

ACURA PHARMACEUTICALS, INC  
Form 10-K  
February 21, 2006

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, 2005

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

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NUMBER 1-10113

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

NEW YORK  
(State or other jurisdiction of  
Incorporation or organization)

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

616 N. NORTH COURT, SUITE 120,  
PALATINE, ILLINOIS  
(Address of principal executive offices)

60067  
(Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE:  
847 705 7709

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:  
(TITLE OF CLASS)  
NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:  
(TITLE OF CLASS)  
COMMON STOCK, PAR VALUE \$0.01

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of  
the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

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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 an accelerated filer (as defined in Rule 12b-2 of the Act). Yes  No

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 February 1, 2006, the registrant had 329,293,522 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, 2005 (\$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 \$39,691,511.

DOCUMENTS INCORPORATED BY REFERENCE  
NONE

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## FORWARD-LOOKING STATEMENTS

Certain statements throughout this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"). 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"), or industry results, 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 technology and product candidates, and the Company's ability to fulfill the U.S. Food and Drug Administration's requirements for approving the Company's product candidates for commercial distribution in the United States. 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 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 primarily engaged in research, development and manufacture of innovative abuse deterrent, abuse resistant and tamper resistant formulations ("Aversion® Technology") intended for use in orally administered opioid-containing pharmaceutical products. The Company's lead product candidate utilizing its Aversion® Technology, OxyADF™ tablets, (formerly referred to by the Company as Product Candidate #2) is being developed pursuant to an active investigational new drug application ("IND") on file with the U.S. Food and Drug Administration ("FDA"). The status of the development of the Aversion® Technology and OxyADF™ tablets are described below under the captions "Aversion® Technology" and "OxyADF™ Development Program". In addition, to a much lesser extent, during 2004 and early 2005, the Company was engaged in the 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 ("APIs"). In early 2005, the Company suspended development and commercialization efforts relating to the Opioid Synthesis Technologies. The status of the Opioid Synthesis Technologies is described below under the caption "Opioid Synthesis Technologies". As of the date of this Report the Company had three US non-provisional and two international patent applications pending relating to its Aversion® Technology. Additionally, as of the date of this Report, the Company had six US patents issued and three US patent applications pending related to its Opioid Synthesis Technologies. As of the date of this Report, the Company retained ownership of all issued patents, patent applications, other intellectual property and commercial rights to its product candidates, Aversion® Technology and Opioid Synthesis Technologies.

The Company conducts research, development, laboratory, manufacturing and warehousing activities for the Aversion® Technology at its Culver, Indiana facility (the "Culver Facility"). The Culver Facility is registered by the U.S. Drug Enforcement Administration (the "DEA") to perform research, development and manufacture for certain Schedule II - V controlled substances in bulk and finished dosage forms. In 2001, the Company filed with the DEA an application for registration (the "Import Registration") to import narcotic raw materials ("NRMs"). The status of the application for the Import Registration is described below under the caption "Import Registration."

The Company performs pre-clinical and clinical research on its product candidates through a combination of internal and external collaborations. The Company has and will continue to rely on contract research organizations ("CROs") to perform key components of its product development activities. In the first quarter of 2004, the Company entered into a Master Services Agreement with a full service CRO with wide ranging capabilities and expertise in regulatory and clinical development consultation, clinical trial and clinical data management, biostatistics, medical writing, and other relevant research and development services. On behalf of the Company, such full service CRO is engaged in writing clinical trial protocols, contracting with clinical trial sites, compilation of regulatory documents, and making various regulatory submissions to the FDA.

To generate revenue, the Company expects to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license the Company's product candidates utilizing the Aversion® Technology and further develop, register and commercialize multiple formulations and strengths of such product candidates in the U.S. and international territories. The Company expects to receive milestone payments and a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Aversion® Technology. As of the date of this Report the Company did not have 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's business involves inherent risk as set forth in Item 1A of this Report. These risks include, among others, the need for FDA approval prior to commercial distribution of the Company's product candidates in the United States, acceptance by healthcare providers and third-party payers of such product candidates, dependence on key personnel, determination of patentability of our Aversion® Technology by the United States Patent and Trademark Office, and freedom to operate for the Company's product candidates.

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The Company is a publicly traded New York corporation established in 1935. 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 to the SEC's website, on [www.acurapharm.com](http://www.acurapharm.com) our annual, quarterly and current reports and amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, 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, Attn: Investor Relations, 847.705.7709

### ***Aversion® Technology***

The Company is focused on research and development of innovative and proprietary abuse deterrent, abuse resistant and tamper resistant formulation technologies ("Aversion® Technology") intended to discourage abuse of orally administered opioid analgesic products. The Company believes that the internally developed Aversion® Technology is applicable to both immediate release and extended release orally administered tablets and capsules which are formulated with an opioid analgesic or other potentially abusable orally administered drug, such as an amphetamine, as an active ingredient. Company research and laboratory experiments to date suggest that the Aversion® Technology may be formulated into an orally administered tablet with the commonly utilized opioid active pharmaceutical ingredients and related salts including morphine, codeine, hydrocodone and oxycodone. The Aversion® Technology utilizes certain pharmaceutical product excipients and other ingredients in addition to the opioid API. The Aversion® Technology does not utilize opioid antagonists. The Company believes that the Aversion® Technology will discourage or deter a pre-existing opioid drug abuser, or a legitimate patient properly using opioid containing analgesics for management of pain, from abusing an orally administered opioid containing product. Provided the Aversion® Technology is appropriately tested and proves successful in clinical trials, of which no assurance can be given, the Company believes that its Aversion® Technology will discourage or deter the three most commonly utilized routes of opioid abuse, including (1) intravenous, (2) intranasal/snorting and (3) excess oral consumption of tablets or capsules. However, the Company can provide no assurance that such clinical testing will demonstrate that the Aversion® Technology will discourage or deter abuse. In addition, if such abuse deterrent characteristics are demonstrated, the Company can provide no assurance that the magnitude of such effect will be statistically significant or clinically meaningful.

We have formulated and evaluated numerous distinct product candidates incorporating the Aversion® Technology. These product candidates are tablet formulations intended for oral administration and contain, among other ingredients, widely prescribed opioid active pharmaceutical ingredients. To date, all product candidates utilizing our Aversion® Technology may be economically produced using a dry blend and direct compression tablet manufacturing process.

Product candidates formulated with Aversion® Technology are intended to reduce or discourage all three common routes of abuse of tablet and capsule pharmaceutical products including (i) intravenous injection of dissolved tablets, (ii) inhalation/nasal snorting of crushed or pulverized tablets, and (iii) intentional consumption of excessive numbers of tablets by oral administration.

The Company's lead product candidate, OxyADF™, (formerly referred to by the Company as Product Candidate #2), incorporates our Aversion® Technology in an immediate release tablet formulation intended for oral administration. The Company has clearance from the U. S. Food and Drug Administration ("FDA") for testing OxyADF™ tablets in a clinical trial program under an active Investigational New Drug application ("IND"). The clinical development

program is designed to evaluate the efficacy, safety and tolerability of OxyADF™ tablets in both 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 an adverse event profile similar to currently marketed products containing the same opioid active ingredient but without our unique Aversion® Technology. The status of the development of OxyADF™ tablets is more fully described below under the caption “OxyADF™ Development Program”.

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To receive clearance from the FDA for distribution and sale in the United States, the Company's product candidates formulated with Aversion® Technology will require the development, compilation, submission, filing and final approval by the FDA of a 505(b)(2) new drug application ("NDA") The FDA requirements for approving product candidates for commercial distribution are more fully described below under the caption "FDA Pharmaceutical Product Approvals". The FDA has confirmed in writing to the Company that OxyADF™ is an appropriate product candidate for submission as a 505(b)(2) NDA. However, at this stage, the Company can provide no assurances that OxyADF™ tablets or any other product candidates formulated with Aversion® Technology will lead to an NDA submission or that if an NDA is submitted, that the FDA will accept the NDA submission and approve these product candidates for commercial distribution and sale.

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

The class of pharmaceutical products exhibiting morphine-like properties is referred to as opioids, opioid agonists or opioid analgesics. The Company believes that healthcare providers are generally not able to determine which, if any, of their prescriptions for opioid analgesics will ultimately be abused or diverted. However, based on primary market research conducted by the Company, U.S. based physicians perceive that nearly one out of six prescriptions for opioid analgesics may be abused. The results of a survey published in 2006 of over 1,500 adults conducted by the market research firm of Schulman, Ronca and Bucuvalas, Inc. revealed that 37% of those surveyed know someone personally who has abused opioid painkillers. Of those reporting knowing someone who has abused opioid painkillers, ten percent revealed that they personally had abused these products and nearly twenty percent of the abusers were identified as coworkers, with the balance being identified as family members or acquaintances. The uncertainty about which, if any, prescriptions for opioid analgesics will be abused or diverted implies that certain segments of the U.S. market for dispensed prescriptions for opioid analgesics represent a major opportunity for products formulated with our Aversion® Technology. The table below sets forth commonly prescribed opioid analgesics in the U.S.

<b>Opioid Active Ingredients (Generic Names)</b>	<b>Frequently Prescribed Opioid Analgesics (Brand Names)</b>
Oxycodone	Percocet®, Oxycontin®
Hydrocodone	Vicodin®, Lortab®, Lorcet®
Morphine	Avinza®, Kadian®, MSContin®
Hydromorphone	Dilaudid®, Palladone®
Codeine	Tylenol® with Codeine
Tramadol	Ultram®, Ultracet®
Propoxyphene	Darvon®, Darvocet®
Fentanyl	Duragesic®, Actiq®

Based on market research data purchased by the Company from IMS Health, for the 12 months ending September 30, 2005, in the U.S. approximately 221 million total prescriptions for the above major brands, minor brands and generic equivalents thereto were dispensed. Of this total, approximately 18 million dispensed prescriptions were for extended release products (usually administered once every 8 to 24 hours) and 203 million dispensed prescriptions were for immediate release products (usually administered every 4 to 6 hours). Extended release products are more commonly prescribed for relief of pain for a duration ranging from a few weeks to several months or longer. Immediate release products are more commonly prescribed for relief of pain for a duration of generally less than 30 days. The Company's primary market research suggests that OxyADF™ tablets will be considered by healthcare providers for use in both the market for immediate release and extended release opioid products.

The potential for the development of tolerance, physical and/or psychological dependence (i.e., addiction) with repeated use is a characteristic feature of most opioid containing drugs. Another concern associated with the use of opioids is the diversion of these drugs from a patient in legitimate pain to other individuals (non-patients) for illegitimate purposes. There are three basic patterns of behavior leading to opioid abuse. The first involves individuals

whose opioid drug use begins in the context of medical treatment and who obtain their initial drug supplies through prescriptions from physicians. The second begins with experimental or "recreational" drug use and progresses to more intensive use. A third pattern of abuse involves users who begin in one or another of the preceding ways but later switch to oral opioids such as methadone, obtained from organized addiction treatment programs. Physicians cannot easily identify or predict which of their patients may fall into one of these behavior patterns.

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Drug abusers and/or addicts typically may obtain a commercial dosage form containing an opioid analgesic and 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 drug becomes available for immediate absorption by injection, inhalation, and/or oral consumption. There are various routes of administration by which an abuser may commonly attempt to abuse an opioid containing drug formulation. The most common methods include (1) intravenous injection, (2) intranasal (e.g., snorting), and (3) repeated oral ingestion of excessive quantities of orally administered tablets or capsules. One mode of abuse of oral solid opioid drug products involves first crushing/pulverizing and then mixing the tablet with water, and then subsequently extracting the opioid component from the mixture for use in a solution suitable for intravenous injection of the opioid to achieve a "high."

Attempts have been made by several companies, as more fully described below under the caption "Competition", to develop technology to deter abuse of orally administered opioid analgesics. Some of these attempts have included the use of an opioid antagonist in the oral dosage form designed to substantially block the analgesic effects of the opioid if one attempts to crush/grind the tablet and snort the resulting powder or dissolve/extract the opioid and administer the opioid drug intravenously. The Aversion® Technology does not utilize opioid antagonists. A clear need exists for a formulation technology for commonly used immediate release and extended release tablets and capsules which discourages misuse and minimizes or reduces the potential for physical or psychological dependency. The need is particularly imperative for opioid analgesics. It is with the growing concern about the illegitimate use of legitimate opioid analgesics described above that the Company is pursuing development of its Aversion® Technology.

#### OxyADF™ Development Program

The Company's lead product candidate, OxyADF™ tablets (formerly referred to by the Company as Product Candidate #2) is an immediate release tablet formulation intended for oral administration being developed pursuant to an active IND on file with the FDA. The FDA has confirmed in written correspondence to the Company that OxyADF™ is an appropriate product candidate for submission as a 505(b)(2) NDA. Refer to the caption, "Government Regulation / FDA Pharmaceutical Product Approvals" in this Report for a description of a 505(b)(2) NDA.

To date the Company, in concert with its CROs has completed one phase I clinical study and one phase II clinical study relating to development of OxyADF™ tablets. The results from the phase I clinical study were used, among other things, to guide the formulation of the OxyADF tablets used in the phase II clinical study. Results from the phase II clinical study suggest that at the anticipated recommended therapeutic doses in normal subjects, OxyADF tablets will provide a side effects profile similar to the same opioid active ingredient formulated in a tablet without the Company's Aversion® Technology. The Company, intends to use the data from such clinical studies in its 505(b)(2) NDA submission for OxyADF™.

The Company, in concert with an independent clinical CRO, has completed a pilot and a pivotal bioequivalence study for OxyADF™ tablets. The pivotal bioequivalence study used tablets from batches manufactured by the Company at its Culver, Indiana facility at a scale of sufficient size to fulfill the FDA's requirements for a 505(b)(2) NDA submission. The final report from the CRO for the pivotal bioequivalence study confirms that OxyADF™ tablets are bioequivalent to the applicable reference listed drug. The Company intends to use such data in its 505(b)(2) NDA submission for OxyADF™.

In addition, the Company, in concert with an independent laboratory CRO, completed a pivotal study to assess certain physical/chemical properties of OxyADF™ using tablets from batches manufactured by the Company at its Culver, Indiana facility at a scale of sufficient size to fulfill the FDA's requirements for a 505(b)(2) NDA submission. The final report from this pivotal laboratory study confirms that extracting the active opioid ingredient from OxyADF™ tablets in a form which may be administered via intravenous injection is substantially more difficult than extracting the active opioid ingredient from several currently marketed opioid-based commercial products. The Company intends to utilize the data from this pivotal laboratory study in its 505(b)(2) NDA submission for OxyADF™.



During the first quarter of 2006, as a routine part of the development process for OxyADF™ tablets, at the Company's written request, the Company and the FDA convened a face-to-face End of Phase II meeting (the "EOP2 Meeting") for OxyADF tablets. As part of the EOP2 Meeting, the Company and the FDA discussed, among other things, the laboratory and clinical studies completed by the Company to date relating to OxyADF™ tablets and the remaining laboratory and clinical studies anticipated to be completed prior to the submission of a 505(b)(2) NDA for OxyADF™ tablets. The Company believes the guidance provided by FDA at the EOP2 Meeting clarifies the remaining development requirements relating to the Company's proposed indication and contemplated labeling for OxyADF™ tablets.

To receive marketing authorization for commercial distribution in the United States, OxyADF™ and any drug product formulated with the Aversion® Technology will require the development, compilation, submission and filing of a NDA and approval of such application by the FDA. Estimating the dates of completion of laboratory and clinical development, and the costs to complete development, of the Company's product candidates, including OxyADF™, would be highly speculative, subjective and potentially misleading. Pharmaceutical products require significant time to research, develop and commercialize. The Company expects to reassess its future research and development plans based on the review of data received from current research and development activities and future guidance from the FDA. 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™, 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 approved by the FDA.

#### Commercial Strategy and Status

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 OxyADF™ tablets and other product candidates utilizing the Aversion® Technology and further develop, register and commercialize multiple formulations and strengths of such product candidates. The Company expects to receive milestone payments and a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Aversion® Technology. Future revenue, if any, would be derived from milestone payments and a share of profits and/or royalty payments relating to our Partners' sale of products incorporating the Aversion® Technology. To date, the Company does 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.

#### *Patents Issued and Pending*

As of the date of this Report, the Company had three US non-provisional and two international patent applications pending relating to its Aversion® Technology. Additionally, as of the date of this Report, the Company had six US patents issued and three US patent applications pending related to its Opioid Synthesis Technologies. As of the date of this Report, the Company retained ownership of all issued patents, patent applications, other intellectual property and commercial rights to its product candidates and its Aversion® Technology and Opioid Synthesis Technology.

The typical review time of a patent application by the United States Patent and Trademark Office ("PTO") varies. Depending on the field of invention, the initial PTO review generally occurs within 30 months from date of filing a non-provisional patent application. At the completion of the initial review, the patent examiner will issue an Office Action letter, detailing any necessary amendments, supplements or reasons for rejection. Subsequent processing of the patent application will depend on the number of Office Action letters issued and the speed of review of an applicant's responses to these letters. If an application is granted, a Notice of Allowance will be issued requiring a payment of the issue fee within three (3) months from the date of the notice. Upon the payment of the fee to the PTO the patent would then be issued.



No assurance can be given that any currently pending patent applications or future patent applications relating to our Aversion® Technology will issue, or if such patents issue, that the claims granted will be sufficiently broad to provide economic value. Moreover, even if such patents issue, there can be no assurance that the commercialization of products incorporating the Aversion® Technology will not infringe the patents or other intellectual property rights of third parties. The Company's success depends in significant part on our to obtain patent protection for the Aversion® Technology, both in the United States and in other countries, to enforce these patents and to avoid infringing third-party patent and intellectual property rights.

### ***Opioid Synthesis Technologies***

Historically 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 ("APIs"). In early 2005, the Company suspended further development and commercialization efforts relating to the Opioid Synthesis Technologies. The Company determined based on, among other factors, the Company's limited cash balances, prospects for third-party financing, the Company's focus on its Aversion® Technology, and the projected timeline and expense for resolution of the Company's application for the Import Registration (see "Import Registration" below), that suspending further activities relating to the Opioid Synthesis Technologies is in the Company's best interests. The Company expects to re-evaluate the development and commercialization of the Opioid Synthesis Technologies after the Administrative Law Judge's determination relating to the Import Registration. No assurance can be given that development and commercialization efforts relating to the Opioid Synthesis Technologies will resume in the future, or even if such activities resume, that the Opioid Synthesis Technologies will be capable of commercial scale up or be commercialized.

### ***Import Registration***

To provide for an economical source of raw materials for the commercial manufacturing of opioids utilizing the Opioid Synthesis Technologies, on January 31, 2001, the Company filed with the DEA an application for registration to import (the "Import Registration") narcotic raw materials ("NRMs") including raw opium, opium poppy and concentrate of poppy straw from certain foreign countries. These NRMs are commonly used as the initial starting materials in the synthesis of certain opioid APIs. Notice of the Company's application was published in the Federal Register on September 6, 2001. Within the 30 day period provided under DEA guidelines, three parties, including two companies that the Company believes are the largest U.S. importers of NRMs requested a hearing to formally object to the Company's request for an Import Registration. Pursuant to established procedures, an evidentiary hearing relating to the Company's Import Registration application was held before a DEA Administrative Law Judge ("ALJ") in August 2003. The ALJ later re-opened the administrative record, at the request of opposing parties, to consider the Company's November and December 2003 announcements concerning the Company restructuring and financing activities. After submission of additional testimony by the Company and certain of the opposing parties, the ALJ closed the evidentiary record on May 25, 2004. As of August 31, 2004, the Company and the opposing parties submitted to the ALJ briefing documents based on the evidentiary record and replies to the opposing parties' briefing documents. At the request of certain opposing parties, the ALJ later allowed the submission of additional briefing documents to consider the Company's February 2005 announcement relating to the suspension of further development of the Opioid Synthesis Technologies. As of September 15, 2005, the Company and the opposing parties submitted to the ALJ additional briefing documents based on the Company's February 2005 announcement relating to the suspension of further development of the Opioid Synthesis Technologies. With the evidentiary record currently closed and all briefing documents and reply briefing documents requested by the ALJ submitted, the Company estimates that within 18 months from September 15, 2005, the ALJ will make findings of fact, draw legal conclusions and make a specific recommendation on the Company's Import Registration application to the DEA Deputy Administrator. Historically, within 14 months after receiving the ALJ's recommendation, the DEA deputy administrator will issue an order relating to the Company's application. Assuming the DEA grants the Company's application, of which no

assurance can be given, the Company would be permitted to import NRMs upon appropriate notice in the Federal Register. However, the opposing parties may challenge the DEA decision to grant the Company's application in an appropriate Court of Appeals. In such a case, assuming the Company opposes an appellate challenge, the Company would likely incur additional time delays and legal expenses prior to the issuance of a final decision by the U.S. Court of Appeals. Provided the Company continues to seek the Import Registration, it is expected that the proceedings will continue through 2006 and beyond.



