

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A  
Amendment No. 2

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

For the fiscal year ended December 31, 1995 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.)

1827 Pacific Street, Brooklyn, New York) 11233  
(Address of principal executive offices) (Zip Code)

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

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

Title of each class:	Name of each exchange on which registered:
Common Stock, Par Value \$0.01	The American Stock Exchange

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

None

Indicate by check mark whether the registrant (1) has filed all reports  
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of  
1934 during the preceding 12 months (or for such shorter period that the  
registrant was required to file such reports), and (2) has been subject to such  
filing requirements for the past 90 days.

Yes No X  
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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 25, 1996, the registrant had 8,486,792 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 25, 1996 (\$6.567), the aggregate market  
value of the voting stock held by non-affiliates of the registrant was  
approximately \$51,278,270.

Documents Incorporated by Reference

Portions of the Proxy Statement for the Annual Meeting of Stockholders to be  
held on June 4, 1996 (Part III)

Page 1 of \_\_\_\_ Pages  
Exhibit Index is on Page \_\_\_\_

TABLE OF CONTENTS

Contents	Page Number
-----	-----
Cover Page	i
PART I	
Item 1. Business	1
PART II	
Item 6. Selected Financial Data	30
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	33
Item 8. Financial Statements and Supplementary Data	42
PART IV	

Item 14. Exhibits, Financial Statement Schedules	44
Signatures	50
Index to Financial Information	F-1
Exhibit Index	51

## PART I

### Item 1. Business. -----

#### Introduction -----

Halsey Drug Co., Inc., a New York corporation established in 1935 ("Halsey"), and its subsidiaries (collectively, the "Company"), 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. ("Cenci"), a California corporation (51% owned), and Cenci Powder Products, Inc. ("Cenci Powder"), a Delaware corporation (51% 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. The Company's ability to develop and manufacture bulk chemical products was enhanced by the acquisition in 1990 of 100% of the capital stock of Houba and the completion by Houba in late 1991 of a new 15,000-square-foot manufacturing facility. Houba currently produces and markets raw materials intended for pharmaceutical and food supplements, as well as solid dosage forms of generic drug products. In October and December 1991, the Company acquired majority interests in Cenci and Cenci Powder, respectively. These acquisitions gave the Company a greater presence on the West Coast of the United States, and added new products. Cenci and Cenci Powder manufacture liquid and powder preparations, respectively, of pharmaceutical products in various dosage forms. The Company's Indiana Chemicals subsidiary is engaged in the manufacture of the specialty vitamin Biotin. Halsey Pharmaceutical is a trading company engaged exclusively in sales operations.

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 the Brooklyn, New York plant. These problems caused the Company to halt production and sale of a number of products and to establish a \$2,000,000 reserve as of December 31, 1992, and a reserve of \$3,875,000 in 1993 to cover estimated costs associated with inventory write-offs, recalls of the affected products and estimated additional legal expenses. The affected products accounted for approximately 28% of the Company's total revenues in 1992 and 1993, respectively. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations -- General."

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 recordkeeping 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 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 commencing in September 1993. Two installments have been paid to date. Only additional partial payments have been paid in the amount of \$90,000. 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 constitutes a default under the Company's Credit Agreement with its banks. 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 Food & Drug Administration (the "FDA") that resulted from the FDA's investigation into the Brooklyn plant's compliance with the FDA's Current Good Manufacturing Practice ("CGMP") regulations. Under the terms of the consent decree, the Company was enjoined from shipping any solid dosage drug products (i.e., excluding liquid

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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 CGMP regulations. As part of satisfying these requirements, the Company is required to validate the manufacturing processes for each solid dosage drug product prior to manufacturing and shipping the drug product. The Company, however, was permitted under the terms of the consent decree to manufacture and ship from the Brooklyn plant six identified solid dosage drug products ("the "Brooklyn Solid Dosage Products") at its own risk provided that: (i) at least twice per month, the Company's independent expert certifies that each batch of drug product upon validation will have been manufactured in accordance with the CGMP Regulations and the formulation described in the drug product's approved New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA"), until such time as validation is completed for these products; and (ii) for any batches of these products that have already been manufactured, such certification will include a certification by a Company representative with personal knowledge of the records relating to such drug that such records are accurate and complete and a certification signed by an independent expert that he has personally reviewed the records, and that in his professional opinion the foregoing requirement concerning validation has been met.

At the beginning of August 1993, the Brooklyn plant resumed shipments of two drug products (Class II narcotics), Oxycodone with Acetaminophen Capsules 5mg/500mg and

Oxycodone with Acetaminophen Tablets 5mg/325mg, and thereafter resumed shipments of a third solid dosage drug product, Acetaminophen, Butalbital and Caffeine Tablets 325mg, 50mg, 40mg. During 1995, the Company sold its Oxycodone with Acetaminophen Tablet business to a company (together with affiliates, "Mallinckrodt") under common control with Mallinckrodt Chemical, Inc. Under a tolling arrangement with Mallinckrodt, the Company will continue to manufacture such tablets for Mallinckrodt for at least two years. See "Business-

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- Dispositions," below. In September 1993, the Company resumed shipments of two other solid dosage drug products, Isoniazid 300mg and Tetracycline 250mg and 500mg capsules, from the Brooklyn plant. After review by the Company of one of the Brooklyn Solid Dosage Products which the Company was permitted to continue to manufacture and ship under the terms of the consent decree, Hydrocodone Bitartrate 5mg and Acetaminophen 500mg Tablets, discrepancies were discovered with some of the data in the Company's ANDA. This resulted in a voluntary recall of this product in November 1993 and the withdrawal of the ANDA. As a result of such recall and the transaction with Mallinckrodt the Company manufactures and ships four solid dosage products from its Brooklyn plant on its own behalf and manufactures one solid dosage product on behalf of Mallinckrodt.

#### Products and Product Development

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##### 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 31 products, consisting of 20 dosage forms and strengths of prescription drugs and 11 dosage forms and strengths of over-the-counter drugs. Each dosage form and strength of a particular drug is considered in the industry to be a separate drug product. The Company's drug products are sold in various forms, including liquid and powder preparations, compressed tablets and two-piece, hard-shelled capsules.

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

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

In October 1991, the FDA suspended review of all of Halsey's (but not Houba's or Halsey's other subsidiaries) applications for new drug approvals. It is unlikely that Halsey will receive any new approvals to market any generic drugs from the FDA in 1996. See "Government Regulation" below.

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. As a result of the FDA consent decree, the Company's strategy at the Brooklyn plant has been to concentrate on conforming the operations of the plant to the FDA's CGMP regulations and to satisfy the conditions for the resumption of shipments of the remaining four Brooklyn Solid Dosage Products described above. However, during 1996, the Company, through its Houba subsidiary, may continue to apply for ANDA approvals. In addition, the Company will continue to pursue the development of its existing pharmaceutical business as well as the development of Houba's chemical products business.

