SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 1996 Commission file No. 1-10113

HALSEY DRUG CO., INC.

(Exact name of registrant as specified in its charter)

New York 11-0853640

(State of Incorporation) (I.R.S. Employer Identification No.)

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

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 19, 1997, the registrant had 13,944,521 shares of Common stock, par value \$0.01, outstanding. Based on the average of the high and low sales prices of the common stock on March 19, 1997 (\$4.87), the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$65,262,953.

Documents Incorporated by Reference

Document Where Incorporated
-----Proxy Statement for the Annual Meeting Part III
to be held on June 4, 1997

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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 services that are important to the Company's growth; availability of qualified personnel; the loss of any significant customers; and other factors both referenced and not referenced in this Report. When used in this Report, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions are intended to identify forward-looking statements.

Item 1. Business.

GENERAL

The Company, a New York corporation established in 1935, and its subsidiaries, are engaged in the 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 Blue Cross Products, Inc., a New York corporation (currently inactive), Houba, Inc. ("Houba"), an Indiana corporation, Halsey Pharmaceutical, Inc. ("Halsey Pharmaceutical"), a Delaware corporation, The Medi-Gum Corporation, a Delaware corporation (currently inactive), and Indiana Fine Chemicals Corporation ("Indiana Chemicals"), a Delaware corporation. Halsey has two additional subsidiaries: H.R. Cenci Laboratories, Inc., a California corporation (97% owned), and Cenci Powder Products, Inc. ("Cenci Powder"), a Delaware corporation (100% owned).

The Company manufactures its products at facilities in New York, Indiana and California. During 1995, in connection with the sale of its Oxycodone with acetaminophen Tablet business, the Company began manufacturing Oxycodone with acetaminophen Tablets 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.

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. On June 21, 1993, the Company entered into a plea agreement with the United States Department of Justice (the "DOJ") to resolve the DOJ's investigation into the manufacturing and record keeping practices at the Company's Brooklyn plant. 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 requires the Company to pay a fine of \$2,500,000 over five years in quarterly installments of \$125,000 commencing in September 1993. Two installments have been paid to date. From April 1995 through December 1996, the Company made additional partial payments to the DOJ aggregating \$100,000. The agreement with the DOJ stipulates that if any payments are not made in a timely fashion the entire amount of the fine shall become due and payable immediately. Such nonpayment also constituted a default under the Company's Credit Agreement with its banks (the "Bank Group") (which expires on June 30, 1997). As a result, the entire amount of the settlement has been classified as current. As of the date of this Report, no action has been initiated to require payment of the entire outstanding amount of the fine.

On June 29, 1993, the Company entered into a consent decree with the U.S. Attorney for the Eastern District of New York on behalf of the U.S. Food and Drug Administration (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 to be used for, manufacturing, processing, packing, labeling and holding any drug, are established, operated, and administered in conformity with the Federal Food, Drug, and Cosmetic Act and all CGM 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.

During 1995, the Company sold its Oxycodone with Acetaminophen Tablet business to an affiliate of Mallinckrodt Chemical Products, Inc. (collectively, "Mallinckrodt"). Under a tolling arrangement with Mallinckrodt, the Company manufactured such tablets for Mallinckrodt for at least two years. Mallinckrodt can, at its option, continue to have the Company manufacture tablets after March 1997 for an additional year. See "Business - Dispositions," below.

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On October 23, 1996, the Company withdrew four of its Abbreviated New Drug Application ("ANDA"), including its ANDA (the "Capsule ANDA") for acetaminophen/oxycodone capsules, 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 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 at the suggestion of the FDA and in anticipation of its release from the FDA's Application Integrity Policy list and its restrictions (collectively, the "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 for 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.

On December 19, 1996 the FDA released the Company from the AIP. Release from the AIP permits the Company to submit ANDA applications to the FDA for review, 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 its review. In addition, the Company had previously submitted a new ANDA with respect to the Capsules, which the Company anticipates will be reviewed in the near future. However, there can be no assurance any of its new ANDAS, including the new Capsule ANDA, will be approved by the FDA. The Company will not be able to market these new products unless and until the FDA approves the new underlying ANDAS. Failure to obtain FDA approval for the new ANDAS, or a significant delay in obtaining such approval, would materially adversely affect the Company's business operations and financial condition.

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 24 products, consisting of 9 dosage forms and strengths of prescription drugs and 15 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:

- Antibiotics,
- 2. Anti-infective and anti-tubercular drugs,
- 3. Neuropharmacological drugs,
- 4. Antihistamines and antihistaminic decongestants, or
- 5. Antitussives.

Upon the release of the Company from the AIP program on December 19, 1996, the FDA resumed review of the parent company's (i.e., Halsey's) applications for new drug approvals, as well as supplemental approvals. Although the Company has filed five new ANDAS with the FDA for its review since the lifting of the suspension, the Company is unable to predict whether it will receive FDA approval to market any new products during 1997. However, on March 11, 1997, the Company has received a supplemental approval from the FDA on two of its products.

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 so that the Company will be among the first to market the new generic drug product. As other off-patent drug manufacturers receive FDA approvals on competing products, prices and revenues typically decline. Accordingly, the Company's ability to attain its previous levels of profitability depends on the Company's ability to develop and introduce new products, the timing of FDA approval of such products and the number and timing of FDA approvals for competing products.

Dispositions

On March 21, 1995 (the "Closing Date"), the Company sold its Tablets ANDA for 5 mg Oxycodone HCl/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") to Mallinckrodt.

Mallinckrodt paid the Company \$2 million of the Purchase Price on the Closing Date, having previously paid \$500,000 in July 1994. The balance (the "Deferred Payment") of the Purchase Price was payable as follows. Mallinckrodt paid \$1 million, on January 9, 1997, following the Company's release from the AIP program. Mallinckrodt will pay the Company the \$1.9 million balance of the Deferred Payment when Mallinckrodt receives certain authorizations (the "Mallinckrodt Authorizations") from the FDA, but in no event later than March 21, 1998.

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 is evidenced by a promissory note (the "Note") with interest accruing at a rate of 8% per annum. The Note, which may be prepaid at any time, is due and payable on the earlier of the date of the Mallinckrodt Authorization or September 21, 1997. Mallinckrodt may offset its Deferred Payment obligations against the amount due on the Note, provided certain conditions are met. The Company may also offset the amount due to Mallinckrodt on the Note against the Deferred Payment obligations when such obligations mature. However, the Company has agreed with its banks (see Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operation") not to exercise its right of offset until the Company has repaid in full the amounts due to its banks. The Note, which is subordinate to future bank indebtedness of up to \$8,000,000, is secured by substantially all of the Company's and Houba's assets.

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. Mallinckrodt may terminate the manufacturing agreement after March 1997. 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 cancel payment of any yet unpaid portion of the Deferred Payment (\$1.9 million) and shall further have the right to a full refund of any portion of the Deferred Payment already made to the Company. On January 9, 1997, Mallinckrodt paid to the Company \$1,000,000, pursuant to the release of the Company from the AIP. The funds were applied to the outstanding Bank Group loan balance.

During the fiscal years ended December 31, 1994, 1993 and 1992, the Company derived net revenues from Tablets of approximately \$6,600,000, \$5,600,000 and \$4,200,000, respectively. Management anticipated that Tablet sales would decline during 1995 as a result of increasing competition. Management's determination that an integrated supplier such as Mallinckrodt would be better suited to increasingly competitive market conditions than the Company was an important factor in the decision to proceed with the sale of the Tablets ANDA.

In connection with the sale of the Tablets ANDA, the Company issued to Mallinckrodt an option exercisable at any time until March 21, 1998, to purchase the Capsule ANDA at an exercise price (the "Option Price") equal to 75% of Net Capsule Revenue, subject to downward adjustment in the event of a decline in pricing levels. Net Capsule Revenue is defined to mean all revenue (net of rebates, adjustments, discounts, allowances, expenses incurred in product recalls and similar items) derived from sales of Capsules during the twelve month period immediately prior to the date the option is exercised. The Option Price is payable as follows: \$200,000 on the later of (i) exercise and (ii) the date when Mallinckrodt or an affiliate qualifies as the new source for certain raw materials, with the remainder of the Option Price due when Mallinckrodt obtains certain authorizations from the FDA or such earlier date as the parties agree. Upon exercise Mallinckrodt will purchase from the Company equipment used to manufacture the capsules for the greater of \$250,000 or the appraised value of the equipment. At such time the Company and Mallinckrodt will enter into agreements pursuant to which the Company will (a) manufacture acetaminophen/oxycodone capsules for Mallinckrodt for a period of time and (b)be prohibited from competing with Mallinckrodt and its affiliates with respect to the production of capsules.

Acquisitions

The Company has engaged Penick Corporation ("Penick") to process certain of the raw materials utilized in the production of acetaminophen/oxycodone capsules. 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 June 1994 both Penick Corporation and Penick Pharmaceutical, Inc, filed petitions under Chapter 11 of the United States Bankruptcy Code.

OTHER TRANSACTIONS

Agreements with Zatpack, Inc.

On March 30, 1995, the Company signed an agreement (the "Zatpack Agreement") with Zatpack, Inc. ("Zatpack"), an affiliate of Zuellig Group N.A.,Inc. ("Zuellig"). The Zatpack Agreement provided for the purchase of 500,000 shares of Common Stock (the "Zatpack Shares") by Zatpack, a British Virgin Islands Company, in consideration of \$1,000,000. The \$1,000,000 purchase price was comprised of a combination of cancellation of indebtedness (primarily incurred by subsidiaries of Halsey for the purchase of raw materials previously delivered and in the process of being delivered from affiliates of Zuellig), purchase of inventory, and surrender of shares of Indiana Fine Chemicals. As a result of this transaction, the Company owns 100% of Indiana Fine Chemicals.

Pursuant to the Zatpack Agreement, the Company issued the Zatpack Note to Zatpack as consideration for cancellation of additional indebtedness. This indebtedness resulted from trade payables and advances to the Company by Zuellig and certain of its subsidiaries. The Zatpack Note is in the original principal amount of \$1,292,242, with accrued interest of \$243,110. The Zatpack Note has been converted into 642,407 shares of Common Stock (the "Note Shares"), in March, 1997, at an adjusted conversion price of \$2.39 per share, thereby canceling the indebtedness.

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," 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 approvals 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 the 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 action such as an injunction against shipment of the Company's products or the seizure of noncomplying drug products, and/or, in serious cases, criminal prosecution. See also "Government Regulation--FDA Investigations" below and Item 3, "Legal Proceedings."

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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.

