

# **ACURA PHARMACEUTICALS, INC**

# FORM 10-K (Annual Report)

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# 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)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2003
[] 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

# HALSEY DRUG CO., INC.

(Exact name of registrant as specified in its charter)

NEW YORK

(State or other jurisdiction of Incorporation or organization)

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

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

> 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)

# SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

**NONE** 

(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 [X] 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 [X]

As of March 31, 2004, the registrant had 21,601,704 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, 2003 (\$0.78) (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 \$11,106,350.

# **DOCUMENTS INCORPORATED BY REFERENCE** NONE

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# 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 Halsey Drug Co., Inc. ("Halsey" 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. Such factors include, among others, the following: changes in general economic and business conditions; loss of market share through competition; introduction of competing products by other companies; the timing of regulatory approval and the introduction of new products by the Company; changes in industry capacity; pressure on prices from competition or from purchasers of the Company's products; regulatory changes in the generic pharmaceutical manufacturing industry; difficulties encountered in the development of novel product synthesis and manufacturing techniques; regulatory obstacles to the introduction of new technologies or products that are important to the Company's growth; availability of qualified personnel; the loss of any significant customers; and other factors both referenced and not referenced in this Report. When used in this Report, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions are intended to identify forward-looking statements.

# **ITEM 1. BUSINESS**

#### GENERAL

The Company, a New York corporation established in 1935, and its subsidiaries, have been engaged in the development, manufacture, sale and distribution of a variety of generic finished dosage pharmaceutical products and active pharmaceutical ingredients ("APIs"). Prior to the restructuring of the Company's operations largely completed on January 30, 2004, the generic drug products manufactured and sold by the Company generally consisted of an analgesic product, anti-infectives, antitussives, cough and cold preparations, and a steroid product. Since March 1999, the Company has manufactured APIs at its Culver, Indiana facility and manufactured, packaged and sold its generic finished dosage products at two leased locations in Congers, New York.

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 in 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. See "Restructure of Operations" below.

As restructured, the Company is a specialty pharmaceutical company presently engaged in research, development and manufacture of innovative abuse deterrent formulations (the "ADF Technology") intended for use in orally administered opioid-containing pharmaceutical products. In addition, the Company is engaged in research, development and manufacture of proprietary, high yield, short cycle time, environmentally sensitive opioid synthetic processes (the "Opioid Synthesis Technologies") intended for use in the commercial production of certain bulk opioid active pharmaceutical ingredients ("APIs"). To date, the Company has filed four patent applications with the U.S. Patent and Trademark office (the "PTO") relating to the ADF Technology and the Opioid Synthesis Technology and has received one notice of allowance from the PTO relating to one of those applications concerning the Opioid Synthesis Technologies.

The Company conducts research, development, laboratory, manufacturing and warehousing activities relating to the ADF Technology and the Opioid Synthesis Technologies (collectively the "Proprietary 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") including raw opium, opium poppy, and concentrate of poppy straw from foreign countries. 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 progress and status of the application for the Import Registration is described below under the caption "Import License Registration." The Company is also engaged in collaborative research and development with a contract research organization and an academic institution in preparation for clinical evaluation and testing of its proprietary ADF Technology.

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 Proprietary Technologies and further develop, register and commercialize multiple formulations and strengths of orally administered opioid-containing finished dosage products utilizing such Proprietary Technologies. The Company expects to receive a share of profits and/or royalty payments derived from the Partners' sale of products incorporating the Proprietary Technologies. 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 opioid APIs and finished dosage form products utilizing the Proprietary Technologies. The Import Registration, if ultimately granted, for which there can be no assurances, 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 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.halseydrug.com. We make available free of charge on www.halseydrug.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:

Halsey Drug Co., Inc. 616 N. North Court, Suite 120 Palatine, Illinois 60067 Attn: Investor Relations 847.705.7709

#### ADF TECHNOLOGY

The class of drugs exhibiting opium or morphine-like properties are referred to as opioids, or opioid agonists. This class of products has experienced substantial growth in recent years due to an increase in the aging population and the more aggressive treatment of pain by physicians. 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 an abuser may commonly attempt to abuse an opioid containing drug formulation. The most common methods include (1) intravenous injection, (2) intransal (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."

Limited attempts have been made to diminish abuse of orally administered opioid drugs. These attempts have generally centered on including an opioid antagonist in the oral dosage form which is not orally active but which will substantially block the analgesic effects of the opioid if one attempts to dissolve/extract the opioid and administer it intravenously. However, a clear patient and societal 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 drugs such as opioid analgesics.

It is with the growing concern about the illegitimate use of legitimate opioid-based drug products described above in mind that the Company is pursuing its abuse deterrent formulation technology (the "ADF Technology"). The Company believes that the internally developed ADF Technology is applicable to both immediate release and extended release orally administered tablets and capsules which are formulated with an opioid analgesic as an active ingredient. Company research and laboratory experiments to date suggest that the ADF Technology may be formulated into an orally administered tablet with many of the commonly utilized opioid active pharmaceutical ingredients and related salts including morphine, codeine, hydrocodone, oxycodone and hydromorphone. The ADF Technology utilizes certain pharmaceutical product excipients in addition to the opioid active ingredients. The Company believes that the ADF 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 tablet. Provided the ADF Technology is appropriately tested and proves successful in clinical trials, of which no assurance can be given, the Company believes that its ADF Technology will discourage or deter the three most commonly utilized routes of opioid abuse including (i) intravenous, (2) intranasal/snorting and (3) consumption of excessive quantities of orally administered tablets or capsules. However, the Company can make no assurances that such clinical testing will in fact demonstrate that the ADF Technology will discourage or deter abuse. In addition, if such abuse

deterrent characteristics are demonstrated, the Company can make no assurances that the magnitude of such effect will be statistically significant or clinically meaningful.

In the fourth quarter of 2003 the Company filed a patent application relating to the ADF Technology with the PTO. The Company can make no assurances that such patent application will ever issue, or that if such application issues, that the issued claims of such application will be sufficiently broad to protect the ADF Technology from competition from similar technologies developed or commercialized by others. Such patent application includes, among other things, laboratory test results demonstrating the ability of the ADF Technology to discourage the intravenous injection of opioids by potential abusers.

In the first quarter of 2004, the Company, at its Congers, New York facility, pursuant to current Good Manufacturing Practices ("cGMP"), formulated, manufactured, packaged and labeled three test batches of different formulations (the "Test Batches") of a tablet product containing a certain opioid active ingredient utilizing the ADF Technology. Such Test Batches met all of the physical specifications established in advance for such Test Batches and were therefore quality assurance released. These Test Batches will be monitored for stability under the appropriate conditions as required by the FDA for drug products. The Company plans to utilize such Test Batches in clinical trials.

In the first quarter of 2004, the Company entered into an agreement with a certain contract research organization to develop, in concert with a certain academic institution and clinical investigators, appropriate clinical trial protocols, to prepare an investigational new drug application ("IND") and to conduct clinical trials. The Company intends to file such IND in 2004 and at the appropriate time thereafter begin clinical testing of its ADF Technology. The Company can make no assurances that such clinical testing will in fact demonstrate that the ADF Technology will discourage or deter abuse. In addition, if such abuse deterrent characteristics are demonstrated, the Company can make no assurances that the magnitude of such effect will be statistically significant or clinically meaningful.

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 ADF Technology and further develop, register and commercialize multiple formulations and strengths of orally administered opioid containing finished dosage products utilizing such ADF 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. The Company can make no assurance that it will be able to negotiate such agreements on favorable terms and, provided that such agreements are successfully executed, that the milestones will be achieved and the milestone payments will be subsequently made by our Partners.

#### OPIOID SYNTHESIS TECHNOLOGIES

The Company is engaged in the research, development and scale-up of its proprietary Opioid Synthesis Technologies described in the table below.

OPIOID SYNTHESIS TECHNOLOGY	STARTING MATERIAL	ESTIMATED YIELD	APPLICABLE DEA REGISTRATIONS	STATUS OF PATENT APPLICATION		
Oxycodone HCl Process #1	Codeine Phosphate	40 - 50%	a) Research b) Manufacturing	One (1) Notice of Allowance issued and one (1) other Patent Pending before the PTO		
Hydrocodone Bitartrate Process #1	Codeine Phosphate	85%	a) Manufacturing	Patent Application Drafted		
Oxycodone HCl Process #2	NRMs	68 - 72%	a) Research b) Manufacturing c) Import	Patent Application draft in process		
Codeine Phosphate Process #1	NRMs	90 - 100%	a) Research b) Manufacturing c) Import	Patent Application Drafted		
Hydrocodone Bitartrate Process #2	Codeine Base	85 - 95%	a) Research b) Manufacturing	Patent Application Drafted		

OPIOID SYNTHESIS TECHNOLOGY	STARTING MATERIAL	ESTIMATED YIELD	APPLICABLE DEA REGISTRATIONS	STATUS OF PATENT APPLICATION
Morphine Sulfate	NRMs	96%	<ul><li>a) Research</li><li>b) Manufacturing</li><li>c) Import</li></ul>	Patent Application draft in process
Dihydrocodeine Bitartrate	Codeine Base	>90%	<ul><li>a) Research</li><li>b) Manufacturing</li></ul>	Patent Application Drafted
Codeine Phosphate Process #2	NRMs	80 - 90%	<ul><li>a) Research</li><li>b) Manufacturing</li><li>c) Import</li></ul>	Patent Application Drafted
Codeine Phosphate Process #3	NRMs	65 - 85%	<ul><li>a) Research</li><li>b) Manufacturing</li><li>c) Import</li></ul>	One (1) Patent Application Pending before the PTO

The Opioid Synthesis Technologies outlined in the Table above are proprietary processes that the Company intends and believes to be efficient and cost-effective methods of manufacturing opioid APIs. The Company believes that the advantages of these processes include a substantial 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 has filed three patents relating to the Opioid Synthesis Technologies including two in June 2003 and one in September of 2003 and intends to prepare and file at least four additional patent applications relating to these technologies. In March 2004 the Company received a notice of allowance from the PTO relating to one of the patent applications filed in June of 2003. The Company intends to pay the issue fee and expects a U.S. patent will be granted from that application. No assurance can be given, however, that any other currently pending patent applications or future patent applications which the Company intends to file relating to the Opioid Synthesis Technologies will be granted by the PTO. Each of the Company's Opioid Synthesis Technologies requires a DEA registration and/or an import registration for NRMs. All such Opioid Synthesis Technologies require a DEA registration for manufacturing Schedule II controlled substances.

The development and ultimate commercialization of APIs and finished dosage products incorporating the Opioid Synthesis Technologies are subject to various factors some of which are outside the Company's control. For example, presently only one of the Opioid Synthesis Technologies has been manufactured in kilogram scale batches and none have been manufactured in commercial scale batches. Each of the Opioid Synthesis Technologies will need to be successfully scaled up to larger batches to be economically viable, of which no assurance can be given.

# 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 U.S. Food and Drug Administration ("FDA"). The Culver Facility is currently registered by the DEA to research and manufacture certain Schedule II - V 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. In their hearing request, the objecting parties opposed the issuance of an Import Registration on various grounds, including (i) that the Company's application should be stayed pending the resolution of pending import registration requests from other parties; (ii) that the issuance of an Import Registration to the Company has the potential for increasing the prices for narcotic raw materials from foreign sources as a result of increased demand from U.S. importers; (iii) that the Company lacks the experience, technology, personnel and capital to process NRMs and, (iv) that the competition in the marketplace for bulk opioid APIs manufactured from the NRMs is adequate. In light of several other recent importer registration decisions, DEA's Office of Diversion Control also opposed registration of additional importers at this time.

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 Company restructuring and financing activities. Pursuant to the ALJ's order on March 30, 2004, the administrative record will remain open for at least 10 days following the Company's filing of this Report to allow the opposing parties to file statements indicating whether they intend to submit additional evidence in response to this Report. Upon the closure of the administrative record, the ALJ will make findings of fact, draw legal conclusions and recommend a specific decision on the Company's Import Registration application to the DEA Deputy Administrator. The Deputy Administrator will then consider the ALJ's decision and administrative record and issue a final order relating to the Company's application. DEA will judge whether the issuance of an Import Registration is appropriate based on, among other considerations, whether adequate security safeguards and controls are maintained at the Culver Facility and at all points in the chain of transfer of the NRMs from foreign suppliers to the Culver Facility, whether the Opioid Synthesis Technologies are viable processes, whether market demand for opioid containing products or other factors support the approval of another import registration, and whether the Company has established itself as an eligible party to obtain NRMs for foreign sources. The Company must continue to maintain compliance with DEA's requirements for maintenance of its Manufacturing Registration in the meantime.

Assuming DEA grants the Company's application, then the Company should be permitted to import NRMs upon appropriate notice in the Federal Register. 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, the proceedings will continue through 2004 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 Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Liquidity and Capital Resources" 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.

#### 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. The plan targeted a reduction in workforce of approximately 70 employees at the Congers Facilities, 25 employees at the Culver Facility and 5 employees in Rockford, Illinois.

In implementing the restructuring plan at the Culver Facility, the reduction in work force involved approximately 25 employees engaged in or supporting the manufacture of doxycycline hyclate and doxycycline monohydrate APIs which were converted to finished dosage products at the Congers Facilities. With the closure of the Congers Facilities the APIs

manufactured in Culver were not required. The Culver Facility work force reduction was substantially completed by December 31, 2003.

In implementing the restructuring plan at the Rockford, Illinois administrative office facility, the Company terminated its Rockford office lease agreement and relocated the administrative functions to Palatine, Illinois. This process was completed on February 29, 2004 resulting in a reduction in work force of 5 employees.

In implementing the restructuring of operations at the Congers Facilities, the reduction in work force involved essentially all of the employees at the site. 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. From approximately March 1, 2004 to March 19, 2004 a small logistics, maintenance and warehouse staff prepared the Congers Facilities for sale to Ivax Pharmaceuticals as described below under the caption "Sale of Assets".

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

- Development of the Company's proprietary abuse deterrent formulation technology (the "ADF 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 ADF Technology.
- Evaluation of certain finished dosage products utilizing the ADF Technology in clinical trials.
- Scale-up and manufacture of commercial quantities of certain products utilizing the ADF Technology for sale by the Company's licensees.
- Research, development and scale up of the Company's novel Opioid Synthesis Technologies.
- Prosecution of the Company's application to the DEA to receive a registration (the "Import Registration") to import Narcotic Raw Materials ("NRMs") for use in the production of opioid API's utilizing the Company's Opioid Synthesis Technologies.
- 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 ADF 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 ADF 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 settings, and none have been tested in 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 process of seeking the Import Registration, the continuing development of the Company's Opioid Synthesis Technologies and the development of finished dosage products utilizing the Company's ADF Technology are planned to continue through 2004. 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 ADF Technology, Opioid Synthesis Technologies and to the prosecution of the Import Registration. The failure of the Company to successfully develop the ADF Technology will have a material adverse effect on the Company's operations and financial condition.

#### 2004 DEBENTURE OFFERING

On February 6, 2004, the Company consummated a private offering of securities for an aggregate purchase price of approximately \$12.3 million (the "2004 Debenture Offering"). The securities issued in the 2004 Debenture Offering consisted of convertible senior secured debentures (the "2004 Debentures"). 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 II, LP ("Care Capital"), Essex Woodlands Health Ventures V, L.P. ("Essex"), Galen Partners III, L.P. and each of the Purchasers listed on the signature page thereto (collectively, the "2004 Debenture Investor Group"). On April 14, 2004 the Company completed an additional closing under the 2004 Purchase Agreement and issued additional 2004 Debentures in the aggregate principal amount of approximately \$579,000, bringing the principal amount of the 2004 Debentures issued by the Company under the 2004 Purchase Agreement to an aggregate amount of approximately \$12.879 million.

Of the approximate \$12.879 million in 2004 Debentures issued in the 2004 Debenture Offering, approximately \$2 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 and Galen Partners III, L.P., Galen International III, L.P., and Galen Employee Fund III, L.P. (collectively, "Galen") during November and December, 2003. The 2004 Purchase Agreement further provides that the Company may issue additional 2004 Debentures in the principal amount of up to approximately \$1.121 million on or prior to June 5, 2004, provided that the aggregate principal amount of 2004 Debentures issued pursuant to the 2004 Purchase Agreement shall not exceed \$14 million without the consent of the holders of 60% of the principal amount of the 2004 Debentures then held by Care Capital, Essex and Galen.

The 2004 Debentures, issued at par, bear interest at the rate of 1.62% per annum, the short-term Applicable Federal Rate on the date of issuance. The 2004 Debentures are secured by a lien on all assets of the Company. In addition, each of Houba, Inc. and Axiom Pharmaceutical Corporation, each a wholly-owned subsidiary of the Company, has executed in favor of the 2004 Debenture holders, an unconditional agreement of guaranty of the Company's obligations under the 2004 Purchase Agreement. Each guaranty is secured by all assets of such subsidiary. In addition, the Company has pledged the stock of each such subsidiary to the holders of the 2004 Debentures to further secure its obligations under the 2004 Purchase Agreement.

In accordance with the terms of an Amended and Restated Subordination Agreement dated as of February 6, 2004 between the Company, the holders of the 2004 Debentures and the holders of the Company's other outstanding debentures, the liens on the Company's and its subsidiary's assets as well as the payment priority of the 2004 Debentures are (i) subordinate to the Company's lien and payment obligations in favor of Watson Pharmaceuticals under the Watson Term Loan Agreement, and (ii) senior to the Company's lien and payment obligations in favor of the holders of the Company's other outstanding debentures in the aggregate principal amount of approximately \$87.7 million.

The 2004 Debentures (including the principal amount plus interest accrued at the date of conversion) will convert automatically into the Company's Series A convertible preferred stock (the "Series A Preferred") immediately following the Company's receipt of shareholder approval at its next shareholders' meeting 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 (the date of such filing, the "Charter Amendment Filing Date"), as provided in the 2004 Purchase Agreement. The 2004 Debentures will convert into Series A Preferred at a price per share (the "Series A Conversion Price") of \$0.6425, representing the average of the closing bid and asked prices of the Company's Common Stock for the twenty

(20) trading days ending February 4, 2004, as reported by the Over-the-Counter ("OTC") Bulletin Board. The Series A Conversion Price is subject to adjustment, from time to time, to equal the consideration per share received by the Company for its Common Stock, or the conversion/exercise price per share of the Company's Common Stock issuable under rights or options for the purchase of, or stock or other securities convertible into, Common Stock ("Convertible Securities"), if lower than the then applicable Series A Conversion Price.

Based on the \$0.6425 Series A Conversion Price of the Series A Shares and estimating the interest accrual under the 2004 Debentures prior to the Charter Amendment Filing Date, the 2004 Debentures with an aggregate principal amount of \$14 million would be convertible into an aggregate of approximately 22 million Series A Preferred shares.

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.

The 2004 Purchase Agreement provides that each of Care Capital, Essex and Galen (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. Effective as of the closing 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).

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 \$87.7 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 190.1 million shares of the Company's Common Stock.

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 2004 Debenture Investor Group 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, each holder of the 2004 Debentures agreed to convert the 2004 Debentures held by such holder into the Company's Series A Preferred shares and each holder of 1998-2002 Debentures agreed to convert 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 Shares together with the Series B Shares are herein referred to as, the "Junior Preferred Shares", and the Junior Preferred Shares together with the Series A Preferred, are collectively referred to as the "Preferred Stock". The Conversion Agreement provides, among other things, for the automatic conversion of the 2004 Debentures and the 1998-2002 Debentures (collectively, the "Outstanding Debentures") into the appropriate class of Preferred Stock immediately following the Company's receipt of shareholder approval to the Charter Amendment authorizing the creation of the Preferred Stock and the filing of the Charter Amendment with the Office of the New York Department of State.

Under the Conversion Agreement, the holders of approximately \$6.7 million in principal amount of 2002 Debentures issued during 2003 will convert such 2002 Debentures (plus accrued and unpaid interest) into Series B Preferred Shares. Of the remaining approximate \$81 million in principal amount of the 1998-2002 Debentures, approximately \$31.6 million is comprised of 1998 Debentures, approximately \$21.8 million is comprised of 1999 Debentures and approximately \$27.6 million is comprised of 2002 Debentures. The 1998 Debentures will be converted into Series C-1 Preferred shares. The 1999 Debentures

will be converted into Series C-2 Preferred shares. The remaining balance of the 2002 Debentures shall be converted into Series C-3 Preferred shares.

The number of Junior Preferred Shares to be received by each holder of 1998-2002 Debentures is based on the respective prices at which the 1998-2002 Debentures were convertible into Common Stock. The 2002 Debentures issued in 2003 have a conversion price of \$0.3420 per share. The 1998 Debentures, 1999 Debentures and the remaining balance of the 2002 Debentures have conversion prices of \$0.5776, \$0.5993 and \$0.3481 per share, respectively. Based on the respective conversion prices of the 1998-2002 Debentures, and estimating the interest accrual on the 1998-2002 Debentures prior to the Charter Amendment Filing Date, the 1998-2002 Debentures are convertible into an aggregate of approximately 20.0 million Series B Preferred shares, 56.5 million Series C-1 Preferred shares, 37.5 million Series C-2 Preferred shares and 80.9 million Series C-3 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 of 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 stockholders, 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.