No assurance can be given that the Company's Import Registration application will be approved by the DEA or that, if granted by DEA, the Import Registration would be upheld following an appellate challenge. Furthermore, the Company's cash flow and limited sources of available financing make it uncertain that the Company will have sufficient capital to continue to fund the development of the Opioid Synthesis Technologies, to obtain required DEA approvals and to fund the capital improvements necessary for the manufacture of APIs and finished dosage products incorporating the Opioid Synthesis Technologies.

### ***Recent Events***

#### **2004 Debenture Offering**

On February 10, 2004, the Company consummated a private offering of convertible senior secured debentures (the "2004 Debentures") in the aggregate principal amount of approximately \$12.3 million (the "2004 Debenture Offering"). The 2004 Debentures were issued by the Company pursuant to a certain Debenture and Share Purchase Agreement dated as of February 6, 2004 (the "2004 Purchase Agreement") by and among the Company, Care Capital Investments, Essex Woodlands Health Ventures, Galen Partners and each of the purchasers listed on the signature page thereto. On April 14, 2004 and May 26, 2004, the Company completed additional closings under the 2004 Purchase Agreement raising the aggregate gross proceeds received by the Company from the offering of the 2004 Debentures to \$14 million. 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.

#### **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 Preferred 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.), 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.

## Bridge Loan Financing

The Company is a party to four Loan Agreements completed in January, 2006, November, 2005, September, 2005 and June, 2005 pursuant to which the Company has received bridge loan financing in the aggregate principal amount of \$3.3 million from Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. and certain other shareholders of the Company listed on the signature page to such Loan Agreements. Reference is made to "Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations -Liquidity and Capital Resources" for a more detailed description of the bridge loan transactions.

## *Segment Reporting*

The Company operates in only one business segment, which is the research, development and manufacture of innovative abuse deterrent, abuse resistant and tamper resistant formulations ("Aversion® Technology") intended for use in orally administered opioid-containing pharmaceutical products. As described above in this Report under the captions "Opioid Synthesis Technologies" the Company has suspended activities relating to its Opioid Synthesis Technologies. Prior to 2005, in addition to its Aversion® Technology research and development activities, 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.

## *Government Regulation*

### General

All pharmaceutical technology and manufacturing firms, including the Company, are subject to extensive regulation by the Federal government, principally by the FDA, and, to a lesser extent, by state and local governments. Additionally, the Company is subject to extensive regulation by the DEA for research, development and manufacturing of controlled substances. 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 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.

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 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 the areas of production and quality control. Failure to so comply risks delays in approval of drugs, disqualification from eligibility to sell to the government, and possible FDA enforcement actions, such as an injunction against shipment of the Company's products, the seizure of non-complying drug products, and/or, in serious cases, criminal prosecution. The Company's manufacturing facility is subject to periodic inspection by the FDA.

In addition to the regulatory approval process, the Company is 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.

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## FDA Pharmaceutical Product Approvals

There are currently three pathways to obtain FDA approval to commercially market and distribute a new pharmaceutical product in the U.S.:

1. New Drug Applications ("NDA"). Unless one of the procedures discussed in paragraph 2 or 3 below is available, a prospective manufacturer must conduct and submit to the FDA complete clinical studies to prove a drug's safety and efficacy, in addition to the bioavailability and/or bioequivalence studies discussed below, and must also submit to the FDA information about manufacturing practices, the chemical make-up of the drug and labeling. Some of the products anticipated to be developed by the Company which will incorporate the Opioid Synthesis Technologies and the Aversion® Technology will require an NDA filing. The full clinical testing required for the preparation and filing of an NDA requires the expenditure of substantial resources. The Company intends to collaborate with third-parties to fund the preparation and filing of any such NDAs. There can be no assurance that any such collaboration will be available on terms acceptable to the Company, if at all.
2. 505(b)(2) NDA. An alternative NDA procedure is provided by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "1984 Act") whereby the applicant may rely on published literature and more limited testing requirements. This application process is useful when the API is commercially available in an alternative dosage form or formulation. The Company has received written confirmation from the FDA that OxyADF™ tablets, the Company's lead product candidate utilizing the Aversion® Technology, is an appropriate product candidate for submission as a 505(b)(2) NDA.
3. Abbreviated New Drug Applications ("ANDAs"). The 1984 Act established the ANDA procedure for obtaining FDA approval for those drugs that are off-patent or whose exclusivity has otherwise expired and that are bioequivalent to certain reference listed drugs ("RLD") in the FDA's Orange Book. An ANDA is similar to an NDA, except that the FDA waives the requirement of conducting complete pre-clinical and clinical studies of safety and efficacy and usually requires bioavailability and bioequivalence studies. "Bioavailability" refers to the concentration of a drug in the blood. "Bioequivalence" means equivalence in bioavailability between two drug products. In general, an ANDA will be approved only upon demonstrating that the drug product subject to the ANDA is bioequivalent to the RLD, i.e., that the rate of absorption and the concentration of a generic drug in the blood are substantially equivalent to those of a previously approved RLD.

## Healthcare Reform

Over the last few years several legislative proposals addressing the cost and availability of healthcare products and services have been introduced in Congress and state legislatures. Such proposals include insurance market reforms, the requirement that businesses provide health insurance coverage for all their employees, significant revisions to the process for administering Medicare and Medicaid expenditures, and stringent government cost controls that would influence insurance premiums and indirectly affect the fees of hospitals, physicians and other healthcare providers. Such proposals could adversely affect the Company's business by, among other things, reducing the demand, and the prices paid, for pharmaceutical products such as those being developed by the Company. Additionally, other developments, such as (i) the adoption of a nationalized health insurance system or a single payor system, (ii) changes in needs-based medical assistance programs, or (iii) greater prevalence of capitated reimbursement of healthcare providers, could adversely affect the demand for the products candidates in development utilizing the Company's Aversion® Technology.

## 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, \$180,000 and \$227,000 in the years ended December 31, 2005, 2004 and 2003, respectively, on environmental compliance relating and disposal of hazardous and controlled substances waste.

***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 is aware of potential competitors that may be developing technologies designed to have one or more of the abuse deterrent, abuse resistant or tamper resistant features of the Company's Aversion® Technology. Such competitors include, but are not limited to, Elite Pharmaceuticals, Inc. of Northvale, New Jersey, Collegium Pharmaceuticals of Cumberland, Rhode Island, New River Pharmaceuticals, Inc. of Radford, Virginia and Pain Therapeutics of South San Francisco, California. In addition, we believe that Purdue Pharma of Stamford, Connecticut, Alpharma Inc. of Fort Lee, New Jersey and Endo Pharmaceuticals of Chadds Ford, Pennsylvania are pursuing abuse deterrent, abuse resistant and tamper resistant formulations of opioid analgesic products. The Company believes that Endo Pharmaceuticals has entered into a license agreement with Collegium Pharmaceuticals to develop pain products with abuse deterrent properties.

### ***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. Axiom Pharmaceutical Corporation, a Delaware corporation, is a wholly-owned subsidiary of the Company and was formerly engaged in generic product manufacturing and distribution in Congers, New York. The Company is in the process of dissolving Axiom Pharmaceutical Corporation.

### ***Employees***

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.

## **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 approximately \$12.1 million for the year ended December 31, 2005 and \$70.0 million, \$48.5 million, and \$59.6 million for 2004, 2003, and 2002, respectively. As of December 31, 2005 our accumulated deficit was approximately \$ 291.6 million. The Company's consolidated financial statements for the years ended December 31, 2005 and 2004 have been prepared on a "going concern" basis; however, in its report dated February 1, 2006 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. 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 receipt of issued patents from the U.S. Patent and Trademark Office ("PTO") 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 proceeds to the Company. 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.

### **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.

### **The Company Is Subject to Restrictions on the Incurrence of Additional Indebtedness, Which May Adversely Impact the Company's Ability to Fund Operations**

Pursuant to the terms of each of the Company's outstanding secured term 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**

Our lead product candidate, OxyADF™ incorporating our Aversion® Technology is a tablet formulation intended for oral administration and has an active IND on file with FDA. The Company is focusing substantially all of its product development activities on 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) new drug application (“NDA”)

with the FDA. There can be no assurance that OxyADF™ tablets or any other product candidate developed using the Aversion® Technology will lead to a NDA submission to the FDA and that if a NDA is submitted, that the FDA will accept such submission and subsequently approve such regulatory application to allow for commercial distribution of the product.

The Company is committing substantially all of its resources and available capital to the development of OxyADF™ tablets and the prosecution of its patent applications for the Aversion® Technology. The failure of the Company to successfully develop a product candidate utilizing the Aversion® Technology, to successfully obtain an issued patent from the PTO relating to the Aversion® Technology and 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.

**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, 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 the Company's operations are subject to compliance with FDA regulations. Failure to adhere to applicable FDA regulations by the Company or its licensees, if any, would have a material adverse effect on the Company's operations and financial condition. In addition, in the event the Company is successful in developing product candidates for sale in other countries, the Company 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 a new drug application ("NDA"), a 505(b)(2) NDA, or an Abbreviated New Drug Application ("ANDA"), 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 to a marketing application (NDA, 505(b)(2) NDA or ANDA). 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 Products 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.

### **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® Technologies. 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 and health administration authorities, private health insurers, and other third-party payors, including Medicaid and Medicare. We cannot predict the availability of reimbursement for newly-approved products incorporating our Aversion® Technology. Third-party payors, 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. There is no assurance that any of our patent applications for our Aversion® Technology will issue or, if issued, that such patent(s) will be valid and enforceable against third-party infringement or that such patent(s) will not infringe any third-party patent or intellectual property. Moreover, even if patents do issue on our Aversion® Technology, the claims allowed may not be sufficiently broad to protect the products incorporating the Aversion® Technology. In addition, issued patents may be challenged, invalidated or circumvented. Even if issued, our patents 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, 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 Products, Aversion® Technology or Opioid Synthesis Technologies 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 products or processes 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 processes or products infringe their patent or other intellectual property rights, we will need to defend against such proceedings.

The costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Many of our 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. 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.

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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 or 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.

Subject to a decision and recommendation by the administrative law judge about our application for a license to import narcotic raw materials, we are concentrating substantial 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 from other companies marketing branded opioid containing products, generic versions of branded opioid containing products and other drugs and technologies that compete with the products incorporating our Aversion® Technology, and the relative timing and sequence of new product approvals. Alternative technologies and products are being developed to improve or replace the use of opioids for pain management, several of which are in clinical trials or are awaiting approval from the FDA. In the event that such alternatives to opioid containing products 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.

### **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 to Meet Commercial Demand 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 or meet commercial demand. There is a risk that DEA regulations may interfere with the supply of the products used in our clinical trials, and, in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

### **We May Not Be Successful in Commercializing Our Opioid Synthesis Technologies**

Historically the Company has been engaged in research, development and manufacture of proprietary, high yield, short cycle time, environmentally sensitive opioid manufacturing processes (the "Opioid Synthesis Technologies") intended for use in the commercial manufacturing of certain bulk opioid active pharmaceutical ingredients ("APIs"). The Company has suspended further development and commercialization efforts relating to its Opioid Synthesis Technologies. We have determined based on our limited cash reserves, the additional funding required for facility improvements for commercial scale up for our Opioid Synthesis Technologies, the projected timeline for resolution of our application to the DEA for a narcotic raw material import registration (the "Import Registration"), and other factors that suspending activities relating to the Opioid Synthesis Technologies is in our best interest. We expect to re-evaluate the development and commercialization of the Opioid Synthesis Technologies after the Administrative Law Judge makes a determination relating to our Import Registration. No assurance can be given that development and commercialization efforts relating to the Opioid Synthesis Technologies will resume in the future, or even if such activities resume, that the Opioid Synthesis Technologies will be capable of commercial scale up or will be commercialized.

### **We May Not Obtain DEA Approval for Our Import Registration**

Since early 2001 we have been engaged in the application process to obtain an Import Registration from the DEA to import narcotic raw materials directly from foreign countries for use in commercial manufacturing certain bulk opioid APIs. No assurance can be given that the Import Registration application will be approved by the DEA or that if granted by DEA, the Import Registration would be upheld following an appellate challenge.

### **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 and the ability of purchasers in the offering to sell the common stock received upon conversion of the Preferred Shares in the secondary market. There is no guarantee that an active trading market for our common stock will be maintained on the OTC Bulletin Board. Investors 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.

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## **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 78% 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 7 members, 4 of whom shall be the designees of GCE Holdings LLC (the assignee of all 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.

## **Key Personnel Are Critical to Our Business, and Our Future Success Depends on Our Ability to Retain Them**

We are highly dependent on the principal members of our management and scientific team, particularly 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.

## **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 February 28, 2007 with an option for a one-year extension. The lease agreement provides for annual rent, property taxes, common area maintenance and janitorial services for 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, 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**

In May 2001, the Company was named as a defendant in an action entitled Alfred Kohn v. Halsey Drug Co. in the Supreme Court of New York, Bronx County. The plaintiff sought, among other things, damages of \$1.0 million for breach of an alleged oral contract to pay a finder's fee for a business transaction involving the Company. The Company's and the Plaintiff's motion for summary judgment were due to be heard by the Court in August 2003. Plaintiff Kohn deceased shortly prior to such hearing date, and the motions for summary judgment and any trial of this matter were stayed pending the substitution of Mr. Kohn's estate as the plaintiff. In February, 2005, with the substitution of Kohn's estate as Plaintiff, the Court ruled in favor of the Company under its motion for summary judgment. In doing so, the Court dismissed all aspects of Plaintiff's complaint, with the exception of Plaintiff's claim for payment of the fair value for the services alleged to have been performed by Plaintiff. In March 2005, the Company and the Estate of Mr. Kohn agreed to settle this matter, pursuant to which the Company would make a one-time payment of \$35,000. Following receipt of the approval of the Bronx, New York Surrogate's Court obtained in November 2005, the Company and the Estate of Mr. Kohn executed the definitive settlement agreement and in December 2005 the Company remitted to the Estate of Mr. Kohn \$35,000 in full settlement and dismissal of this matter.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2005.

**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.

<b>PERIOD</b>	<b>BID PRICE</b>	
	<b>HIGH</b>	<b>LOW</b>
2004 Fiscal Year		
First Quarter	0.82	0.41
Second Quarter	0.62	0.37
Third Quarter	0.53	0.31
Fourth Quarter	0.64	0.32
2005 Fiscal Year		
First Quarter	0.70	0.33
Second Quarter	0.81	0.41
Third Quarter	0.73	0.40
Fourth Quarter	1.36	0.27
2006 Fiscal Year		
First Quarter (through February 1, 2006)	0.50	0.25

*Holder*

There were approximately 689 holders of record of the Company's common stock on February 1, 2006. 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 investors in the 2004 Debentures 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 Financings", and "Item 13. Certain Relationships and Related Transactions") 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, 2005, the Company issued 330,711 shares of the Company's Common Stock in satisfaction of the payment of \$144,521 in accrued interest due December 31, 2005 under the Company's senior secured term note. 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 on below for the years ended December 31, 2005, 2004, 2003, 2002 and 2001 are derived from the Company's audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2005 and 2004, and for each of the years in the three-year period ended December 31, 2005, and the reports thereon, are included elsewhere herein. The selected financial information as of and for the years ended December 31, 2002 and 2001 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."

	YEARS ENDED DECEMBER 31,				
	2005	2004	2003	2002	2001
<b>(IN THOUSANDS, EXCEPT PER SHARE DATA)</b>					
<b>OPERATING DATA:</b>					
Net revenues	\$ --	\$ 838	\$ 5,750	\$ 8,205	\$ 16,929
<b>Operating Costs</b>					
Cost of manufacturing	--	1,435	11,705	12,535	14,857
Research and development	6,265	4,130	1,460	1,517	1,327
Selling, general and Administrative expenses	5,296	5,238	7,903	7,216	6,616
Plant shutdown costs	--	--	1,926	(126)	68
Interest expense	636	2,962	6,001	4,728	3,913
Interest income	(36)	(59)	(25)	(15)	(69)
Amortization of debt discount and deferred private offering costs	--	72,491	24,771	12,558	2,591
Loss (gain) on extinguishments of debt	--	(12,401)	--	28,415	--
Investment in joint venture	--	--	--	--	(202)
Other (income) expense	(86)	(2,962)	464	966	(13)
Loss before income tax benefit	(12,075)	(69,996)	(48,455)	(59,589)	(12,563)
Income tax benefit	--	--	--	--	--
Net loss	\$ (12,075)	\$ (69,996)	\$ (48,455)	\$ (59,589)	\$ (12,563)
Basic and diluted loss per common share	\$ (.18)	\$ (3.20)	\$ (2.28)	\$ (3.90)	\$ (.84)
Weighted average number of outstanding shares	66,573	21,861	21,227	15,262	15,021

	DECEMBER 31,				
	2005	2004	2003	2002	2001
<b>(IN THOUSANDS)</b>					
<b>BALANCE SHEET DATA:</b>					
Working capital (deficiency)	\$ (2,478)	\$ 2,423	\$ (3,770)	\$ 5,933	\$ (8,276)
Total assets	1,792	4,967	6,622	19,364	11,069
Total debt	7,613	5,093	53,142	25,398	67,321
Total liabilities	7,954	6,052	58,689	31,632	76,505
Accumulated deficit	(291,616)	(279,541)	(209,546)	(161,090)	(101,501)
Stockholders' equity (deficit)	\$ (6,162)	\$ (1,085)	\$ (52,067)	\$ (12,268)	\$ (65,436)

## 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," Item 3, "Legal Proceedings" and elsewhere in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"). 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. 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 technology and product candidates, and the Company's ability to fulfill the U.S. Food and Drug Administration's requirements for approving the Company's product candidates for commercial distribution in the United States. 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 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.

### *Company Overview*

Acura Pharmaceuticals, Inc. is a specialty pharmaceutical company primarily engaged in research, development and manufacture of innovative abuse deterrent, abuse resistant and tamper resistant formulations ("Aversion® Technology") intended for use in orally administered opioid-containing pharmaceutical products. The Company's lead product candidate utilizing its Aversion® Technology, OxyADF™ tablets, (formerly referred to by the Company as Product Candidate #2) is being developed pursuant to an active investigational new drug application ("IND") on file with the U.S. Food and Drug Administration ("FDA"). The FDA has confirmed that OxyADF™ is an appropriate product candidate for submission as a 505(b)(2) new drug application ("NDA"). The Company utilizes several contract research organizations and an academic institution for laboratory and clinical evaluation and testing of product candidates incorporating the Aversion® Technology. The status of the development of the Aversion® Technology and the OxyADF™ tablets are described in Item 1, "Business" under the caption "Aversion® Technology". In addition, to a much lesser extent, during 2004 and early 2005, the Company was engaged in the 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 ("APIs"). In early 2005, the Company suspended development and commercialization efforts relating to the Opioid Synthesis Technologies. The status of the Opioid Synthesis Technologies is described in Item 1, "Business" under the caption "Opioid Synthesis Technologies". As of the date of this Report the Company had three US non-provisional and two international patent applications pending relating to its Aversion® Technology. Additionally, as of the date of this Report, the Company had six US patents issued and three US patent applications pending related to its Opioid Synthesis Technologies. As of the date of this Report, the Company retained ownership of all issued patents, patent applications, other intellectual property and commercial rights to its product candidates, Aversion Technology and Opioid Synthesis Technologies.