The Company also is governed by federal, state and local laws of general applicability, such as those regulating working conditions. In addition, the Company is subject, as are manufacturers generally, to various federal, state and local environmental protection laws and regulations, including those governing the discharge of materials into the environment. Compliance with these laws is not expected to have any material effect upon the Company's capital expenditures, earnings or competitive position.

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.
- Abbreviated New Drug Applications ("ANDA"). The Drug Price 2. 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 has not been 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.

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 1996, 1995 and 1994, total research and development expenditures were \$1,854,000, \$818,000 and \$491,000, respectively. During 1997 the Company intends to concentrate its research and development efforts in the following areas:

- Reintroduction of products suspended as a result of the consent decree which require prior FDA validation;
- 2. Reintroduction of products which will require changes in formulation and submission for prior approval from the FDA; and
- Development of new products.

The Company currently maintains a full-time staff of eight in its Research and Development Departments.

MARKETING AND CUSTOMERS

A key element of the Company's marketing strategy is to maintain sufficient raw material and finished good inventories to enable the Company to fill customer orders promptly. This strategy requires a substantial amount of working capital to maintain inventories at a level sufficient to meet anticipated demand.

The Company sells its products primarily through three salaried employees and to a lesser extent through two independent sales representatives, each of whom are compensated on a commission basis. Sales of 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 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. During 1994, the Company had net sales to three customers in excess of 10% of total sales, each aggregating 12% of total sales. Balances due from these customers were approximately 0% and 25% of total accounts receivable at December 31, 1996 and 1995, respectively. The Company believes that the loss of either of these customers could have a material adverse effect on the Company.

The estimated dollar amount of the backlog of orders for future delivery as of February 28, 1997 was approximately \$3,560,000 as compared with approximately \$1,070,000 as of March 31, 1996. Although these orders are subject to cancellation, management expects to fill substantially all orders by the second quarter of 1997.

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. As a result of the Company's release from the AIP, by the FDA, the Company is now able to submit Supplements to the FDA, thereby allowing the Company to purchase raw materials from alternate sources. See Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations- -Liquidity and Capital Resources."

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. These limitations could increase the likelihood of raw material shortages and of manufacturing delays in the event the Company was required to find new suppliers of these raw materials.

EMPLOYEES

As of December 31, 1996, the Company had approximately 200 full-time employees. Approximately 80 are administrative and professional personnel and the balance are in production and shipping. Among the professional personnel, eight are engaged in product development. Approximately 90 employees at the Company's Brooklyn plant are represented by a local collective bargaining unit whose agreement with the Company expires on July 1, 1997. Management believes that its relations with its employees and unions are generally satisfactory; however, the Company has been involved in litigation with respect to certain aspects of its collective bargaining agreement. See Item 7, "Legal Proceedings - Other Pending Legal Proceedings."

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: \$884,000 for the year 1995, \$928,000 for the year 1996 and \$975,000 for the year 1997. These leases expire on December 31, 2005. The buildings leased by Halsey in Brooklyn house research and development and manufacturing facilities and corporate offices.

Houba owns approximately 45,000 square feet of building space on approximately 30 acres of land in Culver, Indiana, which includes a modern 15,000 square foot manufacturing facility. This manufacturing complex 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 on approximately one-half acre of land in Fresno, California. In early 1992, the Company acquired additional land adjoining this property for the purpose of expanding the manufacturing facilities and distribution space located on such property. 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. During the years ended December 31, 1996, 1995 and 1994, Cenci and Cenci Powders paid an aggregate of \$90,000, \$86,000 and \$99,000, respectively, to a former officer of Cenci Laboratories and Cenci Powder in respect to this lease

The Company also leases office space in Westwood, New Jersey for its marketing and sales departments on a year-to-year basis.

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 requires 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 in and the terms of the plea agreement approved by the United States District Court for the District of Maryland on July 16, 1993. Two installments have been paid to date. Only additional partial payments have been paid in the amount of \$100,000. The agreement with the DOJ stipulates that if any payments are not made in a timely fashion the entire amount of the fine shall become due and payable immediately. As a result, the entire amount of the settlement has been classified as current. Such nonpayment also constituted a default under the Company's Credit Agreement with its banks. As of the date of this Report, no action has been initiated to require payment of the entire outstanding amount of the fine.

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

SHAREHOLDER AND DERIVATIVE ACTIONS

On March 31, 1993, and April 1, 1993, five class-action lawsuits were filed in Federal Court by shareholders against the Company and certain of its then directors. Each of the actions alleged that the Company and its directors had made misleading statements and omissions relating to the prospects of the Company's business and products, including products under development, as well as relating to the status of DOJ and FDA investigations. On May 20, 1993 and October 14, 1993, two separate shareholders derivative lawsuits were filed in New York State Court against the Company and certain of

its directors. Each of these lawsuits alleged that the Company and its directors concealed certain government investigations by the FDA and the DOJ. These actions also alleged that the directors breached their fiduciary duty in connection with the dispositions by them of shares of Common Stock on the basis of material information which was not publicly known. In June 1994, the Company agreed to a settlement of these lawsuits. In November 1994, both the Federal and State Courts approved the terms of the settlement, under which the Company agreed to pay \$1,000,000 in cash and, at the Company's option, either (I) to issue shares of Common Stock having an aggregate market value, as of the date of distribution, of \$3,000,000, or (ii) to pay \$3,000,000 in cash, or (iii) to distribute any combination of shares or cash having a combined value as of the date of distribution of \$3,000,000. The initial payment of \$1,000,000 was paid by the Company's insurers. In November 1995 the Company satisfied the remainder of its settlement obligations by issuing to approved class members a total of 824,742 shares of Common Stock at a per share price of \$3.6375, or an aggregate value of \$3,000,000.

OTHER GOVERNMENTAL PROCEEDINGS

By letter dated November 12, 1993, the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") requested that the Company provide to the staff on a voluntary basis, information and documents regarding the ingredients and filings relating to the following drugs: quinidine gluconate, propylthiourical, acetaminophen and codeine phosphate, metronidazole, quinidine sulfate, and hydralazine hydrochloride. The Staff advised the Company that the inquiry relates to public information disseminated by the Company and trading in the Company's securities during the period August 1987 through July 1993. The Company is cooperating with the Staff and has made available various documents. These documents relate to the testing, formulations and sale of these drugs which were maintained by the Company at a facility in Maryland. In April 1994, the Staff requested additional documentation regarding these matters. The Company has complied with the additional request. On July 5, 1994, the Company made a formal submission to the Staff and outlined the parameters of a proposed settlement. In May 1995, a formal Order of Investigation(the "Order") was issued by the Commission covering the foregoing matters. In June 1995, additional documents were submitted. Officers and Directors of the Company also testified before the Staff.

On January 29, 1997, the Commission 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 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

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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.

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. 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.

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. 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 seek unspecified damages. At this early stage of the proceedings, the Company is unable to predict with reasonable certainty the likely outcome of these claims.

CENCI PROCEEDING

The Company had been a defendant in a lawsuit currently pending 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 whereby the Company agreed to purchase 51% of the stock of Cenci.

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The plaintiff, both individually and as a shareholder of Cenci 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 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 loans, made by the plaintiff to Cenci Labs and Cenci Powders, as well as payment of settlement funds. These payments will total \$600,000, with no interest, paid 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, making the Company owner of 100% of Cenci Powder stock and substantially all of Cenci Labs stock. Twenty-five thousand shares of unregistered Common Stock of the Company was tendered to the Plaintiff.

OTHER PENDING LEGAL PROCEEDINGS

The Company was named as a defendant in an action commenced on August 19, 1995 by the Company's former product liability insurer ("Lexington") captioned Lexington Insurance Company v. Halsey Drug Co., Inc., 95 Civ. 3403, pending in the United States District Court for the Eastern District of New York. The Complaint seeks the recovery of sums paid by Lexington to settle a lawsuit brought by Linda K. Walton relating to the ingestion of quinidine gluconate allegedly manufactured by the Company. The Complaint requests not less than \$75,000 in damages and payment by the Company of a \$25,000 deductible, and a declaration that the Walton claim, and other similar claims are not covered under their policy. The Company and Lexington have agreed to a settlement pursuant to which the Company is required to pay an aggregate amount of \$50,000, of which \$10,000 has been paid, with the balance due on April 4, 1997. Lexington will dismiss the declaratory portion of the Complaint without prejudice.

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. Plaintiffs seek approximately \$265,000. On or about February 28, 1997, the Company and the plaintiffs agreed to settle the action. The settlement obligates the Company to remain current on its obligations and to pay portions of the alleged arrearages in installments. The Company has paid the alleged arrearages under the stipulation, but is not current on its obligations as of the date of this filing.

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, entitled 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 Debra Ciavarelli in utero 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 have been commenced and are still pending against the Company along with numerous other pharmaceutical manufacturers in the Pennsylvania Court of Common Pleas, Philadelphia Division, during 1992 and 1993. Each of these actions alleges injury in connection with exposure to the drug diethylstilbestrol (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. Thirty-four similar actions have already been settled and dismissed.

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

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

The Company has been named as a defendant in three 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 action, Hunt v. Halsey Drug Co., Inc. Index No. 33723/93 (New York Supreme Court, Kings County), was commenced on October 21, 1993, and seeks the recovery of \$8,000,000 for alleged personal injuries suffered by a Wells Fargo security guard who had responded to a triggered alarm and was shot by a perpetrator. The action is currently in discovery.

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 1996.

Item 5. Market for the Registrant's Common Equity and Related Security Holder Matters.

(a) 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.

American Stock Exchange	High	Low
1997 Fiscal Year		
First Quarter (through		
March 27, 1997)	6	4 1/2
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
1995 Fiscal Year		
First Quarter	2 1/2	1 7/8
Second Quarter	3 1/16	1 1/4
Third Quarter	4 1/4	1 3/4
Fourth quarter	4 1/4	3 5/16
1994 Fiscal Year		
First Quarter	5 3/8	3 1/8
Second Quarter	4 1/2	2 11/16
Third Quarter	4	2 1/8
Fourth Quarter	3 13/16	1 9/16

There were 956 holders of record of the Company's common stock on March 19, 1997. This number, however, does not reflect the ultimate number of beneficial holders of the Company's common stock.

(b) 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 Company does not intend to pay any cash dividends in the foreseeable future.

Item 6. Selected Financial Data.