The Company was a party to a certain loan agreement with Watson Pharmaceuticals ("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 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 "Amended and Restated Watson Note"). Simultaneous with the issuance of the Amended and Restated Watson Note, each of the Lead 2004 Investors and the other investors in the 2004 Debentures as of February 10, 2004 (collectively, the "Watson Note Purchasers") purchased the Amended and Restated 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.

The Amended and Restated Watson 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% and matures on June 30, 2007.

As of April 14, 2004, after giving effect to the payment to Watson of approximately \$4.3 million to restructure the Watson Term Loan and the payment of legal and other professional fees relating to the 2004 Debenture Offering, the Company realized net proceeds from the 2004 Debenture Offering of approximately \$5.8 million (the "2004 Debenture Offering Proceeds").

# SALE OF ASSETS

In the three months following the Company's November 6, 2003 press release announcing the implementation of the restructuring of the Company's operations, the Company contacted, or was contacted by, a total of 21 parties expressing interest in the Congers Facilities and certain non revenue generating ANDAs. Such parties were provided with a detailed descriptive memorandum relating to the assets and operations of the Congers Facilities. The majority of such parties completed a tour of the facilities and varying degrees of diligence investigation. Of such parties four provided draft letters of intent outlining non-binding terms for the acquisition of the assets of the Congers Facilities, including the direct purchase by such parties of the Company's leased facility located on Brenner Drive, Congers, New York from the landlord of this site.

In February, 2004, the Company sold certain non-revenue generating ANDAs to a third party in consideration of \$2.0 million. In addition, 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 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. Shareholder approval is necessary to complete the IVAX transaction and will be sought at the Company's next annual meeting of shareholders. After giving effect to the payment of legal and other professional fees relating to the IVAX transaction, the Company estimates that it will realize aggregate net proceeds from the IVAX transaction of approximately \$2.3 million. The aggregate proceeds of \$4.3 million from these asset divestment transactions is hereinafter referred to as the "Asset Divestment Proceeds."

# HYDROCODONE OPTION AGREEMENT

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 approximately \$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 expense (collectively, the "API Scale Up Expenses"). The Company is a party to a certain Hydrocodone Option Agreement dated February 6, 2004 with Watson Pharmaceuticals ("Watson") pursuant to which the Company has granted Watson a six (6) month exclusive option to enter into a supply agreement with the Company for supply of hydrocodone bitartrate API (the "Hydrocodone API"). If such option is exercised by Watson, at Watson's sole discretion, of which there can be no assurance, Watson will fund 50% of the API Scale Up Expenses, up to a maximum of \$3.5 million and the Company has agreed to use commercially reasonable efforts to obtain financing dedicated to fund its portion of the API Scale Up Expenses. In the event the Company is unable to secure financing dedicated to fund its portion of the API Scale Up Expenses, the Hydrocodone Option provides that the parties will discuss alternatives relating to the scale up of the its Opioid Synthesis Technology for Hydrocodone API.

There can be no assurance that Watson will exercise the Hydrocodone Option or, even if exercised, that the Company will succeed in obtaining financing dedicated to fund its portion of the API Scale Up Expenses. As described in this Report, no portion of the 2004 Debenture Offering Proceeds or the Asset Divestment Proceeds is budgeted for the API Scale Up Expenses. Until such time, if any, as the Company secures third-party financing dedicated to the API Scale Up Expenses, the Company will be unable to complete the commercial scale up of its Opioid Synthesis Technologies.

#### 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.

# **GOVERNMENT REGULATION**

### **GENERAL**

All pharmaceutical technology and manufacturing firms, including the Company, are subject to extensive regulation 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 API Synthesis Technologies and the ADF 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. 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.

The 1984 Act, in addition to establishing the ANDA procedure, created new statutory protections for approved brand-name drugs. In general, under the 1984 Act, approval of an ANDA for a generic drug may not be made effective until all product and use patents listed with the FDA for the equivalent brand name drug have expired or have been determined to be invalid or unenforceable. The only exceptions are situations in which the ANDA applicant successfully challenges the validity or absence of infringement of the patent and either the patent holder does not file suit or litigation extends more than 30 months after notice of the challenge was received by the patent holder. Prior to enactment of the 1984 Act, the FDA gave no consideration to the patent status of a previously approved drug. Additionally, under the 1984 Act, if specific criteria are met, the term of a product

or use patent covering a drug may be extended up to five years to compensate the patent holder for the reduction of the effective market life of that patent due to federal regulatory review. With respect to certain drugs not covered by patents, the 1984 Act sets specified time periods of two to ten years during which approvals of ANDAs for generic drugs cannot become effective or, under certain circumstances, ANDAs cannot be filed if the equivalent brand-name drug was approved after December 31, 1981.

3. "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 ADF Technology.

#### 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 Proprietary 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. In February of 2001, the Indiana Department of Environmental Management (IDEM) issued a notice of violation to the Culver Facility alleging deficiencies with wastewater management at the site. The Company challenged those allegations and has been engaged in productive discussions with IDEM since that time in an effort to achieve a solution that is satisfactory to the parties. Although this issue remains unresolved, discussions are ongoing. The Company does not believe that the outcome of such discussion will have a material impact on the Company's financial condition or its ability to effectively operate and undertake activities at the Culver Facility.

# **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.

#### **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 in this Report will continue through 2004 and beyond.

#### **SUBSIDIARIES**

The Company's Culver, Indiana research, development, and manufacturing operations are conducted by Houba, 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 will become an inactive subsidiary of the Company.

#### **EMPLOYEES**

As of March 31, 2004, the Company had 18 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 ADF Technology. The remaining 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 a term of one year expiring February 28, 2005. The Company has an option 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's research, development, laboratory, warehouse and manufacturing facility is at 16235 State Road 17, Culver, Indiana. At this location the Company's Houba, Inc. subsidiary owns a 45,000 square foot facility on approximately 30 acres of land. This facility includes an office area for administrative functions and quality assurance functions, an API manufacturing area, an analytical methods development, assay testing and chemistry research laboratory, a product and API stability testing area, a warehouse area, and an area for tablet and capsule finished dosage product manufacturing.

### 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. 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 motion for summary judgment was due to be heard by the Court on August 8, 2003. Plaintiff Kohn deceased shortly prior to such hearing date, and the motion for summary judgment and any trial of this matter have been stayed pending the substitution of Mr. Kohn's estate as the plaintiff. The Company does not believe this action will have a material impact on the Company's financial condition.

On June 13, 2002, the Company was named an additional defendant in an Amended Complaint filed in the matter entitled Vintage Pharmaceuticals, Inc., v. Watson Pharmaceuticals, Inc., and Halsey Drug Company, Inc., pending in the United States District Court for the Northern District of Alabama, Civil Action No. CV 01-B-1847-NE. Vintage seeks unspecified damages from the Company for allegedly interfering with Vintage's contract to produce Monodox(R), the brand name of doxycycline monohydrate, for Watson the Company denies the allegations, and is vigorously defending the action. Watson Pharmaceuticals' motion for summary judgment was approved by the Court on April 13, 2004. The Company intends to file a motion to dismiss the Amended Complaint for failure to state a cause of action based on the summary judgment approval in favor of Watson on the underlying claim.

The Company does not believe this action will have a material impact on the Company's financial condition.

# 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 2003.

#### PART II

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

#### MARKET AND MARKET PRICES OF COMMON STOCK

Set forth below for the periods indicated are the high and low bid price 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
2002 Fiscal Year		
First Quarter	2.4	1.5
Second Quarter	2.75	1.3
Third Quarter	1.95	1.05
Fourth Quarter	1.85	.68
2003 Fiscal Year		
First Ouarter	1.09	.82
Second Quarter	1.11	.76
Third Quarter	1.60	.76
Fourth Ouarter	1.07	.26
2004 Fiscal Year		
First Quarter	.82	.41

### **HOLDERS**

There were approximately 669 holders of record of the Company's common stock on March 31, 2004. 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 Series A Preferred shares issuable by the Company upon conversion of the Company's 5% convertible senior secured debentures issued pursuant to the Debenture and Share Purchase Agreement dated as of February 6, 2004 (the "2004 Debentures") and the Term Loan Agreement assigned by Watson Pharmaceuticals to Care Capital Investments II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P. and 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, 2003, the Company issued the following securities which were not registered under the Securities Act:

(i) 5% convertible senior secured debentures in the aggregate principal amount \$3.5 million (the "Bridge Notes") issued to certain bridge lenders (the "Bridge Lenders") on each of October 7, November 2, December 5, and December 29, 2003; and

(ii) 5% convertible senior secured debentures in the aggregate principal amount of \$427,577 issued in satisfaction of accrued interest under the Company's outstanding 5% convertible senior secured debentures.

Each of the investors in the Bridge Notes and the recipients of 5% convertible senior secured debentures in satisfaction of interest payments is an Accredited Investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act. Each of such securities 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, 2003, 2002, 2001, 2000 and 1999 are derived from the Company's audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2003 and December 31, 2002, and for each of the years in the three-year period ended December 31, 2003, and the report thereon, are included elsewhere herein. The selected financial information as of and for the years ended December 31, 2000 and 1999 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,						
	_	2003		2002	2001	2000	1999
	_				S, EXCEPT PE		)
OPERATING DATA:							
Net revenues	. \$	5,750	\$	8,205	\$ 16,929	\$ 20,223	\$ 11,420
Operating Costs							
Cost of manufacturing		11,705		12,535	14,857	18,743	15,316
Research and development Selling, general and		1,460	\$	1,517	1,327	1,821	1,075
Administrative expenses		7,903	\$	7,216	6,616	•	7,383
Plant shutdown costs		1,926		(126)	68	53	3,220
Interest expense		6,001		4,728	3,913	3,699	2,946
Interest income	. \$	25	\$	15	69	662	95
Amortization of deferred debt							
Discount and private offering							
Costs	. \$	24,771	\$	12,558	2,591	2,448	1,825
Loss on extinguishments of							
Debt	. \$	·	\$	28,415			
Investment in joint venture	. \$	·	\$		(202)	(57)	
Other (income) expense	. \$	464	\$	966	(13)	(101)	(187)
Loss before income tax							
Benefit	. \$	(48,455)	\$	(59,589)	(12,563)	(12,043)	(20,063)
Income tax benefit	. \$		\$			(389)	
Net loss	. \$	3(48,455)	\$	(59,589)	\$(12,563)	\$(11,654)	\$(20,063)
				======			
Basic and diluted loss per							
common share		(2.28)	Ś	(3.90)	\$ (.84)	\$ (.80)	\$ (1.40)
		======		======	=======	=======	=======
Weighted average number of							
outstanding shares	_	21,227		15,262	15,021	14,503	14,326
		======		======		•	
				DECEMBE	R 31,		
200	2 	200		200	1 20	00 19	 a a
		(IN THOU	USAN	DS, EXCEP	T PER SHARE	DATA)	
BALANCE SHEET DATA:							
Working capital							
(deficiency) \$ (3	,770)	\$ 5	,933	\$ (8	,276) \$ (5	,061) \$ (5	,181)
	,622	\$ 19				,209 12	
	,964		,632				,869

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

\$(209,546) \$(161,090)

\$ (52,067) \$ (12,268)

Accumulated deficit

Stockholders' equity (deficit) ......

(88,938)

(53,349)

(77,284)

(42.374)

(101,501)

(65,436)

Certain statements set forth under this caption constitute "forward-looking statements" within the meaning of the Reform Act. See "Special Note Regarding Forward-Looking Statements" on page 2 of this Report for additional factors relating to such

#### Statements.

# **OVERVIEW**

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. The plan targeted a reduction in workforce of approximately 70 employees at the Congers Facilities, 25 employees at the Culver Facility and 5 employees in Rockford, Illinois.

In implementing the restructuring plan at the Culver Facility, the reduction in work force involved approximately 25 employees engaged in or supporting the manufacture of doxycycline hyclate and doxycycline monohydrate APIs which were converted to finished dosage products at the Congers Facilities. With the closure of the Congers Facilities the APIs manufactured in Culver were not required. The Culver Facility work force reduction was substantially completed by December 31, 2003.

In implementing the restructuring plan at the Rockford, Illinois administrative office facility, the Company terminated its Rockford office lease agreement and relocated the administrative functions to Palatine, Illinois. This process was completed on February 29, 2004 resulting in a reduction in work force of 5 employees.

In implementing the restructuring of operations at the Congers Facilities, the reduction in work force involved essentially all of the employees at the site. 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. From approximately March 1, 2004 to March 19, 2004 a small logistics, maintenance and warehouse staff prepared the Congers Facilities for sale to Ivax Pharmaceuticals as described above under the caption "Sale of Assets".

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

- Development of the Company's ADF 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 ADF Technology.
- Evaluation of certain finished dosage products utilizing the ADF Technology in clinical trials.
- Scale-up and manufacture of commercial quantities of certain products utilizing the ADF Technology for sale by the Company's licensees.

- Research, development and scale up of the Company's novel Opioid Synthesis Technologies.
- Prosecution of the Company's application to the DEA to receive a registration to import Narcotic Raw Materials ("NRMs") for use in the production of opioid API's utilizing the Company's Opioid Synthesis Technologies.
- 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 ADF Technology, file for regulatory approval with the FDA and other regulatory authorities and commercialize such products.

# RESULTS OF OPERATIONS

#### **NET REVENUES**

Net product revenues for 2003 of \$5,750,000 represents a decrease of \$2,455,000 in product revenues as compared to 2002. The decrease 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 the agreement, terminated the exclusive supply agreement in March, 2003 and thereafter attempted to reestablish itself in the marketplace by manufacturing and distributing generic products under its Axiom subsidiary label. The Company's relatively narrow generic product line, the entrenched market positions of existing competitors, relatively low market prices and the time required to fulfill the regulatory requirements of reestablishing the generic products under the Company's 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.

Net product revenues for 2002 of \$8,205,000 represents a decrease of \$224,000 in product revenues as compared to 2001. During 2002 the Company obtained sources for the key APIs for the manufacture of butalbital/acetaminophen/caffeine tablets and prednisolone syrup. However due to the length of time these products were not available for sale due to lack of APIs, the Company lost consequential market share. The slow decline of product sales in 2002 was also due in part to the time required to site transfer the products from the Company's Brooklyn, NY facility, which closed in March 2001, to the Company's Congers, NY Facilities. The Company also generated \$8,500,000 in product development revenue in 2001 relating to the Company's sale of an ANDA to Watson.

#### COST OF MANUFACTURING

The Company's cost of manufacturing for 2003 was 203% of net product sales versus 153% of net product sales for 2002. The increased cost as a percent of sales in 2003 was directly attributable to a charge of \$1,354,000 for impairment of inventory in connection with the Company's restructuring.

For 2002, the Company's cost of manufacturing was 153% net product sales versus 176% for 2001, after adjustment of \$8,500,000 for product development revenues in 2001. This improvement occurred because the Company had expanded its laboratory and packaging capabilities allowing for a reduction in the use of third parties to perform these services at a net cost savings to the Company.

#### RESEARCH & DEVELOPMENT EXPENSES

For 2003, research and development expenses amounted to \$1,460,000 compared to \$1,517,000 for 2002. The decrease of \$57,000 or 3.8% reflects the reduction in resources available to fund these activities. The development expenditures in 2003 were primarily related to the Company's development efforts relating to the ADF Technology and the Opioid Synthesis Technologies.

For 2002, research and development expenses amounted to \$1,517,000 compared to \$1,327,000 for 2001. The increase of \$190,000 or 14% reflects development expenses incurred on a number of projects including the development of the Company's Opioid Synthesis Technologies.

The Company has restructured its operations and expects to devote substantially all of its resources in 2004 to research and development activities relating to its ADF Technologies and Opioid Synthesis Technologies.

# SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative costs were \$7,903,000 (138% of net product revenue) for 2003 compared to \$7,216,000 (88% of net product revenue) for 2002. This increase is primarily due to added professional costs associated with the prosecution of the Import Registration of \$233,000, increased bad debt expenses of \$350,000 and sales personnel cost of \$93,000.

Selling, general and administrative costs were \$7,216,000 (88% of net product revenue) for 2002 compared to \$6,616,000 (78% of net product revenue) for 2001 after adjustment of \$8,500,000 in product development revenues in 2001. This increase is primarily due to added professional and personnel costs incurred for patent research and matters associated with prosecution of the Import Registration and on the Opioid Synthesis Technologies of \$174,000, increases in product marketing expenses of \$253,000 and increased corporate insurance premiums of \$173,000.

#### PLANT SHUTDOWN COSTS

On November 6, 2003, the Company announced its intent to restructure the Company's operations to focus its efforts on research and development relating to certain proprietary finished dosage products and active ingredients. As part of that process, in February 2004 the Company discontinued the manufacture and sale of finished dosage generic products at its Congers, New York locations and substantially reduced activities at its active pharmaceutical ingredient facility in Culver, Indiana. As of December 31, 2003, the Company recorded aggregate restructure expenses of approximately \$3,280,000 consisting of an impairment charge of \$1,673,000 against property, plant and equipment, an impairment charge of \$1,354,000 against inventory (charged to cost of sales) and \$253,000 of other costs.

# INTEREST EXPENSE, NET OF INTEREST INCOME

Interest expense, net of interest income for 2003 increased by \$1,263,000 or 26.7% over 2002 reflecting interest expense on the December, 2002 financing and the 2003 bridge financings.

Interest expense, net of interest income for 2002 increased by \$869,000 or 22.6% over 2001 reflecting interest on borrowings under the Galen Bridge Loan Agreement. During 2002, the Company borrowed an aggregate of \$12,500,000 under the Galen Bridge Loan Agreement.

# AMORTIZATION OF DEFERRED DEBT DISCOUNT, AND PRIVATE OFFERING COSTS

In 2003, 2002 and 2001 the Company issued warrants and incurred costs associated with private placements and bridge financings. The value of warrants issued in 2003, 2002, and 2001, as determined by use of the Black-Scholes valuation model, was approximately \$581,000, \$5,115,000 and \$310,000, respectively. The Company incurred private offering costs of approximately \$1,041,000 in 2002. The private placements and bridge financings included beneficial conversion features with an estimated fair value of \$7,178,000 and \$78,364,000 in 2003 and 2002, respectively. The value of the warrants, private offering costs, and beneficial conversion features are being amortized over the life of the underlying debentures and notes. In conjunction with the Company's December 2002 private placement of debentures, the remaining unamortized balance of private offering costs from 1999 were written-off. Amortization expense of deferred debt discount and private offering costs was \$24,771,000, \$12,558,000 and \$2,591,000 in 2003, 2002 and 2001, respectively. At December 31, 2003, there remained \$56,891,000 of debt discount which will be amortized to expense over the remaining life of the related debentures.

# LOSS ON EXTINGUISHMENT OF DEBT

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 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 share settlement provision; and 3) \$14,148,000, representing the incremental increase in the fair value of the remaining 1998 Warrants and 1999 Warrants 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.

# **OTHER INCOME (EXPENSE)**

Included in other income (expense) for the year ended December 31, 2003 and 2002, are charges the Company recorded to earnings of \$457,000 and \$863,000, respectively, representing the incremental increase in the fair value of certain other outstanding warrants as a result of reducing the exercise price of the warrants in accordance with their original terms, as calculated using the Black-Scholes option-pricing model.

# LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2003, the Company had cash and cash equivalents of \$942,000 as compared to \$9,211,000 at December 31, 2002. The Company had a working capital deficit of \$3,770,000 at December 31, 2003.

On February 6, 2004, the Company consummated a private offering of securities for an aggregate purchase price of approximately \$12.3 million (the "2004 Debenture Offering"). The securities issued in the 2004 Debenture Offering consisted of convertible senior secured debentures (the "2004 Debentures"). 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 II, LP ("Care Capital"), Essex Woodlands Health Ventures V, L.P. ("Essex"), Galen Partners III, L.P. and each of the Purchasers listed on the signature page thereto (collectively, the "2004 Debenture Investor Group"). On April 14, 2004 the Company completed an additional closing under the 2004 Purchase Agreement and issued additional 2004 Debentures in the aggregate principal amount of approximately \$579,000, bringing the principal amount of the 2004 Debentures issued by the Company under the 2004 Purchase Agreement to an aggregate amount of approximately \$12.879 million.

Of the approximate \$12.879 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 and Galen Partners III, L.P., Galen International III, L.P., and Galen Employee Fund III, L.P. (collectively, "Galen") during November and December, 2003. The 2004 Purchase Agreement further provides that the Company may issue additional 2004 Debentures in the principal amount of up to approximately \$1.121 million on or prior to June 5, 2004, provided that the aggregate principal amount of 2004 Debentures issued pursuant to the 2004 Purchase Agreement shall not exceed \$14.0 million without the consent of the holders of 60% of the principal amount of the 2004 Debentures then held by Care Capital, Essex and Galen.

