

# **ACURA PHARMACEUTICALS, INC**

# FORM 10-K (Annual Report)

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-K**

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 (Mark One)

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

For the fiscal year ended December 31, 1997

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

For the transition period from _	to
Commission f	file number 1-10113

# HALSEY DRUG CO., INC.

(Exact Name of Registrant as Specified in Its Charter)

New York (State or Other Jurisdiction of Incorporation or Organization)

695 North Perryville Road, Crimson Building No. 2, Rockford, Illinois 61107 (Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code (718) 467-7500

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class: Name of Each Exchange on Which Registered: Common Stock, Par Value \$0.01 The American Stock Exchange

Securities registered Pursuant to Section 12(g) of the Act:

None

None (Title of Class)

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. //

As of March 16, 1998, the registrant had 13,708,081 shares of Common Stock, par value \$0.01, outstanding. Based on the closing price of the

Common Stock on March 16, 1998 ( $\$3\ 1/16$ ), the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$32,933,000.

### DOCUMENTS INCORPORATED BY REFERENCE

Document
----Proxy Statement for the 1998 Annual Meeting of Shareholders

Where Incorporated
----Part III

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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" and elsewhere in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"). Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Halsey Drug Co., Inc. ("Halsey" or the "Company"), or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following:

changes in general economic and business conditions; loss of market share through competition; introduction of competing services by other companies; 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; regulatory obstacles to the introduction of new products 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.

#### PART I

#### ITEM 1. BUSINESS.

#### **GENERAL**

The Company, a New York corporation established in 1935, and its subsidiaries, are engaged in the manufacture, sale and distribution of generic drugs. 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. The Company sells its generic drug products under its Halsey label and under private-label arrangements with drugstore chains and drug wholesalers. 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.

Halsey's wholly-owned subsidiaries include Houba, Inc. ("Houba"), an Indiana corporation, Halsey Pharmaceuticals, Inc. ("Halsey Pharmaceuticals"), a Delaware corporation, Indiana Fine Chemicals Corporation ("Indiana Chemicals"), a Delaware corporation, H.R. Cenci Laboratories, Inc., a California corporation (97% owned) ("Cenci Laboratories"), and Cenci Powder Products, Inc. ("Cenci Powder"), a Delaware corporation. The Company also has two other subsidiaries, Blue Cross Products, Inc., a New York corporation, and The Medi-Gum Corporation, a Delaware corporation, each of which is inactive.

The Company manufactures its products at facilities in New York and Indiana. During 1995, in connection with the sale of its oxycodone with acetaminophen tablet business, the Company began manufacturing such product for a third party. See "Business-- Dispositions," below. During the last several years, the Company has sought to diversify its businesses through strategic acquisitions and through the development, manufacture and sale of bulk chemical products used by others as raw materials in the manufacture of finished drug forms.

#### RECENT EVENTS

#### **Regulatory Compliance**

During the past several years, the Company's business has been adversely affected by the discovery of various manufacturing and record keeping problems identified with certain products manufactured at its Brooklyn, New York plant. In October 1991, the U.S. Food and Drug Administration (the "FDA") placed the Company on the FDA's Application Integrity Policy list and its restrictions (collectively, the "AIP"). Under the AIP, the FDA suspended all of the parent company's applications for new drug approvals, including Abbreviate New Drug Applications ("ANDAs") and Supplements to ANDAs. During the period that followed, the U.S. Department of Justice ("DOJ") conducted an investigation into the manufacturing and record keeping practices at the Company's Brooklyn plant. As a consequence, on June 21, 1993, the Company entered into a plea agreement (the "Plea Agreement") with the DOJ to resolve the DOJ's investigation. Under the terms of the Plea Agreement, the Company agreed to plead guilty to five counts of adulteration of a single drug product shipped in interstate commerce and related record keeping violations. The Plea Agreement also required the Company to pay a fine of \$2,500,000 over five years in quarterly installments of \$125,000 commencing in September 1993. As of February 28, 1998, the Company was in

default of the payment terms of the Plea Agreement and had made payments aggregating \$350,000. On March 30, 1998, the Company and the DOJ signed a Letter Agreement serving to amend the Plea Agreement relating to the terms of the Company's satisfaction of the fine assessed under the Plea Agreement. The Letter Agreement provides, among other things, that the Company will satisfy the remaining \$2,150,000 of the fine through the payment of \$25,000 on a monthly basis commencing May 1, 1998, plus interest on the outstanding balance. The terms of the Letter Agreement are subject to the approval of the U.S. District Court for the District of Maryland. Prior to the execution of the Letter Agreement with the DOJ, the entire \$2,150,000 balance of the fine payable to the DOJ under the Plea Agreement had been classified as current. See "Item 3. Legal Proceedings" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources" for a more detailed description of the Letter Amendment to the Plea Agreement between the DOJ and the Company.

On June 29, 1993, the Company entered into a consent decree (the "Consent Decree") with the U.S. Attorney for the Eastern District of New York on behalf of the FDA that resulted from the FDA's investigation into the Brooklyn plant's compliance with the FDA's Current Good Manufacturing Practices ("CGMP") regulations. Under the terms of the Consent Decree, the Company was enjoined from shipping any solid dosage drug products (i.e., excluding liquid drug formulations) manufactured at the Brooklyn plant until the Company established, to the satisfaction of the FDA, that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling and holding any drug, were established, operated, and administered in conformity with the Federal Food, Drug, and Cosmetic Act and all CGMP Regulations. As part of satisfying these requirements, the Company was required to validate the manufacturing processes for each solid dosage drug product prior to manufacturing and shipping the drug product.

On October 23, 1996, the Company withdrew four of its ANDAs, including its ANDA (the "Capsules ANDA") for acetaminophen/oxycodone capsules (the "Capsules"), and halted sales of the affected products. Net sales derived from the withdrawn Capsule ANDA were approximately \$3 million and \$8 million for the years ended December 31, 1996 and December 31, 1995, respectively, and accounted for approximately 24% and 40% of the Company's total net sales during such twelve month periods. The Company instituted the withdrawal of the Capsule ANDA at the suggestion of the FDA and in anticipation of its release from the AIP. At the FDA's suggestion, the Company retained outside consultants to perform validity assessments of its drug applications. Thereafter, in October 1996, the FDA recommended that several applications, including the Capsule ANDA, be withdrawn. As a basis for its decision, the FDA cited questionable and incomplete data submitted in connection with the applications. The FDA indicated that the withdrawal of the four ANDAs was necessary for the release of the Company from the AIP. The FDA further required submission by the Company of a Corrective Action Plan, which was prepared and submitted by the Company and accepted by the FDA.

On December 19, 1996, the FDA released the Company from the AIP. As a consequence, for the first time since October 1991, the Company was permitted to submit ANDAs to the FDA for review. Since its release from the AIP in December 1996, through the fiscal year ended December 31, 1997, the Company submitted six ANDAs for review by the FDA, including a new ANDA with respect to the Capsules. During the period from the Company's release from the AIP to March 15, 1998, the Company received the following ANDA approvals, all of which relate to ANDA filings made with the FDA subsequent to the Company's release from the AIP:

Product Name (Drug Class)	Strength	Trade Name	Status
Hydrocodone Bitartate and Acetaminophen Tablets (narcotic analgesic)	5mg/500mg	Vicodin (1)	FDA approval of ANDA received September 26, 1997.
Hydrocodone Bitartate and Acetaminophen Tablets (narcotic analgesic)	7.5mg/750mg	VicodinES(R)(1)	FDA approval of ANDA received September 26, 1997.
Hydrocodone Bitartate and Acetaminophen Tablets, CIII (narcotic analgesic)	7.5mg/650mg	Lorcet Plus(R)(2)	FDA approval of ANDA received November 26, 1997.
Hydrocodone Bitartrate and Acetaminophen Tablets, CIII (narcotic analgesic)	10mg/650mg	Lorcet(R)(2)	FDA approval of ANDA received November 26, 1997.
Oxycodone HCI and Acetaminophen Capsules, CII (narcotic analgesic)	5mg/50mg	Tylox(R)(3)	FDA approval of ANDA received January 22, 1998.

<sup>(1)</sup> Registered trademark of Knoll Pharmaceutical Co.

<sup>(2)</sup> Registered trademark of Forest Laboratories, Inc.

<sup>(3)</sup> Registered trademark of McNeil Consumer Products Company

As of March 15, 1998, the Company had submitted two ANDAs for review by the FDA in fiscal 1998 and anticipates the submission of eight additional ANDAs during the balance of fiscal 1998. Although the Company has been successful in receiving the ANDA approvals described above since its release from the AIP in December 1996, there can be no assurance that any of its newly submitted ANDAs, 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 obtaining such approval, would adversely affect the Company's business operations and financial condition.

#### **Private Offering**

On March 10, 1998, the Company completed a private offering of securities (the "Offering") to Galen Partners, III, L.P., Galen Partners International III, 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 dated March 10, 1998 between the Company and such Purchasers (inclusive of Galen, collectively the "Galen Investor Group"). The securities issued in the Offering consisted of 5% convertible senior secured debentures (the "Debentures") and common stock purchase warrants (the "Warrants") exercisable for an aggregate of 4,202,020 shares of the Company common stock. The net proceeds to the Company from the Offering, after the deduction of related Offering expenses, was approximately \$19.6 million.

Immediately prior to the completion of the Offering, the Company was attempting to address various actions and proceedings which threatened the Company's continuing operations, most of which stemmed from the Company's lack of working capital to satisfy outstanding liabilities. In particular, the Company's Banks had given notice of a forced sale of certain of their security relating to the Company's outstanding bank indebtedness, which would have resulted in the loss of Houba's Indiana facility. In addition, the landlord of the Company's Brooklyn facility had served the Company with a notice of eviction and various creditors had obtained judgments against the Company and filed restraining notices against its bank accounts. A lack of funding also resulted in the Company being unable to purchase meaningful quantities of raw materials and left inventories depleted and sales reduced.

The net proceeds of the Offering have, in large part, been used to satisfy a substantial portion of the Company's liabilities and accounts payable. Such liabilities include the full satisfaction of the Company's Bank indebtedness and related fees, payment to the landlord of the Brooklyn facility and satisfaction of outstanding judgments and liens. Such repayments have allowed the Company to avoid the threatened foreclosure sale by its Banks of the Indiana facility securing such indebtedness. Additionally, pursuant to agreements reached with other large creditors in anticipation of the completion of the Offering, including the Company's landlord and the DOJ, the Company has been able to bring these creditors current and will be in compliance with installment payment agreements providing favorable terms to the Company. Satisfaction of the Company's current obligations to its landlord of the Brooklyn facility for accrued and unpaid rent, penalties and expenses has allowed the Company to renegotiate its lease and avoid eviction. The Offering proceeds will also allow the Company to satisfy its outstanding state and Federal payroll tax obligations and meet current payroll tax obligations.

After giving effect to the application of the net proceeds of the Offering, and based on Management's belief as to the Company's ability to defer a portion of the Company's remaining notes and accounts payable and certain other assumptions, the Company believes that it will have working capital of approximately \$3

million. See "Item 7. Management's Discussion and Analysis of the Financial Condition and Results of Operations--Liquidity and Capital Resources."

Under the rules of the American Stock Exchange ("AMEX") on which the Company's shares are listed for trading, the Company was required to obtain the approval of its shareholders in order to complete the Offering. In view of the Company's financial condition, its need for immediate capital and the delay associated with soliciting the approval of its shareholders, the Company requested a waiver from the AMEX in order to complete the Offering without the necessity of obtaining shareholder approval. In requesting the waiver, the Company provided detailed information, including a written submission, to the AMEX and met with representatives of the AMEX to discuss the proposed terms of the Offering, the experience of new Senior Management, Galen's investment history and the urgent need to complete the Offering on or before March 11, 1998 in order to allow for the payment of the liabilities previously described, some of which threatened to cease the Company's continuing operations.

The AMEX granted the Company's request for the waiver from its shareholder approval requirement in connection with the Offering in order to permit its timely completion. As part of this process, the AMEX suspended trading in the Company stock commencing Friday, March 6, 1998. Trading on the AMEX resumed on Monday, March 16, 1998 following the circulation on March 11, 1998 of a Press Release to the Company's shareholders of record describing the terms of the Offering and its completion on March 10, 1998. Such press release was also distributed over the wire services on Friday, March 13, 1998.

Reference is made to the Company's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 24, 1998 which describes, among other things, the Offering and the terms of the Debentures and Warrants issued in the Offering. The Form 8-K is incorporated herein by this reference and attached as Exhibit 10.41 hereto.

#### **Cessation of California Operations**

On March 20, 1998, the Company discontinued the operation of Cenci Laboratories. Cenci Laboratories had been a manufacturer of drug products in liquid and powder preparations. Continuing operating losses and the Company's inability to leverage the manufacturing capacity of Cenci Laboratories were among factors considered by the Board and Management in its determination to cease such operations.

On March 26, 1998, the Company signed a Letter of Intent with Zuellig Botanicals for the sale of substantially all of the non-real property assets of Cenci Powder. The Letter of Intent provides that the purchase price for the assets will consist of the forgiveness by Zuellig Botanicals of approximately \$262,000 in indebtedness owed by Cenci Powder to Zuellig Botanicals related to the purchase of raw materials. The Letter of Intent provides further that Zuellig Botanicals will satisfy the manufacture and delivery requirements of Cenci Powder at its located facility in Fresno, California, under an existing third party supply contract. Additionally, the Letter Agreement contemplates a right of first refusal in favor of an affiliate of Zuellig Botanicals to supply the Company's raw material requirements for the production of doxycycline. The terms of the Letter Intent are subject to the negotiation and execution of definitive purchase agreements, of which there can be no assurance. It is the Company's intent to dispose of the real property owned by Cenci Powder in Fresno, California in the ordinary course. Continuing operating losses and the Company's

inability to leverage the manufacturing capacity of Cenci Powder were among the factors considered by the Board and Management in its determination to terminate the operations of Cenci Powder.

#### PRODUCTS AND PRODUCT DEVELOPMENT

#### **Generic 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 27 products, consisting of 18 dosage forms and strengths of prescription drugs and 9 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, or
- 5. Antitussives.

During fiscal 1997, sales of antitussives and narcotic analgesics accounted for approximately 90% of total net sales during such year. The Company anticipates that sales of antitussives 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. In addition, the Company will continue to pursue the development of its existing pharmaceutical business as well as the development of the chemical products business of its Houba subsidiary.

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.

#### **Bulk Chemical Products**

In the last few years, the Company has increased its efforts to develop, manufacture and market bulk chemical products. The development and sale of bulk chemicals is generally not subject to the same level of regulation as is the development and sale of drug products; accordingly, chemicals may be brought to market substantial sooner than drug products.

### **Dispositions**

On March 21, 1995 (the "Closing Date"), the Company sold to Mallinckrodt its Tablets ANDA for 5 mg Oxycodone HCI/325 mg Acetaminophen tablets ("Tablets"), and certain pieces of equipment utilized in connection with its production activities under the Tablets ANDA, for up to \$5.4 million (the "Purchase Price"). Mallinckrodt paid the Company \$2 million of the Purchase Price on the Closing Date, having previously paid \$500,000 in July 1994. The \$2.9 million balance of the Purchase Price (the "Deferred Payment") was payable as follows. Mallinckrodt paid \$1 million on January 9, 1997, following the Company's release from the AIP program. In connection with the transaction, Mallinckrodt agreed to defer \$1.2 million of the Company's trade debt due to an affiliate of Mallinckrodt. The deferred indebtedness was evidenced by a promissory note (the "Note") with interest accruing at a rate of 8% per annum. On September 21, 1997 Mallinckrodt offset a portion of its remaining Deferred Payment obligations against the amount due on the Note. The remaining portion of the Deferred Payment has been satisfied and the purchase transaction has been finalized.

In connection with the sale of the Tablets ANDA, the Company agreed to manufacture Tablets for Mallinckrodt for a period of three years and Mallinckrodt agreed to order a minimum number of Tablets from the Company for the two year period following the Closing Date. The Company and Mallinckrodt also entered into a non-competition agreement pursuant to which the Company agreed not to compete with Mallinckrodt and its affiliates in the United States with respect to the Tablets ANDA until March 21, 2000. If, prior to the time it is possible for Mallinckrodt to commence production under the Tablets ANDA or any new Tablets ANDA at its own facility, the Company ceases or is forced to cease or substantially curtail production under the Tablets ANDA, as a consequence of (i) any action or communication by the FDA or any other regulatory or governmental authority or (ii) any financial or other business difficulty, then Mallinckrodt has the right to a full refund of any portion of the Deferred Payment already made to the Company. During fiscal 1997, approximately \$2,024,000 of the Company's revenues (approximately 22%) were derived from the toll manufacturing agreement with Mallinckrodt for the Tablets.

In connection with the sale of the Tablets ANDA, the Company issued to Mallinckrodt an option exercisable at any time until March 21, 1998 (the "Option Exercise Date"), to purchase the Capsule ANDA at an exercise price equal to 75% of Net Capsule Revenue, subject to downward adjustment in the event of a decline in pricing levels. Mallinckrodt did not exercise its option to purchase the Tablets ANDA prior to the Option Exercise Date.

### Acquisitions

The Company has engaged Penick Corporation ("Penick") to process certain of the raw materials utilized in the production of acetaminophen/oxycodone tablets. In order to ensure the continued viability of Penick, the Company's Houba subsidiary purchased a 25% equity interest in Penick in mid-1993. In addition, in September 1995, Houba purchased an 8.3% equity interest in Penick Pharmaceutical, Inc., which owns the other 75% of Penick. In May 1996, the Company advanced Penick approximately \$250,000 in

order to continue the supply of raw materials for the production of acetaminophen/oxycodone capsules. In June 1994, both Penick Corporation and Penick Pharmaceutical, Inc, filed petitions under Chapter 11 of the United States Bankruptcy Code. During the first quarter of 1997, the Company ceased purchasing raw materials from Penick in favor of a new raw material supplier. See "Raw Materials."

#### RESEARCH AND DEVELOPMENT

The Company conducts research and development activities at each of its Brooklyn and Indiana facilities. The Company's research and development activities consist primarily of new generic drug product development efforts and manufacturing process improvements, as well as the development for sale of new chemical products. 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 1997, 1996 and 1995, total research and development expenditures were \$979,000, \$1,854,000 and \$818,000 respectively. During 1998 the Company intends to concentrate its research and development efforts in the areas of pain management and steroids:

As of March 15, 1998, the Company maintained a full-time staff of two and a part-time staff of six in its Research and Development Departments.

#### MARKETING AND CUSTOMERS

The application of the AIP 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 resulted in the Company's inability to maintain sufficient raw materials and finish goods inventories to permit the Company to actively solicit customer orders, and when orders were received, to fill such orders promptly. Following the completion of the Offering, new Management adopted a marketing strategy focused on developing and maintaining sufficient raw materials and finish 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. In this regard, the Company has recently hired Stephanie Heitmeyer to serve as Vice President of Sales. The Company believes this addition will substantially enhance the Company's marketing and sales efforts and complement the Company's existing two salaried sales persons. The Company's products are, in large part, be sold by such sales persons and, to a lesser extent, through one independent sales representative, who is compensated on a commission basis. The Company is also considering the addition of one additional independent sales representative. Sales of the Company's drugs in dosage form are made primarily to drug wholesalers, drugstore chains, distributors and other manufacturers and are not concentrated in any specific region.

During 1997, the Company had net sales to one customer in excess of 10% of total sales, aggregating 22.3% of total sales, and sales to a second customer aggregating 9.8% of total sales. The Company believes that the loss of this customer would have a material adverse effect on the Company. During 1996, the Company had net sales to one customer in excess of 10% of total sales, aggregating 10% of total sales. During 1995, the Company had net sales to two customers in excess of 10% of total sales, each aggregating 25% and 11% of total sales, respectively.

The estimated dollar amount of the backlog of orders for future delivery as of March 15, 1998 was approximately \$800,000 as compared with approximately \$3,560,000 as of February 28, 1997. Although these orders are subject to cancellation, management expects to fill substantially all orders by the second quarter of 1998.

#### 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. 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. Recent changes in FDA procedures have increased the time and expense involved in obtaining ANDA approvals and in complying with the FDA's CGMP standards. 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. Generally, a drug which is the generic equivalent of a previously approved prescription drug will be treated as a new drug requiring FDA approval. Furthermore, each dosage form of a specific generic drug product requires separate approval by the FDA. However, as discussed below, less costly and time consuming approval procedures may be used for generic equivalents. Among the requirements for drug approval is that the prospective manufacturer's methods must conform to the 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 inspected on a regular basis by the FDA and by consultants retained by the Company to perform self-auditing functions to ensure compliance on an ongoing basis with CGMPs. See also Item 3. "Legal Proceedings."

In addition, products marketed outside the United States, but which are manufactured inside the United States, are subject to certain FDA regulations, as well as regulation by the country in which the products are to be sold.

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.
- 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 relevant product and use patents for the equivalent brand name drug have expired or have been determined to be invalid. The only exceptions are situations in which the ANDA applicant challenges the validity or applicability 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. Alternative New Drug Applications. An alternative NDA procedure is provided by the 1984 Act whereby the applicant may rely on published literature and more limited testing requirements. That alternative seldom provides advantages over the ANDA procedure, however, and is accordingly rarely 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. The Company was not debarred as a result of the FDA investigation and settlement and the Consent Decree with the FDA makes no provision therefor.

#### **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.

#### **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. The Company believes that

it was at a competitive disadvantage until its release from the AIP program and the FDA's resumption of review of ANDAs submitted by the Company's Brooklyn plant. See "Government Regulation--Generic Drug Enforcement Act" above. 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 bulk pharmaceutical chemicals 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 1997, the Company purchased approximately \$1,187,000 of its raw materials (constituting 24.7% of its aggregate purchases of raw materials) from Mallinckrodt. 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, an acceptable alternative source of raw materials would have a material adverse effect on the Company.