The Company conducts research, development, laboratory, manufacturing and warehousing activities for its Aversion® Technology at its Culver, Indiana facility (the "Culver Facility"). The Culver Facility is registered by the U.S. Drug Enforcement Administration (the "DEA") to perform research, development and manufacture for certain Schedule II - V controlled substances in bulk and finished dosage forms. In 2001, the Company filed with the DEA an application for registration (the "Import Registration") to import narcotic raw materials ("NRMs"). The status of the application for the Import Registration is described in Item 1, "Business" under the caption "Import Registration."

To generate revenue, the Company expects to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license the Company's product candidates utilizing the Aversion® Technology and further develop, register and commercialize multiple formulations and strengths of such product candidates. The Company expects to receive milestone payments and a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Aversion® Technology. As of the date of this Report the Company did not have 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's business involves inherent risk as set forth in Item 1A of this Report. These risks include, among others, the need for FDA approval prior to commercial distribution of the Company's product candidates in the United States, acceptance by healthcare providers and third-party payers of such product candidates, dependence on key personnel, determination of patentability of our Aversion® Technology by the United States Patent and Trademark Office, and freedom to operate for the Company's 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, 2005 and 2004 have been prepared on a going-concern basis; however, in its report dated February 1, 2006 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 receipt of issued patents from the U.S. Patent and Trademark Office ("PTO") for the material claims in the Company's patent applications relating to the Aversion® Technology; (d) 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 (e) 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 and Commercial Focus***

At December 31, 2005, the Company had cash and cash equivalents of approximately \$260,000 compared to approximately \$3.1 million at December 31, 2004. The Company had a working capital deficit of \$2.5 million at December 31, 2005 and working capital of approximately \$2.4 million at December 31, 2004. The Company had an accumulated deficit of approximately \$291.6 and \$279.5 million at December 31, 2005 and December 31, 2004, respectively. The Company incurred a loss from operations of approximately \$11.6 million and a net loss of approximately \$12.1 million during the year ended December 31, 2005, as compared to a loss from operations of \$10.0 million and a net loss of \$70.0 million for the year ended December 31, 2004.

The Company is focused on (a) the development and evaluation, in concert with contract research organizations ("CROs"), in laboratory settings and clinical trials, of product candidates utilizing the Company's Aversion® Technology; (b) the manufacture, quality assurance testing and release, and stability studies of clinical trial supplies and NDA submission batches of certain finished dosage form product candidates utilizing the Company's Aversion® Technology; (c) the prosecution of the Company's patent applications relating to the Aversion® Technology with the PTO and foreign equivalents; (d) the negotiation and execution of license and development agreements with strategic pharmaceutical company partners providing that such licensees will further develop certain finished dosage product candidates utilizing the Aversion® Technology, file for regulatory approval with the FDA and other regulatory authorities and commercialize such products; and (e) the prosecution of the Company's application to the U.S. Drug Enforcement Administration ("DEA") for registration to import narcotic raw materials ("NRMs").

Prior to 2005, in addition to its Aversion® Technology research and development activities, 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.

As of February 1, 2006, the Company had cash and cash equivalents of approximately \$647,000. The Company estimates its current cash reserves will be sufficient to fund the development of the Aversion® Technology and related operating expenses only through mid-to-late March, 2006. See "Liquidity and Capital Resources - Commercial Focus, Cash Reserves and Funding Requirements."

### **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 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	52%

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 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%

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.

Environmental compliance expenses for the year ended December 31, 2005 and 2004, were as follows (in thousands):

<b>12/31/05 ENVIRONMENTAL COMPLIANCE EXPENSES</b>	<b>12/31/04 ENVIRONMENTAL COMPLIANCE EXPENSES</b>	<b>12/31/05-12/31/04 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE</b>	<b>12/31/05-12/31/04 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE</b>
\$ 61	\$ 180	(\$ 119)	(66%)

The environmental compliance expenses, which are included as part of R&D expense in the financial statements, related primarily to disposal of hazardous and controlled substances waste and related personnel costs for environmental compliance incurred while performing research and development activities at the Company's Culver, Indiana facility. The decrease in 2005 from the prior year resulted primarily from the elimination of API manufacturing operations at that site in 2004.



Interest expense, net of interest income for the year ended December 31, 2005 2004 was as follows (in thousands):

<b>12/31/05</b> <b>INTEREST EXPENSE,</b> <b>NET OF INTEREST</b> <b>INCOME</b>	<b>12/31/04</b> <b>INTEREST EXPENSE,</b> <b>NET OF INTEREST</b> <b>INCOME</b>	<b>12/31/05-12/31/04</b> <b>INTEREST EXPENSE,</b> <b>NET OF INTEREST</b> <b>INCOME</b> <b>\$ CHANGE</b>	<b>12/31/05-12/31/04</b> <b>INTEREST EXPENSE,</b> <b>NET OF INTEREST</b> <b>INCOME</b> <b>% CHANGE</b>
\$ 600	\$ 2,903	(\$ 2,303)	(79%)

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

Net loss for the year ended December 31, 2005 and 2004 was as follows (in thousands):

<b>12/31/05</b> <b>NET LOSS</b>	<b>12/31/04</b> <b>NET LOSS</b>	<b>12/31/05-12/31/04</b> <b>NET LOSS</b> <b>\$ CHANGE</b>	<b>12/31/05-12/31/04</b> <b>NET LOSS</b> <b>% CHANGE</b>
\$ 12,075	\$ 69,996	(\$ 57,921)	(83%)

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 expenses occurred in 2004 as a result of restructuring operations and conversion of debt to preferred shares. These expenses included the full amortization of the remaining debt discount and deferred private 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.

### **Results of Operations for the Year Ended December 31, 2004 and 2003**

In comparing results of operations for the year ended December 31, 2004 with those for 2003 it is important to understand that in 2004 the Company focused the majority of its efforts and resources on Aversion® Technology research and development activities and, subsequent to March, 2004, no longer maintained any generic product manufacturing facilities or conducted any manufacturing activities. Net product revenues and manufacturing expenses realized in 2004 were incurred as part of an orderly phase out of all generic product manufacturing activities.



Net product revenues for the year ended December 31, 2004 and 2003 were as follows (in thousands):

<b>12/31/04 NET PRODUCT REVENUES</b>	<b>12/31/03 NET PRODUCT REVENUES</b>	<b>12/31/04-12/31/03 NET PRODUCT REVENUE \$ CHANGE</b>	<b>12/31/04-12/31/03 NET PRODUCT REVENUE % CHANGE</b>
\$ 838	\$ 5,750	(\$4,912)	(85%)

The decrease in net product revenues was a result of discontinuing the manufacture and sale of finished dosage generic pharmaceutical products. The net product revenues for the year ended December 31, 2004 reflect the sale of all remaining inventories of saleable finished dosage generic pharmaceutical products during the first two quarters of 2004. No product sales revenues were recorded for the third or fourth quarter of 2004.

Cost of manufacturing for the year ended December 31, 2004 and 2003 were as follows (in thousands):

<b>12/31/04 COST OF MANUFACTURING</b>	<b>12/31/03 COST OF MANUFACTURING</b>	<b>12/31/04-12/31/03 COST OF MANUFACTURING \$ CHANGE</b>	<b>12/31/04-12/31/03 COST OF MANUFACTURING % CHANGE</b>
\$ 1,435	\$ 11,705	(\$10,270)	(88%)

For the year ended December 31, 2004, cost of manufacturing includes the fixed costs of the Company's generic finished dosage manufacturing operations in the first quarter of 2004 and residual expenses through the second quarter of 2004. The Company's generic finished dosage manufacturing operations ceased in March 2004.

Research and development expenses for the year ended December 31, 2004 and 2003 were as follows (in thousands):

<b>12/31/04 R&amp;D EXPENSES</b>	<b>12/31/03 R&amp;D EXPENSES</b>	<b>12/31/04-12/31/03 R&amp;D EXPENSES \$ CHANGE</b>	<b>12/31/04-12/31/03 R&amp;D EXPENSES % CHANGE</b>
\$4,130	\$1,460	\$2,670	183%

In 2003, research and development expense consisted primarily of generic product development costs. During 2004, research and development expense consists primarily of research and development associated with 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 is primarily related to the Company's strategic decision to devote a major portion of its resources in 2004 to research and development activities relating to its Aversion® Technology and to a lesser extent to its Opioid Synthesis Technologies. The 2004 expenses include a non cash compensation charge of \$553 recorded for the issuance of stock options and \$1,093 of personnel costs for employees which were reassigned to research and development.

Selling, marketing, general and administrative expenses for the year ended December 31, 2004 and 2003 were as follows (in thousands):

<b>12/31/04 SELLING, MARKETING, G&amp;A EXPENSES</b>	<b>12/31/03 SELLING, MARKETING, G&amp;A EXPENSES</b>	<b>12/31/04-12/31/03 SELLING, MARKETING, G&amp;A EXPENSES</b>	<b>12/31/04-12/31/03 SELLING, MARKETING, G&amp;A EXPENSES</b>
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**\$ CHANGE**

**% CHANGE**

\$ 5,238

\$ 7,903

(\$ 2,665)

(34%)

27

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The decrease in selling, marketing, general and administrative expenses resulted from discontinuing the marketing and sale of generic products and reducing its related administrative and manufacturing support staff. The decrease includes \$1,093 of personnel costs for employees which were reassigned to research and development in connection with the Company's strategic decision to devote a major portion of its resources in 2004 to research and development activities, a nonrecurring benefit for settlement of trade payables at a discount of \$194 and a non cash compensation charge of \$1,453 recorded for the issuance of stock options.

Environmental compliance expenses for the year ended December 31, 2004 and 2003, were as follows (in thousands):

<b>12/31/04 ENVIRONMENTAL COMPLIANCE EXPENSES</b>	<b>12/31/03 ENVIRONMENTAL COMPLIANCE EXPENSES</b>	<b>12/31/04-12/31/03 ENVIRONMENTAL COMPLIANCE EXPENSES \$ CHANGE</b>	<b>12/31/04-12/31/03 ENVIRONMENTAL COMPLIANCE EXPENSES % CHANGE</b>
\$ 180	\$ 227	(\$ 47)	(21%)

Environmental compliance expenses related primarily to disposal of hazardous and controlled substances waste and related personnel costs for environmental compliance.

Interest expense, net of interest income for the year ended December 31, 2004 and 2003 was as follows (in thousands):

<b>12/31/04 INTEREST EXPENSE, NET OF INTEREST INCOME</b>	<b>12/31/03 INTEREST EXPENSE, NET OF INTEREST INCOME</b>	<b>12/31/04-12/31/03 INTEREST EXPENSE, NET OF INTEREST INCOME \$ CHANGE</b>	<b>12/31/04-12/31/03 INTEREST EXPENSE, NET OF INTEREST INCOME % CHANGE</b>
\$ 2,903	\$ 5,976	(\$ 3,073)	(51%)

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 and the conversion of the Company's 5% convertible debentures into convertible preferred stock on August 13, 2004.

Debt discount and deferred private debt offering costs for the year ended December 31, 2004 and 2003 were as follows (in thousands):

<b>12/31/04 DEBT DISCOUNT AND DEFERRED PRIVATE DEBT OFFERING COSTS</b>	<b>12/31/03 DEBT DISCOUNT AND DEFERRED PRIVATE DEBT OFFERING COSTS</b>	<b>12/31/04-12/31/03 DEBT DISCOUNT AND DEFERRED PRIVATE DEBT OFFERING COSTS \$ CHANGE</b>	<b>12/31/04-12/31/03 DEBT DISCOUNT AND DEFERRED PRIVATE DEBT OFFERING COSTS % CHANGE</b>
\$72,491, consisting of \$1,030 private debt offering costs and \$71,461 debt discount	\$24,771, consisting of \$1,099 private debt offering costs and \$23,672 debt discount	\$ 47,720	193%





The change in the debt discount and deferred private debt offering costs reflects the amortization of the remaining deferred debt discount and private debt offering costs incurred from all of the Company's debenture and bridge loan financings consummated from March 1998 through May, 2004. As a result of the conversion of all convertible debentures into preferred stock at August 13, 2004, all remaining unamortized debt discount and deferred private debt offering cost balances were written off to expense.

Net loss for the year ended December 31, 2004 and 2003 was as follows (in thousands):

<b>12/31/04</b>	<b>12/31/03</b>	<b>12/31/04-12/31/03</b>	<b>12/31/04-12/31/03</b>
<b>NET LOSS</b>	<b>NET LOSS</b>	<b>NET LOSS</b>	<b>NET LOSS</b>
		<b>\$ CHANGE</b>	<b>% CHANGE</b>
\$ 69,996	\$ 48,455	\$21,541	44%

Included in the net loss for the year ended December 31, 2004 is the full amortization of the remaining debt discount and deferred private 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.

### **Liquidity and Capital Resources**

At December 31, 2005, the Company had cash and cash equivalents of \$260,000 compared to \$3.1 million at December 31, 2004. The Company had a working capital deficit of \$2.5 million at December 31, 2005 compared to working capital of \$2.4 million at December 31, 2004.

#### ***2004 Debenture Offering***

On February 10, 2004, the Company consummated a private offering of convertible senior secured debentures (the "2004 Debentures") in the aggregate principal amount of approximately \$12.3 million (the "2004 Debenture Offering"). The 2004 Debentures were issued by the Company pursuant to a certain Debenture and Share Purchase Agreement dated as of February 6, 2004 (the "2004 Purchase Agreement") by and among the Company, Care Capital Investments, Essex Woodlands Health Ventures, Galen Partners and each of the purchasers listed on the signature page thereto. On April 14, 2004 and May 26, 2004, the Company completed additional closings under the 2004 Purchase Agreement raising the aggregate gross proceeds received by the Company from the offering of the 2004 Debentures to \$14 million. 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.

Pursuant to the terms of the 2004 Purchase Agreement and other documents executed in connection with the 2004 Debentures, effective August 13, 2004, each of the holders of the Company's 2004 Debentures converted the 2004 Debentures into the Company's Series A preferred shares (the "Series A Preferred"). In addition, effective August 13, 2004, each of the holders of the Company's 5% convertible senior secured debentures issued during the period 1998 through and including 2003 converted such debentures into the Company's Series B Preferred Stock (the "Series B Preferred") and/or Series C-1, C-2 and/or C-3 preferred stock (collectively, the "Series C Preferred"). The Series C Preferred shares together with the Series B Preferred shares are herein referred to as the "Junior Preferred Shares". Upon conversion of the Company's outstanding debentures, the Company issued approximately 21.9 million Series A Preferred shares, approximately 20.2 million Series B Preferred shares, approximately 56.4 million Series C-1 Preferred shares, approximately 37.4 million Series C-2 Preferred shares and approximately 81.9 million Series C-3 Preferred shares.

*Conversion of Preferred Shares into Common Stock*

Effective November 10, 2005, all of the Company's issued and outstanding shares of preferred stock were automatically and mandatorily converted into the Company's 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 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.), 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.

*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"). 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. A 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 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.

In addition to Watson's forgiveness of approximately \$16.4 million under the Watson Notes, as additional consideration for the Company's payment to Watson of approximately \$4.3 million and the Company's conveyance of certain Company assets, all supply agreements between the Company and Watson were terminated and Watson waived the dilution protections contained in the Common Stock purchase warrant dated December 20, 2002 exercisable for approximately 10.7 million shares of the Company's Common Stock previously issued by the Company to Watson, to the extent such dilution protections were triggered by the transactions provided in the 2004 Debenture Offering.

*Terms of the 2004 Note*

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% (paid quarterly in the Company's common stock) and matures on June 30, 2007.

*Bridge Loan Financing*

*January 2006 Bridge Loan*

The Company is a party to a Loan Agreement, dated January 31, 2006 (the "January 2006 Bridge Loan Agreement") by and among Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. and such Additional Lenders as may become a party pursuant to the terms of the January 2006 Bridge Loan Agreement (collectively, the "January 2006 Bridge Lenders"). In accordance with the terms of the January 2006 Bridge Loan Agreement, on January 31, 2006 the January 2006 Bridge Lenders provided a bridge loan to the Company in the principal amount of \$750,000. The January 2006 Bridge Loan Agreement also permits the funding of additional loans in the principal amount of up to \$250,000 and, with the consent of any two of Care Capital Investments, Essex Woodlands Health Ventures and Galen Partners, additional loan amounts mutually agreed to by the Company and the January 2006 Bridge Lenders (the "January 2006 Bridge Loan"). No assurance can be given that any additional loans will be made available to the Company under the January 2006 Bridge Loan Agreement. The net proceeds from the January 2006 Bridge Loan, after the satisfaction of related expenses, will be used by the Company to continue the development of its Aversion® Technology and to fund operating expenses. The January 2006 Bridge Loan is secured by a lien on all of the Company's assets, senior in right of payment and lien priority to all other indebtedness of the

Company. The January 2006 Bridge Loan bears interest at the rate of ten percent (10%) per annum and matures on June 1, 2006. The January 2006 Bridge Loan is subject to mandatory pre-payment by the Company upon the Company's completion of equity or debt financing or any sale, transfer, license or similar arrangement pursuant to which the Company or any of its Subsidiaries 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 cash proceeds to the Company, net of all costs and expenses, at least equal to the sum of (i) \$5.05 million, plus (ii) the aggregate principal amount of the January 2006 Bridge Loan (a "Funding Event"). The January 2006 Bridge Loan Agreement restricts the Company's ability to issue any shares of its currently authorized Series A, B or C preferred stock without the prior consent of the January 2006 Bridge Lenders, and grants the January 2006 Bridge Lenders preemptive rights relating to the issuance of the Company's Series A, B and C preferred stock. The January 2006 Bridge Loan Agreement also contains normal and customary affirmative and negative covenants, including restrictions on the Company's ability to incur additional debt or grant any lien on the assets of the Company or its Subsidiaries, subject to certain permitted exclusions.

#### November 2005 Bridge Loan

The Company is a party to a Loan Agreement, dated November 9, 2005 (the “November 2005 Bridge Loan Agreement”) by and among Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. and certain other shareholders of the Company listed on the signature page thereto (collectively, the “November 2005 Bridge Lenders”) providing for bridge financing to the Company in the principal amount of \$1.05 million (the “November 2005 Bridge Loan”). The net proceeds from the November 2005 Bridge Loan, after the satisfaction of related expenses, are being used by the Company to continue the development of its Aversion™ Technology and to fund operating expenses. The terms of the November 2005 Bridge Loan are identical to the terms of the January 2006 Bridge Loan, except that (i) the lien securing the November 2005 Bridge Loan is junior in right of payment and lien priority to the January 2006 Bridge Loan, and (ii) the funding event is \$5.05 million.

#### September 2005 Bridge Loan

The Company is a party to a Loan Agreement, dated September 16, 2005 (the “September 2005 Bridge Loan Agreement”) by and among Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (collectively, the “September 2005 Bridge Lenders”) providing for bridge financing to the Company in the principal amount of \$0.5 million (the “September 2005 Bridge Loan”). The net proceeds from the September 2005 Bridge Loan, after the satisfaction of related expenses, were used by the Company to continue the development of its Aversion™ Technology and to fund operating expenses. The terms of the September 2005 Bridge Loan are identical to the terms of the January 2006 Bridge Loan, except that (i) the September 2005 Bridge Loan required that the Company maintain minimum cash reserves of \$200,000, (ii) the lien securing the September 2005 Bridge Loan is junior in right of payment and lien priority to each of the January 2006 Bridge Loan and the November 2005 Bridge Loan, and (iii) the Funding Event is \$4.0 million. On October 20, 2005, the September 2005 Bridge Lenders waived the requirement that the Company maintain minimum cash reserves of \$200,000 until such time as the Company receives additional financing providing net proceeds to the Company of at least \$2.0 million.

#### June 2005 Bridge Loan

The Company also is a party to a Loan Agreement, dated June 22, 2005 (the “June 2005 Bridge Loan Agreement”) by and among Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (collectively, the “June 2005 Bridge Lenders”) providing for bridge financing to the Company in the principal amount of \$1.0 million (the “June 2005 Bridge Loan”). The net proceeds from the June 2005 Bridge Loan, after the satisfaction of related expenses, were used by the Company to continue the development of its Aversion™ Technology and to fund operating expenses. The terms of the June 2005 Bridge Loan are identical to the terms of the January 2006 Bridge Loan described above, except that (i) the June 2005 Bridge Loan required that the Company maintain minimum cash reserves of \$200,000, (ii) the lien securing the June 2005 Bridge Loan is junior in right of payment and lien priority to each of the January 2006 Bridge Loan, the November 2005 Bridge Loan and the September 2005 Bridge Loan and (iii) the Funding Event amount is \$3.5 million. On October 20, 2005, the June 30, 2005 Bridge Lenders waived the requirement that the Company maintain minimum cash reserves of \$200,000 until such time as the Company receives additional financing providing net proceeds to the Company of at least \$2.0 million.

