

ACURA PHARMACEUTICALS, INC  
Form 10-K  
March 15, 2007

**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, 2006**  
**or**  
 **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**  
**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number 1-10113**

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

**New York** **11-0853640**  
(State or other jurisdiction of Incorporation or (I.R.S. Employer Identification No.)  
organization)

**616 N. North Court, Suite 120, Palatine, Illinois** **60067**  
(Address of principal executive office) (Zip code)

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

**Securities registered pursuant to section 12(b) of the Act:**  
None

**Securities registered pursuant to section 12(g) of the Act:**  
(Title of Class)  
Common Stock, par value \$0.01 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes  No

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

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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

As of March 1, 2007, the registrant had 331,163,803 shares of Common Stock, par value \$0.01, outstanding. Based on the average closing bid and asked prices of the Common Stock on June 30, 2006 (\$0.595) (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$39,975,000.

**Documents incorporated by reference:** None

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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 the actual results, performance or achievements of Acura Pharmaceuticals, Inc. (the "Company"), 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, the Company's ability to secure additional financing to fund continued product development and operations, the Company's ability to enter into contractual arrangements with qualified pharmaceutical partners to license, develop and commercialize the Company's Aversion® (abuse deterrent) Technology and related product candidates, and the Company's ability to fulfill the U.S. Food and Drug Administration's ("FDA") requirements for approving the Company's product candidates for commercial 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 the Company's product candidates, the adequacy of the development program for the Company's product candidates, changes in regulatory requirements, adverse safety findings relating to the Company's product candidates, the risk that the FDA may not agree with the Company's analysis of its 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 or otherwise of the studies, the risk that further studies of the Company's product candidates 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: the Company's ability to attract and retain highly skilled personnel; its ability to secure and protect its patents, trademarks and proprietary rights; its ability to avoid infringement of patents, trademarks and other proprietary rights or trade secrets of third parties; litigation or regulatory action that could require the Company to pay significant damages or change the way it conducts its business; the Company's ability to compete successfully against current and future competitors; its dependence on third-party suppliers of raw materials; its ability to secure U.S. Drug Enforcement Administration ("DEA") quotas and source controlled substances that constitute the active ingredients of the Company's products in development; difficulties or delays in clinical trials for Company products or in the manufacture of Company products; and other risks and uncertainties detailed in this Report. The Company is at development stage and may not ever have any products or technologies that generate revenue. 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

#### *General*

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® (abuse deterrent) 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. OxyADF 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 FDA. The development and intellectual property status of Aversion® Technology and OxyADF Tablets is described below.

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 a number of pharmaceutical product 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 OxyADF Tablets and other product candidates under the direction of the Company.

The Company was historically engaged in development of novel manufacturing processes (the "Opioid Synthesis Technologies") intended for use in the commercial manufacture of certain bulk opioid active pharmaceutical ingredients. In early 2005, the Company announced the suspension of activities relating to the Opioid Synthesis Technologies pending the deputy DEA Administrator's determination relating to the Company's pending application for registration to import narcotic raw materials (the "Narcotic Raw Materials Import Application") filed with the DEA in early 2001. In late 2006, the Company notified the DEA that it was withdrawing the Narcotic Raw Materials Import Application and subsequently the Company has discontinued all activities relating to the Opioid Synthesis Technologies. The withdrawal of the Narcotic Raw Materials Import Application and the discontinuation of all activities relating to the Opioid Synthesis Technologies allow the Company to focus all of its resources on developing and commercializing its Aversion® Technology and related product candidates.

The Company is a publicly traded New York corporation. As such, the Company files 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.

The Company's 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.

### ***Patents***

As of the date of this Report, the Company has one U.S. patent Notice of Allowance relating to its Aversion® Technology. In addition, as of the date of this Report, the Company has two U.S. non-provisional patent publications, one U.S. non-provisional patent application, one U.S. provisional patent application, and two international patent publications pending relating to its Aversion® Technology. The Company also has seven U.S. issued patents and has one U.S. patent publication pending relating to its Opioid Synthesis Technologies. As of the date of this Report, the Company has retained all of the intellectual property and commercial rights to its Aversion® Technology and related product candidates and its Opioid Synthesis Technologies.

### ***Commercialization Strategy***

To generate revenue the Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license product candidates utilizing Aversion® Technology and further develop, register and commercialize multiple strengths and packaging sizes of such product candidates. The Company expects to receive revenue in the form of milestone payments and a share of profits and/or royalty payments derived from the Partners' future sale of products incorporating Aversion® Technology. As of the date of this Report, the Company did not have any executed collaborative agreements with Partners, nor can there be any assurance that the Company will successfully enter into such collaborative agreements in the future.

### ***Aversion® (abuse deterrent) Technology***

Aversion® (abuse deterrent) Technology is applicable to immediate release and extended release, orally administered tablets and capsules. Aversion® Technology can be formulated into orally administered tablets or capsules containing commonly utilized opioid active pharmaceutical ingredients (such as oxycodone, hydrocodone, hydromorphone, oxymorphone, morphine, codeine, tramadol, propoxyphene, etc.), or other potentially abuseable drugs. In addition to the opioid active ingredient, Aversion® Technology utilizes certain combinations of pharmaceutical product inactive excipients and active ingredients intended to discourage or deter pharmaceutical product abuse. Aversion® Technology does not utilize opioid antagonists such as naltrexone and naloxone. Provided product candidates pursued in development prove successful in laboratory testing and clinical trials, of which no assurance can be given, the Company believes that its Aversion® Technology will discourage the three most common methods of opioid pharmaceutical product 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.

OxyADF Tablets, the Company's lead product candidate, incorporates Aversion® Technology with oxycodone HCl as the active analgesic ingredient in an immediate release tablet intended for oral administration. The Company has clearance from the FDA for testing OxyADF Tablets in a clinical trial program under an active IND. The clinical

development program is designed to evaluate the efficacy and safety of OxyADF Tablets in opioid naïve patients and patients with a history of opioid abuse. Our goal is to demonstrate that, when prescribed and used appropriately by patients, OxyADF Tablets will provide effective analgesia and a safety profile similar to currently marketed immediate release products containing oxycodone HCl but without our unique Aversion® Technology. The status of the OxyADF Tablet development program is described below.

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In addition to OxyADF Tablets, as of the date of this Report we are engaged in the formulation development of additional immediate release product candidates intended for oral administration 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®). Each of these additional product candidates is in the formulation stage of development. No assurance can be provided that such development efforts will lead to product candidates for which an IND or NDA submission to the FDA will result or that we will have sufficient cash reserves or sources of financing to fund the continued development of such product candidates. As of the date of this Report, we believe that OxyADF Tablets and the other product candidates targeted for development with Aversion® Technology can be produced economically using a dry blend, direct compression tablet manufacturing process.

To receive approval from the FDA for distribution and sale in the U. S., the Company’s product candidates will require the development, compilation, submission, filing and final approval by the FDA of a new drug application (“NDA”). The FDA has provided written guidance to the Company stating that OxyADF Tablets are an appropriate product candidate for submission as a 505(b)(2) NDA. At this stage there can be no assurance that any of the Company’s research and development efforts, including those for OxyADF Tablets, will lead to a 505(b)(2) NDA submission or that if NDA submissions are made with the FDA, that any such submissions will be accepted for filing or, if accepted for filing, approved by the FDA for commercial distribution in the U.S..

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

Primary market research conducted by the Company 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 opioid based prescriptions 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. The Company believes 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 the Company from IMS Health, for the 12 months ended September 30, 2006, approximately 227 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 13 million were for extended release products (usually administered every 8 to 24 hours) and 214 million were for immediate release products (usually administered every 4 to 6 hours). Extended release products are more commonly prescribed for relief of pain for durations ranging from a few weeks to several months or longer. Immediate release products are more commonly prescribed for relief of pain for durations of generally less than 30 days. According to data published in The National Survey of 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. The Company's primary market research suggests that OxyADF Tablets will be considered by healthcare providers for use in both the immediate release and extended release market segments.

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 numbers of tablets 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. To address this need, the Company is developing Aversion® (abuse deterrent) Technology and related product candidates.

***OxyADF Tablets Development Status***

OxyADF (oxycodone HCl/niacin) Tablets, the Company’s lead product candidate with Aversion® (abuse deterrent) Technology, is an orally administered immediate release tablet containing oxycodone HCl as its sole active analgesic ingredient and a sub therapeutic amount of niacin. The Company intends to file a 505(b)(2) NDA for OxyADF Tablets with an anticipated indication for treating moderate to moderately severe pain. OxyADF Tablets are intended to effectively treat moderate to moderately severe pain while also discouraging or deterring the three most common methods of 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. OxyADF Tablets are being developed pursuant to an active investigational new drug application (“IND”) on file with the FDA. The FDA has provided written guidance to the Company stating that OxyADF Tablets are an appropriate product candidate for submission as a 505(b)(2) NDA and has confirmed in writing to the Company that no additional toxicology studies are required prior to submission of such NDA.

**OxyADF Tablets: Technical and Pre-Clinical Development and Regulatory Affairs Program**

The technical and pre-clinical development program and regulatory strategy and status for OxyADF 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 OxyADF Tablets regulatory requirements prior to their acceptance for filing of a 505(b)(2) NDA submission for OxyADF Tablets.

<b>Technical and Pre-Clinical Development</b>	<b>Status</b>
Formulation development	Complete
Pilot bioequivalence study	Complete
Pivotal oxycodone extraction study	Complete (results summarized below)
Tablet stability for NDA submission	Testing in process. 18 month real time data demonstrates stability acceptable for NDA submission
Toxicology studies	Not required per FDA written guidance to the Company
<b>Regulatory Affairs</b>	<b>Status</b>
Investigational New Drug Application (IND)	Active
End of Phase II meeting with FDA	Completed Q1-06
Factorial design clinical studies	Not required per FDA written guidance to Company
Product labeling	Strategy and concepts discussed with FDA. Written guidance provided by FDA to the Company

Regulatory submission for commercial distribution in the U.S.

OxyADF Tablets are eligible for submission as a 505(b)(2) NDA per FDA written guidance to Company

Phase III pivotal clinical trial

A single phase III efficacy and safety trial is required per FDA written guidance to Company

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**Aversion® Technology: 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 oxycodone-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, OxyADF 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 OxyADF Tablets using any generally available solvent, including water or alcohol, into a volume and form suitable for I.V. injection, the tablet converts into a viscous gel matrix and effectively traps the oxycodone HCl in the gel. Based on controlled in-vitro experiments, the Company believes 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 OxyADF Tablet. As described below, the Company has compared the relative difficulty of extracting oxycodone from OxyADF Tablets to several currently marketed oxycodone-containing products.

**Pivotal Oxycodone Extraction Study:** The Company, in concert with a leading pharmaceutical laboratory CRO (the "Laboratory CRO"), completed a pivotal study to assess certain properties of OxyADF using tablets from batches manufactured by the Company at its 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 intravenous (I.V.) injection from various opioid tablet products. The Laboratory CRO was provided with a list of 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 OxyADF Tablets, OxyContin® Tablets, 40mg, generic oxycodone HCl Tablets, 5mg and Percocet® Tablets (oxycodone HCl/acetaminophen, 5mg/325mg). 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® 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. OxyADF Tablets resulted in a "trace" of oxycodone HCl extracted in 355 minutes and was rated 10 in relative difficulty. The Company intends to utilize the data and results from this pivotal laboratory study in its 505(b)(2) NDA submission for OxyADF Tablets to the FDA.

**Summary Results of OxyADF 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	<u>Difficulty Rating</u> 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 5mg tablets Endo Labs	<10 minutes with vacuum assisted filtration	3 Steps ~75% Yield	3-4

OxyADF Tablets	355 minutes	23 Steps	
8 x 5mg tablets	with no success	~0% Yield	10
Acura Pharmaceuticals			

### **Aversion® Technology: 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. OxyADF Tablets have three mechanisms intended to discourage nasal snorting. First, OxyADF Tablets are formulated with a functional excipient intended to induce mild burning and irritation of the nasal passages if the tablets are crushed and the prospective drug abuser attempts to snort the crushed tablets. Second, when OxyADF Tablets are crushed and snorted, the Company expects the moisture in the nasal passages will form a viscous gel with the crushed tablet powder, trapping the oxycodone in the gel and therefore reducing the amount of oxycodone available to be absorbed through the lining of the nasal passages. Third, the Company expects 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, the Company expects potential nasal abusers of OxyADF Tablets to experience 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. The Company has evaluated the potential for reducing nasal absorption using a standard in-vitro experimental process. As discussed below, the Company intends to further evaluate OxyADF Tablet nasal abuse characteristics in laboratory, animal, and phase I clinical studies.

### **Aversion® Technology: Intended to Deter Swallowing Excess Quantities of Tablets**

OxyADF Tablets contain two active ingredients. In each tablet, oxycodone HCl is included to provide analgesic effects and niacin is included as a second active ingredient in a sub-therapeutic amount. 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 OxyADF Tablet, may cause a combination of unpleasant symptoms, including warmth or flushing, itching, sweating and/or chills, headache and a general feeling of discomfort. 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 OxyADF Tablet. When OxyADF 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 effects of niacin. However, when a person swallows excess quantities of OxyADF Tablets, it is intended that 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 15 minutes after the excess dose is swallowed and self-resolve approximately 90 minutes later. The Company does not expect that the undesirable niacin effects will be “fool-proof” in discouraging swallowing excessive numbers of OxyADF Tablets. However, we anticipate that inclusion of niacin in OxyADF Tablets and other Aversion® Technology product candidates will deter, to a certain degree, legitimate pain patients or potential drug abusers from swallowing excess quantities of OxyADF 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 OxyADF Tablets, and do not have the potential to cause these undesirable niacin effects. As described below, the Company has evaluated the effects of niacin in three phase II clinical studies in subjects with and without a history of opioid abuse.

### **Expectations for OxyADF 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 the Company stating that an indication for abuse deterrence must be supported by data from two adequate and well-controlled clinical trials. The Company does not intend to seek an indication for abuse deterrence for OxyADF Tablets. Instead, the Company is seeking an indication for OxyADF Tablets for treatment of moderate to moderately severe pain. The FDA has also provided written guidance to the Company stating that language regarding abuse deterrence, which is supported by rigorous, scientific data, may be placed into appropriate sections of the OxyADF Tablet product label. In this regard, the Company intends to seek FDA approval of language in the OxyADF Tablet product label describing the physical characteristics of the product and likely results if attempts are made to dissolve tablets in solvents for intravenous injection, and/or snort crushed tablets, and/or swallow excessive numbers of tablets. The Company believes this product labeling strategy will provide a viable promotional platform for the commercialization of OxyADF Tablets and other product candidates utilizing Aversion® Technology. At this stage there can be no assurances that the Company's product labeling strategy for OxyADF Tablets will be successful or that FDA approved product labeling, if any, will provide a viable commercialization platform.

**OxyADF Tablets Clinical Development Program: Completed and Planned Clinical Studies**

The clinical development program for OxyADF Tablets is summarized below. At this stage, the Company 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 OxyADF Tablets.

**OxyADF Tablets Clinical Development Program**

<b>Clinical Study Number</b>	<b>Clinical Study Description</b>	<b>Status</b>
<b>Phase I</b>		
AP-ADF-101	Evaluate optimal amount per tablet of niacin	Final study report complete
AP-ADF-104	Phase I: Bioequivalence to non Aversion® Technology Reference Listed Drug	Final study report complete. OxyADF tablets are bioequivalent to reference listed drug
AP-ADF-106	Evaluate effects of nasal snorting	Received FDA written guidance for protocol design
AP-ADF-108	Single dose pharmacokinetics (dose linearity and food effect)	Received FDA written guidance for protocol design
AP-ADF-109	Multi-dose pharmacokinetics (dose linearity)	Received FDA written guidance for protocol design
AP-ADF-110	Single dose pharmacokinetics and bioavailability. Required if there is not dose linearity	Received initial FDA written guidance for protocol design
<b>Phase II</b>		
AP-ADF-102	Relative likeability in subjects with a history of opioid abuse	Subject enrollment complete. Principal Investigator's report and data analysis complete. Final study report in progress
AP-ADF-103	Repeat dose safety and tolerability study in normal subjects	Final study report complete
AP-ADF-107	Niacin dose-response for safety and tolerability in normal subjects	Subject enrollment complete. Summary study report and preliminary

data analysis complete.  
Final study report in  
progress

### Phase III

AP-ADF-105

Pivotal efficacy and safety

Received FDA written  
guidance for protocol  
design. Special Protocol  
Assessment requested.

### Summary of OxyADF Tablets Phase II Study Designs, Status and Results

**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 Inventory (ARCI) that yielded three scale scores - the Morphine Benzodrine Group Scale (MBG), the LSD Specific Scale (LSD) and the Pentobarbital Chlorpromazine Alcohol Group Scale (PCAG). 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 "How much 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. The Company intends to include the data and results from Study AP-ADF-102 in its 505(b)(2) NDA submission for OxyADF Tablets to the FDA.

**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 OxyADF Tablets in comparison to oxycodone HCl tablets without Aversion® (abuse deterrent) Technology, the Company 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 OxyADF Tablets (with or without niacin) as well as post-treatment safety and tolerability assessments. Efficacy (the tolerability of OxyADF) was evaluated with a Side Effects and Symptoms Questionnaire (SESQ) and an OxyADF 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 OxyADF 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 OxyADF 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 OxyADF 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). The Company intends to include the data and results from Study AP-ADF-103 in its 505(b)(2) NDA submission for OxyADF Tablets to the FDA.



**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 OxyADF 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, as well as 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 taken 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 standardized high-fat breakfast consisting of two fried eggs, hash browns, two fried bacon strips, toast, butter, and whole milk, 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. The Company intends to include the data and results from Study AP-ADF-107 in its 505(b)(2) NDA submission for OxyADF Tablets to the FDA.

#### **Additional OxyADF Tablets Clinical Studies Planned**

The FDA has requested that the Company complete certain additional clinical studies for OxyADF Tablets prior to accepting our 505(b)(2) NDA submission including, as of the date of this Report, the following:

**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 OxyADF (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 Company has submitted the study protocol to the FDA and requested 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. A SPA is binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing is begun. The Company believes the completion of Study AP-ADF-105 is the critical time and events path to 505(b)(2) NDA submission for OxyADF Tablets.

**Study AP-ADF-106.** This will be a phase I clinical study, for use in product labeling, evaluating the nasal irritating characteristics of crushed OxyADF Tablets (with and/or without oxycodone HCl) anticipated to enroll 12-24 normal subjects.

**Studies AP-ADF-108, AP-ADF-109, and if necessary AP-ADF-110.** These will be phase I single dose or multi-dose pharmacokinetic studies anticipated to enroll approximately 25-50 normal subjects per study.

#### **Estimated Timing for submission of a 505(b)(2) NDA for OxyADF Tablets**

Estimating the dates of initiation and completion of clinical studies and the costs to complete development of the Company's product candidates, including OxyADF Tablets, would be speculative and potentially misleading. The Company expects to reassess its future research and development plans pending review of data received from development activities currently in progress and the availability of cash resources to fund such development activities. The cost and pace of future research and development activities are linked and subject to change. At this stage there can be no assurance that any of the Company's research and development efforts, including those for OxyADF Tablets, will lead to a 505(b)(2) NDA submission or that if NDA submissions are made with the FDA, that any such submission will be accepted for filing or approved by the FDA.

#### ***Competition***

The Company competes to varying degrees with numerous companies in the pharmaceutical research, development, manufacturing and commercialization fields. Most of the Company's competitors have substantially greater financial and other resources and are able to expend more funds and effort than the Company in research and development of their competitive technologies and products. Although a larger company with greater resources than the Company 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.

The Company believes potential competitors may be developing opioid abuse deterrent technologies and products. Such competitors may include Alpharma Inc. of Fort Lee, NJ, Elite Pharmaceuticals, Inc. of Northvale, NJ, New River Pharmaceuticals, Inc. of Radford, VA, Pain Therapeutics of South San Francisco, CA, (in collaboration with King Pharmaceuticals of Bristol, TN), Purdue Pharma of Stamford, CT and Endo Pharmaceuticals of Chadds Ford, PA.

#### ***Segment Reporting***

The Company operates in only one business segment, the research, development and manufacture of innovative abuse deterrent, abuse resistant and tamper resistant formulations ("Aversion® Technology") intended for use in orally administered pharmaceutical products.

Prior to 2005, the Company manufactured and sold generic finished dosage pharmaceutical products. The Company discontinued the manufacture and sale of such products in the first quarter of 2004.

Prior to 2005, the Company was engaged in research, development and manufacture of proprietary, high-yield, short cycle time, environmentally sensitive opioid synthesis processes (the "Opioid Synthesis Technologies") intended for use in the commercial production of certain bulk opioid active pharmaceutical ingredients. In early 2005, the Company suspended development and commercialization efforts relating to the Opioid Synthesis Technologies pending the deputy DEA Administrator's determination relating to the Company's pending application for registration to import narcotic raw materials (the "Narcotic Raw Materials Import Application") filed with the DEA in early 2001. In late 2006 the Company notified the DEA that it was withdrawing, without prejudice to possible future resubmission, the Narcotic Raw Materials Import Application and the Company has discontinued all activities relating to the Opioid Synthesis Technologies. The withdrawal of the Narcotic Raw Material Import Application and the discontinuation of all activities relating to the Opioid Synthesis Technologies allow the Company to focus its

resources on developing and commercializing its propriety Aversion® Technology and related product candidates.

***Government Regulation***

All pharmaceutical firms, including the Company, 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, the Company is subject to extensive regulation by the Drug Enforcement Administration ("DEA") for research, development and manufacturing of controlled substances. The Company is 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. The Company cannot predict the extent to which it may be affected by legislative and other regulatory developments concerning its 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 OxyADF 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, the Company believes that OxyADF 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, the Company 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. The Company is 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 the Company stating that OxyADF 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, the Company is subject to regulation under federal, state and local environmental laws. The Company believes it is in material compliance with applicable environmental laws. The Company incurred \$61,650 and \$180,000 in the years ended December 31, 2005 and 2004, respectively, on environmental compliance relating to disposal of hazardous and controlled substances waste primarily associated with the manufacture of finished dosage pharmaceuticals and active pharmaceutical ingredients. These operations were discontinued in 2004. Since 2005 the Company has only incurred the normal waste disposal cost associated with test batch manufacturing for finished dosage forms and research and development laboratory operations.

### ***Raw Materials***

To purchase certain active ingredients required for the Company's development and manufacture of product candidates utilizing its Aversion® Technology, the Company is required to file for and obtain quotas from the DEA. No assurance can be given that the Company 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 the Company's product candidates will supply the Company with its requirements for the active ingredients required for the development and manufacture of its product candidates.

### ***Subsidiaries***

The Company's Culver, Indiana research, development, and manufacturing operations are conducted by Acura Pharmaceutical Technologies, Inc., an Indiana corporation and wholly-owned subsidiary of the Company.

***Directors, Executive Officers, and Employees***

The directors and executive officers of the Company are as follows:

<b>NAME</b>	<b>AGE</b>	<b>POSITION</b>
Andrew D. Reddick	54	President, Chief Executive Officer and Director
Ron J. Spivey	60	Senior Vice President and Chief Scientific Officer Senior Vice President, Chief Financial Officer and
Peter A. Clemens	54	Secretary
James F. Emigh	51	Vice President of Marketing and Administration Vice President, Corporate Controller and
Robert A. Seiser	43	Treasurer
Bruce F. Wesson	64	Director
William A. Sumner	69	Director
Richard J. Markham	56	Director
William G. Skelly	55	Director
Immanuel Thangaraj	36	Director

Andrew D. Reddick has been President and Chief Executive Officer since August, 2003 and a Director of the Company 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 pharmaceuticals from the University of Iowa.

Peter A. Clemens has been Senior Vice President, Chief Financial Officer and Secretary since April 2004. Mr. Clemens was Vice President, Chief Financial Officer and Secretary of the Company from February 1998 to March 2004 and a Director of the Company 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 Vice President of Sales and Marketing. Mr. Emigh joined the Company 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 the Company in March 1998 as the 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 Director of the Company 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 QMed, Inc., 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 Director of the Company 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 acted as a consultant in the pharmaceutical field. 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 Director of the Company 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 Director of the Company since May, 1996 and served as Chairman of the Company 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 Director of the Company 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. He serves as a director of private companies. 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.

As of the date of this Report, the Company had 13 full-time employees, eight 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 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**

### **The Company Received a "Going Concern" Opinion from Its Registered Independent Public Accounting Firm, Has a History of Operating Losses and May Not Achieve Profitability Sufficient to Generate a Positive Return on Shareholders' Investment**

We have incurred net losses of \$6.0 million for the year ended December 31, 2006, \$12.1 million for the year ended December 31, 2005 and \$70.0 million and \$48.5 million for 2004 and 2003, respectively. As of December 31, 2006, our accumulated deficit was approximately \$317.5 million. The Company's consolidated financial statements for the years ended December 31, 2006, 2005 and 2004 were prepared on a "going concern" basis; however, in its report dated March 13, 2007 regarding those financial statements, our registered independent public accounting firm expressed substantial doubt about the Company's ability to continue as a going concern as a result of recurring losses, net capital deficiency and negative cash flows. Our future profitability will depend on many factors, including: (i) the Company's ability to secure additional financing to fund continued operations, (ii) the successful completion of the formulation development, clinical testing and acceptable regulatory review of product candidates utilizing the Aversion® Technology; (iii) the continued receipt of issued patents from the U.S. Patent and Trademark Office ("USPTO") for the material claims in the Company's patent applications relating to the Aversion® Technology; (iv) the Company's ability to negotiate and execute appropriate licensing, development and commercialization agreements with qualified third parties relating to the Company's product candidates; and (v) the successful commercialization by licensees of products incorporating the 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 by the FDA, that we will bring any product to market or, if we are successful in doing so, that we will ever become profitable.

### **We Require Additional Funding**

Our requirements for additional new funding will depend on many factors, including: (i) the time required and expenses incurred in the development and commercialization of products incorporating our Aversion® Technology; (ii) the structure of any future collaborative or development agreements relating to the Aversion® Technology, including the timing and amount of payments, if any, that may be received under possible future collaborative agreements; (iii) our ability to develop additional product candidates utilizing the Aversion® Technology; (iv) our ability to negotiate agreements with qualified third parties for development, manufacture, marketing, sale and distribution of products utilizing our Aversion® Technology; (v) the prosecution, defense and enforcement of patent claims and other intellectual property rights relating to the Aversion® Technology; and (vi) the successful commercialization by licensees of products incorporating our Aversion® Technology without infringing third-party patents or other intellectual property rights.

To continue funding operations the Company must raise additional financing, or enter into alliances or collaborative agreements with third parties providing for net cash proceeds to the Company. The Company is seeking to secure working capital providing gross proceeds to the Company in the range of approximately \$10 million to \$15 million through the private offering of the Company's securities. The terms of any such securities offering, including, without limitation, the type of equity securities (or securities convertible into equity securities) and the price per share, have not been determined and will, in large part, be determined based upon negotiations between the Company and prospective investors in such private offering. No assurance can be given that the Company will be successful in obtaining any such financing or in securing collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or collaborative agreements will provide for payments to the Company sufficient to continue to fund operations. In the absence of such financing or third-party collaborative agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. Even assuming the Company is successful in securing additional sources of financing to fund the continued development of the Aversion® Technology, or enters into alliances or collaborative agreements relating to the Aversion® Technology, there can be no assurance that the Company's development efforts will result in commercially viable products.

**We Have No Near Term Sources of Revenue and Must Rely on Current Cash Reserves, Third-Party Financing, and Technology Licensing Fees to Fund Operations**

Pending the negotiation of appropriate licensing agreements with pharmaceutical company partners, of which no assurance can be given, the Company must rely on its current cash reserves, third-party financing and technology licensing fees to fund the Company's operations. No assurance can be given that current cash resources will be sufficient to fund the continued development of our product candidates until such time as we generate revenue from the license of products incorporating the Aversion® Technology to third parties. Moreover, no assurance can be given that we will be successful in raising additional financing to fund operations or, if funding is obtained, that such funding will be sufficient to fund operations until the Company's product candidates incorporating our Aversion® Technology, may be commercialized.

**We Are Subject to Restrictions on the Incurrence of Additional Indebtedness, Which May Adversely Impact the Company's Ability to Fund Operations and Clinical Trials**

Pursuant to the terms of the Company's outstanding secured loan agreements the Company is limited as to the type and amount of future indebtedness it may incur. The restriction on the Company's ability to incur additional indebtedness in the future may adversely impact the Company's ability to fund the development of its product candidates and commercialization of its products.

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

The Company is committing substantially all of its resources and available capital to the development of OxyADF Tablets. Additional clinical and non-clinical testing will be required to continue development of OxyADF Tablets and for the preparation and submission of a 505(b)(2) NDA with the FDA. There can be no assurance that OxyADF 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 or leading to a NDA submission. If a NDA is submitted to the FDA for OxyADF Tablets or any other product candidates, there can be no assurances that the FDA will accept such submission for filing and subsequently approve such regulatory application with commercially viable product labeling or to ultimately approve such product candidates for commercial distribution. The failure of the Company to successfully develop and achieve final FDA approval of a product candidate utilizing Aversion® Technology will have a material adverse effect on the Company's operations and 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 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 for the majority of this testing with our product candidates. As a result, we have less control over the timing and other aspects of 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 collaborative partners, 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 site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA or other regulatory authorities due to several factors, including ongoing discussions with the FDA or other 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 the FDA or other regulatory authorities, the imposition of a clinical hold by FDA, lack of adequate funding to continue clinical trials; and/or negative or unanticipated results of clinical trials.



Clinical trials, where 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 clinical trials are positive, we and our collaborative partners may have to commit substantial time and additional resources to conduct further pre-clinical and clinical studies before we 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 collaborative partner(s) or the FDA believes that participating patients are being exposed to unacceptable health risks, we or our collaborative partner(s) may have to suspend the clinical trials. Failure can occur at any stage of the trials, and our collaborative partner(s) 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 our targeted 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 collaborative partner to abandon a product candidate and may delay the development of other product candidates.

#### **We 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, if any, 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 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 products to meet, the FDA's requirements for safety, efficacy and quality; and those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. After submission of a marketing application, in the form of an NDA, or a 505(b)(2) NDA the FDA may deny the application, may require additional testing or data and/or may 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 marketing application, including the labeling content, may be more restrictive than we desire and could affect the marketability of the products incorporating the Aversion® Technology.

Even if we comply with all FDA regulatory requirements, we may never obtain regulatory approval for any of our product candidates. If we fail to obtain regulatory approval for any of our product candidates, we will have fewer saleable products and corresponding lower revenues. Even if we receive regulatory approval of our products, such approval may involve limitations on the indicated uses or marketing claims we 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. As any future source of Company revenue will be derived from the sale of FDA approved products, the taking of any such action by the FDA would have a material adverse effect on the Company.

**We Must Maintain FDA Approval to Manufacture 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, as well as those of any third-party manufacturers that we 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 products, 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 must rely on pharmaceutical company partners to manufacture and commercialize products utilizing our Aversion Technology.

**If We Retain Collaborative Partners and Our Partners Do Not Satisfy Their Obligations, We Will Be Unable to Develop Our Partnered Product Candidates**

To complete the development and regulatory approval of our products and commercialize our product candidates, if any are approved by the FDA, we plan to enter into development and commercialization agreements with strategically focused pharmaceutical company partners providing that such partners license our Aversion® Technologies and further develop, register, manufacture and commercialize multiple formulations and strengths of each product candidate utilizing our Aversion® Technology. We expect to receive a share of profits and/or royalty payments derived from such collaborative partners' sale of products incorporating our Aversion® Technology. Currently, we do not have any such collaborative agreements, nor can there be any assurance that we will actually enter into collaborative agreements in the future. Our inability to enter into collaborative agreements, or our failure to maintain such agreements, would limit the number of product candidates that we can develop and ultimately, decrease our potential sources of any future revenues. In the event we enter into any collaborative agreements, we may not have day-to-day control over the activities of our collaborative partners with respect to any product candidate. Any collaborative partner may not fulfill its obligations under such agreements. If a collaborative partner 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 a third-party. In addition, we may encounter delays in the commercialization of the product candidate that is the subject of a collaboration agreement. Accordingly, our ability to receive any revenue from the product candidates covered by collaboration agreements will be dependent on the efforts of our collaborative partner. We could be involved in disputes with a collaborative partner, 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 collaborative partners' commitment to us and reduce the resources they devote to developing and commercializing our products. If any collaborative partner 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 and 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 collaborator, thereby eliminating our opportunity to commercialize other product candidates with other collaborative partners.

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

The commercial success of products incorporating our Aversion® Technology that are 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 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: (i) the relative advantages and disadvantages of our Aversion® Technology compared to competitive abuse deterrent technologies; (ii) the relative timing to commercial launch of products utilizing our Aversion® Technology compared to products incorporating competitive abuse deterrent technologies; (iii) the relative timing of the receipt of marketing approvals and the countries in which such approvals are obtained; (iv) the relative safety and efficacy of products incorporating our Aversion® Technology compared to competitive products; and/or (v) 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 licensed to partners do not achieve market acceptance, we may not be able to generate significant revenues or become profitable.

**In the Event That We 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**

Our ability to commercialize pharmaceutical products successfully 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 to have 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 that there will continue to 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 receive for any products in the future. Further, cost control initiatives could impair our ability or the ability of our partners to commercialize our products and our ability to earn revenues from this commercialization.

**Our Success Depends on Our Ability to Protect Our Intellectual Property**

Our success depends in significant part on our ability to obtain 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 the Company's recent receipt of a Notice of Allowance from the USPTO relating to a non-provisional patent application relating to the Aversion® Technology, there is no assurance that any of our patent application claims contained in the Company's other non-provisional and provisional patent applications for our Aversion® Technology will issue or, 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 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 collaborative partners, 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 effect 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 types of situations in which we may become parties to such litigation or proceedings include: (i) we may initiate litigation or other proceedings against third parties to enforce our patent rights or other intellectual property rights; (ii) we may initiate litigation or other proceedings 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; (iii) 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 (iv) 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. The failure of the Company to avoid infringing third-party patents and intellectual property rights in the commercialization of products utilizing the Aversion® Technology will have a material adverse effect on the Company's 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. Many 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 might have to seek a license to make, use, and sell the patented technologies. In that case, we might not be able to obtain such license on terms acceptable to us, or at all. 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. The Company is 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, the Company 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 the Company is unable to obtain a license on commercially reasonable terms, the Company 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.

The Company expects to seek and obtain licenses to such patents or patent applications when, in the Company's judgment, such licenses are needed. If any such licenses are required, there can be no assurances that the Company would be able to obtain any such license on commercially favorable terms, or at all, and if these licenses are not obtained, the Company might be prevented from making, using and selling the Aversion® Technology and products. The Company's failure to obtain a license to any technology that it may require would materially harm the Company's business, financial condition and results of operations. We cannot assure that the Company's 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 consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise 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 the Company's financial conditions and 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 will not achieve significant product revenues and our financial condition 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 opioid analgesic products and other drugs and technologies 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 the Company's opportunity to generate future revenues and profits.

### **Key Personnel Are Critical to Our Business, and Our Future 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 with the Company 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 such 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 products and bulk 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 clinical trials and commercial distribution 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.

**The Market Price of Our Common Stock May Be Volatile**

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 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, 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.

The Company's common stock trades on the OTC Bulletin Board, a NASD-sponsored inter-dealer quotation system. As the Company's common stock is not quoted on a stock exchange and is not qualified for inclusion on the NASD Small-Cap Market, our common stock could be subject to a rule by the Securities and Exchange Commission that imposes additional sales practice requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent for a transaction prior to sale. Consequently, the rule may affect the ability of broker-dealers to sell the Company's common stock. There is no guarantee that an active trading market for our common stock will be maintained on the OTC Bulletin Board. Shareholders may be not able to sell their shares of common stock quickly or at the latest market price if trading in our common stock is not active.

**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 pathways of our product candidates that could cause our operating results to fluctuate.

**No Dividends**

The Company has not declared and paid cash dividends on its common stock in the past, and the Company does not anticipate paying any cash dividends in the foreseeable future. The Company's senior term loan indebtedness prohibits the payment of cash dividends.

## **Control of the Company**

GCE Holdings LLC beneficially owns approximately 77% of the Company's outstanding common stock. In addition, pursuant to the terms of the Amended and Restated Voting Agreement dated February 6, 2004, as amended, between the Company and the former holders of the Company's outstanding convertible preferred stock, all such shareholders have agreed that the Board of Directors shall be comprised of not more than seven members, four of whom shall be the designees of GCE Holdings LLC (the assignee of all the Company's preferred stock prior to its conversion into common stock formerly held by each of Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners International III, L.P., Galen Partners III, L.P. and Galen Employee Fund III, L.P.). As a result, GCE Holdings LLC, in view of its ownership percentage of the Company and by virtue of its controlling position on the Company's Board of Directors, will be able to control or significantly influence all matters requiring approval by our shareholders, including the approval of mergers or other business combination transactions. The interests of GCE Holdings LLC may not always coincide with the interests of other shareholders and such entity may take action in advance of its interests to the detriment of our other shareholders.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

The Company leases 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 August 31, 2007. The lease agreement provides for rent, property taxes, common area maintenance and janitorial services on an annualized basis of approximately \$29,200 per year. This leased office space is utilized for the Company's administrative, marketing and business development functions.

The Company conducts research, development, laboratory, development scale and NDA submission batch scale manufacturing and warehousing activities relating to the Aversion® Technology at its facility located at 16235 State Road 17, Culver, Indiana (the "Culver Facility"). At this location the Company's Acura Pharmaceutical Technologies, Inc. subsidiary 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. The Culver Facility is subject to a mortgage lien granted in favor of the holders of the Company's 2004 Note. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Amendment to Watson Term Loan Agreement."

**ITEM 3. LEGAL PROCEEDINGS**

None.

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

The Company's 2006 Annual Meeting of Shareholders was held on December 14, 2006 (the "Annual Meeting"). In connection with the Annual Meeting proxies were solicited by management pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended. On the record date for the Annual Meeting, the Company's outstanding voting securities consisted of 330,564,049 shares of common stock, of which 317,755,577 shares were represented in person or by proxy at the Annual Meeting. At the Annual Meeting, the following matters were submitted to a vote of the Company's voting security holders, with the results indicated below:

1. Election of Directors: The following six (6) incumbent directors were elected to serve until the next Annual Meeting of Shareholders. The tabulation of votes was as follows:

Nominee	For	Withheld
Richard J. Markham	317,584,811	170,766
Immanuel Thangaraj	317,541,211	214,366
Bruce F. Wesson	317,542,881	212,696
Andrew D. Reddick	317,526,227	229,350
William A. Sumner	317,573,225	182,352
William G. Skelly	317,614,509	141,068

2. Proposal to grant the Board of Directors authority to amend the Company's Restated Certificate of Incorporation to effect a reverse stock split at one of six ratios. The tabulation of votes was as follows:

For	Against	Abstained	Not Voted
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315,212,251	2,293,924	249,402	0
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3. Proposal to ratify an amendment to the Company's 1998 Stock Option Plan to make such Plan compliant with Section 409A of the Internal Revenue Code of 1986, as amended. The tabulation of votes was as follows:

For	Against	Abstained	Not Voted
276,689,351	685,198	207,693	40,173,335

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4. Proposal to ratify the adoption of the Company's 2005 Restricted Stock Unit Award Plan. The tabulation of votes was as follows:

For	Against	Abstained	Not Voted
270,037,814	7,327,834	216,594	40,173,335

5. Proposal to Ratify the Company's independent registered public accounting firm for the current fiscal year. The tabulation of votes was as follows:

For	Against	Abstained	Not Voted
317,392,094	165,579	197,904	0

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED SECURITY HOLDER MATTERS

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

Set forth below for the periods indicated are the high and low bid prices for the Company's 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 PRICE	
	HIGH \$	LOW \$
<b>2005 Fiscal Year</b>		
First Quarter	0.70	0.33
Second Quarter	0.81	0.41
Third Quarter	0.73	0.40
Fourth Quarter	1.36	0.27
<b>2006 Fiscal Year</b>		
First Quarter	0.91	0.25
Second Quarter	0.79	0.50
Third Quarter	1.09	0.59
Fourth Quarter	0.92	0.56
<b>2007 Fiscal Year</b>		
First Quarter (through February 1, 2007)	0.79	0.69

#### *Holder*

There were approximately 639 holders of record of the Company's common stock on February 1, 2007. This number, however, does not reflect the ultimate number of beneficial holders of the Company's Common Stock.