The 2004 Debentures, issued at par, bear interest at the rate of 1.62% per annum, the short-term Applicable Federal Rate on the date of issuance. The 2004 Debentures are secured by a lien on all assets of the Company. In addition, each of Houba, Inc. and Axiom Pharmaceutical Corporation, each a wholly-owned subsidiary of the Company, has executed in favor of the 2004 Debenture holders, an unconditional agreement of guaranty of the Company's obligations under the 2004 Purchase Agreement. Each guaranty is secured by all assets of such subsidiary. In addition, the Company has pledged the stock of each such subsidiary to the holders of the 2004 Debentures to further secure its obligations under the 2004 Purchase Agreement.

In accordance with the terms of an Amended and Restated Subordination Agreement dated as of February 6, 2004 between the Company, the holders of the 2004 Debentures and the holders of the Company's other outstanding debentures, the liens on the Company's and its subsidiary's assets as well as the payment priority of the 2004 Debentures are (i) subordinate to the Company's lien and payment obligations in favor of Watson Pharmaceuticals under the Watson Term Loan Agreement, and (ii) senior to the Company's lien and payment obligations in favor of the holders of the Company's other outstanding debentures in the aggregate principal amount of approximately \$87.7 million.

The 2004 Debentures (including the principal amount plus interest accrued at the date of conversion) will convert automatically into the Company's Series A convertible preferred stock (the "Series A Preferred") immediately following the

Company's receipt of shareholder approval at its next shareholders' meeting 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 (the date of such filing, the "Charter Amendment Filing Date"), as provided in the 2004 Purchase Agreement. The 2004 Debentures will convert into Series A Preferred at a price per share (the "Series A Conversion Price") of \$0.6425, representing the average of the closing bid and asked prices of the Company's Common Stock for the twenty (20) trading days ending February 4, 2004, as reported by the Over-the-Counter ("OTC") Bulletin Board. The Series A Conversion Price is subject to adjustment, from time to time, to equal the consideration per share received by the Company for its Common Stock, or the conversion/exercise price per share of the Company's Common Stock issuable under rights or options for the purchase of, or stock or other securities convertible into, Common Stock ("Convertible Securities"), if lower than the then applicable Series A Conversion Price.

Based on the \$0.6425 Series A Conversion Price of the Series A Shares and estimating the interest accrual under the 2004 Debentures prior to the Charter Amendment Filing Date, the 2004 Debentures with an aggregate principal amount of \$14 million would be convertible into an aggregate of approximately 22 million Series A Preferred shares.

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.

The 2004 Purchase Agreement provides that each of Care Capital, Essex and Galen (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. Effective as of the closing 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).

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 \$87.7 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.

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 2004 Debenture Investor Group 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, each holder of the 2004 Debentures agreed to convert the 2004 Debentures held by such holder into the Company's Series A Preferred shares and each holder of 1998-2002 Debentures agreed

to convert 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 Shares together with the Series B Shares are herein referred to as, the "Junior Preferred Shares", and the Junior Preferred Shares together with the Series A Preferred, are collectively referred to as the "Preferred Stock". The Conversion Agreement provides, among other things, for the automatic conversion of the 2004 Debentures and the 1998-2002 Debentures (collectively, the "Outstanding Debentures") into the appropriate class of Preferred Stock immediately following the Company's receipt of shareholder approval to the Charter Amendment authorizing the creation of the Preferred Stock and the filing of the Charter Amendment with the Office of the New York Department of State.

Under the Conversion Agreement, the holders of approximately \$6.7 million in principal amount of 2002 Debentures issued during 2003 will convert such 2002 Debentures (plus accrued and unpaid interest) into Series B Preferred Shares. Of the remaining approximate \$81 million in principal amount of the 1998-2002 Debentures, approximately \$31.6 million is comprised of 1998 Debentures, approximately \$21.8 million is comprised of 1999 Debentures and approximately \$27.6 million is comprised of 2002 Debentures. The 1998 Debentures will be converted into Series C-1 Preferred shares. The 1999 Debentures will be converted into Series C-2 Preferred shares. The remaining balance of the 2002 Debentures shall be converted into Series C-3 Preferred shares.

The number of Junior Preferred Shares to be received by each holder of 1998-2002 Debentures is based on the respective prices at which the 1998-2002 Debentures were convertible into Common Stock. The 2002 Debentures issued in 2003 have a conversion price of \$0.3420 per share. The 1998 Debentures, 1999 Debentures and the remaining balance of the 2002 Debentures have conversion prices of \$0.5776, \$0.5993 and \$0.3481 per share, respectively. Based on the respective conversion prices of the 1998-2002 Debentures, and estimating the interest accrual on the 1998-2002 Debentures prior to the Charter Amendment Filing Date, the 1998-2002 Debentures are convertible into an aggregate of approximately 20.0 million Series B Preferred shares, 56.5 million Series C-1 Preferred shares, 37.5 million Series C-2 Preferred shares and 80.9 million Series C-3 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 of 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 stockholders, 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.

The Company was a party to a certain loan agreement with Watson Pharmaceuticals ("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 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 "Amended and Restated Watson Note, each of the Lead 2004 Investors and the other investors in the 2004 Debentures as of February 10, 2004 (collectively, the "Watson Note Purchasers") purchased the Amended and Restated 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.

The Amended and Restated Watson 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% and matures on June 30, 2007.

As of April 14, 2004, after giving effect to the payment to Watson of approximately \$4.3 million to restructure the Watson Term Loan and the payment of legal and other professional fees relating to the 2004 Debenture Offering, the Company realized net proceeds from the 2004 Debenture Offering of approximately \$5.8 million (the "2004 Debenture Offering Proceeds").

In February, 2004, the Company sold certain non-revenue generating ANDAs. In addition, 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 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. Shareholder approval is necessary to complete this transaction and will be sought of the Company's next annual meeting of shareholders. After giving effect to the payment of legal and other professional fees relating to these assets divestment transactions, the Company estimates that it will realize aggregate net proceeds from such transactions of approximately \$4.3 million. (the "Asset Divestment Proceeds").

The development, scale- up and commercialization of APIs incorporating the Company's Opioid Synthesis Technologies and ADF 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 settings, and none have been tested in 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 a registration (the "Import Registration") to import narcotic raw materials ("NRMs") from certain foreign countries as described in Item 1 under the caption "Import License Registration". The process of seeking the Import Registration, the continuing development of the Company's Opioid Synthesis Technologies and the development of finished dosage products utilizing the Company's ADF Technology are planned to continue through 2004. 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 ADF Technology, Opioid Synthesis Technologies and to the prosecution of the Import Registration. The failure of the Company to successfully develop the ADF Technology will have a material adverse effect on the Company's operations and financial condition.

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 approximately \$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 expense (collectively, the "API Scale Up Expenses"). The Company is a party to a certain Hydrocodone Option Agreement dated February 6, 2004 with Watson Pharmaceuticals ("Watson") pursuant to which the Company has granted Watson a six (6) month exclusive option to enter into a supply agreement with the Company for supply of hydrocodone bitartrate API (the "Hydrocodone API"). If such option is exercised by Watson, at Watson's sole discretion, of which there can be no assurance, Watson will fund 50% of the API Scale Up Expenses, up to a maximum of \$3.5 million and the Company has agreed to use commercially reasonable efforts to obtain financing dedicated to fund its portion of the API Scale Up Expenses. In the event the Company is unable to secure financing dedicated to fund its portion of the API Scale Up Expenses, the Hydrocodone Option provides that the parties will discuss alternatives relating to the scale up of the its Opioid Synthesis Technology for Hydrocodone API.

There can be no assurance that Watson will exercise the Hydrocodone Option or, even if exercised, that the Company will succeed in obtaining financing dedicated to fund its portion of the API Scale Up Expenses. As described in this Report, no portion of the 2004 Debenture Offering Proceeds or the Asset Divestment Proceeds is budgeted for the API Scale Up Expenses. Until such time, if any, as the Company secures third-party financing dedicated to the API Scale Up Expenses, the Company will be unable to complete the commercial scale up of its Opioid Synthesis Technologies.

Except for the professional fees related to prosecution of the Import Registration, the 2004 Debenture Offering Proceeds and the Asset Divestment Proceeds, aggregating approximately \$10.1 million, will be dedicated to the development of the Company's ADF Technology, the Opioid Synthesis Technologies and for administrative and related operating expenses.

Subsequent to the completion restructuring of its operations, 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 ADF Technology, the Opioid Synthesis Technologies and related ongoing operating expenses. The Company's future sources of revenue, if any, will be derived from the sale of API manufactured using its Opioid Synthesis Technologies, contract signing fees, milestone payments and royalties and/or profit sharing payments from licensees for the Company's ADF Technology or Opioid Synthesis Technologies. The Company estimates that its current cash reserves will be sufficient to fund the development of the ADF Technology, the Opioid Synthesis Technologies and related operating expenses through January 2005. To fund operations through December, 2005, 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 ADF Technology or the Opioid Synthesis Technologies, or otherwise enters into alliances or collaborative agreements relating to such technologies, there can be no assurance that the Company's development efforts will result in commercial scale technologies, or that if such technologies are capable of being scaled up, that they will result in commercially viable products. The Company is also unable to provide any assurance that it will succeed in its application to the DEA for the Import Registration. The Company's failure to successfully develop the ADF Technology in a timely manner will have a material adverse impact on its financial condition and results of operations.

The following table presents the Company's expected cash requirements for contractual obligations outstanding as of December 31, 2003:

	TOTAL	DUE AS OF 12/31/04	DUE AS OF 12/31/05 AND 12/31/06	DUE AS OF 12/31/07 AND 12/31/08	DUE THEREAFTER
		(	IN THOUSANDS	3)	
Convertible senior secured					
debentures	\$ 86,632	\$	\$ 86,632	\$	\$
Term loan payable	21,401		21,401		
Department of justice settlement	433	300	133		
Bridge loans	2,000		2,000		
Capital leases	137	45	61	31	
Operating leases	228	225	3		
Employment agreements	873	620	253		
Total Contractual Cash					
Obligations	\$111,704	\$3,190	\$108,483	\$ 31	\$
	=======	=====	=======	====	====

#### 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, as contained in the Company's Annual Report on Form 10-K, 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:

# **Revenue Recognition**

The Company recognizes revenue at the time a product is shipped to customers. 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 are 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 are, however, dependent upon future events. Management continually monitors the factors that influence sales allowance estimates and make adjustments to these provisions when allowances may differ from established allowances.

#### **Allowance For Doubtful Accounts**

Estimates are used in determining the allowance for doubtful accounts based on the Company's historical collections experience, current trends, credit policy and a percentage of its accounts receivable by aging category. In determining these percentages, the Company looks at historical write-offs of its receivables. The Company also 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. While credit losses have historically been within expectations and the provisions established, the Company cannot guarantee that it will continue to experience the same credit loss rates that it has in the past.

#### **Inventories**

The Company's inventories are stated at the lower of cost or market, with cost determined on the first-in, first-out basis. 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. As appropriate, the Company records provisions to reduce inventories to their net realizable value.

#### **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. 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.

# **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"). 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

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities" ("SFAS No. 149"), which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 except for the provisions that were cleared by the FASB in prior pronouncements. The adoption of SFAS No. 149 did not have a material impact on the Company's financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("SFAS No. 150"). This statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. In accordance with the standard, financial instruments that embody obligations for the issuer are required to be classified as liabilities. This Statement shall be effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on the Company's financial position or results of operations.

# **CAPITAL EXPENDITURES**

The Company's capital expenditures during 2003, 2002 and 2001 were \$412,000, \$287,000 and \$1,544,000, respectively.

The capital expenditures during these periods are attributable to capital improvements to the Company's Congers, NY and Culver, Indiana facilities. For the Company to receive the DEA Controlled Substance Manufacturing Registration, 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.

Consistent with the Company's restructured operations and its emphasis on research and development, the Company has budgeted approximately \$200,000 for capital expenditures for 2004 primarily for scientific equipment for laboratory use to be funded by the proceeds from the 2004 Debenture Offering and the Asset Divestment.

#### 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.

# 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

Not Applicable

# ITEM 9A. CONTROLS AND PROCEDURES

Within the 90 days prior to the date of this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including its 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.

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 Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures 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 accumulated and communicated to the Company's management, including the Company's principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

# **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	51	Chairman of the Board
Andrew D. Reddick	51	President and Chief Executive Officer
Ron J. Spivey	57	Senior Vice President and Chief Scientific Officer
Vijai Kumar	57	Chief Operations Officer
Peter A. Clemens	51	Senior Vice President, Chief Financial Officer, Secretary and Director
James Emigh	48	Vice President of Marketing and Administration
Robert Seiser	40	Vice President, Corporate Controller and Treasurer

61	Director
74	Director
66	Director
53	Director
45	Director
39	Director
33	Director
	74 66 53 45 39

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. 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.

Vijai Kumar has been Chief Operations Officer of the Company since November, 2002. From 1996 to 2002, Mr. Kumar was President & CEO of Pharmalogix Inc., a pharmaceutical research and development company. From 1992 to 1996, Mr. Kumar was Director, Research and Development for the Warner Chilcott Division of Warner Lambert. In that capacity, he coordinated all technical aspects of the Division responsible for cGMP compliance, formulation development, analytical development and clinical and bioequivalence studies. Mr. Kumar holds B.Sc. in Chemistry from the University of Lucknow, India, a D.Pharm. from the College of Pharmacy, New Delhi, an M.B.A. from Fairleigh Dickinson University and an M.S. in Industrial Pharmacy from Long Island University.

Peter A. Clemens has been Senior Vice President, Chief Financial Officer and Secretary since April 2004 and a Director of the Company since June 1998. Mr. Clemens was Vice President, Chief Financial Officer and Secretary of the Company from February 1998 to March 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.

Alan J. Smith, Ph.D. has been a Director of the Company since 1995. Since 1991, Dr. Smith has been a management consultant specializing in pharmaceutical quality management, quality control, quality assurance and auditing, the Food and Drug Administration's Current Good Manufacturing Practice regulations and technology training, documentary systems and stability programming. From 1985 to 1991, he was Corporate Director of Quality affairs for Whitehall Laboratories, a Division of American Home Products Corporation. Dr. Smith holds B.Sc. and Ph.D. degrees from the University of London.

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.

Srini Conjeevaram has been a Director of the Company since March 1998. Mr. Conjeevaram is a General Partner of Galen Partners III, L.P. Prior to January 1991, he was an Associate in Corporate Finance at Smith Barney, Harris Upham & Co. Inc. from 1989 to 1990 and a Senior Project Engineer for General Motors Corporation from 1982 to 1987. Mr. Conjeevaram serves as a Director of Derma Sciences, Inc., a publicly traded company, and ONI Incorporated. He earned a Bachelor of Science degree in Mechanical Engineering from Madras University, a Masters of Science degree in Mechanical Engineering from Stanford University, and a Masters of Business Administration from Indiana University.

Zubeen Shroff has been a Director of the Company since June 1998. Mr. Shroff is a General Partner of Galen Partners III, L.P. He joined Galen Associates, a health care venture firm, in January 1997 from The Wilkerson Group, a leading provider of management consulting services to the health care industry. Prior to The Wilkerson Group, he worked for Schering-Plough International from 1989 to 1993 in a variety of staff and line management positions and as head of Schering-Plough France's biotech franchise. Mr. Shroff received a Bachelor of Science in Biological Sciences from Boston University in 1986 and a Masters of Business Administration from The Wharton School in 1988. Mr. Shroff serves as a Director of Americas Doctor.com, Cortek, Inc. and Encore Medical Corporation.

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, Alan Smith 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 2003, 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 each of Messrs. Sumner and Smith are deemed independent members 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. Three of the of the nine members of the Board (Messrs. Sumner, Skelly and Smith) 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 is for Board members 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. After a possible candidate is identified, the individual meets with various members of the Board and is sounded out concerning their 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 is 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. A copy of the Code of Ethics has been filed as an Exhibit to this Form 10-K and is posted on the Company's website @ www.halseydrug.com under the caption Investor Relations. Any amendments to or waivers from the Code of Ethics will be posted on the Company's website under the caption Investor Relations.

# 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 and, during the period in which the Company's common stock was traded on the American Stock Exchange, the AMEX. 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 (i) Mr. Reicher filed two Form 4 filings late, (ii) Mr. Thangaraj filed three Form 4 filings late, (iii) Mr. Feinberg filed two Form 4 filings late, and (iv) a Form 3 filing requirement by Mr. Dennis Adams, a beneficial owner of in excess of 10% of the Company's Common Stock, has not been filed to date.

#### 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, 2003, 2002 and 2001 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 2003 exceeded \$100,000:

# SUMMARY COMPENSATION TABLE

		7 NINTI I 7 T	COMPENCA	LONG TERM COMPENSATION		
		ANNUAL COMPENSATION			SECURITIES	
NAME AND PRINCIPAL POSITION	YEAR	SALARY	BONUS	OTHER ANNUAL COMPENSATION	UNDERLYING STOCK OPTIONS	ALL OTHER COMPENSATION
Andrew D. Reddick	2003	\$ 96,923	0			
President and Chief	2002	-0-	0			
Executive Officer	2001	-0-	0	==		
Michael K. Reicher (1)	2003	\$119,231	110,000			
Chairman and Chief	2002	200,000	0			
Executive Officer	2001	191,346	0			
Peter A. Clemens	2003	\$155,000	60,000			
Senior Vice President and	2002	155,000	0			
Chief Financial Officer	2001	149,807	0			
Vijai Kumar	2003	\$180,000	0			
Chief Operations Officer	2002	18,000	0		400,000	
	2001	-0-	0			
James Emigh	2003	\$132,000	0			
Vice President Marketing	2002	132,000	0			
and Administration	2001	125,000	0			

(1) Mr. Reicher's services as Chairman and Chief Executive Officer ceased effective June 16, 2003.

#### OTHER COMPENSATORY ARRANGEMENTS

Executive Officers and key employees participate in medical and disability insurance plans provided to all non-union employees of the Company. The Company also pays the automobiles expenses of an executive officer. Such expenses are less than the lesser of \$6,000 or 10% of such officer's compensation reported above in the Summary Compensation Table.

#### 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 term expiring August 26, 2005. 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. The Employment Agreement also provides for the Company to issue stock options exercisable for up to 5,500,000 shares of Common Stock at an exercise price of \$0.34 per share. The grant of such stock options is subject to the receipt of shareholder approval to amend the Company's 1998 Stock Option Plan to permit the grant of such options. To date, the Company's shareholders have not approved the amendment to the 1998 Stock Option Plan and the options have not been granted. The Employment Agreement also 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 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. The Employment Agreement also provides for the Company to issue stock options exercisable for up to 3,000,000 shares of Common Stock at an exercise price of \$0.13 per share. The grant of such stock options is subject to the receipt of shareholder approval to amend the Company's 1998 Stock Option Plan to permit the grant of such options. 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 also 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 numbers 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 June 28, 2000 and May 4, 2001, provides that Mr. Clemens will serve as the Company's Vice President and Chief Financial Officer for a term expiring April 30, 2005. 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 fiscal 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). The Employment Agreement also 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.

Vijai Kumar is employed pursuant to an Employment Agreement effective as of November 18, 2002, which provides that Mr. Kumar will serve as the Company's Chief Operations Officer for a term expiring November 18, 2004. 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 November 18, 2002 to purchase 400,000 shares of the Company's common stock at an exercise price of \$1.125 per share, which options vest in equal increments of 100,000 annually commencing on November 18, 2003. The Employment Agreement permits the Company to repurchase the vested portion of Mr. Kumar's options upon his termination for Cause (as defined in the Employment Agreement) or his resignation, at a purchase price equal to the positive difference, if any, between 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, 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 (as defined in the Employment Agreement) and without Cause. The Employment Agreement also provides that in the event of a Change of Control (as defined in the Employment Agreement), or if Mr. Kumar's employment with the Company is terminated without Cause, he is entitled to his base salary for the lesser of (i) the remaining term of the Employment Agreement, and (ii) one year. The Employment Agreement also restricts Mr. Kumar from disclosing, disseminating or using for his personal benefit or 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 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 10,000 shares of the Company's common stock (15,000 shares in the case of the Chairman of the Board) 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 April 1, 2004, ISO's to purchase 630,608 shares and non-qualified options to purchase 257,780 shares have been granted under the 1995 Stock Option Plan, leaving 111,612 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 \$1.44. 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 Board will seek authorization at the Company's 2004 Annual Meeting of Shareholders to amend the 1998 Stock Option Plan to (a) increase the number of shares available for grant of options under the Plan from 8,100,000 to 20,000,000 shares, (b) permit the grant of non-qualified stock options having an exercise price per share which is less than the fair market value of the Company's Common Stock, and (c) set a limit of 8,750,000 option awards that may be granted to one individual in any calendar year. 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 April 1, 2004, stock options to purchase 2,691,342 shares of Common Stock had been granted under the 1998 Stock Option Plan. Of such option grants, 1,562,466 are ISOs and 1,128,876 are non-qualified options. The average per share exercise price for all outstanding options under the 1998 Stock Option Plan is approximately \$1.94. 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 10% of 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, 2003 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**

MIIMPED OF CECIIPTETE

			NUMBER OF SECURITIES
			REMAINING AVAILABLE FOR
	NUMBER OF SECURITIES TO	WEIGHTED-AVERAGE	FUTURE ISSUANCE UNDER EQUITY
	BE ISSUED UPON EXERCISE	EXERCISE PRICE OF	COMPENSATION PLANS
	OF OUTSTANDING OPTIONS,	OUTSTANDING OPTIONS,	(EXCLUDING SECURITIES
PLAN CATEGORY	WARRANTS AND RIGHTS	WARRANTS AND RIGHTS	REFLECTED IN COLUMN(a))
	(a)	(b)	(c)
Equity Compensation Plans Approved by Security			
Holders	3,417,270	\$1.83	5,520,270
Equity Compensation Plans Not			
Approved by Security			
Holders	0	0	0
TOTAL	3,417,270	\$1.83	5,520,270

# AGGREGATE OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR END OPTION VALUES

No stock options were granted to or exercised by the named executive officers during 2003. The following table presents information regarding the value of options outstanding at December 31, 2003 for each of the named executive officers.