*Commercial Focus, Cash Reserves and Funding Requirements*

As of February 1, 2006, the Company had cash and cash equivalents of approximately \$647,000. 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 has suspended further development and commercialization efforts relating to the Opioid Synthesis Technologies and expects to minimize the use of cash and cash equivalents for the prosecution of patent applications relating to the Opioid Synthesis Technologies (See "Item 1 - Business - Opioid Synthesis Technologies").

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, including the net proceeds from the January 2006 Bridge Loan will be sufficient to fund the development of the Aversion® Technology and related operating expenses through mid-to-late March, 2006. To fund further operations and product development activities, the Company must raise additional financing, or enter into alliances or collaboration agreements with third parties. 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 obtain an issued U.S. patent 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, 2005 (in thousands):

	TOTAL	DUE IN 2006	DUE IN 2007	DUE IN 2008	DUE THEREAFTER
Notes payable	\$ 7,550	\$ 2,550	\$ 5,000	--	--
Capital leases	63	31	26	6	--
Operating leases	35	30	5	--	--
Annual interest on fixed rate debt (1)	128	128	--	--	--
Employment agreements	740	740	--	--	--
Total contractual obligations	\$ 8,516	\$ 3,479	\$ 5,031	\$ 6	\$ --

Expected cash payments on contractual obligations entered into subsequent to December 31, 2005	TOTAL	DUE IN 2006	DUE IN 2007	DUE IN 2008	DUE THEREAFTER
Notes payable	\$ 750	\$ 750	\$ --	\$ --	\$ --
Annual interest on fixed rate debt (1)	25	25	--	--	--
	\$ 775	\$ 775	\$ --	\$ --	\$ --

(1) Interest on variable rate debt is paid with shares of the Company's common stock. Such interest expense is estimated to be \$600,000 for 2006.

### ***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**



The Company accounts for stock-based employee compensation arrangements in accordance with provisions of APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25") and complies with the disclosure provision of SFAS No. 148, "Accounting for Stock-based Compensation - Transition and Disclosure, an amendment of FASB Statement No. 123" ("SFAS No. 148"). The amounts disclosed include various estimates used to determine fair value of stock options, and restricted stock units. Management determines the amount of the compensation associated with options and restricted stock units, based, in part, by the relative fair values ascribed to these instruments through the use of the Black-Scholes valuation model. Inherent in the Black-Scholes valuation model are assumptions made by management regarding the estimated life of these instruments, the estimated volatility of the Company's common stock (as determined by reviewing its historical public market closing prices) and the expected dividend yield. If the Company were to include the cost of stock-based employee compensation in the financial statements, which it will be required to do starting in 2006, the Company's operating results would decline based on the fair value of the stock-based employee compensation.

## Debt Discount

Debt discount has and will result from the issuance of stock warrants and beneficial conversion features in connection with the issuance of subordinated debt, common stock interest payments and other notes payable. The amount of the discount is recorded as a reduction of the related obligation and is amortized over the remaining life of the related obligations. Management determines the amount of the discount, based, in part, by the relative fair values ascribed to the warrants determined by an independent valuation or through the 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.

## *New Accounting Pronouncements*

### Stock Based Payment

On December 16, 2004, the FASB released FASB Statement No. 123 (revised 2004), "Share-Based Payment, ("FASB 123R")". These changes in accounting replace existing requirements under FASB Statement No. 123, "Accounting for Stock-Based Compensation", and eliminates the ability to account for share-based compensation transaction using APB Opinion No.25, "Accounting for Stock Issued to Employees". The compensation cost relating to share-based payment transactions will be measured based on the fair value of the equity or liability instruments issues. This Statement does not change the accounting for similar transactions involving parties other than employees. Publicly traded companies must apply this Standard as of the beginning of the first annual period that begins after June 15, 2005.

FASB 123R permits public companies to choose between two adoption methods, one of which is the "modified prospective" method. The modified prospective method 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 cumulative effect of initially applying this Statement, if any, is recognized as of the required effective date. The Company's required effective date is January 1, 2006. The Company has not completed its evaluation of the impact of adopting FASB 123R on its consolidated financial statements because it will depend on levels of share-based payments granted in the future. However, the Company has estimated \$100,000 of additional unearned compensation will be recorded and expensed over the applicable remaining vesting periods for all share-based payments granted to employees on or before December 31, 2005 that remain 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.

### 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, and early adoption is permitted. The Company is required to adopt the provision of SFAS 154, as applicable, beginning in fiscal 2006.

### ***Capital Expenditures***

The Company's capital expenditures during 2005, 2004 and 2003 were \$35,000, \$444,000 and \$410,000, respectively. The capital expenditures during 2004 and 2003 are attributable to capital improvements to the Company's Congers, NY and Culver, Indiana facilities. Capital expenditures in 2005 were attributable to the purchase of scientific equipment and improvements to the Culver, Indiana facility.

### ***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-government 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, 2005, our investments consisted primarily of short-term bank commercial paper and checking funds with variable, market rates of interest.

The Company has indebtedness 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 annual interest expense.

## **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 AND EXECUTIVE OFFICERS OF THE REGISTRANT**

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

<b>NAME</b>	<b>AGE</b>	<b>POSITION</b>
Andrew D. Reddick	53	President, Chief Executive Officer and Director
Ron J. Spivey	59	Senior Vice President and Chief Scientific Officer
Peter A. Clemens	53	Senior Vice President, Chief Financial Officer and Secretary
James F. Emigh	50	Vice President of Marketing and Administration
Robert A. Seiser	42	Vice President, Corporate Controller and Treasurer
Bruce F. Wesson	63	Director
William A. Sumner	68	Director
Jerry N. Karabelas	53	Director
William G. Skelly	55	Director
Immanuel Thangaraj	35	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, a pharmaceutical company. From June, 1999 to March, 2000 he served as President of Faulding Laboratories, Inc. Mr. Reddick holds a BA degree in Biology from the University of California and an MBA degree from Duke University.

Ron J. Spivey 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 company providing consulting services to the pharmaceutical industry relating to product research and development. From March, 1998 to May, 2002 he served as Vice President, Scientific Affairs for Alpharma/Purepac Pharmaceuticals. Dr. Spivey holds a BA degree from Indiana University and a Ph.D. degree in pharmaceutics from the University of Iowa.

Peter A. Clemens has been Senior Vice President, Chief Financial Officer and Secretary since April 2004. Mr. Clemens was 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 B.B.A. degree from the University of Notre Dame and an MBA 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 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 B.B.A. degree from Loyola University of Chicago.

Bruce F. Wesson has been a Director of the Company since March, 1998. Mr. Wesson is President of Galen Associates, a health care venture firm, and a General Partner of Galen Partners III, L.P. 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 Encore Medical Corporation, QMed, Inc., and Chemtura Corporation, each a publicly traded company, and several privately held companies. Mr. Wesson earned a 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., a manufacturer and distributor of pharmaceutical products, 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 to various entities in the pharmaceutical field.

Jerry N. Karabelas has been a Director of the Company since December, 2002 and Chairman of the Board from May 2003 through May, 2005. Dr. Karabelas was Head of Healthcare and CEO of Worldwide Pharmaceuticals for Novartis AG from 1998 until July 2000. Prior to joining Novartis, Dr. Karabelas was Executive Vice President of SmithKline Beecham. From July, 2000 until December, 2001, Dr. Karabelas was the Founder and Chairman of the Novartis Bio Venture Fund. Since November, 2001 he has been a Partner with Care Capital LLC. Dr. Karabelas holds a Ph.D. in pharmacokinetics from the Massachusetts College of Pharmacy and serves as a Director of SykePharma Plc., Human Genome Sciences, Nitromed, Anadys and Renova.

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., companies involved in the animal health industry including veterinary biologicals and custom manufacturing of animal sera products. From 1985 to 1990, Mr. Skelly served as President of Martec Pharmaceutical, Inc., a distributor and manufacturer of human generic prescription pharmaceuticals.

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. Prior to joining Essex Woodlands Health Ventures, he helped form 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 and serves as a Director of iKnowMed Systems, Sound ID and CBR Systems.

#### ***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 2005, 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 78% 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.



### ***Nominating Committee***

Currently the entire Board of Directors functions as the Company's nominating committee. As required, 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 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 applying 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, 2005, except that (i) Galen Partners III, L.P. and Care Capital Investments II, LP failed to file Form 4s, (ii) GCE Holdings LLC failed to file a Form 3, and (iii) Peter Clemens filed a Form 4 late.

**ITEM 11. EXECUTIVE COMPENSATION**

The following table sets forth a summary of the compensation paid by the Company for services rendered in all capacities to the Company during the fiscal years ended December 31, 2005, 2004 and 2003 to the Company's Chief Executive Officer and the Company's next four most highly compensated executive officers (collectively, the "named executive officers") whose total annual compensation for 2005 exceeded \$100,000:

**SUMMARY COMPENSATION TABLE**

NAME AND PRINCIPAL POSITION	YEAR	ANNUAL COMPENSATION			LONG TERM COMPENSATION SECURITIES UNDERLYING STOCK			
		SALARY	BONUS	OTHER ANNUAL COMPEN- SATION <sup>(3)</sup>	RESTRICTED STOCK AWARDS <sup>(1)</sup>	OPTIONS RESTRICTED STOCK UNITS (#)	and ALL OTHER COMPEN- SATION	
Andrew D. Reddick President and Chief Executive Officer	2005	\$ 300,000	\$ --	\$ --	\$ 2,660,625	8,250,000	\$ --	
	2004	305,769	60,000	--	--	8,750,000	--	
	2003	96,923	--	--	--	--	--	
Ron J. Spivey Senior Vice President and Chief Scientific Officer	2005	260,000	--	--	2,128,500	10,600,000 <sup>(2)</sup>	--	
	2004	190,000	--	--	--	3,000,000	--	
	2003	-0-	--	--	--	--	--	
Peter A. Clemens Senior Vice President and Chief Financial Office	2005	180,000	--	9,000	1,419,000	4,400,000	--	
	2004	172,789	60,000	9,000	--	375,000	--	
	2003	146,000	60,000	9,000	--	--	--	
James F. Emigh Vice President/Marketing and Administration	2005	140,000	--	--	443,438	1,375,000	--	
	2004	137,692	50,000	4,200	--	249,000	--	
	2003	127,800	--	4,200	--	--	--	
Robert A. Seiser Vice President, Corporate Controller and Treasurer	2005	132,942	--	--	532,125	1,650,000	--	
	2004	123,077	50,000	4,500	--	249,000	--	
	2003	\$ 110,923	\$ 7,000	\$ 4,500	--	--	\$ --	

(1) The dollar value of the Restricted Stock Unit Awards is equal to the difference between (A) the product of (x) the number of shares of the Company's Common Stock underlying each award, multiplied by (y) \$0.3325, the average of the closing bid and asked prices of the Company's Common Stock on December 22, 2005, the date of grant of the Restricted Stock Unit Awards, as reported by the Over-the-Counter Bulletin Board ("OTCBB"), less (B) the par value of \$0.01 per share payable by the recipient of the Restricted Stock Unit Award upon the Company's issuance of the shares. The aggregate number of shares underlying Restricted Stock Unit Awards made by the Company as of December 31, 2005 to Messrs. Reddick, Spivey, Clemens, Emigh and Seiser is 8,250,000, 6,600,000, 4,400,000, 1,375,000 and 1,650,000 shares respectively. The value of the shares underlying Restricted Stock Unit Awards made by the Company as of December 31, 2005 to Messrs. Reddick, Spivey, Clemens, Emigh and Seiser is \$2,103,750, \$1,683,000, \$1,122,000, \$350,625, and \$420,750, respectively, based on the average of the closing bid and asked prices on December 30, 2005 of \$0.265, as reported by the OTCBB. Each of the Restricted Stock Units vests one-third 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 Awards will be issued by the Company on the earlier of (i) a Change of Control (as defined in the Company's 2005 Restricted Stock Unit Award Plan), or (ii) January 1, 2011. In the event of a Change of Control, the issuance of shares by the Company shall be made in a lump sum distribution. In the absence of a Change of Control, the

issuance shall be made in four (4) equal installments on each of January 1, 2011, January 1, 2012, January 1, 2013 and January 1, 2014. The recipients of the Restricted Stock Unit Awards 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 the Company.

(2) Consists of (i) 6,600,000 shares of common stock underlying Restricted Stock Unit Awards, and (ii) 4,000,000 shares of common stock underlying stock options.

(3) Consisted of auto allowances which were discontinued after 2005.

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### ***Other Compensatory Arrangements***

Executive officers and key employees participate in medical, dental, life and disability insurance plans provided to all Company 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 the Company's Chief Executive Officer and President for a term expiring December 31, 2006. 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 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 the Company's 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 the Company's Common Stock was \$0.435. The Employment Agreement also acknowledges the grant to Mr. Reddick of a Restricted Stock Unit Award providing for the Company's issuance of up to 8,250,000 shares of the Company's 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 the Company on the earlier of (i) a Change in Control (as defined in the Company's 2005 Restricted Stock Unit Award Plan), or (ii) January 1, 2011. In the event of a Change in Control, the Company shall 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 the Company 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 the Company's 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 the shares are issued by the Company. 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, the Company is 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 the Company without Cause or by Mr. Reddick for Good Reason, the Company is 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 entitled to continued coverage under the Company's then existing benefit plans, including medical and life insurance, for twelve (12) months from the date of termination. 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 the Company has not breached the terms of the Employment Agreement, from competing with the Company at any time prior to one year after the termination of his employment with the Company.

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, 2006. 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 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 the Company's 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 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 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 the Company's common stock on the date of grant. The Employment Agreement also acknowledges the grant to Mr. Spivey of a Restricted Stock Unit Award providing for the Company's issuance of up to 6,600,000 shares of the Company's 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 the Company on the earlier of (i) a Change in Control (as defined in the Company's 2005 Restricted Stock Unit Award Plan), or (ii) January 1, 2011. In the event of a Change in Control, the Company shall issue the vested shares in a lump sum distribution. In the absence of a Change in Control, the issuance of the vested shares shall be made in four (4) equal installments on each of January 1, 2011, January 1, 2012, January 1, 2013 and January 1, 2014. Upon issuance of the shares underlying the Restricted Stock Unit Award, Mr. Spivey must remit to the Company 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 the Company's common stock was \$0.3325, as reported by the OTCBB. Mr. 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 the shares are issued by the Company. 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 shall 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 the Employment Agreement is terminated by the Company without Cause or by Dr. Spivey for Good Reason, the Company is 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 the Company's 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 (as defined in the Employment Agreement), in which case such termination is considered to be made without Cause, 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 the Company has not breached the terms of the Employment Agreement, from competing with the Company at any time prior to one year after the termination of his employment with the Company.





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, 2006. 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 one hundred eighty (180) 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 the Company's 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 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 grant of stock options on March 10, 1998 to purchase 300,000 shares of the Company's 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 the Company's 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 the Company's issuance of up to 4,400,000 shares of the Company's 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 the Company on the earlier of (i) a Change in Control (as defined in the Company's 2005 Restricted Stock Unit Award Plan), or (ii) January 1, 2011. In the event of a Change in Control, the Company shall issue the vested shares in a lump sum distribution. In the absence of a Change in Control, the issuance of the vested shares shall be made in four (4) equal installments on each of January 1, 2011, January 1, 2012, January 1, 2013 and January 1, 2014. Upon issuance of the shares underlying the Restricted Stock Unit Award, Mr. Clemens must remit to the Company 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 the Company's 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 the shares are issued by the Company. 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 the Company without Cause or by Mr. Clemens for Good Reason, the Company is 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 the Company's 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 the Company has not breached the terms of the Employment Agreement, from competing with the Company at any time prior to two years after the earlier to occur of the expiration of the term and the termination of his employment.

### *Compensation of Directors*

Directors who are employees of the Company receive no additional or special remuneration for their services as Directors. Directors who are not employees of the Company receive an annual grant of options to purchase 50,000 shares of the Company's common stock and \$500 for each meeting attended (\$250 in the case of telephonic meetings). The Company also reimburses 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, the Company granted to each of Messrs. William Sumner and William Skelly Restricted Stock Unit Awards providing for the Company's issuance of up to 1 million shares of the Company's common stock. The Restricted Stock Unit Awards are made pursuant to the Company's 2005 Restricted Stock Unit Award Plan and are in consideration of the services provided by Messrs. Sumner and Skelly to the Company as independent members of the Board and as representatives of the Independent Committee of the Board of Directors for various material transactions undertaken by the Company during the period 2002 through 2005, including, without limitation, the Company's 2002 Debenture Offering, the 2004 Debenture Offering, the conversion of the Company's Preferred Shares into common stock and the various bridge loans financing transactions with the Company, 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 the Company on the earlier of (i) a Change in Control (as defined in the Company's 2005 Restricted Stock Unit Award Plan), or (ii) January 1, 2011. In the event of a Change in Control, the Company 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 to the Company the \$0.01 par value per share.

### *Stock Option Plans*

The Company currently maintains two stock option plans adopted in 1995 and 1998, respectively. The Company in the past has 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 the Company's shareholders in September, 1995. As of the date of this Report, incentive stock options ("ISO's") to purchase 322,510 shares and non-qualified options to purchase 106,390 shares were granted 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 \$1.64.

The 1998 Stock Option Plan. The 1998 Stock Option Plan was adopted by the Board of Directors in April, 1998 and approved by the Company's shareholders in June, 1998. The 1998 Stock Option Plan permits the grant of ISO's and non-qualified stock options to purchase shares of the Company's 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. The Company's 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. The Company's 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. The Company's shareholders ratified the Plan amendment on August 12, 2004. As of the date of this Report, stock options to purchase 19,326,095 shares of Common Stock had been granted under the 1998 Stock Option Plan. Of such option grants, 789,826 are ISOs and 18,536,269 are non-qualified options. The

average per share exercise price for all outstanding options under the 1998 Stock Option Plan is approximately \$0.24. 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 16,823,000 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 adopted 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 believes that the 2005 RSU Plan does not require shareholder approval. Nevertheless, the Company intends to seek shareholder ratification for the 2005 RSU Plan at its next 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 the Company's 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 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. A married recipient of an RSU award may generally only designate 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 the Company's common stock issued pursuant to a distribution under the RSU. The Company will generally be entitled to a tax deduction in the same amount.

As of the date of this Report the Company had granted RSUs providing for the Company's issuance of up to an aggregate of 29,500,000 shares of the Company's common stock. 27,500,000 of such Restricted Stock Unit 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 Restricted Stock Unit 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.



**Securities Authorized For Issuance Under Equity Compensation Plans**

The following table includes information as of December 31, 2005 relating to the Company's 1995 and 1998 Stock Option Plans and the Company's 2005 Restricted Stock Unit Award Plan, which comprise all of the equity compensation plans of the Company. 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	WEIGHTED-AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS	NUMBER OF SECURITIES REMAINING AVAILABLE FOR FUTURE ISSUANCE UNDER EQUITY COMPENSATION PLANS (EXCLUDING SECURITIES REFLECTED IN COLUMN(a))
	(a)	(b)	(c)
Stock Option Equity Compensation Plans Approved by Security Holders	19,754,995	\$ 0.27	616,655
Stock Option Equity Compensation Plans Not Approved by Security Holders	0	0	0
Restricted Stock Unit Equity Compensation Plans Approved by Security Holders	0	0	0
Restricted Stock Unit Equity Compensation Plans Not Approved by Security Holders	27,500,000	\$0.01	2,500,000
<b>TOTAL</b>	<b>47,254,995</b>	<b>\$ 0.11</b>	<b>3,116,655</b>

## OPTION GRANTS AND RESTRICTED STOCK UNIT AWARDS IN 2005

The following tables present information regarding (i) the grant of options to purchase shares of the Company's common stock, and (ii) the award of Restricted Stock Units providing for the Company's future issuance of Common Stock, for each of the named executive officers in 2005.

