscal quarter, and after giving effect to the registrant's 1 for 10 reverse stock split effected December 5, 2007), the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$74,801,626.

As of March 1, 2008, the registrant had 42,706,466 shares of Common Stock, par value \$0.01, outstanding.

**Documents incorporated by reference:** None

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**Acura Pharmaceuticals, Inc.**

**Form 10-K**

**For the Fiscal Year Ended December 31, 2007**

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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") and other pharmaceutical companies, if any, to whom we may license our Aversion® Technology, to obtain necessary regulatory approvals and commercialize products utilizing the Aversion® Technology, the ability to avoid infringement of patents, trademarks and other proprietary rights or trade secrets 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 other laboratory and clinical studies, to support FDA approval of our product candidates, the adequacy of the development program for 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 otherwise, the risk that further studies of our product candidates are not positive or otherwise do not support FDA approval or commercially viable product labeling, and the uncertainties inherent in scientific research, drug development, 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 highly skilled personnel; our ability to secure and protect our patents, trademarks and 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 of our products in development; difficulties or delays in clinical trials for our product candidate 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 are intended to identify forward-looking statements.

## PART I

### ITEM 1. BUSINESS

#### Company Overview

We are a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® Technology and related product candidates. Product candidates developed with Aversion® Technology and containing opioid analgesic active ingredients are intended to effectively treat pain and also discourage the most common methods of pharmaceutical product misuse and abuse including; (i) intravenous injection of dissolved tablets or capsules, (ii) nasal snorting of crushed tablets or capsules and (iii) intentional swallowing of excessive numbers of tablets or capsules. Acurox™ Tablets, our lead product candidate utilizing Aversion® Technology, is being developed pursuant to an active investigational new drug application ("IND") on file with the U.S. Food and Drug Administration ("FDA"). Aversion® Technology is our patented platform technology for developing next-generation pharmaceutical products containing potentially abuseable drugs including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, tramadol, propoxyphene, and many others. Additional Aversion® Technology patents are pending encompassing a wide range of abuseable drugs including stimulants, tranquilizers and sedatives. Aversion® Technology is applicable to orally administered tablets and capsules. In addition to the active ingredient, Aversion® Technology utilizes certain patented compositions of pharmaceutical product inactive excipients and active ingredients intended to discourage or deter pharmaceutical product abuse.



We conduct internal research, development, laboratory, manufacturing and warehousing activities for Aversion® Technology at our Culver, Indiana facility. The 28,000 square foot facility is registered by the U.S. Drug Enforcement Administration (“DEA”) to perform research, development and manufacture of certain Schedule II - V finished dosage form products. In addition to internal capabilities and activities, we engage numerous contract 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 development services for Acurox™ Tablets and other Aversion® product candidates under our direction.

We are focused on:

- research and development of product candidates utilizing our Aversion® Technology;
- manufacture, quality assurance testing and release, and stability studies of clinical trial supplies and NDA submission batches of certain finished dosage form product candidates utilizing Aversion® Technology;
- prosecution of our patent applications relating to Aversion® Technology with the United States Patent and Trademark Office (“USPTO”) and foreign equivalents; and
- negotiation and execution of license and development agreements with pharmaceutical company partners providing that such licensees will further develop certain finished dosage product candidates utilizing the Aversion® Technology and file for regulatory approval with the FDA and other regulatory authorities and commercialize such products.

We are a publicly traded New York corporation and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the “SEC”). These filings are available to the public over the internet at the SEC's web site at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's public reference room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room.

Our internet address is [www.acurapharm.com](http://www.acurapharm.com). We make available free of charge, with a link from our web site to the SEC's website, our annual, quarterly and current reports and amendments to those reports, as soon as reasonably practicable after we electronically file such material with the SEC. In addition, you may request a copy of these filings (excluding exhibits) at no cost by contacting us at Acura Pharmaceuticals, Inc., 616 N. North Court, Suite 120, Palatine, Illinois 60067, Attention: Investor Relations.

## Company Strategy

Our goal is to become a leading specialty pharmaceutical company focused on addressing the growing societal problem of prescription drug abuse by developing a broad portfolio of pharmaceutical products with abuse deterrent features. Specifically we intend to:

- *Capitalize on our Experience and Expertise in the Research and Development of Abuse Deterrent Pharmaceutical Products.* Our approach is to utilize existing active pharmaceutical ingredients with proven safety and efficacy profiles that have known potential for abuse, and develop new products utilizing our proprietary Aversion® (“abuse deterrent”) Technology. We believe that in most cases the FDA's 505(b)(2) NDA approval process may be used with these product candidates. While there can be no assurance, we believe the use of the 505(b)(2) NDA approval process may allow for more efficient and timely approvals as compared to standard NDA filings. The 505(b)(2) NDA regulatory pathway is being utilized in the development of Acurox™ Tablets, our lead product candidate utilizing Aversion® Technology. In addition to Acurox™ Tablets, as of the date of this Report we are engaged in the

development of several additional product candidates incorporating Aversion® Technology, including hydrocodone bitartrate with acetaminophen tablets (marketed generically and by others under the brand names Vicodin®, Lortab®, and Lorcet®), hydromorphone HCl tablets (marketed generically and by Abbott Laboratories under the brand name Dilaudid®) and oxycodone HCl with acetaminophen (marketed generically and by others under the brand names of Percocet®, Tylox®, Endocet®, and Roxicet®). We expect to file an IND for our second Aversion® Technology opioid product candidate in the first half of 2008.

*-Maximize Commercial Value of our Product Candidates Through Out-Licensing to Strategically Focused Pharmaceutical Partners.* 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") opioid analgesic products utilizing Aversion® Technology including Acurox™ Tablets. We believe opportunities exist to enter into similar agreements with other commercial partners for these same opioid products outside the King Territory and in the United States and worldwide for developing additional Aversion® Technology product candidates for other abuseable drugs including tranquilizers, stimulants and sedatives. By partnering with strategically focused companies with expertise and infrastructure in commercialization of pharmaceuticals, we are able to leverage our expertise, intellectual property rights and Aversion® Technology 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® Technology.

*- Expand the Aversion® Technology Intellectual Property Portfolio.* We believe our patent granted by the United States Patent and Trademark Office ("USPTO") in April 2007 for Aversion® Technology provides protection in the U.S. against potential generic product competition through the year 2023 and is a key element for the appeal of our product candidates to King for opioid product candidates and other potential commercial partners for non-opioid product candidates. We have filed additional patent applications with the USPTO which, if issued, will compliment and broaden the scope of our granted patent claims. In addition, we have filed corresponding Aversion® Technology patent applications internationally. All of the Aversion® Technology intellectual property, including all pending and issued patents was developed internally by the Company and as of the date of this Report we believe no enabling licenses from others will be required.

*-Remain focused on Research, Development and Achieving Proof of Concept for Product Candidates Incorporating the Aversion® Technology while Minimizing Internal Fixed Costs through Outsourcing High Fixed Cost Elements of the Development Process.* We maintain a streamlined corporate infrastructure focused on:

- selection, formulation development, laboratory evaluation, manufacture, quality assurance and stability testing of certain finished dosage form product candidates;

- development and prosecution of our patent applications; and

- negotiation and execution of license and development agreements with strategically focused pharmaceutical partners. While we expect to expand our internal staff to enable us to more rapidly develop multiple product candidates, as of the date of this Report we have only 14 employees, 9 of whom are engaged in the research, development and manufacture of product candidates utilizing the Aversion® Technology. We contract with 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 development services for Acurox™ Tablets and other Aversion® product candidates under our direction. By outsourcing the high fixed cost elements of our product development process, we believe that we substantially reduce fixed overhead and capital investment and thereby reduce our business risk.

## **Aversion® Technology Overview**

Aversion® Technology is a patented platform for developing pharmaceutical products containing potentially abuseable drugs including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, tramadol, propoxyphene, and many other opioid analgesics. We believe this platform technology is also applicable to non-opioid products that are subject to abuse and which fall into two broad categories, central nervous system ("CNS") depressants (including tranquilizers and sedatives) and stimulants. Aversion® Technology is applicable to orally



administered tablets and capsules. In addition to the active ingredient, Aversion® Technology utilizes certain proprietary combinations of inactive excipients and active ingredients intended to discourage the most common methods of pharmaceutical product misuse and abuse including; (i) intravenous injection of dissolved tablets or capsules, (ii) nasal snorting of crushed tablets or capsules and (iii) intentional swallowing of excess quantities of tablets or capsules.

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

Prospective drug abusers or recreational drug users may attempt to dissolve currently marketed opioid-containing tablets in water, alcohol, or other common solvents, filter the dissolved solution, and then inject the resulting fluid intravenously to obtain euphoric effects. In addition to its two active ingredients, Acurox™ Tablets also contains a unique combination of inactive ingredients. These "functional" inactive ingredients are commonly used pharmaceutical excipients which elicit no therapeutic effect but which have specific non-therapeutic functions. If a person attempts to extract oxycodone from Acurox™ Tablets using any generally available solvent, including water or alcohol, into a volume and form suitable for intravenous ("I.V.") injection, the tablet converts into a viscous gel mixture and effectively traps the oxycodone HCl in the gel. Based on controlled in-vitro experiments, we believe it is not possible, without extraordinary difficulty, to draw this viscous gel through a needle into a syringe for I.V. injection. We believe that this gel forming feature will substantially discourage prospective I.V. drug abusers or recreational drug users from extracting oxycodone from an Acurox™ Tablet. As described below under the caption "Pivotal Oxycodone Extraction Study", we have compared the relative difficulty of extracting oxycodone from Acurox™ Tablets to several currently marketed oxycodone-containing products.

### **Intended to Deter Nasal Snorting**

In addition to potential intravenous or oral abuse, prospective drug abusers may easily crush or grind currently marketed oxycodone-containing tablet or capsule products. The crushed powder may then be nasally snorted and the oxycodone in the powder is absorbed through the lining of the nasal passages often resulting in a rapid onset of euphoric effects. Acurox™ Tablets have three mechanisms intended to discourage nasal snorting;

- Mild burning and irritation*—if the tablets are crushed and the prospective drug abuser attempts to snort the crushed tablets a mild burning and irritation of the nasal passages is expected to occur
- Viscous gel traps active ingredient*—when Acurox™ Tablets are crushed and snorted, we expect the moisture in the nasal passages will form a viscous gel with the crushed tablet powder thereby trapping the oxycodone in the gel and reducing the amount of oxycodone available for absorption through the lining of the nasal passages
- Gelatinous mass*— we believe that the viscous gel formed in the nasal passages will result in a sticky mass producing an unpleasant sensation in the nasal passages of the prospective abuser

Therefore, we expect potential nasal abusers of Acurox™ Tablets to experience mild burning and irritation of the nasal passages, a lower level of oxycodone available for nasal absorption and a physically unpleasant gelatinous mass to form in the nasal passages. We have evaluated the potential for reducing nasal absorption using a standard in-vitro experimental process. As discussed in the section below regarding Acurox™ Tablets, we intend to further evaluate Acurox™ Tablets nasal abuse characteristics in laboratory and Phase I clinical studies.

### **Intended to Deter Swallowing Excess Quantities of Tablets**

We have included a sub-therapeutic amount of niacin in each tablet of Acurox™ Tablets. We believe that should a person swallow excess quantities of Acurox™ Tablets they will experience an unpleasant combination of symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort. It is expected that these dysphoric symptoms will begin approximately 10-15 minutes after the excess dose is swallowed and self-resolve approximately 75-90 minutes later. We believe that healthcare providers, (including physicians, nurses, and pharmacists) generally understand and recognize that niacin, when administered orally in immediate release tablets in amounts exceeding by several fold the amount in each Acurox™ Tablet, may cause a combination of unpleasant symptoms. In addition, it is generally recognized that niacin has a well established safety profile in long term administration at doses far exceeding the amounts in each Acurox™ Tablet. When Acurox™ Tablets are administered at the anticipated recommended maximum dose of 2 tablets every 6 hours it is intended that legitimate pain patients will receive effective analgesic effects and not be aware of the potential dysphoric effects of niacin. Acurox™ Tablets

are not intended for patients requiring opioid dose escalation due to the possibility of niacin induced flushing as the dose is increased.

We do not expect that the undesirable niacin effects will be “fool-proof” in discouraging swallowing excess quantities of Acurox™ Tablets. However, we anticipate that inclusion of niacin in Acurox™ Tablets and in other Aversion® Technology product candidates will deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of Acurox™ Tablets. We anticipate that most potential drug abusers or recreational drug users will seek alternative opioid analgesic products that are generally much easier to abuse than Acurox™ Tablets and do not have the potential to cause these undesirable niacin effects. As described below under the caption “Status and Expectations For Acurox™ Tablets Clinical Development Program,” we have evaluated the effects of niacin in a number of Phase I and Phase II clinical studies in subjects with and without a history of opioid abuse.

### **U.S. Market for Opioid Analgesic Products Incorporating Aversion® Technology**

Primary market research conducted by us indicates that U.S. based physicians perceive that nearly one out of six prescriptions for oxycodone and hydrocodone containing opioid analgesics may be abused. Such market research also revealed that nearly all physicians questioned reported being the victim of opioid prescription forgeries in the previous year. Physicians believe that drug abusers seeking prescriptions for opioid containing products present a legal and professional risk to their practices. In addition, the results of a survey of over 1,500 adults conducted by the market research firm of Schulman, Ronca and Bucuvalas, Inc. and published in 2006, revealed that 37% of those surveyed know someone personally who has abused opioid painkillers. Of those reporting knowing someone who has abused opioid painkillers, 10% percent indicated that they personally had abused these products. Nearly 20% percent of the abusers were identified as coworkers, with the balance identified as family members or acquaintances. We believe that healthcare providers are generally unable to determine which, if any, of their prescriptions for opioid analgesics will ultimately be abused by their patients or diverted for abuse by others. The uncertainty about which, if any, prescriptions for opioid analgesic products will be abused or diverted implies that certain segments of the U.S. market represent a major opportunity for products incorporating our Aversion® Technology. The table below lists several commonly prescribed opioid analgesics in the U.S that are subject to potential misuse or abuse.

#### **Opioid Active Ingredients (Generic Names)**

Oxycodone  
Hydrocodone  
Morphine  
Hydromorphone  
Codeine  
Tramadol  
Propoxyphene

#### **Frequently Prescribed Opioid Analgesics (Common Brand Names)**

Percocet®, OxyContin®, Roxicet®, Tylox®, Endocet®  
Vicodin®, Lortab®, Lorcet®  
Avinza®, Kadian®, MSContin®  
Dilaudid®  
Tylenol® with Codeine  
Ultram®, Ultram® ER, Ultracet®  
Darvon®, Darvocet®

Based on market research data purchased by us from IMS Health, for the 12 months ended September 30, 2007, approximately 235 million total prescriptions (brands and generics combined) were dispensed in the U.S. for immediate release and extended release tablet and capsule forms of the opioid analgesics listed above. Of these total dispensed prescriptions, approximately 14 million were for extended release products (usually administered every 8 to 24 hours) and 221 million were for immediate release products (usually administered every 4 to 6 hours). Extended release products are more commonly prescribed for relief of chronic pain for durations ranging from several weeks to several months or longer. Immediate release products are more commonly prescribed for relief of acute pain for durations of generally less than 30 days. According to data published in The National Survey on Drug Use and Health Report, Issue 22, 2006, immediate release opioid containing pain relievers are used non-medically approximately ten-fold more often than extended release products.

Recreational drug users, drug abusers and/or drug addicts typically obtain the opioid analgesics products (listed above) in tablet or capsule dosage forms and then crush, shear, grind, chew, dissolve and/or heat, extract or otherwise manipulate the product so that a significant amount, or even the entire amount, of the abuseable drug becomes

available for rapid absorption by injection, and/or snorting, and/or oral swallowing excess quantities of tablets or capsules to achieve a "high". Abuse of pharmaceutical products is a large and growing issue in American society and there is an urgent need for a new technology to discourage and deter misuse and abuse of opioid analgesic tablets and capsules.

**U.S. Market for Non-Opioid Products Incorporating Aversion® Technology**

Aversion® Technology is a platform technology which we believe is also applicable to non-opioid products that are subject to abuse and that are administered in tablet or capsule form. Non-opioid abuseable drugs fall into two broad categories, central nervous system ("CNS") depressants (including tranquilizers and sedatives) and stimulants. According to data published in The National Survey on Drug Use and Health Report, Issue 22, 2006, the estimated number of people in the U.S. aged 12 and over who have abused drugs in these categories is as follows:

<b>Category</b>	<b>During Lifetime (millions)</b>	<b>During Past Year (millions)</b>	<b>Frequently Prescribed (Common Brand Names)</b>
CNS Depressants	30.1	6.0	Valium®, Xanax®, Halcion®, Klonopin®, Ativan®, Nembutal®
Stimulants	20.1	3.4	Dexadrine®, Adderall®, Ritalin®, Concerta®

To date we have devoted limited resources to the development of non-opioid product candidates and can not provide any assurance that future efforts, if any, to develop non-opioid products incorporating the Aversion® Technology will be successful or will result in viable commercial products.

**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 including Acurox™ Tablets. The Agreement provides King with an exclusive license in the King Territory for Acurox™ Tablets and another undisclosed opioid product candidate 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 Acura's Aversion® Technology.

Under the terms of the King Agreement, King made an upfront cash payment to us of \$30 million which was received in December, 2007. Depending on the achievement of certain development and regulatory milestones, King could also make additional cash payments to us of up to \$28 million relating to Acurox™ Tablets and similar amounts with respect to each subsequent Aversion® Technology product developed under the Agreement. King will reimburse us for all research and development expenses incurred beginning from September 19, 2007 for Acurox™ Tablets and all research and development expenses related to future products after King's exercise of its option to an exclusive license for each future product. King will record net sales of all products and for sales occurring following the one year anniversary of the first commercial sale of a licensed product, 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 subject to the Agreement. King will also make a one-time cash payment to us of \$50 million in the first year in which the combined annual net sales of all products exceed \$750 million.

We and King have formed a joint steering committee to coordinate development and commercialization strategies. With King's oversight, we will conduct all Acurox™ Tablet development activities through approval of a 505(b)(2) New Drug Application ("NDA") and thereafter King will commercialize Acurox™ Tablets in the U.S. With respect to all other products subject to the Agreement, King will be responsible for development and regulatory activities following either acceptance of an Investigational New Drug Application ("IND") by the U.S. Food and Drug Administration ("FDA") or our demonstration of certain stability and pharmacokinetic characteristics for each future product. 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.

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## Intellectual Property

In April 2007, the United States Patent and Trademark Office (the “USPTO”) issued to us U.S. Patent No. 7,201,920 titled “Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms”. The 54 allowed patent claims encompass pharmaceutical compositions intended to reduce or discourage the most common methods of prescription opioid analgesic product misuse and abuse. The opioid analgesics in the issued patent claims include oxycodone, hydrocodone, hydromorphone, morphine, codeine, tramadol, propoxyphene and many others.

In addition to issued U.S. Patent No. 7,201,920, as of February 1, 2008, we have pending five U.S. non-provisional pending patent applications, three WO/PCT pending patent applications and multiple additional U.S. provisional and international patent filings relating to compositions containing abuseable drugs.

As of February 1, 2008, except for those rights conferred in the King Agreement, we have retained all of the intellectual property rights to our Aversion® Technology and related product candidates.

## Acurox™ Tablets Development Status and Clinical Trials

Acurox™ Tablets, our lead product candidate with Aversion® Technology, is an orally administered immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient, a sub therapeutic amount of niacin, and a unique composition of functional inactive ingredients. Acurox™ Tablets will have an anticipated indication for treating acute moderate to moderately severe pain and will also have anticipated features to discourage or deter the most common methods of misuse and abuse including (i) intravenous injection of dissolved tablets, (ii) nasal snorting of crushed tablets and (iii) intentional swallowing of excess quantities of tablets. Acurox™ Tablets are being developed pursuant to an active investigational new drug application (“IND”) on file with the FDA. We and King intend to file a 505(b)(2) NDA for Acurox™ Tablets. The FDA has confirmed in writing to us that the proposed NDA would qualify for a Section 505(b)(2) submission.

In September, 2007 we began enrolling patients in clinical Study AP-ADF-105, our pivotal phase III efficacy and safety study being conducted pursuant to a Special Protocol Assessment agreed with the FDA (see description of this study below under the caption “Study AP-ADF-105”). We expect to submit our 505(b)(2) NDA for Acurox™ Tablets to the FDA in the second half of 2008. At the time of NDA submission we intend to request a priority review of the application by the FDA. The FDA has publicly indicated a willingness to consider such action for product candidates incorporating abuse deterrence features. No assurance however can be provided that the FDA will grant a priority review of our 505(b)(2) NDA submission.

## Acurox™ Tablets: Technical and Pre-Clinical Development Program and Regulatory Affairs Strategy

The technical and pre-clinical development program and regulatory strategy and status for Acurox™ Tablets are summarized below. At this stage, we can not provide any assurance that FDA will not require additional pre-clinical studies not listed below, or revise the Acurox™ Tablets regulatory requirements prior to their acceptance for filing of a 505(b)(2) NDA submission for Acurox™ Tablets.

### Technical and Pre-Clinical Development

Formulation development  
 Pilot bioequivalence study  
 Pivotal oxycodone laboratory extraction study  
 Tablet stability for NDA submission  
  
 Toxicology studies

### Status and Expectations

Complete  
 Complete  
 Complete (results summarized in this Report)  
 Testing in process. 24 month real time data demonstrates stability acceptable for NDA submission  
 Not required per FDA written guidance to us





**Regulatory Affairs**

Investigational New Drug Application (IND)  
 End of Phase II meeting with FDA  
 Factorial design clinical studies  
 Phase III pivotal clinical trial  
 Type of regulatory submission for U.S. regulatory approval and commercial distribution in the U.S.  
 505(b)(2) NDA submission

**Status and Expectations**

Active  
 Complete  
 Not required per FDA written guidance to us  
 A single phase III efficacy and safety trial is required per FDA written guidance to us.  
 Acurox™ Tablets are eligible for submission as a 505(b)(2) NDA per FDA written guidance to us  
 Anticipate submission H2-08

**Pivotal Oxycodone Extraction Study:**

We, in concert with a leading pharmaceutical laboratory CRO (the “Laboratory CRO”), completed a pivotal study to assess certain properties of Acurox™ Tablets using tablets from batches manufactured by us at our Culver Facility at a scale of sufficient size to fulfill the FDA’s requirements for a 505(b)(2) NDA submission. The Laboratory CRO was contracted to quantitatively and qualitatively measure the relative difficulty of extracting oxycodone HCl for purposes of I.V. injection from tablet products containing oxycodone HCl. The Laboratory CRO was provided with a list of all ingredients (active and inactive) contained in each product, allotted up to 80 hours total time to complete the evaluations and allowed to use any methodology desired to attempt to extract oxycodone HCl from the tablets in a form suitable for I.V. injection. Products tested were Acurox™ (oxycodone HCl/niacin) Tablets, OxyContin® (oxycodone HCl) Controlled-Release Tablets, generic oxycodone HCl Tablets, and Percocet® (oxycodone HCl/acetaminophen) Tablets. As set forth in the table below, results were reported as (i) percent of drug extracted, (ii) time to extract drug and (iii) difficulty to extract drug on a scale of 1-10, 1 being easy and 10 being extremely difficult. OxyContin® Tablets and generic oxycodone HCl tablets resulted in 71-92% drug extracted in 3-6 minutes and were rated 1-2 in relative difficulty. Percocet® Tablets resulted in 75% oxycodone HCl extracted in 10 minutes (with vacuum assisted filtration) and was rated 3-4 in relative difficulty. Acurox™ Tablets resulted in a “trace” of oxycodone HCl extracted in 355 minutes and was rated 10 in relative difficulty. We intend to utilize the data and results from this pivotal laboratory study in our 505(b)(2) NDA submission to the FDA for Acurox™ Tablets.