The selected consolidated financial data presented on the following pages for the years ended December 31, 1996, 1995, 1994, 1993 and 1992 are derived from the Company's audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 1996 and December 31, 1995, and for each of the years in the three year period ended December 31, 1995, and the report thereon, are included elsewhere herein. The selected financial information as of and for the years ended December 31, 1993 and 1992 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,								
Operating Data:		1996		1995		1994		1993		1992
Net sales	\$	12,379	\$	20,225	\$	24,182	\$	36,024	\$	49,868
Costs and expenses Cost of sales Research and development Selling, general and		16,826 1,854		18,097 818		21,584 502		28,848 2,140		35,769 1,090
administrative Provision for regulatory		7,486		6,098		7,128		8,976		8,616
settlement Interest expense		 1,708		1,307		 735		5,935 631		2,000 372
Gain on sale of assets Provision for stockholders'		(1,000)		(2,288)						
litigation settlement								3,000		
Income (loss) before provision for income taxes, minority interest and cumulative effect of accounting change		(14 405)		(2.007)		(F 767)		(12, 226)		2 010
Provision (benefit) for income taxes		(14,495)		(3,807) 296		(5,767)		(13,326) (2,540)		2,019 1,128
Minority interest in net loss (benefit) of subsidiaries								150		37
Cumulative effect of accounting change								(267)		
Net income (loss)	\$ ==:	(14,495) ======	\$ ===	4,103 ======	\$ ===	(5,767) ======	\$ ===	(10,903) ======	\$ ===	928
Net income (loss) per shares	\$ ==:	(1.49)	\$ ===	(.52) =====	\$ ===	(.80)	\$ ===	(1.57)	\$.13
Weighted average common and common shares equivalents outstanding	Ç	9,724,106	7	,886,101	7	7,173,908	6	6,954,713	7,	157,871

December 3:	1.
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Balance Sheet Data:	1996	1995 (1)	1994	1993	1992	
Working capital (deficiency)	\$(12,201)	\$ (7,393)	\$ (4,451)	\$ (2,801)	\$ 3,461	
Total assets	11,982	18,862	19,276	24,674	33,385	
Total liabilities	19,603	20,402	19,924	20,755	19,347	
Retained earnings (accumulated						
deficit)	(29,484)	14,989	(10,886)	(5,118)	5,785	
Stockholders' equity (deficit)	(7,081	(1,540)	(468)	3,920	14,038	

- (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.
- (2) Earnings before income taxes and minority interest, net earnings and earnings per share were adversely affected by the establishment of a reserve in the amount of \$2,000,000 to cover estimated inventory write-offs, product recalls and additional legal expenses.

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

Sales for the year ended December 31, 1996 were approximately \$12,379,000, as compared to sales of approximately \$20,225,000 for 1995. The net loss for the year ended December 31, 1996 was \$14,495,000, or \$1.49 per share, as compared with the net loss of \$4,103,000 or \$.52 per share for 1995.

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 ANDA's to the FDA for it review. In addition, the Company had previously submitted a new ANDA with respect to the capsules, which the Company anticipates will be reviewed in the near future. However, there can be no assurance any of its new ANDA's, including the new capsule ANDA will be approved by the FDA. The Company will not be able to market these products unless and until the FDA approves the underlying ANDA's. Failure to obtain FDA approval for the new ANDA's, or a significant delay in obtaining such approval, would materially adversely affect the Company's business operations and financial condition. The Company's release from the AIP, on December 19, 1996, related to the October, 1991 suspension, by the FDA, of review of all of Halsey's (but not Halsey's subsidiaries applications for new drug approvals.

The reduction in sales for the year ended December 31, 1996 was primarily attributable to the removal of four products with sales of \$3,300,000 and \$8,400,000 in 1996 and 1995, respectively, from the marketplace and four ANDA's, as a result of the FDA's requirement that withdrawal of the four ANDA's was necessary for the release of the Company from the AIP.

Depreciation and amortization was approximately \$1,906,000 in 1996, as compared to \$1,956,000 in 1995.

For the year ended December 31, 1995, the reduction in sales was primarily attributable to the reduction of shipments of tablet products due to the sale at the end of the First Quarter by the Company of the Tablets ANDA to Mallinckrodt, which was partially offset by manufacturing revenue that the Company received as part of its agreement with Mallinckrodt.

See "Item 3. Legal Proceedings. Government Consent Decrees" for additional information regarding the plea agreements with the DOJ and consent decree on behalf of the FDA.

Outlook

During 1997, the Company intends to focus its research and development program on the reintroduction of certain previously discontinued products as well as the development of new generic pharmaceuticals. See "Item 1. Business Research and Development". As a result of its release from the AIP, the Company is now able to resume the filing of ANDA applications for review with the FDA. As of March 12, 1997 the Company has received FDA approval on a Supplemental Application for two products and has ANDA applications for five products currently under FDA review.

During the year ended December 31, 1996, the Company continued to service the outstanding debt owed to the Bank Group. On January 9, 1997, the Bank Group received payment of \$1,000,000, towards principal reduction interest payments and legal expenses, resulting from a Mallinckrodt payment pursuant to the Company's release from the AIP on December 19, 1996, as a condition of the sale by the Company to Mallinckrodt of the Tablet ANDA. The \$1,000,000 payment from Mallinckrodt is recorded as income to the Company in 1996. This payment further reduced the outstanding principal amount owed to the Bank Group to approximately \$2,500,000. The Bank Group has extended the Maturity Date of the loan to June 30, 1997.

Results of Operations

The following chart reflects expenses, earnings, income, losses and profits expressed as a percentage of net sales for the years 1996, 1995 and 1994.

Year-to-Year Percentage of Net Sales Increase (Decrease) Years ended December 31, Year ended December ----------1995 1994 1995 to 1996 1994 to 1995 1996 ---------(16.4)% Net sales 100.0% 100.0% 100.0% (38.8)Cost of Goods 135.9 89.5 89.2 (7.0)(16.2)----**Gross Profit** -35.9 10.5 10.8 (309.0)(18.1)Research & Development 15.0 4.0 2.0 126.7 62.9 Selling, general and administrative expense 60.5 30.0 29.6 22.8 (14.5)Provision for regulatory settlement ------------(Loss) earnings from operations (111.4)(23.7)(20.8)187.9 (4.8)Provision for stockholders litigation settlement 100.0 Interest expense 30.6 13.9 6.5 3.0 (77.8)(Loss) earnings before income taxes, minority interest (117.1)(18.9)(23.8)280.7 (34.0)(Benefit) provision for income (100)taxes 0.0 1.5 (Loss) earnings before minority interest (23.8)(117.1)(20.4) 253.3 (28.9)Minority interest in net earnings (loss) of 0.0 0.0 0.0 0.0 0.0 subsidiaries Net (loss) earnings (117.1)% (20.4)% (23.8)% 253.3% (28.9)%

Percentage Change

Net Sales

The Company's net sales for the fiscal year ended December 31, 1996 of \$12,379,000 represents a decrease by \$7,846,000 as compared to net sales for the fiscal 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 1996, cost of goods sold decreased by approximately \$1,271,000 as compared to 1995 This decrease is 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 31,1996, 1995 and 1994 was (35.9%), 10.54% and 10.0%, 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 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 1996, 1995 and 1994 were 60.5%, 30.0% and 29.6%, respectively. 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. These expenses decreased by approximately \$1,030,000 or 14.5% in fiscal year 1995 as compared to 1994. The decrease in both years was attributable to cost saving measures effected by management during each year, combined with a decrease in net sales.

Interest Expense

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 1996, 1995 and 1994 since the available loss carryback to prior years was utilized by the net operating loss for 1993 carryback to the prior three years.

Net Loss

For 1996 the Company had a net loss of \$14,495,000 as compared to a net loss of \$4,103,000 for 1995. This net loss is 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 increased research & development expenses.

Liquidity and Capital Resources

At December 31, 1996, the Company had cash and cash equivalents of \$118,000 as compared to \$353,000 at December 31, 1995. The Company had a working capital deficit at December 31, 1996 of \$11,001,000.

The Company consummated a private offering (the "August Private Offering") of 250 units ("Units") of securities on August 6, 1996 for an aggregate purchase price of \$2,500,000. Each Unit consisted of (i) a convertible subordinated debenture ("August Debentures") in the principal amount of \$10,000 issued at par and (ii) 461 redeemable common stock purchase warrants ("August Redeemable Warrants"). The consummation of this private offering during the third quarter of 1996 resulted in net proceeds of approximately \$ 2,160,000. The company was required to use \$391,000 of such 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.

The August Debentures will become due and payable as to principal five years from the date of issuance. Interest, at the rate of 10% per annum, is payable on a quarterly basis. The August Debentures are convertible at any time after issuance into Underlying Shares at a conversion price (the "Conversion Price") of \$3.25 per share, subject to adjustment.

Each August Redeemable Warrant entitles the holder to purchase one Underlying Share for \$3.25 during the five year period commencing on the date of issuance. The August Redeemable Warrants are redeemable by the Company at a price of \$.01 per Warrant at any time commencing one year after issuance, upon not less than 30 days prior written notice, if the last sale price of the Common Stock on the Exchange following such one year anniversary equals or exceeds \$3.25 per share (the "Threshold") for the 20 consecutive trading days ending on the third day prior to the notice of redemption to holders.

On August 18, 1996 and on December 29, 1996, the Company converted July Debentures of \$4,080,000 and the November Debentures of \$3,660,000 into 2,040,000 and 1,464,000 shares of Common Stock, respectively.

In addition, a total of 589,540 warrants of the convertible debentures consisting of 306,000 warrants of the July debentures, 219,000 warrants of the November debentures and 64,540 warrants of August 1996 debentures were exercised for stock, from which the Company derived gross proceeds of \$1,369,256. The Company utilized these proceeds for working capital.

As a result of the decline in shipments of solid dosage products from the Company's Brooklyn plant following the entry of the consent decree, and as a result of the lack of available borrowings under the Company's credit agreement, the Company's liquidity position has been materially adversely affected since June 30, 1993 and the Company's capital resources have been severely limited. The Company has actively sought to reduce its operating costs at the Brooklyn plant, where it has made significant reductions in personnel. In addition, the Company's liquidity position has been affected during the second half of 1994 by the discontinuance of shipments of liquid products from its Cenci subsidiary as a result of review completed by the Company of this liquid operation. In an effort to reduce the loss from lower revenues at this subsidiary, the Company has reduced its operating costs at Cenci through significant reductions of personnel and other expenses.

Under the terms of the plea agreement with the DOJ, the Company has agreed to pay a \$2,500,000 fine, payable in quarterly installments of \$125,000 over five years. Two installments have been paid to date. Only additional partial payments have been paid in the amount of \$100,000. The agreement with the DOJ stipulates if any payments are not made in a timely fashion, the entire amount of the fine shall become due and payable immediately. As a result, the entire amount of the settlement has been classified as current as of December 31, 1996. As of the current date, no action has been initiated to require immediate payment of the entire amount.