The United States Drug Enforcement Administration (the "DEA") limits the quantity of the Company's inventories of certain raw materials used in the production of controlled substances based on historical sales data. In view of the Company's recently depressed sales volume, these DEA limitations 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.

#### **EMPLOYEES**

As of March 15, 1998, the Company had approximately 142 full-time employees. Approximately 30 are administrative and professional personnel and the balance are in production and shipping. Among the professional personnel, 2 are engaged in research and product development. Approximately 65 employees at the Company's Brooklyn plant are represented by a local collective bargaining unit. The collective bargaining agreement between the Company and the union was extended on March 5, 1998 (retroactive to July 2, 1997) and expires June 30, 2000. Management believes that its relations with its employees and the union are satisfactory.

#### **ITEM 2. PROPERTIES**

Halsey leases, as sole tenant, a total of approximately 112,300 square feet, in three buildings on Pacific Street and Dean Street in Brooklyn, New York. Each of these leases is between Halsey and unaffiliated lessors. The approximate aggregate minimum rental commitments under these operating leases are as follows: \$928,000 for the year 1996, \$975,000 for the year 1997 and \$1,029,000 for the year 1998. As part of the completion of the Offering, the Company settled a pending proceeding with its landlord for the Brooklyn facility to, among other things, satisfy rent arrearages, penalties and other charges and to delete certain prior amendments to the Lease Agreements requiring more frequent rental payments and the imposition of substantial penalties. These leases expire on December 31, 2005. The buildings leased by Halsey in Brooklyn house its research and development and manufacturing facilities.

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 lease has a term of two years expiring March 30, 2000 and calls for annual rental, including maintenance and common area expense, of approximately \$50,000 per year. The Company is in the process of making necessary leasehold improvements and additions of computer and office furniture and equipment in order to operate the Company's principal executive offices from this location, including its sales, administration and finance operations.

Houba 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 Doxycycline raw materials, Doxycycline capsules and tablets and Biotin raw materials. In 1996, in conjunction with a settlement with two former employees, the Company acquired real property, improved by a residential property, in Culver, Indiana adjacent to the manufacturing facility. The Company became the lessor of the residential property upon closing of the acquisition.

Cenci Laboratories and Cenci Powder together own approximately 6,700 square feet of manufacturing and distribution building space located on approximately one-half acre in Fresno, California. In addition, Cenci Laboratories and Cenci Powder lease approximately 18,000 square feet of space in a building located in Fresno, California used for manufacturing and corporate offices. This lease is currently on a month-to-month basis and is anticipated to be terminated on or about May 31, 1998 as part of the cessation of the Cenci Laboratories and Cenci Powder operations. See "Item 1. Business - Recent Events

- Cessation of California Operations." During the years ended December 31, 1997, 1996 and 1995, Cenci and Cenci Powders paid an aggregate of \$90,000, \$90,000 and \$86,000 respectively, to a former officer of Cenci Laboratories and Cenci Powder in respect of this lease.

The Company also leases office space in Westwood, New Jersey for its marketing and sales departments on a year-to-year basis. It is anticipated that this lease will be terminated on April 30, 1998 as part of the relocation of the Company's corporate headquarters to Rockford, Illinois.

#### ITEM 3. LEGAL PROCEEDINGS.

#### GOVERNMENT CONSENT DECREES

On June 21, 1993, the Company entered into a Plea Agreement with the DOJ to resolve the DOJ's investigation into the manufacturing and record keeping practices of the Company's Brooklyn plant. Under the terms of the Plea Agreement, the Company agreed to plead guilty to five counts of adulteration of drug products shipped in interstate commerce. Each count involved product adulteration and record keeping deficiencies relating to a single drug product, Quinidine Gluconate (324mg tablets), manufactured at the Brooklyn plant. The Plea Agreement also 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. The Company's plea was entered and the terms of the Plea Agreement were approved by the United States District Court for the District of Maryland on July 16, 1993. As of February 28, 1998, the Company was in default of the payment terms of the Plea Agreement and had made payments aggregating \$350,000. On March 30, 1998, the Company and the DOJ signed a 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 provides that the Company will satisfy the remaining \$2,150,000 of the fine through the payment of \$25,000 on a monthly basis commencing May 1, 1998, plus interest on such outstanding balance (at the

rate calculated pursuant to 28 U.S.C. Section 1961)(currently 5.319%). Such payment schedule will result in the full satisfaction of the DOJ fine in December, 2005. The Letter Agreement also provides certain restrictions on the payment of salary or compensation to any individual in excess of \$150,000 without the written consent of the United States District Court for the District of Maryland, subject to certain exceptions. In addition, the Letter Agreement requires the prepayment of the outstanding fine to the extent of 25% of the Company's after tax profit and 25% of the net proceeds received by the Company on any sale of a capital asset for a sum in excess of \$10,000. The terms of the Letter Agreement are subject to the approval of the U.S. District Court for the District of Maryland.

See "Item 1. Business - Recent Events" for information regarding the release of the Company from the FDA's AIP program and resumption by the FDA of review of ANDAs filed by the Company.

#### OTHER GOVERNMENTAL PROCEEDINGS

By letter dated October 23, 1995, the Company was notified by the New York State Education Department (the "Department") that the Professional Conduct Officer of the Office of Professional Discipline had determined that there was sufficient evidence of professional misconduct on the Company's part to warrant a disciplinary proceeding under New York law. Upon contacting the Deputy Director of the Office of Professional Discipline, counsel for the Company was advised that the alleged misconduct related to the same activities that were the subject of the DOJ investigation. The Company submitted a written response to the Department on November 16, 1995. The Company and the Department entered into a consent order effective July 18, 1997, concluding any disciplinary proceedings. The consent order requires that the Company pay \$175,000 in fines over a period of five years. The consent order also provides that the Company's registration as a manufacturer of drugs in New York State is revoked, but such revocation is stayed and the Company has been placed on probation for a maximum period of five years. The Company has the right to apply for removal from probation two years after the effective date of the consent order.

Immediately prior to the completion of the Offering, the Company was in default under the consent order with the Department for failure to satisfy two of the monthly installments of the fine as provided in the consent order. Prior to the completion of the Offering, the Company advised the Department as to the existence of the default and that such deficiencies would be corrected upon the completion of the Offering. The Company has satisfied these outstanding amounts and is now current under the consent order with the Department. Based on discussions between representatives of the Department and the Company's outside counsel handling this matter, the Company has been advised that the revocation of the Company's registration as a manufacturer of drugs in the State of New York will remain stayed and that the Company continues to have the right to apply for removal from probation after two years from the effective date of the consent order.

On November 9, 1995, the Company received two Notices of Charge of Discrimination from the United States Equal Employment Opportunity Commission relating to two claimed violations of Title VII of the Civil Rights Act of 1964. The first charge of employment discrimination was filed on October 31, 1995 by a female employee of the Company and alleges sexual discrimination and harassment. A second separate charge of discrimination was also filed on October 31, 1995, by another female employee alleging sexual harassment against the same individual named in the first charge of discrimination. On November 20, 1995, the EEOC terminated its process with respect to the charges and issued Notices of Right to Sue to the claimants. In February 1996, two lawsuits were filed in the Eastern District of New York captioned Golovatskaya v. Halsey Drug Co., 96 CIV 0662 and Petrakova v. Halsey Drug Co., 96 CIV 0660 in connection with the above charges. The lawsuits sought unspecified damages. These actions were settled

by the Company on September 26, 1997 and an aggregate payment of \$12,400 made on March 27, 1998 (approximately \$5,200, in the case of Golovatskaya and approximately \$7,200, in the case of Petrakova).

#### **CENCI PROCEEDING**

The Company was named as a defendant in a lawsuit in the United States District Court for the Eastern District of California entitled Cenci v. Halsey Drug Co. The claims in this lawsuit relate to a 1991 Stock Purchase Agreement pursuant to which the Company purchased 51% of the stock of Cenci Labs and Cenci Powder.

The plaintiff, both individually and as a shareholder of Cenci Labs and Cenci Powder, had sued the Company, one of the current officers and two former officers of the Company. The complaint alleged that the Company had breached a number of representations made during the course of the negotiations leading to the stock purchase, including the representation that the Company would provide financial assistance to both Cenci Labs and Cenci Powder. The complaint also alleged misrepresentations relating to the scope of FDA's investigation of the Company.

The Complaint, which included several causes of action, sought unspecified compensatory damages, as well as punitive damages, rescission, specific performance, reformation and a declaration as to what amount, if any, was owed to plaintiff. The counterclaims of the Company sought unspecified compensatory and punitive damages.

On March 10, 1997, a Settlement Agreement and Mutual Release was executed by all parties to the lawsuit, terminating the action. The terms of the Settlement provide for repayment of certain outstanding loan, made by the plaintiff to Cenci Labs and Cenci Powders, as well as payment of settlement funds, aggregating \$600,000, to be paid in equal monthly installments, without interest, from March 1997 to June 1998 and the delivery to the plaintiff of 25,000 shares of unregistered common stock of the Company. The Settlement Agreement further provided for the balance of capital stock of Cenci Labs and Cenci Powder to be conveyed to the Company, making Cenci Powder and Cenci Labs 100% and 97% owned subsidiaries, respectively, of the Company. Following with the completion of the Offering, the Company satisfied its outstanding monetary obligations to the plaintiff under the Cenci litigation in connection with the execution of an Acknowledgment of Partial Satisfaction of Judgment by the plaintiff. The Company, however, is obligated to remove the restrictions on the 25,000 shares of the Company's common stock previously tendered to the plaintiff.

#### OTHER PENDING LEGAL PROCEEDINGS

The Company was named as a defendant in an action captioned Allied Welfare Fund, Vacation Fringe Benefit Fund and Union Mutual Fund v. Halsey Drug Co., 96 Civ 3655, brought in the United States District Court for the Eastern District of New York. The Complaint sought sums allegedly owed to three of the Company's labor union funds under the Company's collective bargaining agreement, in the amount of approximately \$265,000. A settlement agreement was reached between the parties and executed July 31, 1997 requiring the Company to remain current on its obligations under its collective bargaining agreement and to pay portions of the alleged arrearages in installments. Prior to the completion of the Offering, the Company was in default under the settlement agreement. On March 19, 1998, the Company satisfied its obligations under the settlement agreement pursuant to the payment of \$309,151 to the Union

On March 4, 1992, an action was commenced against the Company and numerous other pharmaceutical manufacturers in the Pennsylvania Court of Common Pleas, Philadelphia Division, captioned Ciavarelli and Ciavarelli v. Abbott Laboratories, Inc., et al. The Complaint contains seven causes of action, including negligence, strict liability and breach of warranty, among others, in connection with the alleged exposure of Ms. Ciavarelli to diethylstilbestrol ("DES"). The plaintiff was unable to determine which of the defendants produced the DES used by Ms. Ciavarelli. The Complaint seeks in excess of \$25,000 in compensatory and punitive damages. This matter has been referred to the Company's insurance carrier for defense, which has been assumed. Twenty additional actions commenced during 1992 and 1993 are still pending against the Company along with numerous other pharmaceutical manufacturers in the Pennsylvania Court of Common Pleas, Philadelphia Division. Each of these actions alleges injury in connection with exposure to DES and each seeks in excess of \$25,000 in compensatory and punitive damages. In each suit, the plaintiff was unable to determine which of the defendants produced the DES that was used. Numerous similar actions have already been settled and dismissed with nominal contribution payments made by the Company.

Two DES claims referred to the Company's insurance carriers are pending in jurisdictions other than Pennsylvania.

Each of the foregoing matters has been referred to the Company's insurance carrier for defense. The Company does not believe any of such actions will have a material impact on the Company's financial condition.

The Company has been named a defendant in an action captioned "Raymore

v. Halsey Drug Co., Inc. and Benito Amado" commenced in March, 1997 in the Eastern District of New York, 97 CIV 3116. The complaint alleges sexual misconduct and harassment against a named individual defendant and seeks \$1,000,000 in compensatory and punitive damages. This action is currently in discovery. Various settlement offers have been exchanged, ranging between \$30,000 and \$75,000. The Company does not believe that the ultimate outcome of this proceeding will have a material adverse effect on the Company's financial condition.

The Company has been named as a defendant in four additional actions which have been referred to the Company's insurance carrier and have been accepted for defense. The first action, Alonzo v. Halsey Drug Co., Inc. and K-Mart Corp., No. 64DOT-95111-CT-2736 (Indiana Superior Court, Porter County), was commenced on November 7, 1995 and involves a claim for unspecified damages relating to the alleged ingestion of "Doxycycline 100." The second action, Files

v. Halsey Drug Co., Index No. 198787/93 (New York Supreme Court, Suffolk County), commenced on September 16, 1993, seeks \$10,000,000 in damages for wrongful death allegedly caused by the ingestion of Isoniazid. The action is currently in discovery. The third and fourth actions, entitled Hunt v. Halsey Drug Co., Inc., and McCray v. Halsey Drug Co., Inc. (New York State Supreme Court, Kings County), were commenced on October 21, 1993 and seek the recovery of \$8,000,000 for alleged personal injuries suffered by two Well Fargo security guards who responded to an alarm and were shot, resulting in the death of one and the injury to the other. The Company has impleaded the former security service used by the Company as a third-party defendant. These actions are currently in discovery. At this early stage of the proceedings, the Company is unable to predict with any degree of certainty the likely outcome of these claims and whether they will have a material adverse effect on the Company's financial condition.

In addition to the matter described above, prior to the completion of the Offering, the Company was a defendant in actions brought by various parties, including Merill New York Co., relating to printing

services and expenses of approximately \$164,000, Valley City Disposal, relating to waste disposal services in the amount of approximately \$105,000, Xerox Corp., relating to expenses under office machine contracts of approximately \$58,000, and Atlantic Properties Company, relating to outstanding rent, expenses and penalties of approximately \$400,000. As part of the completion of the Offering, the Company was able to negotiate discounts on the amounts paid to such creditors and has satisfied the outstanding liabilities and settle these matters. See also "Item 2 - Properties."

### 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 1997.

#### PART II

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

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

The Company's Common Stock is listed on the American Stock Exchange (the "Exchange") under the symbol "HDG." Set forth below for the periods indicated are the high and low sales prices for the Common Stock as reported on the Exchange.

Period	High	Low
1998 FISCAL YEAR		
First Quarter (through		
March 15, 1997)	3 5/8	1 1/4
1997 FISCAL YEAR		
First Quarter	6	4 3/8
Second Quarter	5 1/8	2 9/16
Third Quarter	4 13/16	2 5/16
Fourth quarter	4 13/16	1 5/16
1996 FISCAL YEAR		
First Quarter	7 3/4	3
Second Quarter	7 1/4	4
Third Quarter	5 7/8	4
Fourth Quarter	6 3/8	4

#### **Holders**

There were 873 holders of record of the Company's common stock on March 15, 1998. 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 prohibit the Company from paying cash dividends. The Company does not intend to pay any cash dividends in the foreseeable future.

#### **Private Offerings**

As described under the caption "Business - Recent Events," on March 10, 1998, the Company completed a private offering of 5% convertible senior secured debentures in the principal amount of \$20.8 million and warrants exercisable for 4,202,020 shares of the Company's common stock. The securities were offered solely to and purchased solely by accredited investors as defined under Rule 501 of Regulation D promulgated under the Securities Act. The Company relied on

Section 4(2) of the Securities Act and Regulation D promulgated thereunder. Reference is made to the Company's Form 8-K as filed with the Securities and Exchange Commission on March 24, 1998 for a detailed description of the Offering and the terms of the debentures and warrants. The Form 8-K is incorporated herein by this reference and is attached to this Report as Exhibit 10.41.

#### ITEM 6. SELECTED FINANCIAL DATA.

The selected consolidated financial data presented on the following pages for the years ended December 31, 1997, 1996, 1995, 1994 and 1993 are derived from the Company's audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 1997 and December 31, 1996, and for each of the years in the three year period ended December 31, 1997, and the report thereon, are included elsewhere herein. The selected financial information as of and for the years ended December 31, 1994 and 1993 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations," (Item 7).

	Years ended December 31,				
	1997	1996	1995	1994	1993
		(in thousa	ands, except per	snare data)	
OPERATING DATA:					
Net sales	\$ 9,088	\$ 12,379	\$ 20,225	\$24,182	\$36,024
Costs and expenses					
Cost of sales	15,407	16,826	18,097	21,584	28,848
Research and					
development	979	1,854	818	502	2,140
Selling, general					
and					
administrative	630	7,486	6,098	7,128	8,976

		Years ended December 31,			
	1997	1996	1995	1994	1993
		(in thousands, except			
OPERATING DATA:					
Provision for regulatory					
settlement					5,935
Interest expense Loss(Gain) on sale of	1,144	1,708	1,307	735	631
assets Provision for stockholders'	264	(1,000)	(2,288)		
litigation settlement					3,000
Income (loss) before provision for income taxes, minority interest and cumulative effect of accounting change					
	(15,014)	(14,495)	(3,807)	(5,767)	(13,326)(1)
Provision (benefit) for income taxes			296		(2,540)
Minority interest in net loss (benefit) of subsidiaries					150
Cumulative effect of accounting change					(267)
Net income (loss)	\$ (15,014) =======	\$ (14,495) =======	(\$ 4,103) =======	\$ (5,767) ======	\$ (10,903) ======
Net income (loss) per shares	\$ (1.12) =======	\$ (1.49)	\$ (.52)	\$ (.80)	\$ (1.57)
Weighted average common and common shares equivalents					
outstanding	\$ 13,434,215	9,724,106	7,886,101	7,173,908	6,954,713
	=========	=========	=========	=========	=========

			December 31,			
BALANCE SHEET DATA:	1997	1996	1995	1994	1993	
	(In thousands, except per share data)					
Working capital (deficiency)	(\$24,705)	\$(12,201)	\$ (7,393)	\$ (4,451)	\$ (2,801)	
Total assets	7,667	11,982	18,862	19,276	24,674	
Total liabilities	27,523	19,063	20,402	19,924	20,755	
Retained earnings (accumulated	(44,498)	(29,484)	(14,989)	(10,886)	(5,118)	
deficit)						
Stockholders' equity (deficit)	(19,856)	(7,081)	(1,540)	(468)	2,919	

(1) After giving effect to charges to operations aggregating \$5,935,000 arising from, among other things, the Company's consent decree and plea agreement with the DOJ and a \$3,000,000 provision in connection with the settlement of shareholder and derivative litigations.

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

Certain statements set forth under this caption constitute "forward-looking statements" within the meaning of the Reform Act. See "Special Note Regarding Forward-Looking Statements" on page 1 of this Report for additional factors relating to such Statements.

#### General

On December 19, 1996, the Company was released from the FDA Application Integrity Program (the "AIP"), allowing the Company to submit ANDA applications for FDA review for new products, as well as Supplements, for the first time since October 1991. At or about the time of such release, the Company submitted five new ANDAs to the FDA for it review. In addition, the Company had previously submitted a new ANDA with respect to the Capsules. As described under Item 1. Business - Recent Events, the Company received FDA approval for five ANDAs since its release from the AIP in December 1996, has three ANDA applications pending and anticipates the submission of eight additional ANDAs during the balance of 1998. No assurance can be given, however, that pending ANDAs will be approved or that the Company will be successful in submitting its planned ANDAs or in receiving FDA approval for those already filed or to be filed.

Sales for the year ended December 31, 1997 were approximately \$9,088,000 as compared to sales of approximately \$12,379,000 for 1996. The net loss for the year ended December 31, 1997 was \$15,014,000, or \$1.12 per share, as compared with the net loss of \$14,495,000 or \$1.49 per share for 1996.

The reduction in sales for the year ended December 31, 1997 was primarily attributable to the lack of sufficient working capital necessary to purchase raw materials. Without adequate inventory, the Company was unable to satisfy customer orders in a timely fashion.

Depreciation and amortization was approximately \$1,294,000 in 1997, as compared to \$1,906,000 in 1996.

On March 10, 1998, the Company completed a private offering of 5% convertible senior secured debentures in the principal amount of \$20.8 million and common stock purchase warrants exercisable for an aggregate of 4,202,020 shares of the Company's common stock (the "Offering"). The net proceeds to the Company from the Offering was approximately \$19.6 million. In addition to providing the Company with approximately \$3 million in working capital, the net proceeds from the Offering have permitted the Company to, among other things, retire its existing bank indebtedness in the amount of approximately \$3 million, provide the funds necessary to satisfy its outstanding Federal and state payroll tax liabilities, satisfy accrued and unpaid rent at its Brooklyn facility, satisfy a significant portion of the Company's other current liabilities and accounts payable, as well as permit the purchase of raw materials in order to produce finished goods for shipment and to develop a finished goods inventory. See "Liquidity and Capital Resources" and "Item 1. Business - Recent Developments."

### **Results of Operations**

The following chart reflects expenses, earnings, income, losses and profits expressed as a percentage of net sales for the years 1997, 1996 and 1995.