Name	Individual Option Grants				Potential Realizable Value of Assumed Annual Rates of Stock Price Appreciation for Option Term(2)
	Number of Securities Underlying Options Granted	Percent of Total Options Granted in Fiscal Year	Exercise Price Per Share (1)	Expiration Date	

					<b>5%</b>	<b>10%</b>
Andrew D. Reddick	--	--	--	--	--	--
Ron J. Spivey	4,000,000	100%	\$0.13	2014	\$2,489,577	\$4,054,419
Peter A. Clemens	--	--	--	--	--	--
James F. Emigh	--	--	--	--	--	--
Robert A. Seiser	--	--	--	--	--	--

(1) The stock option granted to Dr. Spivey provides for vesting of 3,110,668 shares upon the grant, 444,666 shares on January 1, 2006, and 444,666 shares on April 1, 2006.

(2) The dollar amounts in these columns represent the potential realizable value of each option assuming that the market price of the Company's common stock (based on the average of the closing bid and asked prices of the Company's common stock on December 9, 2005, the date of grant of the stock option, of \$0.485) appreciates in value from the date of grant at the 5% and 10% annual rates prescribed by regulation and therefore are not intended to forecast possible future appreciation, if any, of the price of the Common Stock.

Name	Individual Restricted Stock Unit Awards ("RSUs")					
	Number of Securities Underlying RSUs Granted	% of Total RSUs Granted to Employees in Fiscal Year	Payment Price Per Share (1)	Expiration Date	Potential Realizable value at Assumed Annual Rates of Stock Price Appreciation for the RSU Term(2)	
					5%	10%
Andrew D. Reddick	8,250,000	30%	\$0.01	2014	\$4,173,000	\$6,385,600
Ron J. Spivey	6,600,000	24%	\$0.01	2014	\$3,338,400	\$5,108,500
Peter A. Clemens	4,400,000	16%	\$0.01	2014	\$2,225,600	\$3,405,700
James F. Emigh	1,375,000	5%	\$0.01	2014	\$695,500	\$1,064,300
Robert A. Seiser	1,650,000	6%	\$0.01	2014	\$834,600	\$1,277,100

(1) Each of the Restricted Stock Unit Awards vest 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 Awards will be issued by the Company on the earlier (i) a Change of Control (as defined in the Company's 2005 Restricted Stock Unit Award Plan), or (ii) January 1, 2011. In the event of a Change of Control, the Company's 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 the Company's distribution of the vested shares underlying the Restricted Stock Unit Awards, the recipients must submit to the Company the par value of \$0.01 per share. The recipients of the Restricted Stock Unit Awards 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 the Company.

(2) The dollar amounts in these columns represent the potential realizable value of each RSU assuming that the market price of the Common Stock (based on the average of the closing bid and asked prices of the Company's Common Stock on December 22, 2005, the date of award of Restricted Stock Units, of \$0.3325) appreciates in value from the date of grant at the 5% and 10% annual rates prescribed by regulation and therefore are not intended to forecast possible future appreciation, if any, of the price of the Common Stock.

**AGGREGATE OPTION EXERCISED IN LAST FISCAL YEAR  
AND FISCAL YEAR END OPTION VALUES**

No stock options were exercised by the named executive officers during 2005. The following table presents information regarding the value of options outstanding at December 31, 2005 for each of the named executive officers.

NAME	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT FISCAL YEAR END		VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS AT FISCAL YEAR END (1)	
	EXERCISABLE	UNEXERCISABLE	EXERCISABLE	UNEXERCISABLE
Andrew D. Reddick	7,000,000	1,750,000	\$945,000	\$236,250
Ron J. Spivey	5,777,334	1,222,666	\$779,940	\$165,060
Peter A. Clemens	718,750	281,250	\$12,656	\$37,969
James F. Emigh	213,250	186,750	\$8,404	\$25,211
Robert A. Seiser	213,250	186,750	\$8,404	\$25,211



(1) Value is based upon difference between the exercise price of the options and the average of the closing bid and asked prices of the Company's Common Stock of \$0.265 per share at December 30, 2005.

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**Compensation Committee Interlocks and Insider Participation**

During 2005, the Company's Compensation Committee consisted of Messrs. Karabelas, Skelly and Reddick. During 2005, except for Mr. Reddick, there were no Compensation Committee interlocks or insider participation in compensation decisions.

**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, 2006, for individuals or entities in the following categories: (i) each of the Company's Directors and nominees for Directors; (ii) the Chief Executive Officer and the next four highest paid executive officers of the Company whose total annual compensation for 2005 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. 610 Fifth Ave., 5 <sup>th</sup> Floor, New York, New York 10020	256,325,501(2)	78.2%
Oracle Strategic Partners, L.P. 200 Greenwich Avenue, Suite 3, Greenwich, CT 06830	18,085,708(3)	5.5%
Andrew D. Reddick	7,750,000(4)	2.3%
Ron J. Spivey	7,000,000(5)	2.1%
William G. Skelly	401,000(6)	.*
Bruce F. Wesson	--(2)	*
William A. Sumner	250,000(7)	*
Peter A. Clemens	1,127,823(8)	*
Jerry N. Karabelas	--(2)	*
Immanuel Thangaraj	--(2)	*
Robert A. Seiser	275,250 (9)	*
James F. Emigh	320,000(10)	*
All Directors and Officers as a Group (10 persons)	17,124,323(11)	5.0%

\* 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.

(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, Zubeen Shroff and Srinu Conjeevaram; and (ii) Care Capital Investments II, LP and Care Capital Offshore Investments II, LP, Jan Leschly, Jerry Karabelas and David Ramsay; and (iii) Essex Woodlands Health Ventures V, L.P., Immanuel Thangaraj.

(3) Larry N. Feinberg exercises voting, investment and dispositive rights over the Company's securities held of record by Oracle Strategic Partners, L.P. The information with respect to Oracle Strategic Partners is based on filings with the Commission and/or information provided to the Company.

- (4) Includes 7,750,000 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.
- (5) 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.
- (6) 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.
- (7) 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.
- (8) Includes 812,500 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.
- (9) Includes 275,250 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.
- (10) Includes 275,250 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.
- (11) Includes 16,753,000 shares which Directors and executive officers have the right to acquire within 60 days of February 1, 2006 through exercise of outstanding stock options.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

On February 10, 2004, the Company consummated a private offering of convertible senior secured debentures (the "2004 Debentures") in the aggregate principal amount of approximately \$12.3 million (the "2004 Debenture Offering"). The 2004 Debentures were issued by the Company pursuant to a certain Debenture and Share Purchase Agreement dated as of February 6, 2004 (the "2004 Purchase Agreement") by and among the Company, Care Capital, Essex Woodlands Health Ventures, Galen Partners and each of the purchasers listed on the signature page thereto. Of the approximate \$12.3 million in debentures issued on February 10, 2004 under in the 2004 Debenture Offering, approximately \$2 million of 2004 Debentures were issued in exchange for the surrender of a like amount of principal plus accrued and unpaid interest under the Company's convertible debentures issued to Care Capital, Essex Woodlands Health Ventures and Galen Partners during November and December, 2003.

Effective August 13, 2004, the 2004 Debentures (including the principal amount plus interest accrued at the date of conversion) were converted automatically into the Company's Series A convertible preferred stock ("Series A Preferred") at a price per share (the "Conversion Price") of \$0.6425, representing the average of the closing bid and asked prices of the Company's Common Stock for the 20 trading days ending February 4, 2004, as reported by the OTCBB. The Company issued on an aggregate of approximately 22 million shares of Series A Preferred of which approximately 5.2 million, 6.8 million and 6.8 million were issued to Care Capital, Essex Woodlands Health Ventures and Galen Partners, respectively, under the 2004 Debentures held by such parties (representing 23.8%, 30.9% and 30.9%, respectively, of the total Series A Preferred issuable upon conversion of the 2004 Debentures).

As a condition to the completion of the 2004 Purchase Agreement, the Company, the investors in the 2004 Debentures and the holders of the Company's outstanding 5% convertible senior secured debentures due March 31, 2006 issued by the Company in during the period from 1998 through 2003 (collectively, the "1998-2003 Debentures"), executed a certain Voting Agreement dated as of February 6, 2004 (the "Voting Agreement"). The Voting Agreement provided that each of Care Capital, Essex Woodlands Health Ventures and Galen Partners (collectively, the "Lead 2004 Investors") had the right to designate for nomination one member of the Company's Board of Directors, and that the Lead 2004 Investors collectively may designate one additional member of the Board (collectively, the "Designees"). In connection with the conversion of the Company's Preferred Shares (as described below), the Voting Agreement was amended to reflect to the conveyance by each of Care Capital, Essex Woodlands Health Ventures and Galen Partners of their holdings in the Company's Preferred Shares (prior to its conversion into common stock) to GCE Holdings, LLC, a limited liability company controlled by such parties. As amended, the Voting Agreement provides that the Board of Directors of the Company shall be comprised of not more than seven (7) members, four (4) of whom shall be designees of GCE Holdings, LLC (as the assignee of the Preferred Shares of the Company held by Care Capital, Essex Woodlands Health Ventures and Galen Partners). The designees of GCE Holdings, LLC are Messrs. Karabelas, Thangaraj and Wesson, respectively, each of whom are current Board members. As of the date of this Report, the fourth designee of GCE Holdings had not been determined.

Simultaneous with the execution of a 2004 Purchase Agreement, and as a condition to the initial closing of the 2004 Purchase Agreement, the Company, the investors in the 2004 Debentures and each of the holders of the 1998-2003 Debentures executed a certain Debenture Conversion Agreement dated as of February 6, 2004 (the "Conversion Agreement"). In accordance with the terms of the Conversion Agreement, the 1998-2003 Debentures were converted automatically into the Company's Series B convertible preferred stock (the "Series B Preferred") and/or the Company's Series C convertible preferred stock (the "Series C Preferred"). .

It was a condition to the completion of the 2004 Debenture Offering that the Company's 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 Care Capital, Essex Woodlands Health Ventures, Galen Partners and the other investors in the 2004 Debentures as of February 10, 2004 (collectively, the "Watson Note Purchasers"). Accordingly, simultaneous with the closing of the 2004 Purchase Agreement, each of the Company, Watson and the Watson Note Purchasers executed an Umbrella Agreement dated as of February 10, 2004 (the "Umbrella Agreement"). The Umbrella Agreement provides for (i) the Company's 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 the Company's 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. In addition to Watson forgiveness of approximately \$16.4 million of indebtedness under the Watson Notes, all current supply agreements between the Company and Watson were terminated and Watson waived the dilution protections contained in the warrant previously granted to Watson to purchase approximately 10.7 million shares of Common Stock, to the extent such dilution protections were triggered by the transactions contemplated in the 2004 Debenture Offering.

The 2004 Note in the principal amount of \$5.0 million 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 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 the 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 the Company 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 the Company to Care Capital, Essex Woodlands Health Ventures and Galen Partners, respectively (representing approximately 27%, 35% and 35%, respectively, of the 2004 Note).

Effective November 10, 2005, all of the Company's issued and outstanding shares of preferred stock were automatically and mandatorily converted into the Company's 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 Preferred Stock (prior to its conversion to 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.), 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.

The Company is a party to four (4) Loan Agreements completed in January 2006, November, 2005, September, 2005 and June, 2005 pursuant to which the Company has received bridge financing in the aggregate principal amount \$3.3 million 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. and certain other shareholders of the Company listed on the signature page to such Loan Agreements. Reference is made to "Item 7-Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources" for a more detailed description of the bridge loan transactions.

#### 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 2005 and 2004 were as follows:

<b>BDO Seidman, LLP</b>	<b>2005</b>	<b>2004</b>
Audit Fees	\$67,867	\$45,613
Audit-Related Fees	\$7,480	-
<b>Total Audit and Audit-Related Fees</b>	<b>\$75,347</b>	<b>\$45,613</b>
Tax Fees	\$28,000	-
All Other Fees	-	-
<b>Total for BDO Seidman, LLP</b>	<b>\$103,347</b>	<b>\$45,613</b>

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.

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.



There were no fees billed by our auditors for professional services rendered for products and services provided other than those described above.

*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 2004 and 2005 and related fees (as described in the captions above) were approved in advance by the Audit Committee.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K**

(a)(1) Consolidated Financial Statements -- See Index to Financial Statements.

(a)(2) None

(b) 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.

ACURA PHARMACEUTICALS, INC.

By: /s/ ANDREW D. REDDICK

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Andrew D. Reddick  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: February 14, 2006

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.

/s/ Andrew D. Reddick Andrew D. Reddick	President, Chief Executive Officer and Director (Principal Executive Officer)	February 14, 2006
/s/ Peter A. Clemens Peter Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 16, 2006
/s/ William G. Skelly William G. Skelly	Director	February 15, 2006
/s/ Bruce F. Wesson Bruce F. Wesson	Director	February 16, 2006
/s/ William Sumner William Sumner	Director	February 14, 2006
Jerry Karabelas	Director	February __, 2006
/s/ Immanuel Thangaraj Immanuel Thangaraj	Director	February 16, 2006

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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 Subsidiaries as of December 31, 2005 and 2004 and the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the years then ended. 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 Subsidiaries at December 31, 2005 and 2004, and the results of their operations and their cash flows for the years then ended, 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.

/s/ BDO Seidman, LLP

Chicago, Illinois  
February 1, 2006

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Directors and Stockholders  
ACURA PHARMACEUTICALS, INC.

We have audited the accompanying consolidated statements of operations, shareholders' equity (deficit) and cash flows for the year ended December 31, 2003 of Acura Pharmaceuticals, Inc and Subsidiaries (formerly Halsey Drug Co., Inc. and Subsidiaries) (the "Company"). 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 audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated result of operations and cash flows for the year ended December 31, 2003 of Acura Pharmaceuticals, Inc. and Subsidiaries, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern., The Company incurred a net loss of \$48,455,000 during the year ended December 31, 2003, and, as of that date, the Company's current liabilities exceeded its current assets by \$3,770,000, and its total liabilities exceeded its total assets by \$52,067,000. These factors, among others, as discussed in Note B to the financial statements, raise substantial doubt about the Company's 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.

**/s/ GRANT THORNTON LLP**

New York, New York  
February 26, 2004, except for the second paragraph of Note A, as to which the date is March 19, 2004

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**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****DECEMBER 31, 2005 and 2004****(in thousands)**

<b>ASSETS</b>	<b>2005</b>	<b>2004</b>
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 260	\$ 3,103
Prepaid insurance	179	212
Prepaid expenses and other current assets	5	95
Total current assets	444	3,410
<b>PROPERTY, PLANT &amp; EQUIPMENT, NET</b>	<b>1,341</b>	<b>1,555</b>
<b>DEPOSITS</b>	<b>7</b>	<b>2</b>
<b>TOTAL ASSETS</b>	<b>\$ 1,792</b>	<b>\$ 4,967</b>

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS (CONTINUED)

DECEMBER 31, 2005 and 2004

(in thousands, except share data)

LIABILITIES AND STOCKHOLDERS' DEFICIT	2005	2004
<b>CURRENT LIABILITIES</b>		
Senior secured term notes payable	\$ 2,550	\$ -
Current maturities of capital lease obligations	31	29
Accrued expenses	341	959
Total current liabilities	2,922	988
SECURED TERM NOTE PAYABLE	5,000	5,000
CAPITAL LEASE OBLIGATIONS, less current maturities	32	64
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>TOTAL LIABILITIES</b>	<b>\$ 7,954</b>	<b>\$ 6,052</b>
<b>STOCKHOLDERS' DEFICIT</b>		
Common stock - \$.01 par value; 650,000,000 shares authorized; 329,293,530 and 22,466,967 shares issued and outstanding in 2005 and 2004, respectively	3,293	225
Convertible preferred stock - \$.01 par value; 72,027,014 and 290,000,000 shares authorized and available for issuance in 2005 and 2004, respectively; none and 217,972,986 shares issued and outstanding in 2005 and 2004, respectively	-	2,180
Additional paid-in capital	287,885	277,129
Unearned compensation	(5,724)	(1,078)
Accumulated deficit	(291,616)	(279,541)
<b>STOCKHOLDERS' DEFICIT</b>	<b>(6,162)</b>	<b>(1,085)</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<b>\$ 1,792</b>	<b>\$ 4,967</b>

See accompanying notes to the consolidated financial statements.



**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****YEARS ENDED DECEMBER 31, 2005, 2004 and 2003****(in thousands, except per share data)**

	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net product revenues	\$ -	\$ 838	\$ 5,750
Cost of manufacturing	-	1,435	11,705
Research and development	6,265	4,130	1,460
Selling, marketing, general and administrative	5,296	5,238	7,903
Plant shutdown costs	-	-	1,926
Loss from operations	(11,561)	(9,965)	(17,244)
<u>Other income (expense)</u>			
Interest expense	(636)	(2,962)	(6,001)
Interest income	36	59	25
Amortization and write-off of debt discount and deferred private debt offering costs	-	(72,491)	(24,771)
Gain on debt restructuring	-	12,401	-
Gain on asset disposals	81	2,359	-
Other	5	603	(464)
<b>NET LOSS</b>	<b>\$ (12,075)</b>	<b>\$ (69,996)</b>	<b>\$ (48,455)</b>
Basic and diluted loss per common share	\$ (0.18)	\$ (3.20)	\$ (2.28)
Weighted average number of outstanding common shares	66,573	21,861	21,227

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIT

YEARS ENDED DECEMBER 31, 2005, 2004 and 2003

(in thousands, except par values)

	Common Stock \$.01 Par Value		Preferred Stock \$.01 Par Value		Additional Paid-in		Unearned Compensation	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Capital				
<b>Balance at January 1, 2003</b>	<b>21,035</b>	<b>\$ 211</b>	<b>-</b>	<b>\$ -</b>	<b>\$ 148,611</b>	<b>\$ -</b>	<b>-\$ (161,090)</b>	<b>\$ (12,268)</b>	
Net loss for the year ended December 31, 2003	-	-	-	-	-	-	(48,455)	(48,455)	
Conversion of debentures	567	5	-	-	322	-	-	327	
Issuance of warrant for lending commitment	-	-	-	-	581	-	-	581	
Beneficial conversion features in connection with debt	-	-	-	-	7,178	-	-	7,178	
Issuance of warrant in severance	-	-	-	-	113	-	-	113	
Increase in fair value of warrants	-	-	-	-	457	-	-	457	
<b>Balance at December 31, 2003</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)	
Issuance of Common Shares for payment of interest	865	9	-	-	391	-	-	400	
Intrinsic value of issued options	-	-	-	-	3,030	(3,030)	-	-	
Amortization of unearned compensation	-	-	-	-	55	1,952	-	2,007	
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>
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<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)
Issuance of Common Shares for interest	963	10	-	-	525	-	-	535
Intrinsic value of issued options and restricted stock units	-	-	-	-	11,105	(11,105)	-	-
Amortization of unearned compensation	-	-	-	-	-	6,459	-	6,459
Issuance of Common Shares for exercise of options	35	1	-	-	4	-	-	5
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>

See accompanying notes to the consolidated financial statements.

## ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2005, 2004, and 2003

(in thousands, except supplemental data)

	2005	2004	2003
<b>Cash flows from Operating Activities:</b>			
Net loss	\$ (12,075)	\$ (69,996)	\$ (48,455)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	137	291	811
Amortization of debt discount and deferred private debt offering costs	-	30,684	24,771
Write off unamortized debt discount and deferred private debt offering costs	-	41,807	-
Gain on debt restructuring	-	(12,401)	-
Non-cash stock compensation expense	6,459	2,007	-
Gain on Department of Justice settlement	-	(402)	-
Amortization of deferred product acquisition costs	-	6	42
Provision for losses on accounts receivable	-	(428)	351
(Gain) or loss on asset disposals	(81)	(2,359)	7
Debentures and stock issued for interest expense	535	401	3,241
Change in fair value of warrants due to modification of terms	-	-	457
Impairment reserve against fixed assets	-	-	3,619
Changes in assets and liabilities			
Accounts receivable	-	729	(2,244)
Inventories	-	312	28
Prepaid expenses and other current assets	121	94	(76)
Other assets and deposits	(5)	184	103
Accounts payable	-	(1,882)	(877)
Accrued expenses	(618)	1,460	2,137
Total adjustments	6,548	60,503	32,270
Net cash used in operating activities	(5,527)	(9,493)	(16,085)
<b>Cash flows from Investing Activities:</b>			
Capital expenditures	(35)	(444)	(410)
Proceeds from asset disposals	193	4,538	-
Net cash provided by (used in) investing activities	158	4,094	(410)
<b>Cash flows from Financing Activities:</b>			
Payments on senior secured term notes payable	-	(4,000)	-
Proceeds from issuance of senior secured term notes payable	2,550	-	2,000
Proceeds from the exercise of stock options	5	-	-
Payments to Department of Justice	-	(31)	(328)
Payments on capital lease obligations	(29)	(45)	(46)
	-	11,951	6,600

Proceeds from issuance of subordinated convertible debentures

Payments of private offering costs	-	(315)	-
Net cash provided by financing activities	2,526	7,560	8,226
(Decrease) increase in cash and cash equivalents	(2,843)	2,161	(8,269)
Cash and cash equivalents at beginning of year	3,103	942	9,211
<b>Cash and cash equivalents at end of year</b>	<b>\$ 260</b>	<b>\$ 3,103</b>	<b>\$ 942</b>

See accompanying notes to the consolidated financial statements.

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**ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)**

**YEAR ENDED DECEMBER 31, 2005, 2004, and 2003**  
**(in thousands, except supplemental data)**

Supplemental disclosures of noncash investing and financing activities:

**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 305,829,000 shares of Common Stock.

**Year ended December 31, 2004**

1. The Company's Convertible Subordinated Debentures contained beneficial conversation 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.

**Year ended December 31, 2003**

1. The Company's bridge loans contained beneficial conversion features valued at \$578,000.
2. The Company's convertible debentures contained beneficial conversation features valued at \$6,600,000.
3. The Company issued \$3,241,000 of debentures as payment of like amounts of debenture accrued interest.
4. The Company repaid \$2,037,000 of indebtedness in the form of product deliveries.
5. The Company issued 645,000 warrants with an estimated relative fair value of \$582,000 for the lending commitment in the form of debentures and bridge loans.
6. The Company issued 567,000 shares of common stock upon conversion of \$327,000 of debentures.
7. The Company issued 150,000 warrants with an estimated relative fair value of \$113,000 in connection with the termination of an employment agreement.
8. Equipment financed through capital leases aggregated approximately \$111,000.

See accompanying notes to the consolidated financial statements.

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

**DECEMBER 31, 2005, 2004 and 2003**

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

The Company is a New York corporation established in 1935. Prior to the restructuring of the Company's operations 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. In making its determination, the Board of Directors considered, among other factors, the Company's ability and time required to generate positive cash flow and income from the operation of the Company's manufacturing, packaging, labeling and distribution facilities located in Congers, New York (collectively, the "Congers Facilities") in the manufacture and distribution of Generic Products pursuant to abbreviated new drug applications ("ANDAs").

In implementing the restructuring of operations at the Congers Facilities, Generic Product manufacturing operations substantially ceased on January 30, 2004. Packaging and labeling operations ceased approximately February 12, 2004 and quality assurance and related support activities ceased on approximately February 27, 2004. Such dates also mark the substantial completion of the reduction in work force of approximately 70 employees engaged in these activities at the Congers Facilities. On February 18, 2004, the Company and Mutual Pharmaceuticals, Inc. ("Mutual") entered into an asset purchase agreement pursuant to which the Company sold certain inactive, non-revenue generating ANDAs to Mutual in consideration of \$2.0 million. The decision to divest ANDAs was based, among other things, on the Company's revised business strategy which focuses on research and development of the Aversion® Technology and the Opioid Synthesis Technologies, and that the Company had ceased operations at the Congers Facilities. On March 19, 2004, the Company and its wholly-owned subsidiary, Axiom Pharmaceutical Corporation ("Axiom") entered into an asset purchase agreement with Ivax Pharmaceuticals New York, LLC ("Ivax") pursuant to which the Company and Axiom sold to Ivax substantially all of the Company's assets used at the Congers Facilities in consideration for \$2.5 million. The asset sale transaction with Ivax was completed on August 13, 2004.

As restructured, the Company is a specialty pharmaceutical company primarily engaged in research, development and manufacture of innovative abuse deterrent, abuse resistant and tamper resistant formulations ("Aversion® Technology") intended for use in orally administered opioid-containing pharmaceutical products. The Company's lead product candidate utilizing the Aversion® Technology, OxyADF™ tablets (formerly referred to by the Company as Product Candidate #2) is being developed pursuant to an active investigational new drug application ("IND") on file with the U.S. Food and Drug Administration ("FDA").

To a much lesser extent, during 2004 and early 2005, the Company was engaged in the 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 ("APIs"). In early 2005, the Company suspended development and commercialization efforts relating to the Opioid Synthesis Technologies.

As the date of this Report, the Company had three US non provisional and two international patent applications pending relating to its Aversion® Technology and six (6) issued US patents and three (3) US patent applications pending relating to the Opioid Synthesis Technologies. As of the date of this Report, the Company retained ownership of all issued patents, patent applications, other intellectual property and commercial rights to its product candidates, Aversion® Technology and Opioid Synthesis Technology.



The Company conducts research, development, laboratory, manufacturing and warehousing activities for the Aversion® Technology at its Culver, Indiana facility (the "Culver Facility"). The Culver Facility is registered by the U.S. Drug Enforcement Administration (the "DEA") to perform research, development and manufacture for certain Schedule II - V controlled substances in bulk and finished dosage forms.

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To generate revenue, the Company expects to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license the Company's product candidates utilizing the Aversion<sup>®</sup> Technology and further develop, register and commercialize multiple formulations and strengths of such product candidates in the U.S. and international territories. The Company expects to receive milestone payments and a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Aversion<sup>®</sup> Technology. As 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 subsidiaries, Acura Pharmaceutical Technologies, Inc., and Axiom Pharmaceutical Corporation. All material intercompany accounts and transactions have been eliminated. 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 the inactive subsidiaries had no impact on the consolidated financial position, results of operations or cash flows of the Company. The Company is currently in the process of dissolving Axiom Pharmaceutical Corporation.

#### 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, 2005, 2004 and 2003. In addition, the Company paid cash interest of approximately \$101,000, \$47,000 and \$526,000 for the years ended December 31, 2005, 2004 and 2003, 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, 2005 and 2004. 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):

	2004	2003
Beginning balance	\$ 428	\$ 14
Provision for losses on accounts receivable	-	351
Provision for all other allowances	-	71
Write-offs	(428)	(8)
Ending balance	\$ -	\$ 428

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#### 4. Inventories

The Company had no inventories at each of December 31, 2005 and 2004.

#### 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

#### 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.

#### 7. Deferred Private Debt Offering Costs

Private debt offering costs represented costs incurred by the Company in conjunction with securing debt financing. The Company incurred approximately \$582,000 in private debt offering costs during the year ended December 31, 2003 in conjunction with a lending commitment received for the private offering of securities in the form of Debentures and Bridge Loans. Private debt offering costs were amortized to interest expense over the life of the related obligations. 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.

#### 8. Debt Discount

Debt discount resulting from the issuance of stock warrants in connection with the issuance of subordinated debt and other notes payable as well as beneficial conversion features contained in convertible debt instruments 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 stock warrants issued is determined by a calculation which is 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 outstanding debentures were converted into various series of preferred stock and approximately \$41,090,000 of unamortized and outstanding debt discount was charged to expense.



## **9. Revenue Recognition**

The Company had no Generic Product sales revenues after second quarter 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.

## **10. Shipping and Handling Costs**

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

## **11. 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. During 2005 and beginning in 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 use of external contract research organizations (CROs). Internal R&D expenses include items such as facility overhead, maintenance, repair and depreciation, laboratory supplies, equipment maintenance, repair and depreciation, salaries, benefits, incentive compensation and other administrative expenses. CRO expenses include items such as preclinical laboratory experiments, clinical trials, clinical trial and regulatory consulting 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 rely on an estimate of the costs applicable to the stage completion of a clinical trial. 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.

## **12. 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 bases 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. A valuation allowance is established if it is more likely than not that all, or some portion, of deferred income tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to zero. 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.

## **13. 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. Diluted earnings per share are based on the same number of common shares adjusted for the effect of other potentially dilutive securities. Excluded from the 2005, 2004 and 2003

computation are approximately 63,496,565, 356,204,000 and 249,877,000, respectively, of outstanding restricted stock units, options, and warrants and the effects of outstanding convertible debentures and convertible preferred stock which would have been antidilutive.

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#### 14. 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 H.

The Company accounts for stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations ("APB No. 25") and has 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 FASB Statement No. 123. Under APB No. 25, when the exercise price of the Company's employee stock options or restricted stock units equals the market price of the underlying common stock on the date of grant, no compensation expense is recognized. Accordingly, no compensation expense has 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 or restricted stock units is less than the market price of the underlying common stock on the date of grant, compensation expense is recognized.

The following table illustrates the effect on net loss and loss per share had the Company applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation ("SFAS 123")," to stock-based employee compensation for these types of stock option or restricted stock unit grants.

	<b>Year ended December 31,</b>		
	<b>(in thousands, except per share data)</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss, as reported	\$ (12,075)	\$ (69,996)	\$ (48,455)
Add: total stock-based employee compensation expense included in reported net loss	6,458	1,952	-
Deduct: total stock-based employee compensation expense determined under fair value-based method for all awards	(7,242)	(3,058)	(662)
Net loss, pro forma	\$ (12,859)	\$ (71,102)	\$ (49,117)
<b>Loss per share:</b>			
Basic and Diluted EPS - as reported	\$ (0.18)	\$ (3.20)	\$ (2.28)
Basic and Diluted EPS - as pro forma	\$ (0.19)	\$ (3.25)	\$ (2.31)

Pro forma compensation expense may not be indicative of future expense.

For purposes of estimating the fair value of each stock option or restricted stock 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 and restricted stock units 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 single measure of the fair value of its employee stock options or restricted stock units.

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The weighted-average option and restricted stock unit fair values and the assumptions used to estimate these fair values are as follows:

	2005	Grants issued during 2004	2003
Expected life (years)	4	2 - 5 2.4% -	2.5
Risk-free interest rate	4.5%	4.6%	1.8%
Expected volatility factor	120%	73% - 87%	94%
Dividend yield	0.0%	0.0%	0.0%
Weighted average fair value	\$ 0.37	\$ 0.25	\$ 0.53

During 2005 and 2004, the Company granted approximately 4,000,000 and 13,175,000 stock options, respectively. In 2005, the Company granted 27,500,000 restricted stock units. These stock options and restricted stock units had an exercise price less than the market price of the underlying common stock on the date of grant. Under APB No. 25, compensation expense is recognized for the difference between the exercise price of the employee stock option or restricted stock unit and the market price of the underlying stock on the date of grant. Total compensation expense of approximately \$14,136,000 will be recognized over the vesting period of the options and stock units, of which approximately \$6,459,000 and \$1,952,000 was recorded in 2005 and 2004, respectively.

In 2004, the Company recorded compensation expense of \$55,000 on the issuance of 200,000 stock options in connection with separation agreement of an employee.

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.

#### 15. 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.

#### 16. 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 fair value of the Company's short-term and long-term debt approximates the book value based upon the proximity of the issuance of new debt where the cash consideration received equaled the face value of the debt.

#### 17. Reclassifications

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



## **New Accounting Pronouncements**

### **Share-Based Payment**

On December 16, 2004, the FASB released FASB Statement No. 123 (revised 2004), "Share-Based Payment, ("FASB 123R")". These changes in accounting replace existing requirements under FASB Statement No. 123, "Accounting for Stock-Based Compensation", and eliminates the ability to account for share-based compensation transaction using APB Opinion No.25, "Accounting for Stock Issued to Employees". The compensation cost relating to share-based payment transactions will be measured based on the fair value of the equity or liability instruments issues. This Statement does not change the accounting for similar transactions involving parties other than employees. Publicly traded companies must apply this Standard as of the beginning of the first annual period that begins after June 15, 2005.

FASB 123R permits public companies to choose between two adoption methods, one of which is the "modified prospective" method. The modified prospective method 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 cumulative effect of initially applying this Statement, if any, is recognized as of the required effective date. The Company's required effective date is January 1, 2006. The Company has not completed its evaluation of the impact of adopting FASB 123R on its consolidated financial statements because it will depend on levels of share-based payments granted in the future. However, the Company has estimated \$100,000 of additional unearned compensation will be recorded and expensed over the applicable remaining vesting periods for all share-based payments granted to employees on or before December 31, 2005 that remain 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.

### **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, and early adoption is permitted. The Company is required to adopt the provision of SFAS 154, as applicable, beginning in fiscal 2006.

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

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As restructured, the Company is no longer engaged in the manufacture and sale of Generic Products. As a result, the Company has no ability presently to generate revenue from product sales. Accordingly, 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, including the net proceeds from the January 2006 Bridge Loan described in Note J will be sufficient to fund the development of the Aversion® Technology and related operating expenses through mid-to-late March, 2006. To fund further operations and product development activities, the Company must raise additional financing, or enter into alliances or collaboration agreements with third parties. 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.

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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, to obtain an issued U.S. patent relating to the Aversion<sup>®</sup> 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.

## **NOTE C - FINANCING TRANSACTIONS**

### **2004 Debenture Offering**

On February 10, 2004, the Company consummated a private offering of convertible senior secured debentures (the "2004 Debentures") in the aggregate principal amount of approximately \$12.3 million (the "2004 Debenture Offering"). The 2004 Debentures were issued by the Company pursuant to a certain Debenture and Share Purchase Agreement dated as of February 6, 2004 (the "2004 Purchase Agreement") by and among the Company, Care Capital Investments, Essex Woodlands Health Ventures, Galen Partners and each of the purchasers listed on the signature page thereto. On April 14, 2004 and May 26, 2004, the Company completed additional closings under the 2004 Purchase Agreement raising the aggregate gross proceeds received by the Company from the offering of the 2004 Debentures to \$14 million. 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 (including \$6.6 million in 2003) 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.), 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.

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

Convertible Preferred Stock	Authorized Preferred Shares at 12/31/04	Number of Converted Preferred Shares	Number of Common Shares Issued Upon Conversion	Authorized Preferred Shares Available for Issuance at 12/31/05
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>

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

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

	December 31,	
	2005	2004
Building and building improvements	\$ 1,485	\$ 1,510
Land and land improvements	161	127
Machinery and equipment	2,324	3,425
Scientific equipment	473	450
Computer hardware and software	196	255
Office equipment	42	174
Other personal property	50	48
Construction in progress	1	5
	4,732	5,994
Less accumulated depreciation and amortization (including \$53 in 2005 and \$35 in 2004 on capital leased assets)	(3,271)	(4,301)
	1,461	1,693
Less impairment reserve	(120)	(138)
	\$ 1,341	\$ 1,555

Equipment of \$146,000 is recorded under capitalized leases in categories of scientific equipment and office equipment at December 31, 2005 and 2004.

Depreciation and amortization expense for the years ended December 31, 2005, 2004 and 2003 was approximately \$137,000, \$291,000 and \$811,000, respectively.



**NOTE E - ACCRUED EXPENSES**

Accrued expenses are summarized as follows (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Bonus, payroll, payroll taxes and benefits	\$ 50	\$ 573
Legal fees	74	34
Audit examination and tax preparation fees	65	85
Franchise taxes	20	-
Property taxes	52	30
Clinical, regulatory, trademarks, and patent consulting fees	78	108
Directors fees	2	-
Clinical and laboratory testing services	-	47
Litigation settlement	-	25
Medicaid rebates	-	50
Other fees and services	-	7
	<b>\$ 341</b>	<b>\$ 959</b>

**NOTE F - TERM NOTE PAYABLE AND STOCK WARRANTS**

At December 31, 2005 and 2004, notes payable consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Term note payable (a)	\$ 5,000	\$ 5,000
Bridge loans (b)	\$ 2,550	\$ -
Capital lease obligations	63	93
	2,613	93
Less: Current maturities	(2,581)	(29)
	<b>\$ 32</b>	<b>\$ 64</b>

- (a) 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 \$12.1 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, 2005 was 11.75% and increased to 12.0% on January 31, 2006. The 2004 Note contains cross default provisions with each of the outstanding Bridge Loans.

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**(b) November 2005 Bridge Loan**

The Company is a party to a Loan Agreement, dated November 9, 2005 (the “November 2005 Bridge Loan Agreement”) by and among Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. and certain other shareholders of the Company listed on the signature page thereto (collectively, the “November 2005 Bridge Lenders”) providing for bridge financing to the Company in the principal amount of \$1.05 million (the “November 2005 Bridge Loan”). The net proceeds from the November 2005 Bridge Loan, after the satisfaction of related expenses, are being used by the Company to continue the development of its Aversion® Technology and to fund operating expenses. The terms of the November 2005 Bridge Loan are identical to the terms of the January 2006 Bridge Loan (See Note J), except that (i) the lien securing the November 2005 Bridge Loan is junior in right of payment and lien priority to the January 2006 Bridge Loan, and (ii) the funding event is \$5.05 million.

**September 2005 Bridge Loan**

The Company is a party to a Loan Agreement, dated September 16, 2005 (the “September 2005 Bridge Loan Agreement”) by and among Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (collectively, the “September 2005 Bridge Lenders”) providing for bridge financing to the Company in the principal amount of \$0.5 million (the “September 2005 Bridge Loan”). The net proceeds from the September 2005 Bridge Loan, after the satisfaction of related expenses, were used by the Company to continue the development of its Aversion® Technology and to fund operating expenses. The terms of the September 2005 Bridge Loan are identical to the terms of the January 2006 Bridge Loan (see Note J), except that (i) the September 2005 Bridge Loan required that the Company maintain minimum cash reserves of \$200,000, (ii) the lien securing the September 2005 Bridge Loan is junior in right of payment and lien priority to each of the January 2006 Bridge Loan and the November 2005 Bridge Loan, and (iii) the Funding Event is \$4.0 million. On October 20, 2005, the September 2005 Bridge Lenders waived the requirement that the Company maintain minimum cash reserves of \$200,000 until such time as the Company receives additional financing providing net proceeds to the Company of at least \$2.0 million.

**June 2005 Bridge Loan**

The Company also is a party to a Loan Agreement, dated June 22, 2005 (the “June 2005 Bridge Loan Agreement”) by and among Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (collectively, the “June 2005 Bridge Lenders”) providing for bridge financing to the Company in the principal amount of \$1.0 million (the “June 2005 Bridge Loan”). The net proceeds from the June 2005 Bridge Loan, after the satisfaction of related expenses, were used by the Company to continue the development of its Aversion® Technology and to fund operating expenses. The terms of the June 2005 Bridge Loan are identical to the terms of the January 2006 Bridge Loan (see Note J), except that (i) the June 2005 Bridge Loan required that the Company maintain minimum cash reserves of \$200,000, (ii) the lien securing the June 2005 Bridge Loan is junior in right of payment and lien priority to each of the January 2006 Bridge Loan, the November 2005 Bridge Loan and the September 2005 Bridge Loan and (iii) the Funding Event amount is \$3.5 million. On October 20, 2005, the June 30, 2005 Bridge Lenders waived the requirement that the Company maintain minimum cash reserves of \$200,000 until such time as the Company receives additional financing providing net proceeds to the Company of at least \$2.0 million.

**Stock Warrants**

At December 31, 2005, the Company had outstanding common stock purchase warrants exercisable for an aggregate of 16,241,571 shares of common stock. Of such warrants 5,390,906 were issued in connection with the issuance of convertible debentures, bridge loans and financing commitments during the years 1998 through 2003, 10,700,665

were issued to Watson in connection with their agreement to amend the Watson Loan at December 20, 2002, and 150,000 were issued in 2003 as part of the settlement terms with a former executive officer of the Company. During 2005, approximately 16,635,000 warrants expired unexercised and approximately 197,000, 310,000, 154,000 and 15,581,000 warrants are scheduled to expire if unexercised during the years 2006, 2007, 2008 and years thereafter, respectively.

