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, 2004

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of February 1, 2005, the registrant had 22,466,967 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, 2004 ($0.47) (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 $6,725,372.

DOCUMENTS INCORPORATED BY REFERENCE
NONE

CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Report under the captions Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," Item 1, "Business", 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 Acura Pharmaceuticals, Inc. ("Acura" or 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, general economic conditions, competitive conditions, technological conditions and governmental legislation. More specifically, important factors that may affect future results include, but are not limited to: changes in laws and regulations, particularly those affecting the Company's operations; the Company's ability to continue to attract, assimilate 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 successfully develop and market its products; customer responsiveness to new products and distribution channels; its ability to compete successfully against current and future competitors; its dependence on third-party suppliers of raw materials; the availability of 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 an early stage of development and may not ever have any products 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

The Company is a New York corporation established in 1935. Prior to the restructuring of the Company's operations described below, the Company had been engaged in the development, manufacture, sale and distribution of a variety of generic finished dosage pharmaceutical products and active pharmaceutical ingredients ("APIs"). On November 6, 2003, the Company announced its plan to restructure the Company's operations to focus on research and development related to certain proprietary opioid synthesis and finished dosage formulation technologies. The Board of Directors determined, among other factors, that the Company's ability to generate positive cash flow from the operation of the Company's finished dosage manufacturing, packaging, labeling and distribution facilities located in Congers, New York (collectively, the "Congers Facilities") in the manufacture and distribution of finished dosage generic products pursuant to abbreviated new drug applications ("ANDAs") was compromised by the highly competitive market environment, low market pricing and declining market size for its existing generic products and the lack of new generic products in development. The Board determined that near term sales of the Company's finished dosage generic drug products would likely result in negative gross margins in view of the market environment. Based on this analysis and other factors, the Board concluded that the Company's manufacture and sale of finished dosage products licensed to be produced at the Congers Facilities would result in continuing negative cash flow for the foreseeable future. After due consideration of alternative strategies and considering the optimal use of available funding, the Board adopted a strategy to substantially restructure the Company's business. Manufacturing of the Company's generic finished dosage products at the Congers Facilities substantially ceased on January 30, 2004. Such date also marks the completion, in large part, of the reduction in work force by approximately 100 employees, 70 of whom were employed by the Company at the Congers Facilities, associated with the restructuring of the Company's operations. See "Recent Events - Restructure of Operations" below.

As restructured, the Company is an emerging specialty pharmaceutical company primarily engaged in research, development and manufacture of innovative abuse deterrent formulations ("Aversion ™ Technology") intended for use in orally administered opioid-containing pharmaceutical products. The status of the Aversion ™ Technology development is described below under the caption "Aversion™ Technology". The Company is also engaged, to a much lesser extent, in research, development and manufacture of proprietary, high-yield, short cycle time, environmentally sensitive opioid synthesis processes (the "Opioid Synthesis Technologies" and, collectively with the Aversion ™ Technology, the "Technologies") intended for use in the commercial production of certain bulk opioid APIs. The status of the Opioid Synthesis Technologies is described below under the caption "Opioid Synthesis Technologies". As described below under the caption "Patent Applications", as of February 1, 2005, the Company had one issued US patent, one US Notice of Allowance and 14 patent applications pending, including one (1) issued US patent, one (1) US Notice of Allowance granted, eight (8) US patent applications pending and one (1) foreign patent application pending relating to the Opioid Synthesis Technologies, and four (4) US patent applications pending and one (1) foreign patent application pending relating to the Aversion ™ Technology. As of February 1, 2005, the Company retained ownership of all intellectual property and commercial rights to its product candidates and Technologies.

The Company conducts research, development, laboratory, manufacturing and warehousing activities relating to its Technologies 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 of DEA 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"). NRMs are commonly used as the initial starting materials in the synthesis of certain opioid APIs. The Import Registration, if ultimately granted, for which there can be no assurance, will provide the Company with an economical source of NRMs for use as starting materials in the commercial manufacture and supply of certain opioid APIs utilizing the Opioid Synthesis Technologies. The status of the application for the Import Registration is described below under the caption "Import License Registration."

The Company plans 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 incorporating the Aversion Technology and further develop, register and commercialize multiple formulations and strengths of orally administered opioid-containing finished dosage products utilizing the Aversion ™ Technology. The Company expects to receive milestone payments and a share of profits and/or royalty payments derived from the Partners' sale of finished products incorporating the Aversion ™ Technology. The Company also believes that it may derive revenues through licensing the Opioid Synthesis Technologies, and contract manufacture and supply of clinical trial and commercial supplies of finished dosage products utilizing the Aversion ™ Technologies. As of February 1, 2005, the Company was not a party to any development or commercialization agreement with a third party relating to any of its Technologies and no assurance can be given that the Company will be successful in entering into any such agreement in the future.

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. We make available free of charge on 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 the following address or telephone number:

Acura Pharmaceuticals, Inc.
616 N. North Court, Suite 120
Palatine, Illinois 60067
Attn: Investor Relations
847.705.7709

Aversion™ Technology

The class of drugs exhibiting opium or morphine-like properties is referred to as opioids, or opioid agonists. This class of products has experienced substantial market growth in recent years. Certain opioids act as agonists, interacting with stereo specific and saturable binding sites in the brain and other tissues. Endogenous opioid-like peptides are present in areas of the central nervous system that are presumed to be related to the perception of pain, to movement, mood and behavior, and to the regulation of neuroendocrinological functions. Three classical opioid receptor types, mu ((mu)), delta ((delta)), and kappa ((kappa)), have been studied extensively. Each of these receptors has a unique anatomical distribution in the brain, spinal cord, and the periphery. Most of the clinically used opioids are relatively selective for (mu) receptors, reflecting their similarity to morphine. However, it is important to note that opioid containing drugs that are relatively selective at standard doses will often interact with additional receptor subtypes when given at sufficiently high doses, leading to possible changes in their pharmacological effect. This is especially true as opioid doses are escalated to overcome tolerance.

The potential for the development of tolerance, physical and/or psychological dependence (i.e., addiction) with repeated opioid use is a characteristic feature of most opioid containing drugs. The possibility of developing addiction is one of the major societal concerns in the long-term use of opioids for the management of pain. Another major 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.

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 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.

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 very common mode of abuse of oral solid drug product involves mixing the tablet or capsule with a suitable solvent (e.g., 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 various companies 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 continues to exist to have a delivery system for commonly used oral dosage formulations of drugs (i.e., immediate release, sustained or extended release and delayed release tablets and capsules) which deters abuse 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 in mind about the illegitimate use of legitimate opioid-based drug products described above that the Company is pursuing its abuse deterrent formulation technology (the "Aversion™ Technology"). 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.

To date, the Company has formulated and evaluated two distinct product candidates incorporating the Aversion™ Technology ("Product Candidate #1" and "Product Candidate #2"). Both product candidates are tablet formulations intended for oral administration and contain, among other ingredients, a widely prescribed opioid active pharmaceutical ingredient. During the second half of 2004, the Company and the Food and Drug Administration ("FDA") held two scheduled telephonic meetings relating to the Company's Aversion™ Technology product development efforts. Subsequent to the first meeting the Company received acceptance by the FDA of an Investigational New Drug ("IND") for Product Candidate #1 and clearance to initiate a clinical trial program. The clinical development program included in the IND is designed to optimize the formulation of such product candidate to effectively deter opioid abuse while minimizing the potential for any new adverse events compared to non-Aversion ™ formulated commercially marketed products. After conducting a Phase 1 clinical trial for Product Candidate #1 and following (1) a second teleconference with the FDA, (2) the Company's receipt and analysis of new proprietary Company-initiated primary market research with physicians, and (3) an assessment of the Company's new patent applications and intellectual property relating to the Aversion™ Technology, a strategic decision was made by the Company to shift its Aversion™ Technology development efforts to Product Candidate #2. This decision was based primarily on the Company's belief that the development expense and timeline for Product Candidate #2 would be reduced and the commercial opportunity for success would be increased with Product Candidate #2 as compared with Product Candidate #1.

To date, the Company has performed pre-clinical and clinical research and development on its product candidates through a combination of internal and external collaborative research programs. The Company has and will continue to rely on contract research organizations ("CROs") to perform key components of its product development activities. To date such development efforts have included the completion of two laboratory studies by CROs demonstrating the relative advantages in effectiveness of the Aversion ™ Technology compared to selected currently marketed, widely prescribed opioid products in deterring potential intravenous injection. In addition, 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. Such full service CRO is engaged in writing clinical trial protocols, contracting with clinical trial sites and IND development compilation and submissions to the FDA.

In addition, to the studies outlined above, the Company has evaluated Product Candidate #1 in two clinical studies to assess the bioavailability and bioequivalence ("BA/BE") of such product candidate in comparison to a frequently prescribed, commercially marketed drug products with the same opioid active ingredient but without abuse deterrent properties. The results of the first BA/BE study indicated that Product Candidate #1 was sufficiently bioavailable but not bioequivalent to the reference commercially marketed opioid product. The Company subsequently developed a revised formulation ("Product Candidate #1R"). The second BA/BE study confirmed that Product Candidate #1R is both bioavailable and bioequivalent to the commercially marketed product which does not possess abuse deterrent properties.

Currently, the Company is engaged in pre-clinical studies and manufacturing of clinical trial supplies and contemplates submitting an IND or an IND amendment with the FDA for Product Candidate #2 during the first quarter of 2005. Since the formulation of Product Candidate #2, the Company has suspended all new development activities for Product Candidate #1 and Product Candidate #1R and will focus future development activities primarily on Product Candidate #2. There can be no assurance, however, that any of the Company's product candidates incorporating the Aversion ™ Technology will result in a commercially acceptable drug product.

To receive marketing authorization for commercial distribution in the United States, all drug products formulated with the Aversion ™ Technology will require the development, compilation, submission and filing of a new drug application ("NDA") and approval of such application by the FDA. In the event that Product Candidate #2 is stable and demonstrates acceptable bioequivalence, then additional clinical and non-clinical testing will be required prior to the submission of an NDA. There can be no assurances that Product Candidate #2 will lead to an NDA submission or that if an NDA is filed, that the FDA will approve such regulatory application for commercial distribution of such product candidate.

The Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license the Company's Aversion ™ Technology and further develop, register and commercialize multiple formulations and strengths of orally administered opioid containing finished dosage products utilizing the Aversion™ Technologies. The Company believes that it will derive revenues through licensing fees, milestone payments, profit sharing and/or royalties on net sales of such products as well as from the contract manufacture and supply of clinical trial and commercial supplies of finished dosage products for distribution and sale by such Partners. As of February 1, 2005 the Company did not have any such collaborative agreements. The Company can make no assurance that it will be able to negotiate such agreements on favorable terms and, even assuming that such agreements are successfully executed, that the milestones will be achieved and the milestone payments will be subsequently made by our Partners.

Estimating the dates of completion of clinical development, and the costs to complete development, of the Company's product candidates would be highly speculative, subjective and potentially misleading. Pharmaceutical products take a significant amount of time to research, develop and commercialize, with the clinical trial portion of development generally taking several years to complete. The Company expects to re-assess its future research and development plans based on the review of data received from current research and development activities. The costs and pace of future research and development activities are linked and subject to change.

Opioid Synthesis Technologies

In 2004 the Company was engaged in the research and development of proprietary manufacturing processes for opioid APIs (the "Opioid Synthesis Technologies") including the following:

OPIOID SYNTHESIS TECHNOLOGY	STARTING MATERIAL	ESTIMATED YIELD	APPLICABLE DEA REGISTRATIONS REQUIRED	STATUS OF PATENT APPLICATION
Hydrocodone Bitartrate Process #1	Codeine Phosphate	85%	a) Manufacturing	Filed and pending
Oxycodone HCl Process #2	NRMs	68-72%	a) Research b) Manufacturing c) Import	Filed and pending
Codeine Phosphate Process #1	NRMs	90-100%	a) Research b) Manufacturing c) Import	Filed and pending
Codeine Phosphate Process #2	NRMs	80-90%	a) Research b) Manufacturing c) Import	Filed and pending
Codeine Phosphate Process #3	NRMs	65-85%	a) Research b) Manufacturing c) Import	Filed and pending
Hydrocodone Bitartrate Process #2	Codeine Base	85-95%	a) Research b) Manufacturing	Filed and pending
Morphine Sulfate	NRMs	96%	a) Research b) Manufacturing c) Import	Draft application pending
Dihydrocodeine Bitartrate	Codeine Phosphate	>90%	a) Research b) Manufacturing	Filed and pending
Hydrocodone Derivatives	Dihydrocodeine	90%	a) Research b) Manufacturing	Filed and pending

The Company believes at this stage of development that the above-described Opioid Synthesis Technologies are efficient and cost-effective methods of manufacturing opioid APIs. The Company believes that the primary advantages of these processes include a reduction in the time and number of processing steps required to produce the desired opioid APIs and reduction of the quantity and/or toxicity of the waste products relating to such production. The Company believes that at the current manufacturing scale Hydrocodone Bitartrate Process #1 meets all United States Pharmacopeia ("USP") release testing specification and provides high yields and comparable levels of purity compared to competitive manufacturing processes used for this active ingredient.

The development and documentation of Hydrocodone Bitartrate Process #1 has been completed and the Company believes such process is ready to be tested at full commercial scale. The Company estimates that to scale up its Hydrocodone Bitartrate Process #1 Opioid Synthesis Technology to desirable commercial scale at its Culver Facility, additional funding of at least $7.0 million will be required for facility improvements, the purchase, installation and validation of new API manufacturing equipment, environmental waste management compliance, the preparation of the drug master files for the API to be produced at the facility, and related direct labor expenses (collectively, the "API Scale Up Expenses"). Until such time, if any, as the Company secures third-party financing dedicated to such scale-up expenses the Company will be unable to complete the commercial scale-up of the Hydrocodone Bitartrate Process #1 or the other Opioid Synthesis Technologies in the above table. No assurance can be given that the Company will obtain the third-party financing necessary to scale up the Opioid Synthesis Technologies or that if such financing is obtained, that any one or more of the Opioid Synthesis Technologies will be capable of commercial scale-up. As an alternative to scaling up the Opioid Synthesis Technologies in its own facility, the Company may license out such Technology to third parties on an exclusive or non-exclusive basis. There can be no assurance, however, that the Company will actually enter into any license agreements relating to the Opioid Synthesis Technologies or derive any licensing fees, milestone payments or royalties from such arrangements.

The Company is in the process of suspending further development and commercialization efforts relating to the Opioid Synthesis Technologies. The Company has determined based on, among other factors, the Company's limited cash balances, prospects for third-party financing, the Company's focus on the Aversion™ Technology, the API Scale Up Expenses and the projected timeline for resolution of the Company's application for the Import Registration, 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 (see "Import License Registration" below). 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 commercialized.

Patent Applications

As of February 1, 2005, the Company had one US issued patent, one US Notice of Allowance and 14 patent applications pending, including one (1) issued US Patent, one (1) US Notice of Allowance granted and eight (8) US patent applications pending and one (1) foreign patent application pending relating to the Opioid Synthesis Technologies and four (4) US patents applications pending and one (1) foreign patent application pending relating to the Aversion™ Technology. The typical review time of a US patent application varies. The initial review generally occurs approximately 12 to 18 months from date of patent filing. At the completion of the initial review, the patent examiner will issue an Office Action letter, which will detail any necessary amendments, supplements or reasons for the rejection. Subsequent processing of the patent application will depend on the number of Office Action letters issued and the speed of review of the Company's responses thereto. 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, the patent would be issued.

In September 2004, the Company received from the United States Patent and Trademark Office ("PTO") an issued patent relating to one of the Opioid Synthesis Technologies. In October 2004, the Company received from the PTO a Notice of Allowance for a second patent application relating to one of the Opioid Synthesis Technologies. The Company has paid the issuing fee relating to the Notice of Allowance and expects that the corresponding US patent will be issued. No assurance can be given, however, that any other currently pending patent applications or future patent applications relating to the Opioid Synthesis Technologies will be granted. In addition, the Company is currently unable to provide any assurance that all or any of the US patent applications associated with the 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. For example, if a third party were issued a patent with claims encompassing the Aversion™ Technology or products incorporating such Technology, the Company may need to obtain a license in order to commercialize products utilizing the Aversion™ Technology, should one be available or, alternatively, alter the Aversion™ Technology so as to avoid infringing such third-party patents. If the Company were unable to obtain a license on commercially reasonable terms, the Company could be restricted or prevented from commercializing products utilizing the Aversion™ Technology. The Company's success depends in significant part on the Company's ability to obtain 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.

Import License Registration

The research, development and manufacture of APIs and finished dosage products incorporating the Opioid Synthesis Technologies are subject to extensive regulation by the DEA and the FDA. The Culver Facility is currently registered by the DEA to research and manufacture certain DEA controlled substances (the "Manufacturing Registration"). To provide for an economical source of raw materials for the commercial manufacturing of opioids utilizing the Opioid Synthesis Technologies the Company filed with the DEA an application for registration to import 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.

The Company filed its application for registration to import NRMs on January 31, 2001 (the "Import Registration"). 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 have prepared and submitted to the ALJ briefing documents based on the evidentiary record and replies to the opposing parties' briefing documents. With the evidentiary record closed and the briefing documents and reply briefing documents submitted, the Company estimates that within 18 months from September 1, 2004, 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 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 2005 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. See "Opioid Synthesis Technologies" above for a discussion of the Company's need for additional financing and estimated capital requirements for the scale-up of the Hydrocodone Bitartrate Process #1 Opioid Synthesis Technology and the Company's suspension of development and commercialization efforts relating to the Opioid Synthesis Technologies.

Recent Events

Restructure of Operations

After due consideration of alternative strategies and considering the optimal use of available funding, and the prospects for attracting new funding, on October 30, 2003, the Company's Board of Directors unanimously adopted a strategy to substantially restructure the Company's operations. On November 6, 2003, the Company publicly announced its restructuring plan to focus its efforts on research and development related to certain proprietary finished dosage products and APIs. 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 finished dosage manufacturing, packaging, labeling and distribution facilities located in Congers, New York (collectively, the "Congers Facilities") in the manufacture and distribution of finished dosage generic products pursuant to abbreviated new drug applications ("ANDAs").

The Company incurred losses of $48.5 million in 2003, $59.6 million in 2002 and $12.6 million in 2001. The Board determined that near term sales of the Company's finished dosage generic products would likely result in continued financial losses in view of the highly competitive market environment, low market pricing, declining market size for its existing generic products and the lack of timely new generic product launches. Based on this analysis and other factors, the Board concluded that the Company restructure its operations by closing or divesting the Congers Facilities and reducing certain activities at its Culver Facility.

In implementing the restructuring of operations at the Congers Facilities, finished 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.

In accordance with the restructuring of the its operations, the Company has transitioned to a single vertically integrated operations site located at its Acura Pharmaceutical Technologies, Inc. subsidiary in Culver, Indiana. The Company intends to implement the following strategy and perform relevant key activities primarily at the Culver Facility:

- Development, in concert with Contract Research Organizations ("CROs"), of the Company's proprietary Aversion™ Technology for use in orally administered opioid finished dosage products.

- Manufacture and quality assurance release of clinical trial supplies of certain finished dosage form products utilizing the Aversion™ Technology.

- Evaluation, in concert with CROs, of certain finished dosage products utilizing the Aversion™ Technology in clinical trials.

- Scale-up and manufacture of commercial quantities of certain products utilizing the Aversion™ Technology for sale by the Company's licensees.

- Prosecution of the Company's application to the DEA to receive a registration (the "Import Registration") to import Narcotic Raw Materials ("NRMs").

- Negotiating and executing license and development agreements with strategic pharmaceutical company partners providing that such licensees will further develop certain finished dosage products utilizing the Aversion™ Technology, file for regulatory approval with the FDA and other regulatory authorities and commercialize such products.

The development, scale-up and commercialization of APIs incorporating the Company's Opioid Synthesis Technologies and Aversion ™ Technology are subject to various factors, many of which are outside the Company's control. To date, a portion of such technologies have been tested in laboratory and clinical settings. All such Technologies will need to be successfully scaled up to be commercially viable, of which no assurance can be given. Additionally, the Company must satisfy, and continue to maintain compliance with the DEA's and FDA's requirements for the maintenance of its controlled substances research and manufacturing registrations. The Company is pursuing the Import Registration to import NRMs from certain foreign countries as described above under the caption "Import License Registration". The Company is unable to provide any assurance that such Technologies can be scaled up to commercial scale or that they will be commercially viable. Moreover, no assurance can be given that the Company will succeed in obtaining the Import Registration. The Company is committing substantially all of its resources and available capital to the development of the Aversion ™ Technology and to a lesser extent the Opioid Synthesis Technologies and the prosecution of the Import Registration. The failure of the Company to successfully develop the Aversion™ Technology will have a material adverse effect on the Company's operations and financial condition.