	UNDERLYING	SECURITIES UNEXERCISED USCAL YEAR END	IN-THE-MONE	UNEXERCISED Y OPTIONS AT AR END (2)
NAME	EXERCISABLE	UNEXERCISABLE	EXERCISABLE	UNEXERCISABLE
Andrew D. Reddick Michael K. Reicher(1) Peter A. Clemens Vijai Kumar James Emigh	1,065,170 600,000 100,000 116,000	 25,000 300,000 35,000	\$ \$ \$ \$	\$ \$ \$ \$

- (1) Mr. Reicher's services as Chief Executive Officer ceased effective June 16, 2003.
- (2) Value is based upon the average of the closing bid and asked price of \$.47 per share at December 31, 2003.

## COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

The Company's Compensation Committee consisted of Messrs. Wesson, Conjeevaram, Skelly, Reicher and Thangaraj during fiscal 2003. During 2003, except for Mr. Reicher, there were no Compensation Committee interlocks or insider participation in compensation decisions. Mr. Reicher resigned as a Director of the Company effective September 18, 2003.

# 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 April 1, 2004, 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 2003 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

	CONVERTED AND A	-10 -EVEUCIOE	D DADID
NAME OF BENEFICIAL OWNER	AMOUNT OWNED(1)	PERCENT OF CLASS(2)	PERCENT OF CLASS(3)
Galen Partners III, L.P(4)			
Galen Partners International III, L.P(4) 610 Fifth Avenue, 5th Floor New York, New York 10020	3,796,736(6)	15.0%	5.8%
Oracle Strategic Partners, L.P(4)	13,515,299(7)	38.5%	20.6%
Watson Pharmaceuticals, Inc	10,700,665(8)	33.1%	16.3%
Dennis Adams	2,577,173(9)	10.7%	3.9%
Hemant K. Shah and Varsha H. Shah 29 Christy Drive Warren, New Jersey 07059	1,885,627(10)	8.0%	2.9%
Bernard Selz	974,552(11)	4.3%	1.5%
Michael and Susan Weisbrot	1,626,403(12)	7.0%	2.5%
Andrew D. Reddick		*	*
Michael K. Reicher	1,142,426(13)	5.0%	1.7
William Skelly	211,000(14)	1.0%	*
Bruce F. Wesson	211,000(14)	*	*
		*	*
Srini Conjeevaram		*	*
William A. Sumner	50,000(15)		*
Zubeen Shroff		*	
Peter A. Clemens	774,843(16)	3.5% *	1.2%
Jerry Karabelas		*	*
Immanuel Thangaraj		*	*
Alan Smith	83,468(17)	*	*
Vijai Kumar	100,000(18)		
James Emigh	173,500(19)	*	*
(12 persons)	1,521,311(20)	6.6%	2.3%

<sup>\*</sup> Represents less than 1% of the outstanding shares of the Company's Common Stock.

<sup>(1)</sup> 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 April 1, 2004 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) Despite reasonable efforts, the Company was unable to obtain from its security holders the names of the individuals that exercise voting, investment and dispositive rights over the Company's securities held of record by such entities. The Company was unable to obtain such information without unreasonable effort and expense.
- (5) Includes (i) 22,195,668 shares issuable upon conversion of 1998 Debentures and 1999 Debentures, (ii) 5,068,748 shares issuable upon exercise of 1998 Warrants and 1999 Warrants, (iii) 4,932,231 shares issuable upon exercise of common stock purchase warrants issued in connection with the 1998/1999 and 2001/2002 Galen Bridge Loans, (iv) 4,276,062 shares issuable upon conversion of Debentures issued in lieu of quarterly cash interest payments, and (v) 150,000 shares subject to currently exercisable stock options.
- (6) Includes (i) 2,356,348 shares issuable upon conversion of 1998 Debentures and 1999 Debentures, (ii) 537,358 shares issuable upon exercise of 1998 Warrants and 1999 Warrants, (iii) 447,876 shares issuable upon exercise of common stock purchase warrants issued in connection with the 1998/1999 and 2001/2002 Galen Bridge Loans, and
- (iv) 455,154 shares issuable upon conversion of Debentures issued in lieu of quarterly cash interest payments.
- (7) Includes (i) 8,533,847 shares issuable upon conversion of the 1999 Debentures, and (ii) 1,301,991 shares issuable upon conversion of Debentures issued in lieu of quarterly cash interest payments, and
- (iii) 30,000 shares subject to currently exercisable stock options.
- (8) Includes 10,700,665 shares issuable upon exercise of the Watson Warrant.
- (9) Includes 1,553,641 shares issuable upon conversion of 1998 Debentures and 1999 Debentures.
- (10) Includes 1,053,627 shares issuable upon conversion of 1998 Debentures and 1999 Debentures.
- (11) Includes 614,309 shares issuable upon conversion of 1998 Debentures and 1999 Debentures.
- (12) Includes 814,415 shares issuable upon conversion of 1998 Debentures and 1999 Debentures.
- (13) Includes (i) 62,590 shares issuable upon conversion of 1998 Debentures,
- (ii) 14,666 shares issuable upon conversion of Debentures issued in lieu of quarterly interest payments and (iii) 1,065,170 shares subject to currently exercisable stock options.
- (14) Includes 200,000 shares subject to currently exercisable stock options.
- (15) Includes 50,000 shares subject to currently exercisable stock options.
- (16) Includes (i) 110,908 shares issuable upon conversion of 1998 Debentures, (ii) 17,885 shares issuable upon conversion of Debentures issued in lieu of quarterly interest payments, and (iii) 600,000 shares subject to currently exercisable stock options.
- (17) Includes (i) 50,000 shares subject to currently exercisable common stock purchase options, and (ii) 22,490 shares issuable upon conversion of 1998 Debentures.
- (18) Includes 100,000 shares subject to currently exercisable stock options.
- (19) Includes 128,500 shares subject to currently exercisable stock options.
- (20) Includes 1,408,283 shares which Directors and executive officers have the right to acquire within the next 60 days through the conversion of Debentures and the exercise of outstanding stock options.

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

On December 20, 2002, the Company completed a private offering of securities for an approximate aggregate purchase price of \$26,394,000 (the "2002 Debenture Offering"). The securities issued in the 2002 Debenture Offering consisted of 5% convertible senior secured debentures maturing March 31, 2006 (the "2002 Debentures"). The Debentures were issued by the

Company pursuant to a certain Debenture Purchase Agreement dated December 20, 2002 (the "2002 Purchase Agreement") by and among the Company, Care Capital, Essex, Galen and each of the purchasers listed on the signature page thereto. In accordance with the terms of the 2002 Purchase Agreement, each of Jerry Karabelas, a designee of Care Capital, and Immanuel Thangaraj, a designee of Essex, were appointed to the Company's Board of Directors.

As part of the closing of the 2002 Debenture Offering, the Company's term loan agreement (the "Watson Loan Agreement") with Watson Pharmaceuticals, Inc. ("Watson") was amended to (i) extend the maturity date of the Watson Loan Agreement from March 31, 2003 to March 31, 2006, and (ii) increase the principal amount of the Watson Loan Agreement from \$17,500,000 to \$21,401,331 (the "Watson Term Loan") to reflect the inclusion of approximately \$3,901,331 owed by the Company to Watson under a product supply agreement between the parties. In consideration for the amendment to the Watson Loan Agreement, the Company issued to Watson a Common Stock purchase warrant exercisable for 10,700,665 shares of the Company's Common Stock (the "Watson Warrant"). The Watson Warrant has a term expiring December 31, 2009 and an exercise price of \$.34 per share.

At the Company's request, on May 5, 2003, the Company received a letter executed by each of Care Capital, Galen and Essex (the "Majority 2002 Debentureholders") advising that the Majority 2002 Debentureholders would provide funding to meet the Company's 2003 capital requirements, up to an aggregate amount not to exceed \$8.6 million (the "2003 Letter of Support"). In consideration for the issuance of the 2003 Letter of Support, the Company authorized the issuance of warrants to the Majority 2002 Debentureholders exercisable for an aggregate of 645,000 shares of the Company's Common Stock at an exercise price of \$.34 per share (such exercise price being equal to the conversion price of the 2002 Debentures). In accordance with the terms of the Letter of Support, the Majority 2002 Debentureholders advance to the Company an aggregate principal amount of \$8.6 million during the period from June 16, 2004 through and including December 29, 2003 to fund the Company's operating losses and working capital requirements (the "Letter of Support Advances"). The Letter of Support Advances were made in accordance with the terms of the 2002 Purchase Agreement resulting in the Company's issuance of additional 2002 Debentures in an aggregate principal amount of \$8.6 million (plus additional 2002 Debentures issued in satisfaction of accrued interest on the Letter of Support Advances).

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, Galen 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 2002 Debentures issued to Care Capital, Essex and Galen during November and December, 2003 pursuant to the Letter of Support. On April 14, 2004, the Company completed an additional closing under the 2004 Purchase Agreement pursuant to which the Company issued additional 2004 Debentures in the aggregate principal amount of approximately \$579,000, bringing the aggregate principal amount of 2004 Debentures issued by the Company under the 2004 Purchase Agreement to \$12.879 million.

The 2004 Debentures (including the principal amount plus interest accrued at the date of conversion) will convert automatically into the Company's series A convertible preferred stock (the "Series A Preferred") immediately following the Company's receipt of shareholder approval of the Company's restated Certificate of Incorporation (the "Charter Amendment") to, among other things, authorize the Series A Preferred shares, and the filing of the Charter Amendment with the Office of New York Department of State (the date of such filing, the "Charter Amendment Filing Date"). The Debentures will convert into 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 of the Series A Preferred and estimating the interest accrual under the 2004 Debentures prior to the Charter Amendment Filing Date, the 2004 Debentures are convertible into an aggregate of approximately 19.9 million Series A Preferred shares, of which 5.2 million, 6.8 million and 6.8 million are issuable to Care Capital, Essex and Galen, respectively, under the 2004 Debentures held by such parties (representing 26.1%, 34.2% and 34.2%, 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 Shares 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 1998, 1999, 2002 and 2003 (collectively, the "1998-2002 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 and Galen (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 and Galen 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 1998-2002 Debentures (the 2004 Debentures and the 1998-2002 Debentures are collectively referred to as the "Outstanding 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, each holder of the Outstanding Debentures agreed to convert their debentures into the Company's Preferred Stock. Specifically, the Conversion Agreement provides, among other things, for the automatic conversion of the 2004 Debentures into the Company's Series A Preferred and the automatic conversion of the 1998-2002 Debentures 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") immediately upon the Charter Amendment Filing Date. 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".

After giving effect to the 2004 Debenture Offering and assuming (i) the receipt of shareholder approval of the Charter Amendment, (ii) the filing of the Charter Amendment, (iii) the conversion of the 2004 Debentures into Series A Preferred, and (iv) the conversion of the 1998-2002 Debentures into Junior Preferred Shares, Care Capital, Essex and Galen would control approximately 15.1 %, 17.6 % and 47.9 %, respectively, of the Company's voting securities (or approximately 13.3 %, 15.6 %, 47.9 %, respectively, after giving effect to the conversion of all of the Company's issued and outstanding Common Stock purchase options and warrants).

It was a condition to the completion of the 2004 Debenture Offering that the Watson Loan Agreement 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, Galen 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 6, 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 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 "Amended and Restated Watson Note"), and (ii) Watson's sale and conveyance of the Amended and Restated Watson Note to the Watson Note Purchasers for cash consideration of \$1.0 million.

In accordance with the terms of the Umbrella Agreement, simultaneous with the Company's payment to Watson of approximately \$4.3 million, the Company conveyed to Watson approximately \$165,000 in finished dosage products, at no charge, ANDAs for butalbital/acetaminophen/caffeine tablets, doxycycline hyclate capsules and doxycycline monohydrate capsules, the drug master files and certain related assets for doxycycline monohydrate API and doxycycline hyclate API, and the Company's equipment dedicated to the production of doxycycline API (collectively, the "Transferred Assets"). The Company also granted to Watson an option to enter into a commercial supply agreement for hydrocodone bitartrate API (the "Hydrocodone Option"). In addition to Watson forgiveness of approximately \$16.4 million of indebtedness under the Watson Notes, as additional consideration for the payment to Watson of approximately \$4.3 million, the conveyance of the Transferred Assets, and the grant of the Hydrocodone Option, all current supply agreements between the Company and Watson were terminated and Watson waived the dilution protections contained in the Watson Warrant, to the extent such dilution protections were triggered by the transactions contemplated in the 2004 Debenture Offering.

The Amended and Restated Watson 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 Amended and Restated Watson 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 Amended and Restated Watson Note, approximately \$1,352,000, \$1,754,000, and \$1,754,000, is owed by the Company to Care Capital, Essex and Galen, respectively (representing approximately 27%, 35% and 35%, respectively, of the Amended and Restated Watson Note).

Each of Michael and Susan Weisbrot and Dennis Adams beneficially own in excess of 5% of the Company's voting securities. Each of such security holders participated as an investor in the 2004 Debentures, agreed to convert their 1998-2002 Debentures into Junior Preferred Shares and purchased a portion of the Amended and Restated Watson Note a member of the Watson Note Purchasers. In addition, Bernard Selz, Hemant and Varsha Shah and Oracle Strategic Partners, L.P., each a beneficial owner of in excess of 5% of the Company's voting securities, is a party to the Conversion Agreement pursuant to which each has agreed to automatically convert their respective 1998-2002 Debentures into Junior Preferred Shares on the Charter Amendment Filing Date. 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 the Company's principal accountant for the audit of the Company's annual financial statements for the fiscal years ended December 31, 2002 and December 31, 2003, and for the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q for such fiscal years, were \$176,000 and \$150,623, respectively, all of which were attributable to Grant Thornton LLP.

### **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, 2002 and December 31, 2003 were \$14,180 and \$36,620, respectively, all of which were attributable to Grant Thornton LLP. 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 bills 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, 2002 and December 31, 2003 were \$54,000 and \$51,236, respectively, all of which were attributable to Grant Thornton LLP. 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 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) Reports on Form 8-K

On November 19, 2003, the Company filed a Current Report on Form 8-K. The Form 8-K described the Company's issuance of a press release disclosing the financial results for its third quarter ended September 30, 2003 and the nine months then ended.

#### (c) 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 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 Halsey Drug Co., Inc., 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 10-Q")).
- 10.5(3) Letter Agreement, dated November 16, 1995, among Halsey Drug Co., 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 Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 (the "June 1996 10-Q").
- 10.5(5) Letter Agreement, dated March 25, 1997 among Halsey Drug Co., Inc., 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 Company, Mallinckrodt Chemical Acquisition, Inc. and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.9 of the March 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) Halsey Drug Co., Inc. 1984 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.3 to the 1992 Form 10-K).
- 10.10(2) Halsey Drug Co., Inc. 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) Halsey Drug Co., Inc. Non-Employee Director Stock Option Plan.

- 10.11 Leases, effective February 13, 1989 and January 1, 1990, respectively, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss (incorporated by reference to Exhibits 10.6 and 10.7, respectively, to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1989).
- 10.12 Lease, effective as of April 15, 1988, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, and Rider thereto (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1987).
- 10.12(1) Lease, as of October 31, 1994, among Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, together with Modification, Consolidation and Extension Agreement (incorporated by reference to Exhibit 10.12(i) to the 1995 Form 10-K).
- 10.13 Asset Purchase Agreement dated as of March 21, 1995 among Mallinckrodt Chemical Acquisition, Inc. ("Acquisition"), Mallinckrodt Chemical, Inc., as guarantor and the Registrant (incorporated by reference to Exhibit 10.1 to the March 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 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 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 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 8-K).
- 10.19 Amendment dated March 21, 1995 to Subordination Agreement dated as of July 21, 1994 between Mallinckrodt Chemical, Inc., Mallinckrodt Chemical Acquisition, Inc., 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 8-K).
- 10.20 Agreement dated as of March 30, 1995 between the Registrant and Zatpack, Inc. (incorporated by reference to Exhibit 10.10 to the March 8-K).
- 10.21 Waiver and Termination Agreement dated as of March 30, 1995 between Zuellig Group, W.A., Inc. and Indiana Fine Chemicals Corporation (incorporated by reference to Exhibit 10.11 to the March 8-K).
- 10.22 Convertible Subordinated Note of the Registrant dated December 1, 1994 issued to Zatpack, Inc. (incorporated by reference to Exhibit 10.12 to the March 8-K).
- 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 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 8-K).
- 10.25 Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 6(a) to the June 10-Q).
- 10.26 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 6(a) to the June 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 8-K")).
- 10.28 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the December 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc. dated March 10, 1998 (incorporated by reference to Exhibit 10.3 to the March 1998 8-K).
- 10.36 Form of Guarantor General Security Agreement dated March 10, 1998 (incorporated by reference to Exhibit 10.4 to the March 1998 8-K).
- 10.37 Stock Pledge Agreement dated March 10, 1998 by and between the Registrant and Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.5 to the March 1998 8-K).
- 10.38 Form of Irrevocable Proxy Agreement (incorporated by reference to Exhibit 10.6 to the March 1998 8-K).
- 10.39 Agency Letter Agreement dated March 10, 1998 by and among the Purchasers a party to the Debenture and Warrant Purchase Agreement, dated March 10, 1998 (incorporated by reference to Exhibit 10.7 to the March 1998 8-K).
- 10.40 Press Release of Registrant dated March 13, 1998 (incorporated by reference to Exhibit 99.1 to the March 1998 8-K).
- 10.41 Current Report on Form 8-K as filed by the Registrant with the Securities and Exchange Commission on March 24, 1998.
- 10.42 Letter Agreement between the Registrant and the U.S. Department of Justice dated March 27, 1998 relating to the restructuring of the fine assessed by the Department of

Justice under the Plea Agreement dated June 21, 1993.

- 10.43 Employment Agreement dated as of March 10, 1998 between the Registrant and Michael K. Reicher (incorporated by reference to Exhibit 10.43 to the Registrant's Annual Report of Form 10-K for the year ended December 31, 1997 (the "1997 Form 10-K")).
- 10.44 Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens (incorporated by reference to Exhibit 10.44 to the 1997 Form 10-K.
- 10.45 Amended, Restated and Consolidated Bridge Loan Agreement dated as of December 2, 1998 between the Company, 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 Company 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 Company 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 Halsey Drug Co., Inc. 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 Halsey Pharmaceuticals, Inc., 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).
- 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).
- 10.73 Form of 5% Convertible Senior Secured Debenture issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.73 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
- 10.74 Form of Common Stock Purchase Warrant issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.74 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
- 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 Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
- 10.76 Debenture Purchase Agreement dated December 20, 2002 by and among Halsey Drug Co., Inc., 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 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 Halsey Drug Co., Inc. dated December 20, 2002 between Houba, Inc., Halsey Pharmaceuticals, Inc. and the 2002 Debentureholders (incorporated by reference to Exhibit 10.3 to the December 2002 Form 8-K).
- 10.79 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc., 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).

- Amendment to Debenture and Warrant Purchase Agreement between Halsey Drug Co., Inc., 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).
- 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 Halsey Drug Co., Inc. and Watson Pharmaceuticals, Inc., amending the Loan Agreement dated March 29, 2000 between Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc., Care Capital Investments, II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P. and the other purchasers listed on the signature page thereto (incorporated by reference to Exhibit 10.1 of the February 2004 Form 8-K).
- 10.93 Debenture Conversion Agreement dated as of February 6, 2004 by and among Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc. (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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc., Watson Pharmaceuticals, Care Capital, Essex Woodlands, Galen Partners and the other signatories thereto (incorporated by reference to Exhibit 10.12 of the February 2004 Form 8-K).
- 10.104 Third Amendment to Loan Agreement dated as of February 6, 2004 by and among Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc. 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 Halsey Drug Co, Inc. 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., Axiom Pharmaceutical Corporation and IVAX Pharmaceuticals

  New York LLC (incorporated by reference to Exhibit 10.2 of the March 2004 Form 8-K.)
  - \*14 Code of Ethics
  - 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).

- \*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.