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The following table summarizes information about common stock purchase warrants outstanding at December 31, 2005 (shares in thousands):

Range of Exercise Prices	Warrants outstanding		Weighted Average Remaining Life in Years	Weighted Average Exercise Price
	Shares			
\$ 0.13 to \$0.66	16,242		6.37	\$ 0.34

#### NOTE G - 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,					
	2005		2004		2003	
	Amount	%	Amount	%	Amount	%
Federal statutory rate	\$ (4,105)	(34)%	\$ (23,798)	(34)%	\$ (15,966)	(34)%
Loss for which no benefit was provided	4,104	34	3,716	5.3	4,357	9.2
Non-deductible financing costs	-	-	24,647	35.2	11,589	24.6
Federal tax carryback refund	-	-	(122)	(.2)	-	-
Debt forgiveness	-	-	(4,307)	(6.1)	-	-
Department of Justice settlement	-	-	(137)	(.2)	11	.1
Other	1	-	1	-	9	.1
Actual tax benefit	\$ -	-	\$ -	-	\$ -	-

The Company has net operating loss carryforwards aggregating approximately \$135.9 million, expiring during the years 2009 through 2025.

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.

During 2004, the Company adjusted its net operating loss carryforward. Because a full valuation allowance was placed against the Company's net deferred income tax asset, this adjustment had no effect on the 2004 or prior year financial statements.

The components of the Company's deferred income tax assets (liabilities), pursuant to SFAS No. 109, are summarized as follows (in thousands):

	2005	December 31, 2004	2003
<b>Deferred tax assets:</b>			
Net operating loss carryforwards	\$ 57,748	\$ 55,178	\$ 55,998
Stock compensation	3,555	843	-
Accrued expenses	16	254	205
Accrued shutdown costs	50	71	703
Debt issue costs	12	-	-
Asset reserves	-	-	1,016
Research and development tax credit	-	-	29
Capital loss carryforwards	-	-	212
Other	66	71	73
Depreciation	-	-	20
Gross deferred tax assets	61,447	56,417	58,256
<b>Deferred tax liabilities:</b>			
Depreciation	(38)	(26)	-
<b>Net deferred tax assets before valuation allowance</b>			
	61,409	56,391	58,256
Valuation allowance	(61,409)	(56,391)	(58,256)
<b>Net deferred tax assets</b>	\$ -	\$ -	\$ -

SFAS No. 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. The valuation allowance at December 31, 2005, 2004 and 2003 primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards.

## NOTE H - EMPLOYEE BENEFIT PLANS

### 1. 401(k) and Profit-sharing Plan

Effective October 1, 1998, the Company established a 401(k) and profit-sharing 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 no expense under the plan in 2005, 2004 and 2003.

### 2. Stock Option Plans

In September 1995, the stockholders of the Company approved the adoption of a stock option and restricted stock purchase plan (the "1995 Option Plan"). As of December 31, 2005, incentive stock options to purchase 322,510 shares and non-qualified options to purchase 106,390 shares were granted 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 \$1.64.

At December 31, 2005, options to purchase approximately 428,900 shares remained outstanding.

In June 1998, the stockholders of the Company approved the adoption of a stock option plan (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 Stock Option 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, 2005, options to purchase approximately 19,326,095 shares remained outstanding and 616,655 were available for grant under the 1998 Option Plan.

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A summary of the Company's stock option plans as of December 31, 2005, 2004, and 2003, and for the years then ended consisted of the following (shares in thousands):

	Years Ended December 31,					
	2005		2004		2003	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning	17,499	\$ 0.44	3,525	\$ 1.83	5,009	\$ 1.80
Granted	4,000	0.13	14,475	0.13	45	0.96
Exercised	(35)	0.13	(-)	-	(-)	-
Cancelled	(1,709)	1.65	(501)	1.85	(1,529)	1.69
Outstanding, ending	19,755	\$ 0.27	17,499	\$ 0.44	3,525	\$ 1.83
Options exercisable, end of year	15,698	\$ 0.31	9,558	\$ 0.66	2,871	\$ 1.91

The following table summarizes information about stock options outstanding at December 31, 2005 (shares in thousands):

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Shares	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	
\$0.13 to \$1.00	18,294	8.36	\$ 0.14	14,239	\$ 0.15	
\$1.01 to \$2.00	800	3.39	1.41	798	1.41	
\$2.01 to \$4.38	661	2.77	2.40	661	2.40	
Total	19,755	7.99	\$ 36.05	15,698	\$ 0.31	

### **3. Restricted Stock Unit Award Plan**

On December 22, 2005, the Board of Directors adopted 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 believes that the 2005 RSU Plan does not require shareholder approval. Nevertheless, the Company intends to seek shareholder ratification for the 2005 RSU Plan at its next 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).

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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.

The following table summarizes information about restricted stock unit awards outstanding at December 31, 2005 (in thousands):

<b>Restricted stock units outstanding</b>		
<b>Shares</b>	<b>Number vested</b>	<b>Number issuable</b>
27,500	9,167	-

Of the RSUs granted to date, one third vested upon grant and the other two thirds vest on a straight-line monthly basis through December 2007.

#### **NOTE I - COMMITMENTS AND CONTINGENCIES**

The following table presents the Company's expected cash payments on contractual obligations at December 31, 2005 (in thousands):

	<b>Total</b>	<b>Due in 2006</b>	<b>Due in 2007</b>	<b>Due in 2008</b>	<b>Due Thereafter</b>
Notes payable	\$ 7,550	\$ 2,550	\$ 5,000	\$ -	\$ -
Capital leases	63	31	26	6	-
Operating leases	35	30	5	-	-
Annual interest on fixed rate debt	128	128	-	-	-
Employment agreements	740	740	-	-	-
<b>Total contractual obligations</b>	<b>\$ 8,516</b>	<b>\$ 3,479</b>	<b>\$ 5,031</b>	<b>\$ 6</b>	<b>\$ -</b>

#### **Expected cash payments on contractual obligations entered into subsequent to December 31, 2005**

	<b>Total</b>	<b>Due in 2006</b>	<b>Due in 2007</b>	<b>Due in 2008</b>	<b>Due Thereafter</b>
Notes payable	\$ 750	\$ 750	\$ -	\$ -	\$ -
Annual interest on fixed rate debt	25	25	-	-	-
	<b>\$ 775</b>	<b>\$ 775</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>

### **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, 2006. 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, 2006 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.

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, 2006 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.

### **Legal Proceeding**

In May 2001, the Company was named as a defendant in an action entitled Alfred Kohn v. Halsey Drug Co. in the Supreme Court of New York, Bronx County. The plaintiff sought, among other things, damages of \$1.0 million for breach of an alleged oral contract to pay a finder's fee for a business transaction involving the Company. In March 2005, the Company and the estate of Mr. Kohn agreed to settle this matter, pursuant to which in December 2005 the Company made a one-time payment of \$35,000.

### **NOTE J - SUBSEQUENT EVENT**

#### **January 2006 Bridge Loan**

The Company is a party to a Loan Agreement, dated January 31, 2006 (the "January 2006 Bridge Loan Agreement") by and among Essex Woodlands Health Ventures V, L.P., Care Capital Investments II, LP, Care Capital Offshore Investments II, LP, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. and such Additional Lenders as may become a party pursuant to the terms of the January 2006 Bridge Loan Agreement (collectively, the "January 2006 Bridge Lenders"). In accordance with the terms of the January 2006 Bridge Loan Agreement, on January 31, 2006 the January 2006 Bridge Lenders provided a bridge loan to the Company in the

aggregate principal amount of \$750,000. The January 2006 Bridge Loan Agreement also permits the funding of additional loans in the principal amount of up to \$250,000 and, with the consent of any two of Care Capital Investments, Essex Woodlands Health Ventures and Galen Partners, additional loan amounts mutually agreed to by the Company and the January 2006 Bridge Lenders (the "January 2006 Bridge Loan"). No assurance can be given that additional loans will be made available to the Company under the January 2006 Bridge Loan Agreement. The net proceeds from the January 2006 Bridge Loan, after the satisfaction of related expenses, will be used by the Company to continue the development of its Aversion® Technology and to fund operating expenses. The January 2006 Bridge Loan is secured by a lien on all of the Company's assets, senior in right of payment and lien priority to all other indebtedness of the Company. The January 2006 Bridge Loan bears interest at the rate of ten percent (10%) per annum and matures on June 1, 2006. The January 2006 Bridge Loan is subject to mandatory pre-payment by the Company upon the Company's completion of equity or debt financing or any sale, transfer, license or similar arrangement pursuant to which the Company or any of its Subsidiaries 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 cash proceeds to the Company, net of all costs and expenses, at least equal to the sum of (i) \$5.05 million, plus (ii) the aggregate principal amount of the January 2006 Bridge Loan (a "Funding Event"). The January 2006 Bridge Loan Agreement restricts the Company's ability to issue any shares of its currently authorized Series A, B or C preferred stock without the prior consent of the January 2006 Bridge Lenders, and grants the January 2006 Bridge Lenders preemptive rights relating to the issuance of the Company's Series A, B and C preferred stock. The January Bridge Loan contains cross default provisions with the 2004 Note and each of the outstanding Bridge Loans.

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The January 2006 Bridge Loan Agreement also contains normal and customary affirmative and negative covenants, including restrictions on the Company's ability to incur additional debt or grant any lien on the assets of the Company or its subsidiaries, subject to certain permitted exclusions.

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

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

	For the Three Month Period Ending				
	March 31, 2005	June 30, 2005	September 30, 2005	December 31, 2005	Annual Year 2005
Net product revenues	\$ -	\$ -	\$ -	\$ -	\$ -
Loss from operations	(1,908)	(1,266)	(1,473)	(6,914)	(11,561)
Net loss	(1,948)	(1,382)	(1,635)	(7,110)	(12,075)
Loss per common share - basic and diluted	\$ (.09)	\$ (.06)	\$ (.07)	\$ (.04)	\$ (.18)

	For the Three Month Period Ending				
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004	Annual Year 2004
Net product revenues	\$ 628	\$ 210	\$ -	\$ -	\$ 838
Loss from operations	(2,084)	(2,120)	(3,810)	(1,951)	(9,965)
Amortization and write-off of debt discount and deferred private debt offering costs	(10,843)	(13,812)	(47,836)	(-)	(72,491)
Gain on debt restructuring	12,401	-	-	-	12,401
Gain (loss) on asset disposals	1,754	1	633	(29)	2,359
Net income (loss)	\$ 680	\$ (17,112)	\$ (51,480)	\$ (2,084)	\$ (69,996)
Earnings (loss) per common share - basic	\$ .03	\$ (.79)	\$ (2.35)	\$ (.09)	\$ (3.20)
Earnings (loss) per common share - diluted	\$ .00	\$ (.79)	\$ (2.35)	\$ (.09)	\$ (3.20)

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.

## 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>DOCUMENT</b>
3.1	Certificate of Incorporation and amendments (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on 10-K for the year ended December 31, 1999).
3.2	Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1993).
3.3	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")).
4.1	Form of 5% Convertible Senior Secured Debenture (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated December 20, 2002 (the "December 2002 Form 8-K")).
4.2	Form of Convertible Senior Secured Debenture issued pursuant to the Debenture and Share Purchase Agreement dated as of February 6, 2004 (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K dated February 10, 2004 (the "February 2004 Form 8-K")).
10.1	Credit Agreement, dated as of December 22, 1992, among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1992 (the "1992 Form 10-K")).
10.2	Amendment Two, dated as of January 12, 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A., together with forms of Stock Warrant and Registration Rights Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1993 (the "1993 Form 10-K")).
10.3	Amendment Three, dated as of May 31, 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1994).
10.4	Amendment Four, dated as of July 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994).
10.5	Amendment Five, dated as of March 21, 1995, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K dated March 21, 1995 (the "March 1995 8-K")).
10.5(1)	Form of Warrants issued to The Bank of New York, The Chase Manhattan Bank, N.A. and the Israel Discount Bank (incorporated by reference to Exhibit 10.5(i) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K")).
10.5(2)	Letter Agreement, dated July 10, 1995, among the Registrant, The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995 (the "June 1995 10-Q")).
10.5(3)	Letter Agreement, dated November 16, 1995, among the Registrant, The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.25(iv) to the 1995 10-K).
10.5(4)	Amendment 6, dated as of August 6, 1996, to Credit Agreement among the Registrant, The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 (the "June 1996 10-Q")).
10.5(5)	Letter Agreement, dated March 25, 1997 among the Registrant, The Chase Manhattan Bank, as successor in interest to The Chase Manhattan Bank (National Association), The Bank of

New York and Israel Discount Bank.

10.6 Agreement Regarding Release of Security Interests dated as of March 21, 1995 by and among the Registrant, Mallinckrodt Chemical Acquisition, Inc. and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.9 of the March 1995 8-K).

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<b>EXHIBIT NUMBER</b>	<b>DOCUMENT</b>
10.7	Consulting Agreement dated as of September, 1993 between the Registrant and Joseph F. Limongelli (incorporated by reference to Exhibit 10.6 to the 1993 Form 10-K).
10.8	Employment Agreement, dated as of January 1, 1993, between the Registrant and Rosendo Ferran (incorporated by reference to Exhibit 10.2 to the 1992 Form 10-K).
10.10(1)	Registrant's 1984 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.3 to the 1992 Form 10-K).
10.10(2)	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).
10.10(3)	Registrant's Non-Employee Director Stock Option Plan.
10.11	Leases, effective February 13, 1989 and January 1, 1990, respectively, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss (incorporated by reference to Exhibits 10.6 and 10.7, respectively, to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1989).
10.12	Lease, effective as of April 15, 1988, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, and Rider thereto (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1987).
10.12(1)	Lease, as of October 31, 1994, among Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, together with Modification, Consolidation and Extension Agreement (incorporated by reference to Exhibit 10.12(i) to the 1995 Form 10-K).
10.13	Asset Purchase Agreement dated as of March 21, 1995 among Mallinckrodt Chemical Acquisition, Inc. ("Acquisition"), Mallinckrodt Chemical, Inc., as guarantor and the Registrant (incorporated by reference to Exhibit 10.1 to the March 1995 8-K).
10.14	Toll Manufacturing Agreement for APAP/Oxycodone Tablets dated as of March 21, 1995 between Acquisition and the Registrant (incorporated by reference to Exhibit 10.2 to the March 1995 8-K).
10.15	Capsule ANDA Option Agreement dated as of March 21, 1995 between Acquisition and the Registrant (incorporated by reference to Exhibit 10.3 to the March 1995 8-K).
10.16	Tablet ANDA Non competition Agreement dated as of March 21, 1995 between the Registrant and Acquisition (incorporated by reference to Exhibit 10.4 to the March 1995 8-K).
10.17	Subordinated Non-Negotiable Promissory Term Note in the amount of \$1,200,00 dated March 21, 1995 issued by the Registrant to Acquisition (incorporated by reference to Exhibit 10.5 to the March 1995 8-K).
10.18	Term Note Security Agreement dated as of March 21, 1995 among the Company, Houba, Inc. and Acquisition (incorporated by reference to Exhibit 10.6 to the March 1995 8-K).
10.19	Amendment dated March 21, 1995 to Subordination Agreement dated as of July 21, 1994 between Mallinckrodt Chemical, Inc., Acquisition, the Registrant, The Chase Manhattan Bank (National Association), Israel Discount Bank of New York, The Bank of New York, and The Chase Manhattan Bank (National Association) (incorporated by reference to Exhibit 10.8 to the March 1995 8-K).
10.20	Agreement dated as of March 30, 1995 between the Registrant and Zatpack, Inc. (incorporated by reference to Exhibit 10.10 to the March 8-K).
10.21	Waiver and Termination Agreement dated as of March 30, 1995 between Zuellig Group, W.A., Inc. and Indiana Fine Chemicals Corporation (incorporated by reference to Exhibit 10.11 to the March 1995 8-K).
10.22	Convertible Subordinated Note of the Registrant dated December 1, 1994 issued to Zatpack, Inc. (incorporated by reference to Exhibit 10.12 to the March 8-K).



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- 10.23 Agreement dated as of March 30, 1995 among the Registrant, Indiana Fine Chemicals Corporation, Zuellig Group, N.A., Inc., Houba Inc., Zetapharm, Inc. and Zuellig Botanical, Inc. (incorporated by reference to Exhibit 10.13 to the March 1995 8-K).
- 10.24 Supply Agreement dated as of March 30, 1995 between Houba, Inc. and ZetaPharm, Inc. (incorporated by reference to Exhibit 10.14 to the March 1995 8-K).
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<b>EXHIBIT NUMBER</b>	<b>DOCUMENT</b>
10.25	Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 6(a) to the June 1995 10-Q).
10.26	Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 6(a) to the June 1995 10-Q).
10.27	Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated December 4, 1995 (the "December 1995 8-K")).
10.28	Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the December 1995 8-K).
10.29	Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 99 to the June 1996 10-Q).
10.30	Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the June 1996 10-Q).
10.31	Form of 5% Convertible Senior Secured Debenture (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated March 24, 1998 (the "March 1998 8-K")).
10.32	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the March 1998 8-K).
10.33	Debenture and Warrant Purchase Agreement dated March 10, 1998, by and among the Registrant, Galen Partners III, L.P. and the other Purchasers listed on the signature page thereto (incorporated by reference to Exhibit 10.1 to the March 1998 8-K).
10.34	Form of General Security Agreement of Registrant dated March 10, 1998 (incorporated by reference to Exhibit 10.2 to the March 1998 8-K).
10.35	Form of Agreement of Guaranty of Subsidiaries of Registrant dated March 10, 1998 (incorporated by reference to Exhibit 10.3 to the March 1998 8-K).
10.36	Form of Guarantor General Security Agreement dated March 10, 1998 (incorporated by reference to Exhibit 10.4 to the March 1998 8-K).
10.37	Stock Pledge Agreement dated March 10, 1998 by and between the Registrant and Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.5 to the March 1998 8-K).
10.38	Form of Irrevocable Proxy Agreement (incorporated by reference to Exhibit 10.6 to the March 1998 8-K).
10.39	Agency Letter Agreement dated March 10, 1998 by and among the purchasers a party to the Debenture and Warrant Purchase Agreement, dated March 10, 1998 (incorporated by reference to Exhibit 10.7 to the March 1998 8-K).
10.40	Press Release of Registrant dated March 13, 1998 (incorporated by reference to Exhibit 99.1 to the March 1998 8-K).
10.41	Current Report on Form 8-K as filed by the Registrant with the Securities and Exchange Commission on March 24, 1998.
10.42	Letter Agreement between the Registrant and the U.S. Department of Justice dated March 27, 1998 relating to the restructuring of the fine assessed by the Department of Justice under the Plea Agreement dated June 21, 1993.
10.43	Employment Agreement dated as of March 10, 1998 between the Registrant and Michael K. Reicher (incorporated by reference to Exhibit 10.43 to the Registrant's Annual Report of Form 10-K for the year ended December 31, 1997 (the "1997 Form 10-K")).
10.44	Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens (incorporated by reference to Exhibit 10.44 to the 1997 Form 10-K).
*10.44A	First Amendment to Employment Agreement made as of June 28, 2000 between the Registrant and Peter Clemens

- 10.45 Second Amendment to Executive Employment Agreement between Registrant and Peter A. Clemens, dated as of January 5, 2005 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated January 28, 2005).
- 10.46 Third Amendment to Executive Employment Agreement dated December 22, 2005 between Registrant and Peter A. Clemens (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K dated December 22, 2005 (the "December 2005 Form 8-K").
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<b>EXHIBIT NUMBER</b>	<b>DOCUMENT</b>
10.47	Amended, Restated and Consolidated Bridge Loan Agreement dated as of December 2, 1998 between the Registrant, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. and the other signatures thereto (incorporated by reference to Exhibit 10.45 to the 1998 Form 10-K).
10.48	First Amendment to Amended, Restated and Consolidated Bridge Loan Agreement dated December 7, 1998 between the Registrant and the lenders listed on the signature page thereto (incorporated by reference to Exhibit 10.46 to the 1998 Form 10-K).
10.49	Second Amendment to Amended, Restated and Consolidated Bridge Loan Agreement dated March 8, 1999 between the Registrant and the lenders listed on the signature page thereto (incorporated by reference to Exhibit 10.47 to the 1998 Form 10-K).
10.50	Form of 10% Convertible Secured Note due May 30, 1999 (incorporated by reference to Exhibit 10.48 to the 1998 Form 10-K).
10.51	Form of Common Stock Purchase Warrant issued pursuant to be Amended, Restated and Consolidated Bridge Loan Agreement (incorporated by reference to Exhibit 10.49 to the 1998 Form 10-K).
10.52	Amended and Restated General Security Agreement dated December 2, 1998 between the Company and Galen Partners III, L.P., as Agent (incorporated by reference to Exhibit 10.50 to the 1998 Form 10-K).
10.53	Subordination Agreement dated December 2, 1998 between the Registrant and Galen Partners III, L.P., as Agent (incorporated by reference to Exhibit 10.51 to the 1998 Form 10-K).
10.54	Agency Letter Agreement dated December 2, 1998 by and among the lenders a party to the Amended, Restated and Consolidated Bridge Loan Agreement, as amended (incorporated by reference to Exhibit 10.52 to the 1998 Form 10-K).
10.55	Lease Agreement dated March 17, 1999 between the Registrant and Par Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.53 to the 1998 Form 10-K).
10.56	Lease Agreement dated September 1, 1998 between the Registrant and Crimson Ridge Partners (incorporated by reference to Exhibit 10.54 to the 1998 Form 10-K).
10.57	Manufacturing and Supply Agreement dated March 17, 1999 between the Registrant and Par Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.55 to the 1998 Form 10-K).
10.58	Registrant's 1998 Stock Option Plan (incorporated by reference to Exhibit 10.56 to the 1998 Form 10-K).
10.59	Loan Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.57 to the Registrant's Current Report on Form 8-K dated March 29, 2000 (the "March 2000 8-K")).+
10.60	Amendment to Loan Agreement dated March 31, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.58 to the March 2000 8-K).
10.61	Secured Promissory Note in the principal amount of \$17,500,000 issued by the Registrant, as the maker, in favor of Watson Pharmaceuticals, Inc. dated March 31, 2000 (incorporated by reference to Exhibit 10.59 to the March 2000 8-K).
10.62	Watson Security Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.60 to the March 2000 8-K).
10.63	Stock Pledge Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.61 to the March 2000 8-K).
10.64	Watson Guarantee dated March 29, 2000 between Houba, Inc. and Watson Pharmaceuticals, Inc., as the guarantors, in favor of Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.62 to the March 2000 8-K).
10.65	

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Watson's Guarantors Security Agreement dated March 29, 2000 between Halsey Pharmaceuticals, Inc., Houba, Inc. and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.63 to the March 2000 8-K).