In March 1995, the Company and its banks restructured the Company's amended credit agreement to include an extension of the due date to August 31, 1995, modification of the financial covenants, reduction of the exercise prices of all warrants granted to the banks in excess of \$2.375 per share to \$2.375 per share and extension of the expiration date of the warrants to December 1999. As

consideration for these modifications, the banks received \$1,500,000 of the proceeds received from the transaction with Mallinckrodt. Funds have been applied to reduce outstanding principal by approximately \$1,113,000 to approximately \$3,777,000, to pay accrued interest (approximately \$154,000) and fees (approximately \$233,000). In addition, if the outstanding borrowings were not repaid by August 31, 1995, the Company has been required to pay an additional 3%(\$ 102,000) of the then outstanding principal due to the banks. Such amount has been accrued.

In July 1995, the Company and its banks (the "Banks") amended the credit agreement as a result of the consummation of the July Private Offering. As consideration for waiving any breach or default under the Credit Agreement as a result of the July Private Offering, the Banks received \$500,000 of the proceeds as payment for interest, fees and principal and an extension of the warrant exercise period to July 17, 2000. As a result of the Zatpack transaction, the July Private Offering, and the issuance of 824,742 shares in settlement of the class action litigation, the anti-dilution clauses in the Banks' warrants were triggered, increasing the number of the Banks' warrants and decreasing the corresponding exercise prices. As a result, the Banks now hold warrants to purchase 700,000 shares of the Company's common stock at a price of \$2.05.

The credit agreement with the Bank Group has been extended to June 30, 1997.

On March 21, 1995, the Company sold its Tablets ANDA for 5mg Oxycodone HCl/325mg Acetaminophen tablets and certain pieces of equipment utilized in connection with the production activities under the Tablets ANDA for up to \$5.4 million to Mallinckrodt. Mallinckrodt paid the Company \$2 million of the purchase price on the closing date, having previously paid \$500,000 in July 1994. Mallinckrodt paid on January 9, 1997 \$1 million when the Company received on December 19, 1996 general clearance from the FDA for unrestricted operations at it facility in Brooklyn, New York and written notice from the FDA that it is in compliance with certain provisions of the consent order dated July 9, 1993. Mallinckrodt will pay the Company \$1.9 million balance of the Deferred Purchase Price when Mallinckrodt receives certain authorizations from the FDA, but in no event later than March 21, 1998. See "Item 1. Business. Dispositions" for additional information regarding this transaction.

On March 30, 1995, the Company signed the Zatpack Agreement with Zatpack which provides for the purchase of 500,000 shares of common stock of the Company by Zatpack in consideration of \$1,000,000. The Zatpack Note has been converted into 642,407 shares of Common Stock (the "Note Shares"), in March, 1997, at an adjusted conversion price of \$2.39 per share, thereby canceling the indebtedness. See "Item 1. Business. Other Transactions - Agreements with Zatpack, Inc." for additional information regarding the Zatpack Agreement.

From late December 1996 through March 31, 1997, the Company borrowed an aggregate of approximately \$1,100,000 from certain of the holders of the Company's convertible subordinated debentures. These borrowings, which are evidenced by unsecured promissory notes, are due and payable as to principal on demand. Interest, at the rate of 10% per annum, is payable on a quarterly basis. The Company utilized the proceeds of these borrowings for working capital.

As previously indicated, the Company has continued to actively pursue financing. At the current time, the Company is discussing with several parties obtaining financing which will replace the Company's banks and provide additional working capital. There can be no assurance that the Company will be able to obtain any such financing on commercially acceptable terms.

The Company has insufficient resources to meet both its current obligations at December 31, 1996 and its long-term obligations. To meet such obligations and to pursue the development of new generic drug products, the Company must find alternative sources funding. As previously indicated, the Company has continued to actively pursue financing. At the current time, the Company is discussing with several parties obtaining financing which will replace the Company's banks and provide additional working capital. There can be no assurance that the Company will be able to obtain any such financing on commercially acceptable terms. In addition, the report of the Company's independent certified public accountants contains an explanatory paragraph as to the Company's ability to continue as a going concern. Among the factors cited by the accountants as raising substantial doubt as to the Company's ability to continue as a going concern are: the loss incurred by the Company of approximately \$14,495,000 during the year ended December 31, 1996; the Company's working capital deficiency of approximately \$12,201,000 at that date; the expiration of the Credit Agreement on December 31, 1996 (which subsequently was extended to June 30, 1997, as described above); and the Company not being in compliance with the terms of its banking agreement and convertible subordinated debentures. See Note A of Note to Consolidated Financial Statements.

The Company is delinquent in its payment of payroll taxes to the extent of approximately \$1,500,000. Although the Company anticipates receiving a Federal income tax refund that will offset this liability to a substantial extent, the Company does not currently have the funds available to retire this delinquency. If the Company is unable to pay its payroll taxes, whether due to a denial of the tax refund or otherwise, the Company could be materially adversely affected.

Capital Expenditures

The Company's capital expenditures during 1996, 1995 and 1994 were \$208,000, \$536,000 and \$216,000, respectively. The decrease in capital expenditures in 1996 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 1997 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 1996, 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 1997 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 1996, 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 1997 Annual Meeting of Shareholders, which will be mailed within 120 days after the close of the Company's fiscal year ended December 31, 1996, 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 1997 Annual Meeting of Shareholders, which will be mailed within 120 days after the close of the Company's fiscal year ended December 31, 1996, 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. Financial Statement Schedules
 Not Applicable.
- C. Reports on Form 8-K
- . Exhibits

Exhibit Number

- 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. 33-2471-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 31, 1992 (the "1992 Form 10-K")).
- 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 10.1.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1993 (the "1993 Form 10-K")).
- 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).
- Amendment Four, dated as of July 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994)).

- 10.5 Amendment Five, dated as of March 21, 1995, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K dated March 21, 1995 (the "March 8-K")).
- 10.5(1) Form of Warrants issued to The Bank of New York, The Chase Manhattan Bank, N.A. and the Israel Discount Bank (incorporated by reference to Exhibit 10.5(i) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K")).
- 10.5(2) Letter Agreement, dated July 10, 1995, among Halsey Drug Co.,Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995 (the "June 10-Q")).
- 10.5(3) Letter Agreement, dated November 16, 1995, among Halsey Drug Co.,Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.25(iv) to the 1995 10-K).
- 10.5(4) Amendment 6, dated as of August 6, 1996, to Credit Agreement among Halsey Drug Co.,Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 (the "June 1996 10-Q)).
- *10.5(5) Letter Agreement, dated March 25, 1997 among Halsey Drug Co., Inc., the Chase Manhattan Bank, as successor in interest to The Chase Manhattan Bank (National Association), The Bank of New York and Israel Discount Bank.
- 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).
- 10.9 Employment Agreement, dated as of July 1, 1994, between the Registrant and Leonard H. Weiss (incorporated by reference to Exhibit 10.9 to the 1994 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.
- 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).
- 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).
- 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).
- 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).

- 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).
- 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).
- 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).
- Supply Agreement dated as of March 30, 1995 between Houba, Inc. and Zetapharm, Inc. (incorporated by reference to Exhibit 10.14 to the March 8-K).
- 10.25 Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 6(a) to the June 10-Q).
- 10.26 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 6(a) to the June 10-Q).
- 10.27 Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated December 4, 1995 (the "December 8-K")).
- 10.28 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the December 8-K).
- 10.29 Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 99 to the June 1996 10-Q).
- 10.30 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the June 1996 10-Q).

- 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.
- * Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

> HALSEY DRUG CO., INC. (Registrant)

By: /s/ Rosendo Ferran

Rosendo Ferran, President

March 31 , 1997

Date: March , 1997

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.

Chairman and Director

/s/William G. Skelly

William G. Skelly				
/s/Rosendo Ferran Rosendo Ferran	President, Chief Executive Officer and Director (Principal Executive Officer)	March	31,	1997
/s/Robert J. Mellage Robert J. Mellage	Controller (Principal Accounting Officer)	March	31,	1997
/s/R.H. Francis R.H. Francis	Director	March	31,	1997
/s/Alan J. SmithAlan J. Smith	Director	March	31,	1997

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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, 1996 and 1995, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1996. 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, 1996 and 1995, and the consolidated results of their operations and their consolidated cash flows for each of the three years in the period ended December 31, 1996, in conformity with generally accepted accounting principles.

As more fully discussed in Note A, the accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred a loss of approximately \$14,495,000 during the year ended December 31, 1996, has a deficiency in working capital of approximately \$12,201,000 and an accumulated deficit of approximately \$29,484,000 and owes approximately \$1,500,000 in delinquent payroll taxes. In addition, the Company's current banking agreement expires on June 30, 1997 and the Company is currently not in compliance with the financial covenants of its banking agreement and its convertible subordinated debentures agreement. These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these conditions are described in Note A. The financial statements do not include any adjustments that may result from the outcome of this uncertainty.