# HALSEY DRUG CO., INC.

Date: April 14, 2004

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/ William G. Skelly	Director	April 14, 2004
William G. Skelly		
/s/ Peter Clemens	Vice President, Chief Financial Officer (Principal Financial and Accounting	April 14, 2004
Peter Clemens	Officer) and Director	
/s/ Alan J. Smith	Director	April 14, 2004
Alan J. Smith		
/s/ Bruce F. Wesson	Director	April 14, 2004
Bruce F. Wesson		
/s/ William Sumner	Director	April 14, 2004
William Sumner		
/s/ Srini Conjeevaram	Director	April 14, 2004
Srini Conjeevaram		
/s/ Zubeen Shroff	Director	April 14, 2004
Zubeen Shroff		
/s/ Jerry Karabelas	Director	April 14, 2004
Jerry Karabelas		
/s/ Immanuel Thangaraj	Director	April 14, 2004
Immanuel Thangaraj		

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#### REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

# Directors and Stockholders HALSEY DRUG CO., INC.

We have audited the accompanying consolidated balance sheets of Halsey Drug Co., Inc. and Subsidiaries (a development stage enterprise) (the "Company") as of December 31, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity(deficit) and cash flows for each of the three years in the period ended December 31, 2003. 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 auditing standards generally accepted in the United States of America. 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 Halsey Drug Co., Inc. and Subsidiaries at December 31, 2003 and 2002, and the results of their operations and their consolidated cash flows for each of the three 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). 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.

#### GRANT THORNTON LLP

New York, New York February 26, 2004, except for Note B, as to which the date is March 19, 2004

# CONSOLIDATED BALANCE SHEETS

December 31, (in thousands)

	2	003	2002
CURRENT ASSETS Cash	\$	942	\$ 9,211
Accounts receivable - trade, net of allowances of \$428 and \$14 in 2003 and 2002, respectively Inventories Prepaid expenses and other current assets		312	610 2,285 394
Total current assets	:	2,122	12,500
PROPERTY, PLANT AND EQUIPMENT, NET	:	3,394	5,367
DEFERRED PRIVATE OFFERING COSTS, net of accumulated amortization of \$ 318 and \$9 in 2003			
and 2002, respectively		714	1,032
OTHER ASSETS AND DEPOSITS		392	465
		6,622	\$19,364 ======

# CONSOLIDATED BALANCE SHEETS (CONTINUED)

# December 31, (in thousands, except per share data)

	2003		
CURRENT LIABILITIES  Current maturities of notes payable and capital lease obligations  Accounts payable  Accrued expenses  Department of Justice settlement	\$ 45 1,895 3,652	\$ 33 3,119 3,115 300	
Total current liabilities	5,892	6,567	
TERM NOTE PAYABLE	21,401	21,401	
BRIDGE LOANS Less: debt discount	2,000 (568)	-	
	1,432	-	
CONVERTIBLE SUBORDINATED DEBENTURES  Less: debt discount	86,632 (56,893)	(73,955)	
	29,739	3,163	
CAPITAL LEASE OBLIGATIONS	92	40	
DEPARTMENT OF JUSTICE SETTLEMENT	133	461	
COMMITMENTS AND CONTINGENCIES			
STOCKHOLDERS' EQUITY (DEFICIT)  Common stock - \$.01 par value; authorized,  80,000 shares; issued and outstanding,  21,602 shares and 21,035 shares in  2003 and 2002, respectively	216		
Additional paid-in capital Accumulated deficit	(209,545)	148,611 (161,090)	
		(12,268)	
	\$ 6,622 ======	\$ 19,364	

# CONSOLIDATED STATEMENTS OF OPERATIONS

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

	2003	2002		
Product sales Product development revenues		\$ 8,205		
Net product revenues	5,750	8,205	16,929	
Operating costs				
Cost of manufacturing	11,705	12,535	14,857	
Research and development		1,517		
Selling, general and administrative expenses	7,903	7,216	6,616	
Plant shutdown costs	1,926	(126)	68	
Loss from operations	(17,244)	(12,937)	(5,939)	
Other income (expense)				
Interest expense	(6,001)	(4,728)	(3,913)	
Interest income	25	15	69	
Amortization of deferred debt discount and				
private offering costs	(24,771)	(12,558)	(2,591)	
Loss on extinguishment of debt	_	(28,415)	-	
Investment in joint venture	_	-		
Other income (expense)	(464)	(966)		
NET LOSS	\$(48,455)	\$(59,589)	\$(12,563)	
	======			
Basic and diluted loss per common share	\$ (2.28)	\$ (3.90)	\$ (.84)	
	======	=======	======	
Weighted average number of outstanding shares	21,227	15,262	15,021	
	=======	=======	======	

# CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

# Years ended December 31, 2003, 2002 and 2001

(in thousands)

	Common \$.01 pa		Additional Paid-in	Accumulated	
	Shares	nount	Capital		Total
Balance at January 1, 2002	15,065		\$ 35,914	\$ (101,501)	\$(65,436)
Issuance of common stock in exchange for warrants Beneficial conversion	5,970	60	2,222		2,282
features in connection with debentures (Note H)			74,619		74,619
Issuance of warrant in connection with extension of maturity date of term loan (Note I(a)) Issuance of warrant in connection with Bridge Loans			11,985		11,985
(Note I(b))			5,115		5,115
Beneficial conversion features in connection with issuance of Bridge Loans (Note I (b)) Modification of terms of existing warrants			3,745 15,011		3,745 15,011
Net loss for the year ended December 31, 2002		 		(59,589)	(59,589)
Balance at December 31, 2002	21,035	211	148,611	(161,090)	(12,268)
Conversion of Debentures Issuance of warrant for lending commitment Issuance of beneficial conversion features in connection with debt Issuance of warrant in severance	567	5	322 581 7,178 113		327 581 7,178 113
Increase in fair value of warrants Net loss for the year ended December 31, 2002			457	(48,455)	457 (48,455)
Balance at December 31, 2003	21,602	 \$ 216	 \$157,262	\$ (209,545)	
	======		======	========	======

# CONSOLIDATED STATEMENTS OF CASH FLOWS

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

	2003	2002	2001
Cash flows from operating activities			
Net loss	\$(48,455)	\$(59,589)	\$(12,563)
Adjustments to reconcile net loss to net cash used			
in operating activities			
Depreciation and amortization	811	835	861
Amortization of deferred debt discount and private			
offering costs	24,771	12,558	2,591
Amortization of deferred product acquisition costs	42	37	35
Provision for losses on accounts receivable	351	101	318
(Gain) loss on disposal of assets	7	28	68
Debentures and stock issued for interest expense	3,241	2,191	2,154
Loss on debt extinguishment	-	28,415	-
Change in fair value of warrants due to modification of terms	455	0.60	
with a second to achieve the affiliation	457	863	_
Write-down of investment in affiliate	- 2 610	202	
Impairment reserve against assets	3,619	_	<del>-</del>
Changes in assets and liabilities Accounts receivable	(2,244)	(2,170)	(382)
Inventories	(2,244)	(2,170)	(362)
Prepaid expenses and other current assets	(76)	(156)	952
Other assets and deposits	103	121	
Accounts payable	(877)	853	, ,
Accrued expenses	2,137	3,010	
Rectued expenses			
Total adjustments	32,370	47,130	10,473
Net cash used in operating activities		(12,459)	(2,090)
Cash flows from investing activities			
Capital expenditures	(410)	(287)	(1,544)
Capital contribution to joint venture	-	-	(89)
Net proceeds from sale of assets	_	16	, ,
nee proceeds from sure of assess			
Net cash used in investing activities	(410)	(271)	(1,605)
Cash flows from financing activities			
Proceeds from issuance of notes payable	2,000	12,500	7,700
Payments to Department of Justice	(328)	(313)	(301)
Exercise of stock options	_	_	96
Repayment of debentures	_	_	(2,200)
Payments on notes payable and capital lease obligations	(46)	(147)	(1,855)
Proceeds from issuance of convertible subordinated			
debentures	6,600	10,500	=
Deferred private offering costs	=	(1,041)	=
Net cash provided by financing activities	8,226	21,499	3,440
Net cash provided by rinahering activities			
NET INCREASE (DECREASE) IN CASH AND			
CASH EQUIVALENTS	(8,269)	8,769	(255)
Cash and cash equivalents at beginning of year	9,211	442	697
Cash and cash equivalents at end of year	 \$ 942	\$ 9,211	\$ 442
cash and cash equivalents at end of year	\$ 942 ======		\$ 442 ======

# CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

### Years ended December 31, 2003, 2002 and 2001

(in thousands, except share 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.
- 2. The Company's convertible debentures contained beneficial conversation features, which were valued at \$6,600.
- 3. The Company issued \$3,241 of debentures as payment of like amounts of debenture accrued interest.
- 4. The Company repaid \$2,037 of indebtedness in the form of product deliveries.
- 5. The Company issued 645,000 warrants with an estimated relative fair value of \$582 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 of debentures.
- 7. The Company issued 150,000 warrants with an estimated relative fair value of \$113 in connection with the termination of an employment agreement.
- 8. Equipment financed through capital leases aggregated approximately \$111.

# CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

#### Years ended December 31, 2003, 2002 and 2001

(in thousands, except share data)

# 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 in connection with this transaction.
- 2. The Company issued 10,700,665 warrants with an estimated relative fair value of \$11,985 in connection with the extension of a note payable.
- 3. The Company issued \$15,885 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.
- 5. The Company issued \$2,191 of debentures as payment of like amounts of debenture accrued interest.
- 6. The Company repaid \$1,826 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 in connection with the refinancing of existing bridge loans in January and May 2002.
- 8. The Company issued 600,000 warrants with an estimated relative fair value of \$948 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 in connection with the issuance of bridge loans.
- 10. The Company's bridge loans contained beneficial conversion features, which were valued at \$3,745.
- 11. Equipment financed through capital leases aggregated approximately \$35.

# CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

# Years ended December 31, 2003, 2002 and 2001

(in thousands, except share data)

# Year ended December 31, 2001

- 1. The Company issued 51,924 shares of common stock as payment for approximately \$70 in debenture accrued interest.
- 2. The Company issued 187,500 warrants with an estimated relative fair value of \$310 in connection with the issuance of bridge loans.
- 3. The Company issued \$2,085 of debentures as payment of like amounts of debenture accrued interest.
- 4. The Company has repaid \$3,979 of indebtedness in the form of product deliveries.
- 5. Equipment financed through capital leases aggregated approximately \$79.
- 6. The Company issued \$300 in notes payable in exchange for \$300 in debentures that matured.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2003, 2002 and 2001

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

Halsey Drug Co., Inc. (the "Company" or "Halsey"), a New York corporation established in 1935, and its subsidiaries, was engaged in the development, manufacture, sale and distribution of generic drugs and active pharmaceutical ingredients ("APIs"). A generic drug is the chemical and therapeutic equivalent of a brand-name drug for which patent protection has expired. A generic drug may only be manufactured and sold if patents (and any additional government-granted exclusivity periods) relating to the brand-name equivalent of the generic drug have expired. A generic drug is usually marketed under its generic chemical name or under a brand name developed by the generic manufacturer. Through its strategic alliance with Watson Pharmaceuticals, Inc. ("Watson"), as described below, the Company sold its generic drug products under the Watson name for distribution by Watson to drugstore chains and drug wholesalers. In addition, the Company sold its generic drug products under its own name or that of a wholly-owned subsidiary commencing in the second quarter of 2003. While subject to the same governmental standards for safety and efficacy as its brand-name equivalent, a generic drug is usually sold at a price substantially below that of its brand-name equivalent.

In the fourth quarter of 2003, the Company restructured it operations, as more fully describe in Note B, and substantially ceased the manufacturing of the Company's generic finished dosage products on January 30, 2004.

As restructured, the Company is engaged in the development and commercial scale up of the Company's novel API opioid synthesis technologies at the Culver, Indiana facility, the prosecution of the Company's application to the DEA to receive a registration to import Narcotic Raw Materials ("NRMs") for use in the production of opioid API's, the development of the Company's proprietary abuse deterrent formulation technologies for use in orally administered opioid containing finished dosage products, the manufacture of clinical trial supplies of abuse deterrent formulations, the evaluation of products utilizing abuse deterrent formulation technology in appropriate clinical trials, entering into license agreements with strategic partners providing that such licensees will further develop such abuse deterrent formulation finished dosage products, file for regulatory approval with the U.S. Food and Drug Administration ("FDA") and commercialize such products, and the Company's manufacture of commercial quantities of such products for sale by the Company's licensees. During 2003, Axiom Pharmaceutical Corporation began operations of manufacturing and distributing generic pharmaceutical products under its own label. As of January 30, 2004, substantially all operations of Axiom Pharmaceutical Corporation ceased.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### December 31, 2003, 2002 and 2001

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, Houba, Inc., and Axiom Pharmaceutical Corporation (formerly known as Halsey Pharmaceuticals, Inc.) All material intercompany accounts and transactions have been eliminated. During 2002, the Company dissolved all of its inactive subsidiaries with the exception of Houba, 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 substantial income taxes for the years ended December 31, 2003, 2002 and 2001. In addition, the Company paid cash interest of approximately \$ 526,000, \$136,000 and \$683,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

#### 3. Accounts Receivable - Trade and Allowance Accounts

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.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# December 31, 2003, 2002 and 2001

# NOTE A (CONTINUED)

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

	2003	2002	2001
	(i	n thousand:	s)
Beginning balance	\$ 14	\$ 347	\$ 315
Provision for losses on accounts receivable	351	101	402
Provision for all other allowances	77	_	_
Allowances paid	(6)	(434)	(288)
Write-off	(8)	_	_
Recoveries	_	_	(82)
Ending balance	\$ 428	\$ 14	\$ 347
	======	======	======

#### 4. Inventories

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.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### December 31, 2003, 2002 and 2001

### **NOTE A (CONTINUED)**

### 5. Property, Plant and Equipment

Property, plant and equipment are stated at cost less accumulated depreciation and amortization. Major improvements are capitalized and maintenance and repairs are expensed as incurred. Depreciation and amortization are provided for in amounts sufficient to relate the cost of depreciable assets to operations over their estimated service lives, principally on a straight-line basis.

The estimated lives used in determining depreciation and amortization are:

Building and building improvements 20 - 39 years
Machinery and equipment 3 - 10 years
Leasehold improvements Shorter of the life of the lease or the service life of the asset

#### 6. Impairment of Long-Lived Assets

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. See Note J for the impairment charge related to the write-off of leasehold improvements of the Company's Brooklyn, New York plant, which closed in March 2001. See Note B for impairment charge relating to write-down of manufacturing assets of the Company's Congers, New York and Culver, Indiana plants.

### 7. Deferred Private Offering Costs

Deferred private offering costs represent costs incurred by the Company in conjunction with securing debt financing. The Company incurred approximately \$582,000 in deferred 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 deferred private offering costs during the year ended December 31, 2002 in conjunction with a private offering of securities. (See Note H.) Deferred private offering costs are amortized to interest expense over the life of the related obligations.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

### **NOTE A (CONTINUED)**

#### 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 (Notes H and I) 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.

# 9. Revenue Recognition

The Company recognizes revenue, net of sales discounts and allowances, when title to the product passes to customers, which occurs 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 are 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 are, however, dependent upon future events.

The Company recognizes product development revenue when the Company has earned such revenue in accordance with the achievement of specific criteria as outlined in the applicable products development agreement.

10. Shipping and Handling Costs

The Company includes all shipping and handling expenses incurred as a component of cost of manufacturing.

11. Research and Development Costs

All research and development costs are expensed when incurred.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

### **NOTE A (CONTINUED)**

#### 12. Advertising Costs

Advertising costs are expensed as incurred. Advertising costs charged to operations for the years ended December 31, 2002 and 2001 were approximately \$288,000 and \$39,000, respectively. During the year ended December 31, 2003, the company benefited from previously accrued advertising costs of approximately \$306,000.

#### 13. Income Taxes

The Company accounts for income taxes under the liability method in accordance with Statement of Financial Accounting Standards No. 109 ("SFAS No. 109"), "Accounting for Income Taxes." Under this method, deferred 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.

## 14. Earnings (Loss) Per Share

The computation of basic earnings (loss) per share of common stock is based upon the weighted average number of common shares outstanding during the period. Diluted earnings per share is based on basic earnings per share adjusted for the effect of other potentially dilutive securities. Excluded from the 2003, 2002 and 2001 computation are approximately 249,877,514, 200,368,000 and 52,976,000, respectively, of outstanding warrants and options and the effect of convertible debentures outstanding which would have been antidilutive.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### December 31, 2003, 2002 and 2001

## **NOTE A (CONTINUED)**

#### 15. Stock-Based Compensation

The Company has two stock-based employee compensation plans, which are described more fully in Note N. 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, an amendment of FASB Statement No. 123. ("SFAS No. 148")". 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 employee stock option grants.

The following table illustrates the effect on net income and earnings per share had the Company applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," to stock-based employee compensation.

	Year ended December 31,					
	(	in thousand		except per	sha	re data) 2001
Net loss, as reported  Deduct: Total stock-based employee  compensation expense determined under fair  value-based method for all awards		(48,455)	\$	(59,589)	\$	(12,563)
		(662)		(1,047)		(1,679)
Pro forma net loss	\$ ==	(49,117)	\$	(60,636)	\$	(14,242)
Loss per share:						
Basic and diluted - as reported	\$	(2.28)	\$	(3.90)	\$	(.84)
Basic and diluted - pro forma	\$	(2.31)	\$	(3.97)	\$	(.95)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### December 31, 2003, 2002 and 2001

#### **NOTE A (CONTINUED)**

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			
	2003	2002	2001	
Expected life (years)	2.5	10	10	
Risk-free interest rate	1.8%	4.6%	5.3%	
Expected volatility	94%	888	86%	
Dividend yield	0.0%	0.0%	0.0%	
Weighted-average option fair value	\$ .53	\$ 1.12	\$ 1.87	

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.

#### 16. Use of Estimates in Consolidated Financial Statements

In preparing consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, management makes estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### **NOTE A (CONTINUED)**

### 17. 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.

#### 18. New Accounting Pronouncements

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities," ("SFAS No. 149"), which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 except for the provisions that were cleared by the FASB in prior pronouncements. The adoption of SFAS No. 149 did not have a material impact on the Company's financial position or results of operations.

In May 2003, the FASB issued "SFAS No. 150", "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("SFAS No. 150"). This statement establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. In accordance with the standard, financial instruments that embody obligations for the issuer are required to be classified as liabilities. This Statement shall be effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on the Company's financial position or results of operations.

#### 19. Reclassifications

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## NOTE B - BASIS OF PRESENTATION AND LIQUIDITY MATTERS

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. At December 31, 2003, the Company had cash and cash equivalents of approximately \$942,000, working capital deficit of approximately \$3,770,000 and a stockholders' deficit of approximately \$52,067,000. The Company incurred a loss from operations of approximately \$17,244,000 and a net loss of approximately \$48,455,000 during the year ended December 31, 2003. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans with respect to these matters follow:

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. The plan targeted a reduction in workforce of approximately 70 employees at the Congers Facilities, 25 employees at the Culver Facility and 5 employees in Rockford, Illinois.

In implementing the restructuring plan at the Culver Facility, the reduction in work force involved approximately 25 employees engaged in or supporting the manufacture of doxycycline hyclate and doxycycline monohydrate APIs which were converted to finished dosage products at the Congers Facilities. With the closure of the Congers Facilities the APIs manufactured in Culver were not required. The Culver Facility work force reduction was substantially completed by December 31, 2003.

In implementing the restructuring plan at the Rockford, Illinois administrative office facility, the Company terminated its Rockford office lease agreement and relocated the administrative functions to Palatine, Illinois. This process was completed on February 29, 2004 resulting in a reduction in work force of 5 employees.

In implementing the restructuring of operations at the Congers Facilities, the reduction in work force involved essentially all of the employees at the site. 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. From approximately March 1, 2004 to March 19, 2004 a small logistics, maintenance and warehouse staff prepared the Congers Facilities for sale to IVAX Pharmaceuticals as discussed below.

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

- o Development of the Company's ADF Technology for use in orally administered opioid finished dosage products.
- o Manufacture and quality assurance release of clinical trial supplies of certain finished dosage form products utilizing the ADF Technology.
- o Evaluation of certain finished dosage products utilizing the ADF Technology in clinical trials.
- o Scale-up and manufacture of commercial quantities of certain products utilizing the ADF Technology for sale by the Company's licensees.
- o Research, development and scale up of the Company's novel Opioid Synthesis Technologies.
- o Prosecution of the Company's application to the DEA to receive a registration to import Narcotic Raw Materials ("NRMs") for use in the production of opioid API's utilizing the Company's Opioid Synthesis Technologies.
- o 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 ADF Technology, file for regulatory approval with the FDA and other

regulatory authorities and commercialize such products.

As of December 31, 2003, the Company has recorded aggregate restructure expenses of approximately \$3,280,000 consisting of an impairment charge of \$1,673,000 against property, plant and equipment, an impairment charge of \$1,354,000 against inventory (charged against cost of sales), and 253,000 of other costs.

On February 6, 2004, the Company consummated a private offering of securities for an aggregate purchase price of approximately \$12.3 million (the "2004 Debenture Offering"). The securities issued in the 2004 Debenture Offering consisted of convertible senior secured debentures (the "2004 Debentures"). 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 II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P. and each of the Purchasers listed on the signature page thereto (collectively, the "2004 Debenture Investor Group").