	Percentage of Net Sales Year ended December			Percentage Change Year-to-Year Increase (Decrease) Years ended December 31,	
	1997	1996	1995		1995 to 1996
Net sales	100%	100.0%	100.0%	(26.6)	(38.8)
Cost of Goods	169.5	135.9	89.5	(8.47)	(7.0)
Gross Profit	(69.5)	(35.9)	10.5	42.1	(309.0)
Research & Development	10.8	15.0	4.0	(47.2)	126.7
Selling, general and					
administrative expense	69.4	60.5	30.0	(15.7)	22.8
(Loss) earnings from					
operations	(149.7)	(111.4)	(23.7)	(1.3)	187.9
Interest expense	12.6	13.9	6.5	(33.0)	30.6
Other (income) expenses	2.9	(8.2)	(11.3)	(126.4)	(56.3)
(Loss) earnings before income					
taxes, minority interest	(165.2)	(117.1)	(18.9)	3.6	280.7
(Benefit) provision for income					
taxes			1.5		(100)

	Percentage of Net Sales  Year ended December			Percentage Change Year-to-Year Increase (Decrease) Years ended December 31,	
	1997	1996	1995	1996 to 1997	1995 to 1996
(Loss) earnings before minority interest Minority interest in net	(165.2)	(117.1)	(20.4)	3.6	253.3
earnings (loss) of subsidiaries	-	-	-	-	-
Net (loss) earnings	(165.2%)	(117.1)%	(20.4)%	3.6%	253.3%
		=======	======	====	=====

#### **Net Sales**

Net sales of \$9,088,000 represents a decrease of \$3,291,000 as compared to net sales for the year ended December 31, 1996. The Decrease in 1997 is primarily attributable to a lack of sufficient working capital necessary to purchase raw materials. Without adequate inventory, the Company was unable to satisfy customer orders in a timely fashion. The Company's net sales for the year ended December 31, 1996 of \$12,379,000 represents a decrease by \$7,846,000 as compared to net sales for the year ended December 31, 1995. In 1995, the Company's net sales decreased by \$3,957,000 as compared to 1994. The decrease in 1996 is primarily attributable to the removal from the marketplace of four products and the withdrawal of four ANDA's by the Company, pursuant to a requirement by the FDA, as a pre-condition to release of the Company from the AIP. The decrease in 1995 was primarily attributable to the sale of the Tablets ANDA to Mallinckrodt.

#### Cost of Goods Sold

For 1997 and 1996, cost of goods sold decreased by approximately \$2,782,000 and \$1,272,000, respectively, as compared to 1995. These decreases are attributable to the reduction in shipments of products. For 1995, cost of goods sold decreased by approximately \$3,487,000 as compared to 1994. The decrease for 1995 is primarily attributable to the reduction in shipments of tablet products due to the sale by the Company of the Tablets ANDA combined with significant reductions in manufacturing costs of personnel and other expenses. The Company's gross margin as a percentage of sales for the fiscal years ended December 31,1997, 1996 and 1995 was (69.5%), (35.9%) and 10.54%, respectively. Sales reductions, withdrawal of the ANDA of the Capsule product, unabsorbed manufacturing costs and inventory write-off had a direct impact upon gross margin during 1996.

#### Research & Development expenses

For 1997, research and development expenses amounted to \$978,000 as compared to \$1,854,000 in 1996. This decrease was a result of reductions in personnel necessitated by the Company's liquidity crisis.

For 1996, research & developments expenses amounted to \$1,854,000 as compared to \$818,000 in 1995. This increase is attributable to the Company's effort to actively introduce new products, and to reintroduce products previously discontinued.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses as a percentage of sales for the fiscal years 1997, 1996 and 1995 were 69.4%, 60.5%, and 30.0%, respectively. These expenses decreased by approximately \$1,178,000 or 15.7% in fiscal year 1997 as compared to 1996. The decrease was attributable to cost saving measures effected by management during the 1996 year. These expenses increased by approximately \$1,388,000, or 22.8%, in fiscal year 1996, as compared to 1995. This increase is attributable to additional legal expenses and litigation settlements during the year, as well as consulting expenses for FDA related matters.

#### **Interest Expense**

Interest expense for 1997 decreased by \$564,000 as compared to 1996 due primarily to the conversion in the latter part of 1996 of \$7,740,000 of convertible debentures bearing interest at 10% into common stock. Interest expense for 1996 increased by \$401,000 as compared to 1995 as a result of a higher level of borrowings due to the issuance of convertible subordinated debentures, as well as fees payable to the Company's banks (see "Liquidity and Capital Resources" below). Interest expense for 1995 increased by \$572,000 as compared to 1994 due to the issuance of the convertible subordinated debentures.

#### **Provision for Income Taxes**

The Company had no tax (benefit) provision for 1997, 1996 and 1995 since the available loss carryback to prior years was completely utilized by the net operating loss for 1993 carryback to the prior three years.

#### **Net Loss**

For 1997 and 1996 the Company had net losses of \$15,014,000 and \$14,495,000, respectively, as compared to a net loss of \$4,103,000 for 1995. These net losses are attributable to the reduction in sales not offset by a comparable reduction in cost of goods sold, increased legal expenses, litigation settlements during the year and, in 1997, expenses incurred in discontinuing certain manufacturing operations.

#### **Liquidity and Capital Resources**

At December 31, 1997, the Company had cash and cash equivalents of \$26,000 as compared to \$118,000 at December 31, 1996. The Company had a working capital deficit at December 31, 1997 of \$24,705,000.

On March 10, 1998, the Company completed the Offering to Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen") and each of the Purchasers (along with Galen, collectively the "Galen Investor Group") listed on the signature page to a certain Debenture and Warrant Purchase Agreement dated March 10, 1998 (the "Purchase Agreement"). The net proceeds to the Company from the Offering, after deduction of related Offering expenses, were approximately \$19.6 million. The securities issued in the Offering consisted of 5% convertible senior

secured debentures (the "Debentures") and common stock purchase warrants (the "Warrants") exercisable for an aggregate of 4,202,020 shares of the Company's common stock. See "Item 1. Business - Recent Events" for a discussion of the Debentures and Warrants. Reference is also made to the Company's Form 8-K as filed with the Securities and Exchange Commission on March 24, 1998 for a more detailed description of the Debentures and Warrants, which is hereby incorporated by this reference and is attached as Exhibit 10.41 to this Report.

The Offering net proceeds of approximately \$19.6 million have been allocated to satisfy a substantial portion of the Company's current liabilities and accounts payable. Such liabilities include the full satisfaction of the Company's Bank indebtedness and related fees of approximately \$3 million, payment to the landlord at the Company's Brooklyn facility, and satisfaction of judgments and liens. Such repayments have allowed the Company to avoid a threatened foreclosure sale by its former Banks of Houba's Indiana facility, which secured the bank indebtedness.

In addition, pursuant to agreements reached with other large creditors in anticipation of completing the Offering, including the Company's landlord and the DOJ, the Company has been able to bring these creditors current and in compliance with installment payment agreements providing favorable terms to the Company. The Offering proceeds will allow the Company to satisfy its outstanding state and Federal payroll tax obligations and meet current payroll tax obligations. The Offering proceeds also will allow the Company to satisfy a substantial portion of its extensive arrear accounts payable and to secure discounts relating to such payments. Finally, the significant reduction of the Company's current liabilities combined with the working capital derived from the Offering proceeds, have resulted in the Company's independent certified public accountants issuing a report on the Company's financial statements for the year ended December 31, 1997 which does not contain an explanatory paragraph as to the Company's ability to continue as a going concern, which going concern qualification was included in such reports for fiscal 1996 and 1995.

Prior to the completion of the Offering, the Company was in negotiations with the DOJ to restructure the payment of the \$2,500,000 fine that had been levied under the Plea Agreement in order to address the Company's failure to satisfy the \$125,000 quarterly installments provided for under the Plea Agreement. On March 30, 1998, the Company and the DOJ signed a 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 provides that the Company will satisfy the remaining \$2,150,000 of the fine through the payment of \$25,000 on a monthly basis commencing May 1, 1998, plus interest on such outstanding balance (at the rate calculated pursuant to 28 U.S.C. Section 1961)(currently 5.319%). Such payment schedule would result in the full satisfaction of the DOJ fine in December, 2005. The Letter Agreement also provides certain restrictions on the payment of salary or compensation to any individual in excess of \$50,000 without the written consent of the United States District Court for the District of Maryland, subject to certain exceptions. In addition, the Letter Agreement requires the prepayment of the outstanding fine to the extent of 25% of the Company's after tax profit and 25% of the net proceeds received by the Company on any sale of a capital asset for a sum in excess of \$10,000. The terms of the Letter Agreement are subject to the approval of the U.S. District Court for the District of Maryland.

During the period from May 1997 through July 1997, the Company borrowed approximately \$3 million from Mylan Laboratories, Inc. pursuant to five unsecured, demand promissory notes. The advances made by Mylan Laboratories, Inc. were part of a proposed investment by Mylan Laboratories, Inc. in the Company, including the proposed purchase of the Company's Houba Indiana facility as well as a partial tender offer for the Company's common stock. The Company used the proceeds of these borrowings for working capital. The \$3 million indebtedness relating to such advances remains outstanding and the

Company anticipates negotiating with representatives of Mylan Laboratories, Inc. in an attempt to structure repayment terms acceptable to the Company. While the Company believes that repayment terms acceptable to each of the Company and Mylan Laboratories, Inc. will be agreed upon, no assurance can be made that the Company will be successful in restructuring this indebtedness on terms favorable to the Company. Failure to extend the term over which this indebtedness will be repaid or to permit satisfaction of all or a portion of the indebtedness through delivery of product produced by the Company, may have an adverse effect on the Company's operations and financial condition.

During the period from late 1996 through early March 1998, the Company borrowed an aggregate of approximately \$1,100,000 from certain of the holders of the Company's convertible subordinated debentures and common stock. These borrowings, evidenced by promissory notes, are due and payable as to principal on demand. Interest on these notes, at the rate of 10% per annum, is payable on a quarterly basis. The Company utilized the proceeds of these borrowings for working capital. Upon the completion of the Offering, the Company satisfied \$800,000 of such indebtedness from the net proceeds of the Offering. The remaining \$300,000 of such indebtedness has, by agreement with the holder of such note, been extended for a term of one year.

During fiscal 1997 and up to the completion of the Offering, the Company had insufficient capital resources to meet both its current and long-term obligations. As a result of inadequate working capital, a decline in shipments of solid dosage products from the Company's Brooklyn plant following the entry of the Consent Decree, and the lack of available borrowings under the Company's then existing credit facility, the Company's liquidity position had been materially adversely affected since June 30, 1993 and the Company's capital resources had been severely limited. During this period, the Company actively sought to reduce its operating costs at the Brooklyn plant, including reductions in personnel. Significant liabilities, however, and the absence of adequate working capital, impaired the Company's ability to purchase and process raw materials for sale as finished goods and to satisfy current liabilities and meet operating expenses.

The net proceeds from the Offering has permitted the Company to satisfy a significant portion of its current liabilities and accounts payable. In addition, based on Management's belief as to the Company's ability to defer a portion of the Company's remaining notes and accounts payable and certain other assumptions, including the restructuring of the indebtedness to Mylan Laboratories, Inc., the Company believes that it has approximately 3 million in cash available for working capital derived from the net proceeds of the Offering. The Company estimates that such working capital will permit the Company to purchase needed raw materials and fund near term operating losses for approximately three to six months. In order to supplement such working capital, the Company is in the process of negotiating with a banking institution to secure a \$5 million line of credit. In addition, in accordance with the terms of the Debenture and Warrant Purchase Agreement pursuant to which the Offering was completed, the Company has granted the Galen Investor Group an option to invest an additional \$5 million in the Company at any time within eighteen months from the date of the closing of the Offering in exchange for Debentures and Warrants having terms identical to those issued in the Offering (the "Galen Option"). Galen has expressed an indication of interest to exercise the Galen Option in the event the Company is in need of additional capital. No assurance can be given, however, that the Company will be successful in securing the \$5 million line of credit or that the Galen Option will be exercised. In the event the Company is successful in securing the line of credit or in the event the Galen Option is exercised, the Company believes that it will have sufficient working capital to fund operations for at least the next twelve months.

### **Capital Expenditures**

The Company's capital expenditures during 1997, 1996 and 1995 were \$49,000, \$208,000, and \$536,000, respectively. The decrease in capital expenditures in 1997 as compared to prior years is attributable to the Company's cash conservation measures implemented in 1995.

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See Index to Financial Statements after signature page.

### 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 information required by Item 10 will be included in the Company's Proxy Statement for the 1998 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 1997, and is hereby incorporated herein by reference to such Proxy Statement.

#### ITEM 11. EXECUTIVE COMPENSATION.

The information required by Item 11 will be included in the Company's Proxy Statement for the 1998 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 1997, and is hereby incorporated herein by reference to such Proxy Statement.

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

The information required by Item 12 will be included in the Company's Proxy Statement for the 1998 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 1997, and is hereby incorporated herein by reference to such Proxy Statement.

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

The information required by Item 13 will be included in the Company's Proxy Statement for the 1998 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 1997, and is hereby incorporated herein by reference to such Proxy Statement.

# PART IV

# ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K.

- (a) Financial Statements See Index to Financial Statements.
- (b) Reports on Form 8-K

None.

(c) Exhibits

Exhibit Number	Document
3.1	Certificate of Incorporation and amendments (incorporated by reference to Exhibit 3.1 to Amendment No. 2 to the Registrant's Registration Statement on Form S-18, File No. 2471-NY).
3.2	Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1993).
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 3 1, 1992 (the "1992 Form 10-K")).
10.2	Amendment Two, dated as of January 12, 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A., together with forms of Stock Warrant and Registration Rights Agreement (incorporated by reference to Exhibit 10.1. to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1993 (the "1993 Form 10-K")).
10.3	Amendment Three, dated as of May 31, 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1994).
10.4	Amendment Four, dated as of July 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994)).
10.5	Amendment Five, dated as of March 21, 1995, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K dated March 21, 1995 (the "March 8-K")).
10.5(1)	Form of Warrants issued to The Bank of New York, The Chase Manhattan Bank, N.A. and the Israel Discount Bank (incorporated by reference to Exhibit 10.5(i) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K")).
	30

Exhibit	
Number	Document

- 10.5(2) Letter Agreement, dated July 10, 1995, among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995 (the "June 10-Q")).
- 10.5(3) Letter Agreement, dated November 16, 1995, among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.25(iv) to the 1995 10-K).
- 10.5(4) Amendment 6, dated as of August 6, 1996, to Credit Agreement among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 (the "June 1996 10-Q)).
- 10.5(5) Letter Agreement, dated March 25, 1997 among Halsey Drug Co., Inc., The Chase Manhattan Bank, as successor in interest to The Chase Manhattan Bank (National Association), The Bank of New York and Israel Discount Bank.
- 10.6 Agreement Regarding Release of Security Interests dated as of March 21, 1995 by and among the Company, Mallinckrodt Chemical Acquisition, Inc. and The Chase Manhattan Bank, N.A.(incorporated by reference to Exhibit 10.9 of the March 8-K).
- 10.7 Consulting Agreement dated as of September, 1993 between the Registrant and Joseph F. Limongelli (incorporated by reference to Exhibit 10.6 to the 1993 Form 10-K).
- 10.8 Employment Agreement, dated as of January 1, 1993, between the Registrant and Rosendo Ferran (incorporated by reference to Exhibit 10.2 to the 1992 Form 10-K).

10.10(1) Halsey Drug Co., Inc. 1984 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.3 to the 1992 Form 10-K).

10.10(2) Halsey Drug Co., Inc. 1995 Stock Option and Restricted Stock Purchase Plan (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8, File No. 33-98396).

10.10(3) Halsey Drug Co., Inc. Non-Employee Director Stock Option Plan.

- 10.11 Leases, effective February 13, 1989 and January 1, 1990, respectively, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss (incorporated by reference to Exhibits 10.6 and 10.7, respectively, to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1989).
- 10.12 Lease, effective as of April 15, 1988, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, and Rider thereto (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1987).

- 10.12(1) Lease, as of October 31, 1994, among Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, together with Modification, Consolidation and Extension Agreement (incorporated by reference to Exhibit 10. 12(i) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995).
- 10.13 Asset Purchase Agreement dated as of March 21, 1995 among Mallinckrodt Chemical Acquisition, Inc. ("Acquisition"), Mallinckrodt Chemical, Inc., as guarantor and the Registrant (incorporated by reference to Exhibit 10.1 to the March 8-K).
- 10.14 Toll Manufacturing Agreement for APAP/Oxycodone Tablets dated as of March 21, 1995 between Acquisition and the Registrant (incorporated by reference to Exhibit 10.2 to the March 8-K).
- 10.15 Capsule ANDA Option Agreement dated as of March 21, 1995 between Acquisition and the Registrant (incorporated by reference to Exhibit 10.3 to the March 8-K).
- 10.16 Tablet ANDA Noncompetition Agreement dated as of March 21, 1995 between the Registrant and Acquisition (incorporated by reference to Exhibit 10.4 to the March 8-K).
- 10.17 Subordinated Non-Negotiable Promissory Term Note in the amount of \$1,200,00 dated March 21, 1995 issued by the Registrant to Acquisition (incorporated by reference to Exhibit 10.5 to the March 8-K).
- 10.18 Term Note Security Agreement dated as of March 21, 1995 among the Company, Houba, Inc. and Acquisition (incorporated by reference to Exhibit 10.6 to the March 8-K).
- 10.19 Amendment dated March 21, 1995 to Subordination Agreement dated as of July 21, 1994 between Mallinckrodt Chemical, Inc., Mallinckrodt Chemical Acquisition, Inc., the Registrant, The Chase Manhattan Bank (National Association), Israel Discount Bank of New York, The Bank of New York, and The Chase Manhattan Bank (National Association) (incorporated by reference to Exhibit 10.8 to the March 8-K).
- 10.20 Agreement dated as of March 30, 1995 between the Registrant and Zatpack, Inc. (incorporated by reference to Exhibit 10.10 to the March 8-K).
- 10.21 Waiver and Termination Agreement dated as of March 30, 1995 between Zuellig Group, W.A., Inc. and Indiana Fine Chemicals Corporation (incorporated by reference to Exhibit 10.11 to the March 8-K).
- 10.22 Convertible Subordinated Note of the Registrant dated December 1, 1994 issued to Zatpack, Inc. (incorporated by reference to Exhibit 10.12 to the March 8-K).
- 10.23 Agreement dated as of March 30, 1995 among the Registrant, Indiana Fine Chemicals Corporation, Zuellig Group, N.A., Inc., Houba Inc., Zetapharm, Inc. and Zuellig Botanicals, 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).

Exhibit Number	Document
10.25	Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit $6(a)$ to the June $10-Q$ ).
10.26	Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit $6(a)$ to the June $10-Q$ ).
10.27	Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated December 4, 1995 (the "December 8- K")).
10.28	Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit $4.2$ to the December $8-K$ ).
10.29	Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 99 to the June 1996 $10-Q$ ).
10.30	Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the June 1996 $10-Q$ ).
10.31	Form of 5% Convertible Senior Secured Debenture (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated March 24, 1998 (the "March 1998 8- K")).
10.32	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the March 1998 $8-K$ ).
10.33	Debenture and Warrant Purchase Agreement dated March 10, 1998, by and among the Registrant, Galen Partners III, L.P. and the other Purchasers listed on the Signature Page thereto (incorporated by reference to Exhibit 10.1 to the March 1998 8-K).
10.34	Form of General Security Agreement of Halsey Drug Co., Inc. dated March 10, 1998 (incorporated by reference to Exhibit 10.2 to the March 1998 $8-K$ ).
10.35	Form of Agreement of Guaranty of Subsidiaries of Halsey Drug Co., Inc. dated March 10, 1998 (incorporated by reference to Exhibit 10.3 to the March 1998 $8-K$ ).
10.36	Form of Guarantor General Security Agreement dated March 10, 1998 (incorporated by reference to Exhibit 10.4 to the March 1998 8-K).
10.37	Stock Pledge Agreement dated March 10, 1998 by and between the Registrant and Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.5 to the March 1998 $8-K$ ).
10.38	Form of Irrevocable Proxy Agreement (incorporated by reference to Exhibit 10.6 to the March 1998 $8-K$ ).
10.39	Agency Letter Agreement dated March 10, 1998 by and among the Purchasers a party to the Debenture and Warrant Purchase Agreement, dated March 10, 1998 (incorporated by reference to Exhibit 10.7 to the March 1998 8-K).

Exhibit Number	Document
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
*10.44	Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens 21 Subsidiaries of the Registrant (incorporated by reference to Exhibit 22 to the 1993 Form $10-K$ ).
*23.1	Consent of Grant Thornton LLP, independent certified public accountants.
*27	Financial Data Schedule, which is submitted electronically to the Securities and Exchange Commission for informational purposes only and not filed.

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

## **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, President and Chief Executive Officer (Principal Executive Officer)

Date: April 13, 1998

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	Chairman and Director	April 13, 1998
William G. Skelly		
/s/ Michael Reicher	President, Chief Executive Officer	April 13, 1998
Michael Reicher	and Director (Principal Executive Officer)	
/s/ Peter Clemens	Vice President and Chief Financial	April 13, 1998
Peter Clemens	Officer (Principal Financial and Accounting Officer)	
Alan J. Smith	Director	April, 1998
/s/ Bruce F. WessonBruce F. Wesson	Director	April 13, 1998
/s/ William Sumner	Director	April 13, 1998
William Sumner		
/s/ Srini Conjeevaram	Director	April 13, 1998
Srini Conjeevaram		

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# REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

# **Board of Directors HALSEY DRUG CO., INC.**

We have audited the accompanying consolidated balance sheets of Halsey Drug Co., Inc. and Subsidiaries as of December 31, 1997 and 1996, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1997. 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 generally accepted auditing standards. 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, 1997 and 1996, and the consolidated results of their operations and their consolidated cash flows for each of the three years in the period ended December 31, 1997, in conformity with generally accepted accounting principles.