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. As the conversion price of the 2004 Debentures was less than the fair market value of the Company's common stock on the date of issue, beneficial conversion features were determined to exist. The Company recorded approximately $14.0 million of debt discount limited to the face amount of the new debt. The debt discount was amortized over the life of the debt, which matured on August 13, 2004, the date the 2004 Debentures were automatically converted into the Company's Series A Convertible Preferred Stock (see "Conversion of 2004 Debentures into Series A Preferred Stock" below).

Source and Amount of Funding under 2004 Purchase Agreement

Of the $14.0 million in 2004 Debentures issued in the 2004 Debenture Offering, approximately $2.0 million of 2004 Debentures were issued in exchange for the surrender of like amount of principal plus accrued interest outstanding under Company's 5% convertible senior secured debentures issued pursuant to working capital bridge loan transactions with Care Capital, Essex Woodlands Health Ventures and Galen Partners during November and December, 2003.

Conversion of 2004 Debentures into Series A Preferred Stock

The 2004 Debentures (including the principal amount plus interest accrued) converted automatically into the Company's Series A convertible preferred stock (the "Series A Preferred") on August 13, 2004, the business day following the Company's receipt of shareholder approval to restate the Company's Certificate of Incorporation (the "Charter Amendment") to authorize the Series A Preferred and the Junior Preferred Shares (as described below) and the filing of the Charter Amendment with the Office of the New York Department of State, as provided in the 2004 Purchase Agreement. The 2004 Debentures converted into an aggregate of 21,963,757 Series A Preferred shares based on a $0.6425 per share conversion price.

Series A Preferred Stock Liquidation Preference, Conversion Right and Participation Right

In general, the Series A Preferred shares have a liquidation preference equal to five (5) times the initial $0.6425 Series A conversion price (the "Series A Liquidation Preference"). In addition, the Series A Preferred shares are convertible into the Company's Common Stock, with each Series A Preferred share convertible into the number of shares of Common Stock obtained by dividing (i) the Series A Liquidation Preference, by (ii) the $0.6425 Series A conversion price, as such conversion price may be adjusted, from time to time, pursuant to the dilution protections of such shares. Without limiting the Series A Liquidation Preference, the holders of Series A Preferred shares also have the right to participate with the holders of the Company's Common Stock upon the occurrence of a liquidation event, including the Company's merger, sale of all or substantially all of its assets or a change of control transaction, on an as-converted basis (but for these purposes only, assuming the Series A Preferred shares to be convertible into only thirty percent (30%) of the shares of Common Stock into which they are otherwise then convertible). The holders of Series A Preferred shares also have the right to vote as part of a single class with all holders of the Company's voting securities on all matters to be voted on by such security holders. Each holder of Series A Preferred shares will have such number of votes as shall equal the number of votes he would have had if such holder converted all Series A Preferred shares held by such holder into shares of Common Stock immediately prior to the record date relating to such vote.

Board of Director Representation

The 2004 Purchase Agreement provides that each of Care Capital, Essex Woodlands Health Ventures and Galen Partners (collectively, the "Lead 2004 Investors") has the right to designate for nomination one member of the Company's Board of Directors, and that the Lead Investors collectively may designate one additional member of the Board (collectively, the "Designees"). The Purchase Agreement further provides that the Designees, if so requested by such Designee in his sole discretion, shall be appointed to the Company's Executive Committee, Compensation Committee and any other Committee of the Board of Directors. The Designees of Care Capital, Essex and Galen are Messrs. Karabelas, Thangaraj and Wesson, respectively, each of whom are current Board members. In accordance with the terms of the 2004 Purchase Agreement, the Lead 2004 Investors may collectively nominate one additional Designee to the Board. The Company has agreed to nominate and appoint to the Board of Directors, subject to shareholder approval, one designee of each of Care Capital, Essex and Galen, and one collective designee of the Lead 2004 Investors, for so long as each holds a minimum of 50% of the Series A Preferred shares initially issued to such party (or at least 50% of the shares of Common Stock issuable upon conversion of the Series A Preferred shares).

Impact of Conversion of the Company's Outstanding Debentures

As of February 10, 2004, the date of the initial closing of the 2004 Purchase Agreement, the Company had issued and outstanding and aggregate of approximately $86.6 million in principal amount of 5% convertible senior secured debentures maturing March 31, 2006 issued pursuant to three separate Debenture Purchase Agreements dated March 10, 1998, as amended (the "1998 Debentures"), May 26, 1999, as amended (the "1999 Debentures") and December 20, 2002 (the "2002 Debentures"), respectively. The 1998 Debentures, 1999 Debentures and 2002 Debentures are referred to collectively as the "1998-2002 Debentures". After giving effect to the Company's issuance of additional 5% convertible senior secured debentures in satisfaction of interest payments on the 1998-2002 Debentures, as of February 10, 2004, the 1998-2002 Debentures were convertible into an aggregate of approximately 190.4 million shares of the Company's Common Stock.

Conversion Agreement of Holders of 1998-2002 Debentures

Simultaneous with the execution of the 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 1998-2002 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, effective August 13, 2004, each holder of 1998-2002 Debentures converted the 1998-2002 Debentures held by such holder into the Company's Series B convertible preferred stock (the "Series B Preferred") and/or Series C-1, C-2 and/or C-3 convertible 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".

Under the Conversion Agreement, the holders of approximately $6.6 million in principal amount of 2002 Debentures issued during 2003 converted such 2002 Debentures (plus accrued and unpaid interest) into Series B Preferred Shares. Of the remaining approximate $80 million in principal amount of the 1998-2002 Debentures, approximately $31.2 million was comprised of 1998 Debentures, approximately $21.5 million was comprised of 1999 Debentures and approximately $27.3 million was comprised of 2002 Debentures. Effective August 13, 2004, the 1998 Debentures were converted into Series C-1 Preferred shares, the 1999 Debentures were converted into Series C-2 Preferred shares and the remaining balance of the 2002 Debentures were converted into Series C-3 Preferred shares.

The number of Junior Preferred Shares issued by the Company to each holder of 1998-2002 Debentures was based on the respective prices at which the 1998-2002 Debentures were convertible into Common Stock. The 2002 Debentures issued in 2003 had a conversion price of $0.3420 per share. The 1998 Debentures, 1999 Debentures and the remaining balance of the 2002 Debentures had conversion prices of $0.5776, $0.5993 and $0.3481 per share, respectively. Upon the automatic conversion of the 1998-2002 Debentures on August 13, 2004, the Company issued an aggregate of 20,246,506 million Series B Preferred shares, 56,422,558 million Series C-1 Preferred shares, 37,433,096 million Series C-2 Preferred shares and 81,907,069 million Series C-3 Preferred shares.

Liquidation Preference of Junior Preferred Shares

In general, the Junior Preferred Shares have a liquidation preference equal to one (1) time the principal amount plus accrued and unpaid interest on the 1998-2002 Debentures converted into Junior Preferred Shares. The liquidation preference of the Series B Preferred has priority over, and will be satisfied prior to, the liquidation preference of the Series C Preferred. The liquidation preference for each class of the Junior Preferred Shares is equal to the conversion prices of such shares. The Junior Preferred Shares are convertible into the Company's Common Stock, with each Junior Preferred Share convertible into one share of Common Stock. The holders of the Junior Preferred Shares have the right to vote as part of the single class with all holders of the Company's Common Stock and the holders of the Series A Preferred on all matters to be voted on by such security holders, with each holder of Junior Preferred Shares having such number of votes as shall equal the number of votes he would have had if such holder had converted all Junior Preferred Shares held by such holder into Common Stock immediately prior to the record date relating to such vote.

Common Share Equivalents of the Series A Preferred and Junior Preferred Shares

The Series A Preferred shares, the Series B Preferred shares and the Series C Preferred shares are convertible into approximately 109.8 million, 20.2 million and 175.7 million shares of Common Stock, respectively. If all of such Preferred Shares were converted into Common Stock, the Company would have issued and outstanding approximately 328 million shares of 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 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.

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 first 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.

Sale of Certain Company Assets

On February 18, 2004, the Company and Mutual Pharmaceuticals, Inc. ("Mutual") entered into a certain Asset Purchase Agreement (the "Mutual Asset Purchase Agreement") pursuant to which the Company sold certain inactive, non-revenue generating ANDAs to Mutual in consideration of $2.0 million. The ANDAs sold to Mutual were in various therapeutic categories, including analgesics, anti-infectives, anti-hypertensives, antihistamines, steroids and certain other categories. The decision to divest such 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 its finished dosage manufacturing facilities in Congers, New York and was in the process of negotiating the sale of such 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 the Purchase Agreement, the Company and Axiom agreed to sell to IVAX substantially all of the Company's assets used in the operation of the Company's former generic manufacturing and packaging operations located in Congers, New York in consideration of an immediate payment of $2.0 million and an additional payment $0.5 million upon receipt of shareholder approval of the transaction. Shareholder approval of the asset sale transaction with IVAX was obtained on August 12, 2004 and the closing was completed on August 13, 2004, at which time the Company received the remaining payment of $0.5 million from IVAX.

Marketing and Customers

As a result of restructuring its operations, the Company has discontinued the manufacture and distribution of all of its generic products and therefore at this time is not engaged in product marketing, selling or distributing finished dosage products or bulk API to trade or pharmaceutical industry customers.

Segment Reporting

The Company operates in only one business segment - primarily engaged in research, development and manufacture of innovative abuse deterrent formulations ("Aversion ™ Technology") intended for use in orally administered opioid-containing pharmaceutical products.

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," whether prescription or over-the-counter, can be marketed. A "new drug" is one not generally recognized by qualified experts as safe and effective for its intended use. Such general recognition must be based on published adequate and well controlled clinical investigations. Each dosage form of a specific "new drug" product requires separate approval by the FDA. In general, as discussed below, less costly and time consuming approval procedures may be used for generic equivalents as compared to the innovative products. In addition, certain modifications using existing pharmaceutical products may be subject to streamlined approval procedures, although a case-by-case analysis must be undertaken. 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 facilities are 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.

Drug Approvals

There are currently three ways to obtain FDA approval to commercially market and distribute a new drug 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) or "Paper" NDA. An alternative NDA procedure is provided by 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 believes that the 505(b)(2) application procedure may be applicable to a portion of the products it intends to develop utilizing its Aversion™ Technology.

3. Abbreviated New Drug Applications ("ANDAs"). The Drug Price Competition and Patent Term Restoration Act of 1984 (the "1984 Act") established the ANDA procedure for obtaining FDA approval for those drugs that are off-patent or whose exclusivity has expired and that are bioequivalent to brand-name drugs. An ANDA is similar to an NDA, except that the FDA waives the requirement of conducting complete clinical studies of safety and efficacy, although it may require expanded clinical bioavailability and/or bioequivalence studies. "Bioavailability" means the rate of absorption and levels of concentration of a drug in the blood stream needed to produce a therapeutic effect. "Bioequivalence" means equivalence in bioavailability between two drug products. In general, an ANDA will be approved only upon a showing that the generic drug covered by the ANDA is bioequivalent to the previously approved version of the drug product, i.e., that the rate of absorption and the levels of concentration of a generic drug in the body are substantially equivalent to those of a previously approved equivalent drug product. The principal advantage of this approval mechanism is that an ANDA applicant is not required to conduct the same preclinical and clinical studies to demonstrate that the product is safe and effective for its intended use.

Healthcare Reform

Several legislative proposals to address the rising costs of healthcare have been introduced in Congress and several state legislatures. Many of such proposals include various insurance market reforms, the requirement that businesses provide health insurance coverage for all their employees, significant reductions in the growth of future Medicare and Medicaid expenditures, and stringent government cost controls that would directly control 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 Company's products in development utilizing the Company's Technologies.

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 spent $180,000, $227,000 and $227,000 in the years 2004, 2003 and 2002, respectively, on environmental compliance relating to the disposal of hazardous and controlled substances waste and personnel costs.

Competition

The Company competes to varying degrees with numerous companies in the pharmaceutical research, development, manufacturing and commercialization fields. Most, if not all, 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 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, Purdue Pharma of Stamford, Connecticut and Endo Pharmaceuticals of Chadds Ford, Pennsylvania have announced that they are pursuing abuse deterrent formulations of opioid based products. The Company believes that Endo Pharmaceuticals has entered into a license agreement to evaluate opioid abuse deterrent technologies developed by Collegium Pharmaceuticals.

Raw Materials

The DEA controls both the quantity of controlled substances produced in the U.S. and the quantity of certain raw materials obtained by pharmaceutical developers and manufacturers for the production of controlled substances. In this regard, the Company is required to file for and obtain quotas from the DEA for the purchase and use of controlled substance materials including NRMs. Although the Company has made initial contacts with overseas NRM suppliers, no assurance can be given that the Company will be successful in obtaining an adequate quota from the DEA or (even assuming the Company's Import Registration is granted) in contracting with third-party suppliers in foreign countries for NRMs on commercially acceptable terms for the Company's requirements of NRMs to be used in its controlled substance development and commercialization efforts. Provided the Company continues to seek the Import Registration, the process and proceedings described above under the caption "Import License Registration" will continue through 2005 and beyond.

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. Inasmuch as the Company's generic drug manufacturing and distribution operations have been terminated, Axiom Pharmaceutical Corporation is an inactive subsidiary of the Company.

Employees

As of February 1, 2005, the Company had 17 full-time employees. Twelve of these employees are engaged in activities at the Culver Facility relating to the research, development, scale-up and commercialization of the Opioid Synthesis Technologies and Aversion ™ Technology. The remaining five employees are engaged in administrative, legal, accounting, finance, market research, business development and licensing activities.

ITEM 2. PROPERTIES

The Company leases approximately 1,600 square feet of administrative office space at 616 N. North Court, Suite 120, Palatine, Illinois 60067. The lease agreement is between the Company and an unaffiliated lessor. The lease agreement has an initial term of one year expiring February 28, 2005. The Company has exercised its option under the lease to renew the lease for an additional one year term. The lease agreement provides for annual rent, property taxes, common area maintenance and janitorial services for approximately $29,000 per year. This leased office space is utilized for the Company's administrative, accounting, finance, market research, and business development functions.

The Company conducts research, development, laboratory, manufacturing and warehousing activities relating to the Aversion™ Technology and the Opioid Synthesis Technologies at its facility located at 16235 State Road 17, Culver, Indiana. At this location the Company's Acura Pharmaceutical Technologies, Inc. subsidiary owns a 28,000 square foot facility configured with (approximately) a 7,000 square feet warehouse, 10,000 square feet of manufacturing space, 6,000 square feet of research and development labs and 5,000 square feet of administrative and storage space. The facility is located on approximately 30 acres of land.

ITEM 3. LEGAL PROCEEDINGS

Beginning in 1992, actions were commenced against the Company and numerous other pharmaceutical manufacturers in connection with the alleged exposure to diethylstilbestrol ("DES"). The defense of all of such matters was assumed by the Company's insurance carrier and a substantial number have been settled by the carrier. Currently, several actions remain pending with the Company as a defendant and the insurance carrier is defending each action. Plaintiffs in the pending litigations seek unspecified damages. The Company does not believe any of such actions will have a material impact on the Company's financial condition.

The Company is 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 seeks 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. Discovery in this action is complete. The Company's and the Plaintiff's motion for summary judgment were due to be heard by the Court in August 8, 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. The Estate of Mr. Kohn has been substituted as the plaintiff. In February, 2005, 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. The Company and the Estate of Mr. Kohn have agreed in principle to settle this matter, pursuant to which the Company would make a one-time payment of $35,000. The proposed settlement is subject to the preparation and execution of a definitive settlement agreement and the approval of the Bronx, New York Surrogate's Court.

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 2004.

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.

	BID PRICE	
PERIOD	**HIGH**	**LOW**
2003 Fiscal Year		
First Quarter	1.09	0.82
Second Quarter	1.11	0.76
Third Quarter	1.60	0.76
Fourth Quarter	1.07	0.26
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…	0.50	0.38
(through February 1, 2005)		

Holders

There were approximately 662 holders of record of the Company's common stock on February 1, 2005. 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 Company's Series A Preferred shares and 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 (see "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, 2004, the Company issued 277,715 shares of the Company's Common Stock in satisfaction of the payment of $119,417 in accrued interest due December 31, 2004 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.

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data presented on the following pages for the years ended December 31, 2004, 2003, 2002, 2001 and 2000 are derived from the Company's audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2004 and December 31, 2003, and for each of the years in the three-year period ended December 31, 2004, and the report thereon, are included elsewhere herein. The selected financial information as of and for the years ended December 31, 2001 and 2000 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,				
	2004	2003	2002	2001	2000
	(IN THOUSANDS, EXCEPT PER SHARE DATA)				
OPERATING DATA:					
Net revenues	$ 838	$ 5,750	$ 8,205	$ 16,929	$ 20,223
Operating Costs					
Cost of manufacturing	$ 1,435	$ 11,705	$ 12,535	14,857	18,743
Research and development	$ 4,130	$ 1,460	$ 1,517	1,327	1,821
Selling, general and Administrative expenses	$ 5,238	$ 7,903	$ 7,216	6,616	6,208
Plant shutdown costs	$ —	$ 1,926	$ (126)	68	53
Interest expense	$ 2,962	$ 6,001	$ 4,728	3,913	3,699
Interest income	$ 59	$ 25	$ 15	69	662
Amortization of deferred debt Discount and private offering Costs	$ 72,491	$ 24,771	$ 12,558	2,591	2,448
Loss (gain) on extinguishments of Debt	$ (12,401)	$ —	$ 28,415		
Investment in joint venture	$ —	$ —	$ —	(202)	(57)
Other (income) expense	$ (2,962)	$ 464	$ 966	(13)	(101)
Loss before income tax Benefit	$ (69,996)	$ (48,455)	$ (59,589)	(12,563)	(12,043)
Income tax benefit	$ —	$ —	$ —	—	(389)
Net loss	$ (69,996)	$ (48,455)	$ (59,589)	$ (12,563)	$ (11,654)
Basic and diluted loss per common share	$ (3.20)	$ (2.28)	$ (3.90)	$ (.84)	$ (.80)
Weighted average number of outstanding shares	21,861	21,227	15,262	15,021	14,503

	DECEMBER 31,				
	2004	2003	2002	2001	2000
	(IN THOUSANDS)				
BALANCE SHEET DATA:					
Working capital (deficiency)	$ 2,423	$ (3,770)	$ 5,933	$ (8,276)	$ (5,061)
Total assets	$ 4,967	$ 6,622	$ 19,364	11,069	15,209
Total liabilities	$ 6,052	$ 58,689	$ 31,632	76,505	68,558
Accumulated deficit	$ (279,541)	$ (209,546)	$ (161,090)	(101,501)	(88,938)
Stockholders' equity (deficit)	$ (1,085)	$ (52,067)	$ (12,268)	(65,436)	(53,349)

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 including, without limitation, in this Item 7 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. ("Acura" or 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, general economic conditions, competitive conditions, technological conditions and governmental legislation. More specifically, important factors that may affect future results include, but are not limited to: changes in laws and regulations, particularly those affecting the Company's operations; the Company's ability to continue to attract, assimilate 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 successfully develop and market its products; customer responsiveness to new products and distribution channels; its ability to compete successfully against current and future competitors; its dependence on third-party suppliers of raw materials; the availability of 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 an early stage of development and may not ever have any products that generate significant revenue. When used in this Report, the words “estimate,” “project,” “anticipate,” “expect,” “intend,” “believe,” and similar expressions are intended to identify forward-looking statements. Additionally, such forward-looking statements are subject to the risks and uncertainties discussed below under the section entitled “Risk Factors Relating to the Company”.

Overview

In November 2003, the Company commenced the restructuring of its operations to focus its efforts on research and development relating to the Aversion™ Technology and Opioid Synthesis Technologies and to provide for the cessation of operations, and the sale of assets, relating to the manufacture and distribution of finished dosage generic products conducted at the Company's Congers, New York facilities (the "Congers Facilities").