GRANT THORNTON LLP

New York, New York March 28, 1997

CONSOLIDATED BALANCE SHEETS

December 31, (in thousands)

CURRENT ASSETS Cash \$ 118 \$ 353 Accounts receivable - trade, net of allowances for doubtful accounts of \$424 and \$280		1996	1995
Accounts receivable - trade, net of allowances	CURRENT ASSETS		
· ·	Cash	\$ 118	\$ 353
	·		
in 1996 and 1995, respectively 226 1,689		226	1,689
Other receivable 1,000	Other receivable	1,000	
Inventories 3,758 7,716	Inventories	3,758	7,716
Prepaid insurance and other current assets 252 656	Prepaid insurance and other current assets	252	656
Total current assets 5,354 10,414	Total current assets	5,354	10,414
PROPERTY, PLANT AND EQUIPMENT, NET 6,222 7,394	PROPERTY, PLANT AND EQUIPMENT, NET	6,222	7,394
OTHER ASSETS 406 1,054	OTHER ASSETS	406	1,054
\$11,982 \$18,862		¢11 002	¢10 062
\$11,902 \$16,002 ===================================		Ψ11, 962 ======	Ψ±0,002 ======

CONSOLIDATED BALANCE SHEETS (continued)

December 31, (in thousands)

	1996	1995
CURRENT LIABILITIES Bank overdraft Due to banks Notes payable Convertible subordinated debentures Department of Justice settlement Accounts payable Accrued expenses Advances from minority stockholders	1,625 2,173 2,168 4,533 3,575	3,395 200 7,347 2,000 2,579 1,867 206
Total current liabilities	17,555	
LONG-TERM DEBT	1,508	2,595
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT) Common stock - \$.01 par value; authorized, 20,000,000 shares; issued and outstanding, 13,175,708 shares and 8,973,459 shares in 1996 and 1995, respectively Additional paid-in capital Accumulated deficit		90 14,459 (14,989)
Less treasury stock - at cost (474,603 shares and 500,000 shares in 1996 and 1995, respectively)	(1,044) (7,081)	(440) (1,100) (1,540)
	\$ 11,982 ======	\$ 18,862 ======

CONSOLIDATED STATEMENTS OF OPERATIONS

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

		1995	
Net sales Cost of goods sold	\$ 12,379 16,826	\$ 20,225 18,097	\$ 24,182 21,584
Gross profit		2,128	
Research and development Selling, general and administrative expenses		818 6,098	
Loss from operations	(13,787)	(4,788)	(5,032)
Interest expense Gain on sale of assets	1,708 (1,000)	1,307 (2,288)	735
Loss before income taxes		(3,807)	
Provision for income taxes		296	
NET LOSS		\$ (4,103) ======	
Loss per common share	\$ (1.49) ======	\$ (.52) ======	
Average number of outstanding shares	9,724,106 ======	7,886,101 ======	

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Years ended December 31, 1996, 1995 and 1994 (in thousands)

	Common stock, \$.01 par value		\$.01 par value Additional		Treasury stock, at cost		
	Shares	Amount	capital	Accumulated deficit	Shares	Amount	Total
Balance at January 1, 1994	7,109,537	\$71	\$ 8,967	\$ (5,119)			\$ 3,919
Issuance of common stock Issuance of warrants to banks Net loss	500,000	5	995 200	(5,767)			1,000 200 (5,767)
Balance at December 31, 1994	7,609,537	76	10,162	(10,886)			(648)
Issuance of common stock Issuance of common stock in connection	500,000	5	791				796
with litigation settlement Repurchase of common stock Issuance of warrants with convertible	824,742	8	2,992		(500,000)	\$(1,100)	3,000 (1,100)
subordinated debentures Exercise of stock options Net loss	39,180	1	416 98	(4,103)			416 99 (4,103)
Balance at December 31, 1995 (brought forward)	8,973,459	90	14,459	(14,989)	(500,000)	(1,100)	(1,540)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (continued)

Years ended December 31, 1996, 1995 and 1994 (in thousands)

	Common stock, \$.01 par value		Additional paid-in Accumulated		Treasury stock, at cost			
	Shares	Amount	capital	deficit	Shares	Amount	Total	
Balance at December 31, 1995 (brought forward)	8,973,459	\$ 90	\$14,459	\$(14,989)	(500,000)	\$(1,100)	\$ (1,540)	
Net loss for the year ended December 31, 1996				(14,495)			(14,495)	
Issuance of common stock - conversion of debentures Issuance of shares as settlement Issuance of warrants with convertible	3,504,000 59,550	35	6,724 262		25,397	56	6,759 318	
subordinated debentures Exercise of warrants of convertible			355				355	
debentures Stock options exercised	589,540 49,159	6	1,363 153				1,369 153	
Balance at December 31, 1996	13,175,708	\$131 ====	\$23,316 ======	\$(29,484) ======	\$(474,603)	\$(1,044) ======	\$ (7,081)	

CONSOLIDATED STATEMENTS OF CASH FLOWS

Year ended December 31, (in thousands)

	1996	1995	1994
Cash flows from operating activities Net loss	\$(14,495)	\$ (4,103)	\$ (5,767)
Adjustments to reconcile net loss to net cash used in operating activities Depreciation and amortization	1 906	1,956	2 350
Provision for losses on accounts receivable Provision for loss on investment Provision for inventory losses	144 500 1,095	1,000	271
Gain on sale of assets´ Accrued interest Deferred income taxes	,	(2,288) 77 296	
Changes in assets and liabilities Accounts receivable Inventories Income taxes receivable	2,863	637 (881)	2,389 660
Prepaid insurance and other current assets Accounts payable Accrued expenses	(96) 1,029 2,633	(160) (2,031) 44	(995) 528
Total adjustments	10,673	(2,350)	
Net cash used in operating activities		(6,453)	
Cash flows from investing activities Capital expenditures (Increase) decrease in other assets Net proceeds from sale of assets Deferred income	(390)	(536) 116 1,889	(169)
Net cash provided by (used in) investing activities	(390)	1,469	

CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

Year ended December 31, (in thousands)

	1996	6 	1	995 		1994
Cash flows from financing activities						
(Decrease) increase in notes payable	\$ 2	25	\$(1	,192)	\$	(489)
Proceeds from issuance of common stock	3:	18		796		1,000
Payments to Department of Justice				(90)		(86)
Bank overdraft	7	73		(5)		(224)
Repurchase of common stock			(1	,100)		
Payments to minority stockholders	(20	96)		(212)		(25)
Proceeds from issuance of convertible subordinated						
debentures	2,50	90	7	,740		
Proceeds from exercise of stock options	15	53		99		
Proceeds from exercise of warrants	1,36	69				
Increase in other assets	(25	55)		(727)		
Net cash provided by financing activities	3,97	77 	5	,309		176
NET INCREASE (DECREASE) IN CASH						
AND CASH EQUIVALENTS	(23	35)		325		(4)
Cash and cash equivalents at beginning of year	35	53		28		32
Cash and cash equivalents at end of year	\$ 13	18	\$	353	\$	28
	=====	==	===	====	==	=====

Supplemental disclosures of noncash activities:

- 1. 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.
- 2. 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.
- 4. The valuation of the warrants issued in 1994 , \$200,000, to its banks, is included in additional paid-in capital.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 1996, 1995 and 1994

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.

As of December 31, 1996, the Company has a working capital deficiency of approximately \$12,201,000, has an accumulated deficit of approximately \$29,484,000, has incurred a loss of approximately \$14,495,000 during the year ended December 31, 1996, and is not in compliance with its financial covenants pursuant to its banking agreement and its convertible subordinated debenture agreement. In addition, the Company is delinquent in the payment of its payroll taxes (approximately \$1,500,000) (Note H) and the Company's credit agreement with its banks expires June 30, 1997. These factors and other matters as discussed in Note M, raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments relative to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence. Management's plans with respect to those conditions include seeking alternative sources of financing. In this regard, the Company (a) is reviewing several unsolicited expressions of interest from prospective joint venture partners and investors, (b) plans to refinance or extend the maturity date of the Company's bank debt, (c) has sold the rights to one of its products to a major vendor and has received a commitment for future production of such product (Note I) and (d) submitted Abbreviated New Drug Applications ("ANDA") for approval by the Food and Drug Administration ("FDA") (Note M). There can be no assurance that management can obtain alternative sources of financing or obtain approvals for the ANDA's.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE A (continued)

2. Inventories

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

3. 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 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.

4. Income Taxes

The Company adopted Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("SFAS No. 109"), as of January 1, 1993. The standards for SFAS No. 109 require that the Company utilize an asset and liability approach for financial accounting and reporting for income taxes. The primary objectives of accounting for income taxes under SFAS No. 109 are to (a) recognize the amount of tax payable for the current year and (b) recognize the amount of deferred tax liability or asset based on management's assessment of the tax consequences of events that have been reflected in the Company's financial statements or tax returns.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE A (continued)

5. Loss Per Share

The computation of 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. Fully diluted earnings per share is considered equal to primary earnings per share for all years presented as the effect of other potentially dilutive securities would be antidilutive.

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 income taxes for the years ended December 31, 1995 and 1994 of \$201,000 and \$39,000, respectively. In addition, the Company interest of approximately \$1,173,000, \$786,000 and \$504,000, respectively, for the years ended December 31, 1996, 1995 and 1994. The Company did not pay any income taxes during the year ended December 31, 1996.

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.

8. Reclassifications

Certain reclassifications have been made to the 1995 and 1994 presentation to conform to the 1996 presentation.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE A (continued)

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. The Company has determined that no provision is necessary for the impairment of long-lived assets at December 31, 1996.

10. 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.

NOTE B - FAIR VALUE OF FINANCIAL INSTRUMENTS

Statement of Financial Accounting Standards No. 107 ("SFAS No. 107"), "Fair Value of Financial Instruments," requires disclosure of the estimated fair value of an entity's financial instrument assets and liabilities. For the Company, financial instruments consist principally of subordinated promissory notes and long-term and short-term debt.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE B (continued)

Long-term and short-term

Convertible subordinated

debt

debentures

The following methods and assumptions are used to estimate the fair value of each class of financial instrument for which it is practicable to estimate that value:

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:

	Decemb	er 31,	
1	996	1	.995
Carrying amount	Fair value amount	Carrying amount	Fair value amount
	(in tho	usands)	
\$6,328	\$6,328	\$6,190	\$6,190
2,173	2,173	7,347	7,347

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE C - INVENTORIES

Inventories consist of the following:

	December 31,	
	1996	1995
	(in tho	usands)
Finished goods	\$2,121	\$2,491
Work-in-process	1,018	1,398
Raw materials	619	3,827
	\$3,758	\$7,716
	=====	=====

NOTE D - PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows:

	December 31,	
	1996	1995
	(in t	thousands)
Machinery and equipment	\$11,641	\$11,247
Leasehold improvements	5,708	5,756
Building	1,263	1,203
Land	265	265
	18,877	18,471
Less accumulated depreciation and amortization	12,655	11,077
	\$ 6,222	\$ 7,394
	=====	======

Depreciation expense for the years ended December 31, 1996, 1995 and 1994 was approximately \$1,562,000, \$1,576,000 and \$1,930,000, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE E - DEBT

a. Line of Credit

In December 1992, the Company entered into a credit agreement providing for borrowings of up to \$7,000,000 at the prime rate plus an initial margin of 1/2%, originally maturing in December 1994. Upon certain conditions, as defined in the agreement, the margin rate increases by 2%. Borrowings under the line were available for working capital purposes based upon a percentage of the parent company's eligible accounts receivable and are collateralized by such accounts receivable. The agreement contains certain financial covenants, including minimum interest coverage and working capital ratios, tangible net worth, limitations on capital expenditures, and maximum debt-to-equity ratios. As of December 31, 1996, the Company was not in compliance with the above covenants.