Of the approximate \$12.7 million in 2004 Debentures issued in the 2004 Debenture Offering, approximately \$2 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 and Galen Partners III, L.P., Galen International III, L.P., and Galen Employee Fund III, L.P. during November and December, 2003. The 2004 Purchase Agreement further provides that the Company may issue additional 2004 Debentures in the principal amount of up to approximately \$1.3 million on or prior to June 5, 2004, provided that the aggregate principal amount of 2004 Debentures issued pursuant to the 2004 Purchase Agreement shall not exceed \$14 million without the consent of the holders of 60% of the principal amount of the 2004 Debentures then held by Care Capital, Essex and Galen.

The 2004 Debentures, issued at par, bear interest at the rate of 1.62% per annum, the short-term Applicable Federal Rate on the date of issuance. The 2004 Debentures are secured by a lien on all assets of the Company. In addition, each of Houba, Inc. and Axiom Pharmaceutical Corporation, each a

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### **NOTE B (CONTINUED)**

wholly-owned subsidiary of the Company, has executed in favor of the 2004 Debenture holders, an unconditional agreement of guaranty of the Company's obligations under the 2004 Purchase Agreement. Each guaranty is secured by all assets of such subsidiary. In addition, the Company has pledged the stock of each such subsidiary to the holders of the 2004 Debentures to further secure its obligations under the 2004 Purchase Agreement.

In accordance with the terms of an Amended and Restated Subordination Agreement dated as of February 6, 2004 between the Company, the holders of the 2004 Debentures and the holders of the Company's other outstanding debentures, the liens on the Company's and its subsidiary's assets as well as the payment priority of the 2004 Debentures are (i) subordinate to the Company's lien and payment obligations in favor of Watson Pharmaceuticals under the Watson Term Loan Agreement, and (ii) senior to the Company's lien and payment obligations in favor of the holders of the Company's other outstanding debentures in the aggregate principal amount of approximately \$87.7 million.

The 2004 Debentures (including the principal amount plus interest accrued at the date of conversion) will convert automatically into the Company's Series A convertible preferred stock (the "Series A Preferred") immediately following the Company's receipt of shareholder approval at its next shareholders' meeting 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 (the date of such filing, the "Charter Amendment Filing Date"), as provided in the 2004 Purchase Agreement. The 2004 Debentures will convert into Series A Preferred at a price per share (the "Series A Conversion Price") of \$0.6425, representing the average of the closing bid and asked prices of the Company's Common Stock for the twenty (20) trading days ending February 4, 2004, as reported by the Over-the-Counter ("OTC") Bulletin Board. The Series A Conversion Price is subject to adjustment, from time to time, to equal the consideration per share received by the Company for its Common Stock, or the conversion/exercise price per share of the Company's Common Stock issuable under rights or options for the purchase of, or stock or other securities convertible into, Common Stock ("Convertible Securities"), if lower than the then applicable Series A Conversion Price.

Based on the \$0.6425 Series A Conversion Price of the Series A Shares and estimating the interest accrual under the 2004 Debentures prior to the Charter Amendment Filing Date, the 2004 Debentures with an aggregate principal amount of \$14 million would be convertible into an aggregate of approximately 22 million Series A Preferred shares.

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### **NOTE B (CONTINUED)**

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 asconverted 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.

The 2004 Purchase Agreement provides that each of Care Capital, Essex and Galen (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, Thangjaraj and Wesson, respectively, each of whom are current Board members. Effective as of the closing 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).

As of February 6, 2004, the date of the initial closing of the 2004 Purchase Agreement, the Company had issued and outstanding and aggregate of approximately \$87.7 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.

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 2004 Debenture Investor Group and each of

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### **NOTE B (CONTINUED)**

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, each holder of the 2004 Debentures agreed to convert the 2004 Debentures held by such holder into the Company's Series A Preferred shares and each holder of 1998-2002 Debentures agreed to convert 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", and the Junior Preferred Shares together with the Series A Preferred, are collectively referred to as the "Preferred Stock". The Conversion Agreement provides, among other things, for the automatic conversion of the 2004 Debentures and the 1998-2002 Debentures (collectively, the "Outstanding Debentures") into the appropriate class of Preferred Stock immediately following the Company's receipt of shareholder approval to the Charter Amendment authorizing the creation of the Preferred Stock and the filing of the Charter Amendment with the Office of the New York Department of State.

Under the Conversion Agreement, the holders of approximately \$6.7 million in principal amount of 2002 Debentures issued during 2003 will convert such 2002 Debentures (plus accrued and unpaid interest) into Series B Preferred Shares. Of the remaining approximate \$81 million in principal amount of the 1998-2002 Debentures, approximately \$31.6 million is comprised of 1998 Debentures, approximately \$21.8 million is comprised of 1999 Debentures and approximately \$27.6 million is comprised of 2002 Debentures. The 1998 Debentures will be converted into Series C-1 Preferred shares. The 1999 Debentures will be converted into Series C-2 Preferred shares. The remaining balance of the 2002 Debentures shall be converted into Series C-3 Preferred shares.

The number of Junior Preferred Shares to be received by each holder of 1998-2002 Debentures is based on the respective prices at which the 1998-2002 Debentures were convertible into Common Stock. The 2002 Debentures issued in 2003 have a conversion price of \$0.3420 per share. The 1998 Debentures, 1999 Debentures and the remaining balance of the 2002 Debentures have conversion prices of \$0.5776, \$0.5993 and \$0.3481 per share, respectively. Based on the respective conversion prices of the 1998-2002 Debentures, and estimating the interest accrual on the 1998-2002 Debentures prior to the Charter Amendment Filing Date, the 1998-2002 Debentures are convertible into an aggregate of approximately 20.0 million Series B Preferred shares, 56.5 million Series C-1 Preferred shares, 37.5 million Series C-2 Preferred shares and 80.9 million Series C-3 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 of 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### **NOTE B (CONTINUED)**

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 stockholders, 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.

The Company was a party to a certain loan agreement with Watson Pharmaceuticals ("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 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 "Amended and Restated Watson Note"). Simultaneous with the issuance of the Amended and Restated Watson Note, each of the Lead 2004 Investors and the other investors in the 2004 Debentures as of February 10, 2004 (collectively, the "Watson Note Purchasers") purchased the Amended and Restated Note from Watson in consideration for a payment to Watson of \$1,000,000.

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 current supply agreements between the Company and Watson were cancelled 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.

The Amended and Restated Watson Note in the principal amount of \$5 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% and matures on June 30, 2007.

As part of the restructuring of the Company's operations, in February, 2004, the Company sold certain non-revenue generating abbreviated new drug applications ("ANDAs"). Additionally, 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 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 manufacturing and packaging locations in Congers, New York. Shareholder approval is necessary to complete this transaction and will be sought of the Company's next annual meeting of shareholders. After giving effect to the payment of legal and other professional fees relating to these assets divestment transactions, the Company estimates that it will realize aggregate net proceeds of approximately \$4.3 million from such transactions.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## **NOTE B (CONTINUED)**

The development and commercialization of active pharmaceutical ingredients ("APIs") and finished dosage products incorporating the Company's opiate synthesis and finished dosage formulation technologies are subject to various factors, many of which are outside the Company's control. Specifically, only a limited portion of such technologies have been tested in laboratory settings, none have been tested in clinical settings, and all of such technologies will need to be successfully scaled up to commercial scale 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 manufacturing registrations (the "Manufacturing Registration") and the issuance and maintenance of the DEA raw material import registration (the "Import Registration"). The process of seeking the Import Registration and contesting opposition proceedings, as well as the continuing development of the Company's opiate synthesis and finished dosage formulation technologies, are intended to continue through 2004. The Company is currently 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 opiate synthesis and finished dosage formulation technologies and to the receipt of the Import Registration. The failure of the Company to successfully develop the finished dosage formulation technologies will have a material adverse effect on the Company's operations and financial condition. 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 operations or to otherwise complete the development of the opiate synthesis and finished dosage formulation technologies, to obtain required DEA and FDA approvals and to fund the capital improvements necessary for the manufacture of APIs and finished dosage products incorporating such technologies.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the 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 financial statements do not include any adjustments 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### NOTE C - STRATEGIC ALLIANCE WITH WATSON PHARMACEUTICALS

On March 29, 2000, the Company completed various strategic alliance transactions with Watson Pharmaceuticals, Inc. ("Watson"). The transactions provided for Watson's purchase of a certain pending abbreviated new drug application ("ANDA") from the Company, for Watson's rights to negotiate for Halsey to manufacture and supply certain identified future products to be developed by Halsey, for Watson's marketing and sale of the Company's core products and for Watson's extension of a \$17,500,000 term loan to the Company. (See Note I(a).)

#### 1. Product Acquisition Agreement

The product acquisition portion of the transactions with Watson provided for Halsey's sale of a pending ANDA and related rights (the "Product") to Watson for aggregate consideration of \$13,500,000 (the "Product Acquisition Agreement"). As part of the execution of the Product Acquisition Agreement, the Company and Watson executed ten-year supply agreements covering the active pharmaceutical ingredient ("API") and finished dosage form of the Product pursuant to which Halsey, at Watson's discretion, will manufacture and supply Watson's requirements for the Product API and, where the Product API is sourced from the Company, finished dosage forms of the Product. The purchase price for the Product was payable in three installments as certain milestones were achieved. The first of such milestones was achieved in April of 2000, whereby the Company received FDA approval and Watson paid the Company \$5,000,000. In April 2001, Watson remitted \$5,000,000 to the Company representing the second milestone achievement. The third and last of the milestones was achieved in July 2001, and Watson remitted \$3,500,000 to the Company.

### 2. Right of First Negotiation Agreement

The Company and Watson also executed a right of first negotiation agreement providing Watson with a first right to negotiate the terms under which the Company would manufacture and supply certain specified APIs and finished dosage products to be developed by the Company. The right of first negotiation agreement provides that upon Watson's exercise of its right to negotiate for the supply of a particular product, the parties will negotiate the specific terms of the manufacturing and supply arrangement, including price, exclusivity, minimum purchase requirements, if any, territory and term.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## NOTE C (CONTINUED)

In the event Watson does not exercise its right of first negotiation upon receipt of written notice from the Company as to its receipt of applicable governmental approval relating to a covered product, or in the event the parties are unable to reach agreement on the material terms of a supply arrangement relating to such product within sixty days of Watson's exercise of its right to negotiate for such product, the Company may negotiate with third parties for the supply, marketing and sale of the applicable product. The right of first negotiation agreement has a term of ten years, subject to extension in the absence of written notice from either party for two additional periods of five years each. The right of first negotiation agreement applies only to API and finished dosage products identified in the agreement and does not otherwise prohibit the Company from developing other APIs or finished dosage products for itself or third parties. (See Note B)

#### 3. Core Products Supply Agreement

The Company and Watson also completed a manufacturing and supply agreement providing for Watson's marketing and sale of the Company's existing core products portfolio (the "Core Products Supply Agreement"). The Core Products Supply Agreement obligated Watson to purchase a minimum amount of approximately \$3,060,000 per quarter (the "Minimum Purchase Amount") in core products from the Company, through September 30, 2001 (the "Minimum Purchase Period"). At the expiration of the initial Minimum Purchase Period, if Watson did not continue to satisfy the Minimum Purchase Amount, the Company would then be able to market and sell the core products on its own or through a third party. On August 8, 2001, the Company and Watson executed an amendment to the Core Products Supply Agreement providing (i) for a reduction of the Minimum Purchase Amount from \$3,060,000 to \$1,500,000 per quarter,

(ii) for an extension of the Minimum Purchase Period from the quarter ended September 30, 2001 to the quarter ended September 30, 2002, (iii) for Watson to recover previous advance payments made under the Core Products Supply Agreement in the form of the Company's provision of products having a purchase price of up to \$750,000 per quarter (such credit amount to be in excess of Watson's \$1,500,000 minimum quarterly purchase obligation), and (iv) for the Company's repayment to Watson of any remaining advance payments made by Watson under the Core Products Supply Agreement (and which amount has not been recovered by product deliveries by the Company to Watson as provided in Subsection (iii) above) in two (2) equal monthly installments on October 1, 2002 and November 1, 2002. On December 20, 2002, the Company's remaining advance payments from Watson were \$3,901,331. At such date, this amount was consolidated with the Company's obligations under its term loan with Watson. (See Notes C-4 and B) In March 2003, the Company notified Watson that the Company intended to commence selling the core products independent of, and in addition to, Watson's efforts as provided for under the Core Products Agreement. Those products were sold by the Company's subsidiary, Axiom Pharmaceutical Corporation.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## NOTE C (CONTINUED)

#### 4. Term Loan Agreement

The final component of the Company's strategic alliance with Watson provided for Watson's extension of a \$17,500,000 term loan to the Company ("Watson Term Loan"). The loan was funded in installments upon the Company's request for advances and the provision to Watson of a supporting use of proceeds relating to each such advance. The loan is secured by a first lien on all of the Company's assets, senior to the lien securing all other Company indebtedness, carries a floating rate of interest equal to prime plus two percent and had an initial maturity date of March 31, 2003. As part of the Company's 2002 Debenture Offering (Note H), the Watson Term Loan was amended to (1) extend the maturity date to March 31, 2006, (2) increase the interest rate to prime plus four and one half percent, 8.5% at December 31, 2003, and (3) increase the principal amount by \$3,901,331 to reflect the inclusion of the Core Products Supply Agreement advance payments owed by the Company to Watson. In consideration of the amendment to the Watson Term Loan, the Company issued to Watson a common stock purchase warrant ("Watson Warrant") exercisable for 10,700,665 shares of the Company's common stock at an exercise price of \$.34 per share. The warrant has a term expiring December 31, 2009. The fair value of the Watson Warrant on the date of grant, as calculated using the Black-Scholes option-pricing model, of \$11,985,745 was charged to earnings on the date of grant as a loss on the extinguishment of debt. As of December 31, 2003, Watson had advanced \$21,401,331 to the Company under the Watson Term Loan. (See Notes B and H(a))

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# December 31, 2003, 2002 and 2001

# **NOTE D - INVENTORIES**

# Inventories consist of the following:

	Decemb	per 31,
	2003	2002
	 (in the	ousands)
Finished goods	\$ 357	\$ -
Work-in-process	953	831
Raw materials	356	1,454
	1,666	2,285
Less impairment rese	rve (1,354)	-
	\$ 312	\$ 2,285
	======	======

# NOTE E - PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows:

	December 31,		
	200	3	2002
	(i	 n thous	ands)
Machinery and equipment			\$ 9,120
Construction in progress			157
Leasehold improvements			1,454
Building and building improvements	2,		2,813
Land		44	44
	14,	083	13,588
Less accumulated depreciation and amortization (including \$11 in 2003 and \$8 in 2002 of capitalized lease amortization)	(9,	016)	(8,221)
	5,	067	5,367
Less impairment reserve (Note B)	(1,	673) 	-
	\$ 3,	394 ===	\$ 5,367 ======

Included in machinery and equipment is equipment recorded under capitalized leases at December 31, 2003 and 2002, of approximately \$221,000 and \$108,000, respectively. Depreciation and amortization expense for the years ended December 31, 2003, 2002 and 2001 was approximately \$811,000, \$835,000 and \$861,000, respectively.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# December 31, 2003, 2002 and 2001

# NOTE F - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	Decemb	per 31,
	2003	2002
	(in tho	usands)
Interest	\$1,544	\$ 988
Accrued payroll and payroll taxes	310	497
Professional fees	491	388
Other	1,307	1,242
	\$3,652	\$3,115
	=====	=====

# NOTE G - CONVERTIBLE SUBORDINATED DEBENTURES AND STOCK WARRANTS

At December 31, 2003 and 2002, convertible subordinated debentures outstanding and related debt discount related to the following issuances are as follows:

	December 31,		
	2003	2002	
Issuance of Debentures	(in tho	usands)	
1998 Debentures	\$ 31,212	\$ 30,215	
1999 Debentures	21,485	20,509	
2002 Debentures	27,303	26,394	
2003 Debentures	6,632	=	
	86,632	77,118	
Less: Debt discount	(56,893)	(73,955)	
	\$ 29,739	\$ 3,163	
	=======	=======	

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## **NOTE G (CONTINUED)**

In March and June 1998, the Company consummated a private offering of securities for an aggregate purchase price of approximately \$25,800,000 million (the "Galen Offering"). The securities issued in the Galen Offering consisted of 5% Convertible Senior Secured Debentures (the "1998 Debentures") and Common Stock Purchase Warrants (the "1998 Warrants"). The 1998 Debentures had an initial conversion price of \$1.404 per share, for an aggregate of up to approximately 18,376,068 shares of the Company's Common Stock. The 1998 Warrants were initially exercisable for an aggregate of approximately 5,500,084 shares of the Company's Common Stock. Of such Warrants, 2,784,250 Warrants were exercisable at \$1.404 per share and the remaining 2,715,834 Warrants were exercisable at \$2.279 per share. In connection with the Galen Offering, the Company incurred offering costs of \$1,236,000 for legal and investment banker fees. These related offering costs were amortized over the life of the related debentures. Pursuant to certain provisions contained in the Watson Term Loan (see Note H(a)), certain interest payments on the 1998 Debentures to investors, as agreed, are to be made in the form of additional debentures. As of December 31, 2003 and 2002, the Company has issued additional debentures as payment of accrued interest on the 1998 Debentures of \$4,427,000 and \$3,166,000, respectively.

In May 1999, the Company consummated a private offering of securities for an aggregate purchase price of approximately \$17,862,000(the "Oracle Offering"). The securities issued in the Oracle Offering consisted of 5% Convertible Senior Secured Debentures (the "1999 Debentures") and Common Stock Purchase Warrants (the "1999 Warrants"). The 1999 Debentures had an initial conversion price of \$1.404 per share, for an aggregate of up to approximately 12,722,222 shares of the Company's Common Stock. The 1999 Warrants were initially exercisable for an aggregate of approximately 3,608,602 shares of the Company's Common Stock. Of such Warrants, 1,804,301 Warrants were exercisable at \$1.404 per share and the remaining 1,804,301 Warrants were exercisable at \$2.279 per share. Approximately \$7,037,000 of the 1999 Debentures were issued in exchange for the surrender of a like amount of principal and accrued interest outstanding under the Company's convertible promissory notes issued pursuant to various bridge loans received in the aggregate amount of \$10,533,000 during the period from August 1998 through and including May 1999 (the "1999 Bridge Loans"). In exchange for the creditors granting extensions on maturity dates of the Company's 1999 Bridge Loans, the Company issued warrants to purchase 1,025,049 shares of the Company's common stock at exercise prices ranging from \$1.18 to \$2.32. Pursuant to certain provisions contained in the Watson Term Loan (see Note H(a)), certain interest payments on the 1999 Debentures to investors, as agreed, are to be made in the form of additional debentures. As of December 31, 2003 and 2002, the Company has issued additional debentures as payment of accrued interest on the 1999 Debentures of \$2,647,000 and \$1,718,000, respectively.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### **NOTE G (CONTINUED)**

Each of the 1998 Debentures, 1999 Debentures, 1998 Warrants and 1999 Warrants contain customary antidilution protection. Specifically, each of such convertible securities provides that in the event the Company issues shares of its Common Stock or securities convertible into Common Stock at a price less than the fair market value of the Company's Common Stock on the date of issuance (fair market value being equal to the average of the closing bid and asked price for the Company's Common Stock as reported by the Over-the-Counter Bulletin Board for the 20 trading days preceding the date of issuance), the conversion and exercise prices of the 1998 Debentures, 1999 Debentures, 1998 Warrants and 1999 Warrants are adjusted downward on a weighted-average basis. In addition, once having determined the new conversion/exercise price of such convertible securities, the holder of such convertible securities is entitled to acquire upon conversion or exercise of such instrument, the number of shares of Common Stock obtained by multiplying the conversion/exercise price in effect immediately prior to such adjustment by the number of shares of Common Stock acquirable immediately prior to such adjustments, and dividing the product thereof by the new conversion/exercise price.

On December 20, 2002, the Company consummated a private offering of securities (the "2002 Debenture Offering") for an aggregate purchase price of \$26,394,000. The securities issued consisted of 5% convertible senior secured debentures (the "2002 Debentures"). Of the 2002 Debentures, approximately \$15,894,000 of Debentures were issued in exchange for the surrender of like amount of principal and accrued interest outstanding under various working capital bridge loan transactions during the period from August 15, 2001 through and including December 20, 2002. (See Note H(b).) The 2002 Debentures were issued at par, will become due and payable as to principal on March 31, 2006 and interest is accrued at the rate of 5% per annum and is payable on a quarterly basis. Interest payments on certain of the 2002 Debentures are to be made in the form of additional debentures.