### GRANT THORNTON LLP

New York, New York April 14, 1998

## CONSOLIDATED BALANCE SHEETS

December 31, (in thousands)

	1997	1996
CURRENT ASSETS		
Cash	\$ 26	\$ 118
Accounts receivable - trade, net of allowances for doubtful accounts of \$542 and \$424		
in 1997 and 1996, respectively	62	226
Other receivable		1,000
Inventories	2,456	3,758
Prepaid insurance and other current assets	274	252
Total current assets	2,818	5,354
PROPERTY, PLANT AND EQUIPMENT, NET	4,630	6,222
OTHER ASSETS	219	406
	\$ 7,667	\$11,982
	======	======

# CONSOLIDATED BALANCE SHEETS (CONTINUED)

December 31, (in thousands)

	1997	1996
CURRENT LIABILITIES		
Bank overdraft	\$ 159	\$ 286
Due to banks	2,476	3,195
Notes payable	4,825	1,625
Convertible subordinated debentures	2,244	2,173
Department of Justice settlement	200	2,168
Accounts payable	6,086	4,533
Accrued expenses	7,644	3,575
Deferred gain	1,900	
Total current liabilities	25,534	17,555
LONG-TERM DEBT		1,508
DEPARTMENT OF JUSTICE SETTLEMENT	1,990	
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock - \$.01 par value; authorized,		
20,000,000 shares; issued and outstanding,		
14,029,718 shares and 13,175,708 shares		
in 1997 and 1996, respectively	140	131
Additional paid-in capital	25,489	23,316
Accumulated deficit	(44,497)	(29,484)
	(18,868)	(6,037)
Less treasury stock - at cost ( 439,603 shares and		
474,603 shares in 1997 and 1996, respectively)	(989)	(1,044)
	(19,857)	(7,081)
	\$ 7,667 ======	\$ 11,982 ======

## CONSOLIDATED STATEMENTS OF OPERATIONS

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

	1997	1996	1995
Net sales Cost of goods sold	\$ 9,088	\$ 12,379 16,826	\$ 20,225 18,097
Gross profit	(6,318)	(4,447)	2,128
Research and development Selling, general and administrative expenses	979 6,308 	1,854 7,486	818 6,098
Loss from operations	(13,605)	(13,787)	(4,788)
<pre>Interest expense Other income (expense)</pre>	(1,144) (264)	(1,708) 1,000	(1,307) 2,288
Loss before income taxes	(15,013)	(14,495)	(3,807)
Provision for income taxes			296
NET LOSS	\$(15,013) ======	\$(14,495) ======	\$ (4,103) ======
Basic loss per common share	\$ (1.12) ======	\$ (1.49) ======	\$ (.52) ======
Weighted average number of outstanding shares	13,434	9,724 ======	7,886 =====

# CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

# Years ended December 31, 1997, 1996 and 1995 (in thousands)

	Common stock, \$.01 par value		Additional paid-in	3	Treasury stock, at cost			
	Shares	Amount	capital	Accumulated deficit	Shares	Amount	Total	
Balance at January 1,1995	7,610	\$76	\$10,162	\$(10,886)			\$ (648)	
Issuance of common stock Issuance of common stock in connection with litigation	500	5	791				796	
settlement Repurchase of common stock Issuance of warrants with convertible	825	8	2,992		(500,000)	\$ (1,100)	3,000 (1,100)	
subordinated debentures Exercise of stock options Net loss for the year ended	39	1	416 98				416 99	
December 31, 1996			(4,103)				(4,103)	
Balance at December 31, 1995 (carried forward)	8,974	90	14,459	(14,989)	(500,000)	(1,100)	(1,540)	

# CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (CONTINUED)

# Years ended December 31, 1997, 1996 and 1995

(in thousands)

	Common stock, \$.01 par value		Additional paid-in	Accumulated	Treasury at c		
	Shares	Amount	capital	deficit	Shares	Amount	Total
Balance at December 31, 1995							
(brought forward)	8,974	\$ 90	\$ 14,459	\$(14,989)	(500,000)	\$ (1,100)	\$ (1,540)
Issuance of common stock							
conversion of debentures	3,504	35	6,724				6,759
Issuance of shares as settlement	60		262		25,397	56	318
Issuance of warrants with convertible							
subordinated debentures			355				355
Exercise of warrants of convertible							
debentures	589	6	1,363				1,369
Stock options exercised	49		153				153
Net loss for the year ended							
December 31, 1996				(14,495)			(14,495)
Balance at December 31, 1996							
(carried forward)	13,176	131	23,316	(29,484)	(474,603)	(1,044)	(7,081)

# CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (CONTINUED)

# Years ended December 31, 1997, 1996 and 1995

(in thousands)

	Common stock, \$.01 par value		Additional paid-in Accumulate		Treasury stock, at cost				
	Shares	An	nount	capital	deficit	Shares		mount	Total
Balance at December 31, 1996									
(brought forward)	13,176	\$	131	\$ 23,316	\$(29,484)	(474,603)	\$	(1,044)	\$ (7,081)
Issuance of common stock -									
conversion of debentures	643		7	1,529					1,536
Issuance of shares as payment of									
interest	69		1	224					225
Sale of treasury stock	25			45		35,000		55	100
Exercise of warrants of convertible									
debentures	22			72					72
Stock options exercised	95		1	303					304
Net loss for the year ended									
December 31, 1997					(15,013)				(15,013)
Balance at December 31, 1997	14,030	\$	140	\$ 25,489	\$(44,497)	439,603	\$	(989)	\$(19,857)
	=======	===	=====	=======	=======	=======	==:	=====	=======

# CONSOLIDATED STATEMENTS OF CASH FLOWS

# Year ended December 31, (in thousands)

	1997	1996	1995
Cash flows from operating activities			
Net loss	\$(15,013)	\$(14,495)	\$ (4,103)
Adjustments to reconcile net loss to net			
cash used in operating activities			
Depreciation and amortization	1,733	1,906	1,956
Provision for losses on accounts receivable	118	144	
Provision for loss on investment		500	
Gain on sale of assets	38	(1,000)	(2,288)
Deferred income taxes			296
Changes in assets and liabilities			
Accounts receivable	45	1,319	637
Inventories	1,302	3,958	(881)
Prepaid insurance and other current assets	165	(96)	(160)
Accounts payable	1,851	1,029	(2,031)
Accrued expenses	4,553	2,913	121
Total adjustments	9,805	10,673	(2,350)
Net cash used in operating activities	(5,208)		(6,453)
Cash flows from investing activities			
Capital expenditures	(85)	(390)	(536)
Decrease (increase) in other assets			116
Net proceeds from sale of assets			1,889
Collection of notes receivable	1,000		
Net cash (used in) provided by investing			
activities	915	(390)	1,469

## CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

Year ended December 31, (in thousands)

	1997	1996	1995
Cash flows from financing activities			
Increase (decrease) in notes payable	\$ 3,881	\$ 25	\$(1,192)
Proceeds from issuance of common stock	. ,	318	796
Reissuance of treasury stock	70		
Payments to Department of Justice			(90)
Bank overdraft	(127)	73	(5)
Repurchase of common stock			(1,100)
Payments to minority stockholders		(206)	(212)
Proceeds from issuance of convertible			
subordinated debentures	4,600	2,500	7,740
Proceeds from exercise of stock options	305	153	. 99
Proceeds from exercise of warrants	72	1,369	
Increase in other assets		(255)	(727)
Net cash provided by financing activities	4,201	3,977	5,309
NET (DECREASE) INCREASE IN CASH			
AND CASH EQUIVALENTS	(92)	(235)	325
Cash and cash equivalents at beginning of year	118	353	28
Cash and cash equivalents at end of year	\$ 26	\$ 118	\$ 353
- · · · · · · · · · · · · · · · · · · ·	======	======	======

Supplemental disclosures of noncash activities:

## Year ended December 31, 1997

The Company issued 642,407 shares of common stock to Zatpack, Inc. as payment for an outstanding note payable in the amount of \$1,536,000.

The Company reissued 25,000 shares of treasury stock as payment for \$30,000 in consulting fees and the receipt of \$70,000 in cash.

The Company issued 25,000 shares of common stock as payment for \$225,452 in accrued interest.

The Company recorded the satisfaction of \$1,400,000 of subordinated promissory notes, related accrued interest of \$200,000 and accounts payable of \$300,000 due to Mallinckrodt, in lieu of Mallinckrodt paying \$1,900,000 owed to the Company as described in Note E.

#### Years ended December 31, 1996 and 1995

The issuance of 3,504,000 shares of the Company's common stock upon conversion of \$6,759,000 of convertible subordinated debentures is included in common stock and additional paid-in capital.

The valuation of the warrants issued in 1996 and 1995, of \$355,000 and \$416,000, respectively, with convertible subordinated debentures is included in additional paid-in capital.

The issuance in 1996 and 1995 of 59,550 and 824,742 shares of the Company's common stock is valued at \$318,000 and \$3,000,000, respectively, in connection with litigation settlements.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 1997, 1996 and 1995

## NOTE A - SUMMARY OF ACCOUNTING POLICIES

The Company, a New York-based corporation established in 1935, and its subsidiaries, are engaged in the manufacture, sale and distribution of generic drugs. The Company sells its generic drug products under its Halsey label and under private-label arrangements with drug store chains and drug wholesalers throughout the United States.

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 100% of the accounts of the Company and its wholly-owned subsidiaries, Blue Cross Products Co., Inc., Houba, Inc., Halsey Pharmaceuticals, Inc., and Indiana Fine Chemicals Corporation, The Medi-Gum Corporation, H.R. Cenci Laboratories, Inc. (97% owned) and Cenci Powder Products, Inc. (100% owned). The Medi-Gum Corporation and Halsey Pharmaceuticals have not commenced operations. All material intercompany accounts and transactions have been eliminated.

## 2. Liquidity Matters

As of December 31, 1997, the Company has a working capital deficiency of approximately \$24,705,000, has an accumulated deficit of approximately \$44,496,000 and has incurred a loss of approximately \$15,013,000 for the year then ended. The Company was also not in compliance with its financial covenants pursuant to its banking agreement and its convertible subordinated debenture agreement.

On March 10, 1998, the Company completed a private offering of securities consisting of 5% convertible senior secured debentures and common stock purchase warrants exercisable for an aggregate of 4,202,020 shares of the Company's common stock. The net cash proceeds to the Company from the offering, after the deduction of related cash offering expenses, was approximately \$19.6 million.

The net proceeds of the offering have, in large part, been used to satisfy a substantial portion of the Company's past due liabilities and accounts payable. Such liabilities include the full satisfaction of the Company's bank indebtedness and related fees, payment to the landlord of the Brooklyn

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### December 31, 1997, 1996 and 1995

## **NOTE A (CONTINUED)**

facility and satisfaction of outstanding judgments and liens. Such repayments have allowed the Company to avoid the threatened foreclosure sale by its banks of the Indiana facility securing such indebtedness. Additionally, the satisfaction of the bank indebtedness resulted in curing the Company's default with its subordinated debenture agreement. Further, pursuant to agreements reached with other large creditors in anticipation of the completion of the offering, including the Company's landlord and the Department of Justice ("DOJ"), the Company has been able to bring these creditors current and will be in compliance with installment payment agreements providing favorable terms to the Company. Satisfaction of the Company's current obligations to its landlord of the Brooklyn facility for accrued and unpaid rent, penalties and expenses has allowed the Company to renegotiate its lease and avoid eviction. The offering proceeds will also allow the Company to satisfy its outstanding state and Federal payroll tax obligations and meet current payroll tax obligations.

After giving effect to the application of the net proceeds of the offering, and based on management's belief as to the Company's ability to defer a portion of remaining notes and accounts payable and certain other assumptions, the Company believes it will have approximately \$3,000,000 of cash available for working capital. The Company has submitted Abbreviated New Drug Applications ("ANDA") for approval by the Food and Drug Administration ("FDA") (Note M) and believes that approval of such ANDA, which remains uncertain, will result in generating increased revenues. The Company is also currently in discussions with a financial institution to secure a \$5,000,000 line of credit to supplement its working capital position and could potentially secure an additional \$5,000,000 of working capital in the event that an investor exercises an option to purchase additional securities pursuant to the private placement agreement. No assurance can be given, however, that such financing will be secured on acceptable terms, if at all, or that the investor's option will be exercised.

### 3. Inventories

Inventories are stated at the lower of cost or market; cost is determined using the first-in, first-out method.

## 4. Property, Plant and Equipment

Property, plant and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization are provided for in amounts sufficient to relate the cost of

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

## **NOTE A (CONTINUED)**

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:

Buildings 25 years Machinery and equipment 5 - 10 years Leasehold improvements 5 - 10 years

Leasehold improvements are amortized over the lives of the respective leases or the service lives of the improvements, whichever is shorter.

## 5. Income Taxes

The Company accounts for income taxes utilizing an asset liability method for financial accounting and reporting 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.

### 6. Statements of Cash Flows

For purposes of the statements of cash flows, the Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. The Company paid no income taxes for the years ended December 31, 1997 and 1996 and \$201,000 during the year ended 1995. In addition, the Company paid interest of approximately \$1,113,000, \$1,173,000, \$786,000, respectively, for the years ended December 31, 1997, 1996 and 1995.

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

In preparing consolidated financial statements in conformity with generally accepted accounting principles, management makes estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

## **NOTE A (CONTINUED)**

## 8. 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.

## 9. Impairment of Long-Lived Assets

The Company adopted Statement of Financial Accounting Standards No. 121 ("SFAS No. 121"), "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," during the year ended December 31, 1996. The statement requires that the Company recognize and measure impairment losses of long-lived assets and certain identifiable intangibles and value long-lived assets to be disposed of.

The Company reviews long-lived assets and certain identifiable intangibles held and used for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable (Note I).

## 10. Stock-Based Compensation

In 1996, the Company adopted Statement of Financial Accounting Standards No. 123 ("SFAS No. 123"), "Accounting for Stock-Based Compensation," and continues to apply APB Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its plans and does not recognize compensation expense for its stock-based compensation plans other than for restricted stock (Note K).

### 11. New Pronouncements

## **Earnings (Loss) Per Share**

In 1997, the Company adopted Statement of Financial Accounting Standards No. 128 ("SFAS No. 128"), "Earnings Per Share," which requires public companies to present basic earnings per share and, if applicable, diluted earnings per share. All comparative periods have been restated in accordance with SFAS No. 128.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### December 31, 1997, 1996 and 1995

## **NOTE A (CONTINUED)**

The computation of basic loss per share of common stock is based upon the weighted average number of common shares outstanding during the period, plus (in periods in which they have a dilutive effect) the effect of common shares contingently issuable upon exercise of stock options and warrants. Diluted earnings per share is considered equal to basic earnings per share for all years presented as the effect of other potentially dilutive securities would be antidilutive.

## **Reporting Comprehensive Income**

In June 1997, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 130 ("SFAS No. 130"), "Reporting Comprehensive Income," which is effective for the Company's year ending December 31, 1998. The statement addresses the reporting and displaying of comprehensive income and its components. Earnings per share will only be reported for net income and not for comprehensive income and its components. Adoption of SFAS No. 130 related to disclosure within the financial statements and is not expected to have a material effect on the Company's financial statements.

## **Segment Information**

In June 1997, the FASB also issued Statement of Financial Accounting Standards No. 131 ("SFAS No. 131"), "Disclosure About Segments of an Enterprise and Related Information," which is effective for the Company's year ending December 31, 1998. The statement changes the way public companies report information about segments of their business in their financial statements and requires them to report selected segment information in their quarterly reports. Adoption of SFAS No. 131 relates to disclosure within the financial statements and is not expected to have a material effect on the Company's financial statements.

## 12. Reclassifications

Certain reclassifications have been made to the 1996 and 1995 presentations to conform to the 1997 presentation.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

## NOTE B - FAIR VALUE OF FINANCIAL INSTRUMENTS

## Long-term and Short-term Debt and Convertible Subordinated Debentures

The fair value of the Company's long-term and short-term debt and convertible subordinated debentures is estimated based upon the quoted market prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities.

The carrying amount and fair value of the above financial instruments are as follows:

		December	31,	
	1997		1996	
	CARRYING AMOUNT	Fair value amount	Carrying amount	Fair value amount
		(in tho	usands)	
Long-term and short-term debt Convertible subordinated	\$7,301	\$7,301	\$6,328	\$6,328
debentures	2,244	2,244	2,173	2,173

## **NOTE C - INVENTORIES**

Inventories consist of the following:

	December 31	L ,
	1997	1996
	(in thousand	ds)
Finished goods	\$ 789	\$2,121
Work-in-process	263	1,018
Raw materials	1,404	619
	\$2,456	\$3,758
	=====	=====

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

## NOTE D - PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows:

	December 31,	
	1997	1996
	(in tho	usands)
Machinery and equipment	\$11,478	\$11,641
Leasehold improvements	5,967	5,973
Building	997	998
Land	265	265
	18,707	18,877
Less accumulated depreciation and amortization	14,077	12,655
	\$ 4,630	\$ 6,222
	======	======

Depreciation expense for the years ended December 31, 1997, 1996 and 1995 was approximately \$1,640,000, \$1,562,000 and \$1,576,000, respectively.

#### NOTE E - DEBT

## **Due to Banks**

At December 31, 1997 and 1996, the Company had \$2,476,000 and \$3,195,000 outstanding, respectively, under a line of credit agreement with three participating banks for which the average borrowing rate on these outstanding amounts for the years then ended was 11.9% and 10.43%, respectively. Borrowings under the line were available for working capital purposes based upon a percentage of the parent company's eligible accounts receivable and were collateralized by such accounts receivable. The agreement contained certain financial covenants, for which the Company was not in compliance at December 31, 1997. During March 1998, the Company completely satisfied its bank indebtedness and terminated the line of credit agreement with the bank (see Note Q).

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

## **NOTE E (CONTINUED)**

## **Long-term Debt**

Borrowings under long-term debt are as follows:

	Decembe	er 31,
	1997	1996
	(in thous	sands)
Convertible subordinated promissory note (a)		\$ 1,508
Subordinated promissory notes (b)		1,400
Notes payable (c)	\$ 4,825	225
	4,825	3,133
Less current maturities of long-term debt	(4,825)	(1,625)
	\$	\$ 1,508
	======	======

## (a) Convertible Subordinated Promissory Note

Pursuant to the Zatpack, Inc. ("Zatpack") agreement (Note N), the Company issued a convertible subordinated promissory note dated December 1, 1994, to Zatpack, for the cancellation of trade payables and advances by Zuellig Group N.A., Inc. ("Zuellig") to the Company's subsidiaries, in the amount of \$1,292,000, bearing interest at 8% per annum, compounded annually, due December 1, 1997. The outstanding principal, plus all accrued and unpaid interest, \$1,508,000 at December 31, 1996, was convertible, at the option of Zatpack, into the Company's common stock at the rate of one share of common stock for every \$2.50 of principal and interest being converted (the \$2.50 is subject to the antidilution provisions of the promissory note). In March 1997, the principal amount, with related accrued interest of \$243,110 was converted into 642,407 shares of Common Stock at an adjusted conversion price of \$2.39 per share, thereby cancelling the indebtedness.

## (b) Subordinated Promissory Notes

On March 21, 1995 (see Note I), the Company satisfied certain accounts payable by issuing a subordinated promissory note to Mallinckrodt Chemical Acquisition, Inc. ("Mallinckrodt") for \$1,200,000, bearing interest at 8% per annum, with interest and principal payable at the earlier

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### December 31, 1997, 1996 and 1995

## **NOTE E (CONTINUED)**

of: (i) receipt by Mallinckrodt of all necessary authorizations from the FDA or (ii) March 21, 1998. The note is collateralized by substantially all of the assets of the Company and is subordinated to future bank indebtedness of up to \$8,000,000. The \$1,200,000 note represents the deferral of payment by the Company of a portion of its trade accounts payable due to an affiliate of Mallinckrodt. On July 14, 1995, the Company borrowed from and issued a \$200,000 subordinated promissory note to Mallinckrodt, bearing interest at 8% per annum, with principal and interest payable June 30, 1996. The principal and interest is payable, at the option of Mallinckrodt, in the form of cash or a credit to the Company's accounts receivable due from Mallinckrodt on June 30, 1996. On September 21, 1997, pursuant to the agreement with Mallinckrodt, the Company recorded the satisfaction of the \$1,200,000 note, the subordinated promissory note of \$200,000, related accrued interest of \$200,000 and accounts payable of \$300,000 due to Mallinckrodt in lieu of Mallinckrodt paying the remaining balance of \$1,900,000 owed to the Company as described in Note I.

## (c) Notes Payable

During 1997, the Company borrowed from and issued to several debenture holders and shareholders, unsecured, demand promissory notes in the amount of \$1,125,000, bearing interest at 12% per annum, with interest payable quarterly.

In addition, during the second quarter of 1997, the Company received funds, in the amount of \$3,000,000, from a proposed purchaser of the Company's Indiana facility. These funds were tendered during the due diligence period, as an unsecured advance against anticipated payment, for the proposed purchase transaction. The purchase transaction was not consummated and the advance was converted into five non collateralized promissory notes with maturity dates from May 1, 1998 through June 18, 1998.

During the fourth quarter of 1997, the Company received, from an investor of a proposed joint venture, funds in the amount of \$500,000 represented by a demand promissory note, bearing interest at 10% per annum, secured by the property of Houba. In addition, as part of a proposed financing agreement, the Company received \$200,000 as a promissory note bearing interest at 8% per annum during the fourth quarter of 1997.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

## NOTE F - CONVERTIBLE SUBORDINATED DEBENTURES AND STOCK WARRANTS

In connection with certain 1995 amendments to the line of credit agreement described in Note E, the Company issued stock warrants to the bank, expiring July 17, 2000, to purchase up to 699,696 shares of the Company's common stock at exercise prices ranging from \$1.98 to \$2.07 per share. The fair value of the warrants, \$200,000, as determined by the Company's Board of Directors, was recorded by the Company in 1994 as additional paid-in capital and a discount to bank debt which was fully amortized through the maturity date, August 31, 1995.

On July 18, 1995, the Company issued 408 units, at \$10,000 per unit, in a private placement of its securities ("July Private Placement"). Each unit consists of: (i) a 10% convertible subordinated debenture due July 18, 2000 in the principal amount of \$10,000, interest payable quarterly, and convertible into shares of the Company's common stock at a conversion price of \$2.00 per share, subject to antidilution provisions, and (ii) 750 redeemable common stock purchase warrants ("warrants"). Each warrant entitles the holder to purchase one share of common stock for \$2.00, subject to adjustment during the five-year period commencing July 18, 1995. The warrants were redeemable by the Company at a price of \$.01 per warrant at any time commencing July 18, 1996, provided that at July 18, 1996, the fair market value of the Company's common stock equals or exceeds \$2.00 per share for the 20 consecutive trading days ending on the third day prior to the notice of redemption to the holders of the warrant. The debentures were converted into 2,040,000 shares of common stock in August 1996.