To fund continuing operations and the research and development of the Company's proprietary Technologies, on February 10, 2004, the Company completed a private offering of debentures in the aggregate principal amount of approximately $12.3 million (the "2004 Debenture Offering"). As part of the completion of the 2004 Debenture Offering, the Company retired approximately $16.4 million in indebtedness under the Company's $21.4 million term loan with Watson Pharmaceuticals. On April 14, 2004 and May 26, 2004 the Company completed additional funding under the 2004 Debenture Offering in the aggregate principal amount of approximately $1.7 million resulting in an aggregate principal amount of convertible secured debentures issued as part of the 2004 Debenture Offering of $14.0 million. In accordance with the terms of the documents executed in connection with the 2004 Debenture Offering, effective August 13, 2004, the aggregate principal amount of the 2004 Debentures as well as Company's other convertible debentures issued during the period 1998 through 2003 (aggregating approximately $80.6 million) converted into various classes of the Company's preferred shares. (See "Item 1 - Business - Recent Events - 2004 Debenture Offering").

On February 18, 2004, the Company sold certain of its inactive, non-revenue generating Abbreviated New Drug Applications ("ANDAs") to Mutual Pharmaceutical Company, Inc. in consideration of $2.0 million. On March 19, 2004, the Company and its wholly-owned subsidiary, Axiom Pharmaceutical Corporation, entered into an Asset Purchase Agreement with IVAX Pharmaceuticals New York LLC ("IVAX") pursuant to which the Company and Axiom agreed to sell to IVAX substantially all of the Company's assets used in the operation of the Congers Facilities in consideration of $2.5 million. On August 13, 2004, the Company completed the sale of the assets used in the operation of the Congers Facilities to IVAX.

As restructured, the Company is an emerging specialty pharmaceutical company primarily engaged in research, development and manufacture of innovative abuse deterrent formulations ("Aversion™ Technology") intended for use in orally administered opioid-containing pharmaceutical products. In addition, to a lesser extent, during 2004 and early 2005 the Company was engaged in research, development and manufacture of proprietary, high-yield, short cycle time, environmentally sensitive opioid synthesis processes (the "Opioid Synthesis Technologies" and, collectively with the Aversion™ Technology, the "Technologies") intended for use in the commercial production of certain bulk opioid active pharmaceutical ingredients ("APIs"). The Company is currently in the process of suspending further development and commercialization efforts relating to the Opioid Synthesis Technologies (See "Item 1 -Business - Opioid Synthesis Technologies"). As of February 1, 2005, the Company has one (1) issued US patent, one (1) US Notice of Allowance granted, eight (8) U.S. patent applications and one (1) foreign patent application pending relating to the Opioid Synthesis Technologies. Additionally, the Company has four (4) U.S. patent applications and one (1) foreign patent application pending relating to the Aversion™ Technology. As of February 1, 2005, the Company retained all intellectual property and commercial rights to its product candidates, the Aversion™ Technology and the Opioid Synthesis Technologies.

Company's Present Financial Condition and Commercial Focus

At December 31, 2004, the Company had cash and cash equivalents of approximately $3.1 million compared to $942,000 at December 31, 2003. The Company had working capital of $2.4 million at December 31, 2004 and a working capital deficit of approximately $3.8 million at December 31, 2003. The Company had an accumulated deficit of approximately $279.5 million and approximately $209.5 million at December 31, 2004 and December 31, 2003, respectively. The Company incurred a loss from operations of approximately $9.9 million and a net loss of approximately $70.0 million during the year ended December 31, 2004, as compared to a loss from operations and a net loss of $17.2 million and $48.5 million, respectively, for the year ended December 31, 2003.

In implementing the restructuring adopted by the Board, the Company has transitioned to a single vertically integrated operations facility located in Culver, Indiana. The Company's strategy and key activities to be conducted at the Culver Facility are as follows:

o Development, in concert with Contract Research Organizations ("CROs") of the Company's Aversion ™ Technology for use in orally administered opioid finished dosage product candidates.

o Manufacture and quality assurance release of clinical trial supplies of certain finished dosage form product candidates utilizing the Aversion™ Technology.

o Evaluation, in concert with CROs, of certain finished dosage product candidates utilizing the Aversion™ Technology in clinical trials.

o Scale-up and manufacture of commercial quantities of certain product candidates utilizing the Aversion ™ Technology for sale by the Company's licensees.

o Prosecution of the Company's application to the U.S. Drug Enforcement Administration ("DEA") for registration to import narcotic raw materials ("NRMs").

o Negotiating and executing 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.

The Company has incurred net losses since 1992 and the Company's consolidated financial statements for each of the years ended December 31, 2004 and 2003 have been prepared on a going-concern basis, expressing substantial doubt about the Company's ability to continue as a going-concern as a result of recurring losses and negative cash flows. The Company expects net losses to continue at least through 2005. The Company's future profitability will depend on several factors, including:

o The successful completion of the development, scale-up, clinical testing and acceptable regulatory review of the Aversion ™ Technology;

o The receipt of a notice of allowance from the U.S. Patent and Trademark Office ("PTO") for the material claims in the Company's patent applications relating to the Aversion™ Technology;

o The commercialization of products incorporating the Aversion ™ Technology without infringing the patents and other intellectual property rights of third parties;

o The receipt of approval from the DEA to import NRMs to be used in the Company's development and manufacturing efforts; and

o The interest of third parties in the Technologies and the Company's ability to negotiate and execute commercially viable collaboration agreements with interested third parties relating to the Technologies.

Many of these factors will depend upon circumstances beyond the Company's control.

As of February 25, 2005, the Company had cash and cash equivalents of approximately $2.5 million. The Company estimates its current cash reserves will be sufficient to fund the development of the Aversion ™ Technology and related operating expenses only through May, 2005. See "Liquidity and Capital Resources - Commercial Focus, Cash Reserves and Funding Requirements."

In order to complete the development and regulatory approval of the Company's product candidates and commercialize such products, if any are approved by the FDA, the Company must enter into development and commercialization agreements with third party pharmaceutical company partners providing that such partners license the Company's Technologies and further develop, register and commercialize the Company's orally administered opioid-containing finished dosage products utilizing such Technology. Future revenue, if any, will be derived from milestone payments and a share of profits and/or royalty payments relating to such collaborative partners' sale of products incorporating the Company's Technologies. As of February 1, 2005, the Company did not have any such collaborative agreements, nor can there be any assurance that the Company will enter into collaborative agreements in the future.

Estimating the dates of completion of clinical development, and the costs to complete development, of the Company's product candidates would be highly speculative, subjective and potentially misleading. Pharmaceutical products take a significant amount of time to research, develop and commercialize, with the clinical trial portion of development generally taking several years to complete. The Company expects to reassess its future research and development plans based on the review of data received from current research and development activities. The cost and pace of future research and development activities are linked and subject to change.

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 consider that in 2004 the Company, as restructured, focused the majority of its efforts and resources on research and development activities and, subsequent to March, 2004, no longer maintained any generic manufacturing facilities or conducted any finished dosage manufacturing activities. Net product revenues and manufacturing expenses realized in 2004 were incurred as part of an orderly phase out of all generic manufacturing activities.

Net Product Revenues

The Company's net product revenues for the year ended December 31, 2004 and December 31, 2003 were as follows (in thousands):

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

The decrease in net product revenues was a result of the Company's decision to restructure operations and cease the manufacture 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

The Company's cost of manufacturing for the year ended December 31, 2004 and December 31, 2003 were as follows (in thousands):

12/31/04 COST OF MANUFACTURING	12/31/03 COST OF MANUFACTURING	12/31/04-12/31/03 COST OF MANUFACTURING CHANGE ($)	12/31/04-12/31/03 COST OF MANUFACTURING CHANGE (%)
$ 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

The Company's research and development expenses for the year ended December 31, 2004 and December 31, 2003 were as follows (in thousands):

12/31/04 R&D EXPENSES	12/31/03 R&D EXPENSES	12/31/04-12/31/03 R&D EXPENSES CHANGE ($)	12/31/04-12/31/03 R&D EXPENSES CHANGE (%)
$ 4,130	$ 1,460	$ 2,670	183%

Research and development expense consisted primarily of product development costs prior to the cessation of the manufacture and sale of finished dosage products. During 2004, research and development expense consists primarily of drug development work 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 expenses include a non cash compensation charge of $553 recorded for the issuance of stock options and $1,093 of personnel and departmental type charges, which were reassigned from being chargeable to general and administrative department to being chargeable to research and development.

Selling, Marketing, General and Administrative Expenses

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

12/31/04 SELLING, MARKETING, G&A EXPENSES	12/31/03 SELLING, MARKETING, G&A EXPENSES	12/31/04-12/31/03 SELLING, MARKETING, G&A EXPENSES CHANGE ($)	12/31/04-12/31/03 SELLING, MARKETING, G&A EXPENSES CHANGE (%)
$ 5,212	$ 7,903	($ 2,691)	(34%)

The decrease in selling, marketing, general and administrative expenses resulted from the Company's decision to restructure operations by discontinuing the marketing and sale of generic finished dosage products and reducing its administrative and manufacturing support staff. The decrease includes $1,093 of personnel and departmental type charges, which were reassigned from being chargeable to general and administrative department to being chargeable to research and development, 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

During the year ended December 31, 2004 and December 31, 2003, the Company incurred the following expenses in connection with environmental compliance (in thousands):

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

The environmental compliance expenses related primarily to disposal of hazardous and controlled substances waste and related personnel costs for environmental compliance during the period the Company maintained its manufacturing operations. No environmental compliance costs were incurred subsequent to the second quarter of 2004.

Interest Expense, Net of Interest Income

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

12/31/04 INTEREST EXPENSE, NET OF INTEREST INCOME	12/31/03 INTEREST EXPENSE, NET OF INTEREST INCOME	12/31/04-12/31/03 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE ($)	12/31/04-12/31/03 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (%)
$ 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 as well as the conversion of the Company's 5% convertible debentures into convertible preferred stock on August 13, 2004.

Amortization of Deferred Debt Discount and Private Debt Offering Costs

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

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

The change in the deferred debt discount and 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 during the period 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 deferred debt discount and private debt offering cost balances were written off to expense.

Net Loss

The Company's net loss for the year ended December 31, 2004 and December 31, 2003 was as follows (in thousands):

12/31/04 NET LOSS	12/31/03 NET LOSS	12/31/04-12/31/03 NET LOSS CHANGE ($)	12/31/04-12/31/03 NET LOSS CHANGE (%)
($ 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 deferred debt discount and 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.

Results of Operations for the Year Ended December 31, 2003 and 2002

Net Product Revenues

The Company's net product revenues for the year ended December 31, 2003 and December 31, 2002 were as follows (in thousands):

12/31/03 NET PRODUCT REVENUES	12/31/02 NET PRODUCT REVENUES	12/31/03- 12/31/02 NET PRODUCT REVENUE CHANGE ($)	12/31/03-12/31/02 NET PRODUCT REVENUE CHANGE (%)
$ 5,750	$ 8,205	($ 2,455)	(30%)

The decrease in the 2003-2002 Net Product Revenues resulted primarily from declining purchases by a single customer under an exclusive supply agreement for the Company's major product lines. The Company, pursuant to certain provisions in that agreement, terminated the exclusive supply agreement in March, 2003 and thereafter attempted to re-establish itself in the market place by manufacturing and distributing generic products under its Axiom subsidiary label. The Company's relatively narrow generic product lines, the entrenched market positions of existing competitors, relatively low margins and time required to fulfill the regulatory requirements of re-establishing the Company's generic products under its Axiom label resulted in revenues lower than anticipated. Ultimately, these conditions caused the Company to reassess its strategy and to implement a restructuring of operations. Such restructuring was announced on November 6, 2003.

Cost of Manufacturing

The Company's cost of manufacturing for the year ended December 31, 2003 and December 31, 2002 were as follows (in thousands):

12/31/03 COST OF MANUFACTURING	12/31/02 COST OF MANUFACTURING	12/31/03-12/31/02 COST OF MANUFACTURING CHANGE ($)	12/31/03-12/31/02 COST OF MANUFACTURING CHANGE (%)
$ 11,705	$ 12,535	($ 830)	(7%)

The increased cost as a percentage of sales in 2003, as compared in the year 2002, was directly attributable to a charge of approximately $1,345 in 2003 for impairment of inventory in connection with the Company's restructuring.

Research and Development Expenses

The Company's research and development expenses for the year ended December 31, 2003 and December 31, 2002 were as follows (in thousands):

12/31/03 R&D EXPENSES	12/31/02 R&D EXPENSES	12/31/03-12/31/02 R&D EXPENSES CHANGE ($)	12/31/03-12/31/02 R&D EXPENSES CHANGE (%)
$ 1,460	$ 1,517	($57)	(4%)

The decrease in research and development expenses reflects the reduction in the resources available to fund these activities. The development expenditures in 2003 were primarily related to the Company's Aversion™ Technology and Opioid Synthesis Technologies.

Selling, Marketing, General and Administrative Expenses

Selling, marketing, general and administrative expenses for the year ended December 31, 2003 and December 31, 2002 were as follows (in thousands):

12/31/03 SELLING, MARKETING, G&A EXPENSES	12/31/02 SELLING, MARKETING, G&A EXPENSES	12/31/03-12/31/02 SELLING, MARKETING, G&A EXPENSES CHANGE ($)	12/31/03-12/31/02 SELLING, MARKETING, G&A EXPENSES CHANGE (%)
$ 7,903	$ 7,216	$ 687	10%

The increase in selling, marketing, general and administrative expenses is primarily due to added professional costs associated with the prosecution of the Company's Import Registration of $233,000, increased bad debt expense of $350,000 and sales personnel costs of $93,000.

Environmental Compliance Expenses

During the year ended December 31, 2003 and December 31, 2002, the Company incurred the following expenses in connection with environmental compliance (in thousands):

12/31/03 ENVIRONMENTAL COMPLIANCE EXPENSES	12/31/02 ENVIRONMENTAL COMPLIANCE EXPENSES	12/31/03-12/31/02 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE ($)	12/31/03-12/31/02 ENVIRONMENTAL COMPLIANCE EXPENSES CHANGE (%)
$ 227	$ 227	$ —	— %

The environmental compliance expenses related to disposal of hazardous and controlled substances waste and related personnel costs for environmental compliance during the period the Company maintained its manufacturing operations.

Interest Expense, Net of Interest Income

The Company's interest expense, net of interest income for the year ended December 31, 2003 and December 30, 2002 was as follows (in thousands):

12/31/03 INTEREST EXPENSE, NET OF INTEREST INCOME	12/31/02 INTEREST EXPENSE, NET OF INTEREST INCOME	12/31/03-12/31/02 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE ($)	12/31/03-12/31/02 INTEREST EXPENSE, NET OF INTEREST INCOME CHANGE (%)
$ 5,976	$ 4,713	$1,263	27%

The increase in interest expense, net of income reflects interest expense on the Company's convertible debenture financing completed in December, 2002 and the Company's bridge financings completed during the 2003.

Amortization of Deferred Debt Discount and Private Debt Offering Costs

The Company's deferred debt discount and private debt offering costs for the year ended December 31, 2003 and December 31, 2002 were as follows (in thousands):

12/31/03 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	12/31/02 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS	12/31/03-12/31/02 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE ($)	12/31/03-12/31/02 DEFERRED DEBT DISCOUNT AND PRIVATE DEBT OFFERING COSTS CHANGE (%)
$24,771, consisting of • $ 1,099 private debt offering costs • $ 23,672 deferred debt discount	$12,558, consisting of • $ 751 private debt offering costs • $ 11,807 deferred debt discount	$ 12,213	97%

The Company incurred offering costs associated the issuance of certain convertible debentures and bridge financings in 2003, 2002 and 2001. Additionally, these offerings included warrants and beneficial conversion features which were valued using the Black-Scholes valuation model. The value of the warrants, private offering costs and beneficial conversion features are amortized over the life of the underlying debentures and notes

Net Loss

The Company's net loss for the year ended December 31, 2003 and December 31, 2002 was as follows (in thousands):

12/31/03 NET LOSS	12/31/02 NET LOSS	12/31/03-12/31/02 NET LOSS CHANGE ($)	12/31/03-12/31/02 NET LOSS CHANGE (%)
($ 48,455)	($ 59,589)	$ 10,134	17%

In 2002, the Company recorded a charge to earnings recorded as loss on the extinguishment of debt of $28,415,000 as a result of the Company's 2002 debenture offering. The loss consists of the following amounts: 1) $11,985,000, representing the fair value of 10,700,665 warrants, as calculated using the Black-Scholes option-pricing model, that the Company issued to Watson Pharmaceuticals, Inc. ("Watson") in consideration of Watson's extension of the maturity date of the Watson Term Loan; 2) $2,282,000, representing the fair value of the shares of Common Stock issued on the exercise of 8,145,736 Common Stock Purchase Warrants in excess of the number of shares that would have been issued as a result of a modification of the Warrants' net shares settlement provisions; and 3) $14,148,000, representing the incremental increase in the fair value of the remaining Warrants issued as part of the Company's debenture offerings completed in 1998 and 1999 as a result of reducing their exercise price in connection with the modification of the associated debt agreements, as calculated using the Black-Scholes option-pricing model.

Liquidity and Capital Resources

At December 31, 2004, the Company had cash and cash equivalents of $3.1 million as compared to $942,000 at December 31, 2003. The Company had working capital of $2.4 million at December 31, 2004 as compared to a working capital deficit of $3.8 million at December 31, 2003.

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. As the conversion price of the 2004 Debentures was less than the fair market value of the Company's Common Stock on the date of issue, beneficial conversion features were determined to exist. The Company recorded approximately $14.0 million of debt discount limited to the face amount of the new debt. The debt discount was amortized over the life of the debt, which matured on August 13, 2004, the date the 2004 Debentures were automatically converted into the Company's Series A Convertible Preferred Stock.

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. The Series A Preferred shares and the Junior Preferred Shares are convertible into an aggregate of approximately 349.7 million shares of the Company's Common Stock. Reference is made to "Item 1-Business-Recent Events-2004 Debenture Offering" for a more detailed description of the 2004 Debenture Offering, the conversion of the outstanding debentures into preferred shares and the rights and preferences of the Series A Preferred shares and the Junior Preferred Shares.

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 first lien on all of the Company's and its subsidiaries' assets, senior to the lien securing the Outstanding Debentures and all other Company indebtedness, 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.

Sale of Certain Company Assets

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 the Purchase Agreement, the Company and Axiom agreed to sell to IVAX substantially all of the Company's assets used in the operation of the Company's former generic manufacturing and packaging operations located in Congers, New York in consideration of an immediate payment of $2.0 million and an additional payment $0.5 million upon receipt of shareholder approval of the transaction. Shareholder approval of the asset sale transaction with IVAX was obtained on August 12, 2004 and the closing was completed on August 13, 2004, at which time the Company received the remaining payment of $0.5 million from IVAX.

Commercial Focus, Cash Reserves and Funding Requirements

As of February 25, 2005, the Company had cash and cash equivalents of approximately $2.5 million. 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. Currently the Company is suspending 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").

As restructured, the Company is no longer engaged in the manufacture and sale of finished dosage generic pharmaceutical 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 will be sufficient to fund the development of the Aversion ™ Technology and related operating expenses through May, 2005. To fund operations through March, 2006, the Company estimates that it must raise additional financing, or enter into alliances or collaboration agreements with third parties providing for net proceeds to the Company of at least $5 million. 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 requirements for contractual obligations outstanding as of December 31, 2004:

	TOTAL	DUE IN 2005	DUE IN 2006	DUE IN 2007	DUE THEREAFTER
			(IN THOUSANDS)		
Term loan payable	5,000			5,000	—
Capital leases	93	29	32	—	7
Operating leases	34	29	5	—	—-
Contract research obligations	93	93	—	—	—
Employment agreements	765	640	125	—	—
Total Contractual Cash Obligations	$ 5,985	$ 791	$ 162	$ 5,025	$ 7

Critical Accounting Policies

Financial Reporting Release No. 60, which was released by the Securities and Exchange Commission ("SEC") in December 2001, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. 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 great 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 deferred 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 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. If the Company were to include the cost of stock-based employee compensation in the financial statements, the Company's operating results would decline based on the fair value of the stock-based employee compensation.

Deferred Debt Discount

Deferred debt discount results from the issuance of stock warrants and beneficial conversion features in connection with the issuance of subordinated debt 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 and the expected dividend yield.