In 1994, the Company and its banks amended the credit agreement to include the stock of certain subsidiaries, the accounts receivable of Houba, Inc., and the parent company's inventory and equipment as additional collateral, to increase the initial margin rate to 2% (10.25 % at December 31, 1996), to restrict certain payments made by the Company, to require payment to be made by the Company to the banks of any income tax refunds received by the Company, to extend the maturity date to August 31, 1995, and to agree in principal to modify the financial covenants at a later date. In addition, if the outstanding borrowings were not repaid by August 30, 1995, the Company was required to pay \$102,000, which represented 3% of the then outstanding principal due to the banks. Such amount was accrued in 1995 and fully paid in 1996.

As consideration for the above amendments and the Company's continued borrowings in excess of the borrowing formula, the Company has issued stock warrants to the banks, expiring December 31, 1999, to purchase up to 635,663 shares of the Company's common stock at exercise prices ranging from \$2.35 to \$2.375 per share (subject to the antidilution provisions of the credit agreement, as amended). 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE E (continued)

In addition, the Company and its banks amended the credit agreement as a result of the Company having consummated private offerings of its securities on July 18, 1995 and November 29, 1995. As consideration for waiving any breach or default under the credit agreement as a result of these private offerings, the bank group received \$950,000 of the proceeds as payment for interest, fees and principal and an extension of the warrant exercise period to July 17, 2000. In addition, the exercise prices of all warrants for 699,696 shares of the Company's common stock have been adjusted for antidilution to prices ranging from \$1.98 to \$2.07. On March 25, 1997, the bank group extended the maturity date of the credit agreement to June 30, 1997.

b. 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 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.

c. 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 of: (i) receipt by Mallinckrodt of all necessary authorizations from the FDA or (ii) September 21, 1997. 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE E (continued)

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.

Borrowings under long-term debt are as follows:

	December 31,	
	1996	1995
	 (in th	ousands)
Convertible subordinated promissory note Subordinated promissory notes Other	\$1,508 1,400 225	\$1,395 1,400
	3,133	2,795
Less: current maturities of long-term debt	(1,625)	(200)
	\$1,508 =====	\$2,595 =====

NOTE F - CONVERTIBLE SUBORDINATED DEBENTURES

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 dilution, 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE F (continued)

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 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 bank debt.

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 debentures. The balance held in escrow at December 31, 1996, was approximately \$112,000.

The Company received net proceeds from the 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE G - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	December 31,	
	1996	1995
	(in the	ousands)
Payroll taxes payable (Note H)	\$1,554	\$ 390
Accrued payroll	441	460
Professional fees	227	120
Interest	539	337
Other	814	560
	\$3,575	\$1,867
	=====	=====

NOTE H - INCOME TAXES

		,	Year	ended	December :	31,	
	199	96		199	5	199	4
	Amount	%	A	mount	%	Amount	%
	(in thousands)						
Federal statutory rate Loss of which no tax benefit	\$(4,928)	(34.0)%	\$	(749)	(34.0)%	\$(1,961)	(34.0)%
was provided Losses of subsidiaries with	4,233	29.1		280	12.7	1,223	21.2
no tax benefit Amortization of Warrants	424 32	3.0 .2		240	10.9	479	8.3
Goodwill amortization Department of Justice	73	.5		77	3.5	77	1.3
settlement Other	57 109	. 4 . 8		152	6.9	182	3.2
Actual tax expense	\$		\$			\$	

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE H (continued)

The Company has net operating loss carryforwards aggregating approximately \$16,877,000, expiring during the years 2009 through 2011. In addition, certain of the Company's subsidiaries file separate Federal income tax returns and have separate net operating loss carryforwards aggregating approximately \$5,297,000, expiring during the years 1998 through 2011.

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	1995
	(in thous	ands)
Deferred tax assets Net operating loss carryforward Allowance for doubtful accounts Research and development tax credit Reserve for inventory Litigation settlement Rent Capital loss carryforwards Other	\$ 12,824 178 212 605 284 96 210	\$ 4,792 117 212 65
Gross deferred tax assets	14,506	5,222
Deferred tax liabilities Depreciation Installment sale gain Other	(663) (1,218) (165)	(771) (165)
	(2,046)	(936)
Net deferred tax assets before valuation allowance Valuation allowance	12,460 (12,460)	
Net deferred tax assets	\$ ======	\$ ======

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

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.

The payroll taxes payable at December 31, 1996 include approximately \$1,500,000 of delinquent payroll taxes, substantially all of which liability was incurred in 1996. The Company has accrued interest and penalties on this amount. The Company expects that this liability will be satisfied 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 I - 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) September 21, 1997. Mallinckrodt also agreed to defer \$1,200,000 of the Company trade debt due to an affiliate of Mallinckrodt (Note E). Pursuant to the release of the Company from 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE I (continued)

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 ANDA 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. Upon exercise of the option, the Company and Mallinckrodt would enter into agreements pursuant to which the Company would (i) manufacture acetaminophen/oxycodone capsules for Mallinckrodt for a period of time and (ii) be prohibited from competing with Mallinckrodt and its affiliates with respect to the production of such capsules.

NOTE J - PENSION EXPENSE

The Company maintains the following two pension plans:

1. Management Pension Plan

The Company maintains a defined benefit pension plan covering substantially all nonunion employees.

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. Failure to timely fund these obligations may result in the termination of the Plan and/or other monetary penalties.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE J (continued)

Planned Company contributions over the next several years are expected to improve the funded status of the plan. The plan's assets are diversified in stocks, bonds, mutual funds and short-term and other investments.

	December 31,		
	1996	1995	1994
	(in thousands)
Normal service cost	\$ 24	\$ 49	\$ 50
Interest cost	32	25	27
Actual return on plan assets	(23)	(19)	(18)
Net amortization and deferral	(8)	(9)	(10)
Net pension cost	\$ 25	\$ 46	\$ 49
·	====	====	====

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE J (continued)

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

•	Year ended	d December 31,
		1995
	 (in	thousands)
Actuarial present value of benefit obligations at November 30, 1996 and 1995		
Estimated present value of vested benefits	\$ 440	
Estimated present value of nonvested benefits	52	44
Accumulated benefit obligation	492	
Value of future pay increases	12	22
Projected benefit obligation	504	471
Estimated market value of plan assets		
at November 30, 1996 and 1995	569	456
Excess (deficiency) of plan assets		
over projected benefit obligation	65	(15)
Unrecognized net gain (loss) Unrecognized net asset at December 1,	(72)	33
1987 being amortized over 24 years	(8)	(9)
	\$ (15) =====	\$ 9 =====

The assumptions used as of November 30, 1996 and 1995 in determining pension expense and funded status shown above were as follows:

1996	1995
7.00%	7.00%
4.00	4.00
7.00	7.00
	7.00% 4.00

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE J (continued)

2. Employees' Pension Plan

The Company contributed approximately \$492,000, \$450,000 and \$462,000 in 1996, 1995 and 1994, 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 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 option have been granted under this plan to date.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE K (continued)

The Company has adopted the disclosure provisions of Financial Accounting Standards No. 123. "Accounting for Stock-Based Compensation" (SFAS No. 123). 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 proforma amounts indicated below:

Thousands,	Year ended	Year ended
except per share amounts	December 31, 1996	December 31, 1995
Net loss		
As reported	\$(14,495)	\$(4,103)
Pro forma	(14,902)	(4,459)
Loss per share		
As reported	(1.49)	(.52)
Pro forma	(1.52)	(.56)

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 year ended December 31, 1996 and 1995, respectively; expected volatility of 82 and 71 percent; risk-free interest rates of 6.6 and 5.8 percent; and expected life of 4.6 years and 8.8 years. The weighted-average fair value of options granted during the year ended December 31, 1996 and 1995 for which the exercise price equals the market price on the grant date was \$2.68 and \$2.27, respectively, and the weighted average exercise prices were \$4.19 and \$3.16, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE K (continued)

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 January 1, 1994 Granted Cancelled	413,881 10,000 (201,731)	\$3.88 2.00 3.67
Balance at December 31, 1994	222,150	3.98
Granted Exercised Cancelled	471,600 (39,180) (54,070)	3.16 2.50 3.36
Balance at December 31, 1995	600,500	3.49
Granted Exercised Cancelled	20,000 (49,159) (21,334)	4.19 3.12 4.39
Balance at December 31, 1996	550,007 =====	3.53

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE K (continued)

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

	Options outstanding			Options exe	ercisable
Range of exercise prices	Number outstanding at December 31, 1996	Weighted average remaining contractual life	Weighted average exercise price	Number exercisable at December 31, 1996	Weighted average exercise price
\$1.94 - 4.00 4.25 - 6.25	464,440 85,567	8.41 years 1.48 years	\$3.15 5.67	331,063 75,567	\$3.19 5.84

NOTE L - COMMITMENTS

The Company occupies plant and office facilities under noncancellable operating leases which expired in December 1995. On October 31, 1994, 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, \$86,000 and \$99,000 in 1996, 1995 and 1994, 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, 1996, 1995 and 1994 was approximately \$884,000, \$659,000 and \$582,000, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE L (continued)

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

Twelve months ending December 31,	(in thousands)
1997	\$ 928
1998	975
1999	1,023
2000	1,075
2001	1,128
2002 and thereafter	5,106
Total minimum payments required	\$10,235

On January 1, 1993, the Company entered into an employment agreement with an officer having an initial term of five years. This employment agreement contains change in control provisions that would entitle the officer to receive certain severance benefits if there is a change in control in the Company, as defined, and a termination of employment. The maximum contingent liability as of December 31, 1996 under this agreement is approximately \$878,000.

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.

On October 23, 1996, the Company withdrew four of its ANDAs including its ANDA (the "Capsule ANDA") for acetaminophen/oxycodone capsules, 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). The Company instituted the withdrawal at the suggestion of the FDA and in anticipation of its release from the FDA's Application Integrity Policy list and its restrictions (collectively, the "AIP"). The FDA has placed the Company on the AIP, in October 1991, in connection with its investigation of the Company's

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE M (continued)

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 for 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.

On December 19, 1996, the FDA released the Company from the AIP. Release from the AIP permits the Company to submit ANDA applications to the FDA for review, 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 its review. In addition, the Company had previously submitted a new ANDA with respect to the Capsules, which the Company anticipates will be reviewed in the near future. However, there can be no assurance any of its new ANDAs, including the new Capsule ANDA, will be approved by the FDA. The Company will not be able to market these new products unless and until the FDA approves the new underlying ANDAs. Failure to obtain FDA approval for the new ANDAs, or a significant delay in obtaining such approval, would materially 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 government'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 recordkeeping violations. The plea agreement also requires the Company to pay a fine of \$2,500,000 over five years in quarterly installments of \$125,000 beginning September 15, 1993. Accordingly, the Company recorded a provision of \$2,060,000 (net of imputed interest). As of December 31, 1996, the Company has only paid two quarterly installments and additional partial

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE M (continued)

payments of \$100,000. The plea agreement stipulates that if the Company does not make timely payments, the entire fine becomes due and payable. As a result, the entire DOJ settlement has been reclassified as a current liability in the 1996 and 1995 consolidated balance sheets. At the present time, no action has been initiated by the DOJ to require immediate payment of the entire amount. Should the DOJ require immediate payment, it could result in a material adverse impact on the financial condition of the Company.