On November 29, 1995, the Company issued 366 units, at \$10,000 per unit, in a private placement of its securities ("November Private Placement"). Each unit consists of (i) a 10% convertible subordinated debenture due November 29, 2000 in the principal amount of \$10,000, interest payable quarterly, and convertible into shares of the common stock, at a conversion price of \$2.50 per share, subject to dilution, and (ii) 600 redeemable common stock purchase warrants. The terms and conditions of the warrants issued in connection with the November Private Placement are similar to those issued in the July Private Placement, except that the exercise price of the warrant pursuant to the November Private Placement is \$2.50 per share. These debentures were converted into 1,464,000 shares of common stock in December 1996.

The Company received net proceeds from the July and November Private Placements of \$7,013,000, net of issuance costs of \$727,000, and allocated the market value of the warrants, as determined by the Company's Board of Directors, \$416,000, to additional paid-in capital with a corresponding

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### December 31, 1997, 1996 and 1995

## **NOTE F (CONTINUED)**

adjustment to debt discount. The net proceeds from such issuances have been used for the following purposes: repurchase of 500,000 shares of the Company's common stock, registration of the underlying shares pursuant to the Private Placements, the purchase of equipment, research and development costs and for working capital. In addition, the Company was required to use \$950,000 of the net proceeds to repay a portion of its outstanding bank debt during 1995.

On August 6, 1996, the Company issued 250 units, at \$10,000 per unit, in a private placement of its securities ("August Private Placement"). Each unit consists of: (i) a 10% convertible subordinated debenture due August 6, 2001 in the principal amount of \$10,000, interest payable quarterly, and convertible into shares of the Company's common stock at a conversion price of \$3.25 per share, subject to dilution, and (ii) 750 redeemable common stock purchase warrants ("warrants"). Each warrant entitles the holder to purchase one share of common stock for \$3.25, subject to adjustment during the five-year period commencing August 6, 1996. Pursuant to the agreement, the Company was required to establish an escrow account to repay interest in the outstanding convertible debenture, which was fully paid during 1997. The Company received net proceeds from this private offering of approximately \$2,160,000. The Company was required to use \$391,000 of said net proceeds to repay a portion of its bank debt, accrued interest and legal fees. The Company used the balance of the net proceeds of the Offering for: working capital; registration of the underlying shares under the Securities Act; purchase of equipment; and for research and development expenses.

## **NOTE G - ACCRUED EXPENSES**

Accrued expenses are summarized as follows:

	December 31,	
	1997	1996
		(in thousands)
Payroll taxes payable (Note H)	\$3,290	\$1,554
Interest	1,018	539
Professional fees	537	227
Accrued pension and welfare	501	185
Medicaid rebates payable	481	169
Accrued payroll	420	441
Accrued rent	412	227
Other	985	233
	\$7,644	\$3,575
	====	====

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

## **NOTE G (CONTINUED)**

At December 31, 1997 payroll taxes payable included \$2,900,000 of delinquent payroll taxes due to the Internal Revenue Service and New York State (Note Q).

The payroll taxes payable at December 31, 1997 include approximately \$2,400,000 and \$499,000 of delinquent payroll taxes due to the Internal Revenue Service and the State of New York, respectively, all of which liability was incurred in 1997 and 1996. The Company has accrued interest and penalties of \$364,000 and \$205,000 on these Federal and State liabilities, respectively. The Company expects that the Federal liability will be partially offset by income tax refund claims which were filed. To date, the IRS has not taken action with respect to these refund claims pending the completion of an IRS audit for the year 1993. This audit was recently completed by the IRS auditor with no changes proposed. However completion is pending review within the IRS; therefore, the Company has not recorded tax refund claims.

## **NOTE H - INCOME TAXES**

The actual income tax expense varies from the Federal statutory rate applied to consolidated operations as follows:

			YEAR ENDED DEC	EMBER 31,		
	199'		19 	96 	19 	995
	AMOUNT	90	AMOUNT	8	AMOUNT	8
		-	(IN THOU	SANDS)		-
Federal statutory rate Loss for which no tax benefit	\$(5,105)	(34.0)%	\$(4,928)	(34.0)%	\$(749)	(34.0)%
was provided Losses of subsidiaries with	4,924	32.8	4,233	29.1	280	12.7
no tax benefit			424	3.0	240	10.9
Amortization of Warrants	24	. 2	32	. 2		
Goodwill amortization	12	.1	73	.5	77	3.5
Department of Justice						
settlement			57	. 4		
Other	145	.9	109	.8	152	6.9
Actual tax expense	\$ -	- %	\$ -	- %	\$ -	- %
	=====	====	======	====	=====	====

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

## **NOTE H (CONTINUED)**

The Company has net operating loss carryforwards aggregating approximately \$28,890,000, expiring during the years 2009 through 2012. In addition, certain of the Company's subsidiaries filed separate Federal income tax returns in prior years and have separate net operating loss carryforwards aggregating approximately \$5,297,000 expiring during the years 1998 through 2012.

The tax loss carryforwards of the Company and its subsidiaries are subject to limitation by Section 382 of the Internal Revenue Code with respect to the amount utilizable each year. This limitation reduces the Company's ability to utilize net operating loss carryforwards included above each year. The amount of the limitation has not been quantified by the Company.

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

	December 31,	
		1996
	(in thou	sands)
Deferred tax assets		
Net operating loss carryforwards	\$ 15,115	
Allowance for doubtful accounts	304	178
Research and development tax credit	202	212
Reserve for inventory	886	605
Litigation settlement	195	284
Rent	172	96
Reserve for Medicaid	209	010
Capital loss carryforwards	210 111	210
Reserve for property, plant and equipment Other	44	97
other	44	97
Gross deferred tax assets	17,448	14,506
Deferred tax liabilities		
Depreciation	(828)	(663)
Installment sale gain	(798)	(1,218)
Other	(42)	(165)
	(1,668)	(2,046)
Net deferred tax assets before	45 500	
valuation allowance	•	12,460
Valuation allowance	(15,780)	(12,460)
Net deferred tax assets	\$	\$
	======	-=====

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### December 31, 1997, 1996 and 1995

## **NOTE H (CONTINUED)**

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, 1996 primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards.

## **NOTE I - OTHER INCOME (EXPENSE)**

## **Cessation of California Operations**

During 1997, management decided to shut down its California operations which comprised two of its subsidiaries, Cenci Powder Products, Inc. and Cenci Laboratories, Inc. The Company had not incurred any significant costs to exit these operations other than minimal vacation compensation and salary paid to a former plant employee to manage the exit process.

At December 31, 1997, the net assets of Cenci Laboratories, Inc., consisted primarily of building, equipment and land with a net carrying value of \$528,000 and inventory with a total net carrying value of \$93,000. Accordingly, during 1997 the Company recorded a charge of \$264,000 to reduce the fixed assets to their estimated net realizable value, and a \$93,000 charge to write off the remaining inventory. For the years ended December 31, 1997, 1996 and 1995, these subsidiaries, in aggregate, accounted for revenues of approximately \$400,000, \$290,000, and \$446,000, respectively.

During March 1998, the Company signed a letter of intent to sell substantially all of the non-real property assets of Cenci Powder Products, Inc., consisting primarily of \$90,000 in inventory, to a purchaser/creditor, in exchange for the forgiveness of approximately \$260,000 of the Company's indebtedness.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

## **NOTE I (CONTINUED)**

#### Sale of Assets

(a) On March 21, 1995, the Company sold its Abbreviated New Drug Application ("ANDA") for 5mg Oxycodone HCL/325mg Acetaminophen Tablets ("Tablets") and certain equipment used in the production of the Tablets for up to \$5.4 million to Mallinckrodt. The Company received \$500,000 of the proceeds in July 1994, which was recorded as deferred income on the Company's 1994 consolidated balance sheet. Mallinckrodt also paid the Company \$2,000,000 on March 21, 1995 and the remainder was to be payable as follows: (i) \$1,000,000 upon the Company receiving general clearance from the FDA for unrestricted operations at its Brooklyn facility and written notice from the FDA that it is in compliance with certain provisions of the consent degree dated June 29, 1993 and (ii) \$1,900,000 at the earlier of (a) Mallinckrodt receiving certain authorizations from the FDA or (b) March 21, 1998. Mallinckrodt also agreed to defer \$1,200,000 of the Company's trade debt due to an affiliate of Mallinckrodt (Note E). Pursuant to the release of the Company from the FDA's Application Integrity Policy list and its Restrictions (collectively, the "AIP") by the FDA on December 19, 1996, the Company recorded a gain of \$1,000,000. On January 9, 1997, Mallinckrodt tendered this amount to the Bank Group. Pursuant to the agreement of September 21, 1997, the Company recorded \$1,900,000 as a deferred gain which was recognized on March 21, 1998.

In connection with the agreement, the Company agreed to manufacture Tablets for Mallinckrodt for a period of three years and Mallinckrodt agreed to order a minimum number of Tablets from the Company for two years ending March 21, 1997. The Company and Mallinckrodt entered into a noncompetition agreement pursuant to which the Company agreed not to compete with Mallinckrodt and its affiliates with respect to the Tablets until March 21, 2000.

In addition, the Company issued to Mallinckrodt an option to purchase the ANDA for acetaminophen/oxycodone capsules at an exercise price equal to 3/4 of annual net capsule revenue, as defined. As of March 21, 1998, Mallincrodkt did not exercise the option, which had lapsed at that time.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

### **NOTE J - PENSION EXPENSE**

The Company maintains the following two pension plans:

#### 1. Management Pension Plan

The Company had maintained a defined benefit plan covering substantially all nonunion employees which was terminated in November 1996. Subsequently, all Plan assets were converted to cash and held in a money market fund (to continue the Trust) from which all vested participant interests will be paid. Based on information provided by the Company's actuary, the total liability of the Plan as of the plan year ended November 30, 1997 was \$398,281. The actuary has determined that this amount is sufficient to pay the vested interests of all of the participants who were in the Plan as of November 30, 1996, and for any participants who had terminated with previously vested interests that had not yet been paid. Included in the Plan's assets as of November 30, 1997, were receivables from the Company and the Insurer for \$54,631 and \$57,468, respectively, which were subsequently paid in March 1998. No additional contributions were required to be paid to the Trust for the period ended November 30, 1997.

Pending certain approvals by the Pension Benefit Guarantee Corporation ("PBGC"), relating to plan termination, the plan Trustees will be able to make the distributions to the vested participants. The actuary anticipates these distributions during 1998. Prior to such distributions, any earnings realized on the Plan assets will be added to the vested participant's account proportionately. When all assets are distributed from the Trust, the Trust will terminate and a final filing will be made with the Internal Revenue Service.

Historically, the Company's funding policy for the management pension plan (the "Plan"), had been to contribute amounts equal to its liability as determined under the Employee Retirement Income Security Act of 1974 ("ERISA"). Under this funding policy, contributions would be sufficient to maintain plan assets in excess of the projected benefit obligation. As of December 31, 1996, the Company has not funded its 1995 ERISA obligation of approximately \$92,000 and the remaining balance of its 1993 and 1992 ERISA obligations of approximately \$191,000. As a result of Company contributions during 1997, earnings on plan assets and terminations during 1997, the Company's previous outstanding obligations mentioned above had been satisfied.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

## NOTE J (CONTINUED)

Net pension cost for the Company-sponsored pension plan consists of the following:

		December 31,	
	1997	1996	1995
		(in thousands	)
Normal service cost	\$	\$ 24	\$ 49
Interest cost	31	32	25
Actual return on plan assets	(23)	(23)	(19)
Net amortization and deferral	(8)	(8)	(9)
Net pension cost	\$	\$ 25	\$ 46
	====	====	====

The reconciliation of the funded status of the plan to the amount reported in the Company's balance sheet is as follows:

	Year ended December 31,	
	1997	1996
Actuarial present value of benefit obligations at November 30, 1996 and 1995	(in tho	usands)
Estimated present value of vested benefits Estimated present value of nonvested benefits	\$ 398	\$ 440 52
Accumulated benefit obligation Value of future pay increases	398	492 12 
Projected benefit obligation	398	504
Estimated market value of plan assets at November 30, 1997 and 1996	398 	569 
Excess (deficiency) of plan assets over projected benefit obligation		65
Unrecognized net (gain) loss Unrecognized net asset at December 1,	(15)	(72)
1987 being amortized over 24 years	(8)	(8)
	(23)	\$ (15)
	=====	=====

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### December 31, 1997, 1996 and 1995

## **NOTE J (CONTINUED)**

The assumptions used as of November 30, 1997 and 1996 in determining pension expense and funded status shown above were as follows:

	1997	1996
Discount rate	7.00%	7.00%
Rate of salary progression	0%	4.00
Long-term rate of return on assets	7.00	7.00

## 2. Employees' Pension Plan

The Company contributed approximately \$407,000, \$492,000 and \$450,000 in 1997, 1996 and 1995 respectively, to a multiemployer pension plan for employees covered by collective bargaining agreements. This plan is not administered by the Company and contributions are 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."

### NOTE K - STOCK OPTION PLAN

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 replaces its existing stock option plan which expired in January 1994. 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

## **NOTE K (CONTINUED)**

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.

In October 1996, the Board of Directors of Company adopted a non-employee director stock option plan which provides for the granting of nonqualified stock options not to exceed 100,000 shares in total and at an exercise price per share equal to the fair market value of a share or the respective grant dates. No option can be granted under the plan or after October 16, 2006 and no option can be outstanding for more than ten years after its grant. No options have been granted under this plan to date.

The Company has adopted the disclosure provisions of Statement of Financial Accounting Standards No. 123 ("SFAS No. 123"), "Accounting for Stock-Based Compensation." It applies APB Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its plans and does not recognize compensation expense for its stock-based compensation plans other than for restricted stock. If the Company had elected to recognize compensation expense based upon the fair value at the grant date for awards under these plans consistent with the methodology prescribed by SFAS No. 123, the Company's net income and earnings per share would be reduced to the pro forma amounts indicated below:

	Year ended December 31,		
	1997	1996	1995
	(thousa	nds, except per share a	amounts)
Net loss			
As reported	\$15,013	\$(14,495)	\$(4,103)
Pro forma	15,328	(14,180)	(4,459)
Loss per share			
As reported	\$(1.12)	\$(1.49)	\$(.52)
Pro forma	(1.14)	(1.46)	(.56)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### December 31, 1997, 1996 and 1995

## **NOTE K (CONTINUED)**

These pro forma amounts may not be representative of future disclosures because they do not take into effect pro forma compensation expenses related to grants made before 1995. The fair value of these options was estimated at the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions for the years ended December 31, 1997, 1996 and 1995, respectively: expected volatility of 82%, 82% and 71%; risk-free interest rates of 6.6%, 6.6% and 5.8%; and expected lives of 4 years, 4.6 years and 8.8 years. At the date of grant, all exercise prices equaled the market value of the stock.

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 market 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.

Transactions involving stock options are summarized as follows:

	Stock options outstanding	Weighted average exercise price	
Balance at January 1, 1995	222,150	3.98	
Granted Exercised Cancelled	471,600 (39,180) (54,070)	3.16 2.50 3.36	
Balance at December 31, 1995 (carried forward)	600,500	3.49	

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

# December 31, 1997, 1996 and 1995

## NOTE K (CONTINUED)

	Stock options outstanding	Weighted average exercise price
Balance at December 31, 1995 (brought forward)	600,500	\$3.49
Granted Exercised Cancelled	126,000 (49,159) (21,334)	4.77 3.12 4.39
Balance at December 31, 1996	656,007	3.53
Exercised Cancelled	(89,300) (84,968)	3.22 5.16
Balance at December 31, 1997	481,739 ======	3.60

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

	Options outstanding		Options exercisable		
Ranges of exercise prices	Number outstanding at December 31, 1997	Weighted average remaining contractual life	Weighted average exercise price	Number exercisable at December 31, 1997	Weighted average exercise price
\$1.90 - \$4.00	363,572	7.69	\$3.13	363,572	\$3.13
4.01 - 5.00	95,667	8.53	4.79	14,667	4.34
5.01 - 6.25	22,500	4.37	6.17	19,500	6.15
	481,739			397,739	
	======			======	

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## December 31, 1997, 1996 and 1995

### **NOTE L - COMMITMENTS**

The Company occupies plant and office facilities under noncancellable operating leases which expired in December 1995. The Company entered into a new operating lease for the plant and office facilities covering the period from January 1, 1996 to December 31, 2005. These new operating leases provide for scheduled base rent increases over the term of the lease, however, the total amount of the base rent payments will be charged to operations using the straight-line method over the term of the lease. The leases provide for payment of real estate taxes based upon a percentage of the annual increase. The Company's subsidiaries, H.R. Cenci Laboratories, Inc. and Cenci Powder Products, Inc., lease plant and office facilities on a month-to-month basis from a former officer of the subsidiaries. Rent expense relating to these leases amounted to approximately \$90,000, \$90,000 and \$86,000 in 1997, 1996 and 1995, respectively. In addition, the Company rents certain equipment under operating leases, generally for terms of four years. Total rent expense for the years ended December 31, 1997, 1996 and 1995 was approximately \$1,243,000, \$884,000 and \$659,000, respectively.

The approximate minimum rental commitments under these operating leases are as follows:

Twelve months ending December 31,	(in thousands)
1998	\$ 975
1999	1,023
2000	1,075
2001	1,128
2002	1,186
2003 and thereafter	3,921
Total minimum payments required	\$9,308
	=====

### **NOTE M - CONTINGENCIES**

The Company currently is a defendant in several lawsuits involving product liability and other claims. The Company's insurance carriers have assumed the defense for all product liability and other actions involving the Company. None of the lawsuits is brought as a class action. The ultimate outcome of these lawsuits cannot be determined at this time, and accordingly, no adjustment has been made to the consolidated financial statements.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

## NOTE M (CONTINUED)

On October 23, 1996, the Company withdrew four of its ANDAs including its ANDA for acetaminophen/oxycodone capsules (the "Capsule ANDA"), and halted sales of the affected products. Net sales pursuant to the withdrawn Capsule ANDA were approximately \$3 million and \$8 million for the years ended December 31, 1996 and 1995, respectively, and accounted for approximately 24% and 50% of the Company's total net sales during such twelve-month periods (Note P). There were no related sales during 1997. The Company instituted the withdrawal at the suggestion of the FDA and in anticipation of its release from the FDA's AIP. The FDA had placed the Company on the AIP, in October 1991, in connection with its investigation of the Company's operations which culminated in the 1993 consent decree. Under the AIP, the FDA suspended all of the parent company's (i.e., Halsey Drug Co.'s) applications for new drug approvals, including ANDAs and supplements to ANDAs. At the FDA's suggestion, the Company retained outside consultants to perform validity assessments of its drug applications. Thereafter, in October 1996, the FDA recommended that several applications, including the Capsule ANDA, be withdrawn. As a basis of its decision, the FDA cited questionable and incomplete data submitted in connection with the applications. The FDA indicated that withdrawal of the four ANDAs was necessary for the release of the Company from the AIP. The FDA further required submission by the Company of a Corrective Action Plan. Said Plan was prepared and submitted by the Company and accepted by the FDA during 1997.

On December 19, 1996, the FDA released the Company from the AIP. As a consequence, for the first time since October 1991, the Company was permitted to submit ANDAs to the FDA for review. Since its release from the AIP in December 1996, through the fiscal year ended December 31, 1997, the Company submitted six ANDAs for review by the FDA, including a new ANDA with respect to the Capsules. During the period from the Company's release from the AIP to March 15, 1998, the Company received five ANDA approvals, all of which relate to ANDA filings made with the FDA subsequent to the Company's release from the AIP.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

# **NOTE M (CONTINUED)**

As of March 15, 1998, the Company had submitted two additional ANDAs for review by the FDA in fiscal 1998 and anticipates the submission of eight additional ANDAs during the balance of fiscal 1998. Although the Company has been successful in receiving the ANDA approvals described above since its release from the AIP in December 1996, there can be no assurance that any of its newly submitted ANDAs, 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 obtaining such approval, would adversely affect the Company's business operations and financial condition.

On June 21, 1993, the Company entered into a Plea Agreement with the DOJ to resolve the DOJ's investigation into the manufacturing and record keeping practices of the Company's Brooklyn plant. Under the terms of the Plea Agreement, the Company agreed to plead guilty to five counts of adulteration of drug products shipped in interstate commerce. Each count involved product adulteration, and record keeping deficiencies relating to a single drug product, Quinidine Gluconate (324mg tablets), manufactured at the Brooklyn plant. The Plea Agreement also 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. The Company's plea was entered and the terms of the Plea Agreement were approved by the United States District Court for the District of Maryland on July 13, 1993. As of February 28, 1998, the Company was in default of the payment terms of the Plea Agreement and had made payments aggregating \$350,000. On March 27, 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 provides that the Company will satisfy the remaining \$2,150,000 of the fine through the payment of \$25,000 on a monthly basis commencing May 1, 1998, plus interest on such outstanding balance (at the rate calculated pursuant to 28 U.S.C Section 1961)(currently 5.319%). Such payment schedule will result in the full satisfaction of the DOJ fine in December, 2005. The Letter Agreement also provides certain restrictions on the payment of salary or compensation to any individual in excess of \$150,000 without the written consent of the United States District Court for the District of Maryland, subject to certain exceptions. 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 the remaining balance owed and 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, at any time, the Company does not make the payments required under the Letter Agreement in a timely fashion, the United States will be free to declare that the fine is delinquent and/or in default, and exercise all legal process to immediately collect the full amount of the fine, interest and applicable penalties.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

# **NOTE M (CONTINUED)**

In connection with several shareholder lawsuits, the Company agreed to pay to the plaintiffs \$1,000,000 in cash, which has been paid by the Company's insurance carrier in full. In November 1995, the Company satisfied the remainder of its settlement obligation by issuing 824,742 shares of its common stock valued at \$3,000,000 or \$3.6375 per share.