New Accounting Pronouncements

Consolidation of Variable Entities

In January 2003, the Financial Accounting Standards Board ("FASB"), issued FASB Interpretation of FIN No. 46, "Consolidation of Variable Entities," (VIEs). FIN 46 establishes standards for determining under what circumstances VIEs should be consolidated with their primary beneficiary, including those to which the usual condition of consolidation does not apply. FIN 46 also requires disclosure about unconsolidated VIEs in which the company has a significant interest. The consolidation requirements of FIN 46 apply immediately to older entities the first fiscal year or interim period beginning after June 15, 2003. certain disclosures requirements apply in all financial statements issued after January 31, 2003. The adoption of the accounting pronouncement did not have an impact on our financial position or results of operations.

In December 2003, the FASB publishes FIN No. 46-R, Consolidation of Variable Entities (revised December 2003)," superseding Fin 46, and exempting certain entities from the provisions of FIN 46. Generally, application of FIN 46-R is required in financial statements of nonpublic entities immediately to VIEs or potential VIEs created after December 31, 2003 and for all entities by the beginning of the first annual period beginning after December 31, 2004." The adoption of the accounting pronouncement did not have an impact on our financial position or results of operations.

Accounting for Certain Financial Instruments with the Characteristics of Both Liabilities and Equity

FASB issued Statement No. 150, "Accounting for Certain Financial Instruments with the Characteristics of Both Liabilities and Equity", in June 2003. The Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires an issuer to classify a financial instruments that is within the scope of the pronouncement as a liability. Many of those financial instruments were previously classified as equity. The statement is effective for all financial instruments entered into or modified after May 2003 and otherwise shall be effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of the accounting pronouncement did not have an impact on our financial position or results of operations.

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 interim or annual period that begins after June 15, 2005. This Statement applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date. The cumulative effect of initially applying this Statement, if any, is recognized as of the required effective date. The Company has not completed it evaluation of the impact of adopting FASB 123R on its consolidated financial statements, but anticipates that more compensation costs will be recorded in the future if the use of options for employees and director compensation continues as in the past.

Capital Expenditures

The Company's capital expenditures during 2004, 2003 and 2002 were $444,000, $412,000 and $287,000, respectively. The capital expenditures during these periods are attributable to capital improvements to the Company's Congers, NY and Culver, Indiana facilities. In connection with the Company's prosecution of its Import Registration with the DEA, specific improvements were made for security and related items to the Culver, Indiana facility. Additionally, expenditures were made to improve and expand the manufacturing capabilities of both Congers, NY locations.

Impact of Inflation

The Company believes that inflation did not have a material impact on its operations for the periods reported. Significant increases in labor, employee benefits and other expenses could have a material adverse effect on the Company's performance. 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.

Risk Factors Relating To The Company

The Company Received a "Going Concern" Opinion From Its Independent Auditors, 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 since 1992, including net losses of approximately $70.0 million for the year ended December 31, 2004 and net losses of $48.5, $59.6 and $12.5 million for fiscal 2003, 2002 and 2001, respectively. As of December 31, 2004 our accumulated deficit was approximately $279.5 million. The Company's consolidated financial statements for the year ended December 31, 2004 and 2003 have been prepared on a going-concern basis, expressing substantial doubt about the Company's ability to continue as a going concern as a result of recurring losses and negative cash flows. Our future profitability will depend on several factors, including:

- the successful completion of the formulation development, clinical testing and acceptable regulatory review of our Aversion™ Technology;
- the receipt of a notice of allowance and issued patent from the US Patent and Trademark Office ("PTO") for the material claims in our patent application relating to the Aversion™ Technology;
- the Aversion™ Technology not infringing third-party patents or other intellectual property rights;
- the completion of the development, commercial scale up and acceptable regulatory review of our opioid active pharmaceutical ingredient manufacturing process technology (the "Opioid Synthesis Technologies");
- the receipt of approval from the U.S. Drug Enforcement Administration ("DEA") to import narcotic raw materials to be used in our development and manufacturing efforts; and
- the interest of qualified third parties in our Aversion ™ Technology and our Opioid Synthesis Technologies (collectively the "Technologies") and our ability to negotiate and execute commercially viable collaboration agreements with qualified third parties relating to the Technologies.

Many of these factors will depend on circumstances beyond our control. 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 capital are substantial and will depend on many factors, including:

- the expenses incurred in the development and commercialization of products incorporating our Technologies;
- the structure of any future collaborative or development agreements relating to the Technologies, including the timing and amount of payments, if any, that may be received under possible future collaborative agreements;
- our ability to develop additional products utilizing the Technologies;
- our ability to negotiate agreements with third parties for development, marketing, sale and distribution of products utilizing our Technologies;
- the prosecution, defense and enforcement of patent claims and other intellectual property rights relating to the Technologies; and
- the commercialization of products incorporating our Technologies without infringing third-party patents or other intellectual property rights.

We currently have no committed sources of capital. We anticipate that our existing capital resources will be sufficient to fund operations only through May, 2005. To fund operations through March, 2006, the Company estimates that it must raise additional financing, or enter into alliances or collaborative agreements with third parties providing for net proceeds to the Company of at least $5 million. 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 Technologies, or otherwise enters into alliances or collaborative agreements relating to the Technologies, 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 Capital Resources, Third Party Financing, and Technology Licensing Fees to Fund Operations

Pending the completion of the development and commercial scale up of our Technologies, and the receipt of regulatory approval of products incorporating our Technologies, of which no assurance can be given, the Company must rely on its current capital resources, third-party financing and technology licensing fees to fund the Company's operations. As a consequence of the restructuring of our operations, including the cessation of our finished dosage manufacturing and packaging operations at our former Congers, NY facilities and the sale of such assets and related generic products to third parties, we have no ability to generate revenues from the sale of generic products. As of February 25, 2005, we had cash and cash equivalents of approximately $2.5 million. No assurance can be given that such cash resources will be sufficient to fund the continued development of our Technologies until such time as we generate revenue from the license of products incorporating the Technologies to third parties. Moreover, in the event of a cash shortfall, 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 Technologies, or products incorporating such Technologies, may be commercialized.

Our Product Candidates Are Based on Technologies That Could Ultimately Prove Ineffective

In accordance with the restructuring of the Company's operations, the Company has transitioned to a single operations facility located in Culver, Indiana. At such site, the Company will seek to develop its proprietary Aversion™ Technology and Opioid Synthesis Technologies. With respect to the Aversion™ Technology, the first product candidate ("Product Candidate #1") resulting from the Aversion™ Technology is a tablet formulation intended for oral administration. Six month real time stability data for Product Candidate #1 are satisfactory. However, the Company can provide no assurance that the stability of Product Candidate #1 will result in a commercially acceptable drug product with at least 24 months of acceptable stability data. In addition, Product Candidate #1 was evaluated in a single dose clinical study to assess the bio-availability and bio-equivalence ("BA/BE") of such product candidate in comparison to a frequently prescribed commercially marketed drug product with the same opioid active ingredient but without abuse deterrent properties. The results of the BA/BE study indicate that Product Candidate #1 is sufficiently bioavailable but not bioequivalent to the reference commercially marketed opioid product. The Company subsequently developed a more discriminating dissolution test methodology and a revised formulation of Product Candidate #1 ("Product Candidate #1R"). Based on an additional BA/BE study, we confirmed that Product Candidate #1R is both bioavailable and bioequivalent to a commercially marketed product without the abuse deterrent properties. The Company has additionally formulated another product candidate ("Product Candidate #2") incorporating the Aversion™ Technology and contemplates submitting an IND or an IND amendment with the FDA for Product Candidate #2 during the first half of 2005. Since the formulation of Product Candidate #2, the Company has suspended all new development activities for Product Candidate #1 and Product Candidate #1R and will focus future development activities on Product Candidate #2. Substantial additional clinical and non-clinical testing will be required to continue development and for the preparation and submission of a new drug application ("NDA") filing with the FDA. There can be no assurance that Product Candidate #2 or any other product developed using the Aversion™ Technology will lead to a NDA submission to the FDA and that if an NDA is filed, that the FDA will approve such regulatory application to allow for commercial distribution of the product.

With respect to the Opioid Synthesis Technologies, while the Company believes that such technologies are effective and cost-effective methods of manufacturing opioid APIs, such technologies will need to be scaled up to commercial scale to have economic value, of which no assurance can be given. Additionally, unless the Company secures third-party financing dedicated to the scale up expenses relating to the Opioid Synthesis Technologies (estimated by the Company to be at least $7.0 million), the Company will be unable to complete the commercial scale up of the Opioid Synthesis Technologies. No assurance can be given that the Company will obtain the third-party financing necessary to scale up the Opioid Synthesis Technologies or, if such financing is obtained, that any one or more of the Opioid Synthesis Technologies will be capable of commercial scale up. The Company is currently suspending further development and commercialization efforts relating to the Opioid Synthesis Technologies (See "Item 1 - Business - Opioid Synthesis Technologies").

The Company is committing substantially all of its resources and available capital to the development of the Aversion™ Technology and the prosecution of its patent applications for such Technologies. The failure of the Company to successfully develop the Aversion™ Technology, to successfully obtain an issued patent from the PTO relating to the Aversion™ Technology and product candidates utilizing the Aversion™ Technology, and to avoid infringing third-party patents and intellectual property rights in the commercialization of such Aversion™ Technology will have a material adverse effect on the Company's operations and financial condition.

If Pre-clinical Testing or Clinical Trials For Our Product Candidates Are Unsuccessful or Delayed, We Will Be Unable to Meet Our Anticipated Development and Commercialization Timelines.

To obtain FDA approval for any of our product candidates, we must submit to the FDA an NDA demonstrating, among other things, that the product candidate is safe and effective in humans for its intended use. This demonstration requires significant research and animal tests, which are referred to pre-clinical studies, as well as human tests, which are referred to as clinical trials. As we do not possess the resources or employ all the personnel necessary to conduct clinical trial studies, it is our intention to rely on collaborative partners to conduct Phase II and Phase III clinical trials on our product candidates. As a result, we will have less control over the timing and other aspects of these clinical trials than if we performed the monitoring and supervision of clinical trials entirely on our own. Third parties may not perform their responsibilities for our pre-clinical testing or clinical trials on our anticipated schedule or, for clinical trials, consistent with a clinical trial protocol. Delays in pre-clinical and clinical testing 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 clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient pre-clinical safety data required to obtain regulatory approval to commence a clinical trial;
- reaching agreement 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 a number of 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 resulting in the imposition of a clinical hold;
- lack of adequate funding to continue clinical trials; and/or
- negative results of clinical trials.

Phase III clinical trials, where required by the FDA for commercial approval of the Company's Product Candidates, may not demonstrate the safety or efficacy of our product candidates. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. Even if the results of our pivotal Phase III clinical trials are positive, we and our 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 final FDA approval for our product candidates.

Clinical trials are often very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. Further, if participating patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we, our collaborative partner or the FDA believes that participating patients are being exposed to unacceptable health risks, our collaborative partner may have to suspend the clinical trials. Failure can occur at any stage of the trials, and our collaborative partner could encounter problems that cause 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 product 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 could delay the development of other product candidates.

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 products, 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 Technologies and further develop, register and commercialize multiple formulations and strengths of orally administered opioid-containing finished dosage products utilizing such Technologies. We expect to receive a share of profits and/or royalty payments derived from such collaborative partners' sale of products incorporating the 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 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 pain management products, it may be necessary for us to license all or significant portion of our product candidates to a single collaborator, thereby eliminating our opportunity to commercialize other pain management products with other collaborative partners.

The Market May Not Be Receptive to Products Incorporating Our Technologies

The commercial success of products incorporating our Technologies that are approved for marketing by the FDA and other regulatory authorities will depend upon their acceptance by the medical community and third party payors as clinically useful, cost-effective and safe. There can be no assurance given, even if we succeed in the development of products incorporating our Technologies and receive FDA approval for such products, that our products incorporating the Technologies would be accepted by the medical community and others. Factors that we believe could materially affect market acceptance of these products include:

- the relative advantages and disadvantages of our Technologies and timing to commercial launch of products utilizing our Technologies compared to products incorporating competitive technologies;
- the timing of the receipt of marketing approvals and the countries in which such approvals are obtained;
- the safety and efficacy of products incorporating our Technologies as compared to competitive products; and/or
- the cost-effectiveness of products incorporating our Technologies and the ability to receive third party reimbursement.

Our product candidates, if successfully developed, will compete with a number of products manufactured and marketed by other brand focused pharmaceutical companies, biotechnology companies and manufacturers of generic products. Our products may also compete with new products currently under development by others. Physicians, patients, third-party payors and the medical community may not accept or utilize any of our product candidates. Physicians may not be inclined to prescribe the products utilizing the Aversion™ Technology unless our products bring substantial and demonstrable advantages over other products currently marketed for the same indications. If our products do not achieve market acceptance, we will 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 Medicare.

We cannot predict the availability of reimbursement for newly-approved health care products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. 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 we bring to market, doctors may not prescribe them or patients may ask to have their physicians 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 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, both 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. Although we have filed four (4) patent applications with the PTO and one (1) foreign patent application on our Aversion ™ Technology, there is no assurance that a patent will issue or, if issued, that such patent will be valid and enforceable against third party infringement or that such patent 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 Technologies. 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 or 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:

- we may initiate litigation or other proceedings against third parties to enforce our patent rights or other intellectual property rights;

- 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;

- if our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention; and

- if third parties initiate litigation claiming that our 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. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

Our Technologies may be found to infringe upon claims of patents of 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 Technologies 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 Technologies 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. For example, the Company has recently become aware of certain United States and European patent applications owned by third parties that claim multiple-form 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 in order to commercialize products incorporating the Aversion™ Technology, 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 the Company's Aversion™ Technology will not infringe third-party patents.

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 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 an NDA, a 502(b)(2) application, 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) 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 Company's Technologies.

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 (GMP) 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.

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 chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. 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 Obtain Required DEA Approval for Our Narcotic Raw Materials Import Registration

Our business strategy focuses on the development of opioid containing products incorporating the Technologies. The development, marketing and sale of products incorporating the Technologies is subject to extensive regulation by the DEA and FDA. At present, the Company's facility located in Culver, Indiana is approved by the DEA to manufacture DEA controlled substance active pharmaceutical ingredients ("APIs") and finished dosage products incorporating such API's. We are seeking to obtain a registration from the DEA to import narcotic raw materials ("NRMs") and have been engaged in the application process seeking approval to import NMRs directly from foreign countries for use in our opioid API manufacturing efforts since early 2001.

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. Furthermore, our cash flow and limited sources of available financing make it uncertain that the Company will have sufficient capital to re-initiate the development of the Opioid Synthesis Technologies, to obtain required DEA approvals and to fund the capital improvements necessary for the commercial manufacture of APIs and finished dosage products incorporating the Opioid Synthesis Technologies.

We Must Obtain FDA Approval to Manufacture Our Products at Our Facilities; Failure to Obtain FDA Approval and Maintain Compliance with FDA Requirements May Prevent or Delay the Manufacture of Our Products 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™ 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 (cGMPs) regulations as interrupted 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 obtain. Our Culver, Indiana facility, as well as those of any third-party manufacturers that we may use, are periodically subject to inspection by the FDA and other governmental agencies, and operations at these facilities could be interrupted or halted if such inspections are unsatisfactory.

Failure to comply with FDA or other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production or distribution, suspension of FDA review of our products, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution.

We Face Significant Competition, Which May Result in Others Discovering, 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 opioid analgesics already approved or in development. In addition, many of these competitors either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources then we do as well as significantly greater experience in developing products, conducting pre-clinical testing and human clinical trials, obtaining FDA and other regulatory approvals, formulating and manufacturing drugs, and commercializing drugs.

We will be concentrating all of our efforts on the development of the Technologies. The commercial success of products using our Technologies will depend, in large part, on the intensity of competition from branded opioid containing products, generic versions of branded opioid containing products and other drugs and technologies that compete with the products incorporating our Technologies, as well as the timing of product approval.

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 addition, the opioid active ingredients in all of our product candidates are readily available for use in generic products. Companies selling generic opioid containing products may represent substantial competition. Most of these organizations competing with us have substantially greater capital resources, larger research and development staff and facilities, greater experience in drug development and in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do.

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 May Be Exposed to Product Liability Claims and May Not Be Able to Obtain Adequate Product Liability Insurance

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Product liability claims might be made by consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or that otherwise possess regulatory approval for commercial sale.

We are currently covered by clinical trial product liability insurance in the amount of $1.0 million per occurrence and $3.0 million annually in the aggregate 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 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.

In addition, since the Company's delisting from the American Stock Exchange in September 2000, the Company's common stock has been traded 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 guaranty 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.

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

Galen Partners beneficially owns in excess of an aggregate of approximately 48% of the Company's common stock (after giving effect to the conversion of outstanding common stock purchase warrants held by Galen Partners). In addition, pursuant to the terms of the Amended and Restated Voting Agreement dated February 6, 2004, between the Company and the holders of the Company's outstanding convertible preferred stock, all holders of the Company's convertible preferred stock have agreed that the Board of Directors shall be comprised of not more than 7 members, 4 of whom shall be the designees of each of Care Capital Investments II, LP, Essex Woodlands Health Venture V, L.P. and Galen Partners. Each of Care Capital, Essex Woodlands and Galen Partners has the right to designate one member of the Company's Board of Directors and each of such investors collectively may designate one additional member to the Board. As a result, Galen Partners, in view of its ownership percentage of the Company, and each of Care Capital, Essex Woodlands and Galen Partners, by virtue of their controlling positions 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 Care Capital, Essex Woodlands and Galen Partners may not always coincide with the interests of other shareholders and such entities may take action in advance of their 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 our of management and scientific team, particularly Andrew Reddick, our President and Chief Executive Officer, and Ron 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. We are not aware of any present intention of any our key personnel to leave our Company or to retire. However, while we have employment agreements with certain of our employees, all of our employees are at-will employees who may terminate their employment at any time. We do not currently 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 research, development and business objectives and could materially aversely affect our business, financial condition and results of such operations.

We Expect That 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.

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 $5.0 million senior term loan and the Investor Rights Agreement with the holders of the Company's convertible preferred stock, 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 and commercialization of its products.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing 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, government and non-government debt securities and/or money market funds that invest in such securities. We have no holdings of derivative financial or commodity instruments. As of December 31, 2004, our investments consisted primarily of short-term bank commercial paper and checking funds with variable, market rates of interest.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The response to 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

On October 21, 2004, the Company notified Grant Thornton LLP ("Grant Thornton") of its decision to dismiss Grant Thornton as its independent auditor. BDO Seidman, LLP ("BDO Seidman") was selected to replace Grant Thornton as the Company's independent auditor for the fiscal year ending December 31, 2004. The decision to dismiss Grant Thornton and to select BDO Seidman, which was made to reduce the cost of compliance with SEC accounting rules, was approved by the Company's Audit Committee of the Board of Directors on October 21, 2004 and subsequently approved by the Company's Board of Directors with an effective date of October 22, 2004.

Grant Thornton's audit reports on the consolidated financial statements of the Company and its subsidiaries as of and for the years ended December 31, 2003 and December 31, 2002, respectively, did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles, except to the extent that, as discussed in the former accountant's report, the Company has suffered significant losses and negative cash flows from operations which raised substantial doubt about its ability to continue as a going concern. The Company's financial statements do not include any adjustments that might result from the outcome of this uncertainty.

During the Company's two most recent fiscal years and in the subsequent interim period through October 21, 2004, the Company did not have any disagreements with Grant Thornton on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreements, if not resolved to Grant Thornton's satisfaction would have caused it to make reference to the subject matter of the disagreements in connection with its reports.

During the Company's two most recent fiscal years and in the subsequent interim period through October 21, 2004, there were no "reportable events" as defined in Regulation S-K, Item 304(a)(1)(v).

At the Company's request and after providing Grant Thornton with a copy of the disclosures contained in this Item 9, Grant Thornton provided the Company with a letter addressed to the SEC stating that it agrees with the statements made by the Company in this Item 9.

During the Company's fiscal years ended December 31, 2003 and 2002, and the subsequent interim period through October 21, 2004, neither the Company nor someone acting on the Company's behalf consulted BDO Seideman regarding (i) the application of accounting principles to a specified transaction either completed or proposed, (ii) the type of audit opinion that might be rendered on the Company's financial statements, or (iii) any matter that was either the subject of a disagreement (as defined in Regulation S-K, Item 304(a)(1)(iv)), or a "reportable event" (as defined in Regulation S-K, Item 304(a)(1)(v)).