**Summary Results of Acurox™ Tablets Pivotal Laboratory  
 Oxycodone Extraction Study (described above)**

Product Tested, Oxycodone HCl Strength and Product Supplier	Approximate laboratory time required to produce a form suitable for intravenous injection	Extraction Scheme and Yield	Difficulty Rating 1 = Easy to 10 = Difficult
OxyContin® Tablets 1x 40mg tablet Purdue Pharma	3 minutes	3 steps ~92% Yield	1
Oxycodone HCl Tablets 8 x 5mg tablets, Mallinckrodt	6 minutes	3 Steps ~71% Yield	2
Percocet Tablets 8 x 5/325mg tablets Endo Labs	<10 minutes with vacuum assisted filtration	3 Steps ~75% Yield	3-4
Acurox Tablets 8 x 5/30mg tablets Acura Pharmaceuticals	355 minutes with no success	23 Steps ~0% Yield	10

**Status and Expectations for Acurox™ Tablets Clinical Development Program**

The clinical development program for Acurox™ Tablets is summarized below. At this stage, we cannot provide any assurance that FDA will not require additional clinical studies prior to their acceptance for filing of a 505(b)(2) NDA submission for Acurox™ Tablets.

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**Clinical Studies to Evaluate Pharmacokinetics in Normal Subjects**

AP-ADF-104	Phase I: Bioequivalence to non Aversion® Technology Reference Listed Drug
AP-ADF-108	Phase I: Single dose linearity and food effect
AP-ADF-109	Phase I: Multi-dose linearity
AP-ADF-110	Phase I: Required only if there is not dose linearity in Study AP-ADF-108 and Study AP-ADF-109

**Status and Expectations**

Final study report complete. Acurox™ Tablets are bioequivalent to the Reference Listed Drug. Summary report complete. Acurox Tablets demonstrate single dose linearity. Absorption is delayed by food. Expect subject enrollment Q1-08. As of the date of this Report, we do not anticipate this study will be required.

**Studies AP-ADF-108, AP-ADF-109, and if necessary AP-ADF-110:** These are Phase I single dose or multi-dose pharmacokinetic studies anticipated to enroll approximately 25-50 normal subjects per study. Study AP-ADF-108 was conducted in the fourth quarter of 2007 with the final study report expected in the first quarter of 2008. AP-ADF-109 is being conducted in the first quarter of 2008 with the final study report expected in the second quarter of 2008. Based on Study AP-ADF-108 summary clinical results, we currently do not believe that Study AP-ADF-110 will be necessary.

**Clinical Studies to Evaluate Niacin Dose Response in Normal Subjects**

AP-ADF-101	Phase I: Niacin dose-response (0-75mg)
AP-ADF-103	Phase II: Repeat dose safety and tolerability
AP-ADF-107	Phase II: Niacin dose-response (0-600mg)

**Status and Expectations**

Final study report complete. Final study report complete. Refer to summary in this Report. Final study report complete. Refer to summary in this Report.

**Study AP-ADF-103:** This study is titled, "A Phase II Single-Center, Randomized, Double-Blind, Multiple-Dose Study in Healthy Volunteers to Evaluate the Safety and Tolerability of Niacin in Combination with 5 mg of an Opioid vs. 5 mg of an Opioid Alone." To assess the safety and tolerability of Acurox™ (oxycodone/niacin) Tablets in comparison to oxycodone HCl tablets without niacin, we conducted this Phase II single-center, randomized, double-blind, multiple dose study in 66 healthy adult male and female volunteers. Subjects were randomly assigned to one of three treatment groups (22 subjects per treatment group). A run-in phase was conducted on an outpatient basis for five days and included at-home dosing four times daily and adverse event and tolerability assessments. The treatment phase followed the run-in phase and was conducted on an inpatient basis for five days. The treatment phase included dosing with Acurox™ Tablets (with or without niacin) and post-treatment safety and tolerability assessments. Efficacy (the tolerability of Acurox™) was evaluated with a Side Effects and Symptoms Questionnaire (SESQ) and an Acurox™ Tolerability Rating Scale. Safety was evaluated by adverse events and clinical laboratory and vital signs assessments were conducted periodically during the study. During the run-in phase, comparable tolerability was demonstrated in subjects who took Acurox™ Tablets with and without niacin. The mean post-dose SESQ total score during the run-in phase was very low in all groups (highest possible score = 33; Group results = 0.84 - 1.6) indicating that Acurox™ was generally well-tolerated when taken at recommended doses. During the treatment phase, 64% of subjects in Groups 2 and 3 (oxycodone HCl + niacin) reported side effects and symptoms and 50% of subjects in Group 1 (oxycodone alone) reported side effects and symptoms. Most of the side effects and symptoms observed during the treatment phase were mild or moderate in severity. Irrespective of treatment group, approximately three quarters of subjects reported either "no effect" or "easy to tolerate" on the Acurox™ Tolerability Rating Scale. Oxycodone HCl administered four times a day, with or without niacin, was determined to be well tolerated. Adverse events were reported by 77% of subjects throughout both phases of the study. The majority of subjects (55%) reported adverse events during the treatment phase that were considered mild in severity. No severe adverse events were reported in any treatment group and no clinically important trends over time were observed in any treatment group for vital signs

measurements (blood pressure, heart rate, and respiratory rate). We intend to include the data and results from Study AP-ADF-103 in our 505(b)(2) NDA submission to the FDA for Acurox™ Tablets.

**Study AP-ADF-107:** This study is titled "A Phase II Single-Center, Randomized, Double-Blind Study in Fasted and Non-Fasted Healthy Volunteers to Evaluate the Dose-Response for Flushing and Safety and Tolerability of Escalating Doses of Niacin." The study objective was to evaluate the dose-response for niacin-induced flushing, safety, and tolerability of niacin in the Acurox™ Tablet matrix (excluding oxycodone HCl) at various dose levels in both fasted and fed subjects. This trial was a Phase II single-center, randomized, double-blind study in healthy, adult male and female subjects. A total of 50 subjects were enrolled. The Treatment Phase was conducted on an inpatient basis and included study drug dosing and safety and tolerability assessments. Each subject received eight doses of niacin (30, 60, 90, 120, 240, 360, 480, and 600 mg) and three doses of placebo administered orally in tablet form on eleven separate days in a random sequence. Half of the subjects (n=25) took each dose of study drug following a FDA standardized high-fat breakfast and half (n=25) remained fasted for at least 2 hours after study drug administration. Subjects were discharged from the Clinical Research Unit on Day 11, approximately 6 hours after the last dose of study drug administration.

Tolerability was rated by subjects during the Treatment Phase using a Tolerability Rating Scale (TRS) completed 3 hours after each dose of study drug. Each subject's overall reaction to the study drug was recorded using the following 5-point scale: 0 = No effect; 1 = Easy to tolerate; 2 = Mildly unpleasant, but tolerable; 3 = Unpleasant and difficult to tolerate; 4 = Intolerable and would never take again. The results showed a clear niacin dose-response relationship in both Fasted and Fed subjects as assessed by the 5-point TRS. The response ranged from little or no effect at low niacin doses (30 to 90 mg) to more difficult and unpleasant symptoms at higher doses of niacin (>120 mg). With Fasted subjects, there was minimal or no effect of niacin at doses of 30 to 60 mg, with 96% of subjects reporting either "no effect" or "easy to tolerate". Niacin was also well tolerated at doses of 90 mg, with 86% of Fasted subjects reporting either "no effect" or "easy to tolerate" and 14% reporting "mildly unpleasant, but tolerable". The absence of any notable effects at low doses suggests that niacin will be well tolerated up to 60 mg per dose and will likely be well tolerated at 90 mg per dose. As niacin doses escalated from 120 to 360 mg, a transition occurred resulting in a larger proportion of Fasted subjects (22% to 73%) reporting mildly unpleasant, unpleasant, or intolerable effects. At doses of 480 and 600 mg, most Fasted subjects (386%) reported mildly unpleasant, unpleasant, or intolerable effects. At least 40% of subjects dosed at 480 and 600 mg reported either "unpleasant and difficult to tolerate" or "intolerable and would never take again". The higher doses of niacin clearly produced undesirable side effects. As anticipated, niacin effects were mitigated by food. All Fed subjects (100%) receiving 30 to 240 mg niacin reported "no effect" or "easy to tolerate". Niacin was also generally well tolerated at doses of 360 to 600 mg with most Fed subjects (368%) reporting "no effect" or "easy to tolerate".

In this study there were no significant adverse events or discontinuations due to treatment-emergent adverse events (TEAEs). None of the TEAEs reported were severe in intensity. A clear niacin dose-response relationship was observed in the incidence of AEs. As expected, the most frequently reported TEAE in both Fasted and Fed subjects was flushing. Flushing occurred more frequently in Fasted subjects than in Fed subjects with higher incidence as the niacin dose increased. The majority of Fasted subjects (54% to 88%) reported flushing at doses of 240 to 600 mg; while the majority of Fed subjects (64%) reported flushing only at a dose of 600 mg. Most of the events of flushing were moderate in intensity. No other safety issues were apparent. We intend to include the data and results from Study AP-ADF-107 in our 505(b)(2) NDA submission to the FDA for Acurox™ Tablets.

#### **Clinical Studies to Evaluate Tolerability of Nasal Snorting and Excess Oral Doses in Subjects with a History of Opioid Abuse**

		<b>Status and Expectations</b>
AP-ADF-106	Phase I: Evaluate effects of nasal snorting in subjects with a history of snorting and nasal drug abuse	Expect subject enrollment Q2-08
AP-ADF-102	Phase II: Evaluate relative dislike of oxycodone HCl/niacin versus oxycodone HCl alone	Final study report complete Refer to summary in this Report
AP-ADF-111		

Phase II: Evaluate abuse liability of oxycodone HCl/niacin versus oxycodone HCl alone	Expect subject enrollment Q1 and Q2-08
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**Study AP-ADF-106:** This will be a Phase I clinical study, for use in product labeling, evaluating the characteristics of crushed Acurox™ Tablets when snorted by 12-18 subjects with a history of opioid abuse. We expect to initiate subject enrollment in this study in Q2-08.

**Study AP-ADF-102:** This study is titled, "A Phase II Single-Center, Randomized, Double-Blind Study in Subjects with a History of Opioid Abuse to Evaluate the Dose-Response for Flushing and Safety and Tolerability of Varying Doses of Niacin in Combination with 40mg of an Opioid vs. 40mg of an Opioid Alone." The study objectives were 1) to determine the dose response for niacin-induced flushing in male and female healthy, adult volunteers with a history of opioid abuse when niacin is administered in combination with 40 mg oxycodone HCl; 2) to evaluate the safety and tolerability of niacin-induced flushing following varying niacin doses in combination with 40 mg oxycodone HCl in subjects with a history of opioid abuse; 3) to confirm the appropriate strength of niacin to use in an Aversion® Technology formulation of oxycodone HCl; 4) to determine whether the flushing induced by niacin is of sufficient intensity to deter abuse in a population of subjects with a history of opioid abuse; and 5) to evaluate the effect of food on niacin-induced flushing when niacin is administered in combination with 40 mg oxycodone HCl.

This study was a single-center, double-blind, randomized, placebo-controlled, five-period crossover study conducted on an inpatient basis with 5 cohorts of 5 subjects each. Twenty-five subjects (three female and twenty-two male) were admitted for the study. One male subject completed the first drug condition but thereafter withdrew from the study stating personal reasons unrelated to the study. Twenty-four subjects received a single dose of study drug every 48 hours for 9 days. 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 on Days 1, 3, 5, and 7. On Day 9, a dose of 600 mg niacin in combination with 40 mg oxycodone HCl was administered following a standardized high-fat breakfast. Each dosing day, vital sign measures and subjective and behavioral effects were assessed before dosing and at 0.5, 1, 1.5, 2, 3, 4, 5, 6, and 12 hours after dosing. Vital signs included systolic and diastolic blood pressure, heart rate, oral temperature and respiratory rate. Subjective changes were measured by subject response to a Drug Rating Questionnaire (DRQS). As an additional measure of subjective effects, subjects completed a 40 item short form of an Addiction Research Center Inventory (ARCI) that yielded three sub-scale scores – a euphoria scale, a dysphoria scale and a sedation scale. After completion of the study, subjects responded to a Treatment Enjoyment Assessment Questionnaire to select which of the treatments they would take again. Prior to initiating the study, the hypothesis was that the addition of niacin to oxycodone would produce effects that are disliked by subjects with a history of opioid abuse. 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. Statistical analysis (maximum dislike response in comparison to 0 mg niacin) was conducted for DRQS, ARCI scales and vital signs. Study results were as follows:

- (1) In the fasting state, all three doses of niacin [240mg, 480mg and 600mg] in combination with oxycodone 40mg produced significant ( $p \leq .05$ ) disliking scores compared to oxycodone 40mg alone. The linear regression across niacin dose was not significant. No other subjective measure was significantly affected by the niacin addition to oxycodone.
- (2) The high fat meal eliminated the niacin effect on oxycodone 40 mg. The high fat meal also delayed the time to oxycodone peak blood levels.
- (3) The addition of niacin to oxycodone alters the subjective response to oxycodone as indicated by the significant responses on the disliking scale. 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.
- (4) 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. 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 this pharmacodynamic study (Study AP-ADF-102) support the hypothesis that the addition of niacin to oxycodone in a minimal ratio of 30 mg niacin to 5 mg oxycodone is aversive when compared to oxycodone alone. The addition of niacin does not alter the safety profile of oxycodone alone. We intend to include the data and results from Study AP-ADF-102 in our 505(b)(2) NDA submission for Acurox<sup>TM</sup> Tablets to the FDA.

**Study AP-ADF-111:** This will be a Phase II, single-center, randomized, double-blind assessment of the abuse liability of Acurox™ (oxycodone HCl/niacin) Tablets versus oxycodone HCl alone in approximately 30 subjects with a history of opioid abuse. This clinical study has not been requested by FDA but is being conducted by us with the intent of providing additional clinical data in support of certain targeted Acurox™ Tablet product label claims. We expect to conduct this study in the second quarter of 2008 with the final study report expected in the second half of 2008.

**Clinical Study to Evaluate Efficacy and Safety in Patients with Acute Moderate to Severe Pain**

**Status and Expectations**

AP-ADF-105

Phase III: Pivotal efficacy and safety

Special Protocol Assessment (SPA) agreed by FDA. Patient enrollment in progress. Anticipate final clinical study report in H2-08

**Study AP-ADF-105:** This study is titled “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.” This short term Phase III study is planned to enroll approximately 400 patients with moderate to severe pain following bunionectomy surgery. The primary endpoint is a reduction in the sum of the pain intensity difference for 48 hours (SPID 48) for active drugs versus placebo. We submitted the study protocol to the FDA and requested and received agreement for a Special Protocol Assessment ("SPA"). Clinical protocols for Phase III trials whose data will form the primary basis for an efficacy claim are eligible for a SPA. A SPA from the FDA is an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses plan are acceptable to support regulatory approval and is binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing is begun. On June 19, 2007, we announced that we had reached agreement with the FDA on the SPA for Study AP-ADF-105. We began enrolling patients in September 2007 with top line results anticipated in the third quarter of 2008. We expect to submit a 505(b)(2) NDA for Acurox™ Tablets prior to the end of 2008.

**Expectations for Acurox™ Tablets Product Labeling**

In the U.S., every product approved for commercialization pursuant to an NDA must be marketed in accordance with its FDA approved indications and associated product labeling. The FDA has provided written guidance to us stating that an indication for abuse deterrence must be supported by data from two adequate and well-controlled clinical trials. We do not intend to seek an indication for abuse deterrence for Acurox™ Tablets. Instead, we are seeking an indication for Acurox™ Tablets for treatment of moderate to moderately severe pain. The FDA has also provided written guidance to us stating that language regarding abuse deterrence (as opposed to an indication for abuse deterrence), which is supported by rigorous, scientific data, may be placed into appropriate sections of the Acurox™ Tablet product label. In this regard, we intend to seek FDA approval of language in the Acurox™ Tablet product label describing the physical characteristics of the product and likely results if attempts are made to dissolve tablets in solvents suitable for intravenous injection, and/or snort crushed tablets, and/or swallow excess quantities of tablets. We believe this product labeling strategy will provide a viable promotional platform for the commercialization of Acurox™ Tablets and other product candidates utilizing Aversion® Technology. At this stage there can be no assurances that our product labeling strategy for Acurox™ Tablets will be successful or that FDA approved product labeling, if any, will provide a viable commercialization platform.

**Competition**

We compete to varying degrees with numerous companies in the pharmaceutical research, development, manufacturing and commercialization fields. Most 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 improving the likelihood of obtaining regulatory approval of a commercially viable product or technology than its smaller rivals.

We believe competitors may be developing opioid abuse deterrent technologies and products. Such competitors include, but may not be limited to, Alpharma Inc. of Fort Lee, NJ, Elite Pharmaceuticals, Inc. of Northvale, NJ, Pain Therapeutics of South San Francisco, CA, (in collaboration with King Pharmaceuticals of Bristol, TN), Purdue Pharma of Stamford, CT, Endo Pharmaceuticals of Chadds Ford, PA, Neuromed Pharmaceuticals, of Vancouver, BC and Collegium Pharmaceuticals, Inc., of Cumberland, RI. These companies appear to have focused their development efforts on extended release opioid products (commonly prescribed for relief of chronic pain for durations ranging from several weeks to several months or longer) while our lead product candidate, Acurox™ Tablets, and other Aversion® Technology product candidates under development, are immediate release products (more commonly prescribed for relief of acute pain for durations of generally less than 30 days). We estimate the U.S. market for opioid analgesics, assuming brand pricing for all products, would be approximately \$14 Billion and can be segmented by immediate release versus extended release products as follows:

	<b>Immediate Release Products</b>	<b>Extended Release Products</b>
Dispensed Rx's <sup>1</sup>	221 Million	14 Million
Ratio of Dispensed Rx's <sup>1</sup>		16:1
Ratio of Abuse <sup>2</sup>		10:1
Estimated Ratio of \$ Market Potential <sup>3</sup>		4:1
Identified Competitors	Acura in collaboration with King	<ol style="list-style-type: none"> <li>1. Alpharma</li> <li>2. Pain Therapeutics</li> <li>3. Purdue</li> <li>4. Endo</li> <li>5. Elite</li> <li>6. Neuromed</li> <li>7. Collegium</li> </ol>

<sup>1</sup> IMS America 12 months ending 9/30/07. <sup>2</sup> National Survey on Drug Use and Health Report, Issue 22, 2006

<sup>3</sup> Assuming brand pricing

## Segment Reporting

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

## Government Regulation

All pharmaceutical firms, including us, are subject to extensive regulation by the federal government, principally by the U.S. Food and Drug Administration ("FDA"), and, to a lesser extent, by state and local governments. Additionally, we are subject to extensive regulation by the Drug Enforcement Administration ("DEA") 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.

The Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), the Controlled Substances Act and other federal statutes and regulations govern or influence the testing, manufacture, labeling, storage, record keeping, approval, pricing, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, criminal proceedings, total or partial suspension of production, and refusal of the government to enter into supply contracts or 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. 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 containing drugs, including our Acurox™ Tablets, are regulated, or scheduled, under the Controlled Substances Act. Any of our product candidates containing an opioid analgesic will be subject to such regulation. At this stage, because it contains oxycodone HCl, at launch, 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 by the FDA as safe and effective for its intended use. 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 conform to current Good Manufacturing Practice Regulations ("cGMPs"), which apply to the manufacture, receiving, holding and shipping of all drugs, whether or not approved by the FDA. To ensure full compliance with relevant standards, some of which are set forth in regulations, we must continue to expend time, money and effort in all applicable areas relating to quality assurance. Failure to so comply risks delays in approval of drugs and possible FDA enforcement actions, such as an injunction against shipment of products, the seizure of non-complying products, and/or, in serious cases, criminal prosecution. We are subject to periodic inspection by the FDA and DEA.

### **The FDA Pharmaceutical Product Approval Process**

The process of drug development is complex and lengthy and the activities undertaken before a new pharmaceutical product may be marketed in the U.S. include but are not limited to; preclinical studies, submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials commence, followed by adequate and well-controlled human clinical trials to establish the safety and efficacy of the product, submission to the FDA of a NDA, and FDA approval of the NDA prior to any commercial sale 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 assess the potential safety and efficacy of the product candidate. The results of preclinical studies are then submitted to the FDA as a part of an IND and are reviewed by the FDA prior to the commencement of human clinical trials. Unless the FDA objects to, or otherwise responds to, an IND submission, the IND becomes effective 30 days following its receipt by the FDA. Human clinical trials are typically conducted in three phases that often overlap:

**Phase I:** The 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 conduct a preliminary evaluation of efficacy in Phase I trials for analgesia.

**Phase II:** This phase involves studies in a limited patient or normal subject population to identify possible adverse effects and safety risks, to evaluate the efficacy of the product for specific targeted diseases and to determine optimal dosage and tolerance.

**Phase III:** When Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites.

After clinical trials have been completed, the sponsor must submit to the FDA the results of the preclinical and clinical testing, together with, among other things, detailed information on the manufacture and composition of the product, in a New Drug Application ("NDA"). There are two primary 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 is 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 act as an application for which 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" (21 U.S.C. 355(b)(2)). This provision expressly permits 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 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 has provided written guidance to us stating that Acurox™ Tablets is a suitable product candidate for submission as a 505(b)(2) NDA.

After an NDA is submitted by an applicant and 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 NDA for commercial distribution in the U.S. There can be no assurance that any of our product candidates will receive FDA approval.

Whether or not FDA approval has been obtained, approvals from comparable governmental regulatory authorities in foreign countries must be obtained prior to the commencement of clinical trials and subsequent sales and marketing efforts 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.

## Environmental Compliance

In addition to regulation by the FDA and DEA, we are subject to regulation under federal, state and local environmental laws. We believe we are in material compliance with applicable environmental laws and since 2004 have incurred the normal waste disposal cost associated with small scale pilot plant and laboratory operations.

## 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 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 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.

## Directors, Executive Officers, and Employees

Our directors and executive officers are as follows:

NAME	AGE	POSITION
Andrew D. Reddick	55	President, Chief Executive Officer and Director
Ron J. Spivey	61	Senior Vice President and Chief Scientific Officer
Peter A. Clemens	55	Senior Vice President, Chief Financial Officer and Secretary
James F. Emigh	52	Vice President of Marketing and Administration
Robert A. Seiser	44	Vice President, Corporate Controller and Treasurer
Bruce F. Wesson	65	Director
William A. Sumner	70	Director
Richard J. Markham	57	Director
William G. Skelly	56	Director
Immanuel Thangaraj	37	Director
George K. Ross	66	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.