2002 Debentures issued to certain investors in the aggregate face amount of \$10,000,000 are convertible at any time after issuance into shares of the Company's Common Stock. The remainder of the 2002 Debentures are convertible at any time after the approval of the Company's shareholders and debentureholders to an amendment to the Company's Certificate of Incorporation to increase its authorized shares of Common Stock from 80,000,000 shares to such number of shares as shall provide

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## **NOTE G (CONTINUED)**

sufficient authorized shares to permit the conversion of the 2002 Debentures and the Company's other outstanding convertible securities. Subject to the foregoing, the 2002 Debentures are convertible into shares of Common Stock at a price per share (the "Conversion Price") of \$.34. Until such time as the Company completes a Subsequent Material Offering (as defined below) the Conversion Price is subject to adjustment, from time to time, to equal the consideration per share received by the Company for its Common Stock, or the conversion/exercise price per share of the Company's Common Stock issuable under rights or option for the purchase of, or stock or other securities convertible into, Common Stock ("Convertible Securities"), if lower than the then applicable Conversion Price. Following the Company's completion of a Subsequent Material Offering, the Conversion Price is subject to adjustment from time to time on a weighted-average dilution basis. A "Subsequent Material Offering" is the grant or issuance of Common Stock or Convertible Securities by the Company during any six (6) month period for an aggregate gross consideration of at least \$10,000,000. The 2002 Debentures are initially convertible into an aggregate of approximately 77,629,000 shares of Common Stock. Debentures that are issued to pay interest on the 2002 Debentures are convertible at anytime after issuance into shares of Common Stock at a price per share equal to the average of the closing bid and asked prices of the Common Stock for the twenty (20) trading days immediately preceding the applicable interest payment date under the 2002 Debentures, as reported by the Over-the-Counter ("OTC") Bulletin Board. As a condition of the 2002 Debenture Offering, the maturity of the 1998 Debentures and 1999 Debentures was extended from March 15, 2003 to March 31, 2006.

As part of the completion of the 2002 Debenture Offering, the Company also amended its term loan agreement with Watson and issued to Watson a common stock purchase warrant for 10,700,665 shares (the "Watson Warrant"). (See Note H(a).) The exercise price of the Watson Warrant is \$.34 per share. The fair market value of the Company's Common Stock on December 20, 2002, the date of the closing of the 2002 Purchase Agreement (as calculated in accordance with the definition of fair market value contained in the 1998 Debentures, 1999 Debentures, 1998 Warrants and 1999 Warrants), was \$.99 per share. As the conversion price of the 2002 Debentures and exercise price of the Watson Warrant were less than the fair market value of the Company's Common Stock on the date of issuance of the 2002 Debentures, the dilution adjustment provisions contained in each of the 1998 Debentures, 1999 Debentures, 1998

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## **NOTE G (CONTINUED)**

Warrants and 1999 Warrants were triggered. As a result, the conversion price of the 1998 Debentures was reduced from \$1.34 per share to \$.59 and the conversion price of the 1999 Debentures was reduced from \$1.404 per share to \$.61. Additionally, the exercise price of the 1998 Warrants was reduced from \$1.34 per share to \$.59 per share and from \$2.16 per share to \$.95 per share. The conversion price of the 1999 Warrants was reduced from \$1.404 per share to \$.61 per share and from \$2.285 per share to \$1.00 per share. After giving effect to the Dilution Adjustments, the number of shares issuable upon conversion of the 1998 Debentures and 1999 Debentures has been increased by 41,184,184 shares of Common Stock, from 31,967,120 to 73,151,304 shares. In addition, the number of shares issuable upon exercise of the remaining 1998 Warrants and 1999 Warrants, after taking into effect the Warrant recapitalization, as discussed below, has been increased by 8,023,928 shares, from 5,867,013 to 13,890,941 shares. As a condition of the 2002 Debenture Offering, the maturity date of the 1998 Debentures and 1999 Debentures was extended from March 15, 2003 to March 31, 2006. The Company recorded a charge to earnings, as loss on extinguishments of debt, of \$14,148,757 related to an increase in the fair value of the warrants, as calculated using the Black-Scholes option-pricing model, as a result of the modification of terms of the 1998 Warrants and 1999 Warrants.

The conversion features contained in the Company's 2002 Debentures are considered to be beneficial to the holder as they allow the holder to convert the 2002 Debentures to the Company's common stock at conversion prices that were below the fair market value of the Company's common stock on the date of issuance. The conversion features, as adjusted, contained in certain of the Company's 1998 Debentures and 1999 Debentures are also considered to beneficial to the holder as they allow the holder to convert the 1998 Debentures and 1999 Debentures to the Company's common stock at conversion prices that were below the fair market value of the Company's common stock on the date of issuance. The estimated value of the beneficial conversion features contained in each of the 1998 Debentures, 1999 Debentures and 2002 Debentures of \$74.618,817 has been recorded as debt discounts and is being amortized to expense over the life of the debt.

The 2002 Debentures are secured by a lien on all assets of the Company, tangible and intangible. In addition, each of Houba, Inc. and Axion Pharmaceuticals Corporation has executed in favor of the holders of the 2002 Debentures an unconditional agreement of guarantee of the Company's obligations under the Purchase Agreement. Each guarantee is secured by all assets of such subsidiary, and, in the case of Houba, Inc., by a mortgage lien on its Culver, Indiana real estate. In addition, the Company has pledged the stock of each such subsidiary to the holders of the 2002 Debentures to further secure its obligations under the Purchase Agreement.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## **NOTE G (CONTINUED)**

In accordance with the terms of a Subordination Agreement dated December 20, 2002 between the Company, the holders of the 2002 Debentures, the holders of the 1998 and 1999 Debentures and Watson, the liens on the Company's and its subsidiaries' assets as well as the payment priority of the 2002 Debenture are (i) subordinate to the Company's lien and payment obligations in favor of Watson under the Watson Term Loan, and (ii) senior to the Company's lien and payment obligations in favor of holders of the 1998 and 1999 Debentures.

#### **Warrant Recapitalization**

As part of the completion of the transactions contemplated in the 2002 Purchase Agreement, the Company consummated the terms of a Warrant Recapitalization Agreement dated December 20, 2002 (the "Recapitalization Agreement") between the Company and certain holders of an aggregate of 8,145,736 Common Stock Purchase Warrants issued by the Company (i) pursuant to the 1998 Purchase Agreement (the "1998 Warrants"), (ii) pursuant to the 1999 Purchase Agreement (the "1999 Warrants"), and (iii) pursuant to various bridge loan transactions during the period from 1998 through 2002 (the "Bridge Loan Warrants" and collectively with the 1998 Warrants and 1999 Warrants, the "Recapitalization Warrants"). As part of the closing of the Recapitalization Agreement, the warrant holders surrendered to the Company for cancellation the Recapitalization Warrants in exchange for the issuance of an aggregate of 5,970,083 shares of Common Stock. The Company recorded a charge to earnings as loss on extinguishments of debt, of \$2,282,000, representing the fair value of excess shares of Common Stock granted, related to the warrant recapitalization.

Certain other outstanding warrant agreements were modified as a result of dilution adjustment provisions contained therein. The Company recorded a charge to earnings as other expense, of \$863,000 related to an increase in the fair value of the warrants, as calculated using the Black-Scholes option-pricing model, as a result of the modification of terms.

#### 2003 Financing

At the Company's request, on May 5, 2003, the Company received a letter executed by each of Care Capital Investment II, L.P., Galen Partners and Essex Woodlands Health Ventures V, L.P. (the "Majority 2002 Debentureholders") advising that the Majority 2002 Debentureholders would provide funding to meet the Company's 2003 capital requirements, up to an aggregate amount not to exceed \$8.6 million (the "Letter of Support") and expiring January 1, 2004. The Letter of Support further provided that the terms of any funding provided by the Majority 2002 Debentureholders would be subject to negotiation between the Company and the Majority 2002 Debentureholders at the time of any funding. In consideration for the issuance of the Letter of Support, the Company authorized the issuance of warrants to the Majority 2002 Debentureholders exercisable for an aggregate of 645,000 shares of the Company's Common Stock at an exercise price of \$.34 per share subject to downward adjustment to equal the consideration per share received by the Company for its Common Stock, or the conversion/exercise price per share of the Company's Common Stock issuable under convertible securities, in a third part investment if lower than the exercise price of the warrants. The Company valued the warrants at \$581,000 using the Black-Scholes option-pricing model.

Accordingly, the Company recorded a deferred charge that was amortized as an expense to the Company's operations during 2003, which was the commitment period of the Letter of Support.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## NOTE G (CONTINUED)

During the period from May 5, 2003 and December 31, 2003, Care Capital, Essex Woodlands and Galen Partners (collectively, the "Majority 2002 Debentureholders") had collectively advanced an aggregate of \$8,600,000 to the Company pursuant to a Letter of Support issued by the Majority 2002 Debentureholders dated May 5, 2003 in order to fund the Company's operating losses and capital requirements (the "Letter of Support Advances"). The Letter of Support Advances were made in accordance with the terms of 2002 Debenture Purchase Agreement resulting in the Company's issuance of 2002 Debentures in an aggregate principal amount of \$6,600,000 and \$2,000,000 in Bridge Loans (" the 2003 Bridge Loans" having a maturity date of March 31, 2006 The securities issued in the offering, issued at par, have a conversion price of \$0.3420 per share, bear interest payable quarterly at the rate of 5% per annum. Interest on the 2002 Debentures and the 2003 Bridge Loans will be substantially paid by the Company's issuance of a debenture instrument substantial by identical to the 2002 Debentures issued in the 2002 Debentures of the 2002 Debentures issued in the 2002 Debenture Offering, in the principal amount equal to the accrued interest for each quarterly period.

#### **Related-Party Transactions**

Certain of the 1998 Debentures and 1999 Debentures are held by members of the Company's management and Board of Directors. The aggregate principal amount of such debentures was approximately \$175,000 and \$364,000 at December 31, 2003 and 2002, respectively. Interest expense on these debentures was approximately \$7,000, \$17,000 and \$17,000, for the years ended December 31, 2003, 2002 and 2001, respectively, of which approximately \$5,000, \$16,000 and \$15,000 was paid through the issuance of like debentures.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## NOTE H - NOTES PAYABLE AND STOCK WARRANTS

At December 31, 2003 and 2002, notes payable consisted of the following:

	December 31,			
	2003	2002		
Term note payable (a)	(in tho	,		
Bridge loans (b) Capital lease obligations	\$ 2,000 137	\$ - 73		
	2,137	73		
Less: Current maturities	(45)	(33)		
	\$ 2,092 ======	\$ 40 ======		

(a) In connection with various strategic alliance transactions, Watson advanced \$17,500,000 to the Company under a term loan. The loan is secured by a first lien on all of the Company's assets, senior to the lien securing all other Company indebtedness, and carries a floating rate of interest equal to prime plus two percent and had an original maturity date of March 31, 2003. As part of the Company's 2002 Debenture Offering, the Watson Term Loan was amended to (1) extend the maturity date to March 31, 2006, (2) increase the interest rate to prime plus four and one half percent and (3) increase the principal amount to \$21,401,331 to reflect the inclusion of the Core Products Supply Agreement advance payments. The interest rate at December 31, 2003 was 8.50%. In consideration for the extension of the maturity date of the Watson Term Loan, the Company granted the Watson Warrant described in Notes C and H. The fair value of the warrant on the date of grant, as calculated using the Black-Scholes option-pricing model, of \$11,985,745 was charged to operations on the date of grant as loss on the extinguishment of debt.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### **NOTE H (CONTINUED)**

(b) During the period January 9, 2002 through December 5, 2002, the Company secured various bridge loans in the total principal amount of \$12,500,000 to fund the Company's working capital requirements. These loans bear interest at 10.0% per annum and were convertible at prices ranging from \$2.16 to \$1.28 into a total of 7,389,940 shares of the Company's common stock. The conversion features contained in certain of these bridge loans were considered to be beneficial to the holder as they allowed the holder to convert the bridge loans to the Company's common stock at conversion prices that were below the fair market value of the Company's common stock on the date of issuance. As additional consideration for these bridge loans, the Company issued warrants to purchase 4,255,143 shares of the Company's common stock with exercise prices ranging from \$2.16 to \$1.28. The relative estimated fair value of the warrants of \$5,115,000 and the estimated value of the conversion feature of \$3,745,000 were recorded as additional debt discount and amortized over the life of the bridge loans.

At December 20, 2002, total bridge loans and accrued interest outstanding equaled approximately \$16,022,000, of which approximately \$15,894,000 was surrendered in exchange for the 2002 Debentures and approximately \$128,000 was repaid. The total number of warrants issued in connection with these bridge loans was 4,442,643. Under the terms of the warrant agreements the conversion price of each of these warrants was adjusted to \$.34 (Note G)

During the period from May 5, 2003 through December 31, 2003, certain holders of the Company's 2002 Debentures advanced an aggregate of \$8.6 million consisting of \$6.6 million debentures and \$2.0 million bridge loans to the Company under a Letter of Support dated May 5, 2003. The debentures and bridge loans were made in accordance with the terms of the 2002 Debenture Purchase Agreement and have a maturity date of March 31, 2006. (See Note G).

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# December 31, 2003, 2002 and 2001

# NOTE H (CONTINUED)

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

	Warran		
Ranges of exercise prices	Number outstanding at December 31, 2003	Weighted- average remaining contractual life (years)	Weighted- average exercise price
\$0.34 - \$0.93	34,315,714	4.60	\$0.54 =====

# **NOTE I - INCOME TAXES**

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

	Year ended December 31,						
	2003		2002		2001		
	AMOUNT	8	Amount	%	Amount	%	
			(dollars in	thousands)			
Federal statutory rate Loss for which no tax	\$(15,966)	(34.0)%	\$(20,260)	(34.0)%	\$ (4,271)	(34.0%)	
benefit was provided	4,357	9.2	12,951	21.7	4,231	33.7	
Non-deductible financing costs Federal tax carryback refund	11,589	24.6	7,278	12.2	-	-	
Department of Justice							
settlement	11	.1	16	.1	21	. 2	
Other	9	.1	15 	.0	19 	.1	
Actual tax benefit	\$ - =======	-% 	\$ - ======	-% 	\$ - ======	-% ======	

The Company has net operating loss carryforwards aggregating approximately \$128,789,000, expiring during the years 2011 through 2023.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

#### December 31, 2003, 2002 and 2001

## **NOTE I (CONTINUED)**

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:

	December 31,		
		2002	
	(in the	usands)	
Deferred tax assets			
Net operating loss carryforwards	\$ 55,998	\$ 52,687	
Asset reserves	1,016	320	
Research and development tax credit	29	29	
Accrued expenses	205	294	
Capital loss carryforwards	212	211	
Depreciation and amortization	20	378	
Accrued shutdown costs	703	_	
Other	73	73	
Gross deferred tax assets	58,256	53,992	
Deferred tax liabilities			
Depreciation	_	(93)	
Net deferred tax assets before			
valuation allowance	58,256	53,899	
Valuation allowance	(58,256)	(53,899)	
Net deferred tax assets	\$ -	\$ -	
Nee defeited tax assets	Υ =======	Y =======	

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, 2003 primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### NOTE J - CESSATION OF BROOKLYN, NEW YORK PLANT

The Company's formal decision to discontinue its Brooklyn, New York plant operations was initiated in the fourth quarter of 1999 with notification to its union. The Brooklyn operations ceased in March 2001. The total charge of approximately \$3,220,000 resulting from eliminating the Brooklyn operation taken in 1999 includes the lease termination payment of \$1,150,000, a provision of \$200,000 for plant repairs, the write-off of leasehold improvements of \$1,778,000, severance and other costs for terminated employees of \$730,000, less deferred rent previously expensed of \$638,000.

During the year ended December 31, 2000, the Company recorded a charge of approximately \$53,000 representing additional severance costs. During the year ended December 31, 2001, the Company recorded a charge of approximately \$68,000 representing loss on disposal of idle fixed assets. During the year ended December 31, 2002, the Company recorded a benefit of approximately \$126,000 representing a recovery from the landlord related to the Company's provision of plant repair costs that were not utilized by the landlord.

#### NOTE K - INVESTMENT IN JOINT VENTURE AND IMPAIRMENT CHARGE

The Company entered into a 50% joint venture in February 2000 for the purpose of engaging in the development, manufacture and marketing of various products. The joint venture was accounted for under the equity method. During the fourth quarter of 2001, the Company recorded an impairment charge of \$151,000, as it was determined that the fair value of such investment was zero, due to the uncertainty of the joint venture's ability to raise additional capital or to generate income from operations. During 2003, the partners in the joint venture dissolved the entity.

#### **NOTE L - PRODUCT AGREEMENTS**

1. Acquisition of Barr Laboratories, Inc. ANDA

On April 16, 1999, the Company completed an acquisition agreement with Barr Laboratories, Inc. ("Barr") providing for the Company's purchase of the rights to 50 pharmaceutical products (the "Barr Products"). Under the terms of the acquisition agreement with Barr, the Company acquired all of Barr's rights in the Barr Products, including all related governmental approvals (including ANDAs) and related technical data and information. In consideration for the acquisition of the Barr Products, the Company issued to Barr a common stock purchase warrant exercisable for 500,000 shares of the Company's common stock having an exercise price of \$1.0625 per share (the fair value of the

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## NOTE L (CONTINUED)

Common Stock on the date of issuance) and having a term of five years. The Company valued the warrants at \$350,000 using the Black-Scholes option-pricing model. Accordingly, the Company recorded a deferred charge to be amortized as an expense to the Company's operations over a ten-year period, which is the estimated life of the related ANDAs. The acquisition agreement with Barr also allows Barr to purchase any of the Barr Products manufactured by the Company for a period of five years.

## 2. Commercialization and License Agreement

Effective September 27, 2000, the Company entered into an exclusive license for certain patented technology owned by Bio-Fine Pharmaceuticals, Inc. ("Bio-Fine") for the synthesis of codeine from morphine. The agreement provided for a fixed amount of \$3,175,000 to be paid out as certain milestones are achieved with a total of \$500,000 paid during 2000. The agreement also provided for the grant of 50,000 warrants and an employment agreement, both contingent upon FDA approval and the first commercial sale, which has not yet occurred.

In November 2001, the Company notified Bio-Fine of its election to immediately terminate the commercialization and license agreement. Upon termination of this agreement, the contingent warrant and employment agreement expired.

#### **NOTE M - EMPLOYEE BENEFIT PLANS**

### 1. Employees' Pension Plan

The Company contributed approximately \$19,000 in 2001 to a multiemployer pension plan for employees covered by collective bargaining agreements. The Company has not made any contributions to this plan subsequent to April 1, 2001, since the Company ceased operations at its Brooklyn, New York plant in March 2001, whose employees were covered by this plan. (See Note K.) The Company did not administer this plan and contributions were determined in accordance with provisions of negotiated labor contracts. Information with respect to the Company's proportionate share of the excess, if any, of the actuarially computed value of vested benefits over the total of the pension plan's net assets is not available from the plan's administrator.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### **NOTE M (CONTINUED)**

The Multiemployer Pension Plan Amendments Act of 1980 (the "Act") significantly increased the pension responsibilities of participating employers. Under the provision of the Act, if the plans terminate or the Company withdraws, the Company could be subject to a "withdrawal liability." As of December 31, 2003, the Company has not been notified of any withdrawal liability.

#### 2. 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 1.5% 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 2003, 2002 and 2001, respectively.

#### 3. 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, 2003, approximately 64,000 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. All grants of stock options have been at the fair market value on the date of grant. In June 2001, 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. 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, 2003, approximately 5,349,000 options are available for grant under the 1998 Option Plan.

As discussed in Note N, the Company's Board of Directors approved the granting of an aggregate of 5,500,000 options to purchase the Company's stock at an exercise price of \$0.34 per common share which is subject to shareholder approval of amendments to the Company's 1998 Stock Option Plan. These options have not been granted nor issued for accounting purposes. Upon shareholder approval, if the market price of the common stock is greater than \$0.34 per common share, then compensation expense will be accounted for as prescribed in APB Opinion No. 25, and amortized over the vesting period of the option.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# December 31, 2003, 2002 and 2001

# NOTE M (CONTINUED)

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

	Stock options outstanding	
Balance at December 31, 2001	4,589,950	\$ 1.85
Granted Forfeited	470,000 (51,000)	
Balance at December 31, 2002	5,008,950	1.80
Granted Exercised Forfeited	45,000 - (1,529,280)	.96 - 1.69
Balance at December 31, 2003	3,524,670	\$ 5.46 =====
Granted but subject to shareholder approval	5,500,000	\$ .34 =====

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

	Options outstanding			Options exercisable		
Ranges of exercise prices	Number outstanding at December 31, 2003	Weighted- average remaining contractual life (years)	Weighted- average exercise price	Number exercisable at December 31, 2003	Weighted- average exercise price	
\$ .85 - \$1.88 2.08 - 2.50 3.19 - 4.38	1,853,945 1,658,325 12,400	5.99 3.53 2.42	\$ 1.32 2.38 4.15	1,307,834 1,550,825 12,400	\$ 1.35 2.37 4.15	
	3,524,670	4.82	\$ 5.46	2,871,059	\$ 1.91	

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### NOTE N - COMMITMENTS AND CONTINGENCIES

The Company occupies plant and office facilities under noncancellable operating leases, which expire at various dates through June 2004. These operating leases provide for scheduled base rent increases over the term of the lease. The leases provide for payment of real estate taxes based upon a percentage of the annual increase. In addition, the Company rents certain equipment under operating leases, generally for terms of two years or less. Total rent expense for the years ended December 31, 2003, 2002 and 2001 was approximately \$868,000, \$993,000 and \$986,000, respectively.