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. The Company carried out an evaluation as of December 31, 2004, 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. Disclosure controls and procedures are those controls and other procedures that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. 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 consolidated 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:

NAME	AGE	POSITION
Jerry Karabelas	52	Chairman of the Board
Andrew D. Reddick	52	President, Chief Executive Officer and Director
Ron J. Spivey	58	Senior Vice President and Chief Scientific Officer
Peter A. Clemens	52	Senior Vice President, Chief Financial Officer and Secretary
James Emigh	49	Vice President of Marketing and Administration
Robert Seiser	41	Vice President, Corporate Controller and Treasurer
Bruce F. Wesson	62	Director
William A. Sumner	67	Director
William Skelly	54	Director
Immanuel Thangaraj	34	Director

Jerry Karabelas has been a Director of the Company since December, 2002 and Chairman of the Board since May 2003. 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.

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. and he served as Executive Vice President Marketing, Sales & Business Development with Purepac Pharmaceuticals from August, 1996 to June, 1999. 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. Additionally, Dr. Spivey has served in a number of senior level scientific and leadership positions at Zenith Goldline Pharmaceuticals, Cima Labs Inc., Marion Merrell Dow, Burroughs Wellcome Company and Warner Chilcott Division of Warner Lambert. 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. From February, 1988 until joining the Company, Mr. Clemens was employed by TC Manufacturing Co., Inc. ("TC") which, through its various subsidiaries and divisions, manufactures generic pharmaceuticals, industrial coatings and flexible packaging. Mr. Clemens was TC's President from February, 1996 through February, 1998. Prior to that time, he held the position of Vice President and Chief Financial Officer. 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 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. From 1991 until joining the Company, Mr. Emigh was employed by Organon, Inc., a pharmaceutical company, in various management positions and most recently as its Director of Managed Care and Trade Relations. Mr. Emigh holds a Bachelor of Pharmacy from Washington State University and a Masters of Business Administration from George Mason University.

Robert Seiser has been a Vice President, Corporate Controller and Treasurer since April 2004. Prior to such time, Mr. Seiser was Corporate Controller and Treasurer. From 1992 until joining the Company in March 1998, Mr. Seiser served as Treasurer and Corporate Controller of TC Manufacturing Co., Inc., a privately held company based in Evanston, Illinois. 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 Crompton 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.

William 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 Biomedia, 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 also worked as an Associate for ARCH Venture Partners, LP and managing one of its portfolio companies, a medical information technology company. 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 independent auditors, 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 2004, 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. While Messrs. Wesson and Thangaraj do not satisfy the standards for independence set forth in the American Stock Exchange Listing Standards as a result of the controlling interest 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, 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

The Company does not have a standing nominating committee. Currently the Board of Directors functions as the Company's nominating committee. The Board performs 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 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 size of the Company and the Board, to ensure that candidates are appropriately evaluated and selected. The Board also believes that, given the Company's 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. For these reasons, the Board believes it is not appropriate to have a nominating committee.

The Board's process for recruiting and selecting nominees for Board members is to attempt to identify individuals who are thought to have the business background and experience, industry specific knowledge and general reputation and expertise that would allow them to contribute as effective directors to the Company's governance, and who are 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 is sounded out concerning his/her possible interest and willingness to serve, and Board members discuss amongst themselves the individual's potential to be an effective Board member. If the discussions and evaluation are positive, the individual will 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. However, the Board believes its process for evaluation of nominees proposed by shareholders would be no different from 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 which appears on 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 adopted a Code of Ethics that applies to the Company's principal executive officer, principal financial officer and principal accounting officer. The Code of Ethics is available on the Company's website @ www.acurapharm.com under the caption "Legal". Any amendments to or waivers from the Code of Ethics will be posted on the Company's website under the caption "Legal".

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, 2003, except that Essex Woodlands Health Ventures V, L.P. filed on Form 3 late and Mr. Thangaraj filed three Form 4s 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, 2004, 2003 and 2002 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 2004 exceeded $100,000:

SUMMARY COMPENSATION TABLE

		ANNUAL COMPENSATION			LONG TERM COMPENSATION	
NAME AND PRINCIPAL POSITION	YEAR	SALARY	BONUS	OTHER ANNUAL COMPENSATION	SECURITIES UNDERLYING STOCK OPTIONS	ALL OTHER COMPENSATION
Andrew D. Reddick	2004	$ 305,769	$ 60,000	—	8,750,000	—
President and Chief	2003	96,923	0	—	—	—
Executive Officer	2002	-0-	0	—	—	—
Ron J. Spivey	2004	190,000	0	—	3,000,000	—
Senior Vice President and	2003	-0-	0	—	—	—
Chief Scientific Officer	2002	-0-	0	—	—	—
Peter A. Clemens	2004	181,789	60,000	—	375,000	—
Senior Vice President and	2003	155,000	60,000	—	—	—
Chief Financial Officer	2002	155,000	0	—	—	—
Vijai Kumar[1]	2004	187,539	0	—	200,000	—
Chief Operations Officer	2003	180,000	0	—	—	—
	2002	18,000	0	—	400,000	—
James Emigh	2004	141,892	50,000	—	249,000	—
Vice President Marketing	2003	132,000	0	—	—	—
and Administration	2002	132,000	0	—	—	—

(1) Mr. Kumar's services as Chief Operations Officer ceased effective November 17, 2004.

Other Compensatory Arrangements

Executive officers and key employees participate in medical and disability insurance plans provided to all employees of the Company.

Employment Agreements

Andrew D. Reddick is employed pursuant to an Employment Agreement effective as of August 26, 2003, which provides that Mr. Reddick will serve as the Company's Chief Executive Officer and President for an initial term expiring August 26, 2005. 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 thirty-five percent (35%) 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. Mr. Reddick received a bonus of $60,000 in fiscal 2004. In accordance with the terms of the Employment Agreement, as amended, the Company granted to Mr. Reddick 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 permits the Company to purchase the vested portion of Mr. Reddick's options upon his termination for Cause (as defined in the Employment Agreement) or his resignation other than for Good Reason (as defined in the Employment Agreement) at a purchase price equal to the positive difference, if any, between (i) the average of the closing bid and asked prices of the Company's Common Stock for the five trading days prior to the date of termination or resignation, and (ii) the exercise price of the option shares, multiplied by the numbers shares which, as of the date of termination or resignation, are vested under the stock option. 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 to exercise Mr. Reddick's vested stock options. 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 the greater of (i) the remainder of the initial term of the Employment Agreement, and (ii) 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 a term equal to the greater of (i) the remainder of the initial term of the Employment Agreement, or (ii) 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 of 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, which provides that Dr. Spivey will serve as the Company's Senior Vice President and Chief Scientific Officer for term expiring April 4, 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 thirty-five percent (35%) 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. In accordance with the terms of the Employment Agreement, the Company granted to Dr. Spivey stock options exercisable for up to 3,000,000 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 with the remaining balance vesting in quarterly increments of 333,333 shares at the expiration of each quarterly period commencing with the quarterly period ending December 31, 2004. The Employment Agreement permits the Company to purchase the vested portion of Dr. Spivey's options upon his termination for Cause (as defined in the Employment Agreement) or his resignation other than for Good Reason (as defined in the Employment Agreement) at a purchase price equal to the positive difference, if any, between (i) the average of the closing bid and asked prices of the Company's Common Stock for the five trading days prior to the date of termination or resignation, and (ii) the exercise price of the option shares, multiplied by the number of shares which, as of the date of termination or resignation, are vested under the stock options. 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, Dr. Spivey or his designees shall have a period of twelve (12) months following such termination to exercise Dr. Spivey's vested stock options. 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 of 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, which after giving effect to amendments dated as of June 28, 2000, May 4, 2001 and January 5, 2005, provides that Mr. Clemens will serve as the Company's Senior Vice President and Chief Financial Officer for a term expiring April 30, 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. Mr. Clemens received a bonus of $60,000 in each of fiscal 2004 and 2003. 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. Such stock options vest in equal quarterly increments at the end of each annual period commencing March 9, 2005. The Employment Agreement permits the Company to repurchase the vested portion of Mr. Clemens' options upon his termination for Cause (as defined in the Employment Agreement) or his resignation (other than for Good Reason as defined therein), at a purchase price equal to the positive difference, if any, between (i) the average of the closing price of the Company's common stock for the five trading days prior to the date of termination or resignation, and (ii) the exercise price of the option shares, multiplied by the number of option shares which, as of the date of termination, are vested under the option. 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. The Employment Agreement permits Mr. Clemens to terminate the Employment Agreement in the event of a Change of Control (as defined in the Employment Agreement) and for Good Reason. The Employment Agreement also restricts Mr. Clemens from disclosing, disseminating or using for his personal benefit or for the benefit of others confidential or proprietary information (as defined in the Employment Agreement) and, provided 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.

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 will 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. In September, 1995, the Company established the 1995 Halsey Drug Co., Inc. Stock Option and Restricted Stock Purchase Plan (the "1995 Stock Option Plan"). Under the 1995 Stock Option Plan, the Company may grant options to purchase up to 1,000,000 shares of the Company's Common Stock. Incentive Stock Options ("ISO's") may be granted to employees of the Company and its subsidiaries and non-qualified options may be granted to employees, directors and other persons employed by, or performing services for, the Company and its subsidiaries. Subject to the 1995 Stock Option Plan, the Stock Option Committee determines the persons to whom grants are made and the vesting, timing, amounts and other terms of such grants. 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.

As of February 1, 2005, ISO's to purchase 540,705 shares and non-qualified options to purchase 106,390 shares have been granted under the 1995 Stock Option Plan, leaving 212,445 shares available for grant under the Plan. The average per share exercise price for all outstanding options under the 1995 Stock Option Plan is approximately $1.46. No exercise price of an ISO was set at less than 100% of the fair market value of the underlying Common Stock, except for grants made to any person who owned stock possessing more than 10% of the total voting power of the Company, in which case the exercise price was set at not less than 110% of the fair market value of the underlying Common Stock.

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 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. 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. As of February 1, 2005, stock options to purchase 16,851,820 shares of Common Stock had been granted under the 1998 Stock Option Plan. Of such option grants, 624,519 are ISOs and 16,227,301 are non-qualified options. The average per share exercise price for all outstanding options under the 1998 Stock Option Plan is approximately $ .40. No exercise price of an ISO was set at less than 100% of the fair market value of the underlying Common Stock, except for grants made to any person who owned stock possessing more than 10% of the total voting power of the Company, in which case the exercise price was set at not less than 110% of the fair market value of the underlying Common Stock. The exercise price of non-qualified options exercisable for 13,375,145 shares of common stock has been set at less than the fair market value of the underlying Common Stock. Subject to the terms of the 1998 Stock Option Plan, the Stock Option Committee 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.

Securities Authorized For Issuance Under Equity Compensation Plans

The following table includes information as of December 31, 2004 relating to the Company's 1995 Stock Option Plan and 1998 Stock Option 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 under such plans, the weighted-average exercise price of such 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)
Equity Compensation Plans Approved by Security Holders	17,498,915	$ .44	3,338,625
Equity Compensation Plans Not Approved by Security Holders	0	0	0
TOTAL	17,498,915	$ .44	3,338,625

OPTION GRANTS IN 2004

The following table presents information regarding grants of options to purchase shares of the Company's common stock for each of the named executive officers receiving option grants in 2004.

	Individual Grants					
Name	Number of Securities Underlying Options Granted	Percent of Total Options Granted to Employees in Fiscal Year	Exercise Price Per Share (1)	Expiration Date	Potential Realizable value at Assumed Annual Rates of Stock Price Appreciation for Option Term(2)	
Andrew D. Reddick	8,750,000	65.4%	$ 0.13	2014	$ 5,066,250	$ 8,732,500
Ron J. Spivey	3,000,000	22.4%	$ 0.13	2014	1,737,000	2,994,000
Peter A. Clemens	375,000	2.8%	$ 0.13	2014	217,125	374,250
Vijai Kumar	200,000	1.5%	$ 0.13	2014	115,800	199,600
James Emigh	249,000	1.9%	$ 0.13	2014	144,171	248,502

(1) The stock options granted to Mr. Reddick provide for the vesting of 3,000,000 shares immediately upon the grant of the options, with the balance vesting in monthly increments 250,000 shares at the expiration of each monthly period commencing August 31, 2004. The stock options granted to Dr. Spivey provide for vesting of 1,000,000 shares on October 1, 2004, with the balance vesting in quarterly increments of 333,333 shares at the expiration of each quarterly period commencing with the quarterly period ending December 31, 2004. The remainder of the stock option grants provide for vesting in quarterly increments at the expiration of each annual period commencing with the quarterly period ending March 9, 2005.

(2) The dollar amounts in these columns represent the potential realizable value of each option 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 August 12, 2004 of $0.435 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

The following table presents information regarding the value of options outstanding at December 31, 2004 for each of the named executive officers.

	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT FISCAL YEAR END		VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS AT FISCAL YEAR END (2)	
NAME	EXERCISABLE	UNEXERCISABLE	EXERCISABLE	UNEXERCISABLE
Andrew D. Reddick	4,250,000	4,500,000	$ 1,168,750	$ 1,237,500
Ron J. Spivey	1,333,333	1,666,667	$ 366,667	$ 458,333
Peter A. Clemens	625,000	375,000	$ —	$ 103,125
Vijai Kumar[1]	400,000	200,000	$ 55,000	$ —
James Emigh	144,750	255,250	$ —	$ 68,475

(1) Mr. Kumar's services as Chief Operations Officer ceased effective November 17, 2004.

(2) Value is based upon the average of the closing bid and asked prices of $0.405 per share at December 31, 2004.

Compensation Committee Interlocks and Insider Participation

From January 1, 2004 through August 11, 2004 the Company's Compensation Committee consisted of Messrs. Wesson, Skelly and Thangaraj. From August 12, 2004 through December 31, 2004 the Company's Compensation Committee consisted of Messrs. Karabelas, Skelly and Reddick. During 2004, 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, 2005, 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 2004 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.

	SHARES OF COMMON STOCK ON AN AS-CONVERTED AND AS-EXERCISED BASIS		
NAME OF BENEFICIAL OWNER	AMOUNT OWNED(1)	PERCENT OF CLASS(2)	PERCENT OF CLASS(3)
Galen Partners III, L.P(4) 610 Fifth Avenue, 5th Floor New York, New York 10020	158,503,832(5)	87.9%	42.6%
Galen Partners International III, L.P(4) 610 Fifth Avenue, 5th Floor New York, New York 10020	15,372,245(6)	40.7%	4.1%
Oracle Strategic Partners, L.P(4) 200 Greenwich Avenue Suite 3 Greenwich, CT 06830-2506	24,640,794(7)	56.7%	6.6%
Essex Woodlands Health Ventures V, L.P.. c/o Essex Woodlands Health Ventures V, L.L.C. 190 South LaSalle Street, Suite 2800 Chicago, IL 60603	56,982,825(8)	72.0%	15.3%
Care Capital Investments II, LP (4) c/o Care Capital, L.L.C. Princeton Overlook One 100 Overlook Center, Suite 102 Princeton, New Jersey 08540	45,524,301(9)	67.2%	12.2%
Watson Pharmaceuticals, Inc 311 Bonnie Circle Corona, California 92880	10,700,665(10)	32.3%	2.9%
CI Mutual Funds CI Place 151 Young Street, 11th Flr. Toronto, Canada M5C 2W7	8,184,331(11)	26.7%	2.2%
Dennis Adams 120 Kynlyn Road Radnor, Pennsylvania 19103	5,085,141(12)	19.2%	1.4%
Hemant K. Shah and Varsha H. Shah 29 Christy Drive Warren, New Jersey 07059	2,962,157(13)	12.0%	*
Bernard Selz c/o Furman Selz 230 Park Avenue New York, New York 10069	2,632,909(14)	10.6%	*
Michael and Susan Weisbrot 1136 Rock Creek Road Gladwyne, Pennsylvania 19035	3,725,031(15)	14.7%	1.0%
Andrew D. Reddick	4,750,000(16)	17.5%	1.3%
Ron J. Spivey	1,666,666(17)	6.9%	*
William Skelly	376,000(18)	1.7%	*
Bruce F. Wesson	—	*	*
William A. Sumner	225,000(19)	*	*
Peter A. Clemens	1,034,073(20)	4.4%	*
Jerry Karabelas	—	*	*
Immanuel Thangaraj	—	*	*
Vijai Kumar	400,000(21)	1.7%	*
James Emigh	252,000(22)	1.1%	*
All Directors and Officers as a Group (11 persons)	8,510,740(23)	27.6%	2.3%

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

(1) The information with respect to Hemant K. Shah and Varsha H. Shah, Dennis Adams, Bernard Selz and Michael and Susan Weisbrot and Watson Pharmaceuticals, is based upon filings with the Commission and/or information provided to the Company.

(2) Shows percentage ownership assuming (i) such party converts all of its currently convertible securities or securities convertible within 60 days of February 1, 2005 into the Company's common stock, and (ii) no other Company securityholder converts any of its convertible securities.

(3) Shows percentage ownership assuming such party and all other securityholders of the Company convert all of their convertible securities into the Company's common stock.

(4) The following natural persons exercise voting, investment and dispositive rights over the Company's securities held of record by such entities:

(i) Galen Partners III, L.P. and Galen Partners International III, L.P. - William Grant, Bruce F. Wesson, L. John Wilkenson, Srini Conjeevaram, David W. Jahns and Zubeen Shroff;

(ii) Care Capital Investments II, LP - Jan Leschly, Argeris Karabelas and David Ramsay;

(iii) Essex Woodlands Health Ventures V, L.P. - Immanuel Thangaraj; and

(iv) Oracle Strategic Partners, L.P. - Larry N. Feinberg.

(5) Includes (i) 30,978,600 shares issuable upon conversion of Series A Preferred Shares, (ii) 6,170,157 shares issuable upon exercise of Series B Preferred shares, (iii) 100,801,521 shares issuable upon conversion of Series C Preferred shares, (iv) 19,476,890 shares issuable upon exercise of common stock purchase warrants , and (v) 425,000 shares subject to currently exercisable stock options.

(6) Includes (i) 2,803,960 shares issuable upon conversion of Series A Preferred Shares, (ii) 558,503 shares issuable upon exercise of Series B Preferred shares, (iii) 10,013,122 shares issuable upon conversion of Series C Preferred shares, and (iv) 1,971,555 shares issuable upon exercise of common stock purchase warrants.

(7) Includes (i) 20,991,333 shares issuable upon conversion of Series C Preferred Shares

(8) Includes (i) 33,909,751 shares issuable upon conversion of Series A Preferred Shares, (ii) 6,756,207 shares issuable upon conversion of Series B Preferred Shares, (iii) 15,593,247 shares issuable upon conversion of Series C Preferred Shares, (iv) 345,000 shares issuable upon exercise of common stock purchase warrants, and (v) 75,000 shares subject to currently exercisable stock options.

(9) Includes (i) 24,453,931 shares issuable upon conversion of Series A Preferred Shares, (ii) 6,303,874 shares issuable upon conversion of Series B Preferred Shares, (iii) 14,312,342 shares issuable upon conversion of Series C Preferred Shares, (iv) 150,000 shares issuable upon exercise of common stock purchase warrants, and (v) 75,000 shares subject to currently exercisable stock options

(10) Includes 10,700,665 shares issuable upon exercise of a common stock purchase warrant.

(11) Includes 8,184,331 shares issuable upon conversion of Series A Preferred Shares.

(12) Includes (i) 907,348 shares issuable upon conversion of Series A Preferred Shares, and (ii) 3,146,137 shares issuable upon conversion of Series C Preferred Shares.

(13) Includes 2,130,157 shares issuable upon conversion of Series C Preferred Shares.

(14) Includes 2,272,666 shares issuable upon conversion of Series C Preferred Shares.

(15) Includes 1,125,107 shares issuable upon conversion of Series A Preferred Shares and (ii) 1,777,862 shares issuable upon conversion of Series C Preferred Shares.

(16) Includes 4,750,000 shares subject to currently exercisable stock options.

(17) Includes 1,666,666 shares subject to currently exercisable stock options.

(18) Includes 365,000 shares subject to currently exercisable stock options.

(19) Includes 225,000 shares subject to currently exercisable stock options.

(20) Includes (i) 269,273 shares issuable upon conversion of Series C Preferred Shares, and (ii) 718,750 shares subject to currently exercisable stock options.

(21) Includes 400,000 shares subject to currently exercisable stock options.

(22) Includes 207,000 shares subject to currently exercisable stock options.

(23) Includes 8,408,690 shares which Directors and executive officers have the right to acquire within the next 60 days through the conversion of preferred shares and the 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 Over-the-Counter ("OTC") Bulletin Board. Based on the $0.6425 Conversion Price, 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). The 2004 Purchase Agreement also provides that the holders of the Series A Preferred shall have the right to vote as part of the single class with all holders of the Company's voting securities on all matters to be voted on by such security holders. Each holder of Series A Preferred shall have such number of votes as shall equal the number of votes he would have had if such holder converted all Series A Preferred held by such holder into shares of Common Stock immediately prior to the record date relating to such vote.