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 Commission 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 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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE M (continued)

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, paid 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 share of unregistered Common Stock of the Company was tendered to the plaintiff. At December 31, 1996, the Company recorded a charge of \$309,000 relating to the settlement.

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. Plaintiffs seek approximately \$265,000. On or about February 28, 1997, the Company and the plaintiffs agreed to settle the action. The settlement obligates the Company to remain current on its obligations and to pay portions of the alleged arrearages in installments. The Company has paid the alleged arrearages under the stipulation, but is not current on its obligations as

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE M (continued)

of the date of this filing. The Company's Collective Bargaining Agreement expires in June 1997 for all union employees who represent 45% of the Company's total labor force.

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 owned 70% 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 1993. In July 1995, the Company repurchased the 500,000 shares from Ranbaxy for \$1,100,000.

NOTE 0 - SIGNIFICANT CUSTOMERS AND SUPPLIERS

The Company sells its products to a large number of customers who are primarily drug distributors, drug store 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 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. During 1994, the Company had net sales to three customers in excess of 10% of total sales, each aggregating 12% of total sales. Balances due from these customers were approximately 10% and 25% of total accounts receivable at December 31, 1996 and 1995, respectively. The loss of any of these customers could have a material adverse effect on the Company.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1996, 1995 and 1994

NOTE P - FOURTH QUARTER ADJUSTMENTS

During the fourth quarter, the Company recorded a provision to write down approximately 1.1 million of inventory to its net realizable value.

Exhibit Number	Description	Page Number
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. 33-2471-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 31, 1992 (the "1992 Form 10-K")).	
10.2	Amendment Two, dated as of January 12, 1994, to Credit Agreement among the Registrant and the Chase Manhattan Bank, N.A., together with forms of Stock Warrant and Registration Rights Agreement (incorporated by reference to Exhibit 10.1.1 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)).	

Exhibit Number	Description	Page Number
10.5	Amendment Five, dated as of March 21, 1995, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K dated March 21, 1995 (the "March 8-K")).	
10.5(1)	Form of Warrants issued to The Bank of New York, The Chase Manhattan Bank, N.A. and the Israel Discount Bank (incorporated by reference to Exhibit 10.5(i) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K)).	
10.5(2)	Letter Agreement, dated July 10, 1995, among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995 (the "June 10-Q")).	
10.5(3)	Letter Agreement, dated November 16, 1995, among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.25(iv) to the 1995 10-K).	
10.5(4)	Amendment 6, dated as of August 6, 1996, to Credit Agreement among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 (the "June 1996 10-Q)).	
*10.5(5)	Letter Agreement, dated March 25, 1997 among Halsey Drug Co., Inc., the Chase Manhattan Bank, as successor in interest to The Chase Manhattan Bank (National Association), The Bank of New York and Israel Discount Bank.	

Exhibit Number	Description	Page Number
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 on 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).	
10.9	Employment Agreement, dated as of July 1, 1994, between the Registrant and Leonard H. Weiss (incorporated by reference to Exhibit 10.9 to the 1994 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).	

Exhibit Number	Description	Page Number
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 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).	

Exhibit Number	Description	Page Number
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, N.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).	

Exhibit Number	Description	Page Number
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).	
10.27	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).	
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 22 to the 1993 10-K).	

Exhibit Number	Description	Page Number
*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.	

* Filed herewith.

The Chase Manhattan Bank The Bank of New York Israel Discount Bank of New York

March 25, 1997

Halsey Drug Co., Inc. 1827 Pacific Street Brooklyn, New York 11233

Attn: Mr. Rosendo Ferran, President

Dear Mr. Ferran:

Reference is made to the Credit Agreement, dated as of December 22, 1992 (as amended from time to time prior to the date hereof, the "Credit Agreement") among Halsey Drug Co., Inc. ("Halsey" or the "Borrower"), The Chase Manhattan Bank, as successor in interest to The Chase Manhattan Bank (National Association) ("Chase"), The Bank of New York ("BNY"), Israel Discount Bank of New York ("IDB" and, together with Chase and BNY, the "Banks") and The Chase Manhattan Bank, as successor in interest to The Chase Manhattan Bank (National Association), as agent for the Banks (in such capacity, the "Agent"). Unless otherwise defined herein, capitalized terms used herein shall have the meanings ascribed to them in the Credit Agreement.

Pursuant to the terms of this letter agreement, the Credit Agreement is supplemented and amended as follows:

> (a) The final date upon which the Expiration Date (as defined in the Credit Agreement) shall occur is extended from December 31, 1996 to June 30, 1997 and, accordingly, the definition of "Expiration Date" shall be amended by replacing the date "December 31, 1996" with the date "June 30, 1997."

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- (b) Subject to paragraph (c), upon the timely satisfaction of the following conditions set forth in clauses (i), (ii) and (iii) below, the Banks agree to waive any Event of Default (as defined in the Credit Agreement) based upon the failure to make payments of interest.
 - (i) on or prior to April 7, 1997, the Borrower shall have made all interest payments due and owing as of the first business day of March, 1997 under the terms of the Credit Agreement (determined without giving effect to the waiver contained in this paragraph (b));
 - (ii) on or prior to the first business day of May, 1997, the Borrower shall have made all interest payments due and owing as of the first business day of April, 1997 under the terms of the Credit Agreement (determined without giving effect to the waiver contained in this paragraph (b)); and
 - (iii) on or prior to the first business day of June, 1997, the Borrower shall have made all interest payments due and owing as of the first business day of May, 1997 under the terms of the Credit Agreement (determined without giving effect to the waiver contained in this paragraph (b)).
- (c) The waiver contained in paragraph (b) above shall take effect upon the effectiveness of this letter agreement, but shall immediately cease to be in effect on April 7, 1997 if all interest payments due and owing as of the first business day of March, 1997 (determined without giving effect to the waiver contained in paragraph (b)) have not been paid at such time. Furthermore, the waiver contained in paragraph (b) above shall immediately cease to be in effect if at any time the Borrower fails to satisfy the conditions set forth in clauses (ii) or (iii) of paragraph (b) on or before the dates specified therein. In addition, For the avoidance of doubt, the parties hereto expressly agree that the failure of the Borrower to make any payment mentioned in any of clauses (i), (ii) or (iii) on or before the date specified in such clause shall constitute an Event of Default under the Credit Agreement.

Except as expressly amended above, the terms and conditions of the Credit Agreement and the other Loan Documents shall remain in full force and in effect and are hereby ratified and confirmed. Except as expressly provided in this letter agreement, nothing contained herein shall constitute a waiver, release or modification of any of the Agent's or the Banks' rights and remedies under, or any of the terms and conditions of, the Loan Documents. The Agent and the Banks expressly reserve all of their rights and remedies under the Loan Documents and under applicable law.

This letter agreement shall become effective upon the execution and delivery to the Agent and the Banks of a counterpart of this letter agreement signed by the Borrower and each of the Banks.

Very truly yours,

THE BANK OF NEW YORK

By:

Name: Title:

ISRAEL DISCOUNT BANK OF NEW YORK

By:

Name: Title:

By:

Name: Title:

THE CHASE MANHATTAN BANK as Bank and as Agent

By:

Name: Title:

ACCEPTED AND AGREED:

HALSEY DRUG CO., INC.

By:

Name: Title:

cc: Peter Kakoyiannis, Esq.

Exhibit 10.10(3)

Halsey Drug Co., INC. 1996 NON-EMPLOYEE DIRECTOR STOCK OPTION PLAN

ARTICLE 1. Establishment, Purpose, and Duration

1.1 Establishment of the Plan. Halsey Drug Co., Inc., a New York corporation (the "Company"), hereby establishes a plan to be known as the "Halsey Drug Co., Inc. 1996 Non-Employee Director Stock Option Plan" (the "Plan"), as set forth in this document. The Plan permits the grant of Nonqualified Stock Options to Non-Employee Directors, subject to the terms and provisions set forth herein.

Upon approval by the Board of Directors of the Company, and subject to ratification by an affirmative vote of the Company's shareholders, the Plan shall become effective as of October 17, 1996 (the "Effective Date"), and shall remain in effect as provided in Section 1.3 herein.

- 1.2 Purpose of the Plan. The purpose of the Plan is to provide compensation in the form of an equity participation in the Company to Non-Employee Directors. The Plan is intended to promote the success and enhance the value of the Company by linking the personal interests of Non-Employee Directors to those of Company shareholders.
- 1.3 Duration of the Plan. The Plan shall commence on October 17, 1996 and shall remain in effect, subject to the right of the Board of Directors to terminate the Plan at any time pursuant to Article 7 herein, until all Shares subject to it shall have been purchased or acquired according to the Plan's provisions. However, in no event may an Option be granted under the Plan on or after October 16, 2006.

ARTICLE 2. Definitions

Whenever used in the Plan, the following terms shall have the meanings set forth below:

- 2.1 "Award" means an Option granted under the Plan.
- 2.2 "Award Agreement" means an agreement entered into by and between the Company and a Non-Employee Director, setting forth the terms and provisions applicable to an Award granted under the Plan.

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- 2.3 "Board" or "Board of Directors" means the Board of Directors of the Company.
- 2.4 "Code" means the Internal Revenue Code of 1986, as amended from time to time.
- 2.5 "Company" means Halsey Drug Co., Inc., a New York corporation, or any successor thereto as provided in Section 9.5 herein.
 - 2.6 "Committee" means the Compensation Committee of the Board.
- 2.7 "Date of Termination" means the effective date on which an individual ceases to be a member of the Board of Directors of the Company.
- 2.8 "Director" means any individual who is a member of the Board of Directors of the Company.
- 2.9 "Employee" means any employee of the Company, or any of its subsidiaries or affiliates. For purposes of the Plan, an individual whose only employment relationship with the Company is as a Director, shall not be deemed to be an Employee.
- 2.10 "ERISA" means the Employee Retirement Income Security Act of 1974, as amended from time to time.
- 2.11 "Exchange Act" means the Securities Exchange Act of 1934, as amended from time to time, or any successor act thereto.
- 2.12 "Fair Market Value" means (a) the mean of the high and low sales prices of Shares on the principal exchange or electronic inter-dealer quotation system on which the Shares are traded on the Grant Date, as hereinafter defined, or, (b) if there have been no sales on any such day, the mean of the high and low sales prices of Shares on said exchange or in said system on the last preceding date on which such sales were made, or, (c) if on any day the Shares shall not be quoted on an exchange or in said system, the mean of the highest bid and lowest asked prices on such day in the over-the-counter market as reported by National Quotation Bureau Incorporated, or any similar successor organization. If at any time the Shares are not listed on any national securities exchange or quoted in any electronic inter-dealer quotation system or



market value of the Shares underlying Options to be granted hereunder shall be the fair market value thereof as of such Grant Date, determined in good faith by the Board of Directors.