On January 29, 1997, the Securities and Exchange Commission ("SEC") simultaneously instituted and settled an administrative proceeding against the Company, pursuant to the Company's Offer of Settlement, dated September 13, 1996, as modified by letters dated October 11, 1996 and January 10, 1997. The Order made the following findings, among others, which the Company neither admitted nor denied. The Company's December 31, 1990 and December 31, 1991 Annual Reports on Form 10-K stated that the Company had to follow current Good Manufacturing Practices ("CGMP") regulations at all times during which an FDA-approved drug was manufactured by the Company. These annual reports further stated that the Company had to "expend time, money and effort in the areas of production and quality control to ensure full technical compliance." These annual reports failed to disclose that the Company was not manufacturing drugs in accordance with CGMP, but was using unapproved formulas and procedures, and the Company's employees, at former management's direction, were concealing product adulteration from the FDA. These annual reports also failed to disclose that, since the Company was not manufacturing generic drugs in accordance with CGMP, FDA approval for any or all of the Company's new products could be adversely affected. Based on the foregoing, the Commission found that the Company committed violations of Sections 10(b) and 13(a) of the Exchange Act and Rules 10b-5, 12b-20 and 13a-1 thereunder, by filing with the Commission Annual Reports on Form 10-K for the years ended December 31, 1990 and 1991 that omitted to state material facts necessary to make the statements made, in the light of the circumstances under which they were made, not misleading. The Order also requires the Company to "cease and desist from committing or causing any violation and any future violation" of Sections 10-(b) and 13(a) of the Exchange Act and Rules 10b-5, 12b-20 and 13a-1 thereunder.

In 1995, the SEC filed a complaint requiring the Company to cease and desist from violating Section 17(a) of the Securities Act and Sections 10(b) and 13(a) of the Exchange Act and Rules 10b-5, 12b-20, 13a-1 and 13a-13 thereunder. The complaint alleged that the Company's December 31, 1990 and December 31, 1991 Annual Reports on Form 10-K and March 31, 1991, June 30, 1991, September 30, 1991, March 31, 1992, June 30, 1992 and September 30, 1992 quarterly reports on

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

# **NOTE M (CONTINUED)**

Form 10-Q were materially false and misleading. The SEC complaint conforms in large part to a settlement proposal previously submitted by the Company. The Company, without admitting the allegations, entered into a Consent Decree not to violate the law in the future.

By letter dated October 23, 1995, the Company was notified by the New York State Education Department (the "Department") that the Professional Conduct Officer of the Office of Professional Discipline had determined that there was sufficient evidence of professional misconduct on the Company's part to warrant a disciplinary proceeding pursuant to New York law. Upon contacting the Deputy Director of the Office of Professional Discipline, counsel for the Company was advised that the alleged misconduct related to the same activities that were the subject of the DOJ investigation, indictment and plea. The Company submitted a written response on November 16, 1995. The Company and the Department have agreed to the entry of a Consent Order concluding any disciplinary proceedings. The Company will pay \$175,000 in fines over five years. In addition, the Company's registration as a manufacturer of drugs in New York State is revoked, but such revocation is stayed and the Company has been placed on probation for a maximum of five years. The Company has the right to apply for removal from probation after two years.

A lawsuit was filed by the minority shareholders of H.R. Cenci Laboratories, Inc. and Cenci Powder Products, Inc. against the Company and several of the officers of the Company. The lawsuit alleged that the Company has breached several representations made during the course of negotiations leading to the Company's purchase of 51% of the stock of H.R. Cenci Laboratories, Inc. This action sought unspecified compensatory damages, as well as punitive damages, rescission, specific performance, reformation and a declaration as to what amount, if any, was owed to plaintiff. The Company filed a Counterclaim, seeking unspecified compensatory and punitive damages. On March 10, 1997, a Settlement Agreement and Mutual Release was executed by all parties to the lawsuit, terminating the action. The terms of the Settlement provide for repayment of certain outstanding loans, made by the plaintiff to Cenci Labs and Cenci Powders, as well as payment of settlement funds. These payments total \$600,000, payable in equal monthly installments from March, 1997 to June, 1998. The Settlement Agreement further provided for the balance of Cenci Labs and Cenci Powder stock to be turned over to the Company. Twenty-five thousand shares of unregistered Common Stock of the Company was issued to the plaintiff. (Following the completion of the private offering (Note A), the Company satisfied its outstanding monetary obligations to the plaintiff under the Cenci litigation in connection with the execution of an Acknowledgement of Partial Satisfaction of Judgment by the plaintiff.)

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

# **NOTE M (CONTINUED)**

The Company was named as a defendant in an action captioned Allied Welfare Fund, Vacation Fringe Benefit Fund and Union Mutual Fund v. Halsey Drug Co., 96 Civ 3655, brought in the United States District Court for the Eastern District of New York. The complaint seeks sums allegedly owed to three of the Company's labor union funds under the Company's collective bargaining agreement, in the amount of approximately \$265,000. A settlement agreement was reached between the parties and executed July 31, 1997 requiring the Company to remain current on its obligations under its collective bargaining agreement and to pay portions of the alleged arrearages in installments. Prior to the completion of the Offering, the Company was in default under the settlement agreement. On March 19, 1998, the Company satisfied its obligations under the settlement agreement pursuant to the payment of \$309,151 to the Unions.

#### NOTE N - SALE OF COMMON STOCK

On March 30, 1995, the Company entered into an agreement with Zatpack which provides for the purchase of 500,000 shares of common stock of the Company by Zatpack, with registration rights, in consideration of \$1,000,000. The \$1,000,000 consideration consists of the cancellation of indebtedness (incurred by the Company's subsidiaries for the purchase of raw materials delivered from affiliates of Zuellig) and shares of Indiana Fine Chemicals Corporation. As a result of the above transaction, the Company owns 100% of Indiana Fine Chemical Corporation (prior to the above transaction, the Company owned 70% of Indiana Fine Chemical Corporation). In addition, the Company issued a convertible promissory note to Zatpack, dated December 1, 1994 (Note E). Zatpack has acquired the above assets from Zuellig and its subsidiaries.

On October 27, 1994, the Company sold 500,000 shares of its common stock in exchange for \$1,000,000 from Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"). In connection with these shares, Ranbaxy had the right to have its shares of the Company's common stock registered under the Securities Act of 1933. In July 1995, the Company repurchased the 500,000 shares from Ranbaxy for \$1,100,000.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

### NOTE O - SIGNIFICANT CUSTOMERS AND SUPPLIERS

The Company sells its products to a large number of customers who are primarily drug distributors, drugstore chains and wholesalers and are not concentrated in any specific region. The Company performs ongoing credit evaluations of its customers and generally does not require collateral. During 1997, the Company had net sales to two customers in excess of 10% of total sales, aggregating 32.1% of total sales. During 1996, the Company had net sales to one customer aggregating 10% of total sales. During 1995, the Company had net sales to two customers aggregating 25% and 11% of total sales, respectively.

# **NOTE P - FOURTH QUARTER ADJUSTMENTS**

During the fourth quarter of 1997, the Company recorded a provision to write down approximately \$1,300,000 of inventory to its net realizable value.

Additionally, during the fourth quarter of 1997, the Company accrued approximately \$650,000 in connection with penalties and/or interest on delinquent rent and payroll taxes. Subsequent to year-end, these amounts were substantially paid or incorporated into a repayment schedule with the related creditor.

### **NOTE O - SUBSEQUENT EVENTS**

### **Private Placement**

As described in Note A, effective March 10, 1998 the Company consummated a private offering of securities, simultaneously with a Debenture and Warrant Purchase agreement with multiple investors, in exchange for an aggregate purchase price of \$20,800,000. Net proceeds of this financing approximating \$19,700,000, along with related non-cash issuance costs, will be recorded during the first quarter of 1998. The securities consisted of 5% convertible senior secured debentures and common stock purchase warrants exercisable for 4,202,020 shares of the Company's common stock. The debentures mature on March 15, 2003 with interest payable on a quarterly basis. Also, in accordance with certain "as converted" terms of the purchase agreement, one investor, will likely obtain voting rights enabling it to control approximately 50% of the Company's common stock.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

### December 31, 1997, 1996 and 1995

# **NOTE Q (CONTINUED)**

With respect to the 4,202,020 warrants, 2,101,010 warrants were granted to purchase common shares with a par value of \$.01 at an exercise price of \$1.50 with the remaining 2,101,010 warrants being granted to purchase common shares with a par value of \$.01 at an exercise price of \$2.375. Additionally, the debentures may be converted at any time after issuance into common shares at a price of \$1.50 per share or in accordance with other terms of the purchase agreement.

The net proceeds from this offering have been allocated to satisfy a substantial portion of the Company's current liabilities and accounts payable (approximately \$7,333,000) which include: (i) the complete satisfaction of the Company's bank debt and related fees approximating \$3,000,000 and (ii) an obligation to a landlord and satisfaction of related judgments and liens. Further, pursuant to repayment agreements reached with other large creditors in anticipation of the completed offering creditors (including the Department of Justice as described in Note M), the Company has been able to bring these creditors current and potentially comply with terms for future repayment. Such terms include (i) payment to Internal Revenue Service of approximately \$2,000,000 for delinquent Federal payroll taxes and interest in April 1998 (ii) payment to New York State of \$375,000 for delinquent payroll taxes in March 1998 and (iii) an installment payment program with the Department of Justice which provides for, among other things, the payment of penalties and interest totaling \$2,150,000 to be made in monthly installments of \$25,000 commencing in May 1998 through December 2005.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

December 31, 1997, 1996 and 1995

NOTE Q (CONTINUED)

# **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 three-year period, respectively. The contracts provide for, among other things: (i) annual salaries of \$170,000 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.

Exhibit
Number Document

- 3.1 Certificate of Incorporation and amendments (incorporated by reference to Exhibit 3.1 to Amendment No. 2 to the Registrant's Registration Statement on Form S-18, File No. 2471-NY).
- 3.2 Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1993).
- 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 3 1, 1992 (the "1992 Form 10-K")).
- 10.2 Amendment Two, dated as of January 12, 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A., together with forms of Stock Warrant and Registration Rights Agreement (incorporated by reference to Exhibit 10.1. to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1993 (the "1993 Form 10-K")).
- 10.3 Amendment Three, dated as of May 31, 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1994).
- 10.4 Amendment Four, dated as of July 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994)).
- 10.5 Amendment Five, dated as of March 21, 1995, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K dated March 21, 1995 (the "March 8-K")).
- 10.5(1) Form of Warrants issued to The Bank of New York, The Chase Manhattan Bank, N.A. and the Israel Discount Bank (incorporated by reference to Exhibit 10.5(i) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K")).
- 10.5(2) Letter Agreement, dated July 10, 1995, among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995 (the "June 10-Q")).
- 10.5(3) Letter Agreement, dated November 16, 1995, among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.25(iv) to the 1995 10-K).

Exhibit	
Number	Document

- 10.5(4) Amendment 6, dated as of August 6, 1996, to Credit Agreement among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 (the "June 1996 10-Q)).
- 10.5(5) Letter Agreement, dated March 25, 1997 among Halsey Drug Co., Inc., The Chase Manhattan Bank, as successor in interest to The Chase Manhattan Bank (National Association), The Bank of New York and Israel Discount Bank.
- 10.6 Agreement Regarding Release of Security Interests dated as of March 21, 1995 by and among the Company, Mallinckrodt Chemical Acquisition, Inc. and The Chase Manhattan Bank, N.A.(incorporated by reference to Exhibit 10.9 of the March 8-K).
- 10.7 Consulting Agreement dated as of September, 1993 between the Registrant and Joseph F. Limongelli (incorporated by reference to Exhibit 10.6 to the 1993 Form 10-K).
- 10.8 Employment Agreement, dated as of January 1, 1993, between the Registrant and Rosendo Ferran (incorporated by reference to Exhibit 10.2 to the 1992 Form 10-K).

10.10(1) Halsey Drug Co., Inc. 1984 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.3 to the 1992 Form 10-K).

10.10(2) Halsey Drug Co., Inc. 1995 Stock Option and Restricted Stock Purchase Plan (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8, File No. 33-98396).

10.10(3) Halsey Drug Co., Inc. Non-Employee Director Stock Option Plan.

- 10.11 Leases, effective February 13, 1989 and January 1, 1990, respectively, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss (incorporated by reference to Exhibits 10.6 and 10.7, respectively, to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1989).
- 10.12 Lease, effective as of April 15, 1988, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, and Rider thereto (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1987).
- 10.12(1) Lease, as of October 31, 1994, among Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, together with Modification, Consolidation and Extension Agreement (incorporated by reference to Exhibit 10. 12(i) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995).
- 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).

Exhibit Number	Document
10.14	Toll Manufacturing Agreement for APAP/Oxycodone Tablets dated as of March 21, 1995 between Acquisition and the Registrant (incorporated by reference to Exhibit 10.2 to the March $8-K$ ).
10.15	Capsule ANDA Option Agreement dated as of March 21, 1995 between Acquisition and the Registrant (incorporated by reference to Exhibit 10.3 to the March 8-K).
10.16	Tablet ANDA Noncompetition Agreement dated as of March 21, 1995 between the Registrant and Acquisition (incorporated by reference to Exhibit $10.4$ to the March $8-K$ ).
10.17	Subordinated Non-Negotiable Promissory Term Note in the amount of \$1,200,00 dated March 21, 1995 issued by the Registrant to Acquisition (incorporated by reference to Exhibit 10.5 to the March 8-K).
10.18	Term Note Security Agreement dated as of March 21, 1995 among the Company, Houba, Inc. and Acquisition (incorporated by reference to Exhibit $10.6$ to the March $8-K$ ).
10.19	Amendment dated March 21, 1995 to Subordination Agreement dated as of July 21, 1994 between Mallinckrodt Chemical, Inc., Mallinckrodt Chemical Acquisition, Inc., the Registrant, The Chase Manhattan Bank (National Association), Israel Discount Bank of New York, The Bank of New York, and The Chase Manhattan Bank (National Association) (incorporated by reference to Exhibit 10.8 to the March 8-K).
10.20	Agreement dated as of March 30, 1995 between the Registrant and Zatpack, Inc. (incorporated by reference to Exhibit 10.10 to the March $8-K$ ).
10.21	Waiver and Termination Agreement dated as of March 30, 1995 between Zuellig Group, W.A., Inc. and Indiana Fine Chemicals Corporation (incorporated by reference to Exhibit 10.11 to the March 8-K).
10.22	Convertible Subordinated Note of the Registrant dated December 1, 1994 issued to Zatpack, Inc. (incorporated by reference to Exhibit 10.12 to the March 8-K).
10.23	Agreement dated as of March 30, 1995 among the Registrant, Indiana Fine Chemicals Corporation, Zuellig Group, N.A., Inc., Houba Inc., ZetaPharm, Inc. and Zuellig Botanicals, Inc. (incorporated by reference to Exhibit 10.13 to the March 8-K).
10.24	Supply Agreement dated as of March 30, 1995 between Houba, Inc. and ZetaPharm, Inc. (incorporated by reference to Exhibit $10.14$ to the March $8-K$ ).
10.25	Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit $6(a)$ to the June $10-Q$ ).
10.26	Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit $6(a)$ to the June $10-Q$ ).
10 00	

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")).

Exhibit Number	Document
10.28	Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the December $8-K$ ).
10.29	Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 99 to the June 1996 $10-Q$ ).
10.30	Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the June 1996 $10-Q$ ).
10.31	Form of 5% Convertible Senior Secured Debenture (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated March 24, 1998 (the "March 1998 8- K")).
10.32	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the March 1998 $8-K$ ).
10.33	Debenture and Warrant Purchase Agreement dated March 10, 1998, by and among the Registrant, Galen Partners III, L.P. and the other Purchasers listed on the Signature Page thereto (incorporated by reference to Exhibit 10.1 to the March 1998 8-K).
10.34	Form of General Security Agreement of Halsey Drug Co., Inc. dated March 10, 1998 (incorporated by reference to Exhibit 10.2 to the March 1998 $8-K$ ).
10.35	Form of Agreement of Guaranty of Subsidiaries of Halsey Drug Co., Inc. dated March 10, 1998 (incorporated by reference to Exhibit 10.3 to the March 1998 $8-K$ ).
10.36	Form of Guarantor General Security Agreement dated March 10, 1998 (incorporated by reference to Exhibit 10.4 to the March 1998 $8-K$ ).
10.37	Stock Pledge Agreement dated March 10, 1998 by and between the Registrant and Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.5 to the March 1998 8-K).
10.38	Form of Irrevocable Proxy Agreement (incorporated by reference to Exhibit 10.6 to the March 1998 8-K).
10.39	Agency Letter Agreement dated March 10, 1998 by and among the Purchasers a party to the Debenture and Warrant Purchase Agreement, dated March 10, 1998 (incorporated by reference to Exhibit 10.7 to the March 1998 8-K).
10.40	Press Release of Registrant dated March 13, 1998 (incorporated by reference to Exhibit 99.1 to the March 1998 8-K).
10.41	Current Report on Form 8-K as filed by the Registrant with the Securities and Exchange Commission on March 24, 1998.
*10.42	Letter Agreement between the Registrant and the U. S. Department of Justice dated March 27, 1998 relating to the restructuring of the fine assessed by the Department of Justice under the Plea Agreement dated June 21, 1993.

Exhibit Number	Document	
*10.43	Employment Agreement dated as of March 10, 1998 between the Registrant and Michael K. Reicher	
*10.44	Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens	
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 22 to the 1993 Form $10\text{-K}$ ).	
*23.1	Consent of Grant Thornton LLP, independent certified public accountants.	
*27	Financial Data Schedule, which is submitted electronically to the Securities and Exchange Commission for informational purposes only and not filed.	

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

#### **Exhibit 10.42**

March 27, 1998

VIA FAX (202) 234-1560

John R. Fleder Olsson, Frank and Weeda, P.C. Suite 400 1400 Sixteenth Street, N.W. Washington, D.C. 20036

Re: Halsey Drug Company

Dear Mr. Fleder:

As you know, Halsey Drug Company (Halsey) has not made any payment in the settlement of the criminal fine that was imposed on it by the United States District Court for the District of Maryland since May 1996. Payment of the fine has thus been long delinquent and the United State could, at this time, declare the fine to be in default and initiate a collection action for the full amount of the fine that remains unpaid, \$2.15 million, and additional monetary penalties pursuant to 18 U.S.C. Section 3612.

Rather than initiate such action at this time, I propose the following alternatives. The first alternative is that Halsey pay the full amount now due, \$2.15 million, by May 1, 1998, in full satisfaction of the fine. If Halsey is not able to make such payment by that date, I suggest that, pursuant to 18 U.S.C. Section 3614, we jointly move the Court to modify the original sentence that was imposed on July 23, 1993.

The sentence imposed by the Court included a fine of \$2,500,000, but provided that it be payable pursuant to the following schedule: \$125,000 was to be paid within 60 days of sentencing and an additional \$125,000 was to be paid every 90 days thereafter until the fine was paid in full. The interest requirement was waived.

In light of its current financial circumstances I propose that both Halsey and the United States ask the Court to modify the sentence to allow for the following payment schedule and to provide the additional conditions set forth below.

- 1. Interest shall accrue on all outstanding balances at the rate calculated pursuant to 28 U.S.C. Section 1961, from the date on which the Court modifies the fine payment schedule until the fine and all accrued interest and penalty is paid in full.
- 2. Halsey shall, beginning on May 1, 1998, cause a check drawn in the amount of twenty-five thousand dollars (\$25,000), plus all accrued interest, to be made payable to the Clerk of the United States District Court every month. These monthly payments, via certified check, shall continue thereafter and be sent by Halsey so as to be received by the Clerk of the U.S. District Court for the District of Maryland in Baltimore, by the 7th day of each month. These monthly payments shall continue until Halsey has paid off all of its financial obligations to the United States which have arisen from this case. (When the 7th of any month falls on Saturday, Sunday or a Holiday, the payments shall be sent so that they are received by the Clerk of Court in Baltimore no later than the first business day after the 7th of the month).
- 3. Until such time as this fine, including all applicable interest and penalties (the debt) is paid in full the United States shall have full access to all financial records of Halsey. All financial information requested by the Court or the United States shall be provided promptly.
- 4. Until such time as this debt is paid in full Halsey shall not in any calendar year pay (or obligate itself to pay) to any individual (or on behalf of any individual) more than \$150,000 without the prior written consent of the United States or an order of the U.S. District Court for the District of Maryland. The United States may withhold this consent only if it concludes that these payments are inconsistent with salaries generally paid for similar positions in the pharmaceutical industry in the New York City area and such payments would inhibit Halsey's ability to pay its debt to the United States as outlined in this agreement. Halsey shall provide all information that the United States requests in order for it to make these determinations. Halsey, however, considers the information which it provides about the compensation paid its employee to be exempt from disclosure under the Freedom of Information Act. If the United States has not responded to Halsey's request within 30 days, or if Halsey believes that the United States has inappropriately withheld its consent, Halsey may petition the District Court for authorization to pay the salary and or any other compensation which its management considers appropriate. In any petition to the District Court, Halsey will bear the burden of proof that its proposed compensation is reasonable and appropriate.
- 5. Until such time as this debt is paid in full, if Halsey earns an after tax profit in any calendar year, as determined by generally accepted accounting principles, a sum equal to the lesser of the remaining debt or 25% of that profit shall, within 90 days of the close of the fiscal year, be paid to the United States in further payment of the principal on this fine.
- 6. Until such time as this debt is paid in full, if Halsey sells any capital asset (or group of assets) for a sum in excess of \$10,000 it shall either invest the entire sum in another capital asset, or within 90 days pay a sum equal to the lesser of the remaining debt or 25% of the proceeds of that sale to the United States in further payment of the principal on this fine.

7. If this proposal is accepted by the Court and Halsey makes all payments as specified in this proposal, and pays on time and in full the fine and all interest that may have accrued thereon, at that time, the Government will waive any penalty that could be assessed pursuant to 18 U.S.C. Section 3612(g). If at any time after a modified sentencing order is entered, Halsey does not make the required payments in a timely fashion, the United States will be free to declare that the fine is delinquent and/or in default, and exercise all legal process to immediately collect the full amount of the fine, interest and applicable penalties.