#### **Lease of Congers, New York Facility (Brenner Drive location)**

Effective March 22, 1999, the Company leased, as sole tenant, a pharmaceutical manufacturing facility located in Congers, New York (the "Brenner Drive Facility") from Par Pharmaceuticals, Inc. ("Par") pursuant to an Agreement to Lease (the "Lease"). The Brenner Drive Facility contains office, warehouse and manufacturing space and is approximately 35,000 square feet. The Lease provides for a term of three years, with a two-year renewal option, and provides for annual fixed rent of \$500,000 per year during the primary term of the Lease and \$600,000 per year during the option period. The Lease also covers certain manufacturing and related equipment previously used by Par in its operations at the Brenner Drive Facility (the "Leased Equipment"). In connection with the execution of the Lease, the Company and Par entered into a certain Option Agreement pursuant to which the Company may purchase the Brenner Drive Facility and the Leased Equipment at any time during the lease term for \$5,000,000. The Company paid \$100,000 for the right to exercise the Option Agreement any time during the primary term of three years. In March 2002, the Company paid Par \$150,000 to secure the right to exercise the Option Agreement through March 31, 2004. (See Note B)

As part of the execution of the Lease, the Company and Par entered into a certain Manufacturing and Supply Agreement (the "M&S Agreement") having a minimum term of twenty-seven months. The M&S Agreement provided for the Company's contract manufacture of certain designated products manufactured by Par at the Brenner Drive Facility prior to the effective date of the Lease. The M&S Agreement also provided that Par will purchase a minimum of \$1,150,000 in product during the initial eighteen months of the Agreement. The M&S Agreement ended in July 2001 and was not renewed; however, the Company continued to provide contract manufacturing services to Par. The M&S Agreement further provided that the Company will not manufacture, supply, develop or distribute the designated products to be supplied by the Company to Par under the M&S Agreement to or for any other person for a period of three years. Effective April 2002, the restriction on the designated products to be supplied by the Company to Par was removed.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

### **NOTE N (CONTINUED)**

#### Lease of Congers, New York Facility (Wells Avenue location)

Effective July 1, 2000, the Company leased, as sole tenant, a facility located at 125 Wells Avenue, Congers, New York (the "Wells Avenue Facility"). The Wells Avenue Facility contains office, warehouse and manufacturing space and is approximately 18,000 square feet. The lease provides for a term of four years with an option to renew for an additional three years and provides for annual fixed rent of approximately \$127,000 per year during the first two years of the lease and approximately \$135,000 per year during the last two years. (See Note B)

As of December 31, 2003, the approximate minimum rental commitments under these operating leases are as follows:

Twelve months	ending	December	31,	(in thousands)
2004				\$ 225,140
2005				2,456
2004				950
Total	minimum	payments	required	\$ 228,546

#### **Employment Contracts**

During March 1998, the Company entered into employment contracts with each of two new officers/employees of the Company, which cover a five-year and a three-year period, respectively. The contracts provide for, among other things: (i) annual salaries of \$175,000 and \$140,000 to be paid over the five-year and three-year periods, respectively, and

(ii) an aggregate of 1,300,000 options to purchase the Company's stock at an exercise price of \$2.38 per common share that vest evenly over a three-to-five-year service period and expire in ten years. In April 2000, these contracts were extended to April 30, 2005. In 2001, the annual salaries under these contracts were increased to \$200,000 and \$155,000, respectively.

During November 2002, the Company entered into an employment contract with a new officer/employee of the Company which covers a two-year period. The contract calls for, among other things: (1) annual salary of \$180,000 to be paid over the two-year period, and (2) an aggregate of 400,000 options to purchase the Company's stock at an exercise price of \$1.15 per common share that vest evenly over a four-year period. The employment agreement automatically renews for successive one-year periods unless the Company provides 90 days' notice of nonrenewal.

In May 2003, an employment agreement between the Company and the Company's former Chief Executive Officer was terminated. Pursuant to provisions of a negotiated separation agreement dated September 18, 2003, the Company has accrued for a total value of approximately \$500,000 to such employee including a \$400,000 promissory note plus the estimated the value of benefits provided by the Company to such former employee. The promissory note is payable in quarterly installments commencing October 16, 2003. The separation agreement also granted a warrant to this individual for the purchase of up to 150,000 shares of the Company's common stock at an exercise price of .34 per share. The fair value of the warrant of \$112,000, as calculated using the Black-

Scholes option pricing model, has been charged to operations during the three months ended September 30, 2003. The warrant has a seven-year term and has a cashless exercise clause providing that upon the exercise of the warrant, such individual can receive common shares for the equivalent amount of appreciated value of the warrant at the time of exercise.

On December 4, 2003, the Company and the former Chief Executive Officer amended the separation agreement providing for (i) the termination of the Company's promissory note in the principal amount of \$400,000, and (ii) the Company's payment of \$162,790 in full satisfaction of the Company's severance and other payment obligations under the separation agreement.

During August 2003, the Company entered into an employment agreement with a new officer/employee of the Company. The agreement provides for, among other things: (i) an annual base salary of \$300,000, and (ii) an aggregate of 5,500,000 options to purchase the Company's stock at an exercise price of \$0.34 per common share that vest 1,000,000 option shares on March 31, 2004 and the balance thereafter at a rate of 500,000 per calendar quarter, beginning June 30, 2004 which an exercise term expiring in ten years. The stock option is subject to the shareholders approval to modify the Company's 1998 Stock Option Plan to

(i) increase the number of shares reserved for issuance and (ii) authorize issuance of stock options having an exercise price less than fair market value of the common stock of the Company on the date of issuance. The employment agreement term is for a two year period which automatically renews for successive one-year periods unless either the Company or the employee provides 90 days' notice of non-renewal.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## **NOTE N (CONTINUED)**

#### **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 of the Company's 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. 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 will result in 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 is current in its payment obligations, with a remaining obligation of \$433,000. In February 2004, the Company satisfied its obligation to the DOJ.

#### **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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

## **NOTE N (CONTINUED)**

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 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 has been completed. The Company's motion for summary judgment was due to be heard by the Court on August 8, 2003. Plaintiff Kohn deceased shortly prior to such hearing date, and the motion for summary judgment and any trial of this matter have been stayed pending the substitution of Mr. Kohn's estate as the plaintiff. The Company does not believe this action will have a material impact on the Company's financial condition. The ultimate outcome of this lawsuit cannot be determined at this time, and accordingly, no adjustment has been made to the consolidated financial statements.

On June 13, 2002, the Company was named an additional defendant in an Amended Complaint filed in the matter entitled Vintage Pharmaceuticals, Inc., v. Watson Pharmaceuticals, Inc., and Halsey Drug Company, Inc., pending in the United States District Court for the Northern District of Alabama, Civil Action No. CV 01-B-1847-NE. Vintage seeks unspecified damages from the Company for allegedly interfering with Vintage's contract to produce Monodox(R), the brand name of doxycycline monohydrate, for Watson. The Company denies the allegations, and is vigorously defending the action, and on July 12, 2002, filed a motion to dismiss the Amended Complaint for lack of jurisdiction and for failure to state a cause of action. Watson Pharmaceuticals has filed a motion for summary judgment, which if granted would also terminate the suit as to Halsey. Accordingly, the Court stayed Halsey's motion to dismiss pending the outcome of Watson's motion for summary judgment. That motion was fully briefed and submitted to the Court by December 6, 2002, and the parties are awaiting a decision from the Court. The Company does not believe this action will have a material impact on the Company's financial condition. The ultimate outcome of this lawsuit cannot be determined at this time, and accordingly, no adjustment has been made to the consolidated financial statements.

In addition, the Company is a party to legal matters arising in the general conduct of business. The ultimate outcome of such matters is not expected to have a material adverse effect on the Company's results of operations or financial position.

Each of the purchase agreements for the Company's 1998 Debentures, 1999 Debentures, 2002 Debentures, and 2003 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, 2003, the Company does not believe that any liability has been incurred as a result of these indemnification obligations.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 2003, 2002 and 2001

#### NOTE O - SIGNIFICANT CUSTOMERS AND SUPPLIERS

Through its strategic alliance with Watson, as discussed in Note C, the Company sells its portfolio of core products under the Watson label for distribution by Watson to drugstore chains and drug wholesalers. The Company continues to perform limited contract manufacturing of certain non-core products for other customers. During 2003, the Company had net product revenues from one customer in excess of 10% of total product revenues, accounting for 58% of total product revenues. No accounts receivable was due from this customer at December 31, 2003. During 2002, the Company had net product revenues from two customers in excess of 10% of total product revenues, accounting for 85% and 13%, respectively, of total product revenues, and 82% and 1%, respectively, of gross accounts receivable at December 31, 2002. During 2001 the Company had net product revenues to one customer in excess of 10% of total product revenues aggregating to 86% of total product revenues. At December 31, 2001, accounts receivable from this customer aggregated 61% of gross accounts receivable.

During 2003, 2002 and 2001, the Company purchased approximately \$552,000, \$1,264,000 and \$1,512,000, respectively, of its raw materials, representing approximately 26%, 25%, and 28% in each year, of total raw material purchases from one supplier.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# December 31, 2003, 2002 and 2001

# NOTE P - QUARTERLY FINANCIAL DATA (UNAUDITED)

Quarterly Financial Data (amounts in thousands except per share amounts)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
2003					
Net product revenue Operating loss Net loss Loss per share - basic and diluted	\$ 1,526 (3,387) (10,575) \$ (.50)	(3,552) (11,027)	. , ,	(6,980) (15,263)	\$ 5,750 (17,244) (48,455) \$ (2.28)
2002					
Net product revenue Operating loss Net loss Loss per share - basic and diluted		(3,379)	(3,466) (7,869)	\$ 2,053 (3,204) (38,901) \$ (2.46)	(59,589)

# Halsey Drug Co., Inc. and Subsidiaries

# SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS

(in thousands)

COL. A	COL. B	Additions	COL. C	COL. D	COL. E
Description		_	Additions charged to other accounts	Deductions	Balance at end of period
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 ======
Year ended December 31, 2001					
Allowances - accounts receivable	\$ 315	\$ 402	\$ -	\$ (370)	\$ 347
Valuation allowance - deferred tax assets	====== \$ 35,151	====== \$ 5.797	====== \$ -	====== \$ -	====== \$ 40,948
varuation arrowance - deferred tax assets	35,151	======	ې – ======	ب =======	=======

<sup>(1)</sup> 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 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 Halsey Drug Co., Inc., 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 10-Q")).
- 10.5(3) Letter Agreement, dated November 16, 1995, among Halsey Drug Co., 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 Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 (the "June 1996 10-Q").
- 10.5(5) Letter Agreement, dated March 25, 1997 among Halsey Drug Co., Inc., 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 Company, Mallinckrodt Chemical Acquisition, Inc. and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.9 of the March 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) Halsey Drug Co., Inc. 1984 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.3 to the 1992 Form 10-K).
- 10.10(2) Halsey Drug Co., Inc. 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) Halsey Drug Co., Inc. Non-Employee Director Stock Option Plan.
- 10.11 Leases, effective February 13, 1989 and January 1, 1990, respectively, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss (incorporated by reference to Exhibits 10.6 and 10.7, respectively, to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1989).
- 10.12 Lease, effective as of April 15, 1988, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, and Rider thereto (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1987).

- 10.12(1) Lease, as of October 31, 1994, among Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, together with Modification, Consolidation and Extension Agreement (incorporated by reference to Exhibit 10.12(i) to the 1995 Form 10-K).
- 10.13 Asset Purchase Agreement dated as of March 21, 1995 among Mallinckrodt Chemical Acquisition, Inc. ("Acquisition"), Mallinckrodt Chemical, Inc., as guarantor and the Registrant (incorporated by reference to Exhibit 10.1 to the March 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 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 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 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 8-K).
- 10.19 Amendment dated March 21, 1995 to Subordination Agreement dated as of July 21, 1994 between Mallinckrodt Chemical, Inc., Mallinckrodt Chemical Acquisition, Inc., 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 8-K).
- 10.20 Agreement dated as of March 30, 1995 between the Registrant and Zatpack, Inc. (incorporated by reference to Exhibit 10.10 to the March 8-K).
- 10.21 Waiver and Termination Agreement dated as of March 30, 1995 between Zuellig Group, W.A., Inc. and Indiana Fine Chemicals Corporation (incorporated by reference to Exhibit 10.11 to the March 8-K).
- 10.22 Convertible Subordinated Note of the Registrant dated December 1, 1994 issued to Zatpack, Inc. (incorporated by reference to Exhibit 10.12 to the March 8-K).
- 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 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 8-K).

- 10.25 Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 6(a) to the June 10-Q).
- 10.26 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 6(a) to the June 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 8-K")).
- 10.28 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the December 8-K).
- 10.29 Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 99 to the June 1996 10-0).
- 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc. dated March 10, 1998 (incorporated by reference to Exhibit 10.3 to the March 1998 8-K).
- 10.36 Form of Guarantor General Security Agreement dated March 10, 1998 (incorporated by reference to Exhibit 10.4 to the March 1998 8-K).
- 10.37 Stock Pledge Agreement dated March 10, 1998 by and between the Registrant and Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.5 to the March 1998 8-K).
- 10.38 Form of Irrevocable Proxy Agreement (incorporated by reference to Exhibit 10.6 to the March 1998 8-K).
- 10.39 Agency Letter Agreement dated March 10, 1998 by and among the Purchasers a party to the Debenture and Warrant Purchase Agreement, dated March 10, 1998 (incorporated by reference to Exhibit 10.7 to the March 1998 8-K).
- 10.40 Press Release of Registrant dated March 13, 1998 (incorporated by reference to Exhibit 99.1 to the March 1998 8-K).
- 10.41 Current Report on Form 8-K as filed by the Registrant with the Securities and Exchange Commission on March 24, 1998.

- 10.42 Letter Agreement between the Registrant and the U.S. Department of Justice dated March 27, 1998 relating to the restructuring of the fine assessed by the Department of Justice under the Plea Agreement dated June 21, 1993.
- 10.43 Employment Agreement dated as of March 10, 1998 between the Registrant and Michael K. Reicher (incorporated by reference to Exhibit 10.43 to the Registrant's Annual Report of Form 10-K for the year ended December 31, 1997 (the "1997 Form 10-K")).
- 10.44 Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens (incorporated by reference to Exhibit 10.44 to the 1997 Form 10-K.
- 10.45 Amended, Restated and Consolidated Bridge Loan Agreement dated as of December 2, 1998 between the Company, 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 Company 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 Company 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 Halsey Drug Co., Inc. 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 Halsey Pharmaceuticals, Inc., 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).
- 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).
- 10.73 Form of 5% Convertible Senior Secured Debenture issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.73 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
- 10.74 Form of Common Stock Purchase Warrant issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.74 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
- 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 Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
- 10.76 Debenture Purchase Agreement dated December 20, 2002 by and among Halsey Drug Co., Inc., 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 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 Halsey Drug Co., Inc. dated December 20, 2002 between Houba, Inc., Halsey Pharmaceuticals, Inc. and the 2002 Debentureholders (incorporated by reference to Exhibit 10.3 to the December 2002 Form 8-K).
- 10.79 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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).
- 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 Halsey Drug Co., Inc. and Watson Pharmaceuticals, Inc., amending the Loan Agreement dated March 29, 2000 between Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc., Care Capital Investments, II, LP, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P. and the other purchasers listed on the signature page thereto (incorporated by reference to Exhibit 10.1 of the February 2004 Form 8-K).
- 10.93 Debenture Conversion Agreement dated as of February 6, 2004 by and among Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc. (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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc., Watson Pharmaceuticals, Care Capital, Essex Woodlands, Galen Partners and the other signatories thereto (incorporated by reference to Exhibit 10.12 of the February 2004 Form 8-K).
- 10.104 Third Amendment to Loan Agreement dated as of February 6, 2004 by and among Halsey Drug Co., Inc. 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 Halsey Drug Co., Inc. 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 Halsey Drug Co, Inc. 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., 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 Halsey Drug Co., Inc., Axiom Pharmaceutical Corporation and IVAX Pharmaceuticals New York LLC (incorporated by reference to Exhibit 10.2 of the March 2004 Form 8-K.)
  - \*14 Code of Ethics
  - 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 conferred 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).
- \*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.

<sup>\*</sup> Filed herewith.

<sup>+</sup> 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 14**

#### HALSEY DRUG CO., INC.

#### CODE OF ETHICS

#### I. INTRODUCTION

This Code of Ethics (the "Code") is established pursuant to Section 406 of the Sarbanes-Oxley Act of 2002, which requires that the Company establish a code of ethics to apply to the Company's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions (the "Designated Officers"). The purpose of the Code is to deter wrongdoing and to promote:

- Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- Full, fair, accurate, timely, and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission and in other public communications made by the Company;
- Compliance with applicable governmental laws, rules and regulations;
- The prompt internal reporting of violations of the Code to an appropriate person or persons identified in the Code; and
- Accountability for adherence to the Code.

Designated Officers are expected to be familiar with the Code and from time to time may be asked to affirm their agreement to adhere to its standards.

## II. CONFLICTS OF INTEREST

Designated Officers must avoid any activity or association that creates or appears to create a conflict between the Designated Officer's personal interest and the Company's interest. For example, a possible conflict of interest exists when a Designated Officer or a member of his or her family has a financial or other interest in, or seeks personal loans or services from, a company that does business with the Company. Designated Officers are expected to make prompt and full disclosure in writing to the Chairman of the Audit Committee of any potential conflict of interest. Any transaction in which a Designated Officer may have a conflict of interest must be approved by the Audit Committee. Designated Officers should avoid the receipt of gifts, gratuities, favors or other benefits that might affect or appear to affect the exercise of their judgment on the Company's behalf. Any substantial gift or favor offered by an actual or potential client, contractor, or provider of goods or services, lender, security holder, or other affiliate whether it be in tangible form or in the form of a service or individual benefit, should be refused unless acceptance of such gift or favor has been approved by the Audit Committee. This prohibition is not intended to apply to ordinary courtesies of business life, such as token gifts of insubstantial value, modest entertainment incidental to a business relationship, or the giving or receipt of normal hospitality of a social nature.

#### III. ACCURATE AND TIMELY PERIODIC REPORTS

The Company is committed to full, fair, accurate, timely and understandable disclosure in reports and documents that it files with, or submits to, the Securities and Exchange Commission and in other public communications made by the Company. The Company expects Designated Officers to establish and manage the Company's reporting systems and procedures with due care and diligence to ensure that:

- Reports filed with or submitted to the Securities and Exchange Commission and other public communications contain information that is full, fair, accurate, timely and understandable and do not misrepresent or omit material facts;

- Business transactions are properly authorized and completely and accurately recorded on the Company's books and records in accordance with generally accepted accounting principles and the Company's established financial policies; and
- Retention or disposal of Company records is in accordance with established Company policies and applicable legal and regulatory requirements.

#### IV. COMPLIANCE WITH LAWS, RULES & REGULATIONS

Designated Officers must comply fully with all applicable laws, rules, regulations and corporate governance standards.

#### V. REPORTING VIOLATIONS

Designated Officers must promptly report any violations of the Code to the Chairman of the Audit Committee.

#### VI. DISCIPLINARY MEASURES

Designated Officers who violate any applicable laws, rules or regulations or the Code will face appropriate disciplinary action, as determined by the Audit Committee, which may include discharge. The matter may also be referred to appropriate governmental agencies.

## VII. AMENDMENT, MODIFICATION AND WAIVER

The Code may be amended or modified by the Audit Committee. Any amendments or modifications will be publicly disclosed in accordance with the rules of the Securities and Exchange Commission. The Audit Committee may waive violations of the Code, but any such waiver that constitutes a material departure from a provision of the Code will be publicly disclosed in accordance with the rules of the Securities and Exchange Commission.

#### **EXHIBIT 23.1**

## CONSENT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

We have issued our report dated February 26, 2004, except for Note B, as to which the date is March 19,2004, accompanying the consolidated financial statements and schedules included in the Annual Report of 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 Halsey Drug Co., 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.

## **GRANT THORNTON LLP**

New York, New York

April 19, 2004

#### 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 Halsey Drug Co., Inc., certify that:
- 1. I have reviewed this annual report on Form 10-K of Halsey Drug Co., 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: April 14, 2004

#### 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 Vice President and Chief Financial Officer of Halsey Drug Co., Inc., certify that:
- 1. I have reviewed this annual report on Form 10-K of Halsey Drug Co., 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.

Date: April 14, 2004

/s/ Peter A. Clemens

Peter A. Clemens

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 Halsey Drug Co., Inc. (the "Company") on Form 10-K for the period ending December 31, 2003 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.

Dated: April 14, 2004

/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 Halsey Drug Co., Inc. (the "Company") on Form 10-K for the period ending December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter A. Clemens, the 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.

Dated: April 14, 2004

/s/ Peter A. Clemens

Peter A. Clemens Vice President and Chief Financial Officer