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 provides that each of Care Capital, Essex Woodlands Health Ventures and Galen Partners (collectively, the "Lead 2004 Investors") has 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"). The Designees of Care Capital, Essex Woodlands Health Ventures and Galen Partners are Messrs. Karabelas, Thangaraj and Wesson, respectively, each of whom are current Board members. As of the date of this Report, the collective Designee of the Lead 2004 Investors 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"). The Series B Preferred and the Series C Preferred are referred to collectively as the "Junior Preferred Shares", and the Junior Preferred Shares, together with the Series A Preferred are referred to collectively as the "Preferred Stock".

As of December 31, 2004, after giving effect to the conversion of the 2004 Debentures and the 1998-2003 Debentures, Care Capital, Essex Woodlands Health Ventures and Galen Partners control approximately 14.7%, 17.2% and 46.5%, respectively, of the Company's voting securities (or approximately 12.2 %, 15.3 %, 47.9 %, respectively, after giving effect to the conversion of all of the Company's issued and outstanding convertible securities).

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 first lien on all of the Company's and its subsidiaries' assets, senior in right of payment and lien priority over all other Company indebtedness, carries a floating rate of interest equal to the prime rate plus 4.5% and matures on June 30, 2007.

After giving effect to the transactions provided in the Umbrella Agreement, the Watson Note Purchasers represent the Company's senior lenders. 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).

Each of Michael and Susan Weisbrot beneficially own in excess of 5% of the Company's voting securities. The Weisbrots participated as an investor in the 2004 Debentures and purchased a portion of the 2004 Note as a member of the Watson Note Purchasers. In addition, each of Bernard Selz, Hemant and Varsha Shah, Oracle Strategic Partners, L.P. and Michael and Susan Weisbrot, each a beneficial owner of in excess of 5% of the Company's voting securities, converted their respective 1998-2003 Debentures into Junior Preferred Shares. See "Item 12-Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters".

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit Fees

The aggregate fees billed for professional services rendered by Grant Thornton, LLP, the Company's principal accountant during 2003 and through October 21, 2004, was $209,856 for the audit of the Company's annual financial statements for the fiscal year ended December 31, 2003 and $31,979 for the review of the financial statements included in the Company's Quarterly Reports on Form 10-Q for each of the quarters ended March 31, 2004 and June 30, 2004.

The aggregate fees billed for professional services rendered by BDO Seidman, LLP, the Company's principal accountant commencing October 22, 2004, was $6,112 for the review of the financial statements included in the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2004 and $39,500 for the audit of the Company's annual financial statements for the fiscal year ended December 31, 2004.

Audit - Related Fees

The aggregate fees billed for professional services rendered by the Company's principal accountant and which are reasonably related to the performance of the audit or review of the Company's financial statements and which are not reported above under the caption "Audit Fees" for each of the fiscal years ended December 31, 2003 and December 31, 2004 were $10,724 and $12,500, respectively, all of which is attributable to Grant Thornton.

These fees relate to services provided in connection with the audit of the Company's 401(k) and profit sharing plan.

Tax Fees

The aggregate fees billed for professional services rendered by the Company's principal accountant for tax compliance, tax advice and tax planning for the fiscal years ended December 31, 2003 and December 31, 2004 were $55,071 and $0, respectively, all of which is attributable to Grant Thornton. These services related to the preparation of various state and Federal tax returns.

All Other Fees

There were no fees billed for professional services rendered by the Company's principal accountant for products and services provided, other than those described above under the captions "Audit Fees", "Audit-Related Fees" and "Tax Fees".

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 independent auditor. The Audit Committee's policy is to pre-approve all audit and permissible non-audit services provided by the independent auditor. 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 independent auditor, the Audit Committee considers whether such services are consistent with the auditor's independence, whether the independent auditor 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 Grant Thornton LLP in fiscal year 2003 and 2004 and by BDO Seidman in 2004 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) Consolidated Financial Statement Schedules — See Index to Financial Statements

(b) Exhibits

The following exhibits are included as a part of this Annual Report on Form 10-K or incorporated herein by reference.

EXHIBIT NUMBER	DOCUMENT
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, Inc., 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").

EXHIBIT NUMBER	DOCUMENT
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).
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(l)	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 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 Noncompetition 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 1995 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).

EXHIBIT NUMBER	DOCUMENT
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 1995 8-K).
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).
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).

EXHIBIT NUMBER	DOCUMENT
10.45	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).
10.46	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).
10.47	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).
10.48	Form of 10% Convertible Secured Note due May 30, 1999 (incorporated by reference to Exhibit 10.48 to the 1998 Form 10-K).
10.49	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).
10.50	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).
10.51	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).
10.52	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).
10.53	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).
10.54	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).
10.55	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).
10.56	Registrant's 1998 Stock Option Plan (incorporated by reference to Exhibit 10.56 to the 1998 Form 10-K).
10.57	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")).+
10.58	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).
10.59	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).
10.60	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).
10.61	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).
10.62	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).
10.63	Watson's Guarantors Security Agreement dated March 29, 2000 between the Registrant, Houba, Inc. and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.63 to the March 2000 8-K).
10.64	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).+

10.65 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).

EXHIBIT NUMBER	DOCUMENT
10.66	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).
10.67	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).+
10.68	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).+
10.69	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).+
10.70	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).+
10.71	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).+
10.72	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")).
10.73	Form of 5% Convertible Senior Secured Debenture issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.73 the 1999 Form 10-K).
10.74	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).
10.75	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).
10.76	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")).
10.77	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).
10.78	Form of Agreement of Guaranty of Subsidiaries of the Registrant dated December 20, 2002 between Houba, Inc., the Registrant and the 2002 Debentureholders (incorporated by reference to Exhibit 10.3 to the December 2002 Form 8-K).
10.79	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).
10.80	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).
10.81	Voting Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.6 to the December 2002 Form 8-K).
10.82	Debentureholders Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.7 to the December 2002 Form 8-K).
10.83	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).
10.84	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).

EXHIBIT NUMBER	DOCUMENT
10.85	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).
10.86	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).
10.87	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).
10.88	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).
10.89	Watson Common Stock Purchase Warrant dated December 20, 2002 (incorporated by reference to Exhibit 10.14 to the December 2002 Form 8-K).
10.90	Registration Rights Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.15 to the December 2002 Form 8-K).
10.91	Warrant Recapitalization Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.15 to the December 2002 Form 8-K).
10.92	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 to the Registrant's current report on Form 8-K dated February 10, 2004 (the "February 2004 Form 8-K").
10.93	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).
10.94	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 10.3 of the February 2004 Form 8-K).
10.95	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).
10.96	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).
10.97	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).
10.98	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).
10.99	Company General Security Agreement (incorporated by reference to Exhibit 10.8 of the February 2004 Form 8-K).
10.100	Form of Unconditional Agreement of Guaranty (incorporated by reference to Exhibit 10.9 of the February 2004 Form 8-K).
10.101	Form of Guarantor Security Agreement (incorporated by reference to Exhibit 10.10 of the February 2004 Form 8-K).
10.102	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).
10.103	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).

EXHIBIT NUMBER	DOCUMENT
10.104	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).
10.105	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).
10.106	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).
10.107	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).
10.108	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")).
10.109	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).
10.110	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.)
10.111	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")).
10.112	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).
10.113	Executive Employment Agreement dated as of April 5, 2004 between the Registrant and Ron J. Spivey (incorporated by reference to Exhibit 10.3 to June 2004 10-Q).
10.114	Amendment to Executive Employment Agreement between the Registrant and Andrew D. Reddick, dated May 27, 2004 (incorporated by reference to Exhibit 10.4 to June 2004 10-Q).
10.115	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).
10.116	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).
10.117	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).
10.118	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).
10.119	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).
10.120	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).
14	Code of Ethics (incorporated by reference to Exhibit 14 of the Registrant's Form 10-K filed April __, 2004 (the "2003 Form 10-K").
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 22 to the 1993 Form 10-K).
*23.1	Consent of Grant Thornton LLP, independent certified public accountants, to the incorporation by reference of its report to the consolidated financial statements of the Registrant contained in its Form 10-K for the year ended December 31, 2003, into the Registrant's Registration Statements on Form S-8 (Registration Nos. 333-63288 and 33-98356).

EXHIBIT NUMBER	DOCUMENT
*23.2	Consent of BDO Seidman LLP, independent certified public accountants, to the incorporation by reference of its report to the consolidated financial statements of the Registrant contained in its Form 10-K for the year ended December 31, 2004, 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

+ 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.

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.

Date: February 25, 2005

By: /s/ ANDREW D. REDDICK

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Andrew D. Reddick Andrew D. Reddick	President, Chief Executive Officer and Director	February 25, 2005
/s/ William G. Skelly William G. Skelly	Director	February 25, 2005
/s/ Peter Clemens Peter Clemens	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2005
/s/ Bruce F. Wesson Bruce F. Wesson	Director	February 25, 2005
/s/ William Sumner William Sumner	Director	February 25, 2005
Jerry Karabelas	Director	February __, 2005
/s/ Immanuel Thangaraj Immanuel Thangaraj	Director	February 25, 2005

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheet of Acura Pharmaceuticals, Inc. as of December 31, 2004 and the related consolidated statements of operations, stockholders' deficit, and cash flows for the year then ended. We have also audited the schedule listed in the accompanying index. These financial statements and the financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion of 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Acura Pharmaceuticals, Inc. at December 31, 2004, and the results of its operations and its cash flows for the year 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 discussed 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.

Also, in our opinion, the schedule presents fairly, in all material respects, the information set forth therein.

/s/ BDO Seidman, LLP

Chicago, Illinois
February 9, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Directors and Stockholders
ACURA PHARMACEUTICALS, INC.

We have audited the accompanying consolidated balance sheet of Acura Pharmaceuticals, Inc and Subsidiaries (formerly Halsey Drug Co., Inc. and Subsidiaries) (the "Company") as of December 31, 2003 , and the related consolidated statements of operations, shareholders' equity (deficit) and cash flows for the years ended December 31, 2003 and 2002. 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 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 audits provide a reasonable basis for our opinion.

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

We have also audited the consolidated financial statement schedule listed in the Index at Item 15(a)(2) for the years ended December 31, 2003 and 2002. In our opinion, this schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note B, 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 Note E, as to which the date is March 19, 2004

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

DECEMBER 31,
(in thousands)

	2004	2003
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 3,103	$ 942
Accounts receivable - net of allowance for doubtful accounts of $428 in 2003	-	467
Inventories	-	312
Prepaid expenses and other current assets	307	401
Total current assets	3,410	2,122
PROPERTY, PLANT & EQUIPMENT, NET	1,555	3,394
DEFERRED PRIVATE DEBT OFFERING COSTS, net of accumulated amortization of $318 in 2003	-	714
OTHER ASSETS AND DEPOSITS	2	392
TOTAL ASSETS	$ 4,967	$ 6,622

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS (CONTINUED)

DECEMBER 31,
(in thousands, except share data)

	2004	2003
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Current maturities of capital lease obligations	$ 29	$ 45
Accounts payable	-	1,895
Accrued interest	-	1,544
Accrued expenses	959	2,108
Department of Justice settlement	-	300
Total current liabilities	988	5,892
SENIOR SECURED TERM NOTE PAYABLE	5,000	21,401
BRIDGE LOANS	-	2,000
Less: debt discount	-	(568)
	-	1,432
CONVERTIBLE SUBORDINATED DEBENTURES	-	86,632
Less: debt discount	-	(56,893)
	-	29,739
CAPITAL LEASE OBLIGATIONS, less current maturities	64	92
DEPARTMENT OF JUSTICE SETTLEMENT, less current portion	-	133
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock - $.01 par value; authorized 650,000,000 shares; issued and outstanding, 22,466,967 and 21,601,704 shares in 2004 and 2003, respectively	225	216
Convertible Preferred stock - $.01 par value; authorized 290,000,000 shares; issued and outstanding, 217,972,986 and 0 shares in 2004 and 2003, respectively	2,180	-
Additional paid-in capital	276,051	157,262
Accumulated deficit	(279,541)	(209,545)
STOCKHOLDERS' DEFICIT	(1,085)	(52,067)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 4,967	$ 6,622

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED DECEMBER 31,
(in thousands, except per share data)

	2004	2003	2002
Net product revenues	$ 838	$ 5,750	$ 8,205
Cost of manufacturing	1,435	11,705	12,535
Research and development	4,130	1,460	1,517
Selling, marketing, general and administrative	5,238	7,903	7,216
Plant shutdown costs (benefit)	-	1,926	(126)
Loss from operations	(9,965)	(17,244)	(12,937)
Other income (expense)			
Interest expense	(2,962)	(6,001)	(4,728)
Interest income	59	25	15
Amortization and write-off of deferred debt discount and private debt offering costs	(72,491)	(24,771)	(12,558)
Loss on extinguishment of debt	-	-	(28,415)
Gain on debt restructure	12,401	-	-
Gain on asset disposals	2,359	-	-
Other	603	(464)	(966)
NET LOSS	$ (69,996)	$ (48,455)	$ (59,589)
Basic and diluted loss per Common share	$ (3.20)	$ (2.28)	$ (3.90)
Weighted average number of outstanding Common shares	21,861	21,227	15,262

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

YEARS ENDED DECEMBER 31, 2004, 2003 and 2002
(in thousands, except per share data)

	Common Stock $.01 par value		Convertible Preferred Stock $.01 par value				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2002	**15,065**	**$ 151**	**-**	**$ -**	**$ 35,914**	**$ (101,501)**	**$ (65,436)**
Net loss for the year ended December 31, 2002						(59,589)	(59,589)
Issuance of Common Shares in exchange for warrants	5,970	60			2,222		2,282
Beneficial conversion features in connection with debentures					74,619		74,619
Issuance of warrant in connection with extension of maturity date of term loan					11,985		11,985
Issuance warrant in connection with bridge loans					5,115		5,115
Beneficial conversion features in connection with issuance of bridge loans					3,745		3,745
Modifications of terms of existing warrants					15,011		15,011
Balance at December 31, 2002	**21,035**	**$ 211**	**-**	**$ -**	**$ 148,611**	**$ (161,090)**	**$ (12,268)**
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
Balance at December 31, 2003	**21,602**	**$ 216**	**-**	**$ -**	**$ 157,262**	**$ (209,545)**	**$ (52,067)**

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)

YEARS ENDED DECEMBER 31, 2004, 2003 and 2002
(in thousands, except per share data)

	Common Stock $.01 par value		Convertible Preferred Stock $.01 par value				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2003 (cont'd)	**21,602**	**$ 216**	**-**	**$ -**	**$ 157,262**	**$ (209,545)**	**$ (52,067)**
Net loss for year ended December 31, 2004						(69,996)	(69,996)
Issuance of Common Shares for payment of interest	865	9			391		400
Fair value of options issued to employees					2,007		2,007
Issuance of Series A Convertible Preferred Shares for convertible debentures			21,964	220	13,892		14,112
Issuance of Series B Junior Convertible Preferred Shares for convertible debentures			20,246	203	6,722		6,925
Issuance of Series C-1 Junior Convertible Preferred Shares for convertible debentures			56,423	564	32,025		32,589
Issuance of Series C-2 Junior Convertible Preferred Shares for convertible debentures			37,433	374	22,059		22,433
Issuance of Series C-3 Junior Convertible Preferred Shares for convertible debentures			81,907	819	27,693		28,512
Beneficial conversion features in conjunction with issuance of convertible debentures					14,000		14,000
Balance at December 31, 2004	**22,467**	**$ 225**	**217,973**	**$ 2,180**	**$ 276,051**	**$ (279,541)**	**$ (1,085)**

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2004, 2003, and 2002
(in thousands, except supplemental data)

	2004	2003	2002
Cash flows from Operating Activities:			
Net loss	$ (69,996)	$ (48,455)	$ (59,589)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	291	811	835
Amortization of deferred debt discount and private debt offering costs	30,684	24,771	12,558
Write off unamortized deferred debt discount and private debt offering costs	41,807	--	--
Non-cash compensation charge on options	2,007	--	--
Gain on debt restructuring	(12,401)	--	--
Gain on Department of Justice settlement	(402)	--	--
Amortization of deferred product acquisition costs	6	42	37
Provision for losses on accounts receivable	(428)	351	101
(Gain) loss on assets disposals	(2,359)	7	28
Debentures and stock issued for interest expense	--	3,241	2,191
Loss on extinguishment of debt	--	--	28,415
Change in fair value of warrants due to modification of terms	--	457	863
Write-down of investment in affiliate	--	--	202
Impairment reserve against assets	--	3,619	--
Changes in assets and liabilities			
Accounts receivable	729	(2,244)	(2,170)
Inventories	312	28	444
Prepaid expenses and other current assets	94	(76)	(156)
Other assets and deposits	184	103	(81)
Accounts payable	(1,882)	(877)	853
Accrued expenses	1,861	2,137	3,010
Total adjustments	60,503	32,370	47,130
Net cash used in operating activities	(9,493)	(16,085)	(12,459)
Cash flows from Investing Activities:			
Capital expenditures	(444)	(410)	(287)
Proceeds from asset disposals	4,538	--	16
Net cash provided by (used in) investing activities	4,094	(410)	(271)
Cash flows from Financing Activities:			
Payments on senior secured term note payable	(4,000)	--	--
Proceeds from issuance of notes payable	--	2,000	12,500
Payments to Department of Justice	(31)	(328)	(313)
Payments on capital lease obligations	(45)	(46)	(147)
Proceeds from issuance of subordinated convertible debentures	11,951	6,600	10,500
Payments on private offering costs	(315)	--	(1,041)
Net cash provided by financing activities	7,560	8,226	21,499
Increase (decrease) in cash and cash equivalents	2,161	(8,269)	8,769
Cash and cash equivalents at beginning of year	942	9,211	442
Cash and cash equivalents at end of year	**$ 3,103**	**$ 942**	**$ 9,211**

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

YEAR ENDED DECEMBER 31, 2004, 2003, and 2002
(in thousands, except supplemental data)

Supplemental disclosures of noncash investing and financing activities:

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 has 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 has issued 865,263 shares of common stock as payment of $400,616 of Senior Secured Term Note Payable accrued interest.

5. Convertible Subordinated Debentures of $100,632,000 and accrued interest of $3,939,000 were converted into 217,973,000 shares of Convertible Preferred Stock.

See accompanying notes to the consolidated financial statements.

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

YEAR ENDED DECEMBER 31, 2004, 2003, and 2002
(in thousands, except supplemental data)

Supplemental disclosures of noncash investing and financing activities:

Year ended December 31, 2003

1. The Company's bridge loans contained beneficial conversion features, which were valued at $578,000.

2. The Company's convertible debentures contained beneficial conversation features, which were 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
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

YEAR ENDED DECEMBER 31, 2004, 2003, and 2002
(in thousands, except supplemental data)

Supplemental disclosures of noncash investing and financing activities:

Year ended December 31, 2002

1. The Company issued 5,970,083 shares of common stock as result of recapitalization of warrants to purchase 8,145,736 shares of common stock and recorded a charge to earnings of $2,282,000 in connection with this transaction.

2. The Company issued 10,700,665 warrants with an estimated relative fair value of $11,985,000 in connection with the extension of a note payable.

3. The Company issued $15,885,000 in debentures in exchange for like amounts of notes payable and accrued interest.

4. The Company's convertible debentures contained beneficial conversion features, which were valued at $74,619,000.

5. The Company issued $2,191,000 of debentures as payment of like amounts of debenture accrued interest.

6. The Company repaid $1,826,000 of indebtedness in the form of product deliveries.

7. The Company issued approximately 2,120,000 warrants with an estimated relative fair value of $2,412,000 in connection with the refinancing of existing bridge loans in January and May 2003.

8. The Company issued 600,000 warrants with an estimated relative fair value of $948,000 for the lending commitment of a bridge loan.

9. The Company issued approximately 1,535,000 warrants with an estimated relative fair value of $1,755,000 in connection with the issuance of bridge loans.

10. The Company's bridge loans contained beneficial conversion features, which were valued at $3,745,000.

11. Equipment financed through capital leases aggregated approximately $35,000.

See accompanying notes to the consolidated financial statements.