This proposal is made subject to the approval of the U.S. Attorney for the District of Maryland and the U.S. District Court. If for any reason such approval is not forthcoming, both the United States and Halsey retain all rights and obligations that now exist.

I have submitted this proposal to the U.S. Attorney for approval, and I ask that you promptly submit this proposal to your client for its approval.

Sincerely,

/s/ Lawrence G. McDade

Lawrence G. McDade
Deputy Director
Office of Consumer Litigation
U.S. Department of Justice
1331 Pennsylvania Avenue, N.W.
Suite 950 North
Washington, D.C. 20004
(202) 307-0138

cc: AUSA Barbara S. Sale

### **EXHIBIT 10.43**

# **EMPLOYMENT AGREEMENT**

EMPLOYMENT AGREEMENT made as of the 10th day of March, 1998 between and among HALSEY DRUG CO., INC., a New York corporation (the "Corporation"), with principal executive offices at 1827 Pacific Street, Brooklyn, New York 11233 and MICHAEL K. REICHER residing at 2264 Churchview Drive, Apt. 10, Rockford, Illinois 61107 (the "Employee").

### WITNESSETH

WHEREAS, the Corporation desires to employ the Employee to engage in such activities and to render such services as are required under the terms and conditions hereof and the Board of Directors has authorized and approved the execution of this Agreement; and

WHEREAS, the Employee desires to be employed by the Corporation under the terms and conditions hereinafter provided,

WHEREAS, the Corporation is engaged in the generic drug business as a manufacturer, packager, distributor, and wholesaler thereof and in the development of new generic drugs.

NOW, THEREFORE, in consideration of the mutual covenants and undertakings herein contained, the parties agree as follows:

- 1. Employment, Duties and Acceptance.
- 1.1 Services. The Corporation hereby employs Employee, for the Term (as hereinafter defined in Section 2 hereof), to render exclusive and full-time services to the business and affairs of the Corporation as the Chief Executive Officer and President of the Corporation, subject to the direction and control of the Board of Directors of the Corporation, and, in connection

therewith, the Employee shall be responsible for the day-to-day operations of the Corporation, for development and implementation of annual operating plans, annual capital plans and strategic plans, and to perform such other duties consistent with the office of the Chief Executive Officer and President as he shall reasonably be directed or requested to perform by the Board of Directors, to whom he shall report, and to use his best efforts, skill and abilities to promote the interests of the Corporation and its subsidiaries. Employee shall not be required to relocate his residence to the New York/New Jersey metropolitan area as a condition of his employment. Employee shall, however, spend as much time in the NY/NJ area as may be required in the exercise of his best judgment for the successful operation of the Corporation.

- 1.2 Acceptance. Employee hereby accepts such employment and agrees to render the services described in Section 1.1 hereof.
- 2. Term of Employment.

The term of Employee's employment under this Agreement shall commence on the date of this Agreement and shall terminate on February 28, 2003 (the "Initial Term"), unless sooner terminated pursuant to Section 8 of this Agreement; provided, however, that if the Corporation shall fail to give Employee written notice of non-renewal of Employee's employment with the Corporation not less than 180 days prior to the Initial Term or any Renewal Period (as defined), Employee's term hereunder shall automatically be extended for successive one (1) year periods (each a "Renewal Period" and together with the Initial Term, the "Term").

3. Compensation. In consideration of the services to be rendered by the Employee pursuant to this Agreement, the Employee shall receive from the Corporation the following compensation:

(a) Base Salary. The Corporation shall pay the Employee an aggregate base salary at the annual rate of \$175,000, payable in equal bi-weekly installments, less such deductions or amounts to be withheld as shall be required by applicable laws and regulations.

The Employee's Base Salary shall be subject to increase at the discretion of the Board of Directors of the Corporation, in its sole discretion.

- (b) Annual Bonus. During the Term, Employee shall be entitled to receive from the Corporation an annual bonus in respect of each fiscal year, or portion thereof, of the Corporation as follows:
- (1) commencing with the Corporation's 1998 fiscal year (ending December 31, 1998), in an amount of \$93,750, provided that net sales of the Corporation for the year ending December 31, 1998 are not less than \$28,000,000; and
- (2) thereafter in accordance with such targets, conditions or parameters as may be determined from time to time hereafter by the Compensation Committee of the Board of Directors of the Corporation in its sole and absolute discretion.

# 4. Expenses.

The Corporation shall pay or reimburse Employee for all reasonable expenses which are in accordance with the Corporation's expense policy in force from time to time and which are actually incurred or paid by him during the Term in the performance of his services under this Agreement, upon presentation of expense statements or vouchers or such other supporting information as the Corporation may require.

- 5. Additional Benefits.
- (a) In General. In addition to the compensation and expenses to be paid under

Sections 3 and 4 hereof, Employee will be entitled to all rights and benefits for which he shall be eligible under any insurance, profit-making, incentive, bonus, stock option, pension or other extra compensation or "fringe" benefit plan of the Corporation or any of its subsidiaries now existing or hereafter adopted for the benefit of the executives or employees generally of the Corporation.

- (b) Stock Options. Employee is hereby granted stock options to purchase 1,000,000 shares of the Corporation's common stock, \$.01 par value per share (the "Option") 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 on Wednesday, February 18, 1998) (the "Option Shares"). The Option shall vest and be exercisable in an amount equal to 62,500 Option Shares at the end of each quarterly period during the Term (the first quarterly vesting period to be satisfied on May 1, 1998 and on each August 1, November 1, and February 1, thereafter until fully vested). The Option shall have a ten year term, subject to earlier termination as set forth in paragraph 5(c) upon the termination of Employee's employment with the Corporation and shall be evidenced by the Corporation's standard form stock option agreement. The Employee and the Corporation agree that the Option shall be deemed to have been issued pursuant to one or more plans for the grant of incentive stock options, to the maximum extent permitted by law, and non-qualified stock options. The exercise price and terms of any non-qualified options shall be subject to such revisions as the Employee and the Corporation may agree.
- (c) Purchase of Options. In the event that Employee is terminated for cause (as defined in paragraph 8.3) or resigns, the Corporation shall have the right, but not the obligation, to purchase Employee's vested Option at the Fair Market Value thereof. In the event that the Corporation does not elect to purchase Employee's vested Option within seven days of the date of

Employee's termination for cause or resignation, Employee shall be obligated to exercise his Options in writing within 37 days of such termination or resignation, failing which he shall be deemed to have forfeited his Option to the Corporation. For purposes of this paragraph 5 (c), "Fair Market Value" shall mean the product of (i) the positive difference, if any, between the average of the closing price of the Company's Common Stock as reported by the American Stock Exchange, or such other exchange or over-the-counter market on which the Company's Common Stock may then be listed or admitted for trading, for the five

- (5) trading days prior to the date of termination, multiplied by (ii) the number of Option Shares which, as of the date of termination, are vested under the Option.
- (d) Automobile. The Corporation shall provide the Employee with a company car and shall reimburse the Employee for all gasoline, insurance and maintenance expense associated with the Employee's automobile, to the extent deductible by the Corporation under applicable federal laws and regulations.

### 6. Vacation.

Employee shall be entitled to a vacation period of not less than four weeks during each year of the Term, to be taken at a time or times acceptable to the Corporation.

7. Insurability; Right to Insure. Employee represents and warrants to the Corporation that, to the best of his knowledge, on the date hereof he is, and upon the commencement of the Term he will be, insurable at standard premium rates. Employee agrees that the Corporation shall have the right during the Term to insure the life of Employee by a policy or policies of insurance in such amount or amounts as it may deem necessary or desirable, and the Corporation shall be the beneficiary of any such policy or policies and shall pay the premiums or other costs thereof. The

Corporation shall have the right, from time to time, to modify any such policy or policies of insurance or to take out new insurance on the life of Employee. Employee agrees, upon request, at any time or times prior to the commencement of or during the Term to sign and deliver any and all documents and to submit to any physical or other reasonable examinations which may be required in connection with any such policy or policies of insurance or modifications thereof.

# 8. Termination.

- 8.1 Death. If during the Term Employee shall die, Employee's employment under this Agreement shall terminate as of the date of Employee's death. The base salary payable hereunder to or for the benefit of Employee through the date of death shall be paid to such person or persons ("Employee's Designees") as Employee may designate by notice to the Corporation from time to time or, in the absence of such designation, to his spouse. In addition, the Corporation shall pay the Employee's Designees an amount equal to six months' base salary plus 1/12th of the bonus the Employee would have received had he been alive at the end of the year in which he died, for each complete calendar month from January 1 of the year in which the Employee died, to his date of death.
- 8.2 Disability. In the event of the Employee's "mental or physical disability" (as defined herein) which continues for (i) a period of longer than 90 consecutive days, or (ii) such periods aggregating 120 days during any 365 consecutive days, such that the Employee is, despite reasonable accommodation, unable to substantively perform the essential functions of his position for said period, the determination of which shall be confirmed by the Board of Directors in the manner hereinafter provided, this Agreement shall terminate upon thirty (30) days' prior written notice to the Employee from the Corporation (the "Disability Termination Date"). The Corporation

shall continue to pay to the Employee during the period of his mental or physical disability the base salary and annual bonus provided in Section 3 of this Agreement as well as provide the benefits described herein; provided, however, that the base salary shall be reduced by any disability insurance payments paid to the Employee. On the Disability Termination Date, Employee's base salary shall cease but the Employee shall be entitled to the annual bonus computed in accordance with Section 3(b) hereof for the period ending on the Disability Termination Date. Except for the bonus payment required in the preceding sentence, no annual bonus will accrue or be payable by the Corporation following the Disability Termination Date.

As used herein, the term "mentally or physically disabled" shall have the meaning ascribed thereto in the disability insurance policy then in force and effect with respect to the Employee or, if no such disability policy then exists, it shall mean the inability of the Employee, by reason of injury, illness or other similar cause to perform a material part of his duties and responsibilities in connection with the conduct of the business and affairs of the Corporation as determined by a reputable physician of the Corporation's selection, who has examined the Employee with his consent.

8.3 Termination For Cause. The Corporation may at any time during the Term, by written notice, and after affording the Employee the opportunity to be heard in person by the Board of Directors, terminate this Agreement and discharge Employee for "cause", whereupon the Corporation's obligation to pay compensation or any other amounts payable hereunder to or for the benefit of Employee shall terminate on the date of such discharge except for accrued and unpaid salary and expenses to the date of discharge. For purposes of this Agreement, the term "cause" shall mean (i) excessive absenteeism, alcoholism or drug abuse, (ii) fraud, misappropriation or intentional

material damage to the property or business of the Corporation; (iii) conviction of a felony; (iv) failure of the Employee to perform his duties in accordance with this Agreement after written notice to the Employee by the Board of Directors specifying such failure and giving the Employee eight (8) days to correct the defects in performance; or (v) breach by the Employee of any material provision hereof which, if capable of remedy, remains unremedied for more than 10 days after written notice.

8.4 Termination without Cause. The Corporation shall have the option to terminate this Agreement without cause upon thirty (30) days' written notice to the Employee. In the event the Corporation terminates this Agreement pursuant to this Section 8.4, the Corporation shall pay the Employee an amount equal to (a) his then accrued and unpaid base salary and bonuses through and including the date of termination, and (b) \$350,000 or twice his then Base Salary, whichever is greater payable in 24 equal monthly installments. Upon termination of Employee's employment with the Corporation pursuant to this

Section 8.4, (i) Employee's outstanding Options shall vest in full, notwithstanding any contrary vesting schedule contained herein or in any option agreement between the Corporation and the Employee and shall be exercised within 90 days of the date of vesting, and (ii) the provisions of paragraph 9.3 shall be deemed of no force or effect.

Subject to paragraph 8.4(ii), the obligations of the Employee under Section 9 shall continue notwithstanding the termination of Employee's employment pursuant to this Section 8.4 provided the Corporation complies with its obligations specified in this paragraph.

8.5 Change of Control. Upon the sale or transfer of more than 50% of the outstanding shares of the Corporation (other than to Galen Associates or any of its affiliates) or upon the sale of the whole or a major part of the business of the Corporation, Employee shall be entitled

to terminate this Agreement on the same terms and conditions as set forth in Section 8.4.

- 9. Protection of Confidential Information. In view of the fact that Employee's work for the Corporation will bring him into close contact with all the confidential affairs thereof, and plans for future developments, Employee agrees to the following:
- 9.1 Secrecy. During the term of Employment and for two (2) years thereafter, to preserve the confidential nature of, and not disclose, reveal, or make accessible to anyone other than the Corporation's officers, directors, employees, consultants or agents, otherwise than within the scope of his employment duties and responsibilities hereunder, any and all documents, information, knowledge or data of or pertaining to the Corporation, its subsidiaries or affiliates or pertaining to any other individual, firm, corporation, partnership, joint venture, business, organization, entity or other person with which the Corporation or any of its subsidiaries or affiliates may do business during the Term of Employment (including licensees, licensors, manufacturers, suppliers and customers of the Corporation or any of its subsidiaries or affiliates) and which is not in the public domain, including trade secrets, "know how", names and lists of licensees, licensors, manufacturers, suppliers and customers, programs, statistics, manufacturing and production methods, processes, techniques, pricing, marketing methods and plans, specifications, advertising plans and campaigns or any other matters, and all other confidential information of the Corporation, its subsidiaries and affiliates acquired in connection with Employee's employment (hereinafter referred to as "Confidential Information"). The restrictions on the disclosure of Confidential Information imposed by this Subparagraph 9.1 shall not apply to any Confidential Information that was part of the public domain at the time of its receipt by the Employee or becomes part of the public domain in any manner and for any reason other than an act by the Employee, unless the Employee is legally

compelled (by deposition, interrogatory, request for documents, subpoena, civil investigative demand or similar process) to disclose such Confidential Information, in which event Employee shall provide the Corporation with prompt notice of such requirement so that the Corporation may seek a protective order or other appropriate remedy, and if such protective order or other remedy is not obtained, Employee shall exercise reasonable efforts in good faith to obtain assurance that confidential treatment will be accorded such Confidential Information.

- 9.2 Return Memoranda, etc. To deliver promptly to the Corporation on termination of his employment, or at any other time the Corporation may so request, all memoranda, notes, records, reports, manuals, drawings, blueprints and other documents (and all copies thereof) relating to the Corporation's business and all property associated therewith, which he may then possess or have under his control.
- 9.3 Non-competition. Provided that this Agreement has not been breached by the Corporation, the Employee agrees that he shall not at any time prior to two years after the earlier to occur of (i) the expiration of the Term hereunder and (ii) the termination of his employment with the Corporation, own, manage, operate, be a director or an employee of, or a consultant to any business or corporation which is conducting any business within the generic drug industry or which competes with or conducts the same business as or similar to that conducted by the Corporation in the United States. The Employee further agrees that, provided this Agreement has not been breached by the Corporation, he shall not, at any time prior to two years after the earlier to occur of (i) the expiration of the Term hereunder and (ii) the termination of his employment with the Corporation, assist or allow any such business or corporation to hire anyone who was employed by the Corporation at such time or at any time during the preceding twelve months. If any of the provisions of this section, or

any part thereof, is hereinafter construed to be invalid or unenforceable, the same shall not affect the remainder of such provision or provisions, which shall be given full effect, without regard to the invalid portions. If any of the provisions of this section, or any part thereof, is held to be unenforceable because of the duration of such provision, the area covered thereby or the type of conduct restricted therein, the parties agree that the court making such determination shall have the power to modify the duration, geographic area and/or other terms of such provision and, as so modified, said provision shall then be enforceable. In the event that the courts of any one or more jurisdictions shall hold such provisions wholly or partially unenforceable by reason of the scope thereof or otherwise, it is the intention of the parties hereto that such determination not bar or in any way affect the Corporation's right to the relief provided for herein in the courts of any other jurisdictions as to breaches or threatened breaches of such provisions in such other jurisdictions, the above provisions as they relate to each jurisdiction being, for this purpose, severable into diverse and independent covenants.

- 9.4 Injunctive Relief. The Employee acknowledges and agrees that, because of the unique and extraordinary nature of his services, any breach or threatened breach of the provisions of Sections 9.1, 9.2, or 9.3 hereof will cause irreparable injury and incalculable harm to the Corporation, and the Corporation shall, accordingly, be entitled to injunctive and other equitable relief for such breach or threatened breach and that resort by the Corporation to such injunctive or other equitable relief shall not be deemed to waive or to limit in any respect any right or remedy which the Corporation may have with respect to such breach or threatened breach.
- 9.5 Expenses of Enforcement of Covenants. In the event that any action, suit or proceeding at law or in equity is brought to enforce the covenants contained in Section 9.1, 9.2, or

- 9.3 hereof or to obtain money damages for the breach thereof, the party prevailing in any such action, suit or other proceeding shall be entitled upon demand to reimbursement from the other party for all expenses (including, without limitation, reasonable attorneys' fees and disbursements) incurred in connection therewith.
- 9.6 Non-Solicitation. Employee covenants and agrees not to, directly or indirectly, during the Term of Employment and for a period of two (2) years from and after the effective date of the termination of his employment with the Corporation (for any reason whatsoever), (i) induce or attempt to influence any employee of the Corporation or any of its subsidiaries or affiliates to leave its employ, or (ii) aid any person, business, or firm, including a supplier, a competitor, licensor or customer of or a manufacturer for the Corporation, in any attempt to hire any person who shall have been employed by the Corporation or any of its subsidiaries or affiliates within the period of one (1) year of the date of any such requested aid.

### 10. Indemnification.

- (a) The Corporation will defend and indemnify Employee, to the maximum extent permitted by applicable law and the by-laws of the Corporation, against all claims, costs, charges and expenses incurred or sustained by him in connection with any action, suit or other proceeding to which he may be made a party by reason of (i) his being an officer, director or employee of the Corporation or of any subsidiary or affiliate thereof, or (ii) the Employee's alleged employment of Employee by Ranbaxy Pharmaceuticals, Inc. or his alleged termination thereafter.
- (b) The Corporation will defend and indemnify Employee against all costs, charges and expenses incurred or sustained by him in connection with any action, suit or other proceeding to which he may be made a party by reason of the Employee's prior employment by

Mylan Pharmaceuticals Inc. or any agreement executed in connection with such employment; provided, however, that in no event shall such defense and indemnity obligation exceed \$25,000 in the aggregate.

# 11. Employee Warranties.

Employee hereby warrants that, except as may be alleged by Ranbaxy Pharmaceuticals, Inc., as of the date hereof Employee is not employed (other than by the Corporation) and is not a party to any other employment contract, express or implied. Employee warrants that he has no other obligation, contractual or otherwise, which would prevent him from accepting the Corporation's offer of employment under the terms of this Agreement and from complying with its provisions. Employee warrants that he will not utilize during his employment hereunder any confidential information obtained through or in connection with his prior employment. Employee warrants that he knows of no reason why he would not be able to perform his obligations under this Agreement.

# 12. Notices.

All notices, requests, consents and other communications required or permitted to be given hereunder, shall be in writing and shall be deemed to have been duly given if delivered personally or sent by facsimile, with confirmation of receipt, or mailed first-class, postage prepaid, by registered or certified mail (notices sent by mail shall be deemed to have been given on the date sent), to the parties at their respective addresses hereinabove set forth or to such other address as either party shall designate by notice in writing to the other in accordance herewith.

- 13. General.
- 13.1 Governing Law. This Agreement shall be governed by and construed and

enforced in accordance with the local laws of the State of New York applicable to agreements made and to be performed entirely in New York.

- 13.2 Captions. The section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.
- 13.3 Entire Agreement. This Agreement sets forth the entire agreement and understanding of the parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, relating to the subject matter hereof. No representation, promise or inducement has been made by either party that is not embodied in this Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth.
- 13.4 Assignability. This Agreement, and Employee's rights and obligations hereunder, may not be assigned by Employee. The Corporation may assign its rights, together with its obligations, hereunder in connection with any sale, transfer or other disposition of all or substantially all of its business or assets; in any event the rights and obligations of the Corporation hereunder shall be binding on its successors or assigns, whether by merger, consolidation or acquisition of all or substantially all of its business or assets.
- 13.5 Amendment. This Agreement may be amended, modified, superseded, canceled, renewed or extended and the terms or covenants hereof may be waived, only by a written instrument executed by both of the parties hereto, or in the case of a waiver, by the party waiving compliance. No superseding instrument, amendment, modification, cancellation, renewal or extension hereof shall require the consent or approval of any person other than the parties hereto. The failure of either party at any time or times to require performance of any provision hereof shall

in no matter affect the right at a later time to enforce the same. No waiver by either party of the breach of any term or covenant contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such breach, or a waiver of the breach of any other term or covenant contained in this Agreement.

- 13.6 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which taken together will constitute one and the same instrument.
- 13.7 Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration, conducted before a panel of three arbitrators, in New York, New York, in accordance with the commercial arbitration rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The expense of such arbitration shall be borne as directed by the arbitrator.
- 13.8 Severability. The provisions of this Agreement shall be deemed severable, and if any part of any provision is held illegal, void or invalid under applicable law, such provision may be changed to the extent reasonably necessary to make the provision, as so changed, legal, valid and binding. If any provision of this Agreement is held illegal, void or invalid in its entirety, the remaining provisions of this Agreement shall not in any way be affected or impaired but shall remain binding in accordance with their terms.
- 13.9 Fees and Costs. The Corporation will contribute not more than \$10,000 towards the fees and costs of Employee's counsel in connection with the review of this Agreement and Peter Clemens' Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

ATTEST:	HALSEY DRUG CO., INC.
	By: /s/ William Skelly
	William Skelly, Chairma
WITNESS:	EMPLOYEE
	By: /s/ Michael K. Reicher
	Michael K. Reicher

### **EXHIBIT 10.44**

# **EMPLOYMENT AGREEMENT**

EMPLOYMENT AGREEMENT made as of the 10th day of March, 1998 between and among HALSEY DRUG CO., INC., a New York corporation (the "Corporation"), with principal executive offices at 1827 Pacific Street, Brooklyn, New York 11233 and PETER CLEMENS residing at 20860 Valley Road, Kideer, Illinois 60047 (the "Employee").