10.66 Subordination Agreement dated March 29, 2000 by and among the Registrant, Watson Pharmaceuticals, Inc. 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).+

10.67 Real Estate Mortgage dated March 29, 2000 between Houba, Inc. and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.65 to the March 2000 8-K).

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<b>EXHIBIT NUMBER</b>	<b>DOCUMENT</b>
10.68	Subordination Agreement by and among Houba, Inc., Galen Partners, III, L.P., Oracle Strategic Partners, L.P. and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.66 to the March 2000 8-K).
10.69	Product Purchase Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.67 to the March, 2000 8-K).+
10.70	Finished Goods Supply Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.68 to the March 2000 8-K).+
10.71	Active Ingredient Supply Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.69 to the March 2000 8-K).+
10.72	Right of First Negotiation Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.70 to the March 2000 8-K).+
10.73	Finished Goods Supply Agreement (Core Products) dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.71 to the March 2000 8-K).+
10.74	Debenture and Warrant Purchase Agreement dated May 26, 1999 by and among the Registrant, Oracle Strategic Partners, L.P. and the other purchasers listed on the signature page thereto (the "Oracle Purchase Agreement") (incorporated by reference to Exhibit 10.72 to the Registrant's Annual Report on Form 10-K for the year ended December 31,1999 (the "1999 Form 10-K"))).
10.75	Form of 5% Convertible Senior Secured Debenture issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.73 to the 1999 Form 10-K.
10.76	Form of Common Stock Purchase Warrant issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.74 to the 1999 Form 10-K.
10.77	Lease Termination and Settlement Agreement dated March 20, 2000 between the Registrant and Atlantic Properties Company in respect of the Registrant's Brooklyn, New York leased facility (incorporated by reference to Exhibit 10.75 to the 1999 Form 10-K).
10.78	Debenture Purchase Agreement dated December 20, 2002 by and among the Registrant, Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P. and the other purchasers listed on the signature page thereto (the "2002 Debentureholders") (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K dated December 27, 2002 (the "December 2002 Form 8-K"))).
10.79	Form of General Security Agreement dated December 20, 2002 between the Registrant and the 2002 Debentureholders (incorporated by reference to Exhibit 10.2 to the December 2002 Form 8-K).
10.80	Form of Agreement of Guaranty of Subsidiaries of the Registrant dated December 20, 2002 between Houba, Inc., Halsey Pharmaceuticals, Inc. and the 2002 Debentureholders (incorporated by reference to Exhibit 10.3 to the December 2002 Form 8-K).
10.81	Form of Guarantor General Security Agreement between the Guarantors and the 2002 Debentureholders dated December 20, 2002 (incorporated by reference to Exhibit 10.4 to the December 2002 Form 8-K).
10.82	Stock Pledge Agreement dated December 20, 2002 by and between the Registrant and Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.5 to the December 2002 Form 8-K).
10.83	Voting Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.6 to the December 2002 Form 8-K).

- 10.84 Debentureholders Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.7 to the December 2002 Form 8-K).
- 10.85 Amendment to Debenture and Warrant Purchase Agreement between the Registrant, Galen Partners III, L.P. and other signatories thereto, dated December 20, 2002, amending the Debenture and Warrant Purchase Agreement dated March 10, 1998 between the Company, Galen Partners III, L.P. and the other signatories thereto (incorporated by reference to Exhibit 10.8 to the December 2002 Form 8-K).
- 10.86 Amendment to Debenture and Warrant Purchase Agreement between the Registrant, Oracle Strategic Partners, L.P. and the other signatories thereto, dated December 20, 2002, amending the Debenture and Warrant Purchase Agreement dated May 26, 1999 between the Company, Oracle Strategic Partners, L.P. and the other signatories thereto (incorporated by reference to Exhibit 10.9 to the December 2002 Form 8-K).
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<b>EXHIBIT NUMBER</b>	<b>DOCUMENT</b>
10.87	Amended and Restated 5% Convertible Senior Secured Debenture due March 31, 2006 (incorporated by reference to Exhibit 10.10 to the December 2002 Form 8-K).
10.88	Second Amendment to Loan Agreement dated December 20, 2002, between the Registrant and Watson Pharmaceuticals, Inc., amending the Loan Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.11 to the December 2002 Form 8-K).
10.89	Amended and Restated Secured Promissory Note dated December 20, 2002, issued by the Registrant in favor of Watson Pharmaceuticals, Inc. in the principal amount \$17,500,000 (incorporated by reference to Exhibit 10.12 to the December 2002 Form 8-K).
10.90	Second Amendment to Finished Goods Supply Agreement (Core Products) dated December 20, 2002, between the Registrant and Watson Pharmaceuticals, Inc. amending the Finished Goods Supply Agreement (Core Products) dated March 29, 2000 2008 (incorporated by reference to Exhibit 10.13 to the December 2002 Form 8-K).
10.91	Watson Common Stock Purchase Warrant dated December 20, 2002 (incorporated by reference to Exhibit 10.14 to the December 2002 Form 8-K).
10.92	Registration Rights Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.15 to the December 2002 Form 8-K).
10.93	Warrant Recapitalization Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.15 to the December 2002 Form 8-K).
10.94	Debenture and Share Purchase Agreement dated as of February 6, 2004 by and among the Registrant, Care Capital Investments, II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P. and the other purchasers listed on the signature page thereto (incorporated by reference to Exhibit 10.1 of the February 2004 Form 8-K).
10.95	Debenture Conversion Agreement dated as of February 6, 2004 by and among the Registrant, Care Capital, Essex Woodlands, Galen Partners and the other signatories thereto (incorporated by reference to Exhibit 10.2 of the February 2004 Form 8-K).
10.96	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 10.3 of the February 2004 Form 8-K).
10.97	Investor Rights Agreement dated as of February 6, 2004 by and among the Registrant, Care Capital, Essex Woodlands, Galen Partners and the other signatories thereto (incorporated by reference to Exhibit 10.4 of the February 2004 Form 8-K).
10.98	Amended and Restated Voting Agreement dated as of February 6, 2004 by and among the Registrant, Care Capital, Essex Woodlands, Galen Partners and the other signatories thereto (incorporated by reference to Exhibit 10.5 of the February 2004 Form 8-K).
10.99	Amended and Restated Registration Rights Agreement dated as of February 6, 2004 by and among the Registrant, Watson Pharmaceuticals, Care Capital, Essex Woodlands, Galen Partners and the other signatories thereto (incorporated by reference to Exhibit 10.6 of the February 2004 Form 8-K).
10.100	Amended and Restated Subordination Agreement dated as of February 6, 2004 by and among the Registrant, Care Capital, Essex Woodlands, Galen Partners and the other signatories thereto (incorporated by reference to Exhibit 10.7 of the February 2004 Form 8-K).
10.101	Company General Security Agreement (incorporated by reference to Exhibit 10.8 of the February 2004 Form 8-K).
10.102	Form of Unconditional Agreement of Guaranty (incorporated by reference to Exhibit 10.9 of the February 2004 Form 8-K).
10.103	Form of Guarantor Security Agreement (incorporated by reference to Exhibit 10.10 of the February 2004 Form 8-K).



10.104

Stock Pledge Agreement dated as of February 6, 2004 by and between the Registrant and Galen Partners, as agent (incorporated by reference to Exhibit 10.11 of the February 2004 Form 8-K).

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<b>EXHIBIT NUMBER</b>	<b>DOCUMENT</b>
10.105	Umbrella Agreement dated as of February 6, 2004 by and among the Registrant, Watson Pharmaceuticals, Care Capital, Essex Woodlands, Galen Partners and the other signatories thereto (incorporated by reference to Exhibit 10.12 of the February 2004 Form 8-K).
10.106	Third Amendment to Loan Agreement dated as of February 6, 2004 by and among the Registrant and Watson Pharmaceuticals (incorporated by reference to Exhibit 10.13 of the February 2004 Form 8-K).
10.107	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).
10.108	Hydrocodone API Supply Option Agreement dated as of February 6, 2004 between the Registrant and Watson Pharmaceuticals (incorporated by reference to Exhibit 10.15 of the February 2004 Form 8-K).
10.109	Noteholders Agreement dated as of February 6, 2004 by and among the Registrant, Care Capital, Essex Woodlands, Galen Partners and the other signatories thereto (incorporated by reference to Exhibit 10.16 of the February 2004 Form 8-K).
10.110	Asset Purchase Agreement dated March 19, 2004 by and among the Registrant, Axiom Pharmaceutical Corporation and IVAX Pharmaceuticals New York LLC (incorporated by reference to Exhibit 2.1 of the Registrant's Form 8-K filed March 25, 2004 (the "March 2004 Form 8-K")).
10.111	Voting Agreement dated March 19, 2004 by and among the Registrant, IVAX Pharmaceuticals New York LLC and certain holders of Halsey Drug Co., Inc. voting securities (incorporated by reference to Exhibit 10.1 of the March 2004 Form 8-K).
10.112	Use and License Agreement dated March 19, 2004 by and among the Registrant, Axiom Pharmaceutical Corporation and IVAX Pharmaceuticals New York LLC (incorporated by reference to Exhibit 10.2 of the March 2004 Form 8-K.)
10.113	Executive Employment Agreement dated as of November 18, 2002 between the Registrant and Vijai Kumar (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 (the "June 2004 10-Q")).
10.114	Executive Employment Agreement dated as of August 26, 2003 between the Registrant and Andrew D. Reddick (incorporated by reference to Exhibit 10.2 to June 2004 10-Q).
10.115	Amendment to Executive Employment Agreement between the Registrant and Andrew D. Reddick, dated May 27, 2004 (incorporated by reference to Exhibit 10.4 to the June 2004 10-Q).
*10.116	Second Amendment to Executive Employment Agreement between the Registrant and Andrew D. Reddick, dated May 24, 2005.
10.117	Third Amendment to Executive Employment Agreement between the Registrant and Andrew D. Reddick, dated December 22, 2005 (incorporated by reference to Exhibit 10.1 to the December 2005 Form 8-K).
10.118	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).
10.119	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).
10.120	Separation Agreement and General Release dated September 18, 2003 between the Registrant and Michael K. Reicher (incorporated by reference to Exhibit 10.5 to June 2004 10-Q).
10.121	First Amendment to Separation Agreement and General Release between the Registrant and Michael K. Reicher, December 4, 2003 (incorporated by reference to Exhibit 10.6 to June

2004 10-Q).

- 10.122 Asset Purchase Agreement dated as of February 18, 2004 by and between the Registrant and Mutual Pharmaceutical Company, Inc. (incorporated by reference to Exhibit 10.7 to June 2004 10-Q).
- 10.123 Amendment to Debenture and Share Purchase Agreement by and among the Registrant, Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P. and other signatories thereto, dated as of June 1, 2004 (incorporated by reference to Exhibit 10.8 to June 2004 10-Q).
- 10.124 First Amendment to Debenture Purchase Agreement by and among the Registrant, Galen Partner III, L.P., Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P. and other signatories thereto, dated as of August 11, 2004 (incorporated by reference to Exhibit 10.9 to June 2004 10-Q).
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<b>EXHIBIT NUMBER</b>	<b>DOCUMENT</b>
10.125	Letter of Support from Galen Partner III, L.P., Care Capital Investments II, LP, and Essex Woodlands Health Ventures V, L.P. to the Registrant, dated May 5, 2003 (incorporated by reference to Exhibit 10.10 to June 2004 10-Q).
10.126	Loan Agreement dated June 22, 2005 between the Registrant, Essex Woodlands Health Venture V, L.P., Care Capital Investments II, L.P., Care Capital Offshore Investments II, L.P., Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated June 22, 2005 (the "June 2005 Form 8-K"))).
10.127	Subordination Agreement dated June 22, 2005 between the Registrant, Essex Woodlands Health Venture V, L.P., Care Capital Investments II, L.P., Care Capital Offshore Investments II, L.P., Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., and the other signatories thereto (incorporated by reference to Exhibit 10.3 of the June 2005 Form 8-K).
10.128	Company General Security Agreement dated June 22, 2005 by and between Registrant and Galen Partners III, L.P., as Agent (incorporated by reference to Exhibit 10.4 of the June 2005 Form 8-K).
10.129	Guaranty of Axiom Pharmaceutical Corporation dated June 22, 2005 (incorporated by reference to Exhibit 10.5 of the June 2005 Form 8-K).
10.130	Guaranty of Acura Pharmaceutical Technologies, Inc. dated June 22, 2005 (incorporated by reference to Exhibit 10.6 of the June 2005 Form 8-K).
10.131	Guarantors Security Agreement by and among Axiom Pharmaceutical Corporation, Registrant, and Galen Partners III, L.P., as Agent, dated June 22, 2005 (incorporated by reference to Exhibit 10.7 of the June 2005 Form 8-K).
10.132	Stock Pledge Agreement by and between Registrant and Galen Partners III, L.P., as Agent, dated June 22, 2005 (incorporated by reference to Exhibit 10.8 of the June 2005 Form 8-K).
10.133	Loan Agreement dated September 16, 2005 between the Registrant, Essex Woodlands Health Venture V, L.P., Care Capital Investments II, L.P., Care Capital Offshore Investments II, L.P., Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated September 16, 2005 (the "September 2005 Form 8-K"))).
10.134	Subordination Agreement dated September 16, 2005 between the Registrant, Essex Woodlands Health Venture V, L.P., Care Capital Investments II, L.P., Care Capital Offshore Investments II, L.P., Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., and the other signatories thereto (incorporated by reference to Exhibit 10.3 of the September 2005 Form 8-K).
10.135	Company General Security Agreement dated September 16, 2005 by and between Registrant and Galen Partners III, L.P., as Agent (incorporated by reference to Exhibit 10.4 of the September 2005 Form 8-K).
10.136	Guaranty of Axiom Pharmaceutical Corporation dated September 16, 2005 (incorporated by reference to Exhibit 10.5 of the September 2005 Form 8-K).
10.137	Guaranty of Acura Pharmaceutical Technologies, Inc. dated September 16, 2005 (incorporated by reference to Exhibit 10.6 of the September 2005 Form 8-K).
10.138	Guarantors Security Agreement by and among Axiom Pharmaceutical Corporation, Registrant, and Galen Partners III, L.P., as Agent, dated September 16, 2005 (incorporated by reference to Exhibit 10.7 of the September 2005 Form 8-K).
10.139	Stock Pledge Agreement by and between Registrant and Galen Partners III, L.P., as Agent, dated September 16, 2005 (incorporated by reference to Exhibit 10.8 of the September 2005

Form 8-K).

10.140

Joinder and Amendment to Amended and Restated Voting Agreement dated November 9, 2005 between the Registrant, GCE Holdings, Essex Woodlands Health Venture V, L.P., Care Capital Investments II, L.P., Care Capital Offshore Investments II, L.P., Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated November 9, 2005 (the "November 2005 Form 8-K")).

10.141

Loan Agreement dated November 9, 2005 between the Registrant, Essex Woodlands Health Venture V, L.P., Care Capital Investments II, L.P., Care Capital Offshore Investments II, L.P., Galen Partners III, L.P., Galen Partners International III, L.P., and Galen Employee Fund III, L.P. and the Additional Lenders that become a party thereto (incorporated by reference to Exhibit 10.2 of the November 2005 Form 8-K).

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<b>EXHIBIT NUMBER</b>	<b>DOCUMENT</b>
10.142	Subordination Agreement dated November 9, 2005 between the Registrant, Essex Woodlands Health Venture V, L.P., Care Capital Investments II, L.P., Care Capital Offshore Investments II, L.P., Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P., and the other signatories thereto (incorporated by reference to Exhibit 10.4 of the November 2005 Form 8-K).
10.143	Company General Security Agreement dated November 9, 2005 by and between Registrant and Galen Partners III, L.P., as Agent (incorporated by reference to Exhibit 10.5 of the November 2005 Form 8-K).
10.144	Guaranty of Axiom Pharmaceutical Corporation dated November 9, 2005 (incorporated by reference to Exhibit 10.6 of the November 2005 Form 8-K).
10.145	Guaranty of Acura Pharmaceutical Technologies, Inc. dated November 9, 2005 (incorporated by reference to Exhibit 10.7 of the November 2005 Form 8-K).
10.146	Guarantors Security Agreement by and among Axiom Pharmaceutical Corporation, Registrant, and Galen Partners III, L.P., as Agent, dated November 9, 2005 (incorporated by reference to Exhibit 10.8 of the November 2005 Form 8-K).
10.147	Stock Pledge Agreement by and between Registrant and Galen Partners III, L.P., as Agent, dated November 9, 2005 (incorporated by reference to Exhibit 10.9 of the November 2005 Form 8-K).
*10.148	Voting Agreement by and between Registrant and GCE Holdings, LLC dated as of December 22, 2005
10.149	Registrant's 2005 Restricted Stock Unit Award Plan (incorporated by reference to Exhibit 10.4 to the December 2005 Form 8-K).
14	Code of Ethics (incorporated by reference to Exhibit 14 of the Registrant's Form 10-K filed April 22, 2004 (the "2003 Form 10-K").
*21	Subsidiaries of the Registrant.
*23.1	Consent of Grant Thornton LLP, independent registered public accounting firm, dated February 16, 2006 to the incorporation by reference of its report to the consolidated financial statements of the Registrant for the year ended December 31, 2003 contained in its Form 10-K into the registrant's Registration Statements on Form S-8 (Registration Nos. 333-63288 and 33-98356).
*23.2	Consent of BDO Seidman LLP, independent registered public accounting firm, to the incorporation by reference of its report to the consolidated financial statements of the Registrant for the years ended December 31, 2005 and 2004 contained in its Form 10-K into the Registrant's Registration Statements on Form S-8 (Registration Nos. 333-63288 and 33-98356).
*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.
*32.1	Certification of Periodic Report by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*32.2	Certification of Periodic Report by 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 herewith.

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A portion of this exhibit has been omitted pursuant to an application for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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