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 had been engaged in the development, manufacture, sale and distribution of a variety of generic finished dosage pharmaceutical products and active pharmaceutical ingredients ("APIs"). On November 6, 2003, the Company announced its plan to restructure the Company's operations to focus on research and development related to certain proprietary opioid synthesis and finished dosage formulation technologies. The Board of Directors determined, among other factors, that the Company's ability to generate positive cash flow from the operation of the Company's finished dosage manufacturing, packaging, labeling and distribution facilities located in Congers, New York (collectively, the "Congers Facilities") in the manufacture and distribution of finished dosage generic products pursuant to abbreviated new drug applications ("ANDAs") was compromised by the highly competitive market environment, low market pricing and declining market size for its existing generic products and the lack of new generic products in development. The Board determined that near term sales of the Company's finished dosage generic products would likely result in negative gross margins in view of the market environment. Based on this analysis and other factors, the Board concluded that the Company's manufacture and sale of finished dosage products licensed to be produced at the Congers Facilities would result in continuing negative cash flow for the foreseeable future. After due consideration of alternative strategies and considering the optimal use of available funding, the Board adopted a strategy to substantially restructure the Company's business. Manufacturing of the Company's generic finished dosage products at the Congers Facilities substantially ceased on January 30, 2004. Such date also marks the completion, in large part, of the reduction in work force associated with the restructuring of the Company's operations by approximately 100 employees, 70 of whom were employed by the Company at the Congers Facilities.

As restructured, the Company is an emerging specialty pharmaceutical company primarily engaged in research, development and manufacture of innovative abuse deterrent formulations ("Aversion ™ Technology") intended for use in orally administered opioid-containing pharmaceutical products. The Company is also engaged in collaborative research and development with a contract research organization and an academic institution for clinical evaluation and testing of the Aversion ™ Technology. In addition, to a much lesser extent, during 2004 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" and, collectively with the Aversion™ Technology, the "Technologies") intended for use in the commercial production of certain bulk opioid APIs. As of the date of this Report, the Company had commenced the process of suspending further development and commercialization efforts relating to the Opioid Synthesis Technologies. 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 Company's Import Registration. As of February 1, 2005, the Company had one issued US patent, one US Notice of Allowance and 14 patent applications pending, including one (1) issued US patent, one (1) US Notice of Allowance granted, eight (8) US patent applications pending and one (1) foreign patent application pending relating to the Opioid Synthesis Technologies, and four (4) US patent applications pending and one (1) foreign patent application pending relating to the Aversion ™ Technology. As of February 1, 2005, the Company retained ownership of all intellectual property and commercial rights to its product candidates and Technologies.

The Company conducts research, development, laboratory, manufacturing and warehousing activities relating to the Aversion ™ Technology and the Opioid Synthesis Technologies 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 of Schedule II - V controlled substances in bulk and finished dosage forms. On January 31, 2001, the Company filed with the DEA an application for registration to import narcotic raw materials ("NRMs"). These NRMs are commonly used as the initial starting materials in the synthesis of certain opioid APIs. The Company's application for an importer registration (the "Import Registration") was published in the Federal Register on September 6, 2001.

The Company plans to enter into development and commercialization agreements with strategically focused pharmaceutical company partners (the "Partners") providing that such Partners license the Company's Aversion ™ Technology and further develop, register and commercialize multiple formulations and strengths of orally administered opioid-containing finished dosage products utilizing the Aversion ™ Technology. The Company expects to receive milestone payments as well as a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Aversion ™ Technology. The Company also believes that it will derive revenues through contract manufacture and supply of clinical trial and commercial supplies of finished dosage products for use by such Partners. The Company plans to utilize a single site vertical integration strategy to conduct research, development and manufacturing activities for finished dosage form products utilizing the Aversion ™ Technology. The Import Registration, if ultimately granted, for which there can be no assurance, will provide the Company with an economical source of NRMs for use as starting materials in the commercial manufacture and supply of certain opioid APIs.

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.

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, 2004, 2003 and 2002. In addition, the Company paid cash interest of approximately $47,000, $526,000 and $136,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

3. Accounts Receivable - Trade and Allowance Accounts

Consistent with the cessation of the manufacture and sale of finished dosage products in the first quarter of 2004, the Company had no accounts receivable from customers at December 31, 2004. For prior periods, the Company's accounts receivable - trade are due from customers engaged in the distribution of pharmaceutical products. Credit is extended based on evaluation of a customer's financial condition and, generally, collateral is not required. Accounts receivable are due generally between 30 and 60 days and are stated at amounts due from customers net of allowances for doubtful accounts, returns, term discounts, and other allowances. Accounts outstanding longer than the contractual payment terms are considered past due. Estimates that are used in determining these allowances are based on the Company's historical experience, current trends, credit policy and a percentage of its accounts receivable by aging category. In determining these percentages, the Company looks at the credit quality of its customer base as well as changes in its credit policies. The Company continuously monitors collections and payments from its customers. The Company writes off accounts receivable when they become uncollectible, and payments subsequently received on such receivables are credited to bad debt expense.

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

	2004	2003	2002
Beginning balance	$ 428	$ 14	$ 347
Provision for losses on accounts receivable	-	351	101
Provision for all other allowances	-	77	-
Allowances paid	-	(6)	(434)
Write-off	(428)	(8)	-
Recoveries	-	-	-
Ending balance	$ -	$ 428	$ 14

4. Inventories

Consistent with the cessation of the manufacture and sale of finished dosage products in the first quarter of 2004, the Company had no inventories at December 31, 2004. For prior periods, inventories are stated at the lower of cost or market and include material, labor and manufacturing overhead. The first-in, first-out method is used to determine the cost of inventories. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, remaining shelf life and current and expected market conditions, including levels of competition.

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	20 - 40 years
Land improvements	20 years
Laboratory equipment	10 years
Machinery and equipment	3 - 10 years
Leasehold improvements	Shorter of the life of the lease or the service life of the asset

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 Debt Private Offering Costs

Debt private offering costs represent costs incurred by the Company in conjunction with securing debt financing. The Company incurred approximately $582,000 in debt private 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. The Company incurred approximately $1,041,000 in debt private offering costs during the year ended December 31, 2002 in conjunction with a private offering of securities. Debt private offering costs are 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 $716,000 of unamortized and outstanding deferred debt private offering costs were charged to expense.

8. Deferred 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 is recorded as a reduction of the related obligations and is 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 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 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 deferred debt discount was charged to expense.

9. Revenue Recognition

Consistent with the cessation of the manufacture and sale of finished dosage products in the first quarter of 2004, the Company had no revenues after second quarter 2004. Prior to that, the Company recognized revenue, net of sales discounts and allowances, when title to the product 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 finished dosage 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

Research and development expense consisted primarily of product development costs prior to the cessation of manufacture and sale of finished dosage products. During 2004, research and development expense consist primarily of drug development work 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. These expenses are charged to operations as incurred.

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 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 tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. While the Company has considered future taxable income in assessing the need for the valuation allowance, in the event the Company were to determine that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, an adjustment to the deferred 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 basic earnings per share adjusted for the effect of other potentially dilutive securities. Excluded from the 2004, 2003 and 2002 computation are approximately 356,204,000, 249,877,000 and 200,368,000, respectively, of outstanding warrants and options and the effects of convertible debentures outstanding and convertible preferred stock which would have been antidilutive.

14. Stock-Based Compensation

The Company has two stock-based employee compensation plans, which are described more fully in Note K.

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 equals the market price of the underlying 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 employee stock option grants.

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 grants.

	Year ended December 31, (in thousands, except per share data)		
	2004	2003	2002
Net loss, as reported	$ (69,996)	$ (48,455)	$ (59,589)
Deduct: total stock-based employee compensation expense determined under fair value-based method for all awards	(393)	(662)	(1,047)
Net loss, pro forma	$ (70,389)	$ (49,117)	$ (60,636)
Loss per share:			
Basic EPS - as reported	$ (3.20)	$ (2.28)	$ (3.90)
Basic EPS - as pro forma	$ (3.22)	$ (2.31)	$ (3.97)
Diluted EPS - as reported	$ (3.20)	$ (2.28)	$ (3.90)
Diluted EPS - as pro forma	$ (3.22)	$ (2.31)	$ (3.97)

Pro forma compensation expense may not be indicative of future disclosures because they do not take into effect pro forma compensation expense related to grants before 1995. For purposes of estimating the fair value of each option 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 stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

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

	Grants issued during		
	2004	2003	2002
Expected life (years)	2 - 5	2.5	10
Risk-free interest rate	2.4% - 4.6%	1.8%	4.6%
Expected volatility	73% - 87%	94%	88%
Dividend yield	0.0%	0.0%	0.0%
Weighted-average option fair value	$ .25	$ .53	$ 1.12

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.

During 2004, the Company granted approximately 13,175,000 stock options with an exercise price less than the market price of the underlying 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 and the market price of the underlying stock on the date of grant. Total compensation expense of approximately $3,084,000 will be recognized over the vesting period of the options, of which approximately $2,007,000 was recorded in 2004.

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 and accounts receivable approximates fair value due to the short-term maturities of the instruments. The Company believes that it is not practical to estimate the fair value of its accounts payable based upon the costs that would be incurred to obtain such valuation. 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.

18. New Accounting Pronouncements

Consolidation of Variable Entities
In January 2003, the Financial Accounting Standards Board ("FASB"), issued FASB Interpretation of FIN No. 46, "Consolidation of Variable Entities," (VIEs). FIN 46 establishes standards for determining under what circumstances VIEs should be consolidated with their primary beneficiary, including those to which the usual condition of consolidation does not apply. FIN 46 also requires disclosure about unconsolidated VIEs in which the company has a significant interest. The consolidation requirements of FIN 46 apply immediately to older entities the first fiscal year or interim period beginning after June 15, 2003. certain disclosures requirements apply in all financial statements issued after January 31, 2003. The adoption of the accounting pronouncement did not have an impact on our financial position or results of operations.

In December 2003, the FASB publishes FIN No. 46-R, Consolidation of Variable Entities (revised December 2003)," superseding Fin 46, and exempting certain entities from the provisions of FIN 46. Generally, application of FIN 46-R is required in financial statements of nonpublic entities immediately to VIEs or potential VIEs created after December 31, 2003 and for all entities by the beginning of the first annual period beginning after December 31, 2004." The adoption of the accounting pronouncement did not have an impact on our financial position or results of operations.

Accounting for Certain Financial Instruments with the Characteristics of Both Liabilities and Equity
FASB issued Statement No. 150, "Accounting for Certain Financial Instruments with the Characteristics of Both Liabilities and Equity", in June 2003. The Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires an issuer to classify a financial instrument that is within the scope of the pronouncement as a liability. Many of those financial instruments were previously classified as equity. The statement is effective for all financial instruments entered into or modified after May 2003 and otherwise shall be effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of the accounting pronouncement did not have an impact on our financial position or results of operations.

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 interim or annual period that begins after June 15, 2005. This Statement applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date. The cumulative effect of initially applying this Statement, if any, is recognized as of the required effective date. The Company has not completed it evaluation of the impact of adopting FASB 123R on its consolidated financial statements, but anticipates that more compensation costs will be recorded in the future if the use of options for employees and director compensation continues as in the past.

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 finished dosage generic pharmaceutical 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 will be sufficient to fund the development of the Aversion™ Technology and related operating expenses through May, 2005**.** To fund operations through March, 2006, the Company estimates that it must raise additional financing, or enter into alliances or collaboration agreements with third parties providing for net proceeds to the Company of at least $5 million. 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 Technologies, 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.

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 $14.0 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. As the conversion price of the 2004 Debentures was less than the fair market value of the Company's common stock on the date of issue, beneficial conversion features were determined to exist. The Company recorded approximately $14.0 million of debt discount limited to the face amount of the new debt. The debt discount was amortized over the life of the debt, which matured on August 13, 2004, the date the 2004 Debentures were automatically converted into the Company's Series A Convertible Preferred Stock (see "Conversion of 2004 Debentures into Series A Preferred Stock" below).

Conversion of 2004 Debentures into Series A Preferred Stock

The 2004 Debentures (including the principal amount plus interest accrued) converted automatically into the Company's Series A convertible preferred stock (the "Series A Preferred") on August 13, 2004, the business day following the Company's receipt of shareholder approval to restate the Company's Certificate of Incorporation (the "Charter Amendment") to authorize the Series A Preferred and the Junior Preferred Shares (as described below) and the filing of the Charter Amendment with the Office of the New York Department of State, as provided in the 2004 Purchase Agreement. The 2004 Debentures converted into an aggregate of 21,963,757 Series A Preferred shares based on a $0.6425 per share conversion price.

Series A Preferred Stock Liquidation Preference, Conversion Right and Participation Right

In general, the Series A Preferred shares have a liquidation preference equal to five (5) times the initial $0.6425 Series A conversion price (the "Series A Liquidation Preference"). In addition, the Series A Preferred shares are convertible into the Company's Common Stock, with each Series A Preferred share convertible into the number of shares of Common Stock obtained by dividing (i) the Series A Liquidation Preference, by (ii) the $0.6425 Series A conversion price, as such conversion price may be adjusted, from time to time, pursuant to the dilution protections of such shares. Without limiting the Series A Liquidation Preference, the holders of Series A Preferred shares also have the right to participate with the holders of the Company's Common Stock upon the occurrence of a liquidation event, including the Company's merger, sale of all or substantially all of its assets or a change of control transaction, on an as-converted basis (but for these purposes only, assuming the Series A Preferred shares to be convertible into only thirty percent (30%) of the shares of Common Stock into which they are otherwise then convertible). The holders of Series A Preferred shares also have the right to vote as part of a single class with all holders of the Company's voting securities on all matters to be voted on by such security holders. Each holder of Series A Preferred shares will have such number of votes as shall equal the number of votes he would have had if such holder converted all Series A Preferred shares held by such holder into shares of Common Stock immediately prior to the record date relating to such vote.

Impact of Conversion of the Company's Outstanding Debentures

As of February 10, 2004, the date of the initial closing of the 2004 Purchase Agreement, the Company had issued and outstanding and aggregate of approximately $86.6 million in principal amount of 5% convertible senior secured debentures maturing March 31, 2006 issued pursuant to three separate Debenture Purchase Agreements dated March 10, 1998, as amended (the "1998 Debentures"), May 26, 1999, as amended (the "1999 Debentures") and December 20, 2002 (the "2002 Debentures"), respectively. The 1998 Debentures, 1999 Debentures and 2002 Debentures are referred to collectively as the "1998-2002 Debentures". After giving effect to the Company's issuance of additional 5% convertible senior secured debentures in satisfaction of interest payments on the 1998-2002 Debentures, as of February 10, 2004, the 1998-2002 Debentures were convertible into an aggregate of approximately 190.4 million shares of the Company's Common Stock.

Conversion Agreement of Holders of 1998-2002 Debentures

Simultaneous with the execution of the 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 1998-2002 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, effective August 13, 2004, each holder of 1998-2002 Debentures converted the 1998-2002 Debentures held by such holder into the Company's Series B convertible preferred stock (the "Series B Preferred") and/or Series C-1, C-2 and/or C-3 convertible 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".

Under the Conversion Agreement, the holders of approximately $6.6 million in principal amount of 2002 Debentures issued during 2003 converted such 2002 Debentures (plus accrued and unpaid interest) into Series B Preferred Shares. Of the remaining approximate $80 million in principal amount of the 1998-2002 Debentures, approximately $31.2 million was comprised of 1998 Debentures, approximately $21.5 million was comprised of 1999 Debentures and approximately $27.3 million was comprised of 2002 Debentures. Effective August 13, 2004, the 1998 Debentures were converted into Series C-1 Preferred shares, the 1999 Debentures were converted into Series C-2 Preferred shares and the remaining balance of the 2002 Debentures were converted into Series C-3 Preferred shares.

The number of Junior Preferred Shares issued by the Company to each holder of 1998-2002 Debentures was based on the respective prices at which the 1998-2002 Debentures were convertible into Common Stock. The 2002 Debentures issued in 2003 had a conversion price of $0.3420 per share. The 1998 Debentures, 1999 Debentures and the remaining balance of the 2002 Debentures had conversion prices of $0.5776, $0.5993 and $0.3481 per share, respectively. Upon the automatic conversion of the 1998-2002 Debentures on August 13, 2004, the Company issued an aggregate of 20,246,506 million Series B Preferred shares, 56,422,558 million Series C-1 Preferred shares, 37,433,096 million Series C-2 Preferred shares and 81,907,069 million Series C-3 Preferred shares.

Liquidation Preference of Junior Preferred Shares

In general, the Junior Preferred Shares have a liquidation preference equal to one (1) time the principal amount plus accrued and unpaid interest on the 1998-2002 Debentures converted into Junior Preferred Shares. The liquidation preference of the Series B Preferred has priority over, and will be satisfied prior to, the liquidation preference of the Series C Preferred. The liquidation preference for each class of the Junior Preferred Shares is equal to the conversion prices of such shares. The Junior Preferred Shares are convertible into the Company's Common Stock, with each Junior Preferred Share convertible into one share of Common Stock. The holders of the Junior Preferred Shares have the right to vote as part of the single class with all holders of the Company's Common Stock and the holders of the Series A Preferred on all matters to be voted on by such security holders, with each holder of Junior Preferred Shares having such number of votes as shall equal the number of votes he would have had if such holder had converted all Junior Preferred Shares held by such holder into Common Stock immediately prior to the record date relating to such vote.

Common Share Equivalents of the Series A Preferred and Junior Preferred Shares

As discussed, at August 13, 2004 the holders of the Company's 5% convertible debentures converted their debentures into various series of convertible preferred stock. At December 31, 2004, convertible preferred stock consists of the following:

Convertible Preferred Stock	$.01 Par Value, Authorized Shares	Issued and Outstanding Shares	Par Value	Common Stock Equivalents	Liquidation Preference
Series A	45,000,000	21,963,757	$ 220	109,818,785	$ 70,558,570
Series B Junior	25,000,000	20,246,506	203	20,246,506	6,924,305
Series C-1 Junior	70,000,000	56,422,558	564	56,422,558	32,589,669
Series C-2 Junior	50,000,000	37,433,096	374	37,433,096	22,433,655
Series C-3 Junior	100,000,000	81,907,069	819	81,907,069	28,511,851
Total	290,000,000	217,972,986	$ 2,180	305,828,014	$ 161,018,050

NOTE D - CONVERTIBLE SUBORDINATED DEBENTURES

Convertible Subordinated Debentures consist of the following (in thousands):

	December 31, 2004	December 31, 2003
1998 Debentures	$ 31,212	$ 31,212
1999 Debentures	21,485	21,485
2002 Debentures	27,303	27,303
2003 Debentures	6,632	6,632
2004 Debentures	14,000	-
	100,632	86,632
Debentures converted into Convertible Preferred Stock	(100,632)	-
	-	86,632
Less: Unamortized Debt Discount	(-)	(56,893)
Convertible Subordinated Debentures, net	$ -	$ 29,739

NOTE E - SALE OF CERTAIN COMPANY ASSETS

On February 18, 2004, the Company and Mutual Pharmaceuticals, Inc. ("Mutual") entered into a certain Asset Purchase Agreement (the "Mutual Asset Purchase Agreement") pursuant to which the Company sold certain inactive, non-revenue generating abbreviated new drug applications ("ANDAs") to Mutual in consideration of $2.0 million. The ANDAs sold to Mutual were in various therapeutic categories, including analgesics, anti-infectives, anti-hypertensives, antihistamines, steroids and certain other categories. The decision to divest such 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 its finished dosage manufacturing facilities in Congers, New York and was in the process of negotiating the sale of such 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 the Purchase Agreement, the Company and Axiom agreed to sell to IVAX substantially all of the Company's assets used in the operation of the Company's former generic manufacturing and packaging operations located in Congers, New York in consideration of an immediate payment of $2.0 million and an additional payment $0.5 million upon receipt of shareholder approval of the transaction. Shareholder approval of the asset sale transaction with IVAX was obtained on August 12, 2004 and the closing was completed on August 13, 2004, at which time the Company received the remaining payment of $0.5 million from IVAX.