Ron J. Spivey, Ph.D., has been Senior Vice President and Chief Scientific Officer since April, 2004. From June, 2002 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.

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.

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.

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

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., and Chemtura Corporation, 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. 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 Biomedica, 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 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, Greater New York for World Vision. 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.

As of the date of this Report, the Company had 14 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, business development and product licensing activities. Most of our senior management and our professional employees have had prior experience in pharmaceutical or biotechnology companies. None of our employees is covered by collective bargaining agreements. We believe that our relations with our employees are good.

## ITEM 1A. RISK FACTORS

Our future operating results may vary substantially from anticipated results due to a number of factors, many of which are beyond our control. The following discussion highlights some of these factors and the possible impact of these factors on future results of operations. If any of the following factors actually occur, our business, financial condition or results of operations could be materially harmed. In that case, the value of our common stock could decline substantially.

### *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 \$4.3 million for the year ended December 31, 2007 and net losses of \$6.0 million and \$12.1 million for calendar years 2006, and 2005, respectively. At December 31, 2007, our accumulated deficit was approximately \$321.9 million. Our consolidated financial statements for the calendar years 2006, 2005 and 2004 were prepared on a "going concern" basis. Our future profitability will depend on several factors, including: (i) our receipt of milestone payments and royalties relating to products developed and commercialized under our license agreement with King Pharmaceuticals Research and Development, Inc. ("King") (as more fully described in Item 1, Business - "King Agreement"), and (ii) the successful commercialization by King and other future licensees (if any) of products incorporating our Aversion® Technology 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 revenue of \$6.6 million in the quarter ended December 31, 2007 from payments received under the King Agreement and interest income. However, we have not yet generated any revenues from product sales. Even if we succeed in commercializing one or more of our product candidates, we expect to continue to use cash resources in our operations for the foreseeable future. We anticipate that our expenses may increase in the foreseeable future as a result of continued development of our product candidates, maintaining, defending and expanding the scope of our intellectual property, and the hiring of additional personnel.

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 company partners, 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 company partners, 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 company partners. 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 incorporating our Aversion® Technology may be commercialized.

### **Our Product Candidates Are Based on Technology That Could Ultimately Prove Ineffective**

We are committing a majority of our resources to the development of Acurox™ (oxycodone HCl and niacin) Tablets and other product candidates incorporating our Aversion® Technology. Additional clinical and non-clinical testing will be required to continue development of Acurox™ Tablets and for the development, preparation and submission of a 505(b)(2) New Drug Application (“NDA”) with the FDA. There can be no assurance that Acurox™ Tablets or any other product candidate developed using Aversion® Technology will achieve the primary end points in the required clinical studies or perform as intended in other pre-clinical and clinical studies leading to commercially viable product candidates, product labeling, or leading to a NDA submission. If a NDA is submitted to the FDA for Acurox™ Tablets or any other product candidates, there can be no assurances that the FDA will accept such submission for filing and subsequently approve such NDA with commercially viable product labeling or to ultimately approve such product candidates for commercial distribution. 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.

### **If Pre-Clinical or Clinical 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 market any of our product candidates, we or our licensees must submit to the FDA a NDA demonstrating, among other things, that the product candidate is safe and effective for its intended use. This demonstration requires significant pre-clinical and clinical testing. As we do not possess the resources or employ all the personnel necessary to conduct such testing, we rely on contract research organizations (“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. In addition, many of the factors that may cause, or lead to a delay in the development program, may also ultimately lead to denial of regulatory approval of a product candidate.

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.

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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 ensure 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 may be expensive and 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 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 would 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 many 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 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 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 one to two years to grant final approval for a NDA, or 505(b)(2) 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 products incorporating our Aversion® Technology.

Even if we comply with all 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 saleable 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.

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) 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 constructed and installed the equipment necessary to manufacture clinical trial supplies of our Aversion® 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 current Good Manufacturing Practice (cGMP) regulations as interpreted and enforced by the FDA. 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 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 companies with appropriate facilities and equipment to contract manufacture commercial quantities of products utilizing our Aversion® Technology.

**We Develop and Formulate Our Products, and Manufacture Laboratory and 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 to conduct the development and formulation of our product candidates and the manufacture of laboratory and clinical supplies of our product candidates. If the Culver, Indiana facility were damaged or destroyed, it would be difficult to replace and could require substantial lead-time to repair or replace. If this facility were affected by a disaster, we would be forced to rely on third-party contract research organizations and manufacturers. 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. Any disruptions or delays at our Culver, Indiana facility could impair our ability to develop our product candidates incorporating the Aversion® Technology, 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 Pharmaceuticals Research and Development Inc. (“King”) (as more fully described in Item 1, Business - “King Agreement”). The closing of the King Agreement was completed on December 7, 2007 and on that date we received from King the upfront \$30 million non-refundable cash payment specified in the King Agreement. 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 company partners. 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 incorporating the Aversion® Technology.

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 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 Strategic Alliance 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 incorporating our Aversion® Technology currently requires us to successfully maintain our strategic alliance with King to advance our programs and provide funding to support our expenditures on Acurox™ Tablets and other opioid analgesic product candidates. If we are not able to maintain our existing strategic alliance 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 drug development efforts with respect to Acurox™ Tablets and other opioid analgesic product candidates on our own, we may need to obtain additional capital, 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**

Our ability to commercialize Acurox™ Tablets and other product candidates licensed under the King Agreement and generate royalties from sales of such products will depend on King's abilities in assisting us in developing such products and in obtaining and maintaining regulatory approval and achieving market acceptance of such products once commercialized. King may not proceed with the commercialization of Acurox™ Tablets and other product candidates licensed under the King Agreement with the same degree of urgency as we would because of other priorities they face. If King is not successful in commercializing Acurox™ Tablets for a variety of reasons, including but not limited to, competition from other pharmaceutical companies, or if King fails to perform as we expect, our potential for future revenue from products developed under the King Agreement, if any, could be dramatically reduced and our business and our financial condition would suffer.

#### **The Market May Not Be Receptive to Products Incorporating Our Aversion® Technology**

The commercial success of products incorporating our Aversion® Technology approved for marketing by the FDA and other regulatory authorities 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, even if we or our licensees succeed in the development of products incorporating our Aversion® Technology and receive FDA approval for such products, that products incorporating the Aversion® Technology would be accepted by health care providers and others. Factors that may materially affect market acceptance of products incorporating our Aversion® Technology include but are not limited to:

- the relative advantages and disadvantages of our Aversion® Technology compared to competitive products;

- the relative timing to commercial launch of products utilizing our Aversion® Technology compared to competitive products;
- the relative safety and efficacy of products incorporating our Aversion® Technology compared to competitive products; and
- the willingness of third party payors to reimburse for or otherwise pay for products incorporating our Aversion® Technology.

Our product candidates, if successfully developed and commercially launched, will compete with both currently marketed and new products marketed by other companies. Health care providers may not accept or utilize any of our product candidates. Physicians and other prescribers may not be inclined to prescribe the products utilizing our Aversion® Technology unless our products bring clear and demonstrable advantages over other products currently marketed for the same indications. 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 Side Effects 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**

As part of our and our licensees post-market regulatory responsibilities for our products, we or our licensees are required to report all serious injuries or deaths involving our products. If we, our licensees or others identify side effects after any of our products are on the market:

- 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 introduce 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.

**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 Acceptable Prices or Adequate Reimbursement for Our Products From Third-Party Payors**

The ability of our licensees to successfully commercialize our products may depend in part on the availability of reimbursement for our products from government health administration authorities, private health insurers, and other third-party payors and administrators, including Medicaid and Medicare. We cannot predict the availability of reimbursement for newly-approved products incorporating our Aversion® Technology. Third-party payors and administrators, including state Medicaid programs and Medicare, are challenging the prices charged for pharmaceutical products. Government and other third-party payors 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. The continuing efforts of government and third-party payors to contain or reduce the costs of health care

may limit our commercial opportunity. If government and other third-party payors do not provide adequate coverage and reimbursement for any product incorporating 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 Averse Effect on Our Business, Financial Condition or Results of Operations.**

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislatures, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power. As the healthcare industry consolidates, competition to provide products to industry participants has become and will continue to 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, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations, which may reduce competition, exert further downward pressure on the prices of our product candidates and 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 substantially on our ability to obtain and maintain patent protection for our Aversion® Technology, 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 from the USPTO relating to the Aversion® Technology, there is no assurance that any of our patent claims in our other pending non-provisional and provisional patent applications for our Aversion® Technology 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 the Aversion® Technology may not be sufficiently broad to protect the products incorporating the Aversion® Technology. In addition, issued patent claims may be challenged, invalidated or 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 competitors or others. We may become aware of patents and patent applications belonging to competitors and others that could require us to alter our technologies. Such alterations 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 products incorporating our Aversion® Technology. Even if we can obtain a license, the financial and other terms may be disadvantageous.

Our success also depends on our 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, potential investors and consultants. 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® Technology 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 to seek to invalidate the patents held by such third parties or to obtain a judgment that our product candidates do not infringe such third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention; and
- if third parties initiate litigation claiming that our product candidates infringe their patent or other intellectual property rights, we will need to defend against such proceedings.

Our failure to avoid infringing third-party patents and intellectual property rights in the commercialization of products utilizing the Aversion® Technology will have a material adverse affect on our operations and financial condition.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Most of our 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 Aversion® Technology may be found to infringe upon claims of patents owned by others. If we determine or if we are found to be infringing on a patent held by another, 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 our use of our Aversion® 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 Aversion® Technology and the testing, manufacturing, marketing or sale of one or more of our products could be restricted or prohibited.

Moreover, other parties could have blocking patent rights to products made using the Aversion® Technology. We are aware of certain United States and international pending patent applications owned by third parties claiming abuse deterrent technologies, including at least one pending patent application which, if issued in its present form, may encompass our lead product candidate. If such patent applications result in issued patents, with claims encompassing our Aversion® Technology or products, we or our licensees may need to obtain a license to such patents, should one be available, or alternatively, alter the Aversion® Technology so as to avoid infringing such third-party patents. If we or our licensees are unable to obtain a license on commercially reasonable terms, we or our licensees could be restricted or prevented from commercializing products utilizing the Aversion® Technology. Additionally, any alterations to the Aversion® Technology in view of pending third-party patent applications could be time consuming and costly and may not result in technologies or products that are non-infringing or commercially viable. We cannot assure that our products and/or actions in developing products incorporating our Aversion® Technology will not infringe third-party patents.



### **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, health care providers or pharmaceutical companies 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 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 drugs 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 will not achieve significant product revenues and our financial condition and results of operations will be materially adversely affected.

We 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 drugs than we do.

We are concentrating substantially all of our efforts on developing product candidates incorporating our Aversion® Technology. The commercial success of products using our Aversion® Technology will depend, in large part, on the intensity of competition and the relative timing and sequence of new product approvals from other companies developing, marketing, selling and distributing products that compete with the products incorporating our Aversion® Technology. Alternative technologies and 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 incorporating our Aversion® Technology may be substantially decreased subsequently 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 highly dependent on our management and scientific team, including Andrew D. Reddick, our President and Chief Executive Officer, and Ron J. Spivey, Ph.D. our Senior Vice President and Chief Scientific Officer. 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. Certain opioid active pharmaceutical ingredients in our current product candidates are classified by the DEA as Schedule II substances under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of regulation. Furthermore, the amount of Schedule II substances 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.

***Risks Related to Our Common 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, biopharmaceutical and biotechnology companies, has historically been highly volatile. The stock market from time to time experiences significant price and volume fluctuations that are 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 significant 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 significant impact on the price of our common stock, in addition to the other issues described in the Report, include results of or delays in our pre-clinical and clinical studies, 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 is not active or if the volume is low. There is no guarantee 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 certain new rules. If we were unable to continue to comply with the new 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.

**Our Quarterly Results of Operations Will Fluctuate, and These Fluctuations Could Cause Our Stock Price to Decline**

Our quarterly 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. As a result, in some future quarters 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.

### **We Do Not Anticipate Paying Dividends on Our Common Stock in the Foreseeable Future**

We have not declared and paid cash dividends on our common stock in the past and we do not anticipate paying any cash dividends in the foreseeable future. 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 78% of our outstanding common stock as of March 1, 2008 (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 holder 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 committed 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.

### **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 265,840,164 shares (on a pre-reverse stock basis) in such registration statement. As a result, 342,432,734 shares (representing approximately 66% 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 will likely 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.

In addition, pursuant to the terms of an Amended and Restated Registration Rights Agreement dated February 6, 2004 among us, GCE Holdings LLC and other security holders we have granted such parties demand and piggyback rights to register their shares of our common stock for resale under the Securities Act of 1933. The exercise of such rights



and sale of all or a portion of the shares by such shareholders will likely have the effect of depressing the trading price of our common stock.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

## 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, 2009. 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 warehousing activities relating to the Aversion® Technology at our facility located at 16235 State Road 17, Culver, Indiana (the “Culver Facility”). At this location, our wholly-owned subsidiary Acura Pharmaceutical Technologies, Inc., owns a ~28,000 square foot facility with approximately 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 approximately 30 acres of land.

## ITEM 3. LEGAL PROCEEDINGS

None.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our security holders during the fourth quarter of 2007.

## PART II

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

### *Market and Market Prices of Common Stock*

During 2006, 2007 and the first quarter of 2008 through February 1, 2008, our common stock was traded on the Over-the-Counter (“OTC”) Bulletin Board. Commencing on February 4, 2008, our common stock was admitted for trading on the NASDAQ Capital Market under the symbol “ACUR”. On December 5, 2007, we effected a 1 for 10 reverse split of our common stock. The share price information provided in the tables below gives effect to the reverse stock split.

Set forth below for the periods indicated are the high and low bid prices for our common stock for trading in the 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.

PERIOD	Bid Prices	
	High \$	Low \$
<b>2006 Fiscal Year</b>		
First Quarter	9.10	2.50
Second Quarter	7.90	5.00

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Third Quarter	10.90	5.90
Fourth Quarter	9.20	5.60
<b>2007 Fiscal Year</b>		
First Quarter	9.50	6.90
Second Quarter	11.50	7.60
Third Quarter	28.40	9.30
Fourth Quarter	22.40	6.00
<b>2008 Fiscal Year</b>		
First Quarter (through February 1, 2008)	8.60	5.90

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

PERIOD	Sale Prices	
	High \$	Low \$
<b>2008 Fiscal Year</b>		
First Quarter (from February 4, 2008 through February 29, 2008)	10.50	7.53

## **Holders**

There were approximately 597 holders of record of our common stock on February 29, 2008. This number, however, does not reflect the ultimate number of beneficial holders of our common stock.

## **Dividend Policy**

The payment of cash dividends from current earnings 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. We do not intend to pay any cash dividends in the foreseeable future.

## **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, 2007, 2006, 2005, 2004 and 2003 are derived from our audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2007 and 2006 and for each of the years in the three-year period ended December 31, 2007, and the reports thereon, are included elsewhere in this Report. The selected financial information as of and for the years ended December 31, 2004 and 2003 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 information provided gives effect to the 1 for 10 reverse stock split effected December 5, 2007.

**OPERATING DATA**

(in thousands) except per share data

	2007	2006	2005	2004	2003
Net revenues	\$ 6,404	—	—	\$ 838	\$ 5,750
Operating Costs:					
Cost of manufacturing	—	—	—	1,435	11,705
Research and development	7,169	5,172	6,265	4,130	1,460
Selling, marketing, general and administrative expenses	4,141	5,654	5,296	5,238	7,903
Plant shutdown costs	—	—	—	—	1,926
Interest expense	(1,207)	(1,140)	(636)	(2,962)	(6,001)
Interest income	268	18	36	59	25
Write-off of debt discount and deferred private debt offering costs	—	—	—	(41,807)	—
Amortization of debt discount and deferred private debt offering costs	(2,700)	(183)	—	(30,684)	(24,771)
Gain on debt restructuring	—	—	—	12,401	—
(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	22	(22)	81	2,359	—
Other (expense) income	(3)	(213)	5	603	464
Loss before income tax benefit	(13,914)	(5,967)	(12,075)	(69,996)	(48,455)
Income tax benefit	9,600	—	—	—	—
Net loss	\$ (4,314)	\$ (5,967)	\$ (12,075)	\$ (69,996)	\$ (48,455)
Basic and diluted loss per common share applicable to common stockholders	\$ (0.11)	\$ (0.75)	\$ (1.81)	\$ (32.00)	\$ (22.80)
Weighted average number of outstanding common shares	39,157	34,496	6,680	2,186	2,123

**BALANCE SHEET DATA(3)**

(in thousands)

	2007	2006	2005	2004	2003
Working capital (deficiency)	\$ 22,306	\$ (28,641)	\$ (2,478)	\$ 2,423	\$ (3,770)
Total assets	45,628	1,619	1,792	4,967	6,622
Total debt, net (2)	—	28,787	7,613	5,093	53,142
Total liabilities	26,908	39,899	7,954	6,052	58,689
Accumulated deficit	(321,860)	(317,543)	(291,616)	(279,541)	(209,546)
Stockholders' equity (deficit)	18,720	(38,280)	(6,162)	(1,085)	(52,067)

(1) Reflects the impact of significant corporate and financing restructuring in 2004 as described in Notes C and F to the consolidated financial statements.

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

(3) Reflects impact of \$30 million received from King in December, 2007 as described in Notes B and F to the consolidated financial statements.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included elsewhere in this Report. Operating results are not necessarily indicative of results that may occur in the future periods. Certain statements in this Report under this Item 7, Item 1, "Business", Item 1A, "Risk Factors" and elsewhere in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. See page 1 of this Report 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 innovative Aversion® Technology and related product candidates. Product candidates developed with Aversion® Technology and containing opioid analgesic active ingredients are intended to effectively treat pain and also discourage the most common methods of pharmaceutical product misuse and abuse including; (i) intravenous injection of dissolved tablets or capsules, (ii) nasal snorting of crushed tablets or capsules and (iii) intentional swallowing of excessive numbers of tablets or capsules. Acurox™ Tablets, our lead product candidate utilizing Aversion® Technology, is being developed pursuant to an active investigational new drug application (“IND”) on file with the U.S. Food and Drug Administration (“FDA”). Aversion® Technology is our patented platform technology for developing next-generation pharmaceutical products containing potentially abuseable drugs including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, tramadol, propoxyphene, and many others. Additional Aversion® Technology patents are pending encompassing a wide range of abuseable drugs including stimulants, tranquilizers and sedatives. Aversion® Technology is applicable to orally administered tablets and capsules. In addition to the active ingredient, Aversion® Technology utilizes certain patented compositions of pharmaceutical product inactive excipients and active ingredients intended to discourage or deter pharmaceutical product abuse.

We conduct internal research, development, laboratory, manufacturing and warehousing activities for Aversion® Technology at our Culver, Indiana facility. The 28,000 square foot facility is registered by the U.S. Drug Enforcement Administration (“DEA”) to perform research, development and manufacture of certain Schedule II - V finished dosage form products. In addition to internal capabilities and activities, we engage numerous contract 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 development services for Acurox™ Tablets and other product candidates under our direction.

We are focused on:

- research and development of product candidates utilizing our Aversion® Technology;
- manufacture, quality assurance testing and release, and stability studies of clinical trial supplies and NDA submission batches of certain finished dosage form product candidates utilizing Aversion® Technology;
- prosecution of our patent applications relating to Aversion® Technology with the United States Patent and Trademark Office (“USPTO”) and foreign equivalents; and
- negotiation and execution of license and development agreements with pharmaceutical company partners providing that such licensees will further develop certain finished dosage product candidates utilizing the Aversion® Technology and file for regulatory approval with the FDA and other regulatory authorities and commercialize such products.

## Company’s Present Financial Condition

At December 31, 2007, we had cash and cash equivalents of approximately \$31.4 million compared to approximately \$228,000 at December 31, 2006. We had working capital of \$22.3 million at December 31, 2007 compared to a working capital deficit of \$28.6 million at December 31, 2006. We had an accumulated deficit of approximately \$321.9 million and \$317.5 million at December 31, 2007 and December 31, 2006, respectively. We had a loss from operations of approximately \$4.9 million and a net loss of approximately \$4.3 million for the year ended December 31, 2007 compared to a loss from operations of approximately \$10.8 million and a net loss of approximately \$6.0 million for the year ended December 31, 2006.

As of March 1, 2008, we had cash and cash equivalents of approximately \$31 million. We estimate that our current cash reserves will be sufficient to fund the development of the Aversion® Technology and related operating expenses through at least the next 12 months. See “Liquidity and Capital Resources - Cash Reserves”.

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 certain opioid analgesic products utilizing our proprietary Aversion® Technology in the United States, Canada and Mexico. On December 7, 2007, the King Agreement closed and became effective and on the same date, we received from King a non-refundable cash payment of \$30.0 million. We may receive additional non-refundable cash milestone payments from King based on the successful achievement of certain clinical and regulatory milestones for Acurox™ Tablets, our lead product candidate, and for each other product developed under the King Agreement. We may also receive an additional \$50 million non-refundable cash milestone payment when the aggregate net sales of all products developed under the King Agreement reach \$750 million. In addition, we may receive from King royalty payments for sales occurring following the one year anniversary of the first commercial sale of a licensed product ranging from 5% to 25% based on the combined annual net sales of all products commercialized under the King Agreement.



We had no revenues in 2006. In 2007, we recognized revenue of \$6.4 million derived from the \$30.0 million non-refundable cash payment received from King on December 7, 2007 and the reimbursement of our development expenses incurred under the King Agreement. We have yet to generate any revenues from product sales. Through December 31, 2007, we have recorded an accumulated deficit of approximately \$322 million. 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 and clinical trials as well as clinical 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. We expect to rely on our current cash resources and additional payments that may be made under the King Agreement and under similar license agreements with other pharmaceutical company partners, of which there can be no assurance, in funding our continued operations. Our cash requirements for operating activities may increase in the future as we continue to conduct pre-clinical studies and clinical trials for our product candidates, maintain, defend and expand the scope of our intellectual property, and hire additional personnel.

### **Results of Operations for Year December 31, 2007 and 2006**

#### **Revenue - Program fee revenue**

(\$ in thousands):	Year Ended December 31,		Change	
	2007	2006	Dollars	%
Revenue – Program fee revenue	\$ 3,427	—	\$ 3,427	N/A

King paid us a \$30.0 million upfront fee in connection with the closing of our Agreement with King in December 2007. Revenue recognized in 2007 from amortization of this upfront fee was \$3.4 million. We have assigned a portion of the license fee revenue to each of the product candidates included under the Agreement and expect to recognize the remainder of the program fee ratably over our estimate of the development period for each of the products under the Agreement with King. We currently estimate the development period for the expected drug candidates to extend through December, 2009.

#### **Revenue - Collaboration revenue**

(\$ in thousands):	Year Ended December 31,		Change	
	2007	2006	Dollars	%
Revenue – Collaboration fee revenue	\$ 2,977	—	\$ 2,977	N/A

Collaboration revenue recognized in 2007 was \$3.0 million. This revenue related to reimbursement of our development expenses incurred pursuant to the King Agreement from September 19 to December 31, 2007. We invoice King in arrears on a calendar quarter basis for our development 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.