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 resumption of FDA review of Halsey's application for new drug approvals at its Brooklyn plant, the timing of FDA approval of such products and the number and timing of FDA approvals for competing products.

#### Bulk Chemical Products

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

#### Dispositions

On March 21, 1995 (the "Closing Date"), the Company sold its abbreviated new drug application ("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 is payable as follows. Mallinckrodt will pay \$1 million when the Company receives general clearance from the FDA for unrestricted operations at its Brooklyn facility and written notice from the FDA that the Company is in compliance with certain provisions of the consent order dated July 2, 1993. 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 September 21, 1997.

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," below) 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 two years. 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 with respect to the Tablets ANDA in the United States 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, and 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.

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 ANDA for acetaminophen/oxycodone capsules 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 acetaminophen/oxycodone 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, if any, 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 Corporation. In June 1994 both Penick Corporation and Penick Pharmaceutical, Inc, filed petitions under Chapter 11 of the United States Bankruptcy Code. If Penick were to cease operations, there can be no assurance that the Company would be able to enter into a relationship with another entity licensed by the FDA to process such raw materials on commercially acceptable terms.

## Other Transactions

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### 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 provides for the purchase of 500,000 shares of common stock of Halsey (the "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 Chemicals. Zatpack has the right to have the Shares registered under the Securities Act of 1933, as amended (the "Securities Act"). As a result of the transaction, the Company now owns 100% of Indiana Chemicals.

Pursuant to the Zatpack Agreement, the Company issued a convertible promissory note (the "Zatpack Note"), dated as of December 1, 1994, 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 interest accruing at a rate of 8%, compounded annually. The Zatpack Note was initially convertible into common stock (the "Conversion Shares") of the Company at a price of \$2.50 per share (the "Conversion Price"), subject to adjustment. Since issuance the conversion price has been reduced to \$2.41, as a result of the triggering of anti-dilution clauses. The Zatpack Note is subordinate to all bank and institutional indebtedness of the Company, and may be prepaid by the Company, in whole but not in part, upon 30 days notice to the holders thereof without penalty. The holders of the Zatpack Note have the right to have the Conversion Shares registered under the Securities Act.

In connection with the transactions contemplated by the Zatpack Agreement, a subsidiary of Zuellig agreed to supply a subsidiary of the Company with Methacycline HCl for a three year period.

#### Sale of Stock to Ranbaxy

On October 27, 1994, the Company signed a Letter of Intent ("LOI") with Ranbaxy Pharmaceuticals, Inc. ("RPI"), a wholly owned United States subsidiary of Ranbaxy Laboratories Ltd. of New Delhi, India. The Company received \$1 million from RPI in payment for 500,000 shares of common stock in accordance with the terms of the LOI. The LOI provided for completion of due diligence by RPI within a period of 30 days, after which the parties would negotiate and finalize a definitive agreement. After execution of a definitive agreement, RPI was to have purchased an additional 5,000,000 newly issued shares of common stock for \$10 million. On November 29, 1994, the Company announced that RPI had decided not to proceed with its second purchase of the Company's common stock. In August 1995, the Company repurchased the RPI Shares from RPI for an aggregate purchase price of \$1,100,000, which funds were derived from the proceeds of a private offering of the Company's securities. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

## 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, recordkeeping, 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 two to five 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."

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

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in paragraph 2 or 3 below is available, a prospective manufacturer must conduct and submit to the FDA complete clinical studies to prove a drug's safety and efficacy, in addition to the bioavailability and/or bioequivalence studies discussed below, and must also submit to the FDA information about manufacturing practices, the chemical make-up of the drug and labeling.

##### 2. Abbreviated New Drug Applications ("ANDA"). The Drug Price Competition

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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

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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 patentholder 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

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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 "Act"). The 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 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 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 Act provides for suspension of the marketing of drugs under approved generic drug applications sponsored by affected companies. The 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. The Company does not know when the FDA will resume review of the Company's new drug applications, but such review can begin after the FDA finds that the Company is in compliance with CGMP regulations. To date, the FDA has not made such a finding. See "Item 3. Legal Proceedings -- Government Consent Decrees."

## 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.

## FDA Investigations

In April and May of 1990, the FDA conducted a pre-approval inspection of the Company's Brooklyn plant, certain pending ANDAs relating to one drug product (in four dosages) and the Company's compliance with the CGMPs. The FDA issued Inspectional Observations concerning, and made further investigation of, the Company's recordkeeping practices and the accuracy of certain research and development stage batch records maintained by the Company for one drug product. As a result, the Company voluntarily withdrew the pending ANDAs relating to this product, and shortly thereafter for one other product, which have never been marketed by the Company. At that time, the FDA also inspected ten then currently marketed drug products (23 dosages) and issued no Inspectional Observations with respect to such products.

In late 1991, the Company was notified that the FDA had undertaken a validity assessment, pursuant to which the FDA suspended review of all of Halsey's new drug applications, including four pending ANDAs. At the FDA's suggestion, the Company voluntarily undertook an internal audit and retained an outside consultant to review pending and various filed and approved ANDAs, the results of which were provided to the FDA. Based on this initial review, the Company

voluntarily withdrew in 1991 three ANDAs for the drug fenoprofen calcium.

#### Product Recalls - -----

In March 1993, the Company stopped production and sale of five products previously manufactured at the Company's Brooklyn plant as a result of various problems identified with these products, which related primarily to the addition of unapproved inactive ingredients, processing deviations and recordkeeping discrepancies. The disclosures regarding the affected products, Quinidine Gluconate, Propylthiouracil, Acetaminophen with Codeine, Propoxyphene Napsalate with Acetaminophen and Metronidazole, resulted from investigations by the Company, the FDA and DOJ into the Company's existing and pending ANDA drug approvals and recordkeeping practices.

In response to these problems, the Board of Directors adopted and informed the FDA that the Board would enact a series of measures designed to address the specific problems identified with the affected products and to avoid the recurrence of similar problems. The Company notified the FDA that the Company had indefinitely suspended the manufacture and sale of the affected products, and that it had initiated a recall of those products from distributors and retail sellers. In addition, the Company agreed to withdraw its ANDAs for Propoxyphene Napsalate with Acetaminophen. A number of personnel and related changes at the Brooklyn plant were instituted as part of the plan proposed to the FDA directed at the Company's oversight of regulatory affairs. The plan proposed to the FDA called for, among other things, the hiring of new supervisors in the production department at the Brooklyn plant, including a new head of production. The Company also extended its internal audit of the Company's products at the Brooklyn plant to determine if any other problems existed and to determine the causes of the identified problems. The Company retained an additional qualified outside consultant to assist the Company's then current outside consultant.