### WITNESSETH

WHEREAS, the Corporation desires to employ the Employee to engage in such activities and to render such services as are required under the terms and conditions hereof and the Board of Directors has authorized and approved the execution of this Agreement; and

WHEREAS, the Employee desires to be employed by the Corporation under the terms and conditions hereinafter provided,

WHEREAS, the Corporation is engaged in the generic drug business as a manufacturer, packager, distributor, and wholesaler thereof and in the development of new generic drugs.

NOW, THEREFORE, in consideration of the mutual covenants and undertakings herein contained, the parties agree as follows:

- 1. Employment, Duties and Acceptance.
- 1.1 Services. The Corporation hereby employee, for the Term (as hereinafter defined in Section 2 hereof), to render exclusive and full-time services to the business and affairs of the Corporation as the Chief Financial Officer of the Corporation, subject to the direction and control of the President and the Board of Directors of the Corporation, and, in

connection therewith, the Employee shall be responsible for the duties normally attendant with the position of Chief Financial Officer, and such other duties consistent with the office of Chief Financial Officer as he shall reasonably be directed or requested to perform by the President or the Board of Directors, to whom he shall report, and to use his best efforts, skill and abilities to promote the interests of the Corporation and its subsidiaries. Employee shall not be required to relocate his residence to the New York/New Jersey metropolitan area as a condition of his employment. Employee shall, however, spend as much time in the NY/NJ area as may be required in the exercise of his best judgment for the successful operation of the Corporation.

- 1.2 Acceptance. Employee hereby accepts such employment and agrees to render the services described in Section 1.1 hereof.
- 2. Term of Employment.

The term of Employee's employment under this Agreement shall commence on the date of this Agreement and shall terminate on February 28, 2001 302846-1(the "Initial Term"), unless sooner terminated pursuant to Section 8 of this Agreement; provided, however, that if the Corporation shall fail to give Employee written notice of non-renewal of Employee's employment with the Corporation not less than 180 days prior to the Initial Term or any Renewal Period (as defined), Employee's term hereunder shall automatically be extended for successive one (1) year periods (each a "Renewal Period" and together with the Initial Term, the "Term").

- 3. Compensation. In consideration of the services to be rendered by the Employee pursuant to this Agreement, the Employee shall receive from the Corporation the following compensation:
- (a) Base Salary. The Corporation shall pay the Employee an aggregate base

salary at the annual rate of \$140,000, payable in equal bi-weekly installments, less such deductions or amounts to be withheld as shall be required by applicable laws and regulations.

The Employee's Base Salary shall be subject to increase at the discretion of the Board of Directors of the Corporation, in its sole discretion.

- (b) Annual Bonus. During the Term, Employee shall be entitled to receive from the Corporation an annual bonus in respect of each fiscal year, or portion thereof, of the Corporation as follows:
- (1) commencing with the Corporation's 1998 fiscal year (ending December 31, 1998), in an amount of \$82,500, provided that net sales of the Corporation for the year ending December 31, 1998 are not less than \$28,000,000; and
- (2) thereafter in accordance with such targets, conditions or parameters as may be determined from time to time hereafter by the Compensation Committee of the Board of Directors of the Corporation in its sole and absolute discretion.

# 4. Expenses.

The Corporation shall pay or reimburse Employee for all reasonable expenses which are in accordance with the Corporation's expense policy in force from time to time and which are actually incurred or paid by him during the Term in the performance of his services under this Agreement, upon presentation of expense statements or vouchers or such other supporting information as the Corporation may require.

#### 5. Additional Benefits.

(a) In General. In addition to the compensation and expenses to be paid under Sections 3 and 4 hereof, Employee will be entitled to all rights and benefits for which he shall be

eligible under any insurance, profit-making, incentive, bonus, stock option, pension or other extra compensation or "fringe" benefit plan of the Corporation or any of its subsidiaries now existing or hereafter adopted for the benefit of the executives or employees generally of the Corporation.

- (b) Stock Options. Employee is hereby granted stock options to purchase 300,000 shares of the Corporation's common stock, \$.01 par value per share (the "Option") 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 on Wednesday, February 18, 1998) (the "Option Shares"). The Option shall vest and be exercisable in an amount equal to 25,000 Option Shares at the end of each quarterly period during the Term (the first quarterly vesting period to be satisfied on May 1, 1998 and on each August 1, November 1, and February 1, thereafter until fully vested). The Option shall have a ten year term, subject to earlier termination as set forth in paragraph 5(c) upon the termination of Employee's employment with the Corporation and shall be evidenced by the Corporation's standard form stock option agreement. The Employee and the Corporation agree that the Option shall be deemed to have been issued pursuant to one or more plans for the grant of incentive stock options, to the maximum extent permitted by law, and non-qualified stock options. The exercise price and terms of any non-qualified options shall be subject to such revisions as the Employee and the Corporation may agree.
- (c) Purchase of Options. In the event that Employee is terminated for cause (as defined in paragraph 8.3) or resigns, the Corporation shall have the right, but not the obligation, to purchase Employee's vested Option at the Fair Market Value thereof. In the event that the Corporation does not elect to purchase Employee's vested Option within seven days of the date of Employee's termination for cause or resignation, Employee shall be obligated to exercise his Options

in writing within 37 days of such termination or resignation, failing which he shall be deemed to have forfeited his Option to the Corporation. For purposes of this paragraph 5(c), "Fair Market Value" shall mean the product of (i) the positive difference, if any, between the average of the closing price of the Company's Common Stock as reported by the American Stock Exchange, or such other exchange or over-the-counter market on which the Company's Common Stock may then be listed or admitted for trading, for the five (5) trading days prior to the date of termination, multiplied by (ii) the number of Option Shares which are then vested under the Option.

(d) Automobile. The Corporation shall provide the Employee with a company car and shall reimburse the Employee for all gasoline, insurance and maintenance expense associated with the Employee's automobile, to the extent deductible by the Corporation under applicable federal laws and regulations.

### 6. Vacation.

Employee shall be entitled to a vacation period of not less than four weeks during each year of the Term, to be taken at a time or times acceptable to the Corporation.

7. Insurability; Right to Insure. Employee represents and warrants to the Corporation that, to the best of his knowledge, on the date hereof he is, and upon the commencement of the Term he will be, insurable at standard premium rates. Employee agrees that the Corporation shall have the right during the Term to insure the life of Employee by a policy or policies of insurance in such amount or amounts as it may deem necessary or desirable, and the Corporation shall be the beneficiary of any such policy or policies and shall pay the premiums or other costs thereof. The Corporation shall have the right, from time to time, to modify any such policy or policies of insurance or to take out new insurance on the life of Employee. Employee agrees, upon request, at

any time or times prior to the commencement of or during the Term to sign and deliver any and all documents and to submit to any physical or other reasonable examinations which may be required in connection with any such policy or policies of insurance or modifications thereof.

#### 8. Termination.

- 8.1 Death. If during the Term Employee shall die, Employee's employment under this Agreement shall terminate as of the date of Employee's death. The base salary payable hereunder to or for the benefit of Employee through the date of death shall be paid to such person or persons ("Employee's Designees") as Employee may designate by notice to the Corporation from time to time or, in the absence of such designation, to his spouse. In addition, the Corporation shall pay the Employee's Designees an amount equal to six months' base salary plus 1/12th of the bonus the Employee would have received had he been alive at the end of the year in which he died, for each complete calendar month from January 1 of the year in which the Employee died, to his date of death.
- 8.2 Disability. In the event of the Employee's "mental or physical disability" (as defined herein) which continues for (i) a period of longer than 90 consecutive days, or (ii) such periods aggregating 120 days during any 365 consecutive days, such that the Employee is, despite reasonable accommodation, unable to substantively perform the essential functions of his position for said period, the determination of which shall be confirmed by the Board of Directors in the manner hereinafter provided, this Agreement shall terminate upon thirty (30) days' prior written notice to the Employee from the Corporation (the "Disability Termination Date"). The Corporation shall continue to pay to the Employee during the period of his mental or physical disability the base salary and annual bonus provided in Section 3 of this Agreement as well as provide the benefits

described herein; provided, however, that the base salary shall be reduced by any disability insurance payments paid to the Employee. On the Disability Termination Date, Employee's base salary shall cease but the Employee shall be entitled to the annual bonus computed in accordance with Section 3(b) hereof for the period ending on the Disability Termination Date. Except for the bonus payment required in the preceding sentence, no annual bonus will accrue or be payable by the Corporation following the Disability Termination Date.

As used herein, the term "mentally or physically disabled" shall have the meaning ascribed thereto in the disability insurance policy then in force and effect with respect to the Employee or, if no such disability policy then exists, it shall mean the inability of the Employee, by reason of injury, illness or other similar cause to perform a material part of his duties and responsibilities in connection with the conduct of the business and affairs of the Corporation as determined by a reputable physician of the Corporation's selection, who has examined the Employee with his consent.

8.3 Termination For Cause. The Corporation may at any time during the Term, by written notice, and after affording the Employee the opportunity to be heard in person by the Board of Directors, terminate this Agreement and discharge Employee for "cause", whereupon the Corporation's obligation to pay compensation or any other amounts payable hereunder to or for the benefit of Employee shall terminate on the date of such discharge except for accrued and unpaid salary and expenses to the date of discharge. For purposes of this Agreement, the term "cause" shall mean (i) excessive absenteeism, alcoholism or drug abuse, (ii) fraud, misappropriation or intentional material damage to the property or business of the Corporation; (iii) conviction of a felony; (iv) failure of the Employee to perform his duties in accordance with this Agreement after written notice

to the Employee by the Board of Directors specifying such failure and giving the Employee eight (8) days to correct the defects in performance; or (v) breach by the Employee of any material provision hereof which, if capable of remedy, remains unremedied for more than 10 days after written notice.

8.4 Termination without Cause. The Corporation shall have the option to terminate this Agreement without cause upon thirty (30) days' written notice to the Employee. In the event the Corporation terminates this Agreement pursuant to this Section 8.4, the Corporation shall pay the Employee an amount equal to (a) his then accrued and unpaid base salary and bonuses through and including the date of termination, and (b) \$280,000 or twice his then Base Salary, whichever is greater payable in 24 equal monthly installments. Upon termination of Employee's employment with the Corporation pursuant to this

Section 8.4, (i) Employee's outstanding Options shall vest in full, notwithstanding any contrary vesting schedule contained herein or in any option agreement between the Corporation and the Employee and shall be exercised within 90 days of the date of vesting, and (ii) the provisions of paragraph 9.3 shall be deemed of no force or effect.

Subject to paragraph 8.4(ii), the obligations of the Employee under Section 9 shall continue notwithstanding the termination of Employee's employment pursuant to this Section 8.4 provided the Corporation complies with its obligations specified in this paragraph.

- 8.5 Change of Control. Upon the sale or transfer of more than 50% of the outstanding shares of the Corporation (other than to Galen Associates or any of its affiliates) or upon the sale of the whole or a major part of the business of the Corporation, Employee shall be entitled to terminate this Agreement on the same terms and conditions as set forth in Section 8.4.
- 9. Protection of Confidential Information. In view of the fact that Employee's work for

the Corporation will bring him into close contact with all the confidential affairs thereof, and plans for future developments, Employee agrees to the following:

9.1 Secrecy. During the term of Employment and for two (2) years thereafter, to preserve the confidential nature of, and not disclose, reveal, or make accessible to anyone other than the Corporation's officers, directors, employees, consultants or agents, otherwise than within the scope of his employment duties and responsibilities hereunder, any and all documents, information, knowledge or data of or pertaining to the Corporation, its subsidiaries or affiliates or pertaining to any other individual, firm, corporation, partnership, joint venture, business, organization, entity or other person with which the Corporation or any of its subsidiaries or affiliates may do business during the Term of Employment (including licensees, licensors, manufacturers, suppliers and customers of the Corporation or any of its subsidiaries or affiliates) and which is not in the public domain, including trade secrets, "know how", names and lists of licensees, licensors, manufacturers, suppliers and customers, programs, statistics, manufacturing and production methods, processes, techniques, pricing, marketing methods and plans, specifications, advertising plans and campaigns or any other matters, and all other confidential information of the Corporation, its subsidiaries and affiliates acquired in connection with Employee's employment (hereinafter referred to as "Confidential Information"). The restrictions on the disclosure of Confidential Information imposed by this Subparagraph 9.1 shall not apply to any Confidential Information that was part of the public domain at the time of its receipt by the Employee or becomes part of the public domain in any manner and for any reason other than an act by the Employee, unless the Employee is legally compelled (by deposition, interrogatory, request for documents, subpoena, civil investigative demand or similar process) to disclose such Confidential Information, in which event Employee shall

provide the Corporation with prompt notice of such requirement so that the Corporation may seek a protective order or other appropriate remedy, and if such protective order or other remedy is not obtained, Employee shall exercise reasonable efforts in good faith to obtain assurance that confidential treatment will be accorded such Confidential Information.

- 9.2 Return Memoranda, etc. To deliver promptly to the Corporation on termination of his employment, or at any other time the Corporation may so request, all memoranda, notes, records, reports, manuals, drawings, blueprints and other documents (and all copies thereof) relating to the Corporation's business and all property associated therewith, which he may then possess or have under his control.
- 9.3 Non-competition. Provided that this Agreement has not been breached by the Corporation, the Employee agrees that he shall not at any time prior to two years after the earlier to occur of (i) the expiration of the Term hereunder and (ii) the termination of his employment with the Corporation, own, manage, operate, be a director or an employee of, or a consultant to any business or corporation which is conducting any business within the generic drug industry or which competes with or conducts the same business as or similar to that conducted by the Corporation in the United States. The Employee further agrees that, provided this Agreement has not been breached by the Corporation, he shall not, at any time prior to two years after the earlier to occur of (i) the expiration of the Term hereunder and (ii) the termination of his employment with the Corporation, assist or allow any such business or corporation to hire anyone who was employed by the Corporation at such time or at any time during the preceding twelve months. If any of the provisions of this section, or any part thereof, is hereinafter construed to be invalid or unenforceable, the same shall not affect the remainder of such provision or provisions, which shall be given full effect, without regard to the

invalid portions. If any of the provisions of this section, or any part thereof, is held to be unenforceable because of the duration of such provision, the area covered thereby or the type of conduct restricted therein, the parties agree that the court making such determination shall have the power to modify the duration, geographic area and/or other terms of such provision and, as so modified, said provision shall then be enforceable. In the event that the courts of any one or more jurisdictions shall hold such provisions wholly or partially unenforceable by reason of the scope thereof or otherwise, it is the intention of the parties hereto that such determination not bar or in any way affect the Corporation's right to the relief provided for herein in the courts of any other jurisdictions as to breaches or threatened breaches of such provisions in such other jurisdictions, the above provisions as they relate to each jurisdiction being, for this purpose, severable into diverse and independent covenants.

- 9.4 Injunctive Relief. The Employee acknowledges and agrees that, because of the unique and extraordinary nature of his services, any breach or threatened breach of the provisions of Sections 9.1, 9.2, or 9.3 hereof will cause irreparable injury and incalculable harm to the Corporation, and the Corporation shall, accordingly, be entitled to injunctive and other equitable relief for such breach or threatened breach and that resort by the Corporation to such injunctive or other equitable relief shall not be deemed to waive or to limit in any respect any right or remedy which the Corporation may have with respect to such breach or threatened breach.
- 9.5 Expenses of Enforcement of Covenants. In the event that any action, suit or proceeding at law or in equity is brought to enforce the covenants contained in Section 9.1, 9.2, or 9.3 hereof or to obtain money damages for the breach thereof, the party prevailing in any such action, suit or other proceeding shall be entitled upon demand to reimbursement from the other party for all

expenses (including, without limitation, reasonable attorneys' fees and disbursements) incurred in connection therewith.

9.6 Non-Solicitation. Employee covenants and agrees not to, directly or indirectly, during the Term of Employment and for a period of two (2) years from and after the effective date of the termination of his employment with the Corporation (for any reason whatsoever), (i) induce or attempt to influence any employee of the Corporation or any of its subsidiaries or affiliates to leave its employ, or (ii) aid any person, business, or firm, including a supplier, a competitor, licensor or customer of or a manufacturer for the Corporation, in any attempt to hire any person who shall have been employed by the Corporation or any of its subsidiaries or affiliates within the period of one (1) year of the date of any such requested aid.

#### 10. Indemnification.

The Corporation will defend and indemnify Employee, to the maximum extent permitted by applicable law and the by-laws of the Corporation, against all claims, costs, charges and expenses incurred or sustained by him in connection with any action, suit or other proceeding to which he may be made a party by reason of his being an officer, director or employee of the Corporation or of any subsidiary or affiliate thereof.

#### 11. Employee Warranties.

Employee hereby warrants that as of the date hereof Employee is not employed (other than by the Corporation) and is not a party to any other employment contract, express or implied. Employee warrants that he has no other obligation, contractual or otherwise, which would prevent him from accepting the Corporation's offer of employment under the terms of this Agreement and from complying with its provisions. Employee warrants that he will not utilize during his

employment hereunder any confidential information obtained through or in connection with his prior employment. Employee warrants that he knows of no reason why he would not be able to perform his obligations under this Agreement.

#### 12. Notices.

All notices, requests, consents and other communications required or permitted to be given hereunder, shall be in writing and shall be deemed to have been duly given if delivered personally or sent by facsimile, with confirmation of receipt, or mailed first-class, postage prepaid, by registered or certified mail (notices sent by mail shall be deemed to have been given on the date sent), to the parties at their respective addresses hereinabove set forth or to such other address as either party shall designate by notice in writing to the other in accordance herewith.

#### 13. General.

- 13.1 Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the local laws of the State of New York applicable to agreements made and to be performed entirely in New York.
- 13.2 Captions. The section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.
- 13.3 Entire Agreement. This Agreement sets forth the entire agreement and understanding of the parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, relating to the subject matter hereof. No representation, promise or inducement has been made by either party that is not embodied in this Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth.

- 13.4 Assignability. This Agreement, and Employee's rights and obligations hereunder, may not be assigned by Employee. The Corporation may assign its rights, together with its obligations, hereunder in connection with any sale, transfer or other disposition of all or substantially all of its business or assets; in any event the rights and obligations of the Corporation hereunder shall be binding on its successors or assigns, whether by merger, consolidation or acquisition of all or substantially all of its business or assets.
- 13.5 Amendment. This Agreement may be amended, modified, superseded, canceled, renewed or extended and the terms or covenants hereof may be waived, only by a written instrument executed by both of the parties hereto, or in the case of a waiver, by the party waiving compliance. No superseding instrument, amendment, modification, cancellation, renewal or extension hereof shall require the consent or approval of any person other than the parties hereto. The failure of either party at any time or times to require performance of any provision hereof shall in no matter affect the right at a later time to enforce the same. No waiver by either party of the breach of any term or covenant contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such breach, or a waiver of the breach of any other term or covenant contained in this Agreement.
- 13.6 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which taken together will constitute one and the same instrument.
- 13.7 Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration, conducted before a panel of three arbitrators,

in New York, New York, in accordance with the commercial arbitration rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The expense of such arbitration shall be borne as directed by the arbitrator.

13.8 Severability. The provisions of this Agreement shall be deemed severable, and if any part of any provision is held illegal, void or invalid under applicable law, such provision may be changed to the extent reasonably necessary to make the provision, as so changed, legal, valid and binding. If any provision of this Agreement is held illegal, void or invalid in its entirety, the remaining provisions of this Agreement shall not in any way be affected or impaired but shall remain binding in accordance with their terms.

13.9 Fees and Costs. The Corporation will contribute not more than \$10,000 towards the fees and costs of Employee's counsel in connection with the review of this Agreement and Michael K. Reicher's Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

ATTEST:	HALSEY DRUG CO., INC.
	By: /s/ William Skelly
	William Skelly, Chairman
WITNESS:	EMPLOYEE
	By: /s/ Peter Clemens
	Peter Clemens

## CONSENT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

We have issued our report dated April 14, 1998, accompanying the consolidated financial statements included in the Annual Report of Halsey Drug Co., Inc. on Form 10-K for the year ended December 31, 1997. We hereby consent to the incorporation by reference of said report in the Registration Statements of Halsey Drug Co., Inc. on Form S-8 (File No. 33-98396, effective October 19, 1995).

## **GRANT THORNTON LLP**

New York, New York April 14, 1998

## **ARTICLE 5**

PERIOD TYPE	12 MOS
FISCAL YEAR END	DEC 31 1998
PERIOD START	JAN 01 1997
PERIOD START PERIOD END	DEC 31 1997
CASH	26
SECURITIES  PEGENA PLEG	0
RECEIVABLES	112
ALLOWANCES	50
INVENTORY	2,456
CURRENT ASSETS	2,818
PP&E	18,443
DEPRECIATION	13,813
TOTAL ASSETS	7,667
CURRENT LIABILITIES	27,523
BONDS	0
PREFERRED MANDATORY	140
PREFERRED	0
COMMON	0
OTHER SE	(19,996)
TOTAL LIABILITY AND EQUITY	7,667
SALES	9,088
TOTAL REVENUES	9,088
CGS	15,406
TOTAL COSTS	15,406
OTHER EXPENSES	7,551
LOSS PROVISION	0
INTEREST EXPENSE	1,144
INCOME PRETAX	(15,013)
INCOME TAX	0
INCOME CONTINUING	(15,013)
DISCONTINUED	(10,010)
EXTRAORDINARY	0
CHANGES	0
NET INCOME	(15,013)
EPS PRIMARY	(1.12)
EPS DILUTED	(1.12) $(1.12)$
	(1.12)

# **End of Filing**



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