#### *Dividend Policy*

The payment of cash dividends from current earnings is subject to the discretion of the Board of Directors and is dependent upon many factors, including the Company's earnings, its capital needs and its general financial condition. The terms of the Term Loan Agreement assigned by Watson Pharmaceuticals, Inc. to Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P. and certain other stockholders of the Company as

well as the Bridge Loan Agreements between the Company and the bridge lenders a party thereto (see “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Bridge Loan Financing”, and “Item 13. Certain Relationships and Related Transactions, and Director Independence”) prohibit the Company from paying cash dividends. The Company does not intend to pay any cash dividends in the foreseeable future.

***Recent Sales of Unregistered Securities***

During the quarter ended December 31, 2006, the Company issued 201,365 shares of the Company’s Common Stock in satisfaction of the payment of \$161,000 in accrued interest due December 31, 2006 under the Company’s senior secured term note and 233,054 shares of the Company’s Common Stock in satisfaction of the payment of \$176,000 in accrued interest due December 31, 2006 under the Company’s Bridge Loan agreements. Each of the recipients of such Common Stock is an Accredited Investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act. Such Common Stock was issued without registration under the Securities Act in reliance upon Section 4(2) of the Securities Act and Regulation D promulgated thereunder.



**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, 2006, 2005, 2004, 2003 and 2002 are derived from the Company's audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2006 and 2005 and for each of the years in the three-year period ended December 31, 2006, and the reports thereon, are included elsewhere herein. The selected financial information as of and for the years ended December 31, 2003 and 2002 are derived from the audited Consolidated Financial Statements of the Company not presented herein.

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".

<b>OPERATING DATA (in thousands):</b>	<b>2006</b>	<b>2005</b>	<b>2004 (1)</b>	<b>2003</b>	<b>2002</b>
Net revenues	\$ —	—	—	\$ 838	\$ 8,205
Operating Costs;					
Cost of manufacturing	—	—	1,435	11,705	12,535
Research and development	5,172	6,265	4,130	1,460	1,517
Selling, marketing, general and administrative expenses	5,654	5,296	5,238	7,903	7,216
Plant shutdown costs	—	—	—	1,926	(126)
Interest expense	(1,140)	(636)	(2,962)	(6,001)	(4,728)
Interest income	18	36	59	25	15
Write-off of debt discount and deferred private debt offering costs	—	—	(41,807)	—	—
Amortization of debt discount and deferred private debt offering costs	(183)	—	(30,684)	(24,771)	(12,558)
Gain on debt restructuring	—	—	12,401	—	—
Gain on fair value change of conversion features	4,235	—	—	—	—
Gain on fair value change of common stock warrants	2,164	—	—	—	—
(Loss) gain on asset disposals	(22)	81	2,359	—	—
Other (expense) income	(213)	5	603	464	966
Loss before income tax benefit	(5,967)	(12,075)	(69,996)	(48,455)	(59,589)
Income tax benefit	—	—	—	—	—
Net loss	\$ (5,967)	\$ (12,075)	\$ (69,996)	\$ (48,455)	\$ (59,589)
Basic and diluted loss per common share applicable to common stockholders	\$ (0.08)	\$ (0.18)	\$ (3.20)	\$ (2.28)	\$ (3.90)
Weighted average number of outstanding common shares	344,959	66,799	21,861	21,227	15,262

**DECEMBER 31,**

**2006                      2005                      2004                      2003                      2002**

**BALANCE SHEET DATA (in thousands):**

Working capital (deficiency)	\$	(28,641)	\$	(2,478)	\$	2,423	\$	(3,770)	\$	5,933
Total assets		1,619		1,792		4,967		6,622		19,364
Total debt, net (2)		28,787		7,613		5,093		53,142		25,398
Total liabilities		39,899		7,954		6,052		58,689		31,632
Accumulated deficit		(317,543)		(291,616)		(279,541)		(209,546)		(161,090)
Stockholders' deficit	\$	(38,280)	\$	(6,162)	\$	(1,085)	\$	(52,067)	\$	(12,268)

(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.

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

This discussion and analysis should be read in conjunction with the Company's 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 the actual results, performance or achievements of the Company, 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*

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® (abuse deterrent) 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. OxyADF 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"). 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 of pharmaceutical product 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 OxyADF Tablets and other product candidates under the direction of the Company. As of the date of this Report, the Company has one U.S. patent Notice of Allowance relating to its Aversion® Technology, In addition, as of the date of this Report, the Company has two U.S. non-provisional patent publications, one U.S. non-provisional patent application, one U.S. provisional patent application, and two international patent publications pending relating to its Aversion® Technology. The Company also has seven U.S. issued patents and has one U.S. patent publication pending related to its Opioid Synthesis Technologies. As of the date of this Report, the Company has retained all of the intellectual property and commercial rights to Aversion® Technology and related product candidates, and the Opioid Synthesis Technologies. To generate revenue the Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license product candidates utilizing Aversion® Technology and further develop, register and commercialize multiple strengths and package sizes of such product candidates. The Company expects to receive revenue in the form of milestone payments and a share of profits and/or royalty payments derived from the Partners' future sale of products incorporating Aversion® Technology. As of the date of this Report, the Company did not have any executed collaborative agreements with Partners, nor can there be any assurance that the Company will successfully enter into such collaborative agreements in the future.

The Company was historically engaged in development of novel manufacturing processes (the "Opioid Synthesis Technologies") intended for use in the commercial manufacture of certain bulk opioid active pharmaceutical ingredients. In early 2005, the Company announced the suspension of activities relating to the Opioid Synthesis Technologies pending the deputy DEA Administrator's determination relating to the Company's pending application for registration to import narcotic raw materials (the "Narcotic Raw Materials Import Application") filed with the DEA in early 2001. In late 2006 the Company notified the DEA that it was withdrawing the Narcotic Raw Materials

Import Application and subsequently the Company has discontinued all activities relating to the Opioid Synthesis Technologies. The withdrawal of the Narcotic Raw Material Import Application and the discontinuation of all activities relating to the Opioid Synthesis Technologies allows the Company to focus all of its resources on developing and commercializing its Aversion® (abuse deterrent) Technology and related product candidates.

The Company has incurred net losses since 1992 and the Company's consolidated financial statements for each of the years ended December 31, 2006, 2005 and 2004 have been prepared on a going-concern basis; however, in its report dated March 13, 2007 regarding those financial statements, our registered independent public accounting firm referred to substantial doubt about the Company's ability to continue as a going-concern as a result of recurring losses, net capital deficiency and negative cash flows. The Company's future profitability will depend on several factors, including: (a) the Company's ability to secure additional financing to fund continued operations; (b) the successful completion of the formulation development, clinical testing and acceptable regulatory review of product candidates utilizing the Aversion® Technology; (c) the Company's ability to negotiate and execute appropriate licensing, development and commercialization agreements with interested third parties relating to the Company's product candidates; and (d) the successful commercialization by licensees of products incorporating the Aversion® Technology without infringing the patents and other intellectual property rights of third parties.

### ***Company's Present Financial Condition***

At December 31, 2006, the Company had cash and cash equivalents of approximately \$228,000 compared to approximately \$260,000 at December 31, 2005. The Company had a working capital deficit of \$28.6 million at December 31, 2006 and \$2.5 million at December 31, 2005. The Company had an accumulated deficit of approximately \$317.5 million and \$291.6 million at December 31, 2006 and December 31, 2005, respectively. The Company incurred a loss from operations of approximately \$10.8 million and a net loss of approximately \$6.0 million during the year ended December 31, 2006, as compared to a loss from operations of \$11.6 million and a net loss of \$12.1 million for the year ended December 31, 2005.

As of March 1, 2007, the Company had cash and cash equivalents of approximately \$492,000. The Company estimates that its current cash reserves will be sufficient to fund the development of the Aversion® Technology and related operating expenses through late March, 2007. See "Liquidity and Capital Resources - Cash Reserves and Funding Requirements."

### ***Results of Operations for the Year Ended December 31, 2006 and 2005***

**Research and Development Expenses:** The Company's research and development expenses for the year ended December 31, 2006 and 2005 were as follows (in thousands):

12/31/06	12/31/05	12/31/06-12/31/05	12/31/06-12/31/05
R&D EXPENSES	R&D EXPENSES	R&D EXPENSES	R&D EXPENSES
		\$ CHANGE	% CHANGE
\$ 5,172	\$ 6,265	\$ (1,093)	(17.4)%

Research and development expenses related primarily to development of our Aversion® 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 Company 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.

**Selling, Marketing, General and Administrative Expenses:** The Company's selling, marketing, general and administrative expenses for the year ended December 31, 2006 and 2005 were as follows (in thousands):

<b>12/31/06 SELLING, MARKETING, G&amp;A EXPENSES</b>	<b>12/31/05 SELLING, MARKETING, G&amp;A EXPENSES</b>	<b>12/31/06-12/31/05 SELLING, MARKETING, G&amp;A EXPENSES \$ CHANGE</b>	<b>12/31/06-12/31/05 SELLING, MARKETING, G&amp;A EXPENSES % CHANGE</b>
\$ 5,654	\$ 5,296	\$ 358	6.7%

During the year ended December 31, 2006, the marketing expenses consisted of Aversion® Technology market research studies and payroll costs. The Company's 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 the Company's 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: The Company's interest expense, net of interest income for the year ended December 31, 2006 and 2005 was as follows (in thousands):

<b>12/31/06</b>		<b>12/31/05</b>		<b>12/31/06-12/31/05</b>		<b>12/31/06-12/31/05</b>
<b>INTEREST</b>		<b>INTEREST</b>		<b>INTEREST</b>		<b>INTEREST</b>
<b>EXPENSE, NET</b>		<b>EXPENSE, NET</b>		<b>EXPENSE, NET</b>		<b>EXPENSE, NET</b>
<b>OF</b>		<b>OF INTEREST</b>		<b>OF INTEREST</b>		<b>OF INTEREST</b>
<b>INTEREST</b>		<b>INCOME</b>		<b>INCOME</b>		<b>INCOME</b>
<b>INCOME</b>		<b>INCOME</b>		<b>\$ CHANGE</b>		<b>% CHANGE</b>
\$	1,122	\$	600	\$	522	87.1%

The Company incurs interest at the prime interest rate plus 4.5%, payable quarterly in common stock, on its \$5.0 million secured term note payable. The Company incurs 10% annual interest, payable quarterly, on its \$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 the 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: The Company's net loss for the year ended December 31, 2006 and 2005 was as follows (in thousands):

				<b>12/31/06-12/31/05</b>		<b>12/31/06-12/31/05</b>
<b>12/31/06</b>		<b>12/31/05</b>		<b>NET LOSS</b>		<b>NET LOSS</b>
<b>NET LOSS</b>		<b>NET LOSS</b>		<b>\$ CHANGE</b>		<b>% CHANGE</b>
\$	5,967	\$	12,075	(\$6,108)		(50.6%)

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 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 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, the Company recorded the resulting decrease in value as a \$4,235 gain. The decrease in the Company's 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 the 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 4<sup>th</sup> quarter 2006. Future period fair value adjustments to the warrant liability could result in further gains or losses.

The Company's loss per share in 2006 versus 2005 (\$0.08 versus \$0.18, respectively) was favorably impacted by the conversion on November 10, 2005 of approximately 218.0 million preferred shares into approximately 305.8 million common shares. On a weighted average basis, this increased the number of common shares in the loss per share calculation to approximately 345 million shares in 2006 as compared to 66.6 million shares in 2005. For periods prior to November 10, 2005, the Company's 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.

**Results of Operations for the Year Ended December 31, 2005 and 2004**

In comparing results of operations for the year ended December 31, 2005 with those for 2004 it is important to consider that in 2005 the Company focused all of its efforts and resources on research and development activities and, subsequent to March, 2004, no longer maintained any generic product manufacturing facilities or conducted any finished dosage generic product manufacturing activities. As such, the Company had no product revenues or manufacturing expenses in 2005.

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Research and Development Expenses: The Company's research and development expenses for the year ended December 31, 2005 and 2004 were as follows (in thousands):

<b>12/31/05 R&amp;D EXPENSES</b>	<b>12/31/04 R&amp;D EXPENSES</b>	<b>12/31/05-12/31/04 R&amp;D EXPENSES \$ CHANGE</b>	<b>12/31/05-12/31/04 R&amp;D EXPENSES % CHANGE</b>
\$ 6,265	\$ 4,130	\$ 2,135	51.7%

During 2005 and 2004, research and development expenses consisted primarily of development of 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. The increase in R&D expenses in 2005 versus 2004 is primarily due to the recording of a non cash compensation charge of \$3,325 arising from the issuance of stock options and restricted stock units to R&D personnel as compared to \$553 for such items in 2004. Except for this non cash compensation charge, R&D expenses declined in 2005 versus 2004 by approximately \$637 primarily as a result of elimination in 2004 of the development of generic pharmaceutical products and the suspension in 2005 of further development of the Opioid Synthesis Technologies.

Selling, Marketing, General and Administrative Expenses: The Company's selling, marketing, general and administrative expenses for the year ended December 31, 2005 and 2004 were as follows (in thousands):

<b>12/31/05 SELLING, MARKETING, G&amp;A EXPENSES</b>	<b>12/31/04 SELLING, MARKETING, G&amp;A EXPENSES</b>	<b>12/31/05-12/31/04 SELLING, MARKETING, G&amp;A EXPENSES \$ CHANGE</b>	<b>12/31/05-12/31/04 SELLING, MARKETING, G&amp;A EXPENSES % CHANGE</b>
\$ 5,296	\$ 5,238	\$ 58	1.1%

Included in 2005 selling, marketing, general and administrative expenses is a non cash compensation charge of \$3,133 arising from the issuance of stock options and restricted stock units to SG&A personnel as compared to only \$1,453 for such items in 2004. Except for this charge, SG&A expenses in 2005 decreased approximately \$1,622 as compared to 2004 due primarily to the Company's 2004 discontinuation of the manufacture and sale of generic pharmaceutical products and the related reduction of its administrative and manufacturing support staff.

Interest Expense, net of Interest Income: The Company's interest expense, net of interest income for the year ended December 31, 2005 and 2004 was as follows (in thousands):

<b>12/31/05 INTEREST EXPENSE, NET OF INTEREST INCOME</b>	<b>12/31/04 INTEREST EXPENSE, NET OF INTEREST INCOME</b>	<b>12/31/05-12/31/04 INTEREST EXPENSE, NET OF INTEREST INCOME \$ CHANGE</b>	<b>12/31/05-12/31/04 INTEREST EXPENSE, NET OF INTEREST INCOME % CHANGE</b>
\$ 600	\$ 2,903	(\$ 2,303)	(79.3%)

The change in the interest expense, net of interest income reflects the interest savings from the restructuring of the Company's term note indebtedness to Watson Pharmaceuticals, Inc. in February, 2004 as well as the conversion of the Company's 5% convertible debentures into convertible preferred stock on August 13, 2004.

The Company incurred no amortization of debt discount or deferred private debt offering costs for the year ended December 31, 2005 as all such costs were fully amortized to expense in 2004 (an aggregate charge of \$72.5 million)

when all convertible debentures were converted into preferred stock. Similarly, the extinguishment of approximately \$16.4 million of the Watson debt gave rise in 2004 to a gain of \$12,401.

Net Loss: The Company's net loss for the year ended December 31, 2005 and 2004 was as follows (in thousands):

			12/31/05-12/31/04	12/31/05-12/31/04
12/31/05	12/31/04		NET LOSS	NET LOSS
NET LOSS	NET LOSS		\$ CHANGE	% CHANGE
\$ 12,075	\$ 69,996		(\$ 57,921)	(82.7%)

Included in the net loss for 2005 is a non cash compensation charge of \$6,458 arising from the issuance of stock options and restricted stock units as compared to \$2,006 for such charges in 2004. Certain significant net expenses occurred in 2004 as a result of restructuring operations and conversion of debt to preferred shares. These net expenses included the full amortization of the remaining debt discount and deferred private debt offering costs of \$72,491, gains on debt restructuring of the Watson note of \$12,401 and asset sales of \$2,359, net interest expense of \$2,903 and other income of \$603 relating to settlements of a liabilities at discount.

The Company's loss per share in 2005 versus 2004 (\$0.18 versus \$3.20, respectively) was favorably impacted by the conversion on November 10, 2005 of approximately 218.0 million preferred shares into approximately 305.8 million common shares. On a weighted average basis, this increased the number of common shares in the loss per share calculation to approximately 66.5 million shares in 2005 as compared to 21.9 million shares in 2004. For periods prior to November 10, 2005, the Company's convertible preferred shares were anti-dilutive and therefore excluded from the loss per share calculation.

#### Liquidity and Capital Resources

At December 31, 2006, the Company had cash and cash equivalents of \$228,000 compared to \$260,000 at December 31, 2005. The Company had a working capital deficit of \$28.6 million at December 31, 2006 compared to a working capital deficit of \$2.5 million at December 31, 2005. This large increase is primarily due to pending 2007 debt maturities and related value of embedded conversion features. Cash used in operating activities was \$5,383,000, \$5,527,000 and \$9,493,000 for years ended December 31, 2006, 2005, and 2004, respectively, due principally to cash expenditures related to selling, general and administrative expenses and research and development expenses.

#### Amendment to Watson Term Loan Agreement

The Company was a party to a certain loan agreement with Watson Pharmaceuticals, Inc. ("Watson") pursuant to which Watson made term loans to the Company (the "Watson Term Loan Agreement") in the aggregate principal amount of \$21.4 million as evidenced by two promissory notes (the "Watson Notes"). As part of the Company's 2004 debenture offering, the Company paid Watson the sum of approximately \$4.3 million (which amount was funded from the proceeds of the 2004 debenture offering) and conveyed to Watson certain Company assets in consideration for Watson's forgiveness of approximately \$16.4 million of indebtedness under the Watson Notes. As part of such transaction, the Watson Notes were amended to extend the maturity date of such notes from March 31, 2006 to June 30, 2007, to provide for satisfaction of future interest payments under the Watson Notes in the form of the Company's Common Stock, to reduce the principal amount of the Watson Notes from \$21.4 million to \$5.0 million, and to provide for the forbearance from the exercise of rights and remedies upon the occurrence of certain events of default under the Watson Notes (the Watson Notes as so amended, the "2004 Note"). Simultaneous with the issuance of the 2004 Note, each of Care Capital, Essex Woodlands Health Ventures, Galen Partners and the other investors in the Company's 2004 debentures as of February 10, 2004 (collectively, the "Watson Note Purchasers") purchased the 2004 Note from Watson in consideration for a payment to Watson of \$1.0 million.

The 2004 Note in the principal amount of \$5.0 million as purchased by the Watson Note Purchasers is secured by a lien on all of the Company's and its subsidiaries' assets, including a mortgage lien on the Culver Facility, carries a floating rate of interest equal to the prime rate plus 4.5% (paid quarterly in the Company's common stock) and matures

on June 30, 2007. To the extent cash is not available to the Company to pay of its near-term debt obligations upon maturity, management expects to negotiate with its lenders to arrange for alternative means to settle the obligations, including the extension of maturity or conversion into equity. The lenders have extended the Bridge Loan maturity dates and have added conversion features to those Bridge Loans on multiple occasions during 2005 and 2006. The majority holders of the Bridge Loans also are the majority holders of the 2004 Note maturing June 30, 2007.

*Bridge Loan Financing*

As of the date of this Report, the Company was a party to four (4) loan agreements completed in January 2006, November, 2005, September, 2005 and June, 2005, each as amended to date, pursuant to which the Company has received bridge financing installments in the aggregate principal amount of \$8,744,000 (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 of the Company listed on the signature page to such Bridge Loan agreements. See "Item 13. Certain Relationships and Related Transactions, and Director Independence" for a description of the Bridge Loan Financing.

GCE Holdings LLC, which is controlled by the VC Lenders, beneficially owns approximately 77% of the Company's outstanding common stock and has the right to designate four directors (of which it has exercised the right with respect to three directors) to the Company's Board of Directors. See "Item 13 - Certain Relationships and Related Transactions, and Director Independence."

#### *Cash Reserves and Funding Requirements*

As of March 1, 2007, the Company had cash and cash equivalents of approximately \$492,000. The majority of such cash reserves will be dedicated to the development of the Company's Aversion® Technology, the prosecution of the Company's patent applications relating to the Aversion® Technology and for administrative and related operating expenses.