NOTE F - INVENTORIES

The Company held no inventories at December 31, 2004. The composition of inventories at December 31, 2003 consists of the following (in thousands):

	December 31, 2003
Finished goods	$ 357
Work-in-process	953
Raw materials	356
	1,666
Less impairment reserve	(1,354)
	$ 312

NOTE G - PROPERTY, PLANT AND EQUIPMENT

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

	December 31,	
	2004	2003
Machinery and equipment	$ 4,353	$ 9,457
Construction in progress	5	312
Leasehold improvements	-	1,454
Building and building improvements	1,592	2,816
Land	44	44
	5,994	14,083
Less accumulated depreciation and amortization (including $17 in 2004 and $11 in 2003 of capitalized lease amortization)	(4,301)	(9,016)
	1,693	5,067
Less impairment reserve	(138)	(1,673)
	$ 1,555	$ 3,394

Included in machinery and equipment is equipment recorded under capitalized leases at December 31, 2004 and 2003, of approximately $146,000 and $221,000, respectively. Depreciation and amortization expense for the years ended December 31, 2004, 2003 and 2002 was approximately $291,000, $811,000 and $835,000, respectively.

NOTE H - ACCRUED EXPENSES

Accrued expenses are summarized as follows (in thousands):

	December 31,	
	2004	**2003**
Accrued payroll and payroll taxes	$ 573	$ 310
Legal and audit fees	234	491
Medicaid rebates and other customer allowances	50	50
Other professional fees	40	-
Benefit plan taxes	-	200
Investment and directors fees	-	246
Property and sales taxes	30	142
Other	32	669
	$ 959	$ 2,108

NOTE I - TERM NOTE PAYABLE AND STOCK WARRANTS

At December 31, 2004 and 2003, notes payable consisted of the following (in thousands):

	December 31,	
	2004	**2003**
Term note payable (a)	$ 5,000	$ 21,401
Bridge loans (b)	$ -	$ 2,000
Capital lease obligations	92	137
	92	2,137
Less: Current maturities	(29)	(45)
	$ 63	$ 2,092

(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. 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 first 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 interest rate at December 31, 2004 was 9.75%.

(b) Of the $14.0 million in 2004 Debentures issued in the 2004 Debenture Offering, approximately $2.0 million of 2004 Debentures were issued in exchange for the surrender of like amount of principal plus accrued interest outstanding under Company's 5% convertible senior secured debentures issued pursuant to working capital bridge loan transactions with Care Capital, Essex Woodlands Health Ventures and Galen Partners during November and December, 2003.

At December 31, 2004, warrants to purchase 22,026,267 shares of common stock remain that were issued in connection with the issuance of convertible debentures, bridge loans and financing commitments during the years 1998 through 2003. In 2002 a warrant for 10,700,665 common shares were issued to Watson in connection with their agreement to amend the Watson Loan at December 20, 2002. Also, a warrant for 150,000 common shares was issued in 2003 as part of the settlement terms with a former executive officer of the Company.

The following table summarizes information concerning outstanding and exercisable stock purchase warrants:

	Warrants outstanding		
Range of exercise prices	Number outstanding at December 31, 2004	Weighted-average remaining contractual life(years)	Weighted-average exercise price
$0.13 - $0.97	32,876,932	3.78	$ 0.54

NOTE J - INCOME TAXES

Reconciliations between the Federal income tax rate and the Company's effective income tax rate were as follows (in thousands):

	Year ended December 31,					
	2004		2003		2002	
	AMOUNT	%	Amount	%	Amount	%
Federal statutory rate	$ (23,798)	(34.0)%	$ (15,966)	(34.0)%	$ (20,260)	(34.0)%
Loss for which no tax benefit was provided	3,716	5.3	4,357	9.2	12,951	21.7
Non-deductible financing costs	24,647	35.2	11,589	24.6	7,278	12.2
Federal tax carryback refund	(122)	(.2)	-	-	-	-
Debt forgiveness	(4,307)	(6.1)	-	-	-	-
Department of Justice settlement	(137)	(.2)	11	.1	16	.1
Other	1	-	9	.1	15	.0
Actual tax benefit	$ -	-%	$ -	-%	$ -	-%

The Company has net operating loss carryforwards aggregating approximately $129.7 million, expiring during the years 2009 through 2024.

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 the calendar year, the Company adjusted its net operating loss carryforward. This adjustment has no effect on the current or prior year financial statements.

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

	December 31,	
	2004	2003
Deferred tax assets		
Net operating loss carryforwards	$ 55,178	$ 55,998
Asset reserves	-	1,016
Research and development tax credit	-	29
Accrued expenses	254	205
Capital loss carryforwards	-	212
Stock compensation	843	-
Depreciation and amortization	-	20
Accrued shutdown costs	71	703
Other	71	73
Gross deferred tax assets	56,417	58,256
Deferred tax liabilities		
Depreciation	(26)	-
Net deferred tax assets before valuation allowance	56,391	58,256
Valuation allowance	(56,391)	(58,256)
Net deferred tax assets	$ -	$ -

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, 2004 primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards.

NOTE K - 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 2004, 2003 and 2002, respectively.

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"). The 1995 Option Plan provides for the granting of (i) nonqualified options to purchase the Company's common stock at not less than the fair market value on the date of the option grant, (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 and (iii) rights to purchase the Company's common stock on a "Restricted Stock" basis, as defined, at not less than the fair market value on the date the right is granted. The total number of shares which may be sold pursuant to options and rights granted under the 1995 Option Plan is 1,000,000. No option can be granted under the 1995 Option Plan after May 2005 and no option can be outstanding for more than ten years after its grant. At December 31, 2004, approximately 212,000 shares are available for grant under the 1995 Option Plan.

In June 1998, the stockholders of the Company approved the adoption of a stock option and restricted stock purchase plan (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, 2004, approximately 3,126,000 options are available for grant under the 1998 Option Plan.

Transactions involving stock options under all plans are summarized as follows:

	Stock options outstanding	Weighted-average exercise price
Balance at December 31, 2002	5,008,950	$ 1.80
Granted	45,000	.96
Forfeited	(1,529,280)	1.69
Balance at December 31, 2003	3,524,670	1.83
Granted	14,475,145	.13
Exercised	-	-
Forfeited	(500,900)	1.85
Balance at December 31, 2004	17,498,915	$ .44

The following table summarizes information concerning currently outstanding and exercisable stock options:

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding at December 31, 2004	Weighted-average remaining contractual life (years)	Weighted-average exercise price	Number exercisable at December 31, 2004	Weighted-average exercise price
$ .13 - $1.00	14,475,145	9.29	$ .15	6,758,333	$ .16
1.01 - 2.00	1,557,945	4.84	1.30	1,355,445	1.32
2.01 - 4.38	1,465,825	2.04	2.39	1,443,325	2.38
	17,498,915	8.29	$ .44	9,557,770	$ $ .66

NOTE L - COMMITMENTS AND CONTINGENCIES

The following table presents the Company's expected cash requirements for contractual obligations outstanding as of December 31, 2004 (in thousands):

	TOTAL	DUE IN 2005	DUE IN 2006	DUE IN 2007	DUE THEREAFTER
Term loan payable	$ 5,000	$ --	$ --	$ 5,000	$ --
Capital leases	93	29	32	25	7
Operating leases	34	29	5	--	--
Contract research	93	93	--	--	--
Employment agreements	765	640	125	--	--
Total contractual cash obligations	$ 5,985	$ 791	$ 162	$ 5,025	$ 7

Contractual cash obligations entered into subsequent to December 31, 2004	TOTAL	DUE IN 2005	DUE IN 2006	DUE IN 2007	DUE THEREAFTER
Contract research	295	295	-	-	-
Market research	95	95	-	-	-
	$ 390	$ 390	$ -	$ -	$ -

Employment Contracts

Andrew D. Reddick is employed pursuant to an Employment Agreement effective as of August 26, 2003, which provides that Mr. Reddick will serve as the Company's Chief Executive Officer and President for an initial term expiring August 26, 2005. 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 thirty-five percent (35%) 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. Mr. Reddick received a bonus of $60,000 in fiscal 2004. In accordance with the terms of the Employment Agreement, as amended, the Company granted to Mr. Reddick 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.

Ron J. Spivey, Ph.D., is employed pursuant to an Employment Agreement effective as of April 5, 2004, which provides that Dr. Spivey will serve as the Company's Senior Vice President and Chief Scientific Officer for term expiring April 4, 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 thirty-five percent (35%) 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. In accordance with the terms of the Employment Agreement, the Company granted to Dr. Spivey stock options exercisable for up to 3,000,000 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 with the remaining balance vesting in quarterly increments of 333,333 shares at the expiration of each quarterly period commencing with the quarterly period ending December 31, 2004.

Peter A. Clemens is employed pursuant to an Employment Agreement effective as of March 10, 1998, which after giving effect to amendments dated June 28, 2000, May 4, 2001 and January 5, 2005, provides that Mr. Clemens will serve as the Company's Senior Vice President and Chief Financial Officer for a term expiring April 30, 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. 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. Such stock options vest in equal quarterly increments at the end of each annual period commencing March 9, 2005.

U.S. Department of Justice Settlement

On June 21, 1993, the Company entered into a Plea Agreement with the U.S. Department of Justice (the "DOJ") to resolve the DOJ's investigation into the manufacturing and record keeping practices at the Company's former Brooklyn, New York plant. The Plea Agreement required the Company to pay a fine of $2,500,000 over five years in quarterly installments of $125,000, commencing on or about September 15, 1993.

As of February 28, 1998, the Company was in default of the payment terms of the Plea Agreement and had made payments aggregating $350,000. On May 8, 1998, the Company and the DOJ signed the Letter Agreement serving to amend the Plea Agreement relating to the terms of the Company's satisfaction of the fine assessed under the Plea Agreement (the "Letter Agreement"). Specifically, the Letter Agreement provided that the Company will satisfy the remaining $2,150,000 of the fine through the monthly payments of $25,000 commencing June 1, 1998, plus interest on such outstanding balance (at the rate calculated pursuant to 28 U.S.C. Section 1961 (5.319%)). Such payment schedule provided for the full satisfaction of the DOJ fine in July 2005. The Letter Agreement also provides certain restrictions on the payment of salary or compensation to any individual in excess of certain amounts without the written consent of the DOJ. In addition, the Letter Agreement requires the repayment of the outstanding fine to the extent of 25% of the Company's after-tax profit or 25% of the net proceeds received by the Company on any sale of a capital asset for a sum in excess of $10,000, if not invested in another capital asset. At December 31, 2003, the Company was current in its payment obligations, with a remaining obligation of $433,000. In February 2004, the Company fully satisfied its obligation to the DOJ under the Letter Agreement.

Other Legal Proceedings

Beginning in 1992, actions were commenced against the Company and numerous other pharmaceutical manufacturers, in connection with the alleged exposure to diethylstilbestrol ("DES"). The defense of all of such matters was assumed by the Company's insurance carrier, and a substantial number have been settled by the carrier. Currently, several actions remain pending with the Company as a defendant in the Pennsylvania Court of Common Pleas, Philadelphia Division, and the insurance carrier is defending each action. The Company and its legal counsel do not believe any of such actions will have a material impact on the Company's financial condition. The ultimate outcome of these lawsuits cannot be determined at this time, and accordingly, no adjustment has been made to the consolidated financial statements.

The Company is 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 seeks 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. Discovery in this action is complete. The Company's and the Plaintiff's motion for summary judgment were due to be heard by the Court in August 8, 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. The Estate of Mr. Kohn has been substituted as the plaintiff. In February, 2005, 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. The Company and the Estate of Mr. Kohn have agreed in principle to settle this matter, pursuant to which the Company would make a one-time payment of $35,000. The proposed settlement is subject to the preparation and execution of a definitive settlement agreement and the approval of the Bronx, New York Surrogate's Court.

Each of the purchase agreements for the Company's 1998 Debentures, 1999 Debentures, 2003 Debentures, and 2004 Debentures and Bridge Loans contains provisions by which the Company is obligated to indemnify the purchasers of the debentures for any losses, claims, damages, liabilities, obligations, penalties, awards, judgments, expenses or disbursements arising out of or resulting from the breach of any representation, warranty or agreement of the Company related to the purchase of the debentures and bridge loans. These indemnification obligations do not include a limit on maximum potential future payments, nor are there any recourse provisions or collateral that may offset the cost.

As of December 31, 2004, the Company does not believe that any liability has been incurred as a result of these indemnification obligations.

NOTE M - QUARTERLY FINANCIAL DATA (UNAUDITED)

Quarterly Financial Data (amounts in thousands except per share amounts)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
2004					
Net product revenues	$ 628	$ 210	$ -	$ -	$ 838
Loss from operations	(2,084)	(2,120)	(3,810)	(1,951)	(9,965)
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)
2003					
Net product revenues	$ 1,526	$ 1,206	$ 1,478	$ 1,540	$ 5,750
Loss from operations	(3,387)	(3,552)	(3,325)	(6,980)	(17,244)
Net loss	(10,575)	(11,027)	(11,590)	(15,263)	(48,455)
Loss per common share - basic and diluted	$ (.50)	$ (.52)	$ (.55)	$ (.71)	$ (2.28)
2002					
Net product revenues	$ 1,881	$ 2,258	$ 2,013	$ 2,053	$ 8,205
Loss from operations	(2,888)	(3,379)	(3,466)	(3,204)	(12,937)
Net loss	(5,479)	(7,340)	(7,869)	(38,901)	(59,589)
Loss per common share - basic and diluted	$ (.36)	$ (.49)	$ (.52)	$ (2.46)	$ (3.90)

ACURA PHARMACEUTICALS, INC. AND SUBSIDIARIES

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS

DECEMBER 31,
(in thousands)

COL. A	COL. B		COL. C	COL. D (1)	COL. E
Description	**Balance at beginning of period**	**Additions charged to costs and expenses**	**Additions charged to other accounts**	**Deductions**	**Balance at end of period**
Year ended December 31, 2004					
Allowances - accounts receivable	$ 428	$ -	$ -	$ (428)	$ -
Valuation allowance - deferred tax assets	$ 58,256	$ -	$ -	$ (4,119)	$ 54,137
Year ended December 31, 2003					
Allowances - accounts receivable	$ 14	$ 428	$ -	$ (14)	$ 428
Valuation allowance - deferred tax assets	$ 53,899	$ 4,357	$ -	$ -	$ 58,256
Year ended December 31, 2002					
Allowances - accounts receivable	$ 347	$ 101	$ -	$ (434)	$ 14
Valuation allowance - deferred tax assets	$ 40,948	$ 12,951	$ -	$ -	$ 53,899

(1) Accounts written-off.

EXHIBIT INDEX

EXHIBIT NUMBER	DOCUMENT
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, Inc., 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").

EXHIBIT NUMBER	DOCUMENT
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).
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(l)	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 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 Noncompetition 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 1995 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).

EXHIBIT NUMBER	DOCUMENT
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 1995 8-K).
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).
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).

EXHIBIT NUMBER	DOCUMENT
10.45	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).
10.46	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).
10.47	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).
10.48	Form of 10% Convertible Secured Note due May 30, 1999 (incorporated by reference to Exhibit 10.48 to the 1998 Form 10-K).
10.49	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).
10.50	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).
10.51	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).
10.52	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).
10.53	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).
10.54	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).
10.55	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).
10.56	Registrant's 1998 Stock Option Plan (incorporated by reference to Exhibit 10.56 to the 1998 Form 10-K).
10.57	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")).+
10.58	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).
10.59	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).
10.60	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).
10.61	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).
10.62	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).
10.63	Watson's Guarantors Security Agreement dated March 29, 2000 between the Registrant, Houba, Inc. and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.63 to the March 2000 8-K).
10.64	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).+

10.65	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).

EXHIBIT NUMBER	DOCUMENT
10.66	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).
10.67	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).+
10.68	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).+
10.69	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).+
10.70	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).+
10.71	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).+
10.72	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")).
10.73	Form of 5% Convertible Senior Secured Debenture issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.73 the 1999 Form 10-K).
10.74	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).
10.75	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).
10.76	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")).
10.77	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).
10.78	Form of Agreement of Guaranty of Subsidiaries of the Registrant dated December 20, 2002 between Houba, Inc., the Registrant and the 2002 Debentureholders (incorporated by reference to Exhibit 10.3 to the December 2002 Form 8-K).
10.79	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).
10.80	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).
10.81	Voting Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.6 to the December 2002 Form 8-K).
10.82	Debentureholders Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.7 to the December 2002 Form 8-K).
10.83	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).
10.84	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).

EXHIBIT NUMBER	DOCUMENT
10.85	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).
10.86	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).
10.87	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).
10.88	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).
10.89	Watson Common Stock Purchase Warrant dated December 20, 2002 (incorporated by reference to Exhibit 10.14 to the December 2002 Form 8-K).
10.90	Registration Rights Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.15 to the December 2002 Form 8-K).
10.91	Warrant Recapitalization Agreement dated December 20, 2002 (incorporated by reference to Exhibit 10.15 to the December 2002 Form 8-K).
10.92	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 to the Registrant's current report on Form 8-K dated February 10, 2004 (the "February 2004 Form 8-K").
10.93	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).
10.94	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 10.3 of the February 2004 Form 8-K).
10.95	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).
10.96	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).
10.97	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).
10.98	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).
10.99	Company General Security Agreement (incorporated by reference to Exhibit 10.8 of the February 2004 Form 8-K).
10.100	Form of Unconditional Agreement of Guaranty (incorporated by reference to Exhibit 10.9 of the February 2004 Form 8-K).
10.101	Form of Guarantor Security Agreement (incorporated by reference to Exhibit 10.10 of the February 2004 Form 8-K).
10.102	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).
10.103	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).

EXHIBIT NUMBER	DOCUMENT
10.104	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).
10.105	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).
10.106	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).
10.107	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).
10.108	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")).
10.109	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).
10.110	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.)
10.111	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")).
10.112	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).
10.113	Executive Employment Agreement dated as of April 5, 2004 between the Registrant and Ron J. Spivey (incorporated by reference to Exhibit 10.3 to June 2004 10-Q).
10.114	Amendment to Executive Employment Agreement between the Registrant and Andrew D. Reddick, dated May 27, 2004 (incorporated by reference to Exhibit 10.4 to June 2004 10-Q).
10.115	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).
10.116	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).
10.117	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).
10.118	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).
10.119	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).
10.120	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).
14	Code of Ethics (incorporated by reference to Exhibit 14 of the Registrant's Form 10-K filed April __, 2004 (the "2003 Form 10-K").
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 22 to the 1993 Form 10-K).
*23.1	Consent of Grant Thornton LLP, independent certified public accountants, to the incorporation by reference of its report to the consolidated financial statements of the Registrant contained in its Form 10-K for the year ended December 31, 2003, into the Registrant's Registration Statements on Form S-8 (Registration Nos. 333-63288 and 33-98356).

EXHIBIT NUMBER	DOCUMENT
*23.2	Consent of BDO Seidman LLP, independent certified public accountants, to the incorporation by reference of its report to the consolidated financial statements of the Registrant contained in its Form 10-K for the year ended December 31, 2004, 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

+ 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.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated February 26, 2004, except for Note E, as to which the date is March 19,2004, accompanying the consolidated financial statements and schedule included in the Annual Report of Acura Pharmaceuticals, Inc. (formerly, Halsey Drug Co., Inc.) and Subsidiaries on Form 10-K for the year ended December 31, 2003. We hereby consent to the incorporation by reference of said report in the Registration Statements of Acura Pharmaceuticals, Inc. on Forms S-8 (Registration Nos. 333-63288 and 33-98356), pertaining to the 1998 Stock Option Plan and the 1995 Stock Option Plan.

/s/ GRANT THORNTON LLP

New York, New York

February 23, 2005

EXHIBIT 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Acura Pharmaceuticals, Inc.
Palatine, Illinois

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-63288 and 33-98356) of our report dated February 9, 2005, relating to the consolidated financial statements and schedule of Acura Pharmaceuticals, Inc. appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2004. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

Chicago, Illinois
February 23, 2005

/s/ BDO Seidman, LLP

EXHIBIT 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO RULES 13a-14 AND 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934

I, Andrew D. Reddick, the President and Chief Executive Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Acura Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

c) disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2005

By: /s/ Andrew D. Reddick

Andrew D. Reddick
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO RULES 13a-14 AND 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934

I, Peter A. Clemens, the Senior Vice President and Chief Financial Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Acura Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

(c) disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

COMPANY NAME CORPORATION

Date: February 25, 2005

By: /s/ Peter A. Clemens

Peter A. Clemens
Senior Vice President and Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Acura Pharmaceuticals, Inc., Inc. (the "Company") on Form 10-K for the period ending December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew D. Reddick, the Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2005

By: /s/ Andrew D. Reddick

Andrew D. Reddick
President and Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Acura Pharmaceuticals, Inc., Inc. (the "Company") on Form 10-K for the period ending December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter A. Clemens, the Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(3) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(4) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2005

By: /s/ Peter A. Clemens

Peter A. Clemens
Senior Vice President and Chief Financial Officer