#### **Research and development expenses**

(\$ in thousands):	Year Ended December 31,		Change	
	2007	2006	Dollars	%
Research and development expenses	\$ 7,169	\$ 5,172	\$ 1,997	38%

Research and development expense in the years ended December 31, 2007 and 2006 consisted of development of 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 2007 and 2006 results are non-cash stock-based compensation charges of \$370 and \$2,067, respectively. Excluding the stock-based compensation expense, there is a \$3,694 increase in overall expenses primarily attributable to a) increasing clinical study costs of \$1,820 and b) \$1,140 of staff bonus payments. No bonuses were paid in the prior four years and the amount in 2007 was intended to reward personnel for their successful efforts that resulted in the King Agreement. The decrease in stock-compensation expense of \$1,697 (related to the fair value of stock options and restricted stock units, net of expected forfeitures, granted prior to 2006 which continue to vest and expense over the related employees requisite service periods), is due to the vesting method used for amortization. The fair value of the awards are being amortized using a graded vesting method which treats the award as if the grant was a series of awards rather than a single award and attributes a higher percentage of the reported fair value to the earlier quarters than to the later quarters of the service period. There were no stock options or restricted stock units granted in 2007.

Marketing, general & administrative expenses

(\$ in thousands):	Year Ended December 31,		Change	
	2007	2006	Dollars	%
Marketing, general & administrative expenses	4,141	\$ 5,654	\$ (1,513)	(26)%

During the year ended December 31, 2007, marketing expenses consisted primarily of payroll costs. Our general and administrative expenses primarily consisted of legal, audit and other professional fees, corporate insurance, and payroll costs. Included in the 2007 and 2006 results are non-cash stock-based compensation charges of \$544 and \$3,517, respectively. Excluding the stock-based compensation expense, the expenses increased \$1,460 which is entirely attributable to staff bonus payments. No bonuses were paid in the prior four years and the amount in 2007 was intended to reward personnel for their successful efforts that resulted in the King Agreement. The decrease in stock-compensation expense of \$2,973 (related to the fair value of stock options and restricted stock units, net of expected forfeitures, granted prior to 2006 which continue to vest and expense over the related employees requisite service periods) is due to a nonrecurring \$680 expense immediately recorded in February 2006 on the grant of restricted stock units to our independent directors, and to the vesting method used for amortization. The fair value of the awards is being amortized using a graded vesting method which treats the award as if the grant was a series of awards rather than a single award and attributes a higher percentage of the reported fair value to the earlier quarters than to the later quarters of the service period. There were no stock options or restricted stock units granted in 2007.

Interest expense, net of interest income

(\$ in thousands):	Year Ended December 31,		Change	
	2007	2006	Dollars	%
Interest expense, net of interest income	\$ 939	\$ 1,122	\$ (183)	(16)%

We incurred interest on our \$5.0 million Secured Term Note at the variable rate of prime plus 4.5% up to August 19, 2007 and thereafter at the fixed rate of 10% per annum. Interest on our \$5.0 million Secured Term Note was payable in our common stock through August 19, 2007 and thereafter payable in cash. Such cash interest was deferred until the earlier of (i) the December 31, 2008 maturity date of the Secured Term Note, or (ii) our receipt of proceeds in excess of \$5.0 million from a third party pharmaceutical company or companies pursuant to which we, in one or more transactions, grants such pharmaceutical company or companies' rights to any of our products or product candidates or rights to our Aversion® Technology. Upon the closing of the King Agreement on December 7, 2007, we repaid in full our \$5.0 million Secured Term Note. We also incurred interest on our \$10.544 million Senior Secured Convertible Bridge Notes (collectively, the "Bridge Loans") at the fixed rate of 10%. Interest on such Bridge Loans through June 30,

2006 was paid in cash. Commencing with interest due under such Bridge Loans at September 30, 2006, all such interest was paid in our common stock. 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. The Company's Bridge Loans increased by \$2.7 million since December 31, 2006, however the decrease in interest expense reflects both the reduction in the \$5.0 million Secured Term Note's interest rate and the conversion of all Bridge Loans as discussed above.

Net loss

(\$ in thousands):	Year Ended December 31,		Change	
	2007	2006	Dollars	%
Net loss	\$ 4,314	\$ 5,967	\$ (1,653)	(27)%

The November and December 2006 Bridge Loans for an aggregate face value of \$1,104 included an amended conversion feature which we valued at an aggregate of \$1,034. This value was recorded as a liability with an offsetting \$1,025 debt discount (which was amortized over the term of the Bridge Loans) and \$9 of issuance loss. However, as the debt was issued to controlling shareholders, this loss was recorded as non-cash deemed dividend rather than effecting net loss. Additional issuances of \$896 of Bridge Loans in January and February 2007 similarly had aggregate conversion feature value of \$849 and a loss upon issuance of \$3 recorded as non-cash deemed dividend rather than effecting net loss. The 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 us to record the value of the amended conversion feature on that outstanding debt as a liability and a loss on the modification of debt. We assigned a value of \$19,951 to these conversion features at date of modification and reflected that loss as non-cash deemed dividend in the fourth quarter 2006.

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), we recorded the resulting increase in value as a \$3,483 loss. The increase in our 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 not less than \$0.21 per share. With this limit in place, the outstanding conversion feature no longer had to be reflected as a liability. As such, we recorded a \$21,086 reclassification of that liability to additional paid-in capital.

As a result of the November 2006 amendment to the Bridge Loans, our outstanding common stock purchase warrants started being accounted for as mark-to-market liabilities with a recorded value of \$10,784 at December 31, 2006. Upon revaluing the warrants just before they were exercised or as of March 30, 2007 (the date immediately before further amendment to the Bridge Loans), we recorded the resulting increase in value as a \$1,668 loss. The increase in the our common stock trading price from December 31, 2006 to March 30, 2007 resulted in the increase in the value of the warrant liability. The Bridge Loan amendment on March 30, 2007 limited the conversion price of the post-October 2006 loans to no lower than \$0.21 per share. With this limit in place, the outstanding warrants no longer had to be reflected as a liability. As such, we recorded a \$12,307 reclassification of that liability to additional paid-in capital; in addition to a \$146 reclassification relating to warrants exercised during the first quarter of 2007.

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. In 2007, based upon the receipt of the \$30 million under the King Agreement we were able to determine 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.

In addition to the items discussed above, other items contributing to our reported net loss for the periods were i) \$2,700 of amortization expense related to debt discounts recorded upon issuance of certain debt agreements dated in latter 2006 and throughout 2007, (the year ended December 31, 2006 had no such debt amortization expense), ii) \$142 of share-based compensation expense relating to a dilution adjustment on a previously issued warrant to a former employee pursuant to dilution protections contained in such warrant recorded during 2006, iii) anti-dilution clauses contained in certain warrants were triggered resulting in a loss of \$1,905 with an equal amount recorded against equity

and iv) disposals of capital equipment and other expenses during the periods resulted in reported income of \$22 and a expense of \$22 for 2007 and 2006, respectively.

**Results of Operations for the Year Ended December 31, 2006 and 2005****Research and development expenses**

(\$ in thousands):	Year Ended December 31,		Change	
	2006	2005	Dollars	%
Research and development expenses	\$ 5,172	\$ 6,265	\$ (1,093)	(17)%

Research and development expenses related primarily to development of our Aversion<sup>®</sup> Technology, including costs of preclinical studies, clinical trials, clinical supplies and related formulation and design costs, salaries and other personnel related expenses, and facility costs. Included in the 2006 and 2005 results are non-cash stock-based compensation charges of \$2,067 and \$3,325, respectively, and included in the 2005 result is a \$284 benefit from the reversal of an incentive compensation accrual. Excluding the stock-based compensation expense and the accrued incentive compensation benefit, there was a \$119 decrease in overall research and development expenses. This decrease was primarily the net result of an increase in clinical study and related consulting expenses of \$197 offset by lower wage and benefit costs of \$222 reflecting fewer employees, lower facility operating costs of \$50, and reduced outside testing expenses on discontinued products of \$44 in 2006. The decrease in stock-based compensation expense of \$1,258 occurred because the number of stock options and restricted stock units that vested in 2006 was less than 2005.

**Marketing, general and administrative expenses**

(\$ in thousands):	Year Ended December 31,		Change	
	2006	2005	Dollars	%
Marketing, general and administrative expenses	\$ 5,654	\$ 5,296	\$ 358	7%

During the year ended December 31, 2006, the marketing expenses consisted of Aversion<sup>®</sup> Technology market research studies and payroll costs. Our general and administrative expenses consisted of legal, audit and other professional fees, corporate insurance, and payroll costs. Included in the 2006 and 2005 results is \$3,517 and \$3,133, respectively, of stock-based compensation expense. Also included in the 2005 result is a \$175 benefit from the reversal of an incentive compensation accrual. Excluding the stock-based compensation expense and incentive compensation benefit, the marketing, general and administrative expenses decreased by \$201 primarily attributable to a reduction in legal costs as a result of less corporate and financial restructuring efforts. Of the increase in stock-based compensation expense, \$680 was from the February 2006 grant of two million restricted stock units to our independent directors. The stock-based compensation expense attributable to employees decreased by \$295 because the number of stock options and restricted stock units that vested in 2006 were less than 2005.

**Interest expense, net of interest income**

(\$ in thousands):	Year Ended December 31,		Change	
	2006	2005	2006	2005
Interest expense, net of interest income	\$ 1,122	\$ 600	\$ 522	87%

We incurred interest at the prime interest rate plus 4.5%, payable quarterly in common stock, on our \$5.0 million secured term note payable. We incurred 10% annual interest, payable quarterly, on our \$7.8 million Bridge Loans. Interest on such Bridge Loans through June 30, 2006 was paid in cash. Commencing with interest due under such Bridge Loans at September 30, 2006, all such interest was paid in our Company's Common Stock. The increase in net interest expense in 2006 resulted from the addition of \$5.3 million of Bridge Loans during 2006 and increases in the prime interest rate.

Net loss

(\$ in thousands):	Year Ended December 31,				Change	
	2006		2005		2006	2005
Net loss	\$	5,967	\$	12,075	\$ (6,108)	(51)%

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Included in the net loss for 2006 is a non cash compensation charge of \$5,726 arising from the issuance of stock options and restricted stock units as compared to \$6,459 for such charges in 2005.

The November 2006 amendment of the conversion feature on all of the then outstanding Bridge Loans, coupled with the requirements to separate the value of the conversion feature from the debt, required us to record the value of the amended conversion feature on that outstanding debt as a liability and a loss on the modification of debt. We assigned a value of \$19,951 to these conversion features and reflected the modification loss as a non-cash deemed dividend. While the aggregate non-cash deemed dividend of \$19,960 did not impact reported net loss, it does have an impact on loss per common share.

Upon revaluing the aggregate conversion features on all outstanding Bridge Loans as of December 31, 2006, we recorded the resulting decrease in value as a \$4,235 gain. The decrease in our common stock trading price from November 2006 to year end resulted in the decrease in the value of the conversion liability.

As a result of the November 2006 amendment to our Bridge Loans, a \$12,948 liability and corresponding reduction in additional paid-in capital, for the common stock purchase warrants was recorded. The mark to market fair value adjustments to the warrant liability resulted in a \$2,164 gain recorded in the fourth quarter 2006. Future period fair value adjustments to the warrant liability could result in further gains or losses.

Our loss per share in 2006 compared to 2005 (\$0.75 versus \$1.81, respectively, as calculated after giving effect to the 1 for 10 reverse stock split effected December 5, 2007) was favorably impacted by the conversion on November 10, 2005 of approximately 21.8 million preferred shares into approximately 30.6 million common shares. On a weighted average basis, this increased the number of common shares in the loss per share calculation to approximately 34.5 million shares in 2006 as compared to 6.6 million shares in 2005. For periods prior to November 10, 2005, our convertible preferred shares were anti-dilutive and therefore excluded from the loss per share calculation. Additionally, the 2006 loss per share was impacted by the non-cash deemed dividend described above.

### **Liquidity and Capital Resources**

At December 31, 2007, we had cash and cash equivalents of \$31.4 million compared to \$228,000 at December 31, 2006. We had working capital of \$22.3 million at December 31, 2007 compared to a working capital deficit of \$28.6 million at December 31, 2006. The increase in cash and working capital at December 31, 2007 is due primarily to our receipt of a non-fundable \$30.0 million cash payment from King under the King Agreement, the net proceeds of approximately \$14.2 million received pursuant to our Unit Offering completed in August 2007, the conversion of our entire \$10.544 million in the principal amount of outstanding bridge loans into units in our Unit Offering, and the repayment in full of our \$5 million secured term note on December 7, 2007 in accordance with the terms of the King Agreement and the secured term note.

Net cash provided by operating activities was \$19.2 million for the year ended December 31, 2007 compared to net cash used in operating activities of \$5.4 million for the year ended December 31, 2006 primarily representing our net loss for such years, less non-cash charges related to amortization of debt discount, fair value changes of conversion features and common stock warrants in 2007, and stock compensation and common stock issued for interest in each of 2007 and 2006. Capital expenditures for each year were substantially offset by proceeds from asset disposals. Our financing activities of \$16.8 million in 2007 related principally to our Unit Offering and additional bridge loan borrowings less the repayment of the \$5 million secured term note. Our financing activities of \$5.3 million for 2006 related principally to additional bridge loan borrowings.

### **Satisfaction of Term Debt**



Our secured term note in the principal amount of \$5.0 million was secured by a lien on all of our assets and the assets of our wholly –owned subsidiary, including a mortgage lien on the Culver Facility, carried a fixed rate of interest of 10% and had a maturity date of December 31, 2008. On December 7, 2007, we repaid in full the principal and accrued interest under the \$5.0 million secured term note.

We were a party to four (4) loan agreements completed in January 2006, November, 2005, September, 2005 and June, 2005, each as amended, pursuant to which we received bridge financing installments in the aggregate principal amount of \$10.544 million (the “Bridge Loans”) from Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners International III, L.P., Galen Partners III, L.P., Galen Employee Fund III, L.P. (collectively, the “VC Lenders”) and certain other shareholders listed on the signature page to such Bridge Loan agreements. On August 20, 2007, we completed an offering of our units, consisting of common stocks and warrants (the “Unit Offering”). Calculated on a post reverse stock split basis, approximately 1.4 million of the units issued in the Unit Offering were issued for cash, resulting in net cash proceeds to the Company of approximately \$14.2 million, with the balance of approximately 1.0 million units issued in consideration of the conversion of the entire \$10.544 million principal amount outstanding under our Bridge Loans.

As a result of the repayment of our \$5.0 million secured term note and the conversion of all outstanding Bridge Loans into our units, we have no term indebtedness.

### Cash Reserves

As of March 1, 2008, we had cash and cash equivalents of approximately \$31 million. The majority of such cash reserves will be dedicated to the development of our Aversion® Technology, the formulation and development of product candidates which incorporate Aversion® Technology, the prosecution of our patent applications relating to the Aversion® Technology and for administrative and related operating expenses.

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 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, of 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. We believe that our current cash resources should be sufficient to fund our operations for at least the next 12 months.

The following table presents our expected cash payments on contractual obligations outstanding as of December 31, 2007:

(in thousands)	Total	Due in 2008	Due in 2009	Due Thereafter
Operating leases	37	30	7	—
Clinical studies <sup>1</sup>	3,991	3,991	—	—
Employment agreements	885	885	—	—
Total contractual obligations	\$ 4,913	\$ 4,906	\$ 7	—

<sup>1</sup> Expected to be reimbursed to us by King under the provisions of the King Agreement.

### **Critical Accounting Policies**

Note A of the Notes to Consolidated Financial Statements included as a part of this Report, includes a summary of our significant accounting policies and methods used in the preparation of the financial statements. In preparing these financial statements, we have made our best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. The application of these accounting policies involves the exercise

of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. We do not believe there is a consequential likelihood that materially different amounts would be reported under different conditions or using different assumptions. Our critical accounting policies are as follows:

### Revenue Recognition and Deferred Program Fee Revenue

In connection with our Agreement with King, we recognize program fee revenue, collaboration revenue and milestone revenue. Program fee revenue is derived from the upfront payment from King received in December 2007. We have assigned a portion of the program fee revenue to each of the product candidates included under the Agreement and recognize the program fee revenue ratably over our estimate of the development period for each of the products under the Agreement with King. Collaboration revenues from reimbursement of development expenses, which are invoiced quarterly in arrears, are recognized when costs are incurred pursuant to the Agreement with King. These 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. Milestone revenue is derived from milestone payments from King which are contingent upon the achievement of certain substantive events in the clinical development of Acurox™ Tablets and the other product candidates licensed to King under the Agreement. We recognize milestone payments from King as revenue when we achieve the underlying developmental milestone and the milestone payments are not dependent upon any other future activities or achievement of any other future milestones and the achievement of each of the developmental milestones were substantively at risk and contingent at the effective date of the collaboration. Substantial effort is involved in achieving each of the developmental milestones. These milestones represent the culmination of discrete earnings processes and the amount of each milestone payment is reasonable in relation with the level of effort associated with the achievement of the milestone. Each milestone payment is non-refundable and non-creditable when made.

### Income Taxes

Deferred income taxes are recognized 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. A valuation allowance is established, when necessary, to reduce deferred tax assets to the amount expected to be realized. In estimating future tax consequences, we generally consider all expected future events other than an enactment of changes in the tax laws or rates. We have recorded a valuation allowance to reduce net deferred income tax assets to the amount that is more likely than not to be realized. In the event we are able to determine that we will be able to realize deferred income tax assets in the future, an adjustment to reduce the valuation allowance would increase income in the period such determination was made. In 2007, based upon the receipt of the \$30 million under the King Agreement, we adjusted the valuation allowance by \$9.6 million which is reflected as a tax benefit in the 2007 statement of operations.

### Stock Compensation

On December 16, 2004, the Financial Accounting Standards Board (“FASB”) released FASB Statement No. 123 (revised 2004), “Share-Based Payment, (“FASB 123R”)”. These changes in accounting replaced existing requirements under FASB Statement No. 123, “Accounting for Stock-Based Compensation” (“FASB 123”), and eliminated the ability to account for share-based compensation transaction using APB Opinion No.25, “Accounting for Stock Issued to Employees” (“APB 25”). The compensation cost relating to share-based payment transactions will be measured based on the fair value of the equity or liability instruments issued. This Statement did not change the accounting for similar transactions involving parties other than employees.

We adopted FASB 123R effective January 1, 2006 under the modified prospective method, which recognizes compensation cost beginning with the effective date (a) based on the requirements of FASB 123R for all share-based payments granted after the effective date and to awards modified, repurchased, or cancelled after that date and (b) based on the requirements of FASB Statement No. 123 for all awards granted to employees prior to the effective date of FAS 123R that remain unvested on the effective date. The compensation cost relating to share-based payment transactions is now measured based on the fair value of the equity or liability instruments 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. The 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). Black-Scholes utilizes other assumptions related to the risk-free interest rate, the dividend yield (which is assumed to be zero, as we have has not paid any cash dividends) and employee exercise behavior. 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. Because our employee stock options have characteristics significantly different from those of traded 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.

### Debt Discount

Debt discount resulting from the issuance of common stock warrants in connection with the issuance of subordinated debt and other notes payable in 2004 as well as from beneficial conversion features contained in convertible debt instruments issued in 2004 and prior years, 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. Inherent in the Black-Scholes valuation model are assumptions made by management regarding the estimated life of the warrant, the estimated volatility of our common stock (as determined by reviewing its historical public market closing prices) and the expected dividend yield. In August 2004, all related debt was converted into various series of preferred stock and the entire remaining unamortized debt discount of \$41,090,000 was charged to expense. Subsequently, all outstanding series of preferred stock was converted into common stock in 2005. As described more fully in the notes to the consolidated financial statement, additional debt discount of \$1,025,000 was recorded in 2006 and was amortized through the March 31, 2007 maturity of the related debt.

### Conversion Features and Common Stock Warrants

Certain provisions of the amended conversion features contained in the our outstanding Bridge Loans in November 2006, required us to separate the value of the conversion feature from this debt and record such value as a separate liability which must be marked-to-market each balance sheet date. Future period fair value adjustments to the conversion feature could result in further gains or losses. To compute the estimated value of the conversion features, we used the Black-Scholes option-pricing model. As a result of the November 2006 amendment to the Bridge Loans, all outstanding common stock purchase warrants were fair valued using the Black - Scholes option-pricing model and recorded as a liability with corresponding reduction in additional paid-in capital. The liability must be marked-to-market each balance sheet. Future period fair value adjustments to the warrant liability could result in further gains or losses.

### **New Accounting Pronouncements**

#### Noncontrolling Interests in Consolidated Statements

In December 2007, Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 160 "Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51" ("SFAS 160"). SFAS 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of ARB No. 51's consolidation procedures for consistency with the requirements of SFAS 41 (revised 2007), Business Combinations. SFAS 160 is effective for fiscal years and interim periods within those fiscal years beginning on or after December 15, 2008. Earlier adoption is prohibited. SFAS 160 shall be applied prospectively as of the beginning of the fiscal year in which the Statement is adopted, except for the presentation and disclosure requirements. The presentation and disclosure requirements shall be applied retrospectively for all periods presented.

#### Business Combinations

In December 2007, the FASB issued SFAS No. 141 (revised 2007) "Business Combinations" ("SFAS (141R)"). SFAS 141R retains the fundamental requirements of the original pronouncement requiring that the purchase method be used for all business combinations. SFAS 141R 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. SFAS 141R requires, among other things, that the acquisition related costs be recognized separately from the acquisition. SFAS 141R is applied prospectively to business combinations for which the

acquisition date is on or after January 1, 2009.

#### Fair Value Option for Financial Assets and Financial Liabilities

In February 2007, the FASB issued SFAS No. 159 “The Fair Value Option for Financial Assets and Financial Liabilities –Including an Amendment of FASB Statement No. 115” (“SFAS 159”). SFAS 159 permits an entity to elect to measure eligible items at fair value (“fair value option”) including many financial instruments. The provisions of SFAS 159 are effective for the Company as of January 1, 2008. If the fair value option is elected, the Company will report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. Upfront costs and fees related to an item for which the fair value option is elected shall be recognized in earnings as incurred and not deferred. The fair value option may be applied for a single eligible item without electing it for other identical items, with certain exceptions, and must be applied to the entire eligible item and not to a portion of the eligible item. The Company is currently evaluating the irrevocable election of the fair value option pursuant to SFAS 159.

#### Fair Value Measurements

In September 2006, the FASB issued SFAS No. 157 “Fair Value Measurements” (“SFAS 157”), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for the Company beginning on January 1, 2008. The requirements of SFAS 157 will be applied prospectively except for certain derivative instruments that would be adjusted through the opening balance of retained earnings in the period of adoption. In February 2008, the FASB issued Staff Position No. FAS 157-2 which provides for a one-year deferral of the effective date of SFAS 157 for non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is evaluating the impact of the adoption of SFAS 157 on its financial statements.