The Company must rely on its current cash reserves to fund the development of its Aversion® Technology and related ongoing administrative and operating expenses. The Company's future sources of revenue, if any, will be derived from contract signing fees, milestone payments and royalties and/or profit sharing payments from licensees for the Company's Aversion® Technology. The Company estimates that its current cash reserves will be sufficient to fund the development of the Aversion® Technology and related operating expenses through late March, 2007. To fund further operations and product development activities, the Company must raise additional financing, or enter into alliances or collaboration agreements with third parties resulting in cash payments to the Company. The Company is seeking to secure working capital providing gross proceeds to the Company in the range of approximately \$10 million to \$15 million through the private offering of the Company's securities. The terms of any such securities offering, including, without limitation, the type of equity securities (or securities convertible into equity securities) and the price per share, have not been determined and will, in large part, be determined based upon negotiations between the Company and prospective investors in such private offering. No assurance can be given that the Company will be successful in obtaining any such financing or in securing collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or collaborative agreements will provide for payments to the Company sufficient to continue to fund operations. In the absence of such financing or third-party collaborative agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws.

Even assuming the Company is successful in securing additional sources of financing to fund the continued development of the Aversion® Technology, or otherwise enters into alliances or collaborative agreements relating to the Aversion® Technology, there can be no assurance that the Company's development efforts will result in commercially viable products. The Company's failure to successfully develop the Aversion® Technology in a timely manner, to continue to obtain issued U.S. patents relating to the Aversion® Technology and to avoid infringing third-party patents and other intellectual property rights will have a material adverse impact on its financial condition and results of operations.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying consolidated balance sheets is dependent upon continued operations of the Company, which in turn are dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to succeed in its future operations. The Company's financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

The following table presents the Company's expected cash payments on contractual obligations outstanding as of December 31, 2006 (in thousands):

	<b>TOTAL</b>	<b>DUE IN 2007</b>	<b>DUE IN 2008</b>	<b>DUE THEREAFTER</b>
Notes payable, gross	\$ 12,848	\$ 12,848	\$ —	—
Capital leases	32	25	7	—
Operating leases	19	19	—	—
Clinical studies	162	162	—	—
Annual interest on fixed rate debt (1)	194	194	—	—
Employment agreements	740	740	—	—
Total contractual obligations	\$ 13,995	\$ 13,988	\$ 7	\$ —

Expected cash payments on contractual obligations entered into subsequent to December 31, 2006

	<b>TOTAL</b>	<b>DUE IN 2007</b>	<b>DUE THEREAFTER</b>
Notes payable and related interest	\$ 910	\$ 910	\$ —

- (1) At the Company's option, interest on fixed rate debt is payable in either cash or common shares.

### ***Critical Accounting Policies***

Note A of the Notes to Consolidated Financial Statements included as a part of this Report, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. In preparing these financial statements, the Company has made its 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. The Company does not believe there is a consequential likelihood that materially different amounts would be reported under different conditions or using different assumptions. The Company's critical accounting policies are as follows:

#### ***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, the Company generally considers all expected future events other than an enactment of changes in the tax laws or rates. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to the amount that is more likely than not to be realized. In the event the Company were to determine that it would be able to realize its deferred income tax assets in the future, an adjustment to reduce the valuation allowance would increase income in the period such determination was made.

#### ***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.

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 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, 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. The 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). Black-Scholes utilizes other assumptions related to 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. 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 the Company's 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 the Company's 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 is being 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 Company's outstanding Bridge Loans in November 2006, required the Company 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, the Company 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*

#### *Changes and Error Corrections*

In May 2005, the FASB issued Statement of Financial Accounting Standards No. 154, "Accounting Changes and Error Corrections - A Replacement of APB Opinion No. 20 and FASB Statement No. 3", ("SFAS 154"). SFAS 154 primarily requires retrospective application to prior periods' financial statements for the direct effects of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005.

#### *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 FAS 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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### *Certain Hybrid Financial Instruments*

In February 2006, FASB issued Statement of Financial Accounting Standard No. 155, "Accounting for Certain Hybrid Financial Instruments - an amendment of FASB Statement No. 133 and 140" ("SFAS 155"). SFAS 155 resolves issues addressed in Statement 133 Implementation Issue No. D1, "Application of Statement 133 to Beneficial Interests in Securitized Financial Assets." SFAS 155 is effective for all financial instruments acquired or issued after the beginning of the first fiscal year that begins after September 15, 2006. As such, the Company is required to adopt these provisions at January 1, 2007. The Company is evaluating the impact of SFAS 155, but currently does not anticipate any material impact to its consolidated financial statements.

### *Uncertainty in Income Taxes*

In July 2006, the FASB issued Interpretation No. 48 ("FIN 48") regarding "Accounting for Uncertainties in Income Taxes," which defines 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. FIN 48 also requires explicit disclosure requirements about a Company's uncertainties related to their income tax position, including a detailed rollforward of tax benefits taken that do not qualify for financial statement recognition. This Interpretation is effective for fiscal years beginning after December 31, 2006. The cumulative effect of applying the provisions of FIN 48 will be reported as an adjustment to the opening balance of retained earnings for that fiscal year. The Company is evaluating the possible impact of FIN 48, but currently does not anticipate any material impact to its consolidated financial statements.

### *Fair Value Measurements*

In September 2006, the FASB issued SFAS 157, "Fair Value Measurements." SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently evaluating the impact the adoption of this statement could have on its financial condition, results of operations or cash flows.

### *Capital Expenditures*

The Company's capital expenditures during 2006, 2005 and 2004 were \$85,000, \$35,000 and \$444,000, respectively. Capital expenditures in 2006 and 2005 were attributable to the purchase of scientific equipment and improvements to the Culver, Indiana facility. The capital expenditures during 2004 were attributable to capital improvements to the Company's Culver, Indiana facility and its former Congers, NY facilities.

### *Impact of Inflation*

The Company believes that inflation did not have a material impact on its operations for the periods reported.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

None of the securities that we invest in are subject to market risk. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents in a variety of securities, including commercial paper, governmental and non-governmental debt securities and/or money market funds that invest in such securities. We have no holdings of derivative financial and commodity instruments. As of December 31, 2006, our investments consisted primarily of short-term bank commercial paper and checking funds with variable, market rates of interest.

The Company has indebtedness, some of which incurs interest on a floating basis in relation to the Prime Rate. To the extent that inflation is reflected in higher interest rates, the Company would expect to incur greater interest costs on

this debt. A one-percentage point increase in interest rates would result in a \$50,000 increase in interest expense on an annualized basis. The Company's floating rate debt currently matures in June 2007.

## **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.* The Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including its subsidiaries) required to be included in the Company's periodic Securities and Exchange Commission filings. No significant changes were made in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

*Changes in Internal Control Over Financial Reporting.* There was no change in the Company's 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, the Company's 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**

The directors and executive officers of the Company are identified in "Item 1. Business" herein.

### **Corporate Governance**

#### *Audit Committee*

The Audit Committee of the Board of Directors is composed of Messrs. William A. Sumner, Chairman, Immanuel Thangaraj and Bruce F. Wesson. 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, the Company's independent auditors, approving the services provided by the auditors, reviewing the financial statements of the Company and reporting on the results of the audits to the Board, reviewing the Company's insurance coverage, financial controls and filings with the Securities and Exchange Commission (the "Commission"), including, meeting quarterly prior to the filing of the Company's quarterly and annual reports containing financial statements filed with the Commission, and submitting to the Board its recommendations relating to the Company's financial reporting, accounting practices and policies and financial, accounting and operational controls.

In assessing the independence of the Audit Committee members during 2006, the Company has reviewed and analyzed the standards for independence provided in Section 121A of the American Stock Exchange Listing Standards. Based on this analysis, the Company has determined that Mr. Sumner is deemed an independent member of the Audit Committee. Messrs. Wesson and Thangaraj do not satisfy the standards for independence set forth in the American Stock Exchange Listing Standards as a result of their positions in entities having a controlling interest in GCE Holdings, LLC, the Company's 77% shareholder. GCE Holdings, LLC was the assignee of all the Company's 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 American Stock Exchange Listing Standards. Nevertheless, the Board values the experience of Messrs. Wesson and Thangaraj in the review of the Company's financial statements and believes that each is able to exercise independent judgment in the performance of his duties on the Audit Committee.

The Audit Committee does not have a financial expert (as defined under applicable regulations of the Commission) serving on the Committee. The Board has determined that while none of the Audit Committee members meet all of the criteria established by the Commission to be classified as a "financial expert", the Company believes that in general, the members of the Audit Committee have a sufficient understanding of audit committee functions, internal control over financial reporting and financial statement evaluation so as to capably perform the tasks required of the Audit Committee. The Audit Committee's Charter is available on the Company's website, [www.acurapharm.com](http://www.acurapharm.com), under the link "Audit Charter".

### ***Compensation Committee***

The Compensation Committee of the Board of Directors is composed of Messrs. Andrew D. Reddick, Richard J. Markham and William G. Skelly. 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- - Compensation Discussion and Analysis" below.

### ***Nominating Committee***

Currently the entire Board of Directors functions as the Company's 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 as directors of the Company. Two of the six members of the Board (Messrs. Sumner and Skelly) are "independent" as that term is defined by Section 121(A) of the American Stock Exchange Listing Standards and will participate with the entire Board in the consideration of director nominees. The Board believes that a nominating committee separate from itself is not necessary at this time, given the relative size of the Company and the Board. The Board also believes that, given the Company's relative size and the size of its Board, 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 the Company's governance, and who would be willing to serve as directors of a public company. To date, the Company has not engaged any third party to assist in identifying or evaluating potential nominees. If a possible candidate is identified, the individual will meet with various members 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 to the Company for consideration, and the Company does 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. In evaluating candidates, the Board will require that candidates possess, at a minimum, a desire to serve on the Company's Board, an ability to contribute to the effectiveness of the Board, an understanding of the function of the Board of a public company and relevant industry knowledge and experience. In addition, while not required of any one candidate, the Board would consider favorably experience, education, training or other expertise in business or financial matters and prior experience serving on boards of public companies.

### ***Shareholder Communications to the Board***

Shareholders who wish to send communications to the Company's Board of Directors may do so by sending them in care of the Secretary of the Company 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.

The Secretary of the Company 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 the business or governance of the Company and its subsidiaries, 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***

The Company has a Code of Ethics applicable to the Company's principal executive officer, principal financial officer and principal accounting officer. The Code of Ethics and any amendments to or waivers there from, is available on the Company's website, [www.acurapharm.com](http://www.acurapharm.com), under the link "Code of Ethics".

### ***Section 16(a) Beneficial Ownership Reporting Compliance***

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's Directors and executive officers, and persons who own beneficially more than ten percent (10%) of the Common Stock of the Company, to file reports of ownership and changes of ownership with the Commission. Copies of all filed reports are required to be furnished to the Company pursuant to Section 16(a). Based solely on the reports received by the Company and on written representations from reporting persons, the Company believes that the Directors, executive officers and greater than ten percent (10%) beneficial owners of the Company's Common Stock complied with all Section 16(a) filing requirements during the year ended December 31, 2006, except as noted below. To the extent, and only 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 of the Company's Common Stock, they should have each filed Form 4s with respect to six separate stock issuances in 2006. Essex Woodlands Health Ventures V, L.P. did file in 2007 late Form 4s with respect to such stock issuances.

## **ITEM 11. EXECUTIVE COMPENSATION**

### ***Compensation Discussion and Analysis***

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

### ***Policies for Allocating Between Various Forms of Compensation***

Because we have insufficient cash reserves, our ability to pay cash bonuses, non-equity incentive compensation and increase salaries is limited and is dependent on the willingness of our bridge lenders to provide such financing or upon our ability to complete equity or licensing funding transactions. As a result, until our cash reserve situation improves, we anticipate that most incentive compensation will be paid in the form of equity-based compensation. However, our goal, if allowed by our liquidity, is to provide greater cash bonuses and non-equity incentives. Our equity-based compensation is targeted to allow senior management to own between 5% and 10% of the outstanding common stock, so as to align their interests with shareholders' interests.

In the past, we issued stock options as our form of equity compensation. In 2003, 2004 and 2005 we issued stock options 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 feel the issuance of RSUs presents a few 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, our management has communicated that the vesting schedule of the RSUs avoids the potential excise tax under Section 280G of the Internal Revenue Code upon a change of control. Third, we believe that stock options issued at a discount have generally fallen into disfavor. Fourth, it is difficult to set an exercise price for discounted 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 27,500,000 shares to employees. Of such RSU awards, 30%, 24%, 16%, 6% and 5% were issued to Messrs. Reddick, Spivey, Clemens, Seiser and Emigh, respectively. 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 2,000,000 shares were issued to 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. There are very few shares remaining available under our 2005 RSU Plan. As such, any significant further awards of RSUs would require an amendment to the 2005 RSU Plan.

***Salary, Bonus, and Non-Equity Incentive Compensation***

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. In addition, the employment agreements provide for additional 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. Such executive’s performance targets for 2007 consist of advancing our OxyADF product candidate through clinical development, assisting in the raising of funds to solidify the Company’s liquidity and consummating a collaboration agreement with a pharmaceutical partner for our OxyADF product candidate.

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 a specified limit, for exceeding the target for that measure. In setting compensation levels, the Compensation Committee compares the Company to companies of comparable business focus, market capitalization, technological capabilities and market in which we compete for executives.

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.

Specifically, each of our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer has a provision in his employment contract providing for various levels of incentive cash payments depending on the gross amount of funds raised by us prior to March 31, 2007, from a funding transaction. If a funding transaction of at least \$11 million occurs by March 31, 2007, these officers will be entitled to non-equity incentive compensation of up to between 73.3% and 100% of their base salary based on the gross amount of the funding transaction.

Since such a funding transaction did not occur in 2006, there was no non-equity incentive compensation component of compensation paid to these named executive officers in 2006. These named executive officers received no bonus compensation in 2006.

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 on or about March of each year and establish potential bonus compensation that such executives may earn based upon quantitative and, if applicable, qualitative performance goals established by the Compensation Committee. During 2006, these executives received no bonuses or non-equity incentive compensation.

In addition, 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). No such bonuses were paid to any of the named executive officers listed in the Summary Compensation Table.

### ***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 2003, 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 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 and expire no later than ten years, and in some cases five 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.

***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 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 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 8,250,000, 6,660,000, 4,400,000, 1,650,000 and 1,375,000 underlying shares, respectively. In the case of Messrs. Reddick, Spivey and Clemens, such awards are reflected in their employment agreements. The vesting during 2006 of the RSUs granted in 2005 is reflected in the “Stock Awards” column of the Summary Compensation Table, below.

### ***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 differs, but includes 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 (the “named executive officers”) have no contractual severance benefits if terminated by the Company other than acceleration of shares underlying 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, 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 409 of the Internal Revenue Code 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 - in the case of Mr. Spivey, such termination must be for Good Reason), or we terminate their

employment after a change of control. We feel our change of control provisions incentivise our executives to seek opportunities for us and realize benefits from a change of control 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 be able to 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 such issues to the full Board for approval. All such decisions are made with the consultation of the Chief Executive Officer. With respect to equity compensation awarded to other employees, the Compensation Committee either makes recommendations of grants of options and restricted stock to the Board, with the Board approving such awards or makes the grant itself. These grants are generally based upon the recommendation of the Chief Executive Officer. For example, in awarding RSUs in 2005, the Chief Executive Officer made a recommendation as to the amount of RSUs to be allocated to all employees, and the recommendation was considered by the Compensation Committee and the Board in making such awards.

**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 year ended December 31, 2006 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 exceeded \$100,000:

**Fiscal Year 2006 Summary Compensation Table**

Name and Principal Position	Salary (\$)	Bonus (\$)	Stock Awards <sup>1</sup> (\$)	Option Awards <sup>2</sup> (\$)	Change in Pension Non-Equity Value and Incentive Nonqualified Plan Deferred Compensation			All Other Compensation (\$)	Total (\$)
					Compen-sation (\$)	Earning (\$)	Compen-sation (\$)		
Andrew D. Reddick President and Chief Executive Officer	300,000	—	1,375,000	\$ 77,000	—	—	—	1,752,000	
Peter A. Clemens Senior Vice President and Chief Financial Officer	180,000	—	733,000	23,000	—	—	—	936,000	
Ron J. Spivey Senior Vice President and Chief Scientific Officer	260,000	—	1,110,000	166,000	—	—	—	1,536,000	
James F. Emigh Vice President, Marketing and Administration	140,000	—	229,000	16,000	—	—	—	385,000	
Robert A. Seiser	133,000	—	275,000	16,000	—	—	—	424,000	

Vice President,  
Corporate Controller and  
Treasurer

1. Reflects the vesting in 2006 of outstanding RSUs with respect to 2,750,000, 1,466,000, 2,200,000, 458,333 and 550,000 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 in accordance with FAS 123R, as reflected in our financial statements.

2. Reflects the vesting in 2006 of outstanding options with respect to 1,500,000, 93,750, 4,333,333, 62,250 and 62,250 underlying shares for Messrs. Reddick, Clemens, Spivey, Emigh and Seiser, respectively. The dollar amount reported is the compensation cost for such awards recognized in 2006 in accordance with FAS 123R, as reflected in our financial statements.

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### ***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, 2007. 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. The Employment Agreement provides for an annual base salary of \$300,000, plus the payment of annual bonus of up to one hundred percent (100%) of Mr. Reddick's base salary 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 2006 fiscal year, the Employment Agreement provides for a cash bonus equal to 100% of Mr. Reddick's then current base salary (the "2006 Cash Bonus") upon our receipt of aggregate proceeds of at least \$15.0 million on or before March 31, 2007 from an offering of our equity securities and/or from license fees or milestone payments from third-party licensing or similar transactions (subject to the payment of a pro-rata portion of the 2006 Cash Bonus provided we receive aggregate gross proceeds from such transactions of at least \$11.0 million on or before March 31, 2007). The Employment Agreement also provides for our grant to Mr. Reddick of stock options exercisable for up to 8,750,000 shares of Common Stock at an exercise price of \$0.13 per share. The stock options provide for vesting of 3,000,000 shares on the date of grant of the option, with the balance vesting in monthly increments of 250,000 shares at the expiration of each monthly period thereafter commencing with the month ending August 31, 2004. The exercise price of \$0.13 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 \$0.435. The Employment Agreement also acknowledges the grant to Mr. Reddick of a Restricted Stock Unit Award providing for our issuance of up to 8,250,000 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 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 \$0.3325, 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. Additionally, Mr. Reddick or his designees shall have a period of twelve (12) months following such termination (except for "Cause," in which case it is 40 days) to exercise Mr. Reddick's vested stock options (or, for those vested stock options subject to Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") the lesser of (a) twelve (12) months following the date of termination, or (b) the maximum exercise period permitted under Section 409A). 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, as well as Mr. Reddick's base salary for one year (the "Severance Pay"), payable in equal monthly installments over a period of twelve (12) months. 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 within 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 thirty (30) days of the date of termination, and (ii) all outstanding stock options granted to Mr. Reddick shall fully vest and be immediately exercisable. 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 employee 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.

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, 2007. 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. The Employment Agreement provides for an annual base salary of \$260,000, plus the payment of annual bonus of up to one hundred percent (100%) of Dr. Spivey's base salary 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 2006 fiscal year, the Employment Agreement provides for a cash bonus equal to one hundred percent (100%) of Mr. Spivey's then current base salary (the "2006 Cash Bonus") upon our receipt of aggregate proceeds of at least \$15.0 million on or before March 31, 2007 from an offering of our equity securities and/or from license fees or milestone payments from third-party licensing or similar transactions (subject to the payment of a pro-rata portion of the 2006 Cash Bonus provided we receive aggregate gross proceeds from such transactions of at least \$11.0 million on or before March 31, 2007. The Employment Agreement also provides for our grant to Mr. Spivey of stock options exercisable for up to 7,000,000 shares of Common Stock at an exercise price of \$0.13 per share. The stock option provides for vesting of 1,000,000 shares on October 1, 2004, 333,333 shares on each January 1, 2005, April 1, 2005, July 1, 2005 and October 1, 2005, 3,888,667 shares on January 1, 2006 and 778,001 on April 1, 2006. The exercise price of \$0.13 per share represents a discount to the fair market value of our common stock on the date of grant. The Employment Agreement also acknowledges the grant to Dr. Spivey of a Restricted Stock Unit Award providing for our issuance of up to 6,600,000 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 \$0.3325, 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. Additionally, Dr. Spivey or his designees have a period of twelve (12) months following such termination (except for "Cause," in which case it is 40 days) to exercise Dr. Spivey's vested stock options, (or, for those vested stock options subject to Section 409A, the lesser of (a) twelve (12) months following the date of termination, or (b) the maximum exercise period permitted under Section 409A). 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, as well as Dr. Spivey's base salary for one year (the "Severance Pay"), payable in equal monthly installments over a period of twelve (12) months. 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 thirty (30) days of the date of termination, and (ii) all outstanding stock options granted to Dr. Spivey shall fully vest and be immediately exercisable. 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.

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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, 2007. 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. The Employment Agreement provides for an annual base salary of \$180,000 plus the payment of 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. For our 2006 fiscal year, the Employment Agreement provides for a cash bonus equal to 100% of Mr. Clemens' then current base salary (the "2006 Cash Bonus") upon our receipt of aggregate proceeds of at least \$15.0 million on or before March 31, 2007 from an offering of our equity securities and/or from license fees or milestone payments from third-party licensing or similar transactions (subject to the payment of a pro-rata portion of the 2006 Cash Bonus provided the Company receives aggregate gross proceeds from such transactions of at least \$11.0 million on or before March 31, 2007). The Employment Agreement also provides for the grant of stock options on March 10, 1998 to purchase 300,000 shares of our common stock at an exercise price of \$2.375 per share, which options vest in equal increments of 25,000 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 375,000 shares of Common Stock at an exercise price of \$0.13 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. The Employment Agreement also acknowledges the grant to Mr. Clemens of a Restricted Stock Unit Award providing for our issuance of up to 4,400,000 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 \$0.3325, 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 a lump sum within 30 days of 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. Additionally, Mr. Clemens or his designees shall have a period of twelve (12) months following termination (except for "Cause," in which case it is 40 days) to exercise Mr. Clemens' vested stock options (or, for those vested stock options subject to Section 409A, the lesser of (a) twelve (12) months following the date of termination, or (b) the maximum exercise period permitted under Section 409A). 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). 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.

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, 2006 incentive stock options (“ISO's”) to purchase 262,510 shares and non-qualified options to purchase 116,390 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 \$1.57.

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*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 2,600,000 to 3,600,000 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 3,600,000 to 8,100,000 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 8,100,000 to 20,000,000 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, 2006, stock options to purchase 18,616,095 shares of Common Stock had been granted under the 1998 Stock Option Plan. Of such option grants, 869,826 are ISOs and 17,746,269 are non-qualified options. The average per share exercise price for all outstanding options under the 1998 Stock Option Plan is approximately \$0.23. 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 16,994,145 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.

***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 30 million shares of common stock are authorized for issuance under the 2005 RSU Plan. We believe that the 2005 RSU Plan does 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 us 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.

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 the December 31, 2006 we had granted RSUs providing for our issuance of up to an aggregate of 29,500,000 shares of our common stock. 27,500,000 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 2 million RSU Awards vest 777,778 shares on grant and the balance vest in equal monthly increments on the first day of March 1, 2006 and ending December 1, 2007.

#### ***Quantifying Termination/Change of Control Payments***

Messrs. Emigh and Seiser

If we terminate Robert Seiser's or James Emigh's employment other than for cause (as defined in the 2005 RSU Plan) all unvested RSUs granted to such executive vest in full. As of December 31, 2006, RSUs for 550,000 and 458,333 shares for Messrs. Seiser and Emigh, respectively, remained unvested. As a result, had Messrs. Seiser and Emigh been terminated other than for cause at December 31, 2006, they would have realized a benefit of \$53,000 and \$44,000, respectively.

If a change of control occurs (which constitutes a change of control under the 2005 RSU Plan) then Messrs. Seiser's and Emigh's previously unvested RSUs vest with respect to all underlying shares. In addition, previously unvested options vest (if the change of control qualifies under their stock option agreements) with respect to all underlying shares (options underlying 124,500 and 124,500 shares, in the case of Messrs. Seiser and Emigh, respectively, as of December 31, 2006). Messrs. Seiser and Emigh would realize a benefit of \$124,000 and \$124,000, respectively, from such option vesting if such change of control occurred on December 31, 2006. The combined benefit to Messrs. Seiser and Emigh from RSU vesting and option vesting on a change of control occurring on December 31, 2006 is \$177,500 and \$168,500, respectively. If such a change of control occurs and also 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 exercisability schedule.

The dollar benefits described above are the compensation cost for such awards that would have been recognized in 2006 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, 2006, 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





Triggering Event	Executive	Qualifying Termination Benefit (\$)					Medical, Dental, Health, Disability and Life Insurance Benefits	Total (7)
		Severance	Value of RSUs Vesting (2)	Bonus	Value of Options Vesting (4)			
Termination by Company without Cause or by Employee for Good Reason	Andrew D. Reddick	300,000 (1)(8)	264,000	300,000 (3)	(5)	26,270 (6)	890,270	
	Ron J. Spivey	260,000 (1)(9)	213,000	260,000 (3)	(5)	7,875 (6)	740,875	
	Peter A. Clemens	360,000 (3)(11)	141,000	180,000	—	52,540 (12)	733,540	
Termination by Employee for Good Reason (or any reason in case of Reddick or Clemens) after a Change of Control or by Company (other than for Cause) after a Change of Control	Andrew D. Reddick	300,000 (1)(8)	264,000	300,000 (3)	(5)	26,270(6)	890,270	
	Ron J. Spivey	260,000 (1)(9)	213,000	260,000 (3)	(5)	7,875(6)	740,875	
	Peter A. Clemens	360,000 (3)(11)	141,000	180,000 (3)	12,728	52,540(12)	746,268	
Termination for Death	Andrew D. Reddick	—	264,000	300,000 (3)	—	—	564,000	
	Ron J. Spivey	—	213,000	—	—	—	213,000	
	Peter A. Clemens	—	141,000	—	—	—	141,000	
Termination for Disability	Andrew D. Reddick	—	264,000	300,000 (3)	—	—	564,000	
	Ron J. Spivey	—	213,000	—	—	—	213,000	
	Peter A. Clemens	—	141,000	—	—	—	141,000	
Termination with Cause	Andrew D. Reddick	—	—	—	—	—	—	
	Ron J. Spivey	—	—	—	—	—	—	
	Peter A. Clemens	—	—	—	—	—	—	
Change of Control Without Termination	Andrew D. Reddick	—	264,000	—	(5)	—	264,000	
	Ron J. Spivey	—	213,000	—	(5)	—	213,000	
	Peter A. Clemens	—	141,000	—	12,728	—	153,728	

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

(1) Payable in 12 monthly installments, except on termination after a Change of Control, in which case such amount is payable in a lump sum within 30 days after termination.

(2) The dollar amount reported is the compensation cost for such awards that would have been recognized in 2006 in our financial statements in accordance with FAS 123R, had the unvested RSUs at December 31, 2006 vested at such date, (2,750,000, 2,200,000 and 1,466,667, in the case of Reddick, Spivey and Clemens, respectively).

(3) Payable in a lump sum within 30 days after termination.

(4) The dollar amount reported is the compensation cost for such awards that would have been recognized in 2006 in our financial statements in accordance with FAS 123R had the unvested stock options at December 31, 2006 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 thirty 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. Mr. Reddick is entitled to the greater of the salary remaining on the term of his employment agreement and 12 months of salary.

(9) Represents one year of salary.

(10) Assumes the change of control also constitutes a change of control for the vesting provisions of the 2005 RSU Plan. If such a change of control occurs and also meets the requirements of Section 409A of the Internal Revenue Code, the shares underlying the RSUs are issued (upon payment of the \$.01 par value per share).

(11) Represents two years of base salary.

(12) 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.

**Outstanding Equity Awards at 2006 Year End and Option Exercises in 2006**

The following table presents information regarding outstanding stock options and RSU awards at December 31, 2006 for each of the named executive officers:

**OUTSTANDING EQUITY AWARDS AT 2006 YEAR-END**

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested \$(1)
Andrew D. Reddick	8,750,000	—	\$ 0.13	08/12/2014	2,750,000	\$ 2,035,000
	300,000	—	\$ 2.375	02/19/2008		
	100,000	—	\$ 1.125	03/08/2009		
	125,000	—	\$ 1.875	02/17/2010		
	100,000	—	\$ 1.1125	06/29/2010		
Peter A. Clemens	187,500	187,500	\$ 0.13	03/09/2014	1,466,667	\$ 1,085,334
	3,000,000	—	\$ 0.13	04/15/2014		
Ron J. Spivey	4,000,000	—	\$ 0.13	12/09/2015	2,200,000	\$ 1,628,000
	40,000	—	\$ 2.50	05/29/2008		
	16,000	—	\$ 1.125	03/08/2009		
	30,000	—	\$ 1.875	02/17/2010		
	40,000	—	\$ 1.1125	06/29/2010		
	25,000	—	\$ 2.46	11/15/2011		
Robert A. Seiser	249,000	124,750	\$ 0.13	03/09/2014	550,000	\$ 407,000
	10,000	—	\$ 2.50	05/29/2008		
	10,000	—	\$ 1.50	10/13/2008		
	16,000	—	\$ 1.125	03/08/2009		
	50,000	—	\$ 1.875	02/17/2010		
	40,000	—	\$ 1.1125	06/29/2010		
	25,000	—	\$ 2.46	11/15/2011		
James F. Emigh	249,000	124,750	\$ 0.13	03/09/2014	458,333	\$ 339,166

(1) Based on the Closing Price of \$0.74 reported on the OTCBB on December 30, 2006. Does not take into account the \$.01 par value per share that must be paid on the distribution of shares underlying the RSUs.

The following table presents information regarding the value realized on the vesting during 2006 of RSU awards to the named executive officers. No stock options were exercised by the named executive officers during 2006.

**OPTION EXERCISE AND STOCK VESTED IN FISCAL YEAR 2006**

Name	Number of Shares Vested (#) <sup>(1)</sup>	Stock Awards	
			Value Realized on Vesting (\$) <sup>(2)</sup>
Andrew D. Reddick	2,750,000	\$	1,860,833
Peter A. Clemens	1,466,667		992,444
Ron J. Spivey	2,200,000		1,488,667
James F. Emigh	458,333		310,139
Robert A. Seiser	550,000		372,167

(1) The vested shares underlying the RSUs will be issued by us on the earlier (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, 2006 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)
	18,994,995	\$ 0.26	926,655

Stock Option Equity Compensation Plans Approved by Security Holders			
Stock Option Equity Compensation Plans Not Approved by Security Holders	0	0	0
Restricted Stock Unit Equity Compensation Plans Approved by Security Holders	29,500,000	0.01	500,000
Restricted Stock Unit Equity Compensation Plans Not Approved by Security Holders	0	0	0
<b>TOTAL</b>	<b>48,494,995</b>	<b>\$ 0.11</b>	<b>1,426,655</b>

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**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, 2006:

**YEAR 2006 DIRECTOR COMPENSATION**

<b>Director</b>	<b>Fees Earned or Paid in Cash (\$)</b>	<b>Stock Awards (\$)<sup>(1)</sup></b>	<b>Option Awards (\$)<sup>(2)</sup></b>	<b>Total (\$)</b>
William G. Skelly	8,500	340,000	—	348,500
William A. Sumner	9,500	340,000	—	349,500
Bruce F. Wesson	4,750	—	—	4,750
Richard J. Markham	2,500	—	—	2,500
Immanuel Thangaraj	(4)	—	—	—
Jerry Karabelas <sup>(3)</sup>	750	—	—	750

(1) Messrs. Skelly and Sumner each held RSUs with respect to 1,000,000 underlying shares, as of December 31, 2006, Messrs. Wesson, Markham, Tharangaj and Karabelas held no RSUs. The dollar amount provided is the compensation cost for such awards recognized in 2006 as reported in our financial statements in accordance with FAS 123R.

(2) Messrs. Skelly, Sumner, Wesson, Markham, Tharangaj, and Karabelas held options with respect to 390,000, 250,000, 150,000, 0, 100,000 and 100,000 underlying shares, respectively, as of December 31, 2006. The dollar amount provided is the compensation cost for such awards recognized in 2006 as reported in our financial statements in accordance with FAS 123R.

(3) Dr. Karabelas resigned as our director effective May 11, 2006.

(4) Fee waived.

Directors who are also our employees receive no additional or special remuneration for their services as Directors. Directors who are not our employees are eligible to receive, at the discretion of the Company, an annual grant of options to purchase 50,000 shares of our common stock. No such option grants were made to any director in 2005 or 2006. Additionally, Directors who are not our employees receive \$500 for each meeting attended (\$250 in the case of telephonic meetings). We also reimburse Directors for travel and lodging expenses, if any, incurred in connection with attendance at Board meetings. Directors who serve on any of the Committees established by the Board of Directors receive \$250 for each Committee meeting attended unless held on the day of a full Board meeting. 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 1 million 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 vest 388,889 shares on grant and the balance 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***

Our Compensation Committee consists 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 of the Board of Directors of the Company (the "Compensation Committee") was composed of three directors during 2006. In May 2006, Mr. Markham replaced Dr. Karabelas (who resigned as director) as a member of the Compensation Committee.

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, William G. Skelly, and Andrew D. Reddick**

**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, 2007, 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 2006 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	256,325,501(2)	77.5%
Andrew D. Reddick	8,750,000(3)	2.6%
Ron J. Spivey	7,000,000(4)	2.1%
William G. Skelly	401,000(5)	*
Bruce F. Wesson	—(2)	*
William A. Sumner	250,000(6)	*
Peter A. Clemens	1,221,573(7)	*
Richard J. Markham	—(2)	*
Immanuel Thangaraj	—(2)	*
Robert A. Seiser	337,625(8)	*
James F. Emigh	382,625(9)	*
All Directors and Officers as a Group (10 persons)	18,342,823(10)	5.3%

\* 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, 2006 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, is the assignee of all of the Company's preferred stock (prior to its 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"). Galen, Care Capital and Essex own 43%, 27% and 30%, respectively, of the membership interests in GCE Holdings LLC. The following natural persons exercise voting, investment and dispositive rights over the Company's 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., William Grant, Bruce F. Wesson, L. John Wilkenson, David W. Jahns, and Zubeen Shroff; and (ii) Care Capital Investments II, LP and Care Capital Offshore Investments II, LP, Jan Leschly, Jerry Karabelas, David Ramsay and Richard Markham; and (iii) Essex Woodlands Health Ventures V, L.P., Immanuel Thangaraj.

(3) Includes 8,750,000 shares subject to currently exercisable stock options. Excludes 8,250,000 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.

(4) Includes 7,000,000 shares subject to currently exercisable stock options. Excludes 6,600,000 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.

(5) Includes 390,000 shares subject to currently exercisable stock options. Excludes 1,000,000 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.

(6) Includes 250,000 shares subject to currently exercisable stock options. Excludes 1,000,000 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.

(7) Includes 906,250 shares subject to currently exercisable stock options. Excludes 4,400,000 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.

(8) Includes 337,625 shares subject to currently exercisable stock options. Excludes 1,650,000 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.

(9) Includes 337,625 shares subject to currently exercisable stock options. Excludes 1,375,000 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.

(10) Includes 17,971,500 shares which Directors and executive officers have the right to acquire within 60 days of February 1, 2007 through exercise of outstanding stock options.

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

GCE Holdings LLC, our 77% stockholder (“GCE”) is the assignee of all of the shares of the Company’s preferred stock (prior to its 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”). Galen, Care and Essex own 43%, 27% and 30%, respectively, of the membership interest in GCE. Messrs. Wesson, Markham and Thangaraj, each a Director of the Company, exercise investment control over the membership interests in GCE held by Galen, Care and Essex, respectively, and correspondingly exercise investment control over the Company’s securities held by GCE.

As a condition to the completion of the Company's 2004 debenture offering, we, the investors in the 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 its conversion into common stock) to GCE. As amended, the Voting Agreement provides that our Board of Directors shall be comprised of not more than seven (7) members, four (4) of whom shall be designees of GCE. The designees of GCE are Messrs. Wesson, Markham and Thangaraj. As of the date of this Report, the fourth designee of GCE had not been determined.

It was a condition to the completion of our 2004 debenture offering that our senior term loan agreement (the "Watson Loan Agreement") with Watson Pharmaceuticals, Inc. ("Watson") be restructured to provide for a reduction in the principal amount of the Watson term loan and for the assignment of the Watson term loan as restructured to Galen, Care and Essex and the other investors in our 2004 debentures as of February 10, 2004 (collectively, the "Watson Note Purchasers"). Accordingly, simultaneous with the initial closing of our 2004 debenture offering, we, Watson and the Watson Note Purchasers executed an Umbrella Agreement dated as of February 10, 2004 (the "Umbrella Agreement"). The Umbrella Agreement provided for (i) our payment to Watson of approximately \$4.3 million in consideration of amendments to the Watson term notes in the aggregate principal amount of approximately \$21.4 million evidencing the Watson term loan (the "Watson Notes") (A) to forgive approximately \$16.4 million of indebtedness under that Watson Notes, leaving a \$5.0 million principal balance, (B) to extend the maturity date of the Watson Notes from March 31, 2006 to June 30, 2007, (C) to provide for the satisfaction of future interest payments under the Watson Notes in the form of our common stock, and (D) to provide for the forbearance from the exercise of rights and remedies upon the occurrence of certain events of default under the Watson Notes (the Watson Notes as so amended, the "2004 Note"), and (ii) Watson's sale and conveyance of the 2004 Note to the Watson Note Purchasers for cash consideration of \$1.0 million.

The 2004 Note in the principal amount of \$5.0 million is secured by a lien on all of our and our subsidiary's assets, carries a floating rate of interest equal to the prime rate plus 4.5% and matures on June 30, 2007. The allocation of ownership of the \$5.0 million 2004 Note among each of the Watson Note Purchasers was based on the quotient of the principal amount of our 2004 debentures purchased by such Watson Note Purchaser, divided by approximately \$12.3 million, representing the aggregate principal amount of the 2004 debentures issued by us on February 10, 2004. As such, of the \$5.0 million principal amount of the 2004 Note, approximately \$1,352,000, \$1,754,000, and \$1,754,000, is owed by us to Care, Essex and Galen, respectively (representing approximately 27%, 35% and 35%, respectively, of the 2004 Note). During 2006, we paid interest under the 2004 Note in the aggregate amount of \$623,942, which was satisfied by the issuance of an aggregate of 854,659 shares of our common stock (of which 231,108 shares, 299,895 shares and 299,900 shares were issued to Care, Essex and Galen, respectively).

We are a party to four (4) loan agreements completed in January 2006, November, 2005, September, 2005 and June, 2005, each as amended to date, pursuant to which we have received bridge financing installments in the aggregate principal amount of \$8,744,000 (the "Bridge Loans") from Galen, Care and Essex (collectively, the "VC Lenders") and certain of our other shareholders listed on the signature page to such Bridge Loan agreements. The net proceeds from the Bridge Loans, after the satisfaction of related legal expenses, have been used by us to continue development of our Aversion® Technology and to fund related operating expenses. The Bridge Loans are secured by a lien on all of our assets, senior in right of payment and lien priority to all of our other indebtedness. The Bridge Loans bear interest at the rate of ten percent (10%) per annum, payable quarterly, and mature on March 31, 2007. Interest was paid in cash through the June 30, 2006 interest payment date. Commencing with the September 30, 2006 interest payment date, interest is payable, at our option, in our common stock based upon the average of the closing bid and asked prices of the common stock for the five (5) trading days immediately preceding an interest payment date. The Bridge Loans are subject to mandatory pre-payment upon our completion of equity or debt financing or any sale, transfer, license or similar arrangement pursuant to which we sell, license or otherwise grant rights in any material portion of our intellectual property to any third party, provided that the consummation of any such transaction results in certain minimum amounts of cash proceeds to us, net of all costs and expenses. The Bridge Loans restrict our ability to issue any shares of our currently authorized Series A, B or C convertible preferred stock without the prior consent of the bridge lenders, and grants the bridge lenders preemptive rights relating to the issuance of our Series A, B and C convertible preferred stock. The Bridge Loans contain cross default provisions with the 2004 Note and each of the outstanding Bridge Loans. The Bridge Loans also contain normal and customary affirmative and negative covenants, including restrictions on our ability to incur additional debt or grant any lien on our assets or the assets of its subsidiary, subject to certain permitted exclusions.

In August 2006, the Bridge Loans were amended to allow the bridge lenders to convert all or a portion of the Bridge Loans into our common stock upon our completion of an equity financing. The Bridge Loans and the August 2006 amendment were further amended in November 2006 to permit the bridge lenders to convert the Bridge Loans into our common stock upon the completion of a third-party equity financing providing gross proceeds to us in the aggregate amount of at least \$8 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 VC Lenders may convert \$2.0 million in Bridge Loans into the 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 our common stock for the twenty trading days immediately preceding the public announcement of the Third Party Investor Financing, (ii) the average price of the securities sold by us in such Third Party Equity Financing, and (iii) \$0.44 per share, 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 our common stock for the twenty trading days immediately preceding the public announcement of the Change of Control Transaction or the maturity date, as applicable, and (ii) \$0.44 per share. In addition, upon a Triggering Event, the bridge lenders may convert \$2.55 million of Bridge Loans into our common stock at a conversion price of \$0.20 per share, \$2.3 million of the Bridge Loans at a conversion price of \$0.225 per share and \$1.894 million of the Bridge Loans at a conversion price of \$0.25 per share. Under current accounting guidance, certain provisions of the amended conversion feature required the Company to separate the value of the conversion feature from the debt and record such value as a separate liability which must be marked-to-market each balance sheet date.

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 will be 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.

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 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 \$19,951,000 to these conversion features and reflected the modification loss as a non-cash deemed dividend. While the aggregate non-cash deemed dividend of \$19,960,000 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, the Company recorded the resulting decrease in value as a \$4,235,000 gain. The decrease in the Company's common stock trading price from November 2006 to year end resulted in the decrease in the value of the conversion liability.

During 2006, we paid an aggregate of \$193,739 in cash interest under the Bridge Loans (of which \$58,289, \$58,289 and \$58,289 was paid to Galen, Care and Essex, respectively) and issued an aggregate of 426,501 shares of our common stock in satisfaction of interest payments under the Bridge Loans (of which 139,342 shares, 139,342 shares and 139,342 shares were issued to Galen, Care and Essex, respectively).

The Board has not adopted formalized written policies and procedures for the review or approval of related party transactions. As a matter of practice, however, the 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, Galen, Care, Essex or other significant shareholder) will have a direct or indirect interest in a transaction in which the Company 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 the Company and its 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 behalf of the Company. 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 Director independence as it relates to the Board as a whole and committees of the Board, our Board has reviewed and analyzed the standards for independence provided in Sections 121A, 803 and 805 of the American Stock Exchange Company Guide and Listing Requirements (the "American Stock Exchange Director Independence Requirements"). While we are not subject to the American Stock Exchange Director Independence Requirements, such

standards allow our Board to evaluate the independence of the directors on our Board. Based on an analysis of these standards, our Board has determined that each of Messrs. Sumner and Skelly are independent directors. With respect to our Board committees, our Board has determined that Messrs. Wesson and Thangaraj, each a member of our Audit Committee, and Messrs. Reddick and Markham, each a member of our Compensation Committee, do not meet the American Stock Exchange Director Independence Requirements.

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**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The Company's registered independent public accounting firm is BDO Seidman, LLP. The fees billed by this firm in 2006 and 2005 were as follows:

	2006	2005
Audit Fees	\$ 85,825	\$ 67,867
Audit-Related Fees	-	7,480
Total Audit and Audit-Related Fees	85,825	75,347
Tax Fees	30,168	28,000
All Other Fees	-	-
Total for BDO Seidman, LLP	\$ 115,993	\$ 103,347

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 Securities and Exchange Commission registration statements or other documents filed with the Securities and Exchange Commission 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 Commission 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 2006 and 2005 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

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**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 14, 2007

ACURA PHARMACEUTICALS, INC.

By: /s/ 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.

<b>Signature</b>	<b>Title(s)</b>	<b>Date</b>
<u>/s/ Andrew D. Reddick</u> Andrew D. Reddick	President, Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2007
<u>/s/ Peter A. Clemens</u> Peter A. Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2007
<u>/s/ William G. Skelly</u> William G. Skelly	Director	March 14, 2007
<u>/s/ Bruce F. Wesson</u> Bruce F. Wesson	Director	March 14, 2007
<u>/s/ William A. Sumner</u> William A. Sumner	Director	March 14, 2007
<u>/s/Richard J. Markham</u> Richard J. Markham	Director	March 14, 2007
<u>/s/ Immanuel Thangaraj</u> Immanuel Thangaraj	Director	March 14, 2007



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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, 2006 and 2005 and the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2006. 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we required to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Acura Pharmaceuticals, Inc. and Subsidiary at December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note B to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note B. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As described in Note A.14 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 13, 2007

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## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2006 and 2005

(in thousands)

	2006	2005
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 228	\$ 260
Prepaid insurance	179	179
Prepaid expenses and other current assets	60	5
Total current assets	467	444
PROPERTY, PLANT & EQUIPMENT, NET	1,145	1,341
DEPOSITS	7	7
<b>TOTAL ASSETS</b>	<b>\$ 1,619</b>	<b>\$ 1,792</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES</b>		
Senior secured convertible term notes payable, net	\$ 7,005	\$ 2,550
Conversion features on notes payable	16,750	-
Secured term note payable	5,000	-
Current maturities of capital lease obligations	25	31
Accrued expenses	328	341
Total current liabilities	29,108	2,922
SECURED TERM NOTE PAYABLE	-	5,000
COMMON STOCK WARRANTS	10,784	-
CAPITAL LEASE OBLIGATIONS, less current maturities	7	32
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>TOTAL LIABILITIES</b>	<b>\$ 39,899</b>	<b>\$ 7,954</b>
<b>STOCKHOLDERS' DEFICIT</b>		
Common stock - \$.01 par value; 650,000,000 shares authorized; 330,998,468 and 329,293,530 shares issued and outstanding in 2006 and 2005, respectively	3,310	3,293
Convertible preferred stock - \$.01 par value; 72,027,014 shares authorized and available for issuance	-	-
Additional paid-in capital	275,953	287,885
Unearned compensation	-	(5,724)
Accumulated deficit	(317,543)	(291,616)
<b>STOCKHOLDERS' DEFICIT</b>	<b>(38,280)</b>	<b>(6,162)</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<b>\$ 1,619</b>	<b>\$ 1,792</b>

See accompanying notes to the consolidated financial statements.

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## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2006, 2005 and 2004

(in thousands, except per share data)

	2006	2005	2004
Net product revenues	\$ -	\$ -	\$ 838
Cost of manufacturing	-	-	1,435
Research and development	5,172	6,265	4,130
Selling, marketing, general and administrative	5,654	5,296	5,238
<b>LOSS FROM OPERATIONS</b>	<b>(10,826)</b>	<b>(11,561)</b>	<b>(9,965)</b>
<b><u>OTHER INCOME (EXPENSE)</u></b>			
Interest expense	(1,140)	(636)	(2,962)
Interest income	18	36	59
Write-off of debt discount and deferred private debt offering costs	-	-	(41,807)
Amortization of debt discount and deferred private debt offering costs	(183)	-	(30,684)
Gain on debt restructuring	-	-	12,401
Gain on fair value change of conversion features	4,235	-	-
Gain on fair value change of common stock warrants	2,164	-	-
(Loss) gain on asset disposals	(22)	81	2,359
Other	(213)	5	603
<b>TOTAL OTHER INCOME (EXPENSE)</b>	<b>4,859</b>	<b>(514)</b>	<b>(60,031)</b>
<b>NET LOSS</b>	<b>\$ (5,967)</b>	<b>\$ (12,075)</b>	<b>\$ (69,996)</b>
Basic and diluted loss per common share applicable to common stockholders (Note A)	\$ (0.08)	\$ (0.18)	\$ (3.20)
Weighted average number of outstanding common shares	344,959	66,799	21,861

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIT

YEARS ENDED DECEMBER 31, 2006, 2005 AND 2004

(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, 2004</b>	<b>21,602</b>	<b>\$ 216</b>	<b>-</b>	<b>\$ -</b>	<b>\$ 157,262</b>	<b>\$ -</b>	<b>(209,545)</b>	<b>\$ (52,067)</b>
Net loss for the year ended December 31, 2004	-	-	-	-	-	-	(69,996)	(69,996)
Intrinsic value of issued options	-	-	-	-	3,030	(3,030)	-	-
Amortization of unearned compensation	-	-	-	-	55	1,952	-	2,007
Issuance of Common Shares for payment of interest	865	9	-	-	391	-	-	400
Issuance of Preferred Shares for convertible debentures:								
Series A Convertible	-	-	21,964	220	13,892	-	-	14,112
Series B Junior Convertible	-	-	20,246	203	6,722	-	-	6,925
Series C-1 Junior Convertible	-	-	56,423	564	32,025	-	-	32,589
Series C-2 Junior Convertible	-	-	37,433	374	22,059	-	-	22,433
Series C-3 Junior Convertible	-	-	81,907	819	27,693	-	-	28,512
Beneficial conversion features in conjunction with issuance of convertible debentures	-	-	-	-	14,000	-	-	14,000
<b>Balance at December 31, 2004</b>	<b>22,467</b>	<b>225</b>	<b>217,973</b>	<b>2,180</b>	<b>277,129</b>	<b>(1,078)</b>	<b>(279,541)</b>	<b>(1,085)</b>
Net loss for the year ended December 31, 2005	-	-	-	-	-	-	(12,075)	(12,075)
	-	-	-	-	11,105	(11,105)	-	-

Intrinsic value of issued options and restricted stock units									
Amortization of unearned compensation	-	-	-	-	-	6,459	-	6,459	
Issuance of Common Shares for exercise of options	35	1	-	-	4	-	-	5	
Issuance of Common Shares for interest	963	10	-	-	525	-	-	535	
Conversion of Preferred Shares:									
Series A Convertible Preferred	109,819	1,098	(21,964)	(220)	(878)	-	-	-	
Series B Junior Convertible	20,246	203	(20,246)	(203)	-	-	-	-	
Series C-1 Junior Convertible	56,423	564	(56,423)	(564)	-	-	-	-	
Series C-2 Junior Convertible	37,433	374	(37,433)	(374)	-	-	-	-	
Series C-3 Junior Convertible	81,907	819	(81,907)	(819)	-	-	-	-	
<b>Balance at December 31, 2005</b>	<b>329,293</b>	<b>3,293</b>	<b>-</b>	<b>-</b>	<b>287,885</b>	<b>(5,724)</b>	<b>(291,616)</b>	<b>(6,162)</b>	
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	
Other stock based compensation	-	-	-	-	5,046	-	-	5,046	
Reclassification of value of common stock warrants to liabilities	-	-	-	-	(12,948)	-	-	(12,948)	
Issuance of Common Shares for exercise of options	400	4	-	-	94	-	-	98	
Issuance of Common Shares for interest	1,281	13	-	-	920	-	-	933	
Issuance of Common Shares	24	-	-	-	-	-	-	-	

for cashless exercise of  
warrant

**Balance at December**

<b>31, 2006</b>	<b>330,998</b>	<b>\$ 3,310</b>	<b>- \$</b>	<b>- \$ 275,953</b>	<b>\$</b>	<b>- \$ (317,543)</b>	<b>\$ (38,280)</b>
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See accompanying notes to the consolidated financial statements.

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## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2006, 2005, and 2004

(in thousands, except supplemental data)

	2006	2005	2004
<b>Cash flows from Operating Activities:</b>			
Net loss	\$ (5,967)	\$ (12,075)	\$ (69,996)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	118	137	291
Amortization of debt discount and deferred private debt offering costs	183	-	30,684
Write off unamortized debt discount and deferred private debt offering costs	-	-	41,807
Gain on the fair value change of conversion features	(4,235)	-	-
Gain on the fair value change of common stock warrants	(2,164)	-	-
Gain on debt restructuring	-	-	(12,401)
Non-cash stock compensation expense	5,724	6,459	2,007
Gain on Department of Justice settlement	-	-	(402)
Amortization of deferred product acquisition costs	-	-	6
Provision for losses on accounts receivable	-	-	(428)
Loss (gain) on asset disposals	22	(81)	(2,359)
Stock issued for interest expense	933	535	401
Impairment charge against fixed assets	71	-	-
Changes in assets and liabilities			
Accounts receivable	-	-	729
Inventories	-	-	312
Prepaid expenses and other current assets	(55)	121	94
Other assets and deposits	-	(5)	184
Accounts payable	-	-	(1,882)
Accrued expenses	(13)	(618)	1,460
Total adjustments	584	6,548	60,503
Net cash used in operating activities	(5,383)	(5,527)	(9,493)
<b>Cash flows from Investing Activities:</b>			
Capital expenditures	(85)	(35)	(444)
Proceeds from asset disposals	70	193	4,538
Net cash (used in) provided by investing activities	(15)	158	4,094
<b>Cash flows from Financing Activities:</b>			
Proceeds from issuance of senior secured bridge loan notes payable	5,298	2,550	-
Proceeds from the exercise of stock options	98	5	-
Proceeds from issuance of subordinated convertible debentures	-	-	11,951
Payments on senior secured term notes payable	-	-	(4,000)

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Payments to Department of Justice	-	-	(31)
Payments on capital lease obligations	(31)	(29)	(45)
Payments of private offering costs	-	-	(315)
Net cash provided by financing activities	5,365	2,526	7,560
(Decrease) increase in cash and cash equivalents	(33)	(2,843)	2,161
Cash and cash equivalents at beginning of year	260	3,103	942
<b>Cash and cash equivalents at end of year</b>	<b>\$ 228</b>	<b>\$ 260</b>	<b>\$ 3,103</b>

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, 2006, 2005, and 2004**

Supplemental disclosures of noncash investing and financing activities:

**Year ended December 31, 2006**

1. The Company issued 854,649 shares of Common Stock as payment of \$624,000 of Secured Term Note Payable accrued interest.
2. The Company issued 426,501 shares of Common Stock as payment of \$309,000 of Bridge Loan Notes Payable accrued interest.
3. Warrants to purchase 165,934 shares of Common Stock were exercised in March 2006 at an exercise price of \$0.48 per share in a cashless exercise transaction resulting in the issuance of 19,065 shares of Common Stock.
4. Warrants to purchase 30,698 shares of Common Stock were exercised in May 2006 at an exercise price of \$0.47 per share in a cashless exercise transaction resulting in the issuance of 4,729 shares of Common Stock.
5. A warrant to purchase 150,000 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 \$19,950,000 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 963,000 shares of common stock as payment of \$535,000 of Secured Term Note Payable accrued interest.
2. 217,973,000 shares of Convertible Preferred Stock were converted into 305,828,000 shares of Common Stock.

**Year ended December 31, 2004**

1. The Company's Convertible Subordinated Debentures contained beneficial conversion features which were valued at \$14,000,000.
2. The Company repaid \$166,000 of indebtedness in the form of product deliveries.

3. Bridge Loans of \$2,000,000 and accrued interest of \$49,000 were converted into like amounts of Convertible Subordinated Debentures.
4. The Company issued 865,000 shares of common stock as payment of \$400,000 of Senior Secured Term Note Payable accrued interest.
5. Convertible Subordinated Debentures of \$100,632,000 and accrued interest of \$3,939,000 were converted into 217,973,000 shares of Convertible Preferred Stock.

See accompanying notes to the consolidated financial statements.

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

**DECEMBER 31, 2006, 2005 and 2004**

**NOTE A - DESCRIPTION OF BUSINESS AND SUMMARY OF ACCOUNTING POLICIES**

Acura Pharmaceuticals, Inc., a New York corporation, and its subsidiary (the "Company") is a specialty pharmaceutical company engaged in research, development and manufacture of innovative Aversion® (abuse deterrent) Technology and related product candidates. OxyADF 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").

Prior to the restructuring of its operations (as described below), the Company was engaged in the development, manufacture, sale and distribution of generic finished dosage pharmaceutical products ("Generic Products") and active pharmaceutical ingredients ("APIs"). On November 6, 2003, the Company announced a restructuring plan to focus on research and development related to its Aversion® Technology and Opioid Synthesis Technologies (as described below). During the first quarter of 2004, the Company ceased its Generic Products operations and during the nine months ended September 20, 2004, the Company sold to third parties substantially all of its assets used in the manufacture and sale of its Generic Products for \$4.5 million. During 2004 and early 2005, the Company was also engaged in development of novel opioid manufacturing processes (the "Opioid Synthesis Technologies") intended for use in the commercial manufacture of certain bulk opioid active pharmaceutical ingredients. In early 2005, the Company announced suspension of activities relating to the Opioid Synthesis Technologies pending the deputy DEA Administrator's determination relating to the Company's pending application for registration to import narcotic raw materials (the "Narcotic Raw Materials Import Application") filed with the DEA in early 2001. In late 2006, the Company notified the DEA that it was withdrawing the Narcotic Raw Materials Import Application and subsequently the Company has discontinued all activities relating to the Opioid Synthesis Technologies. The withdrawal of the Narcotic Raw Material Import Application and the discontinuation of all activities relating to the Opioid Synthesis Technologies allow the Company to focus all of its resources on developing and commercializing its Aversion® Technology and related product candidates.

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 DEA to perform research, development and manufacture for certain Schedule II - V finished dosage form products. In addition to internal capabilities and activities the Company engages a number of pharmaceutical product contract research organizations ("CROs") with expertise in regulatory affairs, clinical trial design and monitoring, and clinical data management, biostatistics, medical writing, laboratory testing and related services. Such CROs perform development services for OxyADF Tablets and other product candidates under the direction of the Company.

To generate revenue the Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license product candidates utilizing the Company's Aversion® Technology and further develop, register and commercialize multiple strengths and packing sizes of such product candidates. The Company expects to receive revenue in the form of milestone payments and a share of profits and/or royalty payments derived from the Partners' future sale of products incorporating Aversion® Technology. As of the date of this Report, the Company did not have any executed collaborative agreements with Partners, nor can there be any assurance that the Company will successfully enter into such collaborative agreements in the future.

## **Summary of 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 material intercompany accounts and transactions have been eliminated. In 2006, the Company dissolved Axiom Pharmaceutical Corporation. During 2003, the Company dissolved all of its inactive subsidiaries with the exception of Acura Pharmaceutical Technologies, Inc. and Axiom Pharmaceutical Corporation. The dissolution of these subsidiaries had no impact on the consolidated financial position, results of operations or cash flows of the Company.

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## 2. Statements of Cash Flows

For purposes of the statements of cash flows, the Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. The Company paid no income taxes for the years ended December 31, 2006, 2005 and 2004. In addition, the Company paid cash interest of approximately \$207,000, \$101,000 and \$47,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

## 3. Accounts Receivable - Trade and Allowance Accounts

Consistent with the cessation of the manufacture and sale of Generic Products in the first quarter of 2004, the Company had no accounts receivable from customers at each of December 31, 2006 and 2005. For prior periods, the Company's accounts receivable - trade were due from customers for the purchase of Generic Products. Credit was extended based on evaluation of a customer's financial condition and, generally, collateral was not required. Estimates that were used in determining allowances were based on the Company's historical experience, current trends, credit policy and a percentage of its accounts receivable by aging category.

Changes in the Company's trade allowance accounts are as follows (in thousands):

	<b>2004</b>
Beginning balance	\$ 428
Provision for losses on accounts receivable	-
Provision for all other allowances	-
Write-offs	(428)
Ending balance	\$ -

## 4. Inventories

The Company had no inventories at each of December 31, 2006 and 2005. Purchases of active ingredients required for the Company's development and manufacture of product candidates utilizing its Aversion® Technology, are expensed as incurred.

## 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 assets assigned to the Company's Opioid Synthesis Technologies. The Company has discontinued all activities relating to its Opioid Synthesis Technologies.

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## **7. Deferred Private Debt Offering Costs**

Private debt offering costs represented costs incurred by the Company in conjunction with securing debt financing in February 2004. In August 2004, all outstanding debentures were converted into various series of preferred stock and approximately \$717,000 of unamortized deferred private debt offering costs were charged to expense. All outstanding series of preferred stock was subsequently converted into common stock in 2005.

## **8. 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 the Company's 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 Note F, additional debt discount of \$1,025,000 was recorded in 2006 and is being amortized through the March 31, 2007 maturity of the related debt.

## **9. Conversion Features and Common Stock Warrants**

Certain provisions of the amended conversion features contained in the Company's outstanding 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 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, the Company 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.

## **10. Revenue Recognition**

The Company recorded no Generic Product sales revenues after the second quarter of 2004. Prior to that, the Company recognized revenue, net of sales discounts and allowances, when title to the Generic Products passed to the customer, which occurred upon shipment. The Company established sales provisions for estimated chargebacks, discounts, rebates, returns, pricing adjustments and other sales allowances concurrently with the recognition of revenue. The sales provisions were established based upon consideration of a variety of factors, including, but not limited to, actual return and historical experience by product type, the number and timing of competitive products approved for sale, the expected market for the product, estimated customer inventory levels by product, price declines and current and projected economic conditions and levels of competition. Actual product return, chargebacks and other sales allowances incurred were, however, dependent upon future events.

## **11. Shipping and Handling Costs**

Prior to cessation of the manufacture and sale of Generic Products in the second quarter of 2004, the Company included all shipping and handling expenses incurred as a component of cost of manufacturing.

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## 12. Research and Development

Prior to the cessation of development, manufacture and sale of Generic Products, research and development ("R&D") expenses consisted primarily of activities associated with development of Generic Products and the Company's Opioid Synthesis Technologies. Since the first quarter of 2004, R&D expenses were primarily associated with the Company's Aversion® Technology and, to a much lesser extent, the Company's Opioid Synthesis Technologies. R&D expenses include internal R&D activities and external CROs. Internal R&D expenses include facility overhead, maintenance, repair and depreciation, laboratory supplies, pre-clinical laboratory experiments, equipment maintenance, repairs and depreciation, salaries, benefits, incentive compensation and other administrative expenses. CRO expenses include preclinical laboratory experiments, clinical trials, clinical trial and regulatory consulting, regulatory counsel and patent counsel. R&D expenses are charged to operations as incurred. The Company reviews and accrues clinical trial expenses based on work performed and relies on an estimate of the costs applicable to the stage of completion of a clinical trial as provided by the CRO. Accrued clinical 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. The Company has binding research and development commitments, of which \$162,000 has yet to be incurred and recorded, at December 31, 2006. This amount is expected to be spent by March 31, 2007. The Company had no binding research and development commitments with third parties at December 31, 2005.

## 13. 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 tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Additionally, income tax credit carryforwards are reported as deferred income tax assets. SFAS 109 requires a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. At both December 31, 2006 and 2005, a valuation allowance equal to 100% of the net deferred income tax assets was used and primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards. In the event the Company were to determine that it would be able to realize some or all its deferred income tax assets in the future, an adjustment to the deferred income tax asset would increase income in the period such determination was made.

## 14. 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). Diluted earnings (loss) per share is based on the same number of common shares adjusted for the effect of other potentially dilutive securities. No such adjustments were made for 2006, 2005 or 2004 as their effects would be antidilutive.

Net loss used in the Company's earnings (loss) per share computations includes the impact in 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,		
	2006	2005	2004
Numerator:			
Net loss	\$ (5,967)	\$ (12,075)	\$ (69,996)
Deemed dividend from modification of debt	(19,960)	-	-
Net loss applicable to common stock holders	\$ (25,927)	\$ (12,075)	\$ (69,996)

<b>Denominator:</b>				
Weighted average number of outstanding -				
Common shares	329,858	66,573	21,861	
Vested restricted stock units	15,101	226	-	
	344,959	66,799	21,861	
<b>Basic and diluted loss per common share</b>				
	\$ (0.08)	\$ (0.18)	\$ (3.20)	
<b>Potentially dilutive securities:</b>				
Common stock issuable (1) -				
Employee and director stock options	18,995	19,755	17,499	
Common stock warrants	16,331	16,242	32,877	
Non-vested restricted stock units	9,833	18,333	-	
Convertible debt	33,057	-	-	
Convertible preferred stock	-	-	305,828	
	78,216	54,330	356,204	

(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.



## 15. 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.

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.

	<b>Year ended December 31,</b>	
	<b>(in thousands,</b>	
	<b>except per share data)</b>	
	<b>2005</b>	<b>2004</b>
Net loss, as reported	\$ (12,075)	\$ (69,996)
Add: total stock-based employee compensation expense included in reported net loss	6,459	2,007
Deduct: total stock-based employee compensation expense determined under fair value-based method for all awards	(7,242)	(3,058)
Net loss, pro forma	\$ (12,858)	\$ (71,047)
Loss per share:		
Basic and Diluted EPS - as reported	\$ (0.18)	\$ (3.20)
Basic and Diluted EPS - as pro forma	\$ (0.19)	\$ (3.25)

## 16. 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.

## 17. 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.

## 18. Reclassifications

Certain reclassifications have been made to the prior years' amounts to conform to the current year's presentation.

## 19. New Accounting Pronouncements

### Changes and Error Corrections

In May 2005, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 154, "Accounting Changes and Error Corrections - A Replacement of APB Opinion No. 20 and FASB Statement No. 3", ("SFAS 154"). SFAS 154 primarily requires retrospective application to prior periods' financial statements for the direct effects of changes in accounting principle, unless it is impracticable to determine either the period-specific

effects or the cumulative effect of the change. SFAS 154 was effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005.

### **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 FAS 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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### **Certain Hybrid Financial Instruments**

In February 2006, FASB issued Statement of Financial Accounting Standard No. 155, "Accounting for Certain Hybrid Financial Instruments - an amendment of FASB Statement No. 133 and 140" ("SFAS 155"). SFAS 155 resolves issues addressed in Statement 133 Implementation Issue No. D1, "Application of Statement 133 to Beneficial Interests in Securitized Financial Assets." SFAS 155 is effective for all financial instruments acquired or issued after the beginning of the first fiscal year that begins after September 15, 2006. As such, the Company is required to adopt these provisions at January 1, 2007. The Company is currently evaluating the impact of SFAS 155, but currently does not anticipate any material impact to its consolidated financial statements.

### **Uncertainty in Income Taxes**

In July 2006, the FASB issued Interpretation No. 48 ("FIN 48") regarding "Accounting for Uncertainties in Income Taxes," which defines 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. FIN 48 also requires explicit disclosure requirements about a Company's uncertainties related to their income tax position, including a detailed rollforward of tax benefits taken that do not qualify for financial statement recognition. This Interpretation is effective for fiscal years beginning after December 31, 2006. The cumulative effect of applying the provisions of FIN 48 will be reported as an adjustment to the opening balance of retained earnings for that fiscal year. The Company is evaluating the possible impact of FIN 48, but currently does not anticipate any material impact to its consolidated financial statements.

### **Fair Value Measurements**

In September 2006, the FASB issued SFAS 157, "Fair Value Measurements." SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently evaluating the impact the adoption of this statement could have on its financial condition, results of operations or cash flows.

### **NOTE B - BASIS OF PRESENTATION**

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. At December 31, 2006, the Company had unrestricted cash and cash equivalents of \$0.2 million, a working capital deficit of \$28.6 million, and an accumulated deficit of \$317.5 million. The Company incurred a loss from operations of \$10.8 million and a net loss of \$6.0 million during the year ended December 31, 2006 and a loss from operations of \$11.6 million and a net loss of \$12.1 million during the year ended December 31, 2005. Historically, the Company has incurred significant losses and until such time as its product candidates are commercialized, of which no assurance can be given, the Company will continue incurring losses. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

The Company estimates that its current cash reserves, including the net proceeds from the Bridge Loan Agreements described in Note F, will be sufficient to fund the development of the Aversion® Technology and related operating expenses through late March 2007. To fund further operations and product development activities, the Company must raise additional financing, or enter into alliances or collaboration agreements with third parties resulting in cash payments to the Company relating to its Aversion® Technology. The Company is seeking to secure working capital providing gross proceeds to the Company in the range of approximately \$10 million to \$15 million through the private offering of the Company's securities. The terms of any such securities offering, including, without limitation, the type of equity securities (or securities convertible into equity securities) and the price per share, have not been determined and will, in large part, be determined based upon negotiations between the Company and prospective investors in such private offering. No assurance can be given that the Company will be successful in obtaining any such financing or in

securing collaborative agreements with third parties on acceptable terms, if at all, or if secured, that such financing or collaborative agreements will provide for cash payments to the Company sufficient to continue to fund operations. In the absence of such financing or third-party collaborative agreements, the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws.

Even assuming the Company is successful in securing additional sources of financing to fund the continued development of the Aversion<sup>®</sup> Technology, or otherwise enters into alliances or collaborative agreements relating to the Aversion<sup>®</sup> Technology, there can be no assurance that the Company's development efforts will result in commercially viable products. The Company's failure to successfully develop the Aversion<sup>®</sup> Technology in a timely manner and to avoid infringing third-party patents and other intellectual property rights will have a material adverse impact on its financial condition and results of operations.

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In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the Company's accompanying consolidated balance sheets is dependent upon continued operations of the Company, which in turn are dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to succeed in its future operations. The Company's financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

## **NOTE C - FINANCING TRANSACTIONS**

### **2004 Debenture Offering**

In 2004, the Company consummated private offerings of convertible senior secured debentures (the "2004 Debentures") in the aggregate principal amount of approximately \$14 million (the "2004 Debenture Offering"). The 2004 Debentures carried an interest rate of 1.62% per annum and were secured by a lien on all assets of the Company and the assets of Acura Pharmaceutical Technologies, Inc. and Axiom Pharmaceutical Corporation, each a wholly-owned subsidiary of the Company.

In accordance with the terms of the documents executed in connection with the 2004 Debenture Offering, effective August 13, 2004, the business day following the Company's receipt of shareholder approval to restate the Company's Certificate of Incorporation to authorize the Series A Preferred and the Junior Preferred Shares (as described below) as provided in the 2004 Purchase Agreement, the aggregate principal amount of the 2004 Debentures converted into an aggregate of 21,963,757 shares of the Company's Series A Preferred shares. In addition, effective August 13, 2004, the Company's 5% convertible debentures issued during the period from 1998 through 2003 in the aggregate principal amount of approximately \$86.6 million were converted into the Company's Series B Preferred shares, Series C-1 Preferred shares, Series C-2 Preferred shares and Series C-3 Preferred shares (the "Junior Preferred Shares"). As the result, on August 13, 2004, the Company issued an aggregate of approximately 20.2 million Series B Preferred shares, 56.4 million Series C-1 Preferred shares, 37.4 million Series C-2 Preferred shares and 81.9 million Series C-3 Preferred shares. As a result of the conversion, the Company wrote off \$41.8 million of unamortized debt discount and deferred private debt offering costs.

### **Conversion of Preferred Shares into Common Stock**

Effective November 10, 2005, all of the issued and outstanding preferred shares of the Company were automatically and mandatorily converted into the Company's common stock, \$.01 par value per share (the "Common Stock") in accordance with the terms of the Company's Restated Certification of Incorporation (the "Preferred Stock Conversion"). In accordance with the conversion provisions contained in the Restated Certificate of Incorporation, all issued and outstanding shares of the Company's Series A Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock and Series C-3 Preferred Stock (collectively, the "Preferred Stock") are converted automatically into the Company's Common Stock upon the Company's receipt of the written consent to the Preferred Stock Conversion from the holders of at least 51% of the shares of the Company's Series A Preferred Stock. On November 10, 2005, the Company received the consent to the Preferred Stock Conversion from GCE Holdings LLC (the assignee of all of the Company's Preferred Stock (prior to its conversion into Common Stock) formerly held by each of Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners International III, L.P., Galen Partners III, L.P. and Galen Employee Fund III, L.P.), collectively, the "VC Investors", such entity holding in the aggregate in excess of 51% of the issued and outstanding shares of the Company's Series A Preferred Stock. In accordance with the terms of the Company's Restated Certificate of Incorporation, all shares of the Company's Preferred Stock were automatically converted into an aggregate of approximately 305.4 million shares of the Company's Common Stock. After giving effect to the Preferred Stock Conversion, effective November 10, 2005 the Company had an aggregate of approximately 329.0 million shares of Common Stock issued and outstanding.



At December 31, 2006 and 2005, convertible preferred stock consists of the following (in thousands):

Convertible Preferred Stock	Authorized Preferred Shares at 12/31/04	Number of Preferred Shares Converted in 2005	Number of Common Shares Issued Upon Preferred Shares Conversion in 2005	Authorized Preferred Shares Available for Issuance at 12/31/05 and 12/31/06
Series A	45,000	21,964	109,819	23,036
Series B Junior	25,000	20,246	20,246	4,754
Series C-1 Junior	70,000	56,423	56,423	13,577
Series C-2 Junior	50,000	37,433	37,433	12,567
Series C-3 Junior	100,000	81,907	81,907	18,093
<b>Total</b>	<b>290,000</b>	<b>217,973</b>	<b>305,828</b>	<b>72,027</b>

At December 31, 2006, no Preferred Shares were issued and outstanding.

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

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

	December 31,	
	2006	2005
Building and building improvements	\$ 1,391	\$ 1,485
Land and land improvements	161	161
Machinery and equipment	2,183	2,325
Scientific equipment	481	473
Computer hardware and software	203	196
Office equipment	42	42
Other personal property	50	50
	4,511	4,732
Less accumulated depreciation and amortization (including \$36 in 2006 and \$53 in 2005 on capital leased assets)	(3,200)	(3,271)
	1,311	1,461
Less impairment reserve	(166)	(120)
<b>Total property, plant and equipment, net</b>	<b>\$ 1,145</b>	<b>\$ 1,341</b>

Equipment with a net book value of \$111,000 and \$146,000 is recorded under capitalized leases in categories of scientific equipment and office equipment at December 31, 2006 and 2005, respectively.

Depreciation and amortization expense for the years ended December 31, 2006, 2005 and 2004 was approximately \$118,000, \$137,000 and \$291,000, respectively.

#### NOTE E - ACCRUED EXPENSES



Accrued expenses are summarized as follows (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Bonus, payroll, payroll taxes and benefits	\$ 62	\$ 50
Legal fees	19	74
Audit examination and tax preparation fees	70	65
Franchise taxes	15	20
Property taxes	52	52
Clinical, regulatory, trademarks, and patent consulting fees	60	78
Directors fees	-	2
Other fees and services	50	-
	\$ 328	\$ 341

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**NOTE F - NOTES PAYABLE**

At December 31, 2006 and 2005, notes payable consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Senior secured convertible notes payable (a):		
Face value	\$ 7,848	\$ 2,550
Debt discount	(843)	-
	7,005	2,550
Conversion feature value	16,750	-
	\$ 23,755	\$ 2,550
Secured term note payable (b)	\$ 5,000	\$ 5,000
Capital lease obligations	\$ 32	\$ 63

**(a) Convertible Notes Payable**

Pursuant to a series of loan agreements between the Company, the VC Investors and certain other shareholders of the Company dating from June 2005 to January 2006 - all as amended through November 2006, the Company has borrowed \$7,848,000 as of December 31, 2006 and an additional \$896,000 in January and February, 2007 (the "Bridge Loans"). The proceeds from the Bridge Loans have been and continue to be used by the Company to develop its Aversion® Technology and fund related operating expenses. The Bridge Loans carry an interest rate of 10%, payable quarterly which, pursuant to the November 2006 amendment, is payable, at the Company's option, with shares of its Common Stock. The Bridge Loans, as amended, mature on March 31, 2007.

The Bridge Loans are secured by a lien on all of the Company's assets, senior in right to all other Company indebtedness and restrict its ability to issue any shares of the Company's currently authorized Series A, B or C convertible preferred stock without the prior consent of the bridge lenders, and grants the bridge lenders preemptive rights relating to the issuance of the Company's Series A, B and C convertible preferred stock. The Bridge Loans contain cross default provisions with the 2004 Note (described below) and each of the outstanding Bridge Loans. The Bridge Loans also contain normal and customary affirmative and negative covenants, including restrictions on the Company's ability to incur additional debt or grant any lien on the Company's assets or the assets of its subsidiary, subject to certain permitted exclusions. Additionally, the Bridge Notes require immediate prepayment upon a qualifying common stock equity or debt financing or any sale, transfer license or similar arrangement pursuant to which the Company sells, licenses or otherwise grant rights in any material portion of the Company's intellectual property to any third party, provided that the consummation of any such transaction results in certain minimum amounts of cash proceeds to the Company, net of all costs and expenses.

Through August 2006, the terms of the Bridge Loans did not include any conversion provisions. An August 2006 amendment 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, 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 \$8 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 may convert \$2,000,000 (as of February 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, (ii) the average price of the securities sold by the Company in such Third Party Equity Financing, and (iii) \$0.44 per share, 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 Registrant’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, and (ii) \$0.44 per share. In addition, upon a Triggering Event, the bridge lenders may convert \$2.55 million of Bridge Loans into the Company’s common stock at a conversion price of \$0.20 per share, \$2.3 million of Bridge Loans at a conversion price of \$0.225 per share and \$1.894 million of Bridge Loans at a conversion price of \$0.25 per share. Under current accounting guidance, certain provisions of the amended conversion feature required the Company to separate the value of the conversion feature from the debt and record such value as a separate liability which must be marked-to-market each balance sheet date.

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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 will be 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.

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 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 \$19,951,000 to these conversion features and reflected the modification loss as a non-cash deemed dividend. While the aggregate non-cash deemed dividend of \$19,960,000 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, the Company recorded the resulting decrease in value as a \$4,235,000 gain. The decrease in the Company's common stock trading price from November 2006 to year end resulted in the decrease in the value of the conversion liability.

To compute the estimated value of the conversion features, the Company used the Black-Scholes option-pricing model with the following assumptions:

	<b>November Amendment Date</b>	<b>December 31, 2006</b>
Company stock price	\$ 0.87	\$ 0.74
Exercise price	(1)	(1)
Expected dividend	0.0%	0.0%
Risk -free interest rate	5.0%	5.0%
Expected volatility	85.0%	88.8%
Contracted term	4 months	3 months

(1) The exercise price used to estimate fair value was set to equal the fixed conversion price for each of the respective tranches of Bridge Loans. While the conversion terms do provide for other than fixed conversion rates under certain circumstances, management has determined that the stated fixed rates (i.e., \$0.20, \$0.225, \$0.25 and \$0.44) will most likely be the lowest rate under any of the circumstances and the lender would therefore select that fixed rate.

**(b) Secured Term Note Payable**

The Company was a party to a certain loan agreement with Watson Pharmaceuticals, Inc. ("Watson") pursuant to which Watson made term loans to the Company (the "Watson Term Loan Agreement") in the aggregate principal amount of \$21.4 million as evidenced by two promissory notes (the "Watson Notes"). It was a condition to the completion of the 2004 Debenture Offering that simultaneous with the closing of the 2004 Purchase Agreement, the Company shall have paid Watson the sum of approximately \$4.3 million (which amount was funded from the proceeds of the 2004 Debenture Offering) and conveyed to Watson certain Company assets in consideration for Watson's forgiveness of approximately \$16.4 million of indebtedness under the Watson Notes, resulting in a \$12.4 million gain for the Company. As part of such transaction, the Watson Notes were amended to extend the maturity date of such notes from March 31, 2006 to June 30, 2007, to provide for satisfaction of future interest payments under the Watson Notes in the form of the Company's Common Stock, to reduce the principal amount of the Watson Notes from \$21.4 million to \$5.0 million, and to provide for the forbearance from the exercise of rights and remedies upon the occurrence of certain events of default under the Watson Notes (the Watson Notes as so amended, the "2004

Note"). Simultaneous with the issuance of the 2004 Note, each of Care Capital, Essex Woodland Health Ventures, Galen Partners and the other investors in the 2004 Debentures as of February 10, 2004 (collectively, the "Watson Note Purchasers") purchased the 2004 Note from Watson in consideration for a payment to Watson of \$1.0 million.

The 2004 Note in the principal amount of \$5.0 million, as purchased by the Watson Note Purchasers, is secured by a lien on all of the Company's and its subsidiaries' assets, carries a floating rate of interest equal to the prime rate plus 4.5% and matures on June 30, 2007. The carrying interest rate at December 31, 2006 was 12.75%. The 2004 Note contains cross default provisions with each of the outstanding Bridge Loans.

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**NOTE G - COMMON STOCK WARRANTS**

At December 31, 2006, the Company had outstanding common stock purchase warrants exercisable for an aggregate of 16,331,000 shares of common stock. Of such warrants, 5,194,000 were issued in connection with the issuance of bridge loans and financing commitments from 2000 through 2003, 10,701,000 were issued to Watson Pharmaceuticals in connection with their agreement to amend the Watson Loan at December 20, 2002, and 436,000 (after giving effect to the dilution adjustment described below) were issued in 2003 as part of the settlement terms with a former executive officer of the Company. In March 2006, warrants to purchase 166,000 shares of common stock were exercised at an exercise price of \$0.48 per share in a cashless exercise transaction resulting in the issuance of 19,000 shares of common stock. In May 2006, warrants to purchase 31,000 shares of common stock were exercised at an exercise price of \$0.47 per share in a cashless exercise transaction resulting in the issuance of 5,000 shares of common stock. In August 2006, the warrant issued in 2003 as part of the settlement with a former Company employee was increased by 286,000 warrants as result of anti-dilution provision of such warrant resulting in a \$142,000 stock compensation charge classified as other expense in the statement of operations. At December 31, 2006, outstanding common stock purchase warrants of 310,000, 154,000 and 15,867,000 will expire if unexercised during the years 2007, 2008 and years thereafter, respectively, with a weighted average remaining term of 5.4 years. The exercise prices of the warrants range from \$0.12 to \$0.66 per share, with a weighted average price of \$0.33.

As a result of the November 2006 amendment to the Bridge Loans, a \$12,948,000 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 \$2,164,000 gain recorded in the 4<sup>th</sup> quarter 2006. Future period fair value adjustments to the warrant liability could result in further gains or losses. The Company estimated the warrants' fair value using the Black - Scholes option-pricing model with the following significant expected assumptions:

	<b>November Amendment Date</b>	<b>December 31, 2006</b>
Company stock price	\$ 0.87	\$ 0.74
Exercise price	\$ 0.12 - \$ 0.66	\$ 0.12 - \$ 0.66
Expected dividend	0.0%	0.0%
Risk-free interest rate	4.5% - 5.0%	4.7% - 5.0%
Expected volatility	79.8% - 145.9%	48.4% - 143.5%
Weighted -average volatility	127.4%	127.7%
Contractual term	38 days - 5.4 years	38 days - 5.4 years

**NOTE H - INCOME TAXES**

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,					
	2006		2005		2004	
	Amount	%	Amount	%	Amount	%
Federal statutory rate	\$ (2,029)	(34.0)	\$ (4,105)	(34.0)	\$ (23,798)	(34.0)
State taxes, net of Federal effect	(535)	(9.0)	(609)	(5.0)	(179)	(0.3)
Research and experimental tax credit	(126)	(2.1)	(125)	(1.0)	(131)	(0.2)
Other	26	0.5	39	0.3	(82)	(0.1)
<u>Impact of non-taxable items</u>						
Non-deductible financing costs	320	5.4	-	-	24,647	35.2
Conversion feature fair value change	(1,440)	(24.1)	-	-	-	-
Debt discount amortization	62	1.0	-	-	-	-
Warrant fair value change	(736)	(12.4)	-	-	-	-
Debt forgiveness	-	-	-	-	(4,307)	(6.1)
Federal tax carryback refund	-	-	-	-	(122)	(0.2)
Department of Justice settlement	-	-	-	-	(137)	(0.2)
	(4,460)	(74.7)	(4,800)	(39.7)	(4,109)	(5.9)
Change in valuation allowance	4,460	74.7	4,800	39.7	4,109	5.9
Recorded tax benefit	\$ -	-	\$ -	-	\$ -	-

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The Company has gross Federal, state, and city operating loss carryforwards aggregating \$141.2 million, \$101.0 million, and \$46.3 million, expiring during the years 2009 through 2026. The tax loss carryforwards of the Company and its subsidiaries may be subject to limitation by Section 382 of the Internal Revenue Code with respect to the amount utilizable each year. This limitation reduces the Company's ability to utilize net operating loss carryforwards included above each year. The amount of the limitation has not been quantified by the Company.

The temporary differences that give rise to deferred tax assets and liabilities as of December 31 are as follows (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Deferred tax assets:		
Net operating loss - federal	\$ 48,026	\$ 46,128
Net operating loss - state/city	7,837	7,595
Research and experimental tax credit	382	256
Charitable contributions	2	62
Stock compensation	5,497	3,325
Warrant compensation	56	-
Accrued expenses	15	15
Accrued shutdown costs	38	47
Debt issue costs	7	11
Asset reserves	28	-
Gross deferred tax assets	61,888	57,439
Deferred tax liabilities:		
Depreciation	(25)	(36)
Net deferred tax assets before valuation allowance	61,863	57,403
Valuation allowance	(61,863)	(57,403)
Net deferred tax assets	\$ -	\$ -

## 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 2006, 2005 or 2004.

### 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, 2006, incentive stock options to purchase 262,510 shares and non-qualified options to purchase 116,390 shares, previously



granted under the 1995 Stock Option Plan, remain outstanding. The average per share exercise price for these 378,900 outstanding options under the 1995 Stock Option Plan at December 31, 2006 is \$1.57.

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## 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. At December 31, 2006, incentive stock options to purchase 869,826 shares and non-qualified options to purchase 17,746,269 shares remain outstanding and 926,655 options were available for grant under the 1998 Option Plan. The average per share exercise price for these 18,616,095 outstanding options under the 1998 Stock Option Plan at December 31, 2006 is \$0.23, with vesting requirements generally of 4 years.

A summary of the Company's stock option plans as of December 31, 2006, 2005, and 2004, and for the years then ended consisted of the following:

	Years Ended December 31,					
	2006		2005		2004	
	Number of Shares (000's)	Weighted Average Exercise Price	Number of Shares (000's)	Weighted Average Exercise Price	Number of Shares (000's)	Weighted Average Exercise Price
Outstanding, beginning	19,755	\$ 0.27	17,499	\$ 0.44	3,525	\$ 1.83
Granted	-	-	4,000	0.13	14,475	0.13
Exercised	(400)	0.25	(35)	0.13	-	-
Forfeited or expired	(360)	1.04	(1,709)	1.65	(501)	1.85
Outstanding, ending	18,995	\$ 0.26	19,755	\$ 0.27	17,499	\$ 0.44
Options exercisable, end of year	18,373	\$ 0.26	15,698	\$ 0.31	9,558	\$ 0.66

The following table summarizes information about stock options outstanding at December 31, 2006:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number of Shares (000's)	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares (000's)	Weighted Average Exercise Price	
\$0.12 to \$1.00	17,694	7.62	\$ 0.14	17,072	\$ 0.14	
\$1.01 to \$2.00	710	3.06	1.41	710	1.41	
\$2.01 to \$2.50	591	1.84	2.38	591	2.38	
Total	18,995	7.27	\$ 0.26	18,373	\$ 0.26	

The following table summarizes information about nonvested stock options outstanding:

	<b>Year Ended December 31, 2006</b>		<b>Weighted Average Fair Value</b>
	<b>Number of Shares Not Exercisable (000's)</b>		
Outstanding, beginning	4,057	\$	0.31
Granted	-		-
Vested	(3,435)		0.31
Forfeited or expired	-		-
Outstanding, ending	622	\$	0.31

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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 2004 and 2005 option grants are 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.

	2005	2004
Expected dividend	0.0%	0.0%
Risk-free interest rate	4.5%	2.4% - 4.6%
Expected volatility	120%	73% - 87%
Weighted -average volatility	120%	87%
Expected term	4 years	2 - 5 years
Weighted -average grant date fair value	\$ 0.45	\$ 0.25

As of December 31, 2006, 2005 and 2004, the aggregate intrinsic value of the option awards outstanding and exercisable was \$10,253,000, \$1,971,000 and \$1,330,000, respectively. In addition, the aggregate intrinsic value of option awards exercised during the years ended December 31, 2006 and 2005 was \$178,000 and \$13,000, respectively. The total remaining unrecognized compensation cost related to the unvested option awards amounted to \$42,000 at December 31, 2006 and is expected to be recognized over the sixteen 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, 2006, 2005 and 2004 were \$2,800,000, \$1,067,000 and \$578,000, respectively. The Company recognized stock-based compensation from the option awards of \$462,000, \$2,198,000 and \$2,007,000, during the years ended December 31, 2006, 2005 and 2004, 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 \$178,000 and \$13,000 recorded in calendar years of 2006 and 2005, 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 30 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. No dividends accrue on the shares underlying the RSUs prior to issuance by the Company. The recipients of RSU awards need not be employees or directors of the Company on a distribution date. RSUs may generally not be transferred, except recipients of RSUs may designate beneficiaries to inherit their RSU's upon their death.

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In December 2005, 27,500,000 RSUs were granted to the Company's employees. In February 2006, an aggregate of 2,000,000 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 2006, 10,500,000 RSU's became vested. As such, of the RSU awards granted, 19,667,000 and 9,167,000 were vested as of December 31, 2006 and 2005, respectively and 9,833,000 and 18,333,000 were nonvested as of December 31, 2006 and 2005, respectively. The weighted average fair value of both RSU grants is \$0.35 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 and is expected to be recognized over the next 12 months, the weighted average remaining requisite service period of the unvested RSU award. The Company recognized compensation cost from the RSU awards of \$5,264,000 and \$4,261,000, during the years ended December 31, 2006 and 2005, respectively. No related tax benefits were recorded in calendar year 2006 and 2005. As of December 31, 2006 and 2005, the aggregate intrinsic value of the RSU awards outstanding and vested was \$14,357,000 and \$2,610,000, respectively. As discussed above, the RSU awards are distributable only upon the occurrence of certain events or beginning January 1, 2011.

## **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, 2007. 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. Reddick at least ninety (90) days prior to the expiration of the initial term or any subsequent renewal period. The Employment Agreement provides for an annual base salary of \$300,000 plus the payment of annual bonus of up to one hundred percent (100%) of Mr. Reddick's base salary 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 2006 fiscal year, the Employment Agreement provides for a cash bonus equal to 100% of Mr. Reddick's then current base salary (the "2006 Cash Bonus") upon the Company's receipt of aggregate proceeds of at least \$15.0 million on or before March 31, 2007 from an offering of the Company's equity securities and/or from license fees or milestone payments from third-party licensing or similar transactions (subject to the payment of a pro-rata portion of the 2006 Cash Bonus provided the Company receives aggregate gross proceeds from such transactions of at least \$11.0 million on or before March 31, 2007). 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, 2007 at an annual base salary of \$260,000 plus the payment of an annual bonus of up to one hundred percent (100%) of Dr. Spivey's base salary.

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, 2007 at an annual base salary of \$180,000 plus the payment of an annual bonus of up to one hundred percent (100%) of Mr. Clemens base salary.

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.

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

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

	<b>Three Month Period Ended</b>			
	<b>Mar. 31</b>	<b>June 30</b>	<b>Sept. 30</b>	<b>Dec. 31</b>
<b>Calendar Year 2006:</b>				
Net product revenues	\$ -	\$ -	\$ -	\$ -
Loss from operations	(3,927)	(2,341)	(2,661)	(1,897)
Net (loss) income	(4,155)	(2,615)	(3,097)	3,900
Loss per common share (after deemed dividend) -				
basic and diluted (Note A. 14)	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.04)
<b>Calendar Year 2005:</b>				
Net product revenues	\$ -	\$ -	\$ -	\$ -
Loss from operations	(1,908)	(1,266)	(1,473)	( 6,914)
Net loss	(1,948)	(1,382)	(1,635)	(7,110)
Loss per common share - basic and diluted				
	\$ (0.09)	\$ (0.06)	\$ (0.07)	\$ (0.04)

Effective November 10, 2005, all of the issued and outstanding preferred shares of the Company were automatically and mandatorily converted into an aggregate of approximately 305.4 million shares of the Company's Common Stock, \$.01 par value per share in accordance with the terms of the Company's Restated Certification of Incorporation (see Note C). After giving effect to the conversion, the Company had an aggregate of approximately 329.0 million shares of Common Stock issued and outstanding. The 4<sup>th</sup> Quarter 2005 loss per common share amount of (\$.04) reflects the increased weighted average common shares outstanding due to the preferred stock conversion during the 4<sup>th</sup> Quarter 2005. The impact of the conversion causes the 2005 quarterly loss per share amounts not to add up to and equal the 2005 annual loss per share amount.

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**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 (incorporated by reference to Appendix C to the Registrant's Proxy Statement filed on July 6, 2004).
3.2	Restated By-Laws (incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report Form 10-K for the year ended December 31, 1998 (the "1998 Form 10-K")).
10.1	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).



- 10.2 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).
- 10.3 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).
- 10.4 Loan Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. ("WPI") (incorporated by reference to Exhibit 10.57 to the Registrant's Form 8-K dated March 29, 2000 (the "March 2000 8-K")).+
- 10.5 Amendment to Loan Agreement dated March 31, 2000 between the Registrant and WPI (incorporated by reference to Exhibit 10.58 to the March 2000 8-K).
- 10.6 Secured Promissory Note in the principal amount of \$17,500,000 issued by the Registrant, as the maker, in favor of WPI dated March 31, 2000 (incorporated by reference to Exhibit 10.59 to the March 2000 8-K).
- 10.7 Watson Security Agreement dated March 29, 2000 between the Registrant and WPI (incorporated by reference to Exhibit 10.60 to the March 2000 8-K).
- 10.8 Stock Pledge Agreement dated March 29, 2000 between the Registrant and WPI (incorporated by reference to Exhibit 10.61 to the March 2000 8-K).
- 10.9 Watson Guarantee dated March 29, 2000 between Houba, Inc. and Halsey Pharmaceuticals, Inc., as the guarantors, in favor of WPI (incorporated by reference to Exhibit 10.62 to the March 2000 8-K).
- 10.10 Watson's Guarantors Security Agreement dated March 29, 2000 between Halsey Pharmaceuticals, Inc., Houba, Inc. and WPI (incorporated by reference to Exhibit 10.63 to the March 2000 8-K).
- 10.11 Subordination Agreement dated March 29, 2000 among the Registrant, WPI and the holders of the Registrant's outstanding 5% convertible debentures due March 10, 2003. (incorporated by reference to Exhibit 10.64 to the March 2000 8-K).+
- 10.12 Real Estate Mortgage dated March 29, 2000 between Houba, Inc. and WPI (incorporated by reference to Exhibit 10.65 to the March 2000 8-K).
- 10.13 Subordination Agreement among Houba, Inc., Galen Partners, III, L.P. ("GP III"), Oracle Strategic Partners, L.P. and WPI (incorporated by reference to Exhibit 10.66 to the March 2000 8-K).
- 10.14 Second Amendment to Loan Agreement dated December 20, 2002, between the Registrant and WPI, amending the Loan Agreement dated March 29, 2000 (incorporated by reference to Exhibit 10.11 to the Form 8-K filed December 27, 2002 (the December 2002 Form 8-K"))
- 10.15 Amended and Restated Secured Promissory Note dated December 20, 2002, issued by the Registrant in favor of WPI in the principal amount \$17,500,000 (incorporated by reference to Exhibit 10.12 to the December 2002 Form 8-K).
- 10.16 Watson Common Stock Purchase Warrant dated December 20, 2002 (incorporated by reference to Exhibit 10.14 to the December 2002 Form 8-K).

- 10.17 Registration Rights Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.15 to the December 2002 Form 8-K).
  - 10.18 Warrant Recapitalization Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.15 to the December 2002 Form 8-K).
  - 10.19 Debenture Conversion Agreement dated as of February 6, 2004 among the Registrant, Care Capital Investments II, L.P. (“Care”), Essex Woodlands Health Venture V, L.P. (“Essex”), GPIII and others (incorporated by reference to Exhibit 10.2 of the Form 8-K filed February 10, 2004 (the “February 2004 Form 8-K”)).
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Exhibit Number	Exhibit Description
10.20	Amended and Restated Voting Agreement dated as of February 6, 2004 among the Registrant, Care, Essex, GPIII and others (incorporated by reference to Exhibit 10.5 of the February 2004 Form 8-K).
10.21	Amended and Restated Registration Rights Agreement dated as of February 6, 2004 among the Registrant, WPI, Care, Essex, GPIII and others (incorporated by reference to Exhibit 10.6 of the February 2004 Form 8-K).
10.22	Umbrella Agreement dated as of February 6, 2004 among the Registrant, WPI, Care, Essex, GPIII and the other signatories thereto (incorporated by reference to Exhibit 10.12 of the February 2004 Form 8-K).
10.23	Third Amendment to Loan Agreement dated as of February 6, 2004 among the Registrant and WPI (incorporated by reference to Exhibit 10.13 of the February 2004 Form 8-K).
10.24	Amended and Restated Promissory Note in the principal amount of \$5,000,000 issued by the Registrant in favor of Watson Pharmaceuticals (incorporated by reference to Exhibit 10.14 of the February 2004 Form 8-K).
10.25	Noteholders Agreement dated as of February 6, 2004 among the Registrant, Care, Essex, GPIII and others (incorporated by reference to Exhibit 10.16 of the February 2004 Form 8-K).
10.26	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”)).
10.27	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).
10.28	Second Amendment to Executive Employment Agreement between the Registrant and Reddick, dated May 24, 2005.
10.29	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”)).
10.30	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).
10.31	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).
10.32	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).
10.33	First Amendment to Employment Agreement made as of June 28, 2000 between the Registrant and Clemens

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- 10.34 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).
- 10.35 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).
- 10.36 Loan Agreement dated June 22, 2005 (the "June 2005 Loan Agreement") between the Registrant, Essex, Care, GPIII, and others (incorporated by reference to Exhibit 10.1 to the Form 8-K dated June 22, 2005 (the "June 2005 Form 8-K")).
- 10.37 Subordination Agreement dated June 22, 2005 between the Registrant, Essex, Care, GPIII and the other signatories thereto (incorporated by reference to Exhibit 10.3 of the June 2005 Form 8-K).
- 10.38 Form of Company General Security Agreement with respect to the June 2005 Loan Agreement, the September 2005 Loan Agreement, the November 2005 Loan Agreement and the January 2006 Loan Agreement (the "Loan Agreements") (incorporated by reference to Exhibit 10.4 of the June 2005 Form 8-K).
- 10.39 Form of Guaranty of Axiom Pharmaceutical Corporation ("Axiom") related to the Loan Agreements (other than the January 2006 Loan Agreement) (incorporated by reference to Exhibit 10.5 of the June 2005 Form 8-K).
- 10.40 Form of Guaranty of Acura Pharmaceutical Technologies, Inc. ("APT") related to the Loan Agreements (incorporated by reference to Exhibit 10.6 of the June 2005 Form 8-K).
- 10.41 Form of Guarantors Security Agreement among Axiom, the Registrant, and GPIII, as Agent, with respect to the Loan Agreements (other than the January 2006 Loan Agreement) (incorporated by reference to Exhibit 10.7 of the June 2005 Form 8-K).
- 10.42 Form of Stock Pledge Agreement by and between Registrant and GPIII, as Agent, with respect to the Loan Agreements (incorporated by reference to Exhibit 10.8 of the June 2005 Form 8-K).
- 10.43 Loan Agreement dated September 16, 2005 (the "September 2005 Loan Agreement") between the Registrant, Essex, Care, GPIII, and others (incorporated by reference to Exhibit 10.1 to the Form 8-K dated September 16, 2005 (the "September 2005 Form 8-K")).
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Exhibit Number	Exhibit Description
10.44	Subordination Agreement dated September 16, 2005 between the Registrant, Essex Health Venture V, L.P., Care, GPIII, and the other signatories thereto (incorporated by reference to Exhibit 10.3 of the September 2005 Form 8-K).
10.45	Joinder and Amendment to Amended and Restated Voting Agreement dated November 9, 2005 between the Registrant, GCE Holdings, Essex, Care, GPIII and others (the "November 2005 Loan Agreement") (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K dated November 9, 2005 (the "November 2005 Form 8-K"))).
10.46	Loan Agreement dated November 9, 2005 between the Registrant, Essex, Care, GPIII, Galen Partners International III, L.P., and others (incorporated by reference to Exhibit 10.2 of the November 2005 Form 8-K).
10.47	Subordination Agreement dated November 9, 2005 between the Registrant, Essex, Care, GPIII, and the other signatories thereto (incorporated by reference to Exhibit 10.4 of the November 2005 Form 8-K).
10.48	Loan Agreement among the Registrant Essex, Care, GPIII and others dated January 31, 2006 (the "January 2006 Loan Agreement") (incorporated by reference to the Form 8-K filed on January 31, 2006).
10.49	Form of Secured Promissory Note of the Registrant relating to January 31, 2006 Loan Agreement
10.50	Subordination Agreement among Essex, Care, GPIII, and others dated January 31, 2006 (incorporated by reference to the Form 8-K filed on January 31, 2006)..
10.51	Guarantor Security Agreement among APT and GPIII, as Agent, dated January 31, 2006 (incorporated by reference to the Form 8-K filed on January 31, 2006).
10.52	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)
10.53	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).
10.54	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).
10.55	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).
10.56	

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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).

- 10.57 Voting Agreement by and between Registrant and GCE Holdings, LLC dated as of December 22, 2005
- 10.58 Code of Ethics (incorporated by reference to Exhibit 14 of the Registrant's Form 10-K filed April 22, 2004).
- \*21 Subsidiaries of the Registrant
- \*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.
- \*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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