- 2.13 "Grant Date" shall mean the date on which Options are granted under the Plan. There shall be one Grant Date during the final quarter of each fiscal year of the Plan, commencing with the fiscal year beginning January 1, 1996.
- 2.14 "Non-Employee Director" means any individual who is a Director of the Company, but who is not otherwise an Employee.
- 2.15 "Nonqualified Stock Option" or "NQSO" means an Option to purchase Shares, granted under Article 6 herein.
 - 2.16 "Option" means a Nonqualified Stock Option granted under the Plan.
- 2.17 "Option Price" means the price at which a Share may be purchased under an Option.
- 2.18 "Participant" means a Non-Employee Director of the Company who has been awarded an Option.
- 2.19 "Rule 16b-3" means Rule 16b-3 as promulgated and amended from time to time by the Securities and Exchange Commission pursuant to Section 16 of the Exchange Act.
 - 2.20 "Shares" means shares of common stock of the Company.

ARTICLE 3. Administration

- 3.1 The Board of Directors. The Plan shall be administered by the Committee. The members of the Committee shall be appointed from time to time by, and shall serve at the discretion of, the Board.
- 3.2 Administration by the Committee. The Committee shall have the full power, discretion, and authority to interpret and administer the Plan in a manner which is consistent with the Plan's provisions.
- 3.3 Decisions Binding. All determinations and decisions made by the Committee pursuant to the provisions of the Plan, and all related orders or resolutions of the Committee shall be final, conclusive, and binding on all

persons, including the Company, its shareholders, employees, Participants, and their estates and beneficiaries.

ARTICLE 4. Shares Subject to the Plan

- 4.1 Number of Shares. Subject to the adjustment as provided in Section 4.3 herein, the total number of Shares available for issuance upon the exercise of Options granted under the Plan may not exceed 100,000. These Shares may be either authorized but unissued or reacquired Shares.
- 4.2 Lapsed Awards. If any Option granted under the Plan is canceled, expires, or lapses for any reason, any Shares subject to such Option again shall be available for grant of an Option under the Plan.
- 4.3 Adjustments in Authorized Shares. In the event of any merger, reorganization, consolidation, recapitalization, separation, liquidation, stock dividend, split-up, Share combination, or other change in the corporate structure of the Company affecting the Shares, the Board may make such adjustments to outstanding Awards as may be determined to be appropriate and equitable by the Committee, in its sole discretion, to prevent dilution or enlargement of rights.

ARTICLE 5. Eligibility and Participation

- 5.1 Eligibility. Persons eligible to participate in the Plan are limited to Non-Employee Directors who are serving on the Board on the date of each grant under the Plan. No Option will be granted to a Non-Employee Director, if immediately after the grant of such option such Non-Employee Director would beneficially own Shares amounting to more than five percent of the voting power of the Company's outstanding Shares, including Shares subject to outstanding options held by him.
- 5.2 Actual Participation. All eligible Non-Employee Directors shall receive grants of Options pursuant to the terms and provisions set forth in Article 6 herein.

ARTICLE 6. Nonqualified Stock Options

6.1 Grants of Options. On the initial Grant Date, which date shall occur during the final quarter of the fiscal year ending December 31, 1996, each eligible Non-Employee Director, as set forth in Section 5.1, shall be granted an Option to purchase _____ Shares. Thereafter, during the final quarter of each subsequent fiscal year prior to the termination of the Plan, each Non-Employee

Director shall automatically be issued an Option pursuant to the Plan to purchase _____ Shares. The specific terms and provisions of such Options shall be incorporated in Award Agreements, executed pursuant to Section 6.3 of the Plan.

- 6.2 Limitation on Grant of Options. Other than those grants of Options set forth in Section 6.1, no additional Options shall be granted under the Plan.
- 6.3 Option Award Agreement. Each Option grant shall be evidenced by an Award Agreement that shall specify the Option Price, the duration of the Option, the number of Shares available for purchase under the Option, and such other provisions as the Committee shall determine.
- 6.4 Option Price. The purchase price per Share available for purchase under an Option shall equal the Fair Market Value of a Share on the respective Grant Date.
- $\,$ 6.5 Duration of Options. Each Option shall expire on the tenth anniversary date of its grant.
- 6.6 Vesting of Shares Subject to Option. Each Option granted under this Plan shall be exercisable immediately as of its Grant Date with respect to 25% of the Shares subject to the Option and with respect to an additional 25% at the end of each fiscal year subsequent to the fiscal year in which the Grant Date occurs. All or any part of the Shares with respect to which the right to purchase has vested may be purchased at the time of such vesting or at any time or times thereafter prior to the tenth anniversary of their respective Options' Grant Dates.
- 6.7 Termination of Directorship. In the event a Participant ceases to be a Director for any reason, all outstanding Options, to the extent such Options are exercisable at the Date of Termination, shall remain exercisable for one year following the Date of Termination, or until the expiration date of such Options, whichever period is shorter. Options to which the right of exercise has not vested shall terminate effective the Date of Termination.
- 6.8 Payment. Options shall be exercised by the delivery of a written notice of exercise to the Company, setting forth the number of Shares with respect to which the Option is to be exercised, accompanied by full payment for the Shares. The Option Price upon exercise of any Option

shall be payable to the Company in full in cash or by check acceptable to the Company.

As soon as practicable after receipt of a written notification of exercise and full payment, the Company shall deliver to the Participant, in the Participant's name, Share certificates in an appropriate amount based upon the number of Shares purchased pursuant to the exercise of the Option.

The Company may make such provisions as it deems appropriate for the withholding by the Company pursuant to federal or state income tax laws of such amounts as the Company determines it is required to withhold in connection with any Award. The Company may require a Participant to satisfy any relevant tax requirements before authorizing any issuance of Shares to such Participant upon exercise of an Option hereunder. Any such settlement shall be in the form of cash, check or such other form of consideration as is reasonably satisfactory to the Committee.

- 6.9 Restrictions on Share Transferability. The Committee shall impose such restrictions on any Shares acquired pursuant to the exercise of an Option under the Plan, as it may deem advisable, including, without limitation, restrictions under applicable Federal securities laws, under the requirements of any stock exchange or market upon which such Shares are then listed and/or traded, and under any blue sky or state securities laws applicable to such Shares.
- 6.10 Limited Transferability of Options. The Committee may provide that an Option granted under the Plan may be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated (collectively, a "Transfer"), provided that any such Transfer is to a member of the Optionee's immediate family, a trust or similar entity of which the Optionee or a member of the Optionee's immediate family is a beneficiary, or a charitable organization under the Code.
- ARTICLE 7. Amendment, Modification, and Termination
- 7.1 Amendment, Modification, and Termination. Subject to the terms set forth in this Section 7.1, the Board may terminate, amend, or modify the Plan at any time and from time to time.

Without the approval of the shareholders of the Company (to the extent required by the Code, by Rule 16b-3, by any national securities exchange or system on which the Shares

are then listed or reported, or by a regulatory body having jurisdiction with respect hereto), no such termination, amendment, or modification may:

- (a) Materially increase the total number or value of Shares which may be available for grants of Awards under the Plan, except as provided in Section 4.3 herein; or
- (b) Materially change the class of Participants eligible to participate in the Plan; or
 - (c) Materially increase the benefits accruing to Participants.
- 7.2 Awards Previously Granted. Unless required by law, no termination, amendment, or modification of the Plan shall in any manner adversely affect any Award previously granted under the Plan, without the written consent of the Participant holding the Award.
- 7.3 Section 16(b) Compliance. The Plan and the grant of Awards hereunder are intended to comply with the conditions of Rule 16b-3 and to qualify for the exemption from Section 16(b) of the Exchange Act provided thereunder. Should any provision hereof not be necessary in order to comply with the requirements of Rule 16b-3 or should any additional provisions be necessary in order so to comply, the Board of Directors may amend the Plan accordingly, without the necessity of obtaining the approval of the Company's shareholders.

ARTICLE 8. Beneficiary Designation

Each Participant under the Plan may, from time to time, name any beneficiary or beneficiaries (who may be named contingently or successively) to whom any benefit under the Plan is to be paid in the event of his death (and/or who may exercise the Participant's vested Options following his death). Each designation will revoke all prior designations by the same Participant, shall be in a form prescribed by the Board, and will be effective only when filed by the Participant in writing with the Board during his lifetime. In the absence of any such designation, benefits remaining unpaid at the Participant's death shall be paid to the Participant's estate (and, subject to the terms and provisions of the Plan, any unexercised vested Options may be exercised by the administrator or executor of the Participant's estate).

ARTICLE 9. Miscellaneous

- 9.1 Gender and Number. Except where otherwise indicated by the context, any masculine term used herein also shall include the feminine; the plural shall include the singular and the singular shall include the plural.
- 9.2 Severability. In the event any provision of the Plan shall be held illegal or invalid for any reason, the illegality or invalidity shall not affect the remaining parts of the Plan, and the Plan shall be construed and enforced as if the illegal or invalid provision had not been included.
- 9.3 No Right or Nomination. Nothing in the Plan shall be deemed to create any obligation on the part of the Board to nominate any Director for reelection by the Company's shareholders.
- 9.4 Successors. All obligations of the Company under the Plan, with respect to Awards granted hereunder, shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.
- 9.5 Requirements of Law. The granting of Awards under the Plan shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges or systems as may be required.
- 9.6 Governing Law. To the extent not preempted by Federal law, the Plan, and all agreements hereunder, shall be construed in accordance with and governed by the laws of the State of New York.

Exhibit 23.1

CONSENT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

We have issued our report dated March 28, 1997, 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, 1996. 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 March 28, 1997 This schedule contains summary financial information extracted from the Consolidated Balance Sheets at December 31, 1996 and the Consolidated Statements of Operations for the Year Ended December 31, 1996 and is qualified in its entirety by reference to such financial statements.