In June 1993, the Company entered into a plea agreement with the DOJ and a consent decree with the U.S. Attorney for the Eastern District of New York on behalf of the FDA with respect to the DOJ and FDA investigations of the Company. As a direct result of the consent decree, and a subsequent product recall, the Company is limited to manufacturing and shipping five identified solid dosage drug products from its

Brooklyn plant (the consent decree does not affect the Company's ability to manufacture and ship liquid dosage drug products or affect the Company's operations in its Indiana or California facilities), one of which is being manufactured on behalf of Mallinckrodt. The Company has charged an aggregate of approximately \$5,935,000 to operations with respect to the plea agreement and the consent decree. This amount was comprised of inventory write-offs, product recalls and fines. See "Item 3. Legal Proceedings -- Government Consent Decrees" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

#### Research and Development

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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 1995, 1994 and 1993, total research and development expenditures were \$818,000, \$491,000 and \$2,140,000, respectively. During 1996 the Company intends to concentrate its research and development efforts in the following areas:

1. 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;
3. Reintroduction of the products withdrawn in 1993 and resubmission of the related ANDAs to the FDA; and
4. Development of new products.

There can be no assurance that the FDA will grant the requisite approvals for any such product introductions.

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

#### Marketing and Customers

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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 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. During 1993, the Company had net sales to two customers in excess of 10% of total sales, each aggregating 12% of total sales. Balances due from these customers were approximately 25% and 7% of total accounts receivable at December 31, 1995 and 1994, 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 March 28, 1996 was approximately \$1,070,000 as compared with approximately \$5,000,000 as of March 31, 1995. Although these orders are subject to cancellation, management expects to fill substantially all orders as of March 28, 1996 during the second quarter of 1996.

## Competition

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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 will be at a competitive disadvantage until the FDA resumes 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

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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. During 1995, the Company purchased approximately \$2,741,000 of its raw materials (constituting 38.4% of its aggregate purchases of raw materials) from Mallinckrodt, and as of December 31, 1995 more than 29.7% of the Company's trade payables was owed to this supplier. If the Company became unable to continue to purchase raw materials from this supplier, there can be no assurance that the Company will not face difficulties in obtaining raw materials on commercially acceptable terms, which could have a material adverse effect on the Company. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations -- Liquidity and Capital Resources." The federal drug application process requires specification of raw materials suppliers. If raw materials from a supplier specified in a drug application were to become unavailable on commercially acceptable credit terms, FDA supplemental approval of any new supplier would be required. In view of the FDA consent decree and the suspension of review of the Company's ANDAs by the FDA, the Company would be unable to obtain FDA supplemental approval at the Brooklyn plant for a new supplier except in very limited circumstances.

The 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.

In 1994, one of the Company's suppliers filed a Chapter 11 petition under the United States Bankruptcy Code. Penick continues to supply the Company but there can be no assurance they will continue to do so. See "-Products and Product Developments-Acquisitions."

## Employees

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As of December 31, 1995, the Company had approximately 247 full-time employees. Approximately 120 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 satisfactory.

PART II

Item 6. Selected Financial Data.  
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The following selected consolidated financial data of the Company and its subsidiaries has been derived from the financial statements of the Company. The selected financial data should be read in conjunction with, and is qualified in its entirety by reference to, the financial statements of the Company and the notes thereto included elsewhere in this report. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations -- Results of Operations."

Summary of Statement of Earnings

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	Years ended December 31,				
	-----				
	1995(1)	1994	1993	1992	1991
	----	----	----	----	----
Net sales	\$20,225,000	\$24,182,000	\$36,024,000	\$49,868,000	\$37,462,000
Earnings (Loss)	(\$3,807,000)	(\$5,767,000)	(\$13,326,000)(2)	\$2,019,000(3)	\$3,104,000
Net Earnings	(\$4,103,000)	(\$5,767,000)	(\$10,903,000)	\$928,000	\$1,727,000
Earnings (Loss)	(\$ .52)	(\$0.80)	(\$1.57)	\$ .13	\$ .26

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1 The financial statements for the year ended December 31, 1995 has been restated with respect to the gain recognized on the sale of assets. See Management's Discussion and Analysis of Financial Condition and Results of operations - and Note I of Notes to Consolidated Financial Statements.

2 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.

3 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.

Summary of Balance Sheets  
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	1995 ----	1994 ----	1993 ----	1992 ----	1991 ----
Working	(7,393,000)	(\$ 4,451,000)	(\$ 2,801,000)	\$ 3,461,000	\$ 2,350,000
Total Assets	18,862,000	19,276,000	24,674,000	33,385,000	26,561,000
Long-term	2,595,000	5,492,000	4,513,000	87,000	250,000
Stockholders'	1,540,000	(648,000)	3,919,000	14,038,000	11,117,000

Item 7. Management's Discussion and Analysis of Financial  
Condition and Results of Operations.  
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General

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Sales for the year ended December 31, 1995 are approximately \$20,000,000 as compared to sales of approximately \$24,000,000 for 1994. The net loss for the year ended December 31, 1995 was \$4,103,000 or \$.52 per share, compared with the net loss of \$5,700,000 or \$.80 per share for 1994.

For the year ended December 31, 1995, the reduction in sales was primarily attributable to the reduction in 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 is partially offset by manufacturing revenue that the Company is receiving as part of its agreement with Mallinckrodt. In addition, the decrease is attributable to price reductions effected during the year in order to meet increased competition in the market. Depreciation and amortization was approximately \$1,956,000 in 1995 as compared to \$2,350,000 for 1994.

For the year ended December 31, 1994, the reduction in sales was primarily attributable to the FDA consent decree of June 29, 1993, which resulted in lower sales from July 1993 to December 31, 1994. The net credits issued for recalled products in excess of previous estimated reserves for returns was approximately \$740,000. Cost of Goods Sold includes inventory write-offs in excess of estimated reserves for inventory of recalled products (approximately \$440,000). Depreciation and amortization was approximately \$2,350,000 in 1994 as compared to \$2,104,000 for 1993. The year ended December 31, 1994 had no benefit available for carryback to prior years as a result of the prior year 1993 carryback utilizing the available tax benefit of \$2,500,000.

On June 21, 1993, the Company entered into a plea agreement with the DOJ pursuant to which the Company agreed to plead guilty to five counts of adulteration of a single drug product and related record keeping violations. The Company also agreed to pay a fine in the amount of \$2,500,000, payable in quarterly installments of \$125,000 over five years commencing on September 15, 1993.

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 FDA as a result of the FDA's

investigation into the manufacturing and record keeping practices at the Company's Brooklyn plant.

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

During 1994, the Company completed the validation of the five solid dosage products required by the FDA consent decree in 1994. The Company also completed validation of certain liquid products at the Brooklyn plant. The Company is currently in the process of completing validity assessment studies and preparing validation protocols for products with plans to re-introduce the products in the near future.

#### Outlook

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During 1996, the Company intends to focus its research and development program primarily on the reintroduction of certain previously discontinued products as well as the development of new generic pharmaceuticals. See "Item 1. Business - Research and Development." Moreover, as a result of the consent decree, the Company is conforming the operations of its Brooklyn plant to the FDA's CGMP regulations and to satisfy the conditions for the resumption of shipments of the five products permitted under the consent decree. For the fiscal years ended December 31, 1995, 1994 and 1993, these five solid dosage products accounted for approximately \$12,400,000, \$15,275,000 and \$17,729,000 of sales or 61%, 63% and 49.2% of the total sales for the Company, respectively.

For the fiscal year ended December 31, 1993, Hydrocodone Bitartrate and Acetaminophen Tablets ("HBA") (shipments of which have not been resumed as a result of the validation process) accounted for approximately \$2,922,000 or 8.1% of the total sales of the Company. There were no shipments of this product after June 29, 1993. The Company wrote off inventory of HBA of approximately \$1,000,000 during 1993. There can be no assurance, however, that the Company will be able to achieve similar levels of sales of these products in future periods, or that the Company's current product mix will enable the Company to return to profitability. As a result of the substantial reduction in the number of products manufactured at the Brooklyn plant, however, and as part of the Company's continuing efforts to reduce operating costs at the Brooklyn plant, the Company has achieved substantial workforce reductions, which management estimates will result in annual savings of approximately \$4,500,000. As a result of the foregoing, the historical results of operations reflected in the condensed consolidated financial statements may not be indicative of future operating results.

As a result of problems identified at Cenci, new management conducted an internal review of its operations. This review led Cenci to discover irregularities which prompted it to cease all manufacturing operations and to replace certain key personnel. Cenci has had ongoing discussions with officials of the FDA. Cenci has cooperated with requests from the U.S. Department of Justice/U.S. Attorney for the District of Maryland ("USDOJ"/"USADM") in its investigation into the practices of certain of Cenci's former employees while they were acting on behalf of Cenci. In addition, several current employees have appeared before the grand jury and or spoken with representatives of the USDOJ/USADM. In October 1995 the former regulatory affairs director for Cenci pleaded guilty to making false statements to the FDA. In December 1995 this individual was sentenced. At this time, the Company is unable to predict what other consequences, if any, will result from the USDOJ/USADM's investigation.

#### Results of Operations

The following chart reflects expenses, earnings, income, losses and profits expressed as a percentage of net sales for the years 1995, 1994 and 1993.

	Percentage of Net Sales			Percentage Change Year-to-Year Increase(Decrease)	
	Year ended December			Years ended December 31	
	1995	1994	1993	1994 to 1995	1993 to 1994
Net sales	100%	100.0%	100.0%	(16.4)	(32.9%)
Cost of Goods	87.9	88.4	80.1	(16.8)	(25.2)
Gross Profit	12.1	11.6	19.9	(12.8)	(60.8)
Research & Development	4.0	2.0	5.9	66.6	(77.1)
Selling, general and administrative expenses	28.7	28.6	24.4	(16.0)	(18.9)
Cost of temporary closeing of facility	3.0	1.8			
Provision for regulatory settlement	---	----	16.5	----	(100.0)
(Loss) Earnings from operations	(23.7)	(20.8)	(26.9)	(4.8)	(48.1)
Provision for stockholders litigation settlement			8.3		(100.0)
Gain on the sale of assets	11.3	----	----	100.0	-----
Interest expense	6.5	3.0	1.8	77.8	16.5

(Loss) earnings before income taxes, minority interest and cumulative effect of accounting change	(18.9)	(23.8)	(37.0)	(66.9)	(56.7)
(Benefit) provision for income taxes	1.5	----	(7.0)	100.0	100.0
	---	----	-----		
(Loss) earnings before minority interest and cumulative effect of accounting change	(20.4)	(23.8)	(29.9)	(61.8)	(46.5)
Minority interest in net earnings (loss) of subsidiaries	-----	-----	.4	-----	(100.0)
	-----	-----	--	-----	-----
Loss (earnings) before cumulative effect of accounting change	(20.4)	(23.8)	(29.5)	(61.8)	(45.8)
Cumulative effect of accounting change	----	----	(.7)	-----	(100.0)
		----	----		-----
Net (loss) earnings	(20.4)	(23.8%)	(30.2%)	(61.8)	(47.1%)
	=====	=====	=====	=====	=====

## Net Sales

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The Company's net sales for the fiscal year ended December 31, 1995 of \$20,225,000 represents a decrease by \$3,957,000 as compared to net sales for the fiscal year ended December 31, 1994. The decrease in 1995 is primarily attributable to the sale of the Tablets ANDA to Mallinckrodt. Also, in 1995 the decrease in sales is attributable to price reductions implemented in order to meet increased market competition. In 1994, the Company's net sales decreased by \$11,842,000 as compared to 1993. The decrease in 1994 is primarily attributable to the discontinuance of certain solid dosage products as a result of the June 1993 consent decree on behalf of the FDA. In addition, the Company decided to suspend shipments of liquid products of Cenci for the last six months of 1994 and in 1995. This suspension of shipments contributed to the decline in net sales during 1994. Also impacting 1994 sales are credits issued for recalled products which exceeded the estimated reserves established at December 31, 1993 by approximately \$740,000.

## Cost of Goods Sold

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For 1995, cost of goods sold decreased by approximately \$3,598,000 as compared to 1994, and in 1994 by approximately \$7,476,000 as compared to 1993. 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. However, these reductions were partially offset by increased raw material costs during the year. The decrease for 1994 is primarily attributable to the reduction in units produced and the suspension of shipments of certain solid dosage products. In addition, in 1994, the suspension of shipments of certain liquid products of Cenci as a result of the Company's review of operations at this location and at the Brooklyn plant, resulted in the write-off of inventory for recalled products in excess of the reserve in the amount of approximately \$440,000. Management effected certain cost saving measures such as reducing personnel and other expenditures during 1995. The Company's gross margin as a percentage of sales for the fiscal years ended December 31, 1995, 1994 and 1993 was 12.1%, 11.6% and 20.0%, respectively.

## Selling, General and Administrative Expenses

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Selling, general and administrative expenses as a percentage of sales for the fiscal years 1995, 1994 and 1993 were 28.7%, 28.6% and 24.4%, respectively. These expenses decreased by approximately \$1,118,000 or 16.0% 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, coupled with a decrease in net sales.

#### Cost of Temporary Closing of Facility

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As a result of irregularities identified in the manufacturing operations of H.R. Cenci Laboratories, Inc.(Labs), the Company, in July 1994, ceased all sales activities at Labs. Upon completion of its review and modifications at the facility, the Company reopened Labs in January 1996. In connection with this temporary closure, the company recorded costs of \$ 615,000 and \$ 427,000 for the years ended December 31, 1995 and 1994, respectively. These costs consist of inventory writeoffs, utilities, security and rent.

#### Provision for Stockholders Litigation

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In June 1994, the Company and the plaintiffs in certain class actions and shareholder derivative lawsuits agreed to settle the litigations. 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 paid the remainder of the settlement fund by the issuance of 824,742 shares of common stock at a per share price of \$3.6375, or an aggregate value of \$3,000,000. The Company had previously recorded an estimated provision of \$3,000,000 in the fourth quarter of 1993 as the estimated cost to settle the above shareholder actions.

#### Interest Expense

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Interest expense for 1995 increased by \$572,000 as compared to 1994 as a result of fees payable to the Company's banks, an increase in the level of borrowings due to the issuance of convertible subordinated debentures and an increase in the interest rate after the second quarter of 1994 (see "Liquidity and Capital Resources" below). Interest expense for 1994 increased by \$104,000 as compared to 1993 as a result of an increase in the prime rate in 1994 and an increase in the margin rate in mid-1993 applicable to the Company's borrowings.

#### (Benefit) Provision for Income Taxes

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The Company had no tax (benefit) provision for 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. In 1993 the Company's effective tax benefit rate was approximately 19.2% as compared to an effective income tax rate of 55.8% in

fiscal year 1992. The benefit rate in 1993 arose as a result of a net operating loss carryback to the preceding three years and is attributable to the lack of tax benefit of subsidiary losses combined with the nondeductibility of the DOJ settlement.

#### Net Loss

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For 1995, the Company had a net loss of \$4,103,000 as compared to a net loss of \$5,767,000 for 1994. The decrease in net loss is attributable to the gain on the sale of assets of \$2,288,000 net of the tax provision of \$296,000, or \$1,992,000. The net loss for 1994 of \$5,767,000 represents a decrease in the amount of loss of \$5,136,000 as compared to the net loss for 1993 of \$10,903,000. The loss in 1994 is primarily attributable to the suspension of shipments of certain solid dosage products as part of the aforementioned consent decree in June 1993 combined with the suspension of shipments of liquid products at the subsidiary for the second half of the year.

#### Liquidity and Capital Resources

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At December 31, 1994, the Company had cash and cash equivalents of \$353,000 as compared to \$28,000 at December 31, 1993. The Company had a working capital deficiency at December 31, 1995 of \$7,393,000.

The Company consummated a private offering (the "July Private Offering") of 408 units ("Units") of securities on July 18, 1995 for an aggregate purchase price of \$4,080,000. Each Unit consisted of (i) a convertible subordinated debenture ("July Debentures") in the principal amount of \$10,000 issued at par and (ii) 750 redeemable common stock purchase warrants ("July Redeemable Warrants").

The July 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 July Debentures are convertible at any time after issuance into Underlying Shares at a conversion price (the "Conversion Price") of \$2.00 per share, subject to adjustment.

Each July Redeemable Warrant entitles the holder to purchase one Underlying Share for \$2.00 during the five year period commencing on the date of issuance. The July 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 \$2.00 per share (the "Threshold") for the 20 consecutive trading days ending on the third day prior to the notice of redemption to holders.

The Company consummated a private offering (the "November Private Offering" and, collectively with the July Private Offering, the "Private Offerings") of 336 Units on November 29, 1995 for an aggregate purchase price of \$3,660,000. Each Unit consisted of (i) a convertible subordinated debentures ("November Debentures") in the principal amount of \$10,000 issued at par and (ii) 600 redeemable common stock purchase warrants ("November Redeemable Warrants").

The November 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 November Debentures are convertible at any time after issuance into Underlying Shares at a Conversion Price of \$2.50 per share, subject to adjustment.

Each November Redeemable Warrant entitles the holder to purchase one Underlying Share for \$2.50 during the five year period commencing on the date of issuance. The November 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 \$2.50 for the 20 consecutive trading days ending on the third day prior to the notice of redemption to holders.

Holders of the November Debentures and any shares into which such Debentures are converted, while the November Debentures remain outstanding, have a right of first refusal to participate in any offering of securities by the Company, with certain exceptions, to the extent the gross proceeds from such offering, or series of offerings, in any twelve month period exceed \$200,000.

The net proceeds of the Private Offerings were approximately \$7,013,000. The Company utilized \$1,100,000 of such proceeds to repurchase 500,000 shares of Common Stock (the "RPI Shares") from a former stockholder of the Company. The Company used an additional \$945,000 of such net proceeds to repay a portion of its bank debt. The Company intends to utilize the balance of the net proceeds of the Private Offerings for the following purposes: for working capital; for the purchase of equipment; for research and development expenses; and for the registration of the Underlying Shares under the Securities Act.

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 at the Brooklyn plant. 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 \$90,000. 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, 1994. As of the current date, no action has been initiated to require immediate payment of the entire amount; however, the Company has recently made several partial payments.

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. The Banks now hold warrants to purchase 636,000 shares of the Company's common stock at prices ranging from \$2.13 to \$ 2.275, with an average weighted exercise price of \$2.26.

Although the credit agreement with the Banks expired in March 1996, the Company and the Banks are currently negotiating on an extension of the agreement.

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. The balance of the purchase price is payable as follows: Mallinckrodt will pay \$1 million when the Company receives general clearance from the FDA for unrestricted operations at its 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 Payment when Mallinckrodt receives certain authorizations from the FDA, but in no event later than September 21, 1997. 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. See "Item 1. Business. Other Transactions - Agreements with Zatpack, Inc." for additional information regarding the Zatpack Agreement.

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.

#### Capital Expenditures

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The Company's capital expenditures during 1995, 1994 and 1993 were \$536,000, \$216,000 and \$1,688,000, respectively. The decrease in capital expenditures in 1995 as compared to prior years is attributable to the Company's cash conservation measures implemented in 1994.

#### Item 8. Financial Statements and Supplementary Data.

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See Index to Financial Statements after signature page.

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

Report on Form 8-K dated December 4, 1995 - Item 5 - Other Events.

D. Exhibits

Exhibit  
Number  
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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)).
- 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(i) -----Form of Warrants issued to The Bank of New York, The Chase Manhattan Bank, N.A. and the Israel Discount Bank.
- 10.5(ii) -----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"))).
- 10.6 Agreement Regarding Release of Security Interests dated as of March 21, 1995 by and among the Company, Mallinckrodt Chemical Acquisition, Inc. and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.9 of the March 8-K).
- 10.7 Consulting Agreement dated as of September, 1993 between the Registrant and Joseph F. Limongelli (incorporated by reference to

Exhibit 10.6 to the 1993 Form 10-K).

- 10.8 Employment Agreement, dated as of January 1, 1993, between the Registrant and Rosendo Ferran (incorporated by reference to Exhibit 10.2 to the 1992 Form 10-K).
- 10.9 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(i) -----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(ii) -----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).
- 10.11 -----Leases, effective February 13, 1989 and January 1, 1990, respectively, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss (incorporated by reference to Exhibits 10.6 and 10.7, respectively, to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1989).
- 10.12 -----Lease, effective as of April 15, 1988, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, and Rider thereto (incorporated by reference to Exhibit 10.12 to the Registrant's Annual report on Form 10-K for the year ended December 31, 1987).
- 10.12(i) -----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.

- 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 -----Tablets ANDA Noncompetition Agreement dated as of March 21, 1995 between the Registrant and Acquisition (incorporated by reference to Exhibit 10.4 to the March 8-K).
- 10.17 -----Subordinated Non-Negotiable Promissory Term Note in the amount of \$1,200,00 dated March 21, 1995 issued by the Registrant to Acquisition (incorporated by reference to Exhibit 10.5 to the March 8-K).
- 10.18 -----Term Note Security Agreement dated as of March 21, 1995 among the Company, Houba, Inc. and Acquisition (incorporated by reference to Exhibit 10.6 to the March 8-K).
- 10.19 -----Amendment dated March 21, 1995 to Subordination Agreement dated as of July 21, 1994 between Mallinckrodt Chemical, Inc., Mallinckrodt Chemical Acquisition, Inc., the Registrant, The Chase Manhattan Bank (National Association), Israel Discount Bank of New York, The Bank of New York, and The Chase Manhattan Bank (National Association) (incorporated by reference to Exhibit 10.8

to the March 8-K).

- 10.20 -----Agreement dated as of March 30, 1995 between the Registrant and Zatpack, Inc. (incorporated by reference to Exhibit 10.10 to the March 8-K).
- 10.21 -----Waiver and Termination Agreement dated as of March 30, 1995 between Zuellig Group, W.A., Inc. and Indiana Fine Chemicals Corporation (incorporated by reference to Exhibit 10.11 to the March 8-K).
- 10.22 -----Convertible Subordinated Note of the Registrant dated December 1, 1994 issued to Zatpack, Inc. (incorporated by reference to Exhibit 10.12 to the March 8-K).
- 10.23 -----Agreement dated as of March 30, 1995 among the Registrant, Indiana Fine Chemicals Corporation, Zuellig Group, N.A., Inc., Houba Inc., Zetapharm, Inc. and Zuellig Botanicals, Inc. (incorporated by reference to Exhibit 10.13 to the March 8-K).
- 10.24 -----Supply Agreement dated as of March 30, 1995 between Houba, Inc. and Zetapharm, Inc. (incorporated by reference to Exhibit 10.14 to the March 8-K).
- 10.25(i) -----Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 6(a) to the June 10-Q).
- 10.25(ii) -----Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 6(a) to the June 10-Q).
- 10.25(iii)-----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")).
- 10.25(iv) -----Form of Redeemable Common Stock Purchase

Warrant (incorporated by reference to Exhibit 4.2 to the December 8-K).

- 10.25(v) -----Letter Agreement dated November 16, 1995 between the Company, The Bank of New York, The Chase Manhattan Bank, N.A. and the Israel Discount Bank.
- 22 -----Subsidiaries of the Registrant (incorporated by reference to Exhibit 22 to the 1993 Form 10-K).
- 24 Consent of Grant Thornton LLP, independent certified public accountants.
- \*27 Financial Data Schedule

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\* Filed herewith

SIGNATURES

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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.

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(Registrant)

Date: October 3, 1996

By: /s/ Rosendo Ferran

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Rosendo Ferran

President

Date: October 3, 1996

By: /s/ Robert J. Mallage

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Robert J. Mallage

Corporate Controller

## INDEX TO FINANCIAL STATEMENTS

	Page
	----
Report of Independent Certified Public Accountants	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-5
Consolidated Statement of Stockholders' Equity	F-6
Consolidated Statements of Cash Flows	F-7
Notes to Consolidated Financial Statements	F-9

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, 1995 and 1994, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1995. 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, 1995 and 1994, and the consolidated results of their operations and their consolidated cash flows for each of the three years in the period ended December 31, 1995, 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 \$4,103,000 during the year ended December 31, 1995 and as of that date has a deficiency in working capital of approximately \$7,393,000. In addition, the Company's current banking agreement expires on March 31, 1996 and the Company is currently not in compliance with the financial covenants of its banking agreement and its convertible subordinated debentures agreements. These matters 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.

As discussed in Note I, the financial statements for the year ended December 31, 1995 as previously reported have been restated in regards to the gain recognized on the sale of assets.

GRANT THORNTON LLP

New York, New York  
March 29, 1996 (except for Note I as to which the date  
is September 25, 1996)

Halsey Drug Co., Inc. and Subsidiaries

CONSOLIDATED BALANCE SHEETS

December 31,  
(in thousands)

	1995	1994
	-----	-----
CURRENT ASSETS		
Cash	\$ 353	\$ 28
Accounts receivable - trade, net of allowances for doubtful accounts of \$280 and \$755 in 1995 and 1994, respectively	1,689	2,326
Inventories	7,716	6,835
Prepaid insurance and other current assets	656	496
Deferred income taxes		296
	-----	-----
Total current assets	10,414	9,981
 PROPERTY, PLANT AND EQUIPMENT, NET	 7,394	 8,561
 OTHER ASSETS	 1,054	 734
	-----	-----
	\$18,862	\$19,276
	=====	=====

The accompanying notes are an integral part of these statements.

## Halsey Drug Co., Inc. and Subsidiaries

## CONSOLIDATED BALANCE SHEETS (continued)

December 31,  
(in thousands)

	1995	1994
	-----	-----
CURRENT LIABILITIES		
Bank overdraft	\$ 213	\$ 218
Due to banks	3,395	4,850
Current maturities of long-term debt	200	
Convertible subordinated debentures	7,347	
Department of Justice settlement	2,000	2,013
Accounts payable	2,546	4,414
Accrued expenses	1,867	1,823
Advances from minority stockholders	206	418
Income taxes payable	33	196
Deferred income		500
	-----	-----
Total current liabilities	17,807	14,432
LONG-TERM DEBT	2,595	2,492
LITIGATION SETTLEMENT		3,000
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock - \$.01 par value; authorized, 20,000,000 shares; issued and outstanding, 8,973,459 shares and 7,609,537 shares in 1995 and 1994, respectively	90	76
Additional paid-in capital	14,459	10,162
Accumulated deficit	(14,989)	(10,886)
	-----	-----
	440	(648)
Less treasury stock - at cost (500,000 shares in 1995)	(1,100)	
	-----	-----
	(1,540)	(648)
	-----	-----
	\$ 18,862	\$ 19,276
	=====	=====

The accompanying notes are an integral part of these statements.

## Halsey Drug Co., Inc. and Subsidiaries

## CONSOLIDATED STATEMENTS OF OPERATIONS

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

	1995	1994	1993
	-----	-----	-----
Net sales	\$20,225	\$24,182	\$ 36,024
Cost of goods sold	17,774	21,372	28,848
	-----	-----	-----
Gross profit	2,451	2,810	7,176
Research and development	818	491	2,140
Selling, general and administrative expenses	5,806	6,924	8,796
Temporary closing costs of facility	615	427	
Provision for regulatory settlement			5,935
	-----	-----	-----
Loss from operations	(4,788)	(5,032)	(9,695)
Interest expense	1,307	735	631
Gain on sale of assets	(2,288)		
	-----	-----	-----
Provision for stockholders' litigation settlement			3,000
	-----	-----	-----
Loss before income taxes, minority interest and cumulative effect of accounting change	(3,807)	(5,767)	(13,326)
Provision (benefit) for income taxes	296		(2,540)
	-----	-----	-----
Loss before minority interest and cumulative effect of accounting change	(4,103)	(5,767)	(10,786)
	-----	-----	-----
Minority interest in net loss of subsidiaries			150
Loss before cumulative effect of accounting change	(4,103)	(5,767)	(10,636)
	-----	-----	-----
Cumulative effect of accounting change			(267)
NET LOSS	\$ (4,103)	\$ (5,767)	\$(10,903)
	=====	=====	=====
Loss per common share			
Loss before cumulative effect of accounting change	\$(.52)	\$(.80)	\$(1.53)
Cumulative effect of accounting change			(.04)
	-----	-----	-----
Net loss	\$(.52)	\$(.80)	\$(1.57)
	=====	=====	=====
Average number of outstanding shares	7,886,101	7,173,908	6,954,713
	=====	=====	=====

The accompanying notes are an integral part of these statements.

Halsey Drug Co., Inc. and Subsidiaries

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

Years ended December 31, 1995, 1994 and 1993  
(in thousands)

	Common stock, \$.01 par value		Additional paid-in capital	Retained earnings (accumulated deficit)	Treasury stock, at cost		Total
	Shares	Amount			Shares	Amount	
Balance at January 1, 1992	6,795,217	\$68	\$ 8,186	\$ 5,784			\$ 14,038
Exercise of stock options	314,320	3	781				784
Net loss				(10,903)			(10,903)
	-----	----	-----	-----			-----
Balance at December 31, 1993	7,109,537	71	8,967	(5,119)			3,919
Issuance of common stock	500,000	5	995				1,000
Issuance of warrants to banks			200				200
Net loss				(5,767)			(5,767)
	-----	----	-----	-----			-----
Balance at December 31, 1994	7,609,537	76	10,162	(10,886)			(648)
Issuance of common stock	500,000	5	791				796
Issuance of common stock in connection with litigation settlement	824,742	8	2,992				3,000
Repurchase of common stock					500,000	\$1,100	(1,100)
Issuance of warrants with convertible subordinated debentures			416				416
Exercise of stock options	39,180	1	98				99
Net loss				(4,103)			(4,103)
	-----	----	-----	-----	-----	-----	-----
Balance at December 31, 1995	8,973,459	\$90	\$14,459	\$(14,989)	500,000	\$(1,100)	\$(1,540)
	=====	==	=====	=====	=====	=====	=====

The accompanying notes are an integral part of this statement.

## Halsey Drug Co., Inc. and Subsidiaries

## CONSOLIDATED STATEMENTS OF CASH FLOWS

Year ended December 31,  
(in thousands)

	1995 ----	1994 ----	1993 ----
Cash flows from operating activities			
Net loss	\$(4,103) -----	\$(5,767) -----	\$(10,903) -----
Adjustments to reconcile net loss to net cash (used in) provided by operating activities			
Depreciation and amortization	1,956	2,350	2,104
Provision for losses on accounts receivable		271	365
Gain on sale of assets	(2,288)	(92)	
Accrued Department of Justice interest	77	100	
Deferred income taxes	296		(667)
Minority interest in net loss of subsidiaries			(150)
Settlement of product recall			(985)
Department of Justice settlement			2,060
Provision for stockholders' litigation settlement			3,000
Changes in assets and liabilities			
Accounts receivable	637	2	4,374
Inventories	(881)	2,389	4,085
Income taxes receivable		660	(660)
Prepaid insurance and other current assets	(160)	134	(25)
Accounts payable	(1,868)	(912)	(1,126)
Accrued expenses	44	528	859
Income taxes payable	(163)	(83)	(1,157)
	-----	----	-----
Total adjustments	(2,350) -----	5,347 ----	12,077 -----
Net cash (used in) provided by operating activities	(6,453) -----	(420) ----	1,174 -----
Cash flows from investing activities			
Capital expenditures	(536)	(216)	(1,688)
Decrease in other assets	116	(169)	(75)
Net proceeds from sale of assets	1,889	125	
Deferred income		500	
	-----	----	-----
Net cash provided by (used in) investing activities	1,469 -----	240 ----	(1,763) -----

Halsey Drug Co., Inc. and Subsidiaries  
CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

Year ended December 31,  
(in thousands)

	1995 ----	1994 ----	1993 ----
Cash flows from financing activities			
(Decrease) increase in notes payable	\$(1,192)	\$ (489)	\$ 28
Proceeds from issuance of common stock	796	1,000	
Payments to Department of Justice	(90)	(86)	(61)
Bank overdraft	(5)	(224)	(486)
Repurchase of common stock	(1,100)		
Payments to minority stockholders	(212)	(25)	
Proceeds from issuance of converted subordination debentures	7,740		
Proceeds from exercise of stock options	99		784
Increase in other assets	(727)		
	-----	-----	-----
Net cash provided by financing activities	5,309	176	450
	-----	-----	-----
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	325	(4)	(139)
Cash and cash equivalents at beginning of year	28	32	171
	-----	-----	-----
Cash and cash equivalents at end of year	\$ 353 =====	\$ 28 =====	\$ 32 =====

Supplemental disclosures of noncash activities:

1. The valuation of the warrants issued in 1995, \$416,000, with the convertible subordinated debentures is included in additional paid-in capital.
2. The issuance in 1995 of 824,742 shares of the Company's common stock is valued at \$3,000,000 in connection with the litigation settlement.
3. The valuation of the warrants issued in 1994, \$200,000, to its banks, is included in additional paid-in capital.

The accompanying notes are an integral part of these statements.

Halsey Drug Co., Inc. and Subsidiaries  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
December 31, 1995, 1994 and 1993

NOTE A - SUMMARY OF ACCOUNTING POLICIES

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 (see Note N), its 80%-owned subsidiary, The Medi-Gum Corporation, its 51%-owned subsidiaries, H.R. Cenci Laboratories, Inc. and Cenci Powder Products, Inc. The Medi-Gum Corporation and Halsey Pharmaceuticals have not commenced operations. All material intercompany accounts and transactions have been eliminated.

As of December 31, 1995, the Company has a working capital deficiency of approximately \$7,393,000, has an accumulated deficit of approximately \$14,989,000, has incurred a loss of approximately \$4,103,000 during the year ended December 31, 1995, and is not in compliance with its financial covenants pursuant to its banking agreement and its convertible subordinated debenture agreements. In addition the Company's credit agreement with its banks expires March 31, 1996. These factors and the Food and Drug Administration ("FDA") 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, and (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). There can be no assurance that management can obtain alternative sources of financing.

2. Inventories

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE A (continued)

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. The cumulative effect of this change was to increase the 1993 net loss by \$267,000.

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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE A (continued)

6. Statement 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, 1994 and 1993 of \$201,000, \$39,000 and \$199,000, respectively, and interest of \$786,000, \$504,000 and \$406,000, respectively.

7. Costs in Excess of Net Assets Acquired

The Company amortizes its costs in excess of net assets acquired on a straight-line basis over a five-year period. Amounts paid in excess of net assets acquired of \$1,127,000, net of accumulated amortization of \$932,000 and \$707,000 in 1995 and 1994, respectively, are included in other assets in the accompanying consolidated financial statements. On an ongoing basis, management reviews the valuation and amortization of goodwill to determine possible impairment by comparing the carrying value to the undiscounted cash flows of the related assets.

8. 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.

9. Reclassifications

Certain reclassifications have been made to the 1994 and 1993 presentation to conform to the 1995 presentation.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE A (continued)

10. Accounting Pronouncements Not Yet Adopted

Adoption of 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," is required for fiscal years beginning after December 15, 1995. The standards for SFAS No. 121 require 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 primary objectives under SFAS No. 121 are to: (a) recognize an impairment loss of an asset whenever events or changes in circumstances indicate that its carrying amount may not be recoverable and (b) if planning to dispose of long-lived assets or certain identifiable intangibles, such assets have been reflected in the Company's consolidated balance sheet at the net asset value less cost to sell. At December 31, 1995, the Company has not adopted SFAS No. 121. The impact of adopting SFAS No. 121 on the Company's financial statements has not yet been determined.

Adoption of Statement of Financial Accounting Standards No. 123 ("SFAS No. 123"), "Accounting for Stock-Based Compensation," is required for fiscal years beginning after December 15, 1995 and allows for a choice of the method of accounting used for stock-based compensation. Entities may use the "intrinsic value" method currently based on APB No. 25 or the new "fair value" method contained in SFAS No. 123. The Company intends to implement SFAS No. 123 in fiscal 1996 by continuing to account for stock-based compensation under APB No. 25. As required by SFAS No. 123, the pro forma effects on net income and earnings per share will be determined as if the fair value-based method had been applied and disclosed in the notes to the consolidated financial statements.

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 cash and cash equivalents, subordinated promissory notes and long-term debt.

Halsey Drug Co., Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE B (continued)

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:

1. Cash and Cash Equivalents

The carrying amount reasonably approximates fair value because of the short maturity of those instruments.

2. Long-term Debt and Convertible Subordinated Debentures

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

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

	December 31,			
	1995		1994	
	Carrying amount	Fair value amount	Carrying amount	Fair value amount
	(in thousands)			
Cash and cash equivalents	\$ 353	\$ 353	\$ 28	\$ 28
Long-term debt	6,190	6,190	7,342	7,342
Convertible subordinated debentures	7,347	7,347		

Halsey Drug Co., Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE C - INVENTORIES

Inventories consist of the following:

	December 31,	
	1995	1994
	-----	-----
	(in thousands)	
Finished goods	\$2,491	\$1,990
Work-in-process	1,398	1,301
Raw materials	3,827	3,544
	-----	-----
	\$7,716	\$6,835
	=====	=====

NOTE D - PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows:

	December 31,	
	1995	1994
	-----	-----
	(in thousands)	
Machinery and equipment	\$11,247	\$10,989
Leasehold improvements	5,756	5,656
Building	1,203	1,203
Land	265	265
	-----	-----
	18,471	18,113
Less accumulated depreciation and amortization	11,077	9,552
	-----	-----
	\$ 7,394	\$ 8,561
	=====	=====

Depreciation expense for the years ended December 31, 1995, 1994 and 1993 was approximately \$1,576,000, \$1,930,000 and \$1,880,000, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

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, 1995, 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% (10.5% at December 31, 1995), 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 to the banks stock warrants, expiring December 31, 1999, to purchase up to 635,663 shares of the Company's common stock at exercise prices ranging from \$2.25 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, 1995, 1994 and 1993

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 635,653 shares of the Company's common stock have been adjusted for antidilution to prices ranging from \$2.13 to \$2.275.

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, \$1,395,000 at December 31, 1995, can be converted, 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). The note is subordinated to the bank debt.

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.

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.

Halsey Drug Co., Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE E (continued)

Borrowings under long-term debt are as follows:

	December 31,	
	1995	1994
	-----	-----
	(in thousands)	
Convertible subordinated promissory note	\$1,395	\$1,292
Subordinated promissory notes	1,400	1,200
	-----	-----
	2,795	2,492
Less; current maturities of long-term debt	(200)	-
	-----	-----
	\$2,595	\$2,492
	=====	=====

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 are 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.

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

Halsey Drug Co., Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE F (continued)

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.

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 or will be 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. At December 31, 1995 the Company was in default of its convertible subordinated debentures agreements as a result of its default with its banking agreement, and accordingly, the convertible subordinated debentures are currently due.

NOTE G - ACCRUED EXPENