# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

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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, 2002

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

FOR THE TRANSITION PERIOD FROM

COMMISSION FILE NUMBER 1-10113

HALSEY DRUG CO., INC.
(Exact name of registrant as specified in its charter)

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NEW YORK (State or other jurisdiction of incorporation or organization) 11-0853640 (I.R.S. Employer Identification No.)

695 NORTH PERRYVILLE ROAD,
CRIMSON BUILDING NO. 2
ROCKFORD, ILLINOIS
(Address of principal executive offices)

61107 (Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (815) 399-2060

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

TITLE OF CLASS

NONE

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

(TITLE OF CLASS)

COMMON STOCK, PAR VALUE \$0.01

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [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, 2003, the registrant had 21,035,323 shares of Common Stock, par value \$0.01, outstanding. Based on the average closing bid and asked prices of the Common Stock on June 28, 2002 (\$1.515)(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 \$21,002,667.

# 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  $\check{\text{which}}$  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, are 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 sells its generic drug products under the Watson name for distribution by Watson to drugstore chains and drug wholesalers. In addition, the Company intends to directly market and sell 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.

APIs, also known as bulk chemical products, are used in the development and manufacture of finished dosage pharmaceutical products. The development and sale of APIs generally is not subject to the same level of regulation as is the development and sale of finished dosage products. As a result, APIs may be brought to market substantially sooner than finished dosage products.

The Company manufactures its products at facilities in New York and Indiana. During the last several years, the Company has sought to diversify its businesses through strategic acquisitions and alliances and through the development of technologies for the synthesis and production of APIs intended for sale to third parties as well as for use by the Company and others as raw materials in the manufacture of finished drug forms. The Company's primary emphasis in this regard, and for which the Company is committing the substantial majority of the Company's resources and sources of available capital, is the development of novel opiate synthesis technologies which the Company expects to use in the manufacture of APIs and finished dosage products indicated for pain management.

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

Our principal 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 additional, you may request a copy of these filings (excluding exhibits) at no cost by writing or telephoning us at the following address or telephone number:

Halsey Drug Co., Inc. 695 No. Perryville Rd. Crimson Bldg. 2 Rockford, Illinois 61107 Attn: Investor Relations (815) 399-2060

# RECENT EVENTS

# DEBENTURE OFFERING

On December 20, 2002, the Company consummated a private offering of securities for an approximate aggregate purchase price of \$26,394,000 (the "Offering"). The securities issued in the Offering consisted of

5% convertible senior secured debentures (the "Debentures"). The Debentures were issued by the Company pursuant to a certain Debenture Purchase Agreement dated December 20, 2002 (the "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 "2002 Debenture Investor Group").

Of the \$26,394,000 in Debentures issued in the Offering, approximately \$15,894,000 of Debentures were issued in exchange for the surrender of a like amount of principal and accrued interest outstanding under Company's 10% convertible promissory notes issued pursuant to various working capital bridge loan transactions with Galen Partners III, L.P., Galen International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen") and certain other lenders, during the period from August 15, 2001 through and including December 20, 2002.

The Debentures, issued at par, will become due and payable as to principal on March 31, 2006. Interest on the principal amount of the Debentures, at the rate of 5% per annum, is payable on a quarterly basis. With the exception of the Debentures issued to Care Capital, interest on the Debentures will be paid by the Company's issuance of a debenture instrument substantially identical to the Debentures issued in the Offering, in the principal amount equal to the accrued interest for each quarterly period (the "Interest Debentures"). Debentures issued to Care Capital provide that fifty percent (50%) of the interest payments under such Debentures will be satisfied in cash with the balance satisfied by Company's issuance of Interest Debentures.

The Debentures issued to each of Care Capital and Essex are convertible at any time after issuance into shares of the Company's Common Stock, \$.01 per value per share (the "Common Stock"). The Debentures issued to Galen and the other investors in the Offering (excluding Care Capital and Essex) are convertible at any time after the approval of the Company's shareholders and debentureholders of 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 sufficient authorized shares to permit the conversion of such Debentures and Company's outstanding convertible securities, as provided in the Purchase Agreement. Subject to the foregoing, the 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 options 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 month period for an aggregate gross consideration of at least \$10,000,000. The Conversion Price is also subject to adjustment to give effect to additional Debentures, if any, that may be issued under the Purchase Agreement and in the event of a subsequent recapitalization of the Company's outstanding common stock purchase warrants issued to Galen in prior debenture offerings and in consideration for various bridge loans to the Company.

The Interest Debentures are convertible at any time 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 Debentures, as reported by the Over-the-Counter ("OTC") Bulletin Board.

Assuming the conversion of the Debentures at the initial Conversion Price of \$.34 per share, the Debentures are convertible into an aggregate of approximately 77,629,000 shares of the Company's Common Stock.

The Purchase Agreement provides that the holders of the Debentures shall have the right to vote as part of a single class with all holders of the Company's Common Stock on all matters to be voted on by such stockholders. Each Debenture holder shall have such number of votes as shall equal the number of votes he would have had if such holder converted the entire outstanding principal amount of his Debenture into shares

of Common Stock immediately prior to the record date relating to such vote; provided, however, that any Debentures held by Care Capital shall, for so long as they are held by Care Capital, have no voting rights. The Purchase Agreement also provided for the execution of a Debentureholder Agreement providing the holders of the Debentures with veto rights relating to certain material Company transactions.

The Debentures are secured by a lien on all assets of the Company, tangible and intangible. In addition, each of Houba, Inc. and Halsey Pharmaceuticals, Inc., each a wholly-owned subsidiary of the Company, has executed in favor of the 2002 Debenture Investor Group an Unconditional Agreement of Guaranty of the Company's obligations under the Purchase Agreement. Each Guaranty is secured by all assets of such subsidiary, and, in the case of Houba, Inc., by a mortgage lien on its real estate. In addition, the Company has pledged the stock of each such subsidiary to the 2002 Debenture Investor Group to further secure its obligations under the Purchase Agreement.

In accordance with the terms of a Subordination Agreement dated December 20, 2002 between the Company, the holders of the Debentures, the holders of the Company's 5% Convertible Senior Secured Debentures issued pursuant to that certain Debenture and Warrant Purchase Agreement (the "1998 Purchase Agreement") between the Company, Galen and other signatories thereto, dated March 10, 1998 (the "Galen Group Debentures"), the holders of the Company's 5% Convertible Senior Secured Debentures issued pursuant to that certain Debenture and Warrant Purchase Agreement (the "1999 Purchase Agreement") between the Company, Oracle Strategic Partners, L.P. and other signatories thereto, dated May 26, 1999 (the "Oracle Group Debentures" and together with the Galen Group Debentures, the "Existing Debentures"), and Watson Pharmaceuticals, Inc. ("Watson"), the liens on the Company's and its Subsidiaries' assets as well as the payment priority of the Debentures are (i) subordinate to the Company's lien and payment obligations in favor of Watson under the Company's Loan Agreement with Watson pursuant to which Watson has made a term loan to the Company in the principal amount of \$21,401,331 (as amended, the "Watson Loan Agreement"), and (ii) senior to the Company's lien and payment obligations in favor of the holders of the Existing Debentures in the aggregate principal amount of approximately \$50,723,938. In addition to the subordination of the liens and the payment priority of the Existing Debentures in favor of the Debentures issued in the Offering, as part of the completion of the Offering, each of the holders of the Galen Group Debentures and the Oracle Group Debentures agreed to extend the maturity date of the Existing Debentures from March 15, 2003 to March 31, 2006.

As part of the closing of the Offering, the Watson Loan Agreement was amended to (i) extend the maturity date of the Watson Loan Agreement from March 31, 2003 to March 31, 2006, (ii) increase the interest rate from prime plus two and one-half percent (2.5%) to prime plus four and one-half percent (4.5%), and (iii) increase the principal amount of the Watson Term Loan from \$17,500,000 to \$21,401,331 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.

As part of the completion of the transactions contemplated in the 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 warrantholders a party thereto surrendered to the Company for cancellation the Recapitalization Warrants in exchange for the issuance of an aggregate of 5,970,083 shares of the Company's Common Stock.

# OPIATE SYNTHESIS TECHNOLOGIES

Halsey has developed internally both an opiate isolation synthesis process which the Company believes provides an efficient and cost-effective alternative to the extraction of morphine and codeine from raw opium (the "IMP Process"), and an alternate development synthesis route for the manufacture of other pain management products (the "New Synthesis Process", and together with the IMP Process, collectively the "Opiate Synthesis Technologies"). To date, the Company has successfully completed laboratory-scale proof of concept testing on each of the IMP Process and the New Synthesis Process. The Company will continue the development of the IMP Process and the New Synthesis Process, including the construction of pilot and commercial scale manufacturing facilities within existing Company manufacturing facilities, with the expectation of manufacturing opiate-derived APIs and finished dosage pain management products in the future.

Each of the Opiate Synthesis Technologies are novel processes intended to be more efficient and cost effective methods of deriving APIs to be used in the manufacture of finished dosage pain management products by substantially reducing the time and steps required to produce the desired API as well as the waste product relating to such production. It is the Company's expectation to prepare and file patent applications covering each of the IMP Process and the New Synthesis Process. No assurance can be given, however, that a patent will be issued on any of the Opiate Synthesis Technologies.

The development of the Opiate Synthesis Technologies demonstrates the Company's continuing efforts to develop and manufacture APIs and finished dosage products with an emphasis on pain management products. The Company estimates that the market for pain management products in the United States is approximately \$2 billion and is growing at approximately 20% per year. In addition to its development efforts relating to the Opiate Synthesis Technologies, the Company is a party to agreements with Watson (see "Recent Events -- Strategic Alliance" below) providing for Watson's right to negotiate for a supply of select APIs currently in development and to be developed by the Company. It is the Company's intention to continue its focus on pain management products by developing APIs incorporating the Opiate Synthesis Technologies and other technologies developed internally by the Company or licensed from third parties. Such development efforts may be performed solely by the Company or in partnership with third-party manufacturers. It is the Company's expectation to use such APIs in the Company's own manufacture and sale of finished dosage pharmaceutical products as well as to sell such APIs to third parties.

The development, marketing and sale of pain management products incorporating the Opiate Synthesis Technologies is subject to extensive regulation by the U.S. Drug Enforcement Administration ("DEA") and the U.S. Food and Drug Administration ("FDA"). The Company's API manufacturing facility located in Culver, Indiana is DEA approved to manufacture Schedule II to V controlled substances (the "Manufacturing Registration"). In order to continue the development and ultimate commercialization of the Opiate Synthesis Technologies, the Company has filed for DEA approval to import raw poppy directly from India and Turkey to be used in the Company's API development and manufacturing efforts (the "Import Registration"). At present, the Company believes that only three manufacturers in the United States possess such import registrations.

The Company's application for an Import Registration was published in the Federal Register on September 6, 2001. Within the 30 day period provided under DEA guidelines, three parties, including the two companies that represent the largest importers of narcotic raw materials used to manufacture controlled substances, requested a hearing to formally object to the Company's request for an Import Registration. In their hearing request, the objecting parties oppose the DEA's issuance to the Company of an Import Registration on various grounds, including that the Company's application be stayed pending the resolution of three (3) pending import registration requests from other parties, 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. manufacturers, that the Company lacks the experience, technology, personnel and capital to process narcotic raw materials, and that the competition in the marketplace for pain management products is adequate.

The Company's hearing before the Office of Administrative Law Judge ("OALJ") relating to its Import Registration application is expected to be held in the third quarter of 2003. The Company estimates that a ruling by the OALJ will occur during the first quarter of 2004. No assurance can be given that the Company's Import Registration application will be approved by the DEA. As part of the DEA's analysis as to whether the issuance of an Import Registration to the Company is appropriate, the DEA will consider, among other things, whether adequate security safeguards and controls exist at the Company's Culver, Indiana facility and at all points in the chain of transfer of the raw poppy from suppliers in India and Turkey to the Company's Culver facility, whether the Opiate Synthesis Technologies are viable and efficient processes, whether market demand for pain management products supports the approval of another import source, and whether the Company has established itself as an eligible party to source and obtain raw poppy supplies from foreign sources. The Company is currently making the necessary upgrades to its Culver, Indiana facility and establishing points of supply in foreign markets to meet these DEA requirements.

The development and commercialization of APIs and finished dosage products incorporating the Opiate Synthesis Technologies are subject to various factors, many of which are outside the Company's control. Specifically, the Opiate Synthesis Technologies have been tested only in laboratory settings and will need to be successfully "scaled up" in order 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 requirements for the maintenance of its Manufacturing Registration and the issuance and maintenance of the Import Registration. Even assuming the Company can satisfy the DEA's requirements in this regard, no assurance can be given that the Company will prevail in any hearings with the OALJ at which third-party manufacturers already possessing import registrations will object to any proposed issuance by the DEA of the Import Registration to the Company. The process of seeking the Import Registration and contesting opposition proceedings, as well as the continuing development of the Opiate Synthesis Technologies, will likely continue through 2004. The Company is currently unable to provide any assurance that the Opiate Synthesis Technologies will be commercially viable or that the Company will succeed in obtaining an Import Registration. The Company is committing the substantial majority of its resources, available capital and cash flow from operations to the development of the Opiate Synthesis Technologies and to the receipt of the Import Registration. The failure of the Company to successfully develop the Opiate Synthesis Technologies or to obtain the Import Registration 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 Technologies, to obtain required DEA approvals and to fund the capital improvements necessary for the manufacture of APIs and finished dosage products incorporating the Opiate 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 development of the Opiate Synthesis Technologies, for the receipt of DEA approvals and for improvements to its manufacturing facilities.

# STRATEGIC ALLIANCE WITH WATSON

On March 29, 2000, the Company completed various strategic alliance transactions with Watson Pharmaceuticals, Inc. ("Watson"). The transactions with Watson provided for Watson's purchase of the Company's then pending ANDA for doxycycline capsules USP, 50 mg and 100 mg (the "doxycycline ANDA"), 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.

The product acquisition portion of the transactions with Watson provided for the Company's sale of the pending doxycycline ANDA and related rights (the "Product") to Watson for an aggregate consideration of \$13,500,000 (the "Product Acquisition Agreement"). The final installment of the purchase price for the Product of \$3.5 million was paid by Watson to the Company on July 10, 2001. As part of the execution of the Product Acquisition Agreement, the Company and Watson executed ten year supply agreements covering the 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 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. In the event Watson does not exercise its right of first negotiation upon notice from the Company, 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 (60) 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 APIs or finished dosage products for itself or third parties.

The Company's strategic alliance with Watson also provides for Watson's extension of the Watson Term Loan to the Company. The Watson Term 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 four and one-half percent (4.5%). On December 20, 2002, the Watson Loan Agreement was amended to increase the principal amount of the loan from \$17,500,000 to \$21,401,331 reflecting the inclusion of the Company's payment obligations to Watson under the Core Products Supply Agreement between the parties (see below). As of December 31, 2002, the entire principal amount available under the Watson Term Loan had been advanced to the Company. The net proceeds from the term loan have, in large part, been used to upgrade and equip the API manufacturing facility of Houba, Inc. located in Culver, Indiana, the Company's wholly-owned subsidiary, to upgrade and equip the Company's Congers, New York leased facilities, to satisfy approximately \$3,300,000 in bridge financing provided by Galen Partners and for working capital to fund continued operations.

The Company and Watson also executed 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"). Pursuant to the terms of the Core Products Supply Agreement, Watson was required to purchase and pay for on a quarterly basis a minimum of \$3,060,000 for products supplied by the Company under such Agreement. For the three quarters ending December 31, 2000, Watson made an advance payment to the Company of approximately \$4,402,000 as required under the terms of the Core Products Supply Agreement to be applied against future product purchases under such Agreement. The advance payments and any additional advance payments made by Watson under the Core Products Supply Agreement will require that the Company supply Watson with a like amount of products without additional payments from Watson at such time. On August 8, 2001, the Company and Watson executed an amendment to the Core Products Supply Agreement (the "Core Products Amendment") providing (i) for a reduction of Watson's minimum purchase requirements from \$3,060,000 to \$1,500,000 per quarter, (ii) for an extension of Watson's minimum purchase requirements from the quarter ending September 30, 2001 to quarter ending 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. As part of the completion of the Company's Offering of Debentures (as described above under the caption "Debenture Offering"), on December 20, 2002, the Company and Watson further amended the Core Products Supply Agreement to provide for the Company's satisfaction of its outstanding payment obligations to Watson of approximately \$3,901,331 under such Agreement by the

transfer of such payment obligation to the principal amount of the Watson Loan Agreement. As a consequence, the Watson Loan Agreement was amended to increase the principal amount of the Watson Term Loan from \$17,500,000 to \$21,401,331. In addition, the maturity date of the Watson Loan Agreement was extended from March 31,2003 to March 31, 2006.

# ACQUISITION OF PRODUCT ANDAS

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 market value of the Common Stock on the date of issuance) and having a term of five years. 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.

The Barr Products acquired by the Company were previously marketed by Barr, prior to its decision to strategically refocus its generic product portfolio several years ago. While the Barr Products cover a broad range of therapeutic applications and are the subject of approved ANDAs, the Company will be required to obtain approval from the FDA to permit manufacture and sale of any of the Barr Products, including site specific approval. The Company initially has identified 8 of the products for which it will devote substantial effort in seeking approval from the FDA for manufacture and sale. The Company estimates that certain of these Barr Products will be available for sale in the fourth quarter of 2003, although no assurance can be given that any of the Barr Products will receive FDA approval or that if approved, that the Company will be successful in the manufacture and sale of such products. It is the Company's intention to continue to evaluate the remaining Barr Products on an ongoing basis to assess their prospects for commercialization and likelihood of obtaining regulatory approval.

# PRODUCTS AND PRODUCT DEVELOPMENT

# GENERIC FINISHED DRUG PRODUCTS

The Company historically has manufactured and sold a broad range of prescription and over-the-counter drug products. The Company's pharmaceutical product list currently includes a total of approximately 26 products, consisting of 20 dosage forms and strengths of prescription drugs and 6 dosage forms and strengths of over-the-counter drugs. Each dosage form and strength of a particular drug is considered in the industry to be a separate drug product. The Company's drug products are sold in various forms, including liquid and powder preparations, compressed tablets and two-piece, hard-shelled capsules.

Most of the generic drug products manufactured by the Company can be classified within one of the following categories:

- 1. Antibiotics,
- 2. Narcotic analgesics,
- 3. Anti-infective and anti-tubercular drugs,
- 4. Antihistamines and antihistaminic decongestants,
- 5. Antitussives, or
- 6. Steroids

During fiscal 2002, sales of antibiotics and narcotic analgesics accounted for approximately 75% of net product sales during such year. The Company anticipates that sales of antibiotics and narcotic analgesics will continue to represent a significant portion of the Company's revenue.

The Company's development strategy for new drug products has been to focus on the development of a broad-range of generic form drugs, each of which (i) has developed a solid market acceptance with a wide base of customers, (ii) can be sold on a profitable basis notwithstanding intense competition from other drug manufacturers, and (iii) is no longer under patent protection. The Company has also diversified its current product line to include some less widely prescribed drugs as to which limited competition might be expected.

During the fiscal year ended December 31, 2002, the Company received 21 ANDA amendments consisting of products transferred from other Company locations and submitted 16 ANDA supplements or amendments to the FDA. During fiscal 2003, the Company anticipates the submission of 10 ANDA supplements or amendments to the FDA. The supplements and amendments relate to the transfer of existing ANDAs from the Company's Brooklyn, New York facility (at which operations were discontinued in March 2001) to its Congers facility as well as the transfer of certain ANDAs obtained from Barr Laboratories. Although the Company has been successful in receiving ANDA approvals since its release from the FDA's Application Integrity Policy list in December 1996, there can be no assurance that any newly submitted ANDAs, or supplements or amendments thereto or those contemplated to be submitted, will be approved by the FDA. The Company will not be permitted to market any new product unless and until the FDA approves the ANDA relating to such product. Failure to obtain FDA approval for the Company's pending ANDAs, or a significant delay in submitting for or obtaining such approval, would adversely affect the Company's business operations and financial

Development activities for each new generic drug product begin several years in advance of the patent expiration date of the brand-name drug equivalent. This is because the profitability of a new generic drug usually depends on the ability of the Company to obtain FDA approval to market that drug product upon or immediately after the patent expiration date of the equivalent brand-name drug. Being among the first to market a new generic drug product is vital to the profitability of the product. As other off-patent drug manufacturers receive FDA approvals on competing generic products, prices and revenues typically decline. Accordingly, the Company's ability to attain profitable operations will, in large part, depend on its ability to develop and introduce new products, the timing of receipt of FDA approval of such products and the number and timing of FDA approvals for competing products.

While the Company will continue the development of its finished goods pharmaceutical business, including the rehabilitation of the product ANDAs acquired from Barr, the Company will dedicate the substantial majority of its resources to the expansion and enhancement of its operations devoted to the development and manufacture of APIs and finished dosage products incorporating the Opiate Synthesis Technologies. See "Recent Events -- Opiate Synthesis Technologies".

# ACTIVE PHARMACEUTICAL INGREDIENTS

As discussed above under the caption "Opiate Synthesis Technologies", in the last few years, the Company has increased its efforts to develop and manufacture APIs, also known as bulk chemical products. The development and sale of APIs generally is not subject to the same level of regulation as is the development and sale of drug products. Accordingly, APIs may be brought to market substantially sooner than drug products. Although the Company did not generate revenues from the sale of API's in fiscal 2002 it is the Company's expectation that its strategic alliance with Watson and the continued development of the Opiate Synthesis Technologies and other API development efforts, in addition to assisting in the expansion of the Company's line of finished dosage products, will generate revenues from the sale of products using internally produced APIs starting in the fourth quarter of 2003 and such revenue segment will likely increase thereafter as a percentage of total revenue.

# RESEARCH AND DEVELOPMENT

The Company currently conducts research and development activities at each of its Congers, New York and Culver, Indiana facilities. The Company's research and development activities consist primarily of the development of the Opiate Synthesis Technologies, including the development for sale of new chemical products and the development of APIs, as well as new generic drug product development efforts and

manufacturing process improvements. New drug product development activities are primarily directed at conducting research studies to develop generic drug formulations, reviewing and testing such formulations for therapeutic equivalence to brand name products and additional testing in areas such as bioavailability, bioequivalence and shelf-life. For fiscal years 2002, 2001 and 2000, total research and development expenditures were \$1,517,000, \$1,327,000 and \$1,821,000, respectively. During 2003, the Company's research and development efforts will cover finished dosage products and APIs in a variety of therapeutic applications, with an emphasis on pain management products.

As of March 31, 2003, the Company maintained a full-time staff of 9 in its Research and Development Department.

#### MARKETING AND CUSTOMERS

The application of the FDA Application Integrity Policy list to the Company's operations until December 1996, combined with the Company's continuing operating losses and lack of adequate working capital during fiscal 1997 and the first quarter of 1998 resulted in the Company's inability to maintain sufficient raw materials and finished goods inventories to permit the Company to actively solicit customer orders, and when orders were received, to fill such orders promptly. Following the completion in March 1998 of the offering with Galen Partners (the "Galen Offering") pursuant to the 1998 Purchase Agreement, new management adopted a marketing strategy focused on developing and maintaining sufficient raw materials and finished goods inventories so as to permit a targeted sales effort by the Company to a core customer group, with an emphasis on quality, prompt product delivery and excellent customer service.

The strategic alliance with Watson entered into on March 29, 2000 provided for the Company's core products portfolio to be sold by Watson's sales force under Watson's label. Accordingly, following its alliance with Watson, the Company discontinued its own sales efforts of these products. In an effort to increase the sales of the Company's core products, the Company intends to begin marketing such products under its own label or that of a wholly owned subsidiary commencing in the second quarter of 2003. In addition to sales of the Company's core products, the Company continues to perform limited contract manufacturing of certain non-core products for other pharmaceutical companies.

During 2002, 85% of the Company's total product revenues were derived from sales to Watson pursuant to the Core Products Supply Agreement between the Company and Watson (See "Recent Events -- Strategic Alliance with Watson"). The Company believes that the loss of this customer would have a material adverse effect on the Company. During 2001 and 2000, 86% and 59%, respectively of the Company's total product revenues were derived from sales to Watson Pharmaceuticals.

The estimated dollar amount of the backlog of orders for future delivery as of March 31, 2003 was approximately \$1,233,000 as compared with approximately \$5,200,000 as of March 31, 2002. Although these orders are subject to cancellation, management expects to fill substantially all orders by the second and third quarter of 2003. The decrease in the Company's backlog as of March 31, 2003 compared to that for the comparable date in 2002 is largely a function of increased manufacturing output at the Company's Congers, New York facility allowing for the filling of open orders on a more timely basis.

# GOVERNMENT REGULATION

# **GENERAL**

All pharmaceutical manufacturers, including the Company, are subject to extensive regulation by the Federal government, principally by the FDA, and, to a lesser extent, by state and local governments. Additionally, the Company is subject to extensive regulation by the U.S. Drug Enforcement Agency ("DEA") as a manufacturer 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 generally. The Federal Food, Drug, and Cosmetic Act, the Generic Drug Enforcement Act of 1992, the Controlled Substance Act and other Federal statutes and regulations govern or influence the testing, manufacture, safe 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 approvals of new drug applications. The ANDA drug development and approval process now averages approximately eight months to two years. The approval procedures are generally costly and time consuming.

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. No "new drug" may be introduced into commerce without FDA approval. A drug which is the "generic" equivalent of a previously approved prescription drug also will require FDA approval. Furthermore, each dosage form of a specific generic 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. Among the requirements for drug approval is that the prospective manufacturer's methods must conform to the current Good Manufacturing Practice Regulations ("CGMPs"). CGMPs apply to the manufacture, receiving, holding and shipping of all drugs, whether or not approved by the FDA. CGMPs must be followed at all times during which the drug is manufactured. To ensure full compliance with 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 noncomplying 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 of a new drug.

- 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 Opiate Synthesis Technologies may require the filing of an NDA. The full clinical testing required for the preparation and filing of an NDA requires the expenditure of substantial resources. The Company will likely need to collaborate with a third-party to fund the preparation and filing of an NDA. 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 ("ANDA"). 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, 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. 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. "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. While that alternative sometimes provides advantages over the ANDA procedure, it is not frequently used.

# GENERIC DRUG ENFORCEMENT ACT

As a result of hearings and investigations concerning the activities of the generic drug industry and the FDA's generic drug approval process, Congress enacted the Generic Drug Enforcement Act of 1992 (the "Generic Drug Act"). The Generic Drug Act confers significant new authority upon the FDA to impose debarment and civil penalties for individuals and companies who commit certain illegal acts relating to the generic drug approval process.

The Generic Drug Act requires the mandatory debarment of companies or individuals convicted of a federal felony for conduct relating to the development or approval of any ANDA, and gives the FDA discretion to debar corporations or individuals for similar conduct resulting in a federal misdemeanor or state felony conviction. The FDA may not accept or review during the period of debarment (one to ten years in the case of mandatory, or up to five years in the case of permissive, debarment of a corporation) any ANDA submitted by or with the assistance of the debarred corporation or individual. The Generic Drug Act also provides for temporary denial of approval of generic drug applications during the investigation of crimes that could lead to debarment. In addition, in more limited circumstances, the Generic Drug Act provides for suspension of the marketing of drugs under approved generic drug applications sponsored by affected companies. The Generic Drug Act also provides for fines and confers authority on the FDA to withdraw, under certain circumstances, approval of a previously granted ANDA if the FDA finds that the ANDA was obtained through false or misleading statements. As all of the Company's revenue is derived from the sale of FDA approved products, the taking of any such action by the FDA would have a material adverse effect on the Company.

# 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 produced and marketed 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.

# **ENVIRONMENTAL COMPLIANCE**

In addition to regulation by the FDA and DEA, the Company is subject to regulation under Federal, state and local environmental laws. While the Company believes it is in material compliance with applicable environmental laws, continued compliance may require substantial capital expenditures. The Company has budgeted approximately \$300,000 in 2003 for the construction of a production waste tank system at its Culver, Indiana facility in order to comply with applicable waste discharge regulations.

# COMPETITION

The Company competes in varying degrees with numerous companies in the health care industry, including other manufacturers of generic drugs (among which are divisions of several major pharmaceutical companies) and manufacturers of brand-name drugs. Many of the Company's competitors have substantially greater financial and other resources and are able to expend more money and effort than the Company in areas such as marketing and product development. Although a company with greater resources will not necessarily receive FDA approval for a particular generic drug before its smaller competitors, relatively large research and development expenditures enable a company to support many FDA applications simultaneously, thereby improving the likelihood of being among the first to obtain approval of at least some generic drugs.

One of the principal competitive factors in the generic pharmaceutical market is the ability to introduce generic versions of brand-name drugs promptly after a patent expires. Other competitive factors in the generic pharmaceutical market are price, quality and customer service (including maintenance of sufficient inventories for timely deliveries).

# RAW MATERIALS

The raw materials essential to the Company's business are APIs purchased from numerous sources. Raw materials are generally available from several sources. The Federal drug application process requires specification of raw material suppliers. If raw materials from a supplier specified in a drug application were to become unavailable on commercially acceptable terms, FDA supplemental approval of a new supplier would be required. During 2002, 2001 and 2000, the Company purchased approximately \$1,264,000, \$1,512,000 and \$1,485,000,respectively, of its raw materials (constituting 26%, 25% and 28% of each year's aggregate purchases of raw materials) from one supplier. Although the Company is now able to submit supplements to the FDA in order to allow the Company to purchase raw materials from alternate sources, there can be no assurance that if the Company were unable to continue to purchase raw materials from this supplier, that the Company would be successful in receiving FDA approval to such supplement or that it would not face difficulties in obtaining raw materials on commercially acceptable terms. Failure to receive FDA approval for, and to locate, acceptable alternative sources of raw materials would have a material adverse effect on the Company. The Company experienced a shortage of two raw materials in during 2002. These shortages are not expected to continue in 2003.

The DEA limits the quantity of the controlled substance inventories of certain raw materials used by pharmaceutical manufacturers in the production of controlled substances based on historical sales data. As part of the Company commercialization of controlled substance products the Company is required to file for and obtain quotas from the DEA for the purchase and use of controlled substance raw materials. In view of the Company's recently depressed sales volume, any DEA quotas obtained by the Company may have the effect of limiting such materials and could increase the likelihood of raw material shortages and of manufacturing delays in the event the Company experiences increased sales volume or is required to find new suppliers of these raw materials.

As described under the caption "Recent Events -- Opiate Synthesis Technologies", the Company is developing certain opiate technologies to be used in the manufacture of controlled substances. The Company is also seeking to obtain an import registration from the DEA to import raw poppy to be used in such development and manufacturing efforts directly from third-party suppliers in opiate producing countries. No assurance can be given that the Company will be successful in identifying and contracting with third-party suppliers in opiate producing countries on commercially acceptable terms for the Company's requirements of raw materials to be used in its controlled substance development and commercialization efforts.

#### **SUBSIDIARIES**

The Company's Culver, Indiana manufacturing operations are conducted by Houba, Inc., an Indiana corporation and wholly-owned subsidiary of the Company. Halsey Pharmaceuticals, Inc., a Delaware corporation, is a wholly-owned subsidiary which is currently inactive.

#### **EMPLOYEES**

As of March 31, 2003, the Company had approximately 114 full-time employees. Approximately 50 employees are administrative and professional personnel and the balance are in production and shipping. Among the professional personnel, 9 are engaged in research and product development. Management believes that its relations with its employees are satisfactory.

#### ITEM 2. PROPERTIES

The Company leases, as sole tenant, a pharmaceutical manufacturing facility of approximately 35,000 square feet located at 77 Brenner Drive, Congers, New York. The Agreement of Lease, with an unaffiliated third party, contains a three year term 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 renewal period. The term of the Lease expires on March 21, 2004. The leased facility houses a portion of the Company's manufacturing operations and includes office and warehouse space. The Lease also contains an option pursuant to which the Company may purchase the leased premises and improvements (including certain production and related equipment) for a purchase price of \$5 million, exercisable at any time during the Lease term.

Halsey leases, as sole tenant, a facility located at 125 Wells Avenue, Congers, New York. The 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

Halsey leases approximately 4,700 square feet of office space located at 695 North Perryville Road, Building No. 2, Rockford, Illinois. The lease is between the Company and an unaffiliated lessor. The original lease term of two years expired August 31, 2000. There are five one-year renewal options, which the last renewal period will expire on August 31, 2005. The lease calls for annual rental, including maintenance and common area expense, of approximately \$46,000 per year. This leased facility houses the Company's principal executive offices, including its sales, administration and finance operations.

The Company's Houba, Inc. subsidiary owns approximately 45,000 square feet of building space on approximately 30 acres of land in Culver, Indiana, which includes a 15,000 square foot manufacturing facility. This manufacturing facility houses separate plants for the production of certain raw materials as well as finished dosage products in capsule and tablet form.

# 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 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. It is the Company's expectation to file for summary judgment in this action. In the event the Company is unsuccessful in its motion for summary judgment, a trial on this action will follow. 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 2002.

#### PART TT

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

#### MARKET AND MARKET PRICES OF COMMON STOCK

Set forth below for the periods indicated are the high and low bid 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.

BID PRICE* PERIOD HIGH LOW 2001 Fiscal Year First
Quarter
1.24 .69 Second
Quarter
2.45 1.01 HITTU
3.41 1.81 Fourth
Quarter
3.5 1.51 2002 Fiscal Year First Quarter
2.4 1.5 Second
Quarter
2.75 1.3 Third
Quarter
Quarter
1.85 .68 2003 Fiscal Year First
Quarter
1.09 .02

<sup>\*</sup> 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.

# **HOLDERS**

There were approximately 750 holders of record of the Company's common stock on March 31, 2003. This number, however, does not reflect the ultimate number of beneficial holders of the Company's common stock.

# DIVIDEND POLICY

The payment of cash dividends from current earnings is subject to the discretion of the Board of Directors and is dependent upon many factors, including the Company's earnings, its capital needs and its general financial condition. The terms of the Company's 5% convertible senior secured debentures and the Loan Agreement with Watson 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, 2002, the Company issued the following securities which were not registered under the Securities Act:

- (i) 10% convertible promissory notes in the aggregate principal amount \$2,500,000 (the "Bridge Notes") issued to bridge lenders (the "Bridge Lenders") on each of October 1, November 4, November 12, November 21, and December 5, 2002.
- (ii) Common Stock purchase warrants (the "Bridge Warrants") issued to the Bridge Lenders on each of October 1, November 4, November 12, November 21, and December 5, 2002 exercisable for an aggregate of 168,554 shares of the Company's Common Stock at exercise prices ranging from \$1.28 to \$1.77 per share;
- (iii) 5% Convertible Senior Secured Debentures in the aggregate principal amount of \$26,394,000 (the "Debentures") on December 20, 2002. The Debentures were issued in consideration for cash proceeds of \$10,500,000 and the surrender and cancellation of Bridge Notes issued during 2001 and 2002 in the aggregate principal amount of \$15,894,000. The Debentures are convertible into the Company's Common Stock at a price of \$.34 per share; and
- (iv) 5,970,083 shares of the Company's Common Stock issued on December 20, 2002 in exchange for common stock purchase warrants exercisable for an aggregate of 8,145,734 shares of the Company's Common Stock (the "Warrant Recap Shares" and together with the Bridge Notes, the Bridge Warrants and the Debentures, collectively, the "Securities").

Each of the holders of the Securities is an Accredited Investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act. Each of the 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, 2002, 2000, 1999 and 1998 are derived from the Company's audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2002 and December 31, 2001, and for each of the years in the three-year period ended December 31, 2002, and the report thereon, are included elsewhere herein. The selected financial information as of and for the years ended December 31, 1999 and 1998 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."

2002 2001
2000 1999 1998
(IN THOUGANDS EVEEDT DED
- (IN THOUSANDS, EXCEPT PER
SHARE DATA) OPERATING DATA:
Net product
revenues \$ 8,205
\$ 16,929 \$ 20,223 \$ 11,420 \$
8,841 Operating Costs Cost of
manufacturing\$
12,535 14,857 18,743 15,316
12,712 Research and
development \$ 1,517
1,327 1,821 1,075 651
Selling, general and
administrative
expenses \$ 7,216 6,616
6,208 7,383 8,078 Plant
shutdown costs\$
(126) 68 53 3,220 Interest
expense\$
4,728 3,913 3,699 2,946 1,388
Interest
income \$ 15
· · · · · · · · · · · · · · · · · · ·
69 662 95 103 Amortization of

YEARS ENDED DECEMBER 31, ----

```
2000 1999 1998 -----
--- ------
 - (IN THOUSANDS, EXCEPT PER
    SHARE DATA) Loss on
    extinguishments of
debt.....
$ 11,985 Investment in joint
venture..... $ -- (202) (57)
    -- -- Other (income)
  expense..... $ 3,248
(13) (101) (187) (1,822) Loss
     before income tax
benefit.....
 $(45,441) (12,563) (12,043)
(20,063) (12,724) Income tax
benefit..... $ -- --
     (389) -- -- Net
loss.....
$(45,441) $(12,563) $(11,654)
$(20,063) $(12,724) =======
 ====== Basic and diluted
     loss per common
 share..... $
  (2.98) $ (.84) $ (.80) $
  (1.40) $ (.92) =======
 ====== Weighted average
   number of outstanding
  shares..... 15,262
 15,022 14,503 14,326 13,813
 DECEMBER 31, -----
----- 2002 2001
2000 1999 1998 ----- --
------ ------ ------ -
  ----- (IN THOUSANDS,
  EXCEPT PER SHARE DATA)
BALANCE SHEET DATA: Working
        capital
(deficiency).....
$ 5,933 $ (8,276) $ (5,061)
 $ (5,181) $ (6,665) Total
assets..... $
19,364 11,069 15,209 12,495
      16,413 Total
liabilities..... $
31,632 76,505 68,558 54,869
    45,366 Accumulated
   deficit.....
   $(146,942) (101,501)
(88,938) (77,284) (57,221)
   Stockholders' equity
(deficit).....
   $ (12,268) (65,436)
(53, 349) (42, 374) (28, 953)
       MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS
TTFM 7.
       OF OPERATIONS
    Certain statements set forth under this caption constitute "forward-looking
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YEARS ENDED DECEMBER 31, ----

OVERVIEW

relating to such Statements.

The Company reported a net loss of \$45,441,000 or \$2.98 per share for the year ended December 31, 2002 as compared to a net loss of \$12,563,000 or \$.84 per share for 2001. Included in net product revenues for 2001 was \$8.5 million

statements" within the meaning of the Reform Act. See "Special Note Regarding Forward-Looking Statements" on page 2 of this Report for additional factors

of a total \$13.5 million earned from Watson Pharmaceuticals representing the sum of the second and the final payments for a product ANDA sold by the Company to Watson in March, 2000. Excluding the payments made by Watson to the Company for a product ANDA, net revenues for the year ended December 31, 2001 representing product sales, were approximately \$8,429,000.

The Company reduced its loss from operations by \$1,502,000 to \$12,937,000 in 2002 as compared to \$14,439,000 for 2001 after adjusting for the \$8,500,000 of product development revenues earned in 2001. This was achieved even after increases in research and development expenses and selling, general and administrative expenses during 2002 of \$190,000 and \$600,000, respectively.

The Company had the following significant achievements in 2002:

- Received approval from the DEA to manufacture Schedule II to V controlled substances at the Company's Culver, Indiana facility.
- Completed a debenture offering in the principal amount of approximately \$26,394,000.
- Recapitalized common stock purchase warrants exercisable for approximately 8,145,000 shares in exchange for approximately 5,970,000 shares of Common Stock.

- Extended the maturity date of the Company's term loan agreement with Watson from March 31, 2003 to March 31, 2006.
- Extended the maturity date of the Company's outstanding 5% Convertible Senior Secured Debentures in the aggregate principal amount of approximately \$50,723,000 from March 15, 2003 to March 31, 2006.

# RESULTS OF OPERATIONS

#### **NET REVENUES**

Net product revenues for 2002 of \$8,205,000 represents a decrease of \$224,000 in product sales as compared to \$8,429,000 in 2001 and a decrease of \$8,500,000 in product development revenues in 2002 as compared to 2001. The Company had earned \$8,500,000 in product development revenues from Watson in 2001 relating to the Company's sale of a product ANDA to Watson.

Net product revenues for 2001 of \$16,929,000 represents a decrease of \$3,294,000 as compared to net product revenues for 2000. Net product revenues for 2001 are comprised of sales of products totaling \$8,429,000 and revenues from product development of \$8,500,000. The Company had \$5,000,000 of product development revenue in 2000. The decrease in sales of products is attributable primarily to raw material shortages required for the manufacture of two products.

# COST OF MANUFACTURING

The Company's cost of manufacturing for 2002 was 153% of net product sales versus 176% of net product sales for 2001 after adjustment of \$8,500,000 for product development revenues in 2001. The improvement in 2002 is due primarily to the transition of both outside packaging and laboratory services to internal departments. During 2001, the Company utilized both third party packaging operations and laboratory services.

The Company's cost of manufacturing for 2001 improved to 88% of net product sales versus 93% of net product sales for 2000. The improvement in 2001 is due primarily to the addition of the \$8,500,000 of product development revenue. The development costs associated with this revenue were substantially incurred in years prior to 2000 and were expensed at that time. The cost of manufacturing for 2001 on product sales alone was 176% due primarily to underutilized productive capacity and the significant fixed costs associated with pharmaceutical production regardless of sales volume.

# RESEARCH & DEVELOPMENT EXPENSES

For 2002, research and development expenses amounted to \$1,517,000 as 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 Opiate Synthesis Technologies.

For 2001, research and development expenses amounted to \$1,327,000 as compared to \$1,821,000 for 2000. The decrease of \$494,000 or 27% primarily reflects the absence of \$500,000 in costs associated with licensing a codeine technology in 2000. Such codeine license agreement has since been terminated by the Company.

The Company expects research and development expenses to increase in 2003 as compared to 2002 consistent with its plans to develop and manufacture APIs and finished dosage products incorporating the Opiate Synthesis Technologies and in the rehabilitation of certain product ANDAs acquired from Barr.

# SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

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 legal expenses incurred for patent research and regulatory matters associated with the DEA manufacturing and import license registrations on

the Opiate Synthesis Technologies, as well as increases in product marketing expenses and corporate insurance premiums.

Selling, general and administrative costs were \$6,616,000 (39% of net product revenue) for 2001 compared to \$6,208,000 (31% of net product sales) for 2000. This increase is primarily due to the added legal expenses associated with the Opiate Synthesis Technologies.

# INTEREST EXPENSE, NET OF INTEREST INCOME

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

Interest expense, net of interest income for 2001 increased by \$807,000 or 26.6% over that of 2000 reflecting interest on borrowings under the Watson Term Loan. During 2001, the Company borrowed an additional \$5,500,000 under the Watson Term Loan.

# AMORTIZATION OF DEFERRED DEBT DISCOUNT, AND PRIVATE OFFERING COSTS

In 2002, 2001 and 2000 the Company issued warrants and incurred costs associated with private placements and bridge financings. The value of warrants issued in 2002, 2001, and 2000, as determined by use of the Black-Scholes valuation model, was approximately \$5,115,000, \$310,000, and \$125,000 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 \$78,364,000 in 2002. 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 December 2002 private placement of the remaining unamortized balance of private offering costs from 1999 was written-off. Amortization expense of deferred debt discount and private offering costs was \$12,558,000, \$2,591,000, and \$2,448,000 in 2002, 2001, and 2000, respectively. At December 31, 2002, the Company recorded debt discount of \$73,955,000 which will be amortized to expense over the remaining life of the related debentures through March 31, 2006.

# Loss on Extinguishment of Debt

In 2002, the Company recorded a loss on the extinguishment of debt of \$11,985,000 which represents the fair value of 10,700,665 warrants that the Company issued to Watson in consideration of Watson's extension of the maturity date of the Watson Term Loan.

# Other Income (Expense)

In 2002, the Company recorded a charge to earnings of \$2,282,000 in connection with the issuance of 5,920,083 shares of common stock in exchange for 8,145,736 warrants. The Company also recorded a charge to earning of \$863,000 as a result of the modification of the terms of certain outstanding warrants to purchase common stock.

# LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2002, the Company had cash and cash equivalents of \$9,211,000 as compared to \$422,000 at December 31, 2001. The Company had working capital of \$5,933,000 at December 31, 2002.

In addition to the other strategic alliance transactions with Watson completed on March 29, 2000, the Company and Watson executed a Loan Agreement providing for Watson's extension of a \$17,500,000 term loan to the Company (the "Watson Term Loan"). On December 20, 2002, the Company and Watson amended the Watson Term Loan to (i) increase the principal amount of the Watson Term Loan from \$17,500,000 to \$21,401,331 to reflect the Company's then outstanding payment obligation of \$3,901,331 to Watson under the terms of the Company's Core Products Supply Agreement with Watson, (ii) increase the interest rate under the Watson Term Loan from prime plus 2.5% to prime plus 4.5%, and (iii) extend the

maturity date of the Watson Term Loan from March 31, 2003 to March 31, 2006. The Watson Term Loan is secured by a first lien on all of the Company's assets, senior to the liens securing all other Company indebtedness. The net proceeds of the Watson Term Loan were used in part to satisfy certain bridge loans made by Galen Partners III, L.P. ("Galen") to the Company during 2000, to satisfy Company's payment obligations under the Settlement Agreement with the landlord of its Brooklyn, New York facility, to fund capital improvements and to fund the Company's working capital requirements.

As described under Item 1, Recent Events-Debenture Offering, on December 20, 2002, the Company completed a private offering of 5% convertible senior secured debentures (the "2002 Debentures") in the principal amount \$26,394,000 (the "Offering"). The 2002 Debentures were issued pursuant to a certain Debenture Purchase Agreement dated December 20, 2002 (the "Purchase Agreement") by and among the Company, Care Capital Investments II, LP ("Care Capital"), Essex Woodlands Health Ventures V, L.P. ("Essex"), Galen and each of the purchasers listed on the signature page thereto.

The 2002 Debentures, issued at par, will become due and payable as to principal on March 31, 2006. Interest on the principal amount of the 2002 Debentures, at the rate of 5% per annum, is payable on a quarterly basis. With the exception of the 2002 Debentures issued to Care Capital, interest will be paid by the Company's issuance of a debenture instrument substantially identical to the 2002 Debentures issued in the Offering, in the principal amount equal to the accrued interest for each quarterly period (the "Interest Debentures"). The 2002 Debentures issued to Care Capital provide that fifty percent (50%) of the interest payment under such 2002 Debentures will be satisfied in cash with the balance satisfied by the Company's issuance of Interest Debentures.

The Debentures issued to each of Care Capital and Essex are convertible at any time after issuance into shares of the Company's Common Stock. The 2002 Debentures issued to Galen and the other investors in the Offering (excluding Care Capital and Essex) are convertible at any time after the approval of the Company's shareholders and debentureholders of 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 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. Assuming the conversion of the 2002 Debentures at the initial Conversion Price of \$.34 per share, the 2002 Debentures are convertible into an aggregate of approximately 77,629,000 shares of Common Stock.

The Interest 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.

The Purchase Agreement provides that the holders of the 2002 Debentures shall have the right to vote as part of a single class with all holders of the Company's Common Stock on all matters to be voted upon by such stockholders. Each 2002 Debentureholder shall have such number of votes as shall equal the number of votes he would have had if such holder converted the entire outstanding principal amount of his 2002 Debenture into shares of Common Stock immediately prior to the record date relating to such vote; provided, however, that any Debentures initially held by Care Capital shall, for so long as they are held by Care Capital, have no voting rights.

The 2002 Debentures are secured by a lien on all assets of the Company, tangible and intangible. In addition, each of Houba, Inc. and Halsey Pharmaceuticals, Inc., each a wholly-owned subsidiary of the Company, 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 secured its obligations under the Purchase Agreement.

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 Existing 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 Existing Debentures in the aggregate principal amount of approximately \$50,724,000.

Of the \$26,394,000 in Debentures issued in the Offering, approximately \$15,894,000 Debentures were issued in exchange for the surrender of a like amount of principal and accrued interest on the Company's outstanding 10% convertible promissory notes issued pursuant to various working capital bridge loan transactions with Galen and the certain other lenders during the period from August 15, 2001 through and including December 20, 2002.

The development and commercialization of APIs and finished dosage products incorporating the Opiate Synthesis Technologies are subject to various factors, many of which are outside the Company's control. Specifically, the Opiate Synthesis Technologies have been tested only in laboratory settings and will need to be successfully "scaled up" in order 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 requirements for the maintenance of its Manufacturing Registration and the issuance and maintenance of the Import Registration. The process of seeking the Import Registration and contesting opposition proceedings, as well as the continuing development of the Opiate Synthesis Technologies, will likely continue through 2004. The Company is currently unable to provide any assurance that the Opiate Synthesis Technologies will be commercially viable or that the Company will succeed in obtaining the Import Registration. The Company is committing the substantial majority of its resources, available capital and cash flow from operations to the development of the Opiate Synthesis Technologies and to the receipt of the Import Registration. The failure of the Company to successfully develop the Opiate Synthesis Technologies or to obtain the Import Registration 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 Technologies, to obtain required DEA approvals and to fund the capital improvements necessary for the manufacture of APIs and finished dosage products incorporating the Opiate Synthesis Technologies.

The Company has budgeted approximately \$2,500,000 in 2003 for the continued development and commercialization of the Opiate Synthesis Technologies. Of such amount, approximately \$2,000,000 relates to capital expenditures for facility improvements and the purchase of equipment at the Company's Culver, Indiana facility, approximately \$300,000 relates to capital expenditures for environmental compliance waste discharge storage tanks at the Culver facility, and approximately \$200,000 relates to the legal fees and related expenses for the OALJ hearing and third party opposition proceedings in connection with the Company's application for the Import Registration. Until such time as the Company successfully develops and commercializes new finished dosage products and APIs, of which there can be no assurance, the majority of the Company's revenues are expected to be derived from the Core Products Supply Agreement with Watson, with the balance of the Company's revenues derived from a combination of the Company's own selling efforts for the Company's core products, which sales efforts are anticipated to commence in the second quarter of 2003, and the Company's manufacture of non-core products for third parties. The Company estimates that during 2003 and 2004, the Company will continue to incur operating losses and negative cash flow. The Company believes that the net proceeds of the Debenture Offering completed on December 20, 2002 will provide the working capital necessary to fund operating losses only through June 2003.

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 "Letter of Support"). The Letter of Support provides that the amount of any funding provided by the Majority 2002 Debentureholders would be reduced to the extent of any funding obtained by the Company from third-party sources during 2003. The Letter of Support further provides that the terms of any funding provided by the Majority 2002 Debentureholders will be subject to negotiation between the Company and the Majority 2002 Debentureholders at the time of any such funding. The terms of any such funding will be subject to approval by those directors of the Company that are unaffiliated with the Majority 2002 Debentureholders. While the terms of any funding to meet the Company's 2003 capital requirements are currently unknown, it is likely that such terms will result in significant additional dilution to holders of the Company's Common Stock. 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 (which is equivalent to the conversion price of the 2002 Debentures), 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 party investment if lower than the exercise price of the warrants.

The Company believes that the remaining net proceeds of the 2002 Debenture Offering, along with the funding to be provided under the Letter of Support combined with cash flow from operations, will be sufficient to satisfy the Company's working capital requirements through January 1, 2004.

Failure to obtain a third party investment or to reach agreement with the Majority 2002 Debentureholders on mutually acceptable terms to fund the Company's capital requirements for 2003 will require the Company to (i) significantly curtail product commercialization efforts, including the development and commercialization of the Opiate Synthesis Technologies, (ii) if available, obtain funding through arrangements with collaborative partners or others on terms that may require the Company to relinquish certain rights in its Opiate Synthesis Technologies, which the Company could otherwise pursue on its own, or that would significantly dilute the Company's stockholders, (iii) significantly scale back or terminate operations, and/or (iv) seek relief under applicable bankruptcy laws. Any extended delay in obtaining necessary financing will result in the cessation of the Company's continuing development efforts relating to its Opiate Synthesis Technologies and will have a material adverse effect on the Company's financial condition and results of operations.

The following table presents the Company's expected cash requirements for contractual obligations outstanding as of December 31, 2002:

```
DUE AS OF DUE AS OF 12/31/04
 12/31/06 DUE AS OF AND AND
 DUE TOTAL 12/31/03 12/31/05
12/31/07 THEREAFTER -----
-----
--- (IN THOUSANDS)
 Convertible senior secured
debentures.....
$ 77,118 $ -- $ -- $77,118 $-
       - Term loan
payable..... 21,401
-- -- 21,401 -- Department of
        justice
settlement.....
 761 300 461 -- -- Capital
 leases..... 73
   33 40 -- -- Operating
leases..... 1,068
  844 224 -- -- Employment
 agreements..... 1,247
535 712 -- -- -----
   ----- ----- -- Total
     Contractual Cash
Obligations.....
  $101,668 $1,712 $1,437
 $98,519 $-- =======
```

# 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 this 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, net of sales discounts and allowances, when title to the product passes to customers, which generally 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.

Management continually monitors the factors that influence sales allowance estimates and makes adjustments to these provisions when allowances may differ from established allowances.

# 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 customers' financial condition and, generally, collateral is not required. Accounts receivable are due within 30 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.

#### **INVENTORIES**

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

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.

# STOCK COMPENSATION

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. 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

Debt discount resulting from the issuance of stock warrants in connection with the issuance of subordinated debt and other notes payable as well as beneficial conversion features contained in convertible debt instruments is recorded as a reduction of the related obligations and is amortized over the remaining life of the related obligations. Debt discount related to the stock warrants issued is determined by a calculation which is based on the relative fair values ascribed to such warrants determined by an independent valuation or 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.

# NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets." ("SFAS No. 142"). SFAS No. 142

requires that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also requires that intangible assets with definite useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of," as amended. The Company adopted the provisions of SFAS No. 142 effective January 1, 2002. The adoption of SFAS No. 142 had no effect on the financial position or results of operations of the Company.

In October 2001, the FASB issued SFAS No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"). SFAS No. 144 requires that long-lived assets be measured at the lower of carrying amount or fair value less cost to sell, whether reported in continuing operations or in discontinued operations, Therefore, discontinued operations will no longer be measured at net realizable value or include amounts for operating losses that have not yet occurred. SFAS No. 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001 and, generally, is to be applied prospectively. The adoption of SFAS No. 144 had no effect on the Company's financial position or results of operations.

In April 2002, the FASB issued SFAS No. 145 ("FSAS No. 145"), "Rescission of FASB statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections." This statement eliminates the requirement to report gains and losses from extinguishment of debt as extraordinary unless they meet the criteria of APB Opinion 30. SFAS No. 145 also requires sale-leaseback accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. The changes related to lease accounting are effective for transactions occurring after May 15, 2002 and the changes related to debt extinguishment are effective for fiscal years beginning after May 15, 2002. The impact of adopting the provisions related to debt extinguishments during the year ended December 31, 2002. The adoption did not have a material impact on the Company's financial position or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN No. 46") "Consolidation of Variable Interest Entities." In general, a variable interest entity is a corporation, partnership, trust, or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. A variable interest entity often holds financial assets, including loans or receivables, real estate or other property. A variable interest entity may be essentially passive or it may engage in activities on behalf of another company. Until now, a company general has included another entity in its consolidated financial statements only if it controlled the entity through voting interests. FIN No. 46 changes that by requiring a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. FIN No. 46's consolidation requirements apply immediately to variable interest entities created or acquired after January 31, 2003. The consolidation requirements apply to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The Company has adopted FIN No. 46 effective January 31, 2003. The Company does not anticipate that the adoption of FIN 46 will have a material impact on the Company's consolidated financial condition or results of operations taken as a whole.

# CAPITAL EXPENDITURES

The Company's capital expenditures during 2002, 2001 and 2000 were \$287,000, \$1,544,000 and \$2,962,000, respectively. The capital expenditures during these periods is attributable to capital improvements to the Company's Congers, NY and Culver, Indiana facilities. In order for the Company to receive the Manufacturing Registration, specific improvements were made for security and related items to the Culver, Indiana facility. Additionally, expenditures were made to significantly improve and expand the manufacturing capabilities of both Congers, NY locations. The Company has budgeted for capital expenditures approximately \$2,500,000 in fiscal 2003. A portion of such amounts will be funded from the net proceeds of the Debenture Offering, with the balance from third party financing to be sought by the Company during 2003.

# 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.

# PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

THE DIRECTORS AND EXECUTIVE OFFICERS OF THE COMPANY ARE AS FOLLOWS:

Michael K.  Reicher
55 Chief Operations Officer Peter A.  Clemens
Vice President, Chief Financial Officer and Director Bruce F. Wesson
73 Director William A.  Sumner
Sumner
Skelly
Conjeevaram
Shroff
Liffmann
Karabelas
Thangaraj
Emigh
Whitney
56 Vice President Administration Robert
Seiser

MICHAEL K. REICHER has been Chairman of the Board of Directors since June 29, 2000 and Chief Executive Officer and a Director of the Company since February 19, 1998. In 1980, Mr. Reicher founded UDL Laboratories, Inc., a manufacturer of human generic pharmaceuticals, and served as its President through February 1998. In February 1996, UDL Laboratories, Inc. was purchased by Mylan Laboratories, Inc., and Mr. Reicher remained in the office of President until joining the Company in February 1998.

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 the Vice President and Chief Financial Officer of the Company since February 1998 and a Director of the Company since June 1998. 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.

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 Witco Corporation, 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 Chief Financial Officer of Galen Associates, a health care venture firm, and 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. 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 AmericasDoctor.com and Encore Medical Corporation.

JOEL D. LIFFMANN has been a Director of the Company since 1999. Mr. Liffmann is a General Partner of Oracle Partners, L.P. Prior to joining Oracle Partners in 1996, Mr. Liffmann was Senior Vice President of Business Development at Merck-Medco, Inc. Prior to such time, Mr. Liffmann was Vice President/Business Development at Medco Containment Services and Vice President of Equity Research and later was Vice President of Corporate Finance at Drexel Burnham Lambert. Mr. Liffmann holds a degree from Boston University.

JERRY KARABELAS has been a Director of the Company since December 2002. Mr. Karabelas was Head of Healthcare and CEO of Worldwide Pharmaceuticals for Novartis AG from 1998 until July 2000. Prior to joining Novartis, Mr. Karabelas was Executive Vice President of SmithKline Beecham. From July 2000 until December 2001, Mr. Karabelas was the Founder and Chairman of the Novartis Bio Venture Fund. Since

November 2001 he has been a Partner with Care Capital LLC. Mr. Karabelas holds a Ph.D. in pharmacokinetics from the Massachusetts College of Pharmacy and serves as a Director of SkyePharma Plc., Human Genome Sciences, Nitromed, Anadys and Renova.

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.

JAMES EMIGH has been Vice President of Sales and Marketing since November 2002. 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.

PHYLLIS A. LAMBRIDIS has been Vice President of Corporate Compliance since March 19, 2001. From 1998 until joining the Company, Ms. Lambridis was employed by Schein Pharmaceutical, Inc. (subsequently acquired by Watson Pharmaceuticals, Inc. in 2000) as its Director, Corporate Quality Standards, Policies & Systems. From 1987 to 1998 Ms. Lambridis was employed by Barr Laboratories, Inc. in a number of quality and regulatory positions, most recently as Director of Regulatory Compliance. Ms. Lambridis holds a Masters of Science in Bacteriology from Wagner College and a Bachelor of Arts in Microbiology from Rutgers College.

CAROL WHITNEY has been Vice President of Administration since April 1998. From 1992 until joining the Company, Ms. Whitney served as Director of Human Resources for UDL Laboratories, Inc., a generic pharmaceutical manufacturer located in Rockford, Illinois.

ROBERT SEISER has been Corporate Controller and Treasurer since March 1998. From 1992 until joining the Company, 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.

# 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 complied with all Section 16(a) filing requirements during the year ended December 31, 2002, except that (i) a Form 3 filing requirement for Mr. Vijai Kumar following his appointment as the Company's Chief Operations Officer was filed late (ii) a Form 4 filing requirement by each of Galen Partners III, L.P. and Galen Partners International III, L.P., each a beneficial owner of in excess of 10% of the Company's Common Stock, were filed late, and (iii) 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, 2002, 2001 and 2000 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 2002 exceeded \$100,000:

### SUMMARY COMPENSATION TABLE

LONG TERM **COMPENSATION** ANNUAL COMPENSATION ----------SECURITIES OTHER UNDERLYING ANNUAL STOCK ALL OTHER NAME AND PRINCIPAL POSITION YEAR SALARY BONUS **COMPENSATION** OPTIONS COMPENSATION - ---------------- ---- -------- ------------ Michael K. Reicher.... 2002 \$200,000 0 ---- -- Chairman and Chief 2001 191,346 0 -- -- --Executive Officer 2000 175,000 0 --100,000 -- Gerald F. Price(1)..... 2002 \$163,654 0 ---- -- President and Chief 2001 176,346 0 -- -- --Operating Officer 2000 49,846 0 --850,000 -- Peter Α. Clemens..... 2002 \$155,000 0 ---- -- Vice President and Chief 2001 149,807 0 -- -- --Financial Officer 2000 140,000 0 --100,000 -- Phyllis A. Lambridis(2)... 2002 \$166,006 0 ---- -- Vice President -- 2001 115,384 0 --75,000 --Corporate Compliance James Emigh..... 2002 \$139,565 0 ---- -- Vice President -- 2001 125,000 0 --25,000 --Operations 2000 125,000 0 --90,000 --

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- (1) Mr. Price's services as President and Chief Operating Officer ceased effective November 7, 2002
- (2) Ms. Lambridis was appointed Vice President -- Corporate Compliance effective March 19, 2001.

### 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 provided automobiles to certain of its executive Officers. Although the Company is unable to assign a precise value to the possible personal benefit derived from the use of the automobiles, the Company believes that, as to each officer, such personal benefit amount is less than the lesser of \$6,000 or 10% of such officer's compensation reported above in the Summary Compensation Table.

#### **EMPLOYMENT AGREEMENTS**

Michael K. Reicher is employed pursuant to an Employment Agreement effective as of March 10, 1998, which after giving effect to amendments dated May 24, 2000 and May 4, 2001, provides that Mr. Reicher will serve as the Company's Chief Executive Officer for a term expiring April 30, 2005. The Agreement provides for an annual base salary of \$200,000 plus the payment of an annual bonus to be determined based on the satisfaction of such targets, conditions or parameters as may be set from time to time by the Compensation Committee of the Board of Directors. No bonus was paid for fiscal 2002. The Employment Agreement also provides for the grant of stock options on March 10, 1998 to purchase 1,000,000 shares of the Company's Common Stock at an exercise price of \$2.375 per share (representing the closing price for the Company's common stock as reported by the American Stock Exchange ("AMEX") on the day preceding the grant of the option), which options vest in equal increments of 62,500 option shares at the end of each quarterly period during the term of the Agreement (as such vesting schedule may be amended by mutual agreement between

Mr. Reicher and the Board of Directors). The Employment Agreement also permits the Company to repurchase the vested portion of Mr. Reicher's options upon his termination for cause (as defined in the Agreement) or his resignation (other than for "Good Reason" as defined therein), 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 Agreement) and without cause. In the event the Employment Agreement is terminated by the Company without cause or by Mr. Reicher for Good Reason (as defined in the Agreement), the Company is required to pay Mr. Reicher an amount equal to \$350,000 or twice his then base salary, whichever is greater, payable in 24 equal monthly installments and to continue to provide Mr. Reicher 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. Reicher to terminate the Agreement in the event of a change of control and for Good Reason (as defined in the Agreement). The Agreement also restricts Mr. Reicher 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.

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 an annual base salary of \$155,000 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. No bonus was paid for fiscal 2002. 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 remaining terms of Mr. Clemens' Employment Agreement with the Company are substantially identical to that of Mr. Reicher.

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 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. 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 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 Agreement) and without cause. The Employment Agreement also provides that in the event of a change of control (as defined in the Agreement), 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 Agreement, and (ii) one year. The 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 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 March 31, 2003, ISO's to purchase 689,813 shares and non-qualified options to purchase 257,780 shares have been granted under the 1995 Stock Option Plan, leaving 52,407 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 1998 Stock Option Plan permits the grant of incentive stock options ("ISO's") and non-qualified stock options to purchase shares of the Company's Common Stock. As of March 31, 2003, ISO's to purchase 1,653,151 shares and non-qualified options to purchase 1,562,466 shares have been granted under the 1998 Stock Option Plan, leaving 4,884,383 shares available for grant under the Plan. The average per share exercise price for all outstanding options under the 1998 Stock Option Plan is approximately \$1.97. 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. Subject to the terms of the 1998 Stock Option Plan, the Stock Option Committee determines the person's 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 applied 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, 2002 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

NUMBER OF SECURITIES NUMBER OF SECURITIES TO WEIGHTED-AVERAGE REMAINING AVAILABLE FOR BE ISSUED UPON EXERCISE EXERCISE PRICE OF FUTURE ISSUANCE UNDER **EQUITY OF** OUTSTANDING OPTIONS, OUTSTANDING OPTIONS, COMPENSATION PLANS (EXCLUDING PLAN CATEGORY WARRANTS AND RIGHTS WARRANTS AND RIGHTS SECURITIES REFLECTED IN COLUMN (A)) - ---------\_\_\_\_\_\_ (A) (B) (C) Equity Compensation Plans Approved by Security Holders... 5,008,950 \$1.79 3,928,590 Equity Compensation Plans Not Approved by Security Holders..... 0 0 0 TOTAL:...... 5,008,950 \$1.79 3,928,590

# 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 2002. The following table presents information regarding the value of options outstanding at December 31, 2002 for each of the named executive officers.

Gerald F.
Price(1)
425,000 425,000 26,000 26,000
Peter A.
Clemens
487,500 137,500 Phyllis
Lambridis
18,750 56,250 James
Emigh
83,250 67,750

- -----

- (1) Mr. Price's services as President and Chief Operating Officer ceased effective November 7, 2002.
- (2) Value is based upon the average of the closing bid and ask price of \$.96 per share at December 31, 2002.

## COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

The Company's Compensation Committee consisted of Messrs. Wesson, Conjeevaram, Skelly and Reicher during fiscal 2002. During 2002, except for Mr. Reicher, the Company's Chairman and Chief Executive Officer, there were no Compensation Committee interlocks or insider participation in compensation decisions.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information regarding the beneficial ownership of the Common Stock, as of April 1, 2003 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 2002 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.

AMOUNT PERCENT NAME OF BENEFICIAL OWNER OWNED(1) OF CLASS
Galen Partners III, L.P.
Adams
Selz
Weisbrot
Reicher
Wesson
Conjeevaram * Alan J.
Smith

AMOUNT PERCENT NAME OF BENEFICIAL OWNER OWNED(1) OF
CLASS
William A.
Sumner
50,000(15) * Zubeen
Shroff
* Peter A.
Clemens
722,294(16) 3.3% Joel D.
Liffmann
* Jerry
Karabelas
* Immanuel
Thangaraj
- * Phyllis
Lambridis
56,250(17) * James
Emigh
154,750(18) * All Directors and Officers as a Group
(17 persons) 3,097,008(19) 13%

- -----

- \* Represents less than 1% of the outstanding shares of the Company's Common Stock.
- (1) The information with respect to Hemant K. Shah and Varsha H. Shah, Dennis Adams, Bernard Selz and Michael and Susan Weisbrot and Watson Pharmaceuticals, is based upon filings with the Commission and/or information provided to the Company.
- (2) Includes (i) 18,524,915 shares issuable upon conversion of 1998 Debentures and 1999 Debentures, (ii) 5,483,034 shares issuable upon exercise of 1998 Warrants and 1999 Warrants, (iii) 5,851,500 shares issuable upon exercise of common stock purchase warrants issued in connection with the 2001/2002 Galen Bridge Loans, (iv) 3,937,678 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.
- (3) Includes (i) 1,966,652 shares issuable upon conversion of 1998 Debentures and 1999 Debentures, (ii) 583,157 shares issuable upon exercise of 1998 Warrants and 1999 Warrants, (iii) 525,545 shares issuable upon exercise of common stock purchase warrants issued in connection with the 2001/2002 Galen Bridge Loans, and (iv) 418,996 shares issuable upon conversion of Debentures issued in lieu of quarterly cash interest payments.
- (4) Includes (i) 7,122,508 shares issuable upon conversion of the 1999 Debentures, and (ii) 1,227,156 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.
- (5) Includes 14,705,882 shares issuable upon conversion of 2002 Debentures.
- (6) Includes 14,705,882 shares issuable upon conversion of 2002 Debentures.
- (7) Includes 10,700,665 shares issuable upon exercise of the Watson Warrant.
- (8) Includes 1,296,698 shares issuable upon conversion of 1998 Debentures and 1999 Debentures.
- (9) Includes 916,403 shares issuable upon conversion of 1998 Debentures and 1999 Debentures.
- (10) Includes 512,714 shares issuable upon conversion of 1998 Debentures and 1999 Debentures
- (11) Includes 679,726 shares issuable upon conversion of 1998 Debentures and 1999 Debentures.
- (12) Includes (i) 266,502 shares issuable upon conversion of 1998 Debentures, (ii) 62,213 shares issuable upon conversion of Debentures issued in lieu of quarterly interest payments and (iii) 1,343,750 shares subject to currently exercisable stock options.
- (13) Includes 200,000 shares subject to currently exercisable stock options.
- (14) Includes (i) 50,000 shares subject to currently exercisable Common Stock

- Purchase Options and (ii) 42,952 shares issuable upon conversion of Debentures.
- (15) Includes 50,000 shares subject to currently exercisable stock options.
- (16) Includes (i) 211,821 shares issuable upon conversion of 1998 Debentures, (ii) 35,678 shares issuable upon conversion of Debentures issued in lieu of quarterly interest payments, and (iii) 568,750 shares subject to currently exercisable stock options.
- (17) Includes 31,250 shares subject to currently exercisable stock options.

- (18) Includes 109,750 shares subject to currently exercisable stock options.
- (19) Includes 3,723,126 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 March 10, 1998, the Company completed a private offering of securities (the "Galen Offering") to Galen Partners III, L.P., Galen Partners International, L.P., Galen Employee Fund III, L.P., (collectively "Galen") and each of the purchasers listed on the signature page to a certain Debenture and Warrant Purchase Agreement (the "1998 Purchase Agreement") dated March 10, 1998 (inclusive of Galen, collectively the "Galen Investor Group"). 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"). After giving effect to the Company's issuance of additional debentures to Galen in satisfaction of interest payments under the 1998 Debentures and the 1999 Debentures described below, as well as the 2002 Debentures issued to Galen in the 2002 Debenture Offering (as further described below), an aggregate of approximately 123,302,173 shares are issuable to Galen upon conversion of outstanding convertible debentures and exercise of outstanding common stock purchase warrants issued to Galen. See "Item 12 -- Security Ownership of Certain Beneficial Owners and Management."

Each of Messrs. Wesson, Conjeevaram and Shroff, members of the Board of Directors, are designees of the Galen Investor Group pursuant to the terms of the 1998 Purchase Agreement which provides, among other things, that the Company must nominate and appoint to the Board of Directors, subject to shareholder approval, three designees of the Galen Investor Group for 2003, and two designees of the Galen Investor Group thereafter, for so long as the 1998 Debentures and 1998 Warrants remain outstanding. Each of Messrs. Wesson, Conjeevaram and Shroff is a General Partner of Galen Associates, an affiliate of each of the Galen entities included in the Galen Investor Group.

The Company secured bridge financing from Galen and certain other lenders in the aggregate principal amount of approximately \$15,277,761, funded through numerous bridge loan transactions during the period from August 15, 2001 through December 2002 (collectively, the "2001/2002 Galen Bridge Loans"). Approximately \$14,770,186 in aggregate principal amount of the 2001/2002 Galen Bridge Loans was advanced by Galen with a balance of approximately \$507,575 advanced by certain members of the Galen Investor Group. As part of the closing of the 2002 Debenture Offering, as defined and provided below, the Company issued 2002 Debentures to Galen in the aggregate principal amount \$15,483,731 in exchange for the surrender of a like amount of principal and accrued interest then outstanding under the 10% Convertible Promissory Notes ("Convertible Notes") issued to Galen in the 2001/2002 Galen Bridge Loans. Prior to the surrender of the Convertible Notes for 2002 Debentures issued in the 2002 Debenture Offering, the 2001/2002 Galen Bridge Loans accrued interest at the rate of 10% per annum and were secured by a lien on all the Company's assets. In consideration for the extension of the 2001/2002 Galen Bridge Loans, the Company issued Common Stock purchase warrants to Galen to purchase an aggregate of 6,401,029 shares of the Company's Common Stock. The warrants issued pursuant to the 2001/2002 Galen Bridge Loans have an exercise price equal to the fair market value of the Company's Common Stock on the date of issuance of such warrants and are substantially identical to those issued in the Galen Offering. The 2001/2002 Galen Bridge Loans were obtained by the Company in order to provide necessary working capital.

Galen controls approximately 85.7% of the Company's voting securities (or approximately 55.9% after giving effect to the conversion of other convertible securities issued by the Company). Holders of the 1998 Debentures and the 1999 Debentures (as defined in the paragraph below) are permitted to vote on all matters submitted to a vote of shareholders, voting together with holders of common stock as one class and having such number of votes as equals the number of votes represented by the Common Stock that would be acquired upon conversion of such debentures into common stock. In addition, in accordance with the terms of the 2002 Debenture Offering, the Company is obligated to seek shareholder approval to amend its Certificate of Incorporation to grant voting rights to the holders of the 2002 Debentures. Assuming the receipt of shareholder approval to the Company's Certificate of Incorporation to grant such voting rights, holders of the

2002 Debentures, including Galen, would be permitted to vote on all matters submitted to a vote of shareholders of the Company, voting together with holders of Common Stock as one class and having such number of votes as equal the numbers of votes represented by the Common Stock that would be acquired upon conversion of the 2002 Debenture into Common Stock. Assuming the receipt of shareholder approval to the Company's Certificate of Incorporation to grant voting rights to the holders of 2002 Debentures, Galen would control approximately 85.7% of the Company's voting securities (or approximately 55.9% after giving effect to the conversion of other convertible securities issued by the Company). Accordingly, Galen possesses sufficient voting rights to control the nomination and election of the board of directors of the Company without the need to convert its debentures into common stock.

On May 26, 1999, the Company completed a private offering of securities for an aggregate purchase price of up to approximately \$22.8 million (the "Oracle Offering"). The securities issued in the Oracle Offering consist of 5% convertible senior secured debentures (the "1999 Debentures") and common stock purchase warrants (the "1999 Warrants"). The 1999 Debentures and 1999 Warrants were issued by the Company pursuant to a certain Debenture and Warrant Purchase Agreement dated May 26, 1999 (the "1999 Purchase Agreement") by and among the Company, Oracle Strategic Partners, L.P. ("Oracle") and such other investors in the Galen Offering electing to participate in the Oracle Offering (inclusive of Oracle, collectively, the "Oracle Investor Group"). On the closing date of the Oracle Offering, the Company issued an aggregate of approximately \$12,862,000 in principal amount of 1999 Debentures. In accordance with the Oracle Purchase Agreement, Oracle funded an additional \$5 million investment installment on July 27, 1999. Pursuant to an agreement reached between the Company and Oracle on March 20, 2000, the final \$5 million investment to be made to Oracle under the 1999 Purchase Agreement has been waived.

The holders of the 1999 Debentures (including Oracle) are permitted to vote on all matters submitted to a vote of shareholders of the Company, voting together with holders of common stock as one class and having such number of votes as equals the number of votes represented by the common stock that would be acquired upon conversion of the 1999 Debentures into Common Stock. Accordingly, Oracle controls approximately 34.8% of the Company's voting securities without the need to convert the 1999 Debentures into Common Stock. The Oracle Purchase Agreement also provides that the Company must nominate and appoint to the Board of Directors, subject to shareholder approval, one designee of the Oracle Investor Group for so long as the 1999 Debentures and 1999 Warrants remain outstanding. Mr. Joel D. Liffmann, a current member of the Board of Directors, is a designee of the Oracle Investor Group and is a General Partner of Oracle Partners, L.P.

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 (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 Investments II, LP ("Care Capital"), Essex Woodlands Health Ventures V, L.P. ("Essex"), Galen and each of the purchasers listed on the signature page thereto (collectively, the "2002 Debenture Investor Group").

The 2002 Purchase Agreement provides that the holders of the 2002 Debentures shall have the right to vote as part of a single class with all holders of the Company's Common Stock on all matters to be voted on by such stockholders. Each 2002 Debenture holder shall have such number of votes as shall equal the number of votes he would have had if such holder converted the entire outstanding principal amount of his 2002 Debenture into shares of Common Stock immediately prior to the record date relating to such vote; provided, however, that any 2002 Debentures held by Care Capital shall, for so long as they are held by Care Capital, have no voting rights. In accordance with the terms of the 2002 Purchase Agreement, the Company will seek shareholder approval at its 2003 Annual Meeting of Shareholders to amend its Certificate of Incorporation to provide as-converted voting rights to the holders of the 2002 Debentures. Assuming the receipt of shareholder approval, Essex would control approximately 41.2% of the Company's voting securities (without giving effect to the conversion of other convertible securities issued by the Company).

The 2002 Purchase Agreement also provides that each of Care Capital and Essex has the right to designate one person for nomination to be a member of the Company's Board of Directors as of the closing date of the 2002 Debenture Offering (collectively, the "Designees"). The Purchase Agreement further provides that the Designees shall be, if so requested by such Designee in his sole discretion, appointed to the Company's Executive Committee, Compensation Committee and any other Committee of the Board of Directors. Accordingly, effective as of the closing of the 2002 Purchase Agreement, the Board of Directors appointed each of Jerry Karabelas and Immanuel Thangaraj to the Company's Board of Directors. Mr. Karabelas is a General Partner of Care Capital Investments II, LP an affiliate of Care Capital, LLC. Mr. Thangaraj is a Managing Director of Essex Woodlands Health Ventures V, an affiliate of Essex. The Company has agreed to nominate and appoint to the Board of Directors, subject to shareholder approval, one designee of each of the Care Capital and Essex for so long as each holds the 2002 Debentures.

As part of the closing of the 2002 Purchase Agreement, the Company and the purchasers of the 2002 Debentures, including Care, Essex and Galen, executed a certain Debentureholders Agreement providing, among other things, that the approval of the holders of at least sixty six and two-thirds percent (66 2/3%) of the aggregate principal amount of the 2002 Debentures is required to authorize (a) any modification of the rights of the holders of the 2002 Debentures, (b) any issuance of securities of the Company which rank senior or pari passu to the 2002 Debentures, (c) any dividends or distributions on, or redemption of, any securities ranking junior in priority to the 2002 Debentures, other than dividends or distributions payable in the Company's Common Stock or cash interest paid to individual investors in the Company's 1998 Debentures and 1999 Debentures (collectively, the "Existing Debentures"), (d) the merger or consolidation of the Company, the sale, transfer, lease or other disposition of all or substantially all the Company's consolidated assets, or the liquidation, recapitalization or reorganization of the Company, other than any such transaction where the cash, securities and/or other liquid consideration received for the voting stock of the Company in such transaction is at least four (4) times the then applicable conversion price of the 2002 Debentures, (e) any increase in the number of members comprising the Company's Board of Directors above eleven (11) members, and (f) the consummation of a strategic alliance, business combination, licensing arrangement or other corporate partnering involving the issuance by the Company of in excess of \$10,000,000 in equity securities of the Company.

The Debentureholders Agreement further provides that the holders of at least sixty six and two-thirds percent (66 2/3%) of the aggregate principal amount of the 2002 Debentures and Existing Debentures is required in order to authorize (a) any amendment to the Company's Certificate of Incorporation, (b) dividends or distributions on, or redemptions of, any securities ranking junior to the Existing Debentures, other than distributions or dividends payable in the Company's capital stock or cash interest paid to individual investors in the Existing Debentures, (c) any issuance of the Company's securities ranking senior or pari passu to the Existing Debentures, and (d) the completion of any transaction described in subsections (d), (e) and (f) in the preceding paragraph.

As part of the closing of the 2002 Purchase Agreement, each of Galen, Oracle, Michael Reicher, the Company's Chief Executive Officer, and Peter Clemens, the Company's Chief Financial Officer (collectively, the "Voting Agreement Parties") executed a Voting Agreement dated December 20, 2002 pursuant to which each agreed to vote all of their respective voting securities of the Company in favor of the amendments to the Company's Charter to increase the Company's authorized shares in order to permit the conversion of the 2002 Debentures and the Company's other outstanding convertible securities, and to provide voting rights to the holders of the 2002 Debentures. The voting securities held by the Voting Agreement Parties represent an aggregate of approximately 64.3% of the voting rights under the Company's outstanding voting securities.

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 has an exercise price of \$.34 per share. After giving effect to the terms of a Reserved Share Waiver (as defined and described in the paragraph below) the Watson Warrant is immediately exercisable for approximately 33.7% of the Company's Common Stock (without giving effect to the conversion of other convertible securities issued by the Company, including those issued to Galen).

In furtherance of the completion of the 2002 Debenture Offering, each of the Company, Galen, Oracle, Care Capital, Essex and Watson executed a certain Reserved Share Waiver Agreement dated December 20, 2002 (the "Reserved Share Agreement"). Under the terms of the Reserved Share Agreement, each of Galen and Oracle authorized the release of shares previously reserved by the Company for issuance under the 1998 Debentures, 1999 Debentures, 1998 Warrants and 1999 Warrants previously issued to Galen and Oracle, in order to provide sufficient authorized and unreserved shares to permit the conversion of the 2002 Debentures issued to each of Care Capital and Essex as well as the exercise of the Watson Warrant. As a consequence, even in the absence of the approval of the amendment to the Company's Charter described in Proposal 2 to this Proxy Statement, an aggregate of 40,112,429 shares of the Company's authorized Common Stock have been reserved for issuance in the event of the conversion of the 2002 Debentures issued to each of Care Capital and Essex and in the event Watson's exercise of the Watson Warrant.

On December 20, 2002, as part of the completion of the 2002 Debenture Offering, the Company consummated the terms of a Warrant Recapitalization Agreement (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 warrantholders a party thereto 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.

Each of Oracle, Michael and Susan Weisbrot, Dennis Adams, Bernard Selz and Hemant and Varsha Shah beneficially own in excess of 5% of the Company's voting securities. (See "Security Ownership of Certain Beneficial Owners and Management"). Each of such security holders participated in the Recapitalization Agreement. Oracle surrendered 4,786,956 Recapitalization Warrants in exchange for 3,649,461 shares of Common Stock. Michael and Susan Weisbrot surrendered 557,319 Recapitalization Warrants in exchange for 405,727 shares of Common Stock. Dennis Adams surrendered 913,034 Recapitalization Warrants in exchange for 608,844 shares of Common Stock. Bernard Selz surrendered 489,765 Recapitalization Warrants in exchange for 360,243 shares of Common Stock. Hemant and Varsha Shah surrendered 741,388 Recapitalization Warrants in exchange for 497,727 shares of Common Stock.

In addition to their participation in the Recapitalization Agreement, Michael and Susan Weisbrot and Bernard Selz surrendered their 10% Convertible Promissory Notes (issued by the Company pursuant to the 2001/2002 Galen Bridge Loans), plus accrued and unpaid interest in the aggregate amount of \$40,590 and \$342,454, respectively, in exchange for a 2002 Debenture in a like principal amount. Hemant and Varsha Shah surrendered their 10% Convertible Notes to the Company on December 20, 2002 for payment in full of \$128,535.

### ITEM 14. 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 IV

- ITEM 15. EXHIBITS, CONSOLIDATED FINANCIAL STATEMENTS, CONSOLIDATED 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 December 27, 2002, the Company filed a Current Report on Form 8-K. The Form 8-K described the completion of private offering of securities for an aggregate purchase price of \$26,394,000 (the "Offering"). The securities issued in the Offering consisted of 5% Convertible Senior Secured Debentures (the "Debentures"). The Debentures were issued by the Company pursuant to a certain Debenture Purchase Agreement dated December 20, 2002 (the "Purchase Agreement") by and among the Company, Care Capital Investments II, Essex Woodlands Health Ventures V, L.P., Galen Partners III, L.P. and each of the purchasers listed on the signature page thereto.

The Form 8-K also described the amendment to the Company's term loan agreement with Watson pursuant to which the principal amount of the Company's term loan from Watson was increased from \$17,500,000 to \$21,401,331 to reflect the inclusion of approximately \$3,901,331 owed by the Company to Watson under a product supply agreement between the parties. The term loan agreement with Watson was also amended to extend the maturity date from March 31, 2003 to March 31, 2006.

Finally, the Form 8-K described the completion of a Warrant Recapitalization Agreement dated December 20, 2002 pursuant to which common stock purchase warrants exercisable for an aggregate of 8,145,736 shares were recapitalized for an aggregate of 5,970,083 shares of common stock.

## (c) Exhibits

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

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 vear ended December 31, 1999). 3.2

**EXHIBIT** 

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")).

**EXHIBIT** NUMBER DOCUMENT - ---------- 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.

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(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
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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
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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
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EXHIBIT NUMBER DOCUMENT - ---------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/0xycodone 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).

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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
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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).

(incorporated

**EXHIBIT** NUMBER DOCUMENT - ---------- 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

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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
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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).

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EXHIBIT NUMBER
DOCUMENT - ----
 -----
 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
 Éxhibit 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, Tnc. (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).+

EXHIBIT NUMBER DOCUMENT - -------- ------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).

```
EXHIBIT NUMBER
DOCUMENT - ----
 -----
 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). 21 Subsidiaries of the Registrant. \*23.1 Consent of Grant Thornton LLP, independent certified public accountants. \*99.1 Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934. \*99.2 Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934. \*99.3 Certification of Periodic Report by Chief Executive Officer. \*99.4 Certification of Periodic Report by Chief Financial Officer.

\* Filed herewith.

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<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.

## 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.

By: /s/ MICHAEL REICHER

Michael Reicher, Chairman and Chief Executive Officer (Principal Executive Officer)

Date: May 6, 2003

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	May	6,	2003
William G. Skelly	·-			
/s/ MICHAEL REICHER	Chief Executive Officer and Director (Principal Executive Officer)	May	6,	2003
Michael Reicher				
	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer) and Director	May	6,	2003
Peter Clemens				
/s/ ALAN J. SMITH	Director	May	6,	2003
Alan J. Smith				
/s/ BRUCE F. WESSON	Director	May	6,	2003
Bruce F. Wesson	<del></del>			
/s/ WILLIAM SUMNER	Director	May	6,	2003
William Sumner	· <del>-</del>			
/s/ SRINI CONJEEVARAM	Director	May	6,	2003
Srini Conjeevaram	·-			
/s/ ZUBEEN SHROFF	Director	May	6,	2003
Zubeen Shroff				
/s/ JOEL LIFFMANN	Director	May	6,	2003
Joel Liffmann	· <del>-</del>			
/s/ JERRY KARABELAS	Director	May	6,	2003
Jerry Karabelas	·-			
/s/ IMMANUEL THANGARAJ	Director	May	6,	2003
Immanuel Thangaraj	·-			

## INDEX TO FINANCIAL STATEMENTS

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Certified Public Accountants
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### REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors and Stockholders HALSEY DRUG CO., INC.

We have audited the accompanying consolidated balance sheets of Halsey Drug Co., Inc. and Subsidiaries as of December 31, 2002 and 2001, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with 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 as of December 31, 2002 and 2001, and the consolidated results of their operations and their consolidated cash flows for each of the three years in the period ended December 31, 2002, 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.

GRANT THORNTON LLP

New York, New York February 26, 2003, except for Note B, as to which the date is May 5, 2003

## CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2002 2001
(IN THOUSANDS) CURRENT ASSETS
Cash
\$ 9,211 \$ 442 Accounts receivable trade, net of
allowances of \$14 and \$347 in 2002 and 2001,
respectively 610 367
Inventories
2,285 2,729 Prepaid expenses and other current
assets 394 238 Total
current assets 12,500
3,776 PROPERTY, PLANT AND EQUIPMENT,
NET 5,367 5,998 DEFERRED
PRIVATE OFFERING COSTS, net of accumulated amortization
of \$9 and \$1,471 in 2002 and 2001,
respectively
1,032 672 OTHER ASSETS AND
DEPOSITS 465 623
\$19,364 \$11,069 ====== =====

## CONSOLIDATED BALANCE SHEETS (CONTINUED)

DECEMBER 31, 2002 2001 (IN THOUSANDS, EXCEPT PER SHARE DATA) CURRENT LIABILITIES Current maturities of notes payable and capital lease
bbligations\$ 33 \$ 2,568 Accounts
payable3,119 2,979 Accrued
expenses
3,115 6,205 Department of Justice
settlement 300 300 Total current
liabilities 6,567 12,052
TERM NOTE
PAYABLE
21,401 17,500 CONVERTIBLE SUBORDINATED
DEBENTURES 77,118 48,534
Less: debt
discount
(73,955) (2,355) 3,163 46,179 CAPITAL LEASE
OBLIGATIONS
DEPARTMENT OF JUSTICE
SETTLEMENT
COMMITMENTS AND
CONTINGENCIES
STOCKHOLDERS' EQUITY (DEFICIT) Common stock \$.01
par value; authorized, 80,000 shares; issued and
outstanding, 21,035 shares and 15,065 shares in 2002 and 2001, respectively
151 Additional paid-in
capital
Accumulated
deficit
(161,090) (101,501) (12,268)
(65,436) \$ 19,364 \$ 11,069
======= =======

## CONSOLIDATED STATEMENTS OF OPERATIONS

YEAR ENDED DECEMBER 31,
2002 2001 2000 (IN THOUSANDS, EXCEPT PER SHARE DATA) Product
sales
\$ 8,205 \$ 8,429 \$ 15,223 Product development revenues
manufacturing
development
costs (126)
68 53 Loss from
operations (12,937) (5,939) (6,602) Other income (expense) Interest
expense
(4,728) (3,913) (3,699) Interest
income
costs
venture (202)
(57) Other income
(expense) (103) 13 101 Loss before
income tax benefit(59,589) (12,563) (12,043) Income tax
benefit
LOSS
\$(59,589) \$(12,563) \$(11,654) ======= ======
====== Basic and diluted loss per common share \$ (3.90) \$ (.84) \$ (.80) ======= ============================
of outstanding shares 15,262 15,021 14,503 =======

## CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000
TREASURY PAID- IN ACCUMULATED STOCK, SHARES
AMOUNT CAPITAL DEFICIT AT COST TOTAL
(IN THOUSANDS) Balance at January 1, 2000 14,830 \$148 \$ 35,751 \$ (77,284) \$(989) \$(42,374) Issuance of shares in payment of
interest
debentures 9 12 12 Deferred private issuance costs 125 125 Issuance of shares in payment of legal
fees
payable
2000
at December 31, 2000 14,961 149 35,440 (88,938) (53,349) Issuance of shares in payment of
interest
debt
2001 (12,563) (12,563) Balance
at December 31, 2001 15,065 151 35,914 (101,501) (65,436) Issuance of common stock in exchange for warrants 5,970 60
warrants
connection with debt 95,464 95,464 Modification of terms of existing
warrants 15,011 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) ======
=======================================

## CONSOLIDATED STATEMENTS OF CASH FLOWS

YEAR ENDED DECEMBER 31, (IN THOUSANDS, EXCEPT SHARE DATA) Cash flows from operating activities Net
loss\$(59,589) \$(12,563) \$(11,654)
amortization
acquisition costs 37 35 61 Provision for losses on accounts receivable 101 318 129 (Gain) loss on disposal of assets
(93) Common stock issued for legal expense 15 Common stock issued for trade payables 23  Debentures and stock issued for interest
expense 2,191 2,154 1,858 Loss on debt extinguishment 29,278 Write-own of investment in
affiliate
(382) (906) Inventories444 40 732 Prepaid expenses and other current
assets (156) 952 (809) Other assets and deposits
853 2,324 388 Accrued expenses
adjustments
(12,459) (2,090) (6,671) Cash flows from investing activities Capital expenditures
(287) (1,544) (2,962) Capital contribution to joint venture
16 28 93 Net cash used in investing activities (271) (1,605) (3,039) Cash flows from financing activities Proceeds from issuance of notes
payable
Exercise of stock  options96  Repayment of
debentures
issuance of convertible subordinated debentures
stock
provided by financing activities
year 442 697 786 Cash and cash equivalents at end of year \$ 9,211 \$ 442 \$ 697 =======
=======================================

# CONSOLIDATED STATEMENTS OF CASH FLOWS -- (CONTINUED) YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000 (IN THOUSANDS, EXCEPT SHARE DATA)

Supplemental disclosures of noncash investing and financing activities:

Year ended December 31, 2002

- 1. The Company issued 5,970,083 shares of common stock as result of recapitalization of warrants to purchase 8,145,736 shares of common stock and recorded a charge to earnings of \$2,282 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.
- The Company issued \$2,191 of debentures as payment of like amounts of debenture accrued interest.
- 6. The Company has 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, 2002, 2001 AND 2000 (IN THOUSANDS, EXCEPT SHARE DATA)

## Year ended December 31, 2001

- 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.
- 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.
- Equipment financed through capital leases aggregated approximately \$79.
- The Company issued \$300 in notes payable in exchange for \$300 in debentures that matured.

### Year ended December 31, 2000

- The Company issued 89,638 and 32,000 shares of common stock as payment for \$252 in debenture accrued interest and \$38 in trade payables and legal expenses.
- 2. The Company issued warrants to purchase 125,000 shares of common stock for the extension of the 2000 Galen Bridge Loan(s) maturity dates and recorded \$125 as deferred private issuance costs. The issuance costs were fully expensed during 2000.
- 3. The Company issued \$1,858 of debentures as payment for like amounts of debenture accrued interest.
- 4. Debentures of \$12 were converted into 8,834 shares of the Company's common stock.
- 5. The Company has paid \$1,003 of indebtedness in the form of product deliveries.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2002, 2001 AND 2000

### 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, are engaged in the development, manufacture, sale, and distribution of generic drugs and active pharmaceutical ingredients ("APIs"). During the last several years, the Company has sought to diversify its businesses through strategic acquisitions and alliances and through the development of technologies for the synthesis and production of APIs intended for sale to third parties as well as for use by the Company and others as raw materials in the manufacture of finished drug forms.

A summary of the significant accounting policies consistently applied in the preparation of the accompanying consolidated financial statements follows.

### 1. Principles of Consolidation and Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Houba, Inc., and 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 Halsey Pharmaceuticals, Inc. 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, 2002, 2001 and 2000. In addition, the Company paid interest of approximately \$136,000, \$683,000 and \$1,253,000 for the years ended December 31, 2002, 2001 and 2000, 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 within 30 days and are stated at amounts due from customers net of allowances for doubtful accounts, returns, term discounts, and other allowances. Accounts outstanding longer than the contractual payment terms are considered past due. Estimates that are used in determining these allowances are based on the Company's historical experience, current trends, credit policy and a percentage of its accounts receivable by aging category. In determining these percentages, the Company looks at the credit quality of its customer base as well as changes in its credit policies. The Company continuously monitors collections and payments from its customers. The Company writes off accounts receivable when they become uncollectible, and payments subsequently received on such receivables are credited to bad debt expense.

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

2002 2001 (IN THOUSANDS) Beginning
balance \$347
\$315 Provision for losses on accounts
receivable 101 402 Allowances
paid (434)
(286)
Recoveries
(84) Ending
balance\$
14 \$347 ==== ====

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

### 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.

## 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 K 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.

## 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 \$1,041,000 in deferred private offering costs during the year ended December 31, 2002 in conjunction with a private offering of securities. (See Notes B and H.) Deferred private offering costs are amortized to interest expense over the life of the related obligations.

### 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 by an independent valuation or 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 generally occurs upon shipment. The Company established sales provisions for estimated chargebacks, discounts, rebates, returns, pricing adjustments and other sales allowances concurrently with the

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

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.

## 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, including payments related to licensing agreements on products under development and research consulting agreements, are expensed when incurred.

### 12. Advertising Costs

Advertising costs are expensed as incurred. Advertising costs charged to operations for the years ended December 31, 2002, 2001 and 2000 were approximately \$288,000, \$39,000 and \$31,000, respectively.

### 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 2002, 2001 and 2000 computation are approximately 200,368,000, 52,976,000 and 50,636,000, respectively, of outstanding warrants and options and the effect of convertible debentures outstanding which would have been antidilutive.

## 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." 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

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, -----
----- 2002 2001 2000 -----
 ----- (IN
THOUSANDS, EXCEPT PER SHARE DATA) ------
----- Net loss,
       as
reported.....
 $(59,589) $(12,563) $(11,654) Deduct:
 Total stock-based employee compensation
expense determined under fair value-based
      method for all
awards.....
(1,047) (1,679) (2,099) -----
      ----- Pro forma net
 loss.....
 $(60,636) $(14,242) $(13,753) =======
 ====== Loss per share: Basic
    and diluted -- as
 reported..... $ (3.90) $
(.84) $ (.80) ------
     Basic and diluted -- pro
 forma..... $ (3.97) $
```

Pro forma compensation expense may not be indicative of future disclosures because they do not take into effect pro forma compensation expense related to grants before 1995. For purposes of estimating the fair value of each option on the date of grant, the Company utilized the Black-Scholes option-pricing model.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

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

GRANTS ISSUED DURING 2002 2001 2000 Expected life
(years)
10 10 Risk-free interest
rate 4.6%
5.3% 7.0% Expected
volatility
88% 86% 73% Dividend
yield
0.0% 0.0% 0.0% Weighted-average option fair
value \$1.12 \$1.87 \$1.38

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

## 17. New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also requires that intangible assets with definite useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of," as amended. The Company adopted the provisions of SFAS No. 142 effective January 1, 2002. The adoption of SFAS No. 142 had no effect on the financial position or results of operations of the Company.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 requires that long-lived assets be measured at the lower of carrying amount or fair value less cost to sell, whether reported in continuing operations or in discontinued operations. Therefore, discontinued operations will no longer be measured at net realizable value or include amounts for operating losses that have not yet occurred. SFAS No. 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001 and, generally, is to be applied prospectively. The adoption of SFAS No. 144 had no effect on the Company's financial position or results of operations.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections." This statement eliminates the requirement to report gains and losses from extinguishment of debt as extraordinary unless they meet the criteria of APB Opinion 30. SFAS No. 145 also requires sale-leaseback accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. The changes related to lease accounting are effective for transactions occurring after May 15, 2002 and the changes related to debt extinguishment are effective for fiscal years beginning after May 15, 2002. The impact of adopting the provisions related to lease accounting did not have a material impact on the Company's financial position or results of operations. The Company early adopted the provisions related to debt extinguishments during the year ended December 31, 2002. The adoption did not have a material impact on the Company's financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 nullifies Emerging Issues Task Force Issue No. 94-3 and requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. This statement also establishes that fair value is the objective for initial measurement of the liability. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The impact of the adoption of SFAS No. 146 is not expected to have a material impact on the Company's financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation -- Transition and Disclosure, an amendment of FASB Statement No. 123." SFAS No. 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for an entity that voluntarily changes to the fair value-based method of accounting for stock-based employee compensation. It also amends the disclosure provisions of that Statement to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation. The Company has chosen to continue to account for stock-based compensation using the intrinsic value method prescribed in APB Opinion No. 25 and related interpretations as provided for under SFAS No. 148. Accordingly, compensation expense is only recognized when the market value of the Company's stock at the date of the grant exceeds the amount an employee must pay to acquire the stock. The Company has adopted the annual disclosure provisions of SFAS No. 148 in its financial reports for the year

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

ended December 31, 2002 and will adopt the interim disclosure provisions for its financial reports for the quarter ended March 31, 2003. The adoption of SFAS No. 148 did not have a material impact on the Company's financial position or results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN No. 45 requires that upon issuance of a guarantee, a guarantor must recognize a liability for the fair value of an obligation assumed under a guarantee. FIN No. 45 also requires additional disclosures by a guarantor in its interim and annual financial statements about the obligations associated with guarantees issued. The recognition provisions of FIN No. 45 are effective for any guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of the disclosure requirements of FIN No. 45 did not have a material impact on the Company's financial position or results of operations. The Company is currently evaluating the effects of the recognition provision of FIN No. 45, but does not expect the adoption to have a material impact on the Company's financial position or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 "Consolidation of Variable Interest Entities." In general, a variable interest entity is a corporation, partnership, trust, or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. A variable interest entity often holds financial assets, including loans or receivables, real estate or other property. A variable interest entity may be essentially passive or it may engage in activities on behalf of another company. Until now, a company generally has included another entity in its consolidated financial statements only if it controlled the entity through voting interests. FIN No. 46 changes that by requiring a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. FIN No. 46's consolidation requirements apply immediately to variable interest entities created or acquired after January 31, 2003. The consolidation requirements apply to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The Company has adopted FIN No. 46 effective January 31, 2003. The Company does not anticipate that the adoption of FIN No. 46 will have a material impact on the Company's consolidated financial condition or results of operations taken as a whole.

### 18. Reclassifications

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

## NOTE B -- BASIS OF PRESENTATION AND LIQUIDITY MATTERS

At December 31, 2002, the Company had cash and cash equivalents of \$9,211,000, working capital of approximately \$5,933,000 and a stockholders' deficit of approximately \$12,268,000. The Company incurred a loss from operations of approximately \$12,937,000 and a net loss of \$59,589,000 during the year ended December 31, 2002.

On December 20, 2002, the Company consummated a private offering of securities for an approximate aggregate purchase price of \$26,394,000 (the "2002 Debenture Offering"). The securities issued in the Offering consisted of 5% convertible senior secured debentures (the "2002 Debentures"). Of the \$26,394,000 in 2002 Debentures issued in the 2002 Debenture Offering, approximately \$15,894,000 of the 2002 Debentures were issued in exchange for the surrender of a like amount of principal and accrued interest

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

outstanding under Company's 10% convertible promissory notes issued pursuant to various working capital bridge loan transactions with Galen Partners III, L.P., Galen International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen") and certain other lenders, during the period from August 15, 2001 through and including December 20, 2002. The 2002 Debentures, issued at par, will become due and payable as to principal on March 31, 2006. Interest on the principal amount of the 2002 Debentures, at the rate of 5% per annum, is payable on a quarterly basis. Interest on the 2002 Debentures will be substantially paid by the Company's issuance of a debenture instrument substantial identical to the 2002 Debentures issued in the 2002 Debenture Offering, in the principal amount equal to the accrued interest for each quarterly period. (See Note H)

Until such time as the Company successfully develops and commercializes new finished dosage products and active pharmaceutical ingredients, of which there can be no assurance, the Company will continue to incur operating losses and negative cash flow from operations. The Company believes that the proceeds received in the 2002 Debenture Offering, will be sufficient to satisfy the Company's working capital requirements only through June 2003. At the Company's request, on May 5, 2003, the Company received a letter executed by each of Care Capital Investments II, LP, Galen 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"). The Letter of Support provides that the amount of any funding provided by the Majority 2002 Debentureholders would be reduced to the extent of any funding obtained by the Company from third-party sources during 2003. The Letter of Support further provides that the terms of any funding provided by the Majority 2002 Debentureholders will be subject to negotiation between the Company and the Majority 2002 Debentureholders at the time of any such funding. The terms of any such funding will be subject to approval by those directors of the Company that are unaffiliated with the Majority 2002 Debentureholders. While the terms of any funding to meet the Company's 2003 capital requirements are currently unknown, it is likely that such terms will result in significant additional dilution to holders of the Company's Common Stock. 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 (which is equivalent to the conversion price of the 2002 Debentures), 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 party investment if lower than the exercise price of the warrants.

The Company believes that the remaining net proceeds of the 2002 Debenture Offering, along with the funding to be provided under the Letter of Support combined with cash flow from operations, will be sufficient to satisfy the Company's working capital requirements through January 1, 2004.

Failure to obtain a third party investment or to reach agreement with the Majority 2002 Debentureholders on mutually acceptable terms to fund the Company's capital requirements for 2003 will require the Company (i) to delay or cease the continued development of its licensed technologies and the completion of planned capital expenditures, (ii) to obtain funds through arrangements with third parties on terms that may require the Company to relinquish rights to its licensed technologies, which the Company would otherwise pursue on its own or that would dilute the Company's stockholders, (iii) significantly scale back or terminate operations and/or (iv) seek protection under applicable bankruptcy laws. An extended delay or a cessation of the Company's continuing development efforts related to its opiate synthesis technologies or delays in obtaining required DEA approvals, will have a material adverse effect on the Company's financial condition and results of operations.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

### 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, whereby \$3,500,000 was received from Watson.

## 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. 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.

## 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,

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

(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. The Company's remaining advance payments from Watson were \$3,901,331 at September 30, 2002. (See Note C-4.) 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.

## 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 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, 2002, Watson has advanced \$21,401,331 to the Company under the Watson Term Loan. (See Note I(a).)

## NOTE D -- 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 fair value of the Company's accounts payable, long-term and short-term debt cannot be determined without incurring excessive costs.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

## NOTE E -- INVENTORIES Inventories consist of the following: DECEMBER 31, ----- 2002 2001 -----(IN THOUSANDS) Finished goods.....\$ -- \$ 38 Work-inprocess..... 831 1,076 Raw materials..... 1,454 1,615 ----- \$2,285 \$2,729 ====== ===== NOTE F -- PROPERTY, PLANT AND EQUIPMENT Property, plant and equipment are summarized as follows: DECEMBER 31, ------ 2002 2001 -----(IN THOUSANDS) Machinery and equipment..... \$ 9,120 \$10,373 Construction in progress..... 157 730 Leasehold improvements..... 1,407 Building and building Land..... 44 44 ----- 13,588 14,897 Less accumulated depreciation and amortization (including \$15 in 2002 and \$3 in 2001 of capitalized lease amortization)..... (8,221) (8,899) ------ \$ 5,367 \$ 5,998 ====== ====== Included in machinery and equipment is equipment recorded under capitalized leases at December 31, 2002 and 2001, of \$114,000 and \$79,000, respectively. Depreciation and amortization expense for the years ended December 31, 2002, 2001 and 2000 was approximately \$835,000, \$861,000 and \$644,000, respectively. NOTE G -- ACCRUED EXPENSES Accrued expenses are summarized as follows: DECEMBER 31, ----- 2002 2001 ----- (IN THOUSANDS) Interest..... \$ 988 \$1,001 Accrued payroll and payroll taxes..... 497 177 Professional fees..... 388 314 Deferred product obligation..... -- 3,645

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

### NOTE H -- CONVERTIBLE SUBORDINATED DEBENTURES AND STOCK WARRANTS

At December 31, 2002 and 2001, convertible subordinated debentures outstanding and related debt discount related to the following issuances are as follows:

DECEMBER 31,
(IN THOUSANDS) ISSUANCE OF DEBENTURES 1998
Debentures
\$ 30,215 \$28,954 1999
Debentures
20,509 19,580 2002
, ,
Debentures
26,394 77,118 48,534 Less: Debt
·
discount
(73,955) (2,355)
=======================================

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 I(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, 2002 and 2001, 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 I(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, 2002 and 2001, the Company has issued

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

additional debentures as payment of accrued interest on the 1999 Debentures of \$2,647,000 and \$1,718,000, respectively.

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 I(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 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

The 2002 Purchase Agreement provides that the holders of the 2002 Debentures shall have the right to vote as part of a single class with all holders of the Company's Common Stock on all matters to be voted on by such stockholders. Each 2002 Debenture holder shall have such number of votes as shall equal the number of votes he would have had if such holder converted the entire outstanding principal amount of his 2002 Debenture into shares of Common Stock immediately prior to the record date relating to such vote, provided, however, that any Debentures held by a certain investor shall, for so long as they are held by that investor, have no voting rights.

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 I(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 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 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 Halsey Pharmaceuticals, Inc. 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, 2002, 2001 AND 2000

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 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 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.

### **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 \$364,000 and \$348,000 at December 31, 2002 and 2001, respectively. Interest expense on these debentures was approximately \$17,000, \$17,000 and \$16,000, for the years ended December 31, 2002, 2001 and 2000, respectively, of which approximately \$16,000, \$15,000 and \$10,000 was paid through the issuance of like debentures.

### NOTE I -- NOTES PAYABLE AND STOCK WARRANTS

At December 31, 2002 and 2001, notes payable consisted of the following:

DECEMBER 31, 2002 2001
(IN THOUSANDS) Term note
payable(a)
\$21,401 \$17,500 ======
loans(b)
\$ \$ 2,500 Capital lease
obligations 73 68
73 2,568 Less: Current
maturities (33)
(2,568) \$ 40 \$ ======

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

- (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, 2002 was 8.75%. 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.
- (b) On August 15, 2001, the Company executed a Bridge Loan Agreement pursuant to which the Company received \$2,500,000 (the "2001 Bridge Loan"). The proceeds of the 2001 Bridge Loan were used by the Company to satisfy in full the Company's 10% convertible subordinated debentures in the principal amount of \$2,500,000 issued in August 1996 and which matured on August 6, 2001. The 2001 Bridge Loan bore interest at the rate of 10% per annum. The 2001 Bridge Loan was convertible into common stock at a conversion price of \$3.012 per share, which conversion price equals the average trading price of the Company's common stock for the 20 days preceding the closing date. In consideration for the extension of the 2001 Bridge Loan, the Company issued warrants expiring August 15, 2008, to purchase an aggregate of 187,500 shares of the Company's common stock at an exercise price of \$3.012 per share. The relative estimated fair value of the warrants, \$310,000, was recorded as additional debt discount and was amortized over the life of the bridge loan.

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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

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

NOTE J -- INCOME TAXES

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

YEAR ENDED DECEMBER 31, ----\_\_\_\_\_ -----2002 2001 2000 -------- ----------- AMOUNT % AMOUNT % AMOUNT % -----(DOLLARS IN THOUSANDS) Federal statutory rate..... \$(20,260) (34.0)% \$(4,271) (34.0)% \$(4,095) (34.0)% Loss for which no tax benefit was provided..... 20,229 33.9 4,231 33.7 4,045 33.6 Federal tax carryback refund...... (389) (3.4) Department of Justice settlement..... 16 .1 21 .2 26 .2 Other..... 15 .0 19 .1 24 .2 ---------- ----- ----- --------- Actual tax benefit..... \$ -- --% \$ -- --% \$ (389) (3.4)% ======= ====== ===== =======

The Company has net operating loss carryforwards aggregating approximately \$147,800,000, expiring during the years 2011 through 2022.

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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

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

DECEMBER 31, 2002 2001
(IN THOUSANDS) Deferred tax assets Net operating loss
carryforwards \$ 66,484 \$ 39,455
Asset
reserves 320
315 Research and development tax
credit 29 104 Accrued
expenses 294
397 Capital loss
carryforwards 211 213
Depreciation and
amortization 378 408
Other
73 56 Gross deferred tax
assets 67,789 40,948
Deferred tax liabilities
Depreciation
(93) Net deferred tax assets before
valuation allowance 67,696 40,948 Valuation
allowance
(67,696) (40,948) Net deferred tax
assets \$ \$ ======
======

SFAS No. 109 requires a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. The valuation allowance at December 31, 2002 primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards.

## NOTE K -- CESSATION AND RELOCATION OF BROOKLYN, NEW YORK PLANT OPERATIONS

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 L -- 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

venture's ability to raise additional capital or to generate income from operations. During 2002, the partners in the joint venture began proceedings to dissolve the entity.

#### NOTE M -- 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 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 N -- EMPLOYEE BENEFIT PLANS

## 1. Employees' Pension Plan

The Company contributed approximately \$19,000 and \$56,000, in 2001 and 2000, respectively, 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). This plan was not administered by the Company 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.

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, 2002, the Company has not been notified of any withdrawal liability.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

## 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 2002, 2001 and 2000, 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, 2002, 8,207 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, 2002, 3,920,383 options are available for grant under the 1998 Option Plan.

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

WEIGHTED- STOCK AVERAGE OPTIONS EXERCISE OUTSTANDING PRICE Balance at January 1,
2000
Granted
2,262,000 1.50
Forfeited
(350,902) 2.04 Balance at December 31, 2000 4,521,317 1.86
Granted
540,000 2.15
Exercised
(52,000) 1.84
Forfeited
(419,367) 2.29 Balance at December 31, 2001 4,589,950 1.85
Granted
470,000 1.29
Forfeited
(51,000) 2.28 BALANCE AT DECEMBER 31, 2002 5,008,950 \$1.80

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

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

OPTIONS OUTSTANDING
OPTIONS
EXERCISABLE WEIGHTED
EXERCISABLE WEIGHTED
NUMBER AVERAGE WEIGHTED-
NUMBER WETGHTED-
OUTSTANDING AT REMAINING
AVERAGE EXERCISABLE AT
AVERAGE RANGES OF
DECEMBER 31, CONTRACTUAL
EXERCISE DECEMBER 31,
EXERCISE EXERCISE PRICES
2002 LIFE (YEARS) PRICE
2002 PRICE
\$
\$ .64-\$1.88
\$ .64-\$1.88
\$ .64-\$1.88
\$ .64-\$1.88
\$ .64-\$1.88
\$ .64-\$1.88
\$.64-\$1.88
\$.64-\$1.88
\$.64-\$1.88
\$.64-\$1.88
\$.64-\$1.88
\$.64-\$1.88
\$.64-\$1.88

## NOTE O -- 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, 2002, 2001 and 2000 was approximately \$993,000, \$986,000 and \$1,517,000, 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,

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

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 continues to provide contract manufacturing services to Par. The M&S Agreement further provides 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.

## 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.

As of December 31, 2002, the approximate minimum rental commitments under these operating leases are as follows:

	(IN THOUSANDS)			5		,	
2003.							
			\$ 844				
2004							
	224	Tot	al mini	mum pay	ments		
	required			\$1	1,068 ==	====	

### **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.

## 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

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, 2002, the Company is current in its payment obligations, with a remaining obligation of \$761,000.

### OTHER LEGAL PROCEEDINGS

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

The Company is named as a defendant in an action entitled Alfred Kohn v. Halsey Drug Co. in the Supreme Court of New York, Bronx County. The Plaintiff seeks damages of \$1 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. It is the Company's expectation to file for summary judgment in this action. In the event the Company is unsuccessful in its motion for summary judgment, a trial on this action will follow. 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.

## INDEMNIFICATIONS

Each of the purchase agreements for the Company's 1998 Debentures, 1999 Debentures and 2002 Debentures 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. These indemnification obligations do not include a limit

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED) DECEMBER 31, 2002, 2001 AND 2000

on maximum potential future payments, nor are there any recourse provisions or collateral that may offset the cost. As of December 31, 2002, the Company has not recorded a liability for any obligations arising as a result of these indemnification obligations.

#### NOTE P -- 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 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 and 2000, the Company had net product revenues to one customer in excess of 10% of total product revenues aggregating to 86% and 59%, respectively, of total product revenues. At December 31, 2001, accounts receivable from this customer aggregated 61% of gross accounts receivable. The loss of these customers would have a material adverse impact on the Company.

During 2002, 2001 and 2000, the Company purchased approximately \$1,264,000, \$1,512,000 and \$1,485,000 respectively, of its raw materials, representing approximately 26%, 25%, and 28% in each year, of total raw material purchases from one supplier.

NOTE Q -- QUARTERLY FINANCIAL DATA (UNAUDITED)

QUARTERLY FINANCIAL DATA

```
1ST 2ND 3RD 4TH QUARTER
 QUARTER QUARTER YEAR
-----
  --- (AMOUNTS IN
 THOUSANDS EXCEPT PER SHARE
  AMOUNTS) 2002 NET PRODUCT
REVENUES..... $ 1,881
  $ 2,258 $ 2,013 $ 2,053 $
      8,205 OPERATING
   LOSS.....
   (2,888) (3,379) (3,466)
    (3,204) (12,937) NET
   (5,479) (7,340) (7,869)
  (38,901) (59,589) LOSS PER
     SHARE -- BASIC AND
DILUTED.....
  $ (.36) $ (.49) $ (.52) $
  (2.46) $ (3.90) 2001 Net
product revenues.....
  $ 7,966 $ 1,962 $ 5,326 $
  1,675 $ 16,929 Operating
income (loss)..... 1,431
(2,985) (293) (4,092) (5,939)
          Net
loss.....
(106) (4,596) (1,903) (5,958)
 (12,563) Loss per share --
        basic and
diluted.....
  $ (.01) $ (.30) $ (.13) $
       (.40) $ (.84)
```

## SCHEDULE II -- VALUATION AND QUALIFYING ACCOUNTS

CHARGED TO CHARGED TO BALANCE AT BEGINNING COSTS AND OTHER END OF DESCRIPTION OF PERIOD EXPENSES
ACCOUNTS DEDUCTIONS PERIOD
(IN
THOUSANDS) YEAR ENDED DECEMBER 31,
2002 ALLOWANCES ACCOUNTS
RECEIVABLE \$ 347 \$ 101 \$
\$(434) \$ 14 ====== ===========================
===== YALUATION ALLOWANCE
DEFERRED TAX
ASSETS
\$40,948 \$26,748 \$ \$ \$67,696
====== ===== =====
====== YEAR ENDED DECEMBER 31,
2001 Allowances accounts
receivable \$ 315 \$ 402 \$
\$(370) \$ 347 ====== ======
===== ================================
deferred tax
assets
\$35,151 \$ 5,797 \$ \$ \$40,948
====== ===== =====
====== YEAR ENDED DECEMBER 31,
2000 Allowances accounts
receivable \$ 425 \$ \$
\$(110) \$ 315 ====== ============================
===== ================================
deferred tax
assets
\$29,404 \$ 5,747 \$ \$ \$35,151
====== ===== =====
======

ADDITIONS ADDITIONS BALANCE AT

## CONSENT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

We have issued our report dated February 26, 2003, except for Note B, as to which the date is May 5, 2003 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, 2002. 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 May 5, 2003 CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934

- I, Michael K. Reicher, the Chief Executive Officer of Halsey Drug Co., Inc., certify that:
- 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-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures 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 as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 6, 2003

/s/ Michael K. Reicher
Michael K. Reicher
Chief Executive Officer

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

- I, Peter A. Clemens, the Chief Financial Officer of Halsey Drug Co., Inc., certify that:
- I have reviewed this annual report on Form 10-K of Halsey Drug Co., Inc.;
- Based on my knowledge, this annual report does not contain any 2. 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;
- Based on my knowledge, the financial statements, and other financial 3. 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;
- The registrant's other certifying officers and I are responsible for 4. establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures 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 as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- The registrant's other certifying officers and I have indicated in 6. this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 6, 2003

/s/ Peter A. Clemens Peter A. Clemens

Chief Financial Officer

## CERTIFICATION OF PERIODIC REPORT

- I, Michael K. Reicher, the Chief Executive Officer of Halsey Drug Co., Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:
- (1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2002 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); 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: May 6, 2003

/s/ Michael K. Reicher
Michael K. Reicher
Chief Executive Officer

## CERTIFICATION OF PERIODIC REPORT

I, Peter A. Clemens, the Chief Financial Officer and Vice President of Halsey Drug Co., Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

- (1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2002 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); 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: May 6, 2003

/s/ Peter A. Clemens

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Peter A. Clemens Chief Financial Officer and Vice President