#### Share-Based Payment

The Company adopted FASB 123R effective January 1, 2006 under the modified prospective method, which recognizes compensation cost beginning with the effective date (a) based on the requirements of FASB 123R for all share-based payments granted after the effective date and to awards modified, repurchased, or cancelled after that date and (b) based on the requirements of FASB Statement No. 123 for all awards granted to employees prior to the effective date of FASB 123R that remain unvested on the effective date. The only cumulative effect of initially applying this Statement for the Company was to reclassify \$5,724,000 of previously recorded unearned compensation into paid-in capital. The Company has estimated that an additional \$5,827,000 will be expensed over the applicable remaining vesting periods for all share-based payments granted to employees on or before December 31, 2005 which remained unvested on January 1, 2006. The Company anticipates that more compensation costs will be recorded in the future if the use of options and restricted stock units for employees and director compensation continues as in the past.

### **Capital Expenditures**

Our capital expenditures during 2007, 2006 and 2005 were \$31,000, \$85,000 and \$35,000, 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 its 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, 2007, our investments consisted primarily of investments in corporate and government notes and obligations or in money market accounts and checking funds with variable, market rates of interest.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

This item is submitted as a separate section of this Report commencing on page F-1.



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

Not Applicable.

### ITEM 9A. CONTROLS AND PROCEDURES

*Evaluation of Disclosure Controls and Procedures.* We have carried out 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, 2007. 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, 2007, our internal control over financial reporting is effective based on those criteria.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only

management's report in this annual report.

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*Changes in Internal Control Over Financial Reporting.* There was no change in our internal control over financial reporting that occurred during the period covered by this Report that has materially affected, or is reasonably likely to materially affect, our internal control over-financial reporting.

## **Item 9B. OTHER INFORMATION**

Not Applicable.

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

#### **Directors and Executive Officers**

Our directors and executive officers are identified in “Item 1. Business”.

#### **Corporate Governance**

##### **Audit Committee**

During 2007, the members of Audit Committee of the Board of Directors were William A. Sumner, Chairman, Immanuel Thangaraj and Bruce F. Wesson. On January 24, 2008, the Audit Committee was reconstituted and effective at such date, the members are 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 members during 2007, 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 Mr. Sumner was an independent member of the Audit Committee, and that Messrs. Wesson and Thangaraj did not satisfy such standards for independence as a result of their positions in entities having a controlling interest in GCE Holdings, LLC, our 78% shareholder. GCE Holdings, LLC was the assignee of all our preferred shares previously held by each of Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P. and Galen Partners III, L.P. In view of the controlling interests in GCE Holdings, LLC held by each of Galen Partners III, L.P., of which Mr. Wesson is a general partner, and Essex Woodlands Health Ventures V, L.P., of which Mr. Thangaraj is a general partner, each of Messrs. Wesson and Thangaraj fail to satisfy the standards for independence set forth in the listing standards of the NASDAQ Capital Market and applicable SEC regulations. Nevertheless, our Board valued the experience of Messrs. Wesson and Thangaraj in the review of our financial statements in 2007 and believes that each was able to exercise independent judgment in the performance of his duties on the Audit Committee during 2007.

In assessing the independence of the Audit Committee as currently comprised, 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](http://www.acurapharm.com), under the link “Ethics/Audit Charter.”

## **Compensation Committee**

During 2007, the members of Compensation Committee of the Board of Directors were Andrew D. Reddick, Richard J. Markham and William G. Skelly. On January 24, 2008, the Compensation Committee was reconstituted and effective at such date, the members are 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 Compensation Committee does not have a formal written charter. See "Item 11. Executive Compensation — Compensation Discussion and Analysis " below.

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 six 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.

## **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](http://www.acurapharm.com), under the link “Ethics/Audit Charter”.

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## 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, 2007, except as noted below.

GCE Holdings LLC filed a late Form 3 and reported late on Form 4 the conversion of preferred stock into common stock in 2005. Essex Woodlands Health Ventures Fund V, LP reported late on three Form 4s relating to the conversion by GCE Holdings LLC of preferred shares to common stock in 2005, the receipt of common stock in satisfaction of interest payments on outstanding notes in 2005, 2006 and 2007, and the receipt of a warrant to purchase common stock in 2004. Immanuel Tharangaj, as a managing partner of Essex Woodlands Health Ventures Fund V, LP, disclaimed beneficial ownership of securities held by Essex Woodlands Health Ventures V, LP (except to the extent of his pecuniary interest therein) but reported late on three Form 4s relating to the above described transactions of Essex Woodlands Health Ventures Fund V, LP. To the extent, Galen Partners III, L.P., Galen Partners International, III, L.P, Galen Employee Fund III, L.P., Care Capital Offshore Investments II, LP and Care Capital Investments II, LP are deemed to own beneficially the shares of the Company's Common Stock held by GCE Holdings LLC or are members of a group which in the aggregate are deemed to own beneficially ten percent or more of the Company's Common Stock, they should have each filed Form 4s with respect to the receipt of common stock in satisfaction of interest payments on outstanding notes in 2007.

## 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 that was effected 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*

In the past few years, 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 2004, 2005 or 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 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, stock options issued at a discount have unfavorable tax and accounting consequences. Fourth, it is difficult to set an exercise price for options 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. Of such RSU awards, 30%, 24%, 16%, 6% and 5% were issued to Messrs. Reddick, Spivey, Clemens, Seiser and Emigh, respectively (the “named executive officers”). It is likely we will maintain a similar ratio of distribution of equity awards in the future, to those persons and/or persons in similar positions. In addition, RSUs with respect to 100,000 shares were issued to each of our two independent directors in 2006. The number of RSUs we issued was influenced by the closing price of the stock underlying the RSUs on the date of grant. 50,000 shares remain available for issuance under our 2005 RSU Plan. As such, any significant further awards of RSUs would require an amendment to the 2005 RSU Plan to increase the number of shares available under the 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*”. While we also intend to award equity-based compensation, our objective is to award cash bonuses and grant 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 named 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 named executive officers in 2004 and 2005 and determined that additional equity incentive compensation was not warranted in 2007.

#### *Salary and Bonus*

Each of Andrew Reddick, Ron Spivey 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. Effective January 1, 2008, Mr. Reddick’s, Spivey’s and Clemens’ salaries were increased to \$365,000 (from \$300,000), \$315,000 (from \$260,000) and \$205,000 (from \$180,000), respectively. In addition, the 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. In determining the salary increase for each of Messrs. Reddick, Spivey and Clemens, the Compensation Committee and the Board considered that, due to our insufficient cash reserves, such executive officers had not received any salary increase or bonuses during the prior four years. The amount of the salary increases were based on a percentage increase, on average, slightly greater than the Consumer Price Index year for each during the four year period ended December 31, 2007. In addition, in December 2007, Messrs. Reddick, Spivey and Clemens were awarded bonuses of \$850,000, \$650,000 and \$180,000, respectively. These amounts were based on a percentage of such executive’s base salary, ranging from 25% to 70%, for each year during the four year period ended December 31, 2007 (corresponding to the period over which no bonuses were paid to senior management because of our limited cash reserves). The salary and bonus performance targets for Messrs. Reddick, Spivey and Clemens for 2008 consist of advancing our Acurox™ (oxycodone HCl and niacin) Tablets and other products using our Aversion® Technology through proof of concept and clinical developments, implementing the King Agreement, licensing of additional products to King through the exercise of King’s options under the King Agreement and licensing products derived from our Aversion® Technology outside of North America.

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. 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. In 2007, as reflected in the Summary Compensation Table, bonuses were paid after the closing of the King Agreement.

For those named executive officers not subject to an employment contract (Messrs. Emigh and Seiser), the Compensation Committee will set the annual salary for such named 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. Effective January 1, 2008, Messrs. Emigh's and Seiser's salaries were increased to \$160,000 (from \$140,000) and \$160,000 (from \$133,000), respectively. In determining the salary increase for each of Messrs. Emigh and Seiser, the Compensation Committee and the Board considered that, due to our insufficient cash reserves, such executive officers had not received any salary increase or bonuses during the prior four years. The amount of the salary increases were based on a percentage increase, on average, slightly greater than the Consumer Price Index for each year during the four year period ended December 31, 2007. In addition, in December 2007, Messrs. Emigh and Spivey were each awarded bonuses of \$140,000. This amount was based on a percentage of such executive's base salary, ranging from 26% to 32%, for each year in the four year period ended December 31, 2007 (corresponding to the period over which no bonuses were paid to senior management because of our limited cash reserves).

#### *Stock Options*

One 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, during 2004 and 2005, we issued stock options to our employees at a discount to the trading price of our common stock. The vesting of these options during 2006 and 2007 is reflected in the "Option Awards" options column of the Summary Compensation Table below. It is our expectation that discounted stock option grants will occur 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 ten years after grant. Executives will generally be subject to limitations in selling the option stock immediately due to securities law considerations, and therefore will have an incentive to increase shareholder value. As of December 31, 2007, Messrs. Reddick and Spivey were fully vested in their stock options. Stock options for 9,375, 6,225, and 6,225 shares remain to vest for Messrs. Clemens, Emigh and Seiser, respectively. In 2007 no additional option grants were made to the named 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.

#### *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 new executive officers will likely be the date of their employment or execution of their agreements. Any such options may be issued at a discount to take into account the limited public float and the wide ranges in our stock price.

### *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. In the case of Messrs. Reddick, Spivey and Clemens, such awards are reflected in their employment agreements. The vesting during 2006 and 2007 of the RSUs granted in 2005 is reflected in the “Stock Awards” column of the Summary Compensation Table, below. As of December 31, 2007, all named executive officers were fully vested in their RSUs. In 2007 no additional RSUs were granted to the named 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.

### *Termination/Severance Benefits*

The employment agreement of each of Messrs. Reddick, Clemens and Spivey provides 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 even while we are experiencing some financial difficulties and gives 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, Spivey 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 the Company 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, Spivey and Clemens, and in stock option agreements, in the case of Messrs. Emigh and Seiser) for all named 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, Spivey 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 feel 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 so-called "parachute" tax imposed by Internal Revenue Code Section 280G, our named 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 named executive officers for any taxes imposed as a result of these additional excise taxes. We will pay taxes incurred by Messrs. Reddick and Spivey on a lump sum distribution of the value of twelve months of benefits, which they may elect in lieu of continued benefits, in the event their employment terminates under certain circumstances.

### *Perquisites and Other Benefits*

Our named 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 named 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 the named executive officers 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. With respect to cash or equity compensation awards to our other employees, the Compensation Committee makes recommendations of bonus awards, salary increases, equity grants to the Board, with the Board approving such awards. 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 2007, 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 (excluding Mr. Reddick) 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 the fiscal years ended December 31, 2006 and December 31, 2007 to our Chief Executive Officer, Chief Financial Officer and our next three most highly compensated executive officers (collectively, the "named executive officers") whose total annual compensation for 2006 and/or 2007 exceeded \$100,000:

**Summary Compensation Table**

<b>Name and Principal Position</b>	<b>Year</b>	<b>Base Salary (\$)</b>	<b>Bonus (\$)</b>	<b>Stock Awards<sup>1</sup> (\$)</b>	<b>Option Awards<sup>2</sup> (\$)</b>	<b>Total (\$)</b>
Andrew D. Reddick	2006	300,000	—	1,375,000	\$ 77,000	1,752,000
President & CEO	2007	300,000	850,000	264,000	0	1,414,000
Peter A. Clemens	2006	180,000	—	733,000	23,000	936,000
SVP & CFO	2007	180,000	180,000	141,000	11,000	512,000
Ron J. Spivey	2006	260,000	—	1,110,000	166,000	1,536,000
SVP and Chief Scientific Officer	2007	260,000	650,000	211,000	0	1,121,000
James F. Emigh	2006	140,000	—	229,000	16,000	385,000
VP, Marketing & Administration	2007	140,000	140,000	44,000	7,000	331,000
Robert A. Seiser	2006	133,000	—	275,000	16,000	424,000
VP, Corporate Controller & Treasurer	2007	133,000	140,000	53,000	7,000	333,000

1. The 2006 and 2007 entries reflect the vesting in each of 2006 and 2007 of outstanding RSUs with respect to 275,000, 146,600, 220,000, 45,833 and 55,000 underlying shares for Messrs. Reddick, Clemens, Spivey, Emigh and Seiser, respectively. The dollar amount provided is the compensation cost for such awards recognized in 2006 and 2007 in accordance with FAS 123R, as reflected in our financial statements disregarding the risk of forfeiture relating to service – based vesting conditions.

2. The 2006 entries reflect the vesting in 2006 of outstanding options with respect to 150,000, 9,375, 433,333, 6,225 and 6,225 underlying shares for Messrs. Reddick, Clemens, Spivey, Emigh and Seiser, respectively. The 2007 entries reflect the vesting in 2007 of outstanding options with respect to 9,375, 6,225 and 6,225 underlying shares for Messrs. Clemens, Emigh and Seiser, respectively. The dollar amount reported is the compensation cost for such awards recognized in 2006 and 2007 in accordance with FAS 123R, as reflected in our financial statements.

**Other Compensatory Arrangements**

The named 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 expiring December 31, 2008. 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. Mr. Reddick's base salary under the Employment Agreement is \$365,000 (increased by the Board from \$300,000 effective January 1, 2008). 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 2007 fiscal year, Mr. Reddick was awarded a bonus of \$850,000 due to, among other reasons, the successful completion of our Unit Offering and the King Agreement. The Employment Agreement also provides for our grant 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. The 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 the grant 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. 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 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. 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.

Ron J. Spivey, Ph.D., is employed pursuant to an Employment Agreement effective as of April 5, 2004, as amended, which provides that Dr. Spivey will serve as our Senior Vice President and Chief Scientific Officer for term expiring December 31, 2008. 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 Dr. Spivey at least ninety (90) days prior to the expiration of the initial term or any subsequent renewal period. Dr. Spivey's base salary under the Employment Agreement is \$315,000 (increased by the Board from \$260,000 effective January 1, 2008). Pursuant to the Employment Agreement Dr. Spivey is eligible for annual bonuses 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. In 2007, Dr. Spivey was awarded a bonus of \$650,000 due to, among other reasons, the completion of our Unit Offering and the King Agreement. The Employment Agreement also provides for our grant to Mr. Spivey of stock options exercisable for up to 700,000 shares of Common Stock at an exercise price of \$1.30 per share. The stock option provides for vesting of 100,000 shares on October 1, 2004, 33,333 shares on each January 1, 2005, April 1, 2005, July 1, 2005 and October 1, 2005, 388,867 shares on January 1, 2006 and 77,800 on April 1, 2006. 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. Because 600,000 of the discounted options are subject to Section 409A, in 2007, we established an exercise schedule to comply with Section 409A for such 600,000 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 their expiration dates. The Employment Agreement also acknowledges the grant to Dr. Spivey of a Restricted Stock Unit Award providing for our issuance of up to 660,000 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. 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, Dr. Spivey must remit to us the par value of \$0.01 per share. 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. Dr. Spivey 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 Dr. Spivey terminates the Employment Agreement for Good Reason, we are required to pay Dr. Spivey 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 Dr. Spivey'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 Dr. Spivey 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 equal monthly installments. In addition, Dr. Spivey is 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 permits Dr. Spivey to terminate the Employment Agreement in the event of a Change in Control for Good Reason (as defined in the Employment Agreement), entitling Dr. Spivey 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) options granted to Dr. Spivey vest and become exercisable as set forth in the table below entitled, "Events Affecting Option Vesting and Exercise." The Employment Agreement restricts Dr. Spivey 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, Dr. Spivey has agreed not to (and not to cause or direct any person to) hire or solicit for employment any of our employees or those of our subsidiaries or affiliates (i) for six (6) months following the

termination of his employment by us without Cause or by him for Good Reason, prior to a Change of Control, (ii) for twelve (12) months following the termination of his employment for Cause, prior to a Change of Control, or (iii) twenty-four (24) months following a Change of Control. The table entitled “Events Affecting Option Vesting and Exercise,” below, summarizes the vesting and exercisability of Mr. Spivey’s 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 expiring December 31, 2008. 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. Mr. Clemens current base salary under the Employment Agreement is \$205,000 (increased from \$180,000 effective January 1, 2008). 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 2007, Mr. Clemens was awarded a bonus of \$180,000 due to, among other reasons, the completion of our Unit Offering and the King Agreement. 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. 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. 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. 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 \$310,000 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. Clemen's options following a number of termination scenarios or a Change of Control.

**EVENTS AFFECTING STOCK OPTION VESTING AND EXERCISE  
(FOR MESSRS. REDDICK, SPIVEY AND CLEMENS)**

	<b>Vesting of All Options</b>	<b>Exercisability of Options not subject to Section 409A</b>	<b>Exercisability of Options Subject to Section 409A</b>
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	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, Qualifying under Section 409A	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

Messrs. Seiser and Emigh are not parties to employment agreements.

## Stock Option Plans

We currently maintain two stock option plans adopted in 1995 and 1998, 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, 2007 incentive stock options ("ISO's") to purchase 26,251 shares and non-qualified options to purchase 10,639 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 approximately \$15.82.

### 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. As of December 31, 2007, stock options to purchase 1,821,609 shares of Common Stock had been granted under the 1998 Stock Option Plan. Of such option grants, 85,982 are ISOs and 1,735,627 are non-qualified options. The average per share exercise price for all outstanding options under the 1998 Stock Option Plan is approximately \$2.27. 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 1,699,414 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, Spivey, Seiser and Emigh. In no event are these options exercisable outside the calendar year in which they first become exercisable. See "Events Affecting Option Vesting and Exercise" above for the vesting and exercise of options granted to Messrs. Reddick, Spivey and Clemens.

### **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. 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. RSUs for up to 3 million shares of common stock are authorized for issuance under the 2005 RSU Plan. 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.

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 awardee (the "Immediate Family Members"), (ii) a trust or trusts for the exclusive benefit of such Immediate Family Members, or (iii) a partnership in which such Immediate Family Members are the only partners, provided that (x) there may be no consideration for any such transfer, (y) subsequent transfers of transferred RSUs shall be prohibited except those made by will or by the laws of descent or distribution, and (z) such transfer is approved in advance by the Committee (or Board in absence of a Committee). A married recipient may generally designate only a spouse as a



beneficiary unless spousal consent is obtained.

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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.

As of December 31, 2007 we had granted RSUs providing for our issuance of up to an aggregate of 2,950,000 shares of our common stock. 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. The remaining 200,000 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.

### Outstanding Equity Awards at 2007 Year End and Option Exercises in 2007

The following table presents information regarding outstanding stock awards at December 31, 2007 for each of the named executive officers: All RSU awards granted to named executive officers had vested at December 31, 2007.

#### OUTSTANDING EQUITY AWARDS AT 2007 YEAR-END

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Awards		Option Expiration Date
			Option Exercise Price (\$)		
Andrew D. Reddick	875,000	—	\$ 1.30		08/12/2014
Peter A. Clemens	30,000	—	\$ 23.75		02/19/2008
	10,000	—	\$ 11.25		03/08/2009
	12,500	—	\$ 18.75		02/17/2010
	10,000	—	\$ 11.125		06/29/2010
	28,125	9,375	\$ 1.30		03/09/2014
Ron J. Spivey	300,000	—	\$ 1.30		04/15/2014
	400,000	—	\$ 1.30		12/09/2015
Robert A. Seiser	4,000	—	\$ 25.00		05/29/2008
	1,600	—	\$ 11.25		03/08/2009
	3,000	—	\$ 18.75		02/17/2010
	4,000	—	\$ 11.125		06/29/2010
	2,500	—	\$ 24.60		11/15/2011
	18,675	6,225	\$ 1.30		03/09/2014
James F. Emigh	1,000	—	\$ 25.00		05/29/2008
	1,000	—	\$ 15.00		10/13/2008
	1,600	—	\$ 11.25		03/08/2009
	5,000	—	\$ 18.75		02/17/2010
	4,000	—	\$ 11.125		06/29/2010
	2,500	—	\$ 24.60		11/15/2011
	18,675	6,225	\$ 1.30		03/09/2014

The following table presents information regarding the value realized on the vesting during 2007 of RSU awards to the named executive officers. No stock options were exercised by the named executive officers during 2007.

### OPTION EXERCISE AND STOCK VESTED IN FISCAL YEAR 2007

Name	Number of Shares Vested (#) <sup>(1)</sup>	Stock Awards	
		Value Realized on Vesting (\$) <sup>(2)</sup>	
Andrew D. Reddick	275,000	\$	3,331,625
Peter A. Clemens	146,667		1,776,859
Ron J. Spivey	220,000		2,665,300
James F. Emigh	45,833		555,267
Robert A. Seiser	55,000		666,325

(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 OTCBB on each vesting date and multiplying the result by the number of shares underlying the RSUs that vested on such date and then aggregating those results.

### Securities Authorized For Issuance Under Equity Compensation Plans

The following table includes information as of December 31, 2007 relating to our 1995 and 1998 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 (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a) (c)
Stock Option Equity Compensation Plans Approved by Security Holders	1,858,499	\$ 2.53	102,666
Stock Option Equity Compensation Plans Not Approved by Security Holders	0	0	0
Restricted Stock Unit Equity Compensation Plans Approved by Security Holders	2,950,000	0.01	50,000
Restricted Stock Unit Equity Compensation Plans Not Approved by Security Holders	0	0	0
<b>TOTAL</b>	<b>4,808,499</b>	<b>\$ 0.99</b>	<b>152,666</b>

**Potential Payments Upon Termination or Change in Control**Messrs. Emigh and Seiser

Options. If a change of control occurs (which constitutes a change of control under the stock option agreements) previously unvested options vest with respect to all underlying shares (relating to 6,225 shares for each of Messrs. Emigh and Seiser, as of December 31, 2007. Messrs. Emigh and Seiser would realize a benefit of \$442 and \$442, respectively, from such option vesting if such change of control had occurred on December 31, 2007. 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 each of Messrs. Emigh and Seiser to purchase 24,900 shares of common stock become exercisable in full.

RSUs. As of December 31, 2007, all RSUs granted to Messrs. Emigh and Seiser had vested. 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 2007 in our financial statements in accordance with FAS 123R, had such accelerated vesting/distribution occurred.

Messrs. Reddick, Spivey and Clemens

Based upon a hypothetical triggering date of December 31, 2007, the quantifiable benefits for Messrs. Andrew Reddick, Peter Clemens and Ron Spivey upon a termination/change of control would have been as set forth the table below:

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Triggering Event	Executive	Severance	Bonus	Value of Options Vesting (4)	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	300,000(1)(8)	—(3)	(5)	26,270(6)	326,270
	Ron J. Spivey	260,000(1)(9)	—(3)	(5)	7,875(6)	267,875
	Peter A. Clemens	360,000 <sup>(2)</sup> (10)	(3)	666	52,540 <sup>(11)</sup>	413,206
Termination for Death	Andrew D. Reddick	—	(3)	—	—	—
	Ron J. Spivey	—	—	—	—	—
	Peter A. Clemens	—	—	—	—	—
Termination for Disability	Andrew D. Reddick	—	(3)	—	—	—
	Ron J. Spivey	—	—	—	—	—
	Peter A. Clemens	—	—	—	—	—
Termination with Cause	Andrew D. Reddick	—	—	—	—	—
	Ron J. Spivey	—	—	—	—	—
	Peter A. Clemens	—	—	—	—	—
Change of Control	Andrew D. Reddick	—	—	(5)	—	—
Without Termination	Ron J. Spivey	—	—	(5)	—	—
	Peter A. Clemens	—	—	666	—	666

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, 2007, named executives would not have been entitled to any additional bonuses upon termination at December 31, 2007.

(4) The dollar amount reported is the compensation cost for such awards that would have been recognized in 2007 in our financial statements in accordance with FAS 123R had the unvested stock options at December 31, 2007 vested at such date. See "Employment Agreements" for a description of the exercise periods following termination.

(5) Messrs. Reddick and Spivey have no outstanding unvested options. See "Employment Agreements" for discussion of option vesting and exercisability upon termination.

(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, 2007. Effective January 1, 2008, Mr. Reddick's salary was increased to \$365,000 per annum.

(9) Represents one year of salary, at the rate in effect on December 31, 2007. Effective January 1, 2008, Mr. Spivey's salary was increased to \$315,000 per annum.

(10) Represents two years of base salary, at the rate in effect on December 31, 2007. Effective January 1, 2008, Mr. Clemens salary was increased to \$205,000 per annum.

(11) 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, 2007:

### 2007 DIRECTOR COMPENSATION

Director	Fees Earned or Paid in Cash (\$)	Stock Awards (\$) <sup>(1)</sup>	Option Awards (\$) <sup>(2)</sup>	Total (\$)
William G. Skelly	11,500	—	—	11,500
William A. Sumner	12,000	—	—	12,000
Bruce F. Wesson	5,250	—	—	5,250
Richard J. Markham	6,250	—	—	6,250
Immanuel Thangaraj	(3)	—	—	—

(1) Messrs. Skelly and Sumner each held fully vested RSUs with respect to 100,000 underlying shares, as of December 31, 2007. Messrs. Wesson, Markham and Thangaraj held no RSUs. The dollar amount provided is the compensation cost for such awards recognized in 2007 is as reported in our financial statements in accordance with FAS 123R.

(2) Messrs. Skelly, Sumner, Wesson, Markham and Thangaraj, held vested options with respect to 29,000, 5,000, 15,000, 0 and 10,000 underlying shares, respectively, as of December 31, 2007. The dollar amount provided is the compensation cost for such awards recognized in 2007 is as reported in our financial statements in accordance with FAS 123R.

(3) Fee waived.

Under the Director compensation program in effect in 2006 and 2007, non-employee Directors received \$500 for each meeting attended (\$250 in the case of telephonic meetings) and non-employee Directors who served on any of the Committees established by the Board of Directors received \$250 for each Committee meeting attended unless held on the day of a full Board meeting. Non-employee Directors were eligible to receive, at the discretion of the Board, an annual grant of options to purchase 5,000 shares of our common stock. No such option grants were made to any Director in 2006 or 2007. We also reimbursed Directors for travel and lodging expenses, if any, incurred in connection with attendance at Board meetings.

In January 2008, in order to retain and attract excellent directors, our Board amended the Director compensation program to provide 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, except in the case of the stock option grants for 2008, in which case the exercise price was equal to the last sale price for our common stock on January 24, 2008 (the date of adoption by the Board of the new board compensation program) as reported by the OTC Bulletin Board. 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 continue to reimburse Directors for travel and lodging expenses, if any, incurred in connection with attendance at Board meetings.

In addition, on February 11, 2006, we granted to each of Messrs. William Sumner and William Skelly Restricted Stock Unit Awards providing for our issuance of up to 100,000 shares of our common stock. The Restricted Stock Unit Awards are made pursuant to our 2005 Restricted Stock Unit Award Plan and are in consideration of the services provided to us by Messrs. Sumner and Skelly as independent members of the Board and as representatives of the Independent Committee of the Board of Directors for various material transactions undertaken by us during the period 2002 through 2005, including, without limitation, our debenture offerings in 2002 and 2004, the conversion of our preferred stock into common stock and various bridge loans financing transactions, as well as for their continued service as directors of the Company. The Restricted Stock Unit Awards to each of Messrs. Sumner and Skelly vested 38,889 shares on grant and the balance vest in equal monthly installments on the first day of each month beginning March 1, 2006 and ending December 1, 2007. The vested shares underlying the Restricted Stock Unit Awards will be issued by us on the earlier of (i) a Change in 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 in Control, we will issue the vested shares underlying the Restricted Stock Unit Award 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 the issuance of the vested shares underlying the Restricted Stock Unit Awards, Messrs. Sumner and Skelly must pay us the \$0.01 par value per share.

### **Compensation Committee Interlocks and Insider Participation**

During 2007 our Compensation Committee consisted of Messrs. Markham, Skelly and Reddick. Except for Mr. Reddick, who is our President and Chief Executive Officer, there were no Compensation Committee interlocks or insider participation in compensation decisions. See Employment Agreements” for a discussion of Mr. Reddick’s employment agreement.

### **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, 2008, 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 2007 exceeded \$100,000 (the "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)	77.7%
Vivo Ventures Fund VI, L.P. 575 High St, Suite 201 Palo Alto, CA 9430131	2,450,000(3)	5.7%
Andrew D. Reddick	875,000(4)	2.0%
Ron J. Spivey	700,000(5)	1.6%
William G. Skelly	33,333(6)	*
Bruce F. Wesson	—(2)(7)	*
William A. Sumner	24,000(8)	*
Peter A. Clemens	105,080(9)	*
Richard J. Markham	—(2)(10)	*
Immanuel Thangaraj	—(2)(11)	*
Robert A. Seiser	40,000(12)	*
James F. Emigh	44,500(13)	*
George K. Ross	5,000(14)	*
All Officers and Directors as a Group (11 persons)	1,826,913(15)	4.1%

\* 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, 2008 into the Company's common stock, and (ii) no other Company securityholder converts any of its convertible securities. No shares held by any Director or 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 Wilkenson, 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.

(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. 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.

- (4) Includes 875,000 shares subject to currently exercisable stock options. Excludes 825,000 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 700,000 shares subject to currently exercisable stock options. Excludes 660,000 RSUs granted to Dr. Spivey. Dr. Spivey 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 29,000 shares subject to currently exercisable stock options. 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) Mr. Wesson's holdings do not include securities held by GCE or (i) 183,886 shares; (ii) 470,184 shares underlying warrants; or (iii) 15,000 shares underlying options, held by Galen.
- (8) Includes 5,000 shares subject to currently exercisable stock options. 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 100,000 shares subject to stock options exercisable with 60 days of March 1, 2008. Excludes 440,000 RSUs granted to Mr. Clemens. 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 4,780 shares held by minor children.
- (10) Mr. Markham's holdings do not include amounts held by GCE or (i) 111,689 shares; or (ii) 15,000 shares underlying warrants, held by Care Capital.
- (11) Mr. Thangaraj's holdings do not include GCE's holdings or (i) 136,178 shares; (ii) 34,500 shares underlying warrants; or (iii) 10,000 shares underlying options, held by Essex.
- (12) Includes 40,000 shares subject to stock options exercisable within sixty days of March 1, 2008. Excludes 165,000 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 40,000 shares subject to stock options exercisable within 60 days of March 1, 2008. Excludes 137,500 RSUs granted to Mr. Emigh. Mr. Emigh 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 5,000 shares which Mr. Ross has the right to acquire within 60 days of February 1, 2008 through exercise of outstanding stock options.
- (15) Includes 36,103 shares which Directors and executive officers have the right to acquire within 60 days of February 1, 2008 through exercise of outstanding stock options.



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

### Certain Relationships and Related Transactions

GCE Holdings LLC, our 78% stockholder ("GCE") is the assignee of all of our shares of preferred stock (prior to their conversion 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.

We were a party to a certain loan agreement with each of the VC Investors and certain of our other shareholders dated February 10, 2004 (the "\$5.0 Million Secured Term Note"). The \$5.0 Million Secured Term Note was in the principal amount of \$5.0 million and was secured by a lien on all of our assets and the assets of our subsidiary. On June 28, 2007, the \$5.0 Million Secured Term Note was amended to extend the maturity date from June 30, 2007 to September 30, 2007 and further amended on August 20, 2007 to extend the maturity date from September 30, 2007 to December 31, 2008. In addition, the August 20, 2007 amendment to the \$5.0 Million Secured Term Note reduced the interest rate from a variable rate of prime plus 4.5%, to a fixed rate of 10.0% per annum and to provide for interest payments in the form of cash instead of our common stock. During September 2007 approximately \$8,000 of principal was repaid under the \$5.0 Million Secured Term Note leaving a principal balance of \$4,992,000. In accordance with the terms of the \$5.0 million Secured Term Note on December 7, 2007, simultaneous with our receipt of the non-refundable \$30 million upfront cash payment received from King under the King Agreement, we satisfied in full all of our obligations under the \$5.0 Million Secured Term Note.

During the period from June 2005 through July 2007 we borrowed an aggregate of \$10.544 million pursuant to a series of loan agreements between us, the VC Investors and certain other shareholders (the "Bridge Loans). We used the net proceeds from the Bridge Loans to develop our Aversion® Technology and fund related operating expenses. The Bridge Loans carried an interest rate of 10%, payable quarterly which, pursuant a November 2006 amendment, was payable, at the Company's option, with shares of its Common Stock. The Bridge Loans, as amended in March 2007, had a scheduled maturity date of September 30, 2007. In accordance with the conversion provisions contained in the Bridge Loans, the outstanding \$10.544 million principal balance under Bridge Loans was converted into our units upon the closing of our Unit Offering described below. As a result, the Bridge Loan Agreements and all related security agreements and guaranties were terminated.

During 2007, we paid an aggregate of \$145,000 in cash interest under the Bridge Loans (of which \$47,000 was paid to each of Galen, Care and Essex) and issued an aggregate of 47,300 shares of our common stock in satisfaction of interest payments under the Bridge Loans (of which 15,300 shares were issued to each of Galen, Care and Essex)(on a post reverse stock split basis).

On August 20, 2007, we entered into a Securities Purchase Agreement with GCE Holdings LLC, our controlling shareholder, and the investors named therein (collectively, the “Unit Investors”). Pursuant to the Agreement, the Unit Investors purchased in the aggregate (on a post reverse stock split basis) 2,365,185 of our Units (“Units”), at a price of \$10.80 per Unit (the “Unit Offering”). Each Unit consisted of four shares of common stock and a warrant to purchase one share of common stock (the “Warrants”). 1,388,889 of the Units were issued for cash, with the balance of 996,296 Units issued to GCE Holdings LLC, as assignee of the Bridge Loans from the VC Investors, in consideration of the conversion of an aggregate of \$10.544 million in principal amount under our outstanding Bridge Loans. The net cash proceeds to us after expenses of the Unit Offering were approximately \$14.2 million.



The Warrants issued in the Unit Offering are immediately exercisable at a price of \$3.40 per share (on a post reverse stock split basis) and expire August 20, 2014. The Warrants may be exercised for cash, or on a cashless basis commencing 180 days after the closing if at the time of exercise the shares underlying the Warrants are not covered by an effective registration statement filed with the SEC.

At the time of issuance, the common stock and shares of common stock underlying the Warrants sold pursuant to the Unit Offering were not registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States in the absence of an effective registration statement or exemption from registration requirements. 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 (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 six 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 78% 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 2007 and 2006 were as follows:

	2006	2007
Audit Fees	\$ 87,600	\$ 85,825
Audit-Related Fees	-	-
Total Audit and Audit-Related Fees	87,600	85,825
Tax Fees	25,600	30,168
All Other Fees	1,333	-
Total for BDO Seidman, LLP	\$ 114,533	\$ 115,993

Audit Fees include professional services rendered in connection with the annual audits of our financial statements, and the review of the financial statements included in our Forms 10-Q for the related annual periods. Additionally, Audit Fees include other services that only an independent registered public accounting firm can reasonably provide, such as services associated with SEC registration statements or other documents filed with the SEC or used in connection with financing activities.

Audit-Related Fees include the audits of employee benefit plans and 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 and federal tax returns and review of Section 409 compliance.

### 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 2007 and 2006 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 5, 2008

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 5, 2008
/s/ Peter A. Clemens Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2008
/s/ William G. Skelly William G. Skelly	Director	March 5, 2008
/s/ Bruce F. Wesson Bruce F. Wesson	Director	March 5, 2008
/s/ William A. Sumner William A. Sumner	Director	March 5, 2008
/s/Richard J. Markham Richard J. Markham	Director	March 5, 2008
/s/ Immanuel Thangaraj Immanuel Thangaraj	Director	March 5, 2008
/s/ George K. Ross George K. Ross	Director	March 5, 2008

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**Report of Independent Registered Public Accounting Firm**

Board of Directors and Stockholders  
ACURA PHARMACEUTICALS, INC.  
Palatine, Illinois

We have audited the accompanying consolidated balance sheets of Acura Pharmaceuticals, Inc. and Subsidiary as of December 31, 2007 and 2006 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, 2007. 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 consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Acura Pharmaceuticals, Inc. and Subsidiary at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

As described in Note A.13 to the consolidated financial statements, effective January 1, 2006, the Company adopted the fair value method of accounting provisions of Statement of Financial Accounting Standard No. 123 (revised 2004), "Share Based Payment".

/s/ BDO Seidman,  
LLP

Chicago, Illinois  
March 5, 2008



**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS****DECEMBER 31, 2007 and 2006****(in thousands except share data)**

	<b>2007</b>	<b>2006</b>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 31,368	\$ 228
Collaboration revenue receivable	2,977	-
Prepaid clinical study costs	388	-
Prepaid insurance	202	179
Prepaid expenses and other current assets	47	60
Deferred income taxes	9,600	-
Total current assets	44,582	467
Property, plant and equipment, net	1,046	1,145
Deposits	-	7
Total assets	\$ 45,628	\$ 1,619
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities		
Senior secured convertible bridge term notes, net	\$ -	\$ 7,005
Conversion features on bridge term notes	-	16,750
Secured term note	-	5,000
Current maturities of capital lease obligations	-	25
Deferred program fee revenue – current portion	21,942	-
Accrued expenses	334	328
Total current liabilities	22,276	29,108
Non-current liabilities		
Common stock warrants	-	10,784
Capital lease obligations, less current maturities	-	7
Deferred program fee revenue - non current portion	4,632	-
Total liabilities	26,908	39,899
Commitments and contingencies (Note J)		
Stockholders' equity (deficit)		
Common stock - \$.01 par value; 650,000,000 shares authorized; 42,706,466 and 33,099,846 shares issued and outstanding in 2007 and 2006, respectively	427	331
Additional paid-in capital	340,153	278,932
Accumulated deficit	(321,860)	(317,543)
Total stockholders' equity (deficit)	18,720	(38,280)
Total liabilities and stockholders' equity	\$ 45,628	\$ 1,619

See accompanying notes to the consolidated financial statements.

**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF OPERATIONS****YEARS ENDED DECEMBER 31, 2007, 2006 and 2005****(in thousands except per share data)**

	2007	2006	2005
<b>Revenues</b>			
Program fee revenue	\$ 3,427	\$ -	\$ -
Collaboration revenue	2,977	-	-
Total revenue	6,404	-	-
<b>Operating expenses</b>			
Research and development expense	7,169	5,172	6,265
Marketing, general and administrative expense	4,141	5,654	5,296
Total operating expenses	11,310	10,826	11,561
Loss from operations	(4,906)	(10,826)	(11,561)
<b>Other income (expense)</b>			
Interest income	268	18	36
Interest expense	(1,207)	(1,140)	(636)
Amortization of debt discount	(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	-
Gain (loss) on asset disposals	22	(22)	81
Other (expense) income	(3)	(213)	5
Total other income (expense)	(9,008)	4,859	(514)
Loss before income tax benefit	(13,914)	(5,967)	(12,075)
Income tax benefit	(9,600)	-	-
Net loss	\$ (4,314)	\$ (5,967)	\$ (12,075)
<b>Basic and diluted loss per share applicable to common stockholders (Note A)</b>	\$ (0.11)	\$ (0.75)	\$ (1.81)
<b>Weighted average shares used in computing basic and diluted loss per share allocable to common stockholders</b>	39,157	34,496	6,680

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005

(in thousands except par values)

	Common Stock \$0.01 Par Value		Preferred Stock \$0.01 Par Value		Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
<b>Balance at January 1, 2005</b>	2,247	\$ 23	217,973	\$ 2,180	\$ 277,330	\$ (1,078)	\$ (279,541)	\$ (1,086)
Net loss for the year ended December 31, 2005							(12,075)	(12,075)
Intrinsic value of issued options and restricted stock units					11,105	(11,105)		-
Amortization of unearned compensation						6,459		6,459
Issuance of Common Shares for exercise of options	3	-			5			5
Issuance of Common Shares for interest	96	1			534			535
Conversion of Preferred Shares:								
Series A Convertible Preferred	10,982	110	(21,964)	(220)	110			-
Series B Junior Convertible	2,025	20	(20,246)	(203)	183			-
Series C-1 Junior Convertible	5,642	56	(56,423)	(564)	508			-
Series C-2 Junior Convertible	3,743	37	(37,433)	(374)	337			-
Series C-3 Junior Convertible	8,191	82	(81,907)	(819)	737			-
<b>Balance at December 31, 2005</b>	32,929	\$ 329	-	\$ -	\$ 290,849	\$ (5,724)	\$ (291,616)	\$ (6,162)
Net loss for the year ended December 31, 2006							(5,967)	(5,967)
Deemed dividend related to debt modification							(19,960)	(19,960)
Adoption of FAS 123R					(5,724)	5,724		-
Issuance of restricted stock units					680			680
					5,046			5,046

Other stock based compensation									
Reclassification of value of common stock warrants to liabilities					(12,948)			(12,948)	
Issuance of Common Shares for exercise of options	40	1			97			98	
Issuance of Common Shares for interest	128	1			932			933	
Issuance of Common Shares for cashless exercise of warrant	2							-	
<b>Balance at December 31, 2006</b>	33,099	\$ 331	-	\$ -	\$ 278,932	\$ -	\$ (317,543)	\$ (38,280)	
Net loss for the year ended December 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)	-			-			-	
<b>Balance at December 31, 2007</b>	42,706	\$ 427	-	\$ -	\$ 340,153	\$ -	\$ (321,860)	\$ 18,720	

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2007, 2006, and 2005

(in thousands, except supplemental data)

	2007	2006	2005
Cash flows from operating activities:			
Net loss	\$ (4,314)	\$ (5,967)	\$ (12,075)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	130	118	137
Amortization of debt discount	2,700	183	-
Loss (gain) on the fair value change of conversion features	3,483	(4,235)	-
Loss (gain) on the fair value change of common stock warrants	1,905	(2,164)	-
Non-cash stock compensation expense	915	5,724	6,459
(Gain) loss on asset disposals	(22)	22	(81)
Common stock issued for interest	812	933	535
Deferred income taxes	(9,600)	-	-
Impairment charge against fixed assets	-	71	-
Changes in assets and liabilities			
Collaboration revenue receivable	(2,977)	-	-
Prepaid expenses and other current assets	(398)	(55)	121
Other assets and deposits	7	-	(5)
Accrued expenses	5	(13)	(618)
Deferred program fee revenue	26,574	-	-
Net cash provided by (used in) operating activities	19,220	(5,383)	(5,527)
Cash flows from investing activities:			
Capital expenditures	(31)	(85)	(35)
Proceeds from asset disposals	22	70	193
Net cash (used in) provided by investing activities	(9)	(15)	158
Cash flows from financing activities:			
Proceeds from issuance of senior secured bridge term notes	2,696	5,298	2,550
Repayments on secured term note	(5,000)	-	-
Net proceeds from the unit offering	14,146	-	-
Proceeds from exercise of stock options	119	98	5
Payments on capital lease obligations	(32)	(31)	(29)
Net cash provided by financing activities	11,929	5,365	2,526
Net increase (decrease) in cash and cash equivalents	31,140	(33)	(2,843)
Cash and cash equivalents at beginning of period	228	260	3,103
Cash and cash equivalents at end of period	\$ 31,368	\$ 228	\$ 260

Cash paid during the period:

Interest	\$	395	\$	207	\$	101
Income taxes	\$	-	\$	-	\$	-

See accompanying notes to the consolidated financial statements.

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**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)**  
**YEAR ENDED DECEMBER 31, 2007, 2006, and 2005**

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

Year ended December 31, 2007

1. The Company issued 47,552 shares of common stock valued at \$460,000 as payment of Senior Secured Convertible Bridge Term Notes Payable accrued interest.
2. The Company issued 36,150 shares of common stock valued at \$352,000 as payment of Secured Term Note Payable accrued interest.
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.

Year ended December 31, 2006

1. The Company issued 85,464 shares of Common Stock as payment of \$624,000 of Secured Term Note Payable accrued interest.
2. The Company issued 42,650 shares of Common Stock as payment of \$309,000 of Bridge Loan Notes Payable accrued interest.
3. Warrants to purchase 16,593 shares of Common Stock were exercised in March 2006 at an exercise price of \$4.80 per share in a cashless exercise transaction resulting in the issuance of 19,065 shares of Common Stock.
4. Warrants to purchase 3,069 shares of Common Stock were exercised in May 2006 at an exercise price of \$4.70 per share in a cashless exercise transaction resulting in the issuance of 473 shares of Common Stock.
5. A warrant to purchase 15,000 shares of Common Stock was modified due to its anti-dilution clause resulting in a \$142,000 stock compensation expense.
6. The modification of conversion features embedded within Bridge Loan Notes Payable was valued at \$19,951,000 and the issuance of \$1,104,000 of Bridge Loan Notes Payable contained conversion features valued at \$1,035,000. The change in the conversion feature's fair value through December 31, 2006 resulted in a gain of \$4,235,000.
7. Due to certain debt conversion feature modifications, the then current fair value of all 16,331,000 outstanding common stock warrants of \$12,948,000 was reclassified from equity to liabilities. The change in the common stock warrants fair value through December 31, 2006 resulted in a gain of \$2,164,000.

8. Bridge Loan Notes Payable of \$1,104,000 contained \$1,025,000 of debt discount.

Year ended December 31, 2005

1. The Company issued 96,300 shares of common stock as payment of \$535,000 of Secured Term Note Payable accrued interest.
2. 21,797,300 shares of Convertible Preferred Stock were converted into 30,582,800 shares of Common Stock.

See accompanying notes to the consolidated financial statements.

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**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**DECEMBER 31, 2007, 2006 and 2005**

**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 innovative Aversion® Technology and related product candidates. Product candidates developed with Aversion® Technology and containing opioid analgesic active ingredients are intended to effectively treat pain and also discourage the three most common methods of pharmaceutical product misuse and abuse including; (i) intravenous injection of dissolved tablets or capsules, (ii) nasal snorting of crushed tablets or capsules and (iii) intentional swallowing of excessive numbers of tablets or capsules. ACUROX™ Tablets, the Company’s lead product candidate utilizing Aversion® Technology, is being developed pursuant to an active investigational new drug application (“IND”) on file with the U.S. Food and Drug Administration (“FDA”). Aversion® Technology is our patented platform technology for developing next-generation pharmaceutical products containing potentially abuseable drugs including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, tramadol, propoxyphene, and many others. Additional Aversion® Technology patents are pending encompassing a wide range of abuseable drugs including stimulants, tranquilizers and sedatives. Aversion® Technology is applicable to orally administered tablets and capsules. In addition to the active ingredient, Aversion® Technology utilizes certain patented compositions of pharmaceutical product inactive excipients and active ingredients intended to discourage or deter pharmaceutical product abuse.

The Company conducts internal research, development, laboratory, manufacturing and warehousing activities for Aversion® Technology at its Culver, Indiana facility. The 28,000 square foot facility is registered by the U.S. Drug Enforcement Administration (“DEA”) to perform research, development and manufacture of certain Schedule II - V finished dosage form products. In addition to internal capabilities and activities, the Company engages numerous contract 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 development services for ACUROX™ Tablets and other product candidates under the direction of the Company.

Amounts presented have been rounded to the nearest thousand, except where indicated, share and per share data. The equity amounts and all share and per share data of the Company have been retroactively adjusted to reflect a one-for-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. During 2006, the Company dissolved Axiom Pharmaceutical Corporation. The dissolution of this subsidiary had no impact on the consolidated financial position, results of operations or cash flows of the Company.

**2. Cash, Cash Equivalents, and Credit Risk**

The Company considers all highly liquid financial instruments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist of cash maintained at two financial institutions and in repurchase agreement investments at year end. We believe the financial risks associated with these instruments to be minimal. We have not experienced any losses from our investments in these securities.

### **3. 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.

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#### 4. Inventories

The Company had no inventories at each of December 31, 2007 and 2006. Purchases of active pharmaceutical ingredients required for the Company's development and manufacture of product candidates utilizing its Aversion® Technology, are expensed as incurred. To purchase certain active ingredients required for our development and manufacture, we are required to file for and obtain quotas from the DEA.

#### 5. 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. Amortization of capital lease assets is included in depreciation expense. 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 building 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
Furniture and fixtures	10 years

#### 6. Asset Impairment

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying value may not be recoverable. Impairment is measured by comparing the carrying value of the long-lived assets to the estimated undiscounted future cash flows expected to result from use of the assets and their ultimate disposition. To the extent impairment has occurred, the carrying amount of the asset would be written down to an amount to reflect the fair value of the asset. During the fourth quarter of 2006, the Company provided a \$71,000 reserve against the net book value of assets assigned to the Company's Opioid Synthesis Technologies as the Company had discontinued all activities relating to this technology. At December 31, 2006, the net book value of all asset groups under reserve was \$166,000. During 2007, group assets in the amount of \$59,000 from the Opioid Synthesis Technologies were disposed of resulting in a recorded gain of \$20,000. Additional other reserved assets of \$25,000 were also disposed of resulting in neither gain nor loss. At December 31, 2007 the net book value of group assets under reserve was \$82,000.

#### 7. Debt Discount

Debt discount resulting from the issuance of common stock warrants in connection with the issuance of 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. Inherent in the Black-Scholes valuation model are assumptions made by management regarding the estimated life of the warrant, the estimated volatility of the Company's common stock (as determined by reviewing its historical public market closing prices) and the expected dividend yield.

#### 8. Debt Conversion Features and Common Stock Warrants

Certain provisions of the amended conversion features contained in the Company's Bridge Loans required the Company to separate the value of the conversion feature from this debt and record such value as a separate liability which was marked-to-market 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 recording of further gains and losses.

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As a result of the amendment to the Bridge Loans, 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 which resulted in recording of further gains and losses.

## **9. Revenue Recognition and Deferred Program Fee Revenue**

We recognize revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements" ("SAB 104"). We have also adopted the provisions of Emerging Issues Task Force, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). Revenue is recognized 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 Agreement with King, we recognize program fee revenue, collaboration revenue and milestone revenue. Program fee revenue is derived from the upfront payment from King received in December 2007. We have assigned a portion of the license fee revenue to each of the product candidates included under the Agreement and recognize the program fee ratably over our estimate of the development period for each of the products under the Agreement with King. Collaboration revenues from reimbursement of development expenses, which are invoiced quarterly in arrears, are recognized when costs are incurred pursuant to the Agreement with King. King is obligated to pay us milestone payments contingent upon the achievement of certain substantive events in the clinical development of ACUROX™ Tablets and the other product candidates under the Agreement. We recognize milestone payments from King as revenue when we achieve the underlying developmental milestone as the milestone payments are not dependent upon any other future activities or achievement of any other future milestones and the achievement of each of the developmental milestones were substantively at risk and contingent at the effective date of the collaboration. Substantial effort is involved in achieving each of the developmental milestones. These milestones represent the culmination of discrete earnings processes and the amount of each milestone payment is reasonable in relation with the level of effort associated with the achievement of the milestone. Each milestone payment is non-refundable and non-creditable when made. 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 \$3,427,000 of program fee revenue, \$2,977,000 of collaboration revenue and \$0 of milestone revenue in 2007.

## **10. 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, regulatory counsel, and patent 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 including payments in advance of the study starting date. The Company reviews and accrues CRO and clinical trial study expenses based on work performed and rely on estimates of those costs applicable to the stage of completion of a study 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 \$388,000 was prepaid at December 31, 2007. The unfunded CRO commitments were \$3,991,000 and \$162,000 at December 31, 2007 and 2006, respectively, 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 in accordance with Statement of Financial Accounting Standards No. 109 ("SFAS No. 109"), "Accounting for Income Taxes." 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. SFAS 109 requires a valuation allowance 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 the Fourth Quarter 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 a \$9.6 million adjustment to the deferred income tax asset valuation allowance. This adjustment recognized a benefit from income taxes in our income for such period and provided a current deferred income tax asset. At both December 31, 2007 and 2006, a valuation allowance equal to 100% of the remaining net deferred income tax assets was used and primarily pertains 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 (Loss) 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 2007, 2006 or 2005 as their effects would be antidilutive.

Net loss used in the Company's earnings (loss) per share computations includes the impact in 2007 and 2006 of dividends deemed to have been issued to certain common shareholders as a result of modifications to debt agreements with those shareholders as further described in Note F.

(in thousands except per share data)	Year ended December 31,		
	2007	2006	2005
<b>Numerator:</b>			
Net loss	\$ (4,314)	\$ (5,967)	\$ (12,075)
Deemed dividend from modification of debt	(3)	(19,960)	-
Net loss applicable to common stock holders	\$ (4,317)	\$ (25,927)	\$ (12,075)
<b>Denominator:</b>			
<b>Weighted average number of outstanding -</b>			
Common shares	36,656	32,986	6,657
Vested restricted stock units	2,501	1,510	23
Weighted average shares	39,157	34,496	6,680
Basic and diluted loss per common share	\$ (0.11)	\$ (0.75)	\$ (1.81)

## Potentially dilutive securities:

## Common stock issuable (1) -

## Employee and director stock

options	1,858	1,900	1,975
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Common stock warrants	3,972	1,633	1,624
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## Non-vested restricted stock

units	-	983	1,834
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Convertible debt	-	3,306	-
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Convertible preferred stock	-	-	-
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Dilutive shares	4,820	7,822	5,433
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(1) Number of shares issuable 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 required if the securities were dilutive.

**13. Stock-Based Compensation**

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

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On January 1, 2006, the Company adopted Financial Accounting Standards Board Statement No. 123 (revised 2004), "Share-Based Payment", ("FASB 123R"). This change in accounting replaces existing requirements under Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation ("SFAS 123") and eliminates the ability to account for share-based compensation transaction using Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations ("APB No. 25"). 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, the Company 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 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 had previously accounted for stock-based compensation using the intrinsic value method in accordance with APB No. 25 and had adopted the disclosure provisions of Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure, ("SFAS No. 148"), an amendment of SFAS 123. Under APB No. 25, when the exercise price of the Company's 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 the Company's 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 of SFAS No. 123(R).

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.

The following table illustrates the effect on net loss and loss per share had the Company applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation for its' stock option grant awards. Pro forma compensation expense may not be indicative of future expense.

Year ended December 31, 2005  
(in thousands except per share data)

Net loss, as reported	\$ (12,075)
Add: total stock-based employee compensation expense included in reported net loss	6,459
Deduct: total stock-based employee compensation expense determined under fair value-based method for all awards	(7,242)

Net loss, pro forma	\$	(12,858)
Loss per share:		
Basic and Diluted EPS - as reported	\$	(1.81)
Basic and Diluted EPS - as pro forma	\$	(1.90)

#### 14. Carrying Amount and Fair Value of Financial Instruments

The carrying amount of cash and cash equivalents approximates fair value due to the short-term maturities of the instruments. The carrying value of the Company's debt approximates fair value because the debt bears terms that are reflective of those terms should the Company secure additional financing.

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## **15. New Accounting Pronouncements**

### **Noncontrolling Interests in Consolidated Statements**

In December 2007, Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 160 “Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51” (“SFAS 160”). SFAS 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of ARB No. 51’s consolidation procedures for consistency with the requirements of SFAS 41 (revised 2007), Business Combinations. SFAS 160 is effective for fiscal years and interim periods within those fiscal years beginning on or after December 15, 2008. Earlier adoption is prohibited. SFAS 160 shall be applied prospectively as of the beginning of the fiscal year in which the Statement is adopted, except for the presentation and disclosure requirements. The presentation and disclosure requirements shall be applied retrospectively for all periods presented.

### **Business Combinations**

In December 2007, the FASB issued SFAS No. 141 (revised 2007) “Business Combinations” (“SFAS (141R)”). SFAS 141R retains the fundamental requirements of the original pronouncement requiring that the purchase method be used for all business combinations. SFAS 141R 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. SFAS 141R requires, among other things, that the acquisition related costs be recognized separately from the acquisition. SFAS 141R is applied prospectively to business combinations for which the acquisition date is on or after January 1, 2009.

### **Fair Value Option for Financial Assets and Financial Liabilities**

In February 2007, the FASB issued SFAS No. 159 “The Fair Value Option for Financial Assets and Financial Liabilities –Including an Amendment of FASB Statement No. 115” (“SFAS 159”). SFAS 159 permits an entity to elect to measure eligible items at fair value (“fair value option”) including many financial instruments. The provisions of SFAS 159 are effective for the Company as of January 1, 2008. If the fair value option is elected, the Company will report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. Upfront costs and fees related to an item for which the fair value option is elected shall be recognized in earnings as incurred and not deferred. The fair value option may be applied for a single eligible item without electing it for other identical items, with certain exceptions, and must be applied to the entire eligible item and not to a portion of the eligible item. The Company is currently evaluating the irrevocable election of the fair value option pursuant to SFAS 159.

### **Fair Value Measurements**

In September 2006, the FASB issued SFAS No. 157 “Fair Value Measurements” (“SFAS 157”), which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 is effective for the Company beginning on January 1, 2008. The requirements of SFAS 157 will be applied prospectively except for certain derivative instruments that would be adjusted through the opening balance of retained earnings in the period of adoption. In February 2008, the FASB issued Staff Position No. FAS 157-2 which provides for a one-year deferral of the effective date of SFAS 157 for non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is evaluating the impact of the adoption of SFAS 157 on its financial statements.

### **Share-Based Payment**

The Company adopted FASB 123R effective January 1, 2006 under the modified prospective method, which recognizes compensation cost beginning with the effective date (a) based on the requirements of FASB 123R for all share-based payments granted after the effective date and to awards modified, repurchased, or cancelled after that date and (b) based on the requirements of FASB Statement No. 123 for all awards granted to employees prior to the effective date of FASB 123R that remain unvested on the effective date. The only cumulative effect of initially applying this Statement for the Company was to reclassify \$5,724,000 of previously recorded unearned compensation into paid-in capital. The Company has estimated that an additional \$5,827,000 will be expensed over the applicable remaining vesting periods for all share-based payments granted to employees on or before December 31, 2005 which remained unvested on January 1, 2006. The Company anticipates that more compensation costs will be recorded in the future if the use of options and restricted stock units for employees and director compensation continues as in the past.

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**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® (abuse deterrent) Technology including ACUROX™ Tablets. The Agreement provides King with an exclusive license in the King Territory for ACUROX™ Tablets and another undisclosed opioid product candidate utilizing Acura's 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 Acura's Aversion® Technology.

Under the terms of the King Agreement, King made an upfront cash payment to Acura of \$30 million which was received in December, 2007. Depending on the achievement of certain development and regulatory milestones, King could also make additional cash payments to Acura of up to \$28 million relating to ACUROX™ Tablets and similar amounts with respect to each subsequent Aversion® Technology product developed under the Agreement. King will reimburse Acura for all research and development expenses incurred beginning from September 19, 2007 for ACUROX™ Tablets and all research and development expenses related to future products after King's exercise of its option to an exclusive license for each future product. King will record net sales of all products and for sales occurring following the one year anniversary of the first commercial sale of a licensed product, and King will pay Acura a royalty at one of 6 rates ranging from 5% to 25% based on the level of combined annual net sales for all products subject to the Agreement. King will also make a one-time cash payment to Acura of \$50 million in the first year in which the combined annual net sales of all products exceed \$750 million.

King and Acura have formed a joint steering committee to coordinate development and commercialization strategies. With King's oversight, Acura will conduct all ACUROX™ Tablet development activities through approval of a New Drug Application (“NDA”) and thereafter King will commercialize ACUROX™ Tablets in the U.S. With respect to all other products subject to the Agreement, King will be responsible for development and regulatory activities following either acceptance of an Investigational New Drug Application by the U.S. Food and Drug Administration (“FDA”) or Acura's demonstration of certain stability and pharmacokinetic characteristics for each future product. 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 products licensed.

**NOTE C – PREFERRED SHARES**

Effective November 10, 2005, all of the issued and outstanding \$0.01 par value preferred shares of the Company were automatically and mandatorily converted into the Company's common stock in accordance with the terms of the Company's Restated Certification of Incorporation. There is no convertible preferred stock outstanding at either December 31, 2007 or 2006 and share information consists of the following (in thousands):

Convertible Preferred Stock	Authorized and Available for Issuance at 12/31/07 and 12/31/06
Series A	23,036
Series B Junior	4,754
Series C-1 Junior	13,577
Series C-2 Junior	12,567
Series C-3 Junior	18,093
Total	72,027



**NOTE D - PROPERTY, PLANT AND EQUIPMENT**

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

	2007	December 31,	
		2006	
Building and building improvements	\$ 1,391	\$ 1,391	
Land and land improvements	161	161	
Machinery and equipment	598	2,183	
Scientific equipment	445	481	
Computer hardware and software	201	203	
Office equipment	42	42	
Other personal property	48	50	
	2,886	4,511	
Less accumulated depreciation and amortization (including \$36 in 2006 on capital leased assets)	(1,758)	(3,200)	
	1,128	1,311	
Less impairment reserve	(82)	(166)	
Total property, plant and equipment, net	\$ 1,046	\$ 1,145	

During 2007, the Company acquired its only asset under a capitalized lease. Equipment with a net book value of \$111,000 was recorded under capitalized leases in categories of scientific equipment and office equipment at December 31, 2006.

Depreciation and amortization expense for the years ended December 31, 2007, 2006 and 2005 was \$130,000, \$118,000 and \$137,000, respectively.

**NOTE E - ACCRUED EXPENSES**

Accrued expenses are summarized as follows (in thousands):

	2007	December 31,	
		2006	
Bonus, payroll, payroll taxes and benefits	\$ 63	\$ 62	
Legal fees	35	19	
Audit examination and tax preparation fees	120	70	
Franchise taxes	15	15	
Property taxes	34	52	
Clinical, regulatory, trademarks, and patent consulting fees	50	60	
Other fees and services	17	50	
	\$ 334	\$ 328	

**NOTE F – NOTES PAYABLE**

The Company does not have any notes payable outstanding at December 31, 2007. At December 31, 2006, notes payable consisted of the following (in thousands):

Senior secured convertible bridge term notes:	
Face value	\$ 7,848
Debt discount	(843)
	7,005
Conversion feature value	
	16,750
	\$ 23,755
Secured term note payable	
	\$ 5,000
Capital lease obligations	
	\$ 32

**(a) Convertible Bridge Term Notes**

As of August 19, 2007, the Company had borrowed \$10.544 million pursuant to a series of loan agreements dated between June 2005 to January 2006 – all as amended through July 2007 (the “Bridge Loans”), between the Company, Galen Partners III, L.P. and its affiliates, Care Capital Investments II, LP and its affiliate, and Essex Woodlands Health Ventures V, L.P. (collectively, the “VC Investors”), and certain other shareholders of the Company. The proceeds from the Bridge Loans were used by the Company to develop its Aversion® Technology and fund related operating expenses. The Bridge Loans carried an interest rate of 10%, payable quarterly which, pursuant a November 2006 amendment, was payable, at the Company’s option, with shares of its Common Stock. The Bridge Loans, as amended in March 2007, had a scheduled maturity date of September 30, 2007. On August 20, 2007, the entire \$10.544 million principal amount of the Bridge Loans was converted into the Company’s Units in the Unit Offering pursuant to the terms of the Securities Purchase Agreement dated August 20, 2007 between the Company and each of the investors listed therein.

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Through August 2006, the Bridge Loans did not include conversion provisions. An amendment to the Bridge Loans effected in August 2006 added a conversion feature which allowed, at the lenders' option, the Bridge Loans to be converted into the Company's Common Stock upon a qualifying equity financing at a conversion price equal to the per share price implicit in such equity financing. The Company did not assign any value to the new conversion feature as it did not provide the lenders with an opportunity to receive value in a conversion in excess of the face value of the debt regardless of the per share price of that equity financing.

In November 2006 and March 2007, the conversion feature of the Bridge Loans was further amended to allow the bridge loan lenders to convert the Bridge Loans into the Company's common stock, upon the completion of a third-party equity financing providing gross proceeds to the Company in the aggregate amount of at least \$5.0 million (a "Third Party Equity Financing"), a Change of Control Transaction or upon the maturity date of the Bridge Loans (each a "Triggering Event"). Upon the occurrence of a Triggering Event, the bridge lenders could convert \$3.8 million (as of August 9, 2007) of Bridge Loans into the Company's common stock at a conversion price equal to (A) in the case of the completion of a Third Party Equity Financing, the lesser of (i) 80% of the average closing bid and asked prices of the Company's common stock for the twenty trading days immediately preceding the public announcement of the Third Party Investor Financing, but not less than \$2.10 per share (ii) the average price of the securities sold by the Company in such Third Party Equity Financing (80% of such average price in the case of \$1.8 million of Bridge Loans), and (iii) \$4.40 per share for \$2.0 million of Bridge Loans and \$4.60 per share for \$1.8 million of Bridge Loans and (B) in the case of a Change of Control Transaction or upon the maturity date of the Bridge Loans, the lesser of (i) 80% of the average closing bid and asked prices of the Company's common stock for the twenty trading days immediately preceding the public announcement of the Change of Control Transaction or the maturity date, as applicable, but not less than \$2.10 per share, and (ii) \$4.40 per share for \$2.0 million of Bridge Loans and \$4.60 per share for \$1.8 million of Bridge Loans. In addition, upon a Triggering Event, the bridge lenders could convert \$2.55 million of Bridge Loans into the Company's common stock at a conversion price of \$2.00 per share, \$2.3 million of Bridge Loans at a conversion price of \$2.25 per share and \$1.894 million of Bridge Loans at a conversion price of \$2.50 per share.

The November and December 2006 issuances of Bridge Loans for an aggregate face value of \$1,104,000 included this amended conversion feature which the Company valued at an aggregate of \$1,034,000. This value was recorded as a liability with an offsetting \$1,025,000 debt discount (which was amortized over the term of the Bridge Loans) and \$9,000 of issuance loss. However, as the debt was issued to shareholders who control the Company, this loss was recorded as a non-cash deemed dividend rather than effecting net loss. Additional issuances of \$896,000 of Bridge Loans in January and February 2007 similarly had aggregate conversion feature value of \$849,000 and a loss upon issuance of \$3,000, which was recorded as a non-cash deemed dividend rather than effecting net loss.

The 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 and a loss on the modification of debt. The Company assigned a value of \$19.951 million to these conversion features at date of modification and reflected that loss as non-cash deemed dividend.

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 \$3.483 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.

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

	Mar 30, 2007	Dec 31, 2006
Company stock price	\$ 8.50	\$ 7.40
	(see #1 below)	(see #1 below)
Exercise price		
Expected dividend	0.0%	0.0%
Risk-free interest rate	5.07%	5.0%
Expected volatility	none	88.8%
Contracted term	1 day	3 months

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(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 \$1.8 million Bridge Note issuances (dated March 30, 2007, April 2, 2007, May 17, 2007, and July 10, 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 \$339,000, \$170,000, \$443,000 and \$600,000, respectively, was recorded as additional paid in capital and as debt discount, which will be amortized over the term of the notes. Upon conversion of the Bridge Loans into Units of the Unit Offering dated August 20, 2007, \$544,000 of unamortized beneficial conversion features reflected as debt discount was recorded as a reduction to additional paid in capital.

### **(b) Secured Term Note**

The Company was a party to a certain loan agreement with each of the VC Investors and certain other shareholders of the Company dated February 10, 2004 (the "2004 Secured Term Note"). The 2004 Secured Term Note was in the principal amount of \$5.0 million and was secured by a lien on all of the Company's and its subsidiary's assets. On June 28, 2007, the 2004 Secured Term Note was amended to extend the maturity date from June 30, 2007 to September 30, 2007 and further amended on August 20, 2007 to extend the maturity date from September 30, 2007 to December 31, 2008. In addition, the August 20, 2007 amendment to the 2004 Secured Term Note reduced the interest rate from a variable rate of prime plus 4.5%, to a fixed rate of 10.0% per annum and to provide for interest payments in the form of cash instead of the Company's common stock. On September 24, 2007, the 2004 Secured Term Note was further amended to provide for the accrual and deferral of accrued interest payments. Simultaneous with the Company's receipt of the \$30 million upfront cash payment received pursuant to the closing of the Agreement with King, the Company prepaid the principal amount plus \$236,000 unpaid interest relating to the 2004 Secured Term Note on December 7, 2007.

### **NOTE G – COMMON STOCK WARRANTS**

As a result of the November 2006 amendment to the outstanding Bridge Loans, the Company's outstanding common stock purchase warrants commenced being accounted for as mark-to-market liabilities with an initial recorded liability of \$12,948,000 and corresponding reduction in additional paid-in capital. The mark to market fair value adjustments to the warrant liability resulted in a \$2,164,000 gain recorded in the 4<sup>th</sup> quarter 2006 and a recorded liability of \$10,784,000 at December 31, 2006. Upon revaluing the warrants just before their exercise or 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 \$1,668,000 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 warrant liability. A Bridge Loan agreement 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 warrants were no longer required to be reflected as Company liabilities. As such, the Company recorded a \$12,307,000 million reclassification of that liability to additional paid-in capital in addition to a \$146,000 reclassification related to warrants exercised during the first quarter of 2007.

At December 31, 2007, the Company had outstanding common stock purchase warrants, exercisable for an aggregate of approximately 3,972,000 shares of common stock, all of which contained cashless exercise features. During 2007, warrants to purchase an aggregate 580,092 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 313,616 shares of Common Stock. At December 31, 2007, outstanding common stock purchase warrants of 47,000, 409,000, 81,000

and 3,435,000 will expire if unexercised during the 2008, 2009, 2010 and years thereafter, respectively, and have a weighted average remaining term of 5.76 years. The exercise prices of these warrants range from \$1.20 to \$9.90 per share, with a weighted average price of \$3.20.

#### **NOTE H - INCOME TAXES**

In July 2006, the Financial Accounting Standards Board ("FASB") issued Interpretation No. 48 regarding "Accounting for Uncertainty in Income Taxes," an interpretation of FASB Statement No. 109 ("FIN 48"), defining 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. The Company has reviewed its tax positions for tax years 2003 through 2005 and the adoption of FIN 48 on January 1, 2007 did not result in establishing a contingent tax liability reserve or a corresponding charge to retained earnings. The Company has substantial tax benefits derived from its net operating loss ("NOL") carryforwards but has provided 100% valuation allowances against such tax benefits as described in Note A- 11.

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The reconciliations between the statutory federal income tax rate and the Company's effective income tax rate were as follows (in thousands):

	Years Ended December 31,					
	2007		2006		2005	
	Amount	%	Amount	%	Amount	%
Federal statutory rate	\$ (4,731)	(34.0)	\$ (2,029)	(34.0)	\$ (4,105)	(34.0)
State taxes, net of Federal effect	(413)	(3.0)	(537)	(9.0)	(609)	(5.0)
Research credits	(220)	(1.6)	(126)	(2.1)	(125)	(1.0)
Other	(20)	(0.1)	26	0.5	39	0.3
<b>Impact of non-taxable items</b>						
Reduction in NOL carryforwards	1,338	9.6	-	-	-	-
Conversion feature fair value change	1,184	8.5	(1,440)	(24.1)	-	-
Debt discount amortization	918	6.6	62	1.0	-	-
Warrant fair value change	648	4.7	(736)	(12.4)	-	-
Non-deductible financing costs	311	2.2	320	5.4	-	-
Wage limitation	51	0.4	-	-	-	-
Other	(95)	(0.7)	-	-	-	-
	(1,029)	(7.4)	(4,460)	(74.7)	(4,800)	(39.7)
Change in valuation allowance	10,629	76.4	4,460	74.7	4,800	39.7
Recorded tax benefit	\$ 9,600	69.0	\$ -	-	\$ -	-

The Company has gross Federal, state, and city operating loss carryforwards aggregating \$135.3 million, \$109.8 million, and \$46.3 million, respectively, expiring during the years 2009 through 2027. During 2007, the Company determined it was more likely than not that it would be able to realize some of its net deferred income tax assets in the near future, and a \$9.6 million adjustment to the net deferred income tax asset valuation allowance was made causing increased income in our 2007 Fourth Quarter. Future determinations to realize the Company's net deferred income tax assets would cause reductions in the valuation allowance and further income statement beneficial adjustments. At both December 31, 2007 and 2006, a 100% valuation allowance exists against the remaining net deferred income tax assets as we are uncertain to future utilization of NOL 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. Such attributes include general business credits. The Section 382 limitation applies on an annual basis to tax years ending after the date of the ownership change. The Section 382 limitation reduces the value of our pre-ownership change NOL carryforwards by limiting our annual utilization of the NOL carryforwards (and certain other tax attributes) against future income and gains. The tax loss carryforwards of the Company and its subsidiary are subject to limitation by Section 382 with respect to the amount utilizable each year. After our findings have been finalized and the limitation has been quantified, we may

seek further specific guidance from the Internal Revenue Service. Our net deferred income tax assets will be adjusted for this limitation; however the Company expects no income statement effect as a 100% valuation allowance has been placed against net deferred income tax assets at December 31, 2007.

The temporary differences that give rise to deferred income tax assets and liabilities are as follows (in thousands):

	December 31,	
	2007	2006
Deferred income tax assets:		
NOL carryforwards - federal	\$ 45,993	\$ 48,026
NOL carryforwards – state/city	8,304	7,837
Research credits	625	382
Stock based compensation	5,852	5,497
Warrant compensation	21	56
Other	55	90
Deferred income tax assets	60,850	61,888
Deferred income tax liabilities:		
Depreciation	(16)	(25)
Gross deferred income tax assets	60,834	61,863
Valuation allowance	(51,234)	(61,863)
Net deferred income tax assets	\$ 9,600	\$ -

**NOTE I - EMPLOYEE BENEFIT PLANS****1. 401(k) and Profit-sharing Plan**

Effective October 1, 1998, the Company established a 401(k) and Profit-Sharing Plan (the "Plan") for all employees other than those covered under collective bargaining agreements. Eligible 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 incurred neither matching nor profit sharing contribution expense under the Plan in 2007, 2006 or 2005.

**2. Stock Option Plans****1995 Stock Option Plan**

In September 1995, the stockholders of the Company approved the adoption of a stock option and restricted stock purchase plan for its employees and non-employee directors (the "1995 Option Plan"). In May 2005, the 1995 Stock Option Plan expired and the remaining unissued shares allocated to the plan were terminated. At December 31, 2007, stock options to purchase 36,890 shares, previously granted under the 1995 Stock Option Plan, remain outstanding, with an average per share exercise price of \$15.82.

**1998 Stock Option Plan**

In June 1998, the stockholders of the Company approved the adoption of a stock option plan for its employees and non-employee directors (as amended to date, the "1998 Option Plan"). The 1998 Option Plan provides for the granting of (i) nonqualified options to purchase the Company's common stock at a price determined by the Company's Stock Option Committee (effective second quarter 2004, the duties of the Company's Stock Option Committee was assigned to the Company's Compensation Committee), and (ii) incentive stock options to purchase the Company's common stock at not less than the fair market value on the date of the option grant. In June 2002, the shareholders of the Company approved a resolution to increase the total number of shares which may be sold pursuant to options and rights granted under the 1998 Option Plan to 8,100,000. In August 2004, the shareholders of the Company approved a resolution to increase this amount to 20,000,000. No option can be granted under the 1998 Option Plan after April 2008 and no option can be outstanding for more than ten years after its grant. Vesting requirements are generally 4 years. At December 31, 2007, 102,066 shares were available for future grants and stock options to purchase 1,821,609 shares remain outstanding with an average per share exercise price of \$2.27.

A summary of the Company's stock option plans as of December 31, 2007, 2006, and 2005, and for the years then ended consisted of the following:

	Years Ended December 31,					
	2007		2006		2005	
	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	1,899	\$ 2.60	1,975	\$ 2.70	1,750	\$ 4.40
Granted	-	-	-	-	400	1.30
Exercised	(31)	3.80	(40)	2.50	(4)	1.30
Forfeited or expired	(10)	3.60	(36)	10.40	(171)	16.50
Outstanding, ending	1,858	\$ 2.60	1,899	\$ 2.60	1,975	\$ 2.70

Options exercisable, end of year	1,827	\$	2.56	1,837	\$	2.60	1,569	\$	3.10
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The following table summarizes information about stock options outstanding at December 31, 2007 (number of options in thousands):

Range of Exercise Prices	Number of Options (000's)	Options Outstanding		Weighted Average Exercise Price	Options Exercisable	
		Weighted Average Remaining Contractual Life			Number of Vested Options (000's)	Weighted Average Exercise Price
\$ 1.30 to \$10.00	1,729	6.62	\$	1.34	1,698	\$ 1.34
\$10.01 to \$20.00	70	2.06		14.29	70	14.29
\$20.01 to \$25.00	59	0.84		23.81	59	23.81
<b>Total</b>	<b>1,858</b>	<b>6.27</b>	<b>\$</b>	<b>2.54</b>	<b>1,827</b>	<b>\$ 2.56</b>

The following table summarizes information about nonvested stock options outstanding at December 31, 2007 (number of options in thousands):

	Number of Options Not Exercisable	Weighted Average Fair Value
Outstanding at December 31, 2006	62	\$ 3.10
Granted	-	-
Vested	(31)	3.10
Forfeited or expired	-	-
Outstanding at December 31, 2007	31	\$ 3.10

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. The fair value of the option grants in 2005 is being amortized using a graded vesting method. This method treats the award as if the grant was a series of awards rather than a single award and attributes a higher percentage of the reported fair value to the earlier years than to the later years of the service period because the early years of service are part of the vesting period for later awards in the series. No options were granted in 2007 and 2006. Assumptions used in the 2005 grants were:

	2005
Expected dividend	0.0%
	4.5%

Risk-free interest rate	
Expected volatility	120%
Weighted average volatility	120%
Forfeitures	0.0%
	4
Expected term	years
Weighted average grant date fair value	\$ 4.50

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As of December 31, 2007, 2006 and 2005 the aggregate intrinsic value of the option awards outstanding and exercisable was \$8,083,000, \$10,253,000 and \$1,971,000, respectively. In addition, the aggregate intrinsic value of option awards exercised during the years ended December 31, 2007 and 2006 was \$492,000 and \$178,000, respectively. The total remaining unrecognized compensation cost related to the unvested option awards amounted to less than \$10,000 at December 31, 2007 and is expected to be recognized over the next three month weighted average remaining requisite service period of the unvested option awards. The total fair value of the option awards that vested during the years ended December 31, 2007, 2006 and 2005 were \$97,000, \$2,800,000 and \$1,067,000, respectively. The Company recognized stock-based compensation from the option awards of \$36,000, \$321,000 and \$2,198,000, during the years ended December 31, 2007, 2006 and 2005, respectively. As discussed in Note H, a 100% valuation reserve has been recorded against the Company's deferred tax assets, which includes the related gross tax benefits of \$483,000 and \$178,000 recorded in calendar years of 2007 and 2006, respectively, for allowable deductions arising from the exercise of non qualified stock options.

### 3. Restricted Stock Unit Award Plan

On December 22, 2005, the Board of Directors approved the Company's 2005 Restricted Stock Unit Award Plan (the "2005 RSU Plan") for its employees and non-employee directors. A Restricted Stock Unit ("RSU") represents the contingent obligation of the Company to deliver a share of its common stock to the holder of the RSU on a distribution date. RSUs for up to 3.0 million shares of common stock are authorized for issuance under the 2005 RSU Plan. The Company believed that the 2005 RSU Plan did not require shareholder approval. Nevertheless, the Company's shareholders ratified the 2005 RSU Plan at its December, 2006 Annual Shareholders' Meeting.

The RSU Plan is administered by the Company's Board of Directors or a Committee appointed by the Board of Directors. RSUs granted under the 2005 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 with the Company 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 the Company's 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.

During December 2005, an aggregate of 2,750,000 RSUs were granted to the Company's employees. During February 2006, an aggregate of 200,000 RSUs were granted to the Company's two independent directors. Of the RSUs granted to date, approximately one third vested upon grant and the other two thirds will vest on a straight-line monthly basis through December 2007. During 2007 and 2006, 983,300 and 1,050,000 RSUs became vested, respectively. As such, of the RSU awards granted, 2,950,000 and 1,966,700 were vested as of December 31, 2007 and 2006, respectively and none and 983,000 were nonvested as of December 31, 2007 and 2006, respectively. The weighted average fair value of both RSU grants is \$3.50 per share.

The stock-based compensation cost to be incurred on the RSUs is the RSU's fair value, 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 in 2006 and 2005 was \$680,000 and \$9,724,000, respectively. The fair value of the 2006 RSU grant was entirely expensed on the grant date as the grant was made for performance of past service. The fair value of the 2005 RSU grant is being amortized using a graded vesting method. This method treats the award as if the grant was a series of awards rather

than a single award and attributes a higher percentage of the reported fair value to the earlier years than to the later years of the service period because the early years of service are part of the vesting period for later awards in the series. The total remaining unrecognized compensation cost related to the unvested RSU awards amounted to \$879,000 at December 31, 2006. The Company recognized compensation cost from the RSU awards of \$879,000 and \$5,264,000 during the year ended December 31, 2007 and 2006, respectively. No related tax benefits were recorded in calendar year 2007 and 2006. As of December 31, 2007 and 2006, the aggregate intrinsic value of the RSU awards outstanding and vested was \$17,966,000 and \$14,357,000, respectively. As discussed above, the RSU awards are distributable only upon the occurrence of certain events or beginning January 1, 2011.

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## **NOTE J - COMMITMENTS AND CONTINGENCIES**

### **Employment Contracts**

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 the Company's Chief Executive Officer and President for a term expiring December 31, 2008. The Employment Agreement provides for an annual base salary of \$365,000 plus the payment of 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 the Company's 2007 fiscal year, Mr. Reddick was awarded a bonus of \$850,000 due to, among other reasons, the successful completion of our Unit Offering and the King Agreement. The Employment Agreement also provides for the Company's grant of stock options and restricted stock units to Mr. Reddick. The Employment Agreement contains standard termination provisions, including upon death, disability, for Cause, for Good Reason and without Cause, which in certain cases provides for severance payments equal to one year's salary and other termination benefits.

Ron J. Spivey, Ph.D., is employed pursuant to an Employment Agreement effective as of April 5, 2004, as amended, which provides that Dr. Spivey will serve as the Company's Senior Vice President and Chief Scientific Officer for term expiring December 31, 2008 at an annual base salary of \$315,000. Pursuant to the Employment Agreement Dr. Spivey is eligible for annual bonuses 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. In 2007, Dr. Spivey was awarded a bonus of \$650,000 due to, among other reasons, the completion of our Unit Offering and the King Agreement.

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 the Company's Senior Vice President and Chief Financial Officer for a term expiring December 31, 2008 at an annual base salary of \$205,000. 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 2007, Mr. Clemens was awarded a bonus of \$180,000 due to, among other reasons, the completion of our Unit Offering and the King Agreement.

The terms of the Employment Agreements with Dr. Spivey and Mr. Clemens are similar to those of Mr. Reddick. The term of the Employment Agreements with each of Messrs. Reddick, Spivey and Clemens provides for automatic one (1) year renewals in the absence of written notice to the contrary from the Company or such executive at least ninety (90) days prior to the expiration.

### **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 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 fee assuming 100% exercise of such warrants, is \$255,000. 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 and charged against earnings as and if the warrants are exercised.

**NOTE K - QUARTERLY FINANCIAL DATA (UNAUDITED)**

Selected quarterly consolidated financial data is shown below. On December 5, 2007, the Company affected a one-for-ten reverse stock split. All share and per share information herein reflects this reverse stock split (in thousands, except per share data):

Calendar Year 2007	Mar. 31	Three Month Period Ended			Dec. 31
		June 30	Sept. 30		
Total revenue	\$ -	\$ -	\$ -	\$	6,404
Loss from operations	(1,974)	(1,340)	(1,420)		( 172)
Net income (loss)	(9,159)	(2,199)	(2,476)		9,521
Income (loss) per common share (after deemed dividend) (Note A)					
Basic	\$ (0.26)	\$ (0.06)	\$ (0.06)	\$	0.21
Diluted	\$ (0.26)	\$ (0.06)	\$ (0.06)	\$	0.20

  

Calendar Year 2006	Mar. 31	June 30	Sept. 30	Dec. 31
Total revenue	\$ -	\$ -	\$ -	\$ -
Loss from operations	(3,927)	(2,341)	(2,661)	( 1,897)
Net income (loss)	(4,155)	(2,615)	(3,097)	3,900
Income (loss) per common share (after deemed dividend) (Note A)				
Basic	\$ (0.12)	\$ (0.08)	\$ (0.11)	\$ (0.44)
Diluted	\$ (0.12)	\$ (0.08)	\$ (0.11)	\$ (0.44)

Effective August 20, 2007, the Company entered into a Securities Purchase Agreement with an investor group and under the Unit Offering, issued an aggregate 9.5 million shares of the Company's common stock. The 3rd Quarter 2007 loss per common share amount of \$.06 reflects the increased weighted average common shares outstanding from the Unit Offering and the impact of this issuance causes the 2007 quarterly loss per share amounts not to add up to and equal the 2007 annual loss per share amount.

**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.

<b>Exhibit Number</b>	<b>Exhibit Description</b>
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Appendix C to the Registrant's Proxy Statement filed on July 6, 2004).
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 October 12, 2007).
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	Common Stock Purchase Warrant issued to Watson Pharmaceuticals, Inc. ("WPI") dated December 20, 2002 (incorporated by reference to Exhibit 10.15 to the Form 8-K filed on December 27, 2002).
10.5	Form of Warrants dated August 15, 2001 issued to Galen Partners III, L.P., Galen Partners International, III, L.P. and Galen Employee Fund III, L.P. (currently exercisable at \$9.90 per share) (incorporated by reference to Exhibit 10.3 to the Form S-3 filed on October 1, 2007 (the "October 2007 S-3"))).
10.6	Form of Warrants dated January 9, 2002, February 1, 2002, March 1, 2002, and April 5, 2002 issued to Galen Partners III, L.P., Galen Partners International, III, L.P. and Galen Employee Fund III, L.P. (currently exercisable at an exercise price of \$3.40 per share) (incorporated by reference to Exhibit 10.4 to the October 2007 S-3).
10.7	Form of Warrants dated May 8, 2002, June 3, 2002, July 1, 2002, July 23, 2002, August 5, 2002, September 3, 2002, October 1, 2002, November 4, 2002, November 12, 2002, November 21, 2002 and December 5, 2002 issued to Galen Partners III, L.P., Galen Partners International, III, L.P. and Galen Employee Fund III, L.P. (currently exercisable at an exercise price of \$3.40 per share) (incorporated by reference to Exhibit 10.5 to the October 2007 S-3).
10.8	

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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 (currently exercisable at an exercise price of \$1.285 per share) (incorporated by reference to Exhibit 10.6 to the October 2007 S-3).

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<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.9	Amended and Restated Voting Agreement dated as of February 6, 2004 among the Registrant, Care Capital Investments II, LP, Essex Woodlands Health Ventures 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"))).
10.10	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 dated November 9, 2005).
10.11	Second Amendment to Amended and Restated Voting Agreement dated as of January 24, 2008 between the Registrant and GCE Holdings, LLC (incorporated by reference to Exhibit 10.1 to the Form 8-K filed January 28, 2008).
10.12	Amended and Restated Registration Rights Agreement dated February 6, 2004 among the Registrant, WPI, 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 10.6 of the February 2004 Form 8-K).
10.13	Registrant's 1995 Stock Option and Restricted Stock Purchase Plan (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8, File No. 33-98396).
10.14	Registrant's 1998 Stock Option Plan, as amended (incorporated by reference to Appendix C to the Registrant's Proxy Statement filed on November 16, 2006).
10.15	Registrant's 2005 Restricted Stock Unit Award Plan, as amended (incorporated by reference to Appendix D to the Registrant's Proxy Statement filed on November 16, 2006).
10.16	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"))).
10.17	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).
10.18	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).
10.19	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"))).
*10.20	Fourth Amendment to Executive Employment Agreement between the Registrant and Reddick dated December 16, 2007.
10.21	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).

- 10.22           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).
- \*10.23          Second Amendment to Executive Employment Agreement dated December 19, 2007 between the Registrant and Ron J. Spivey.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.24	Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens (“Clemens”) (incorporated by reference to Exhibit 10.44 to the 1997 Form 10-K, File No. 001-10113).
10.25	First Amendment to Employment Agreement made as of June 28, 2000 between the Registrant and Clemens (incorporated by reference to Exhibit 10.44A to the Registrant’s 2005 Form 10-K).
10.26	Second Amendment to Executive Employment Agreement between Registrant and Clemens, dated as of January 5, 2005 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K dated January 28, 2005).
10.27	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).
*10.28	Fourth Amendment to Executive Employment Agreement dated December 16, 2007 between Registrant and Clemens.
10.29	Loan Agreement among the Registrant Essex Woodlands Health Ventures Fund V, L.P., Care Capital Investments II, LP, Galen Partners III, L.P. and others dated January 31, 2006 (the “Loan Agreement,” and together with certain other bridge loan agreements, the “Loan Agreements”) (incorporated by reference to the Form 8-K filed on January 31, 2006).
10.30	Form of Secured Promissory Note of the Registrant relating to January 31, 2006 Loan Agreement.
10.31	Subordination Agreement among Essex Woodlands Health Ventures Fund V, L.P., Care Capital Investments II, LP, Galen Partners III, L.P., and others dated January 31, 2006 (incorporated by reference to the Form 8-K filed on January 31, 2006).
10.32	Guarantor Security Agreement among Acura Pharmaceutical Technologies, Inc. (“APT”) and Galen Partners III, L.P., as Agent, dated January 31, 2006 (incorporated by reference to the Form 8-K filed on January 31, 2006).
10.33	Omnibus Amendment effective as of May 24, 2006 among the Registrant and APT and certain lenders amending the Loan Agreements (incorporated by reference to the Form 8-K filed on May 24, 2006).
10.34	Omnibus Amendment effective as of August 16, 2006 among the Registrant, APT and certain lenders, amending among other things, the Loan Agreements (incorporated by reference to the Form 8-K filed on August 16, 2006).
10.35	Omnibus Amendment effective as of September 22, 2006 among the Registrant, APT and certain lenders, amending among other things, the Loan Agreements (incorporated by reference to the Form 8-K filed on September 25, 2006).
10.36	Omnibus Amendment effective as of October 20, 2006 among the Registrant, APT and certain lenders, amending among other things, the Loan Agreements (incorporated by reference to the Form 8-K filed on October 20, 2006).

- 10.37 Omnibus Amendment effective as of November 30, 2006 among the Registrant and APT and certain lenders, amending among other things, the Loan Agreements (incorporated by reference to the Form 8-K filed on December 4, 2006).

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<b>Exhibit Number</b>	<b>Exhibit Description</b>
10.38	Omnibus Amendment and Consent dated March 30, 2007 among the Registrant, Galen Partners III, L.P., Care Capital Investments II, LP, Essex Woodlands Health Ventures Fund V, L.P. and the other signatories thereto (incorporated by referenced to Exhibit 10.1 of the Form 8-K filed April 2, 2007).
10.39	Omnibus Amendment and Consent effective as of July 10, 2007 among the Registrant, Galen Partners III, L.P., Care Capital Investments II, LP, Essex Woodlands Health Ventures Fund V, L.P. and the other signatories thereto (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on July 10, 2007).
10.40	Fourth Amendment, Waiver and Consent to Loan Agreement dated as of June 28, 2007 between the Registrant and Galen Partners III, LP, as agent (incorporated by reference to Exhibit 10.1 of the Form 8-K filed on July 5, 2007 (the "July 5, 2007 8-K")).
10.41	Consent and Amendment to Noteholders Agreement among Essex Woodlands Health Ventures Fund V, L.P., Galen Partners III, L.P. and Care Capital Investments II, LP, and certain other signatories thereto (incorporated by reference to Exhibit 10.2 of the July 5, 2007 8-K).
10.42	Amended Secured Promissory Note dated as of December 20, 2002 in the principal amount of \$5,000,000 issued by the Registrant, as the maker, in favor of Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.3 of the July 5, 2007 8-K).
10.43	Fifth Amendment, Waiver and Consent to Loan Agreement dated as of August 20, 2007 between the Registrant and Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on August 21, 2007).
10.44	Amended Secured Promissory Note dated as of December 20, 2002 in the principal amount of \$5,000,000 issued by the Registrant, as the maker, in favor of Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.3 of the Form 8-K filed on August 21, 2007).
10.45	Sixth Amendment, Waiver and Consent to Loan Agreement dated as of September 27, 2007 between the Registrant and Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on September 24, 2007).
10.46	Amended Secured Promissory Note originally issued as of December 20, 2002 in the principal amount of \$5,000,000 issued by the Registrant, as the maker, in favor of Galen Partners III, L.P., as Agent (incorporated by reference to Exhibit 10.2 of the Form 8-K filed on September 24, 2007).
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 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.

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Exhibit Number	Exhibit Description
*32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\*Filed or furnished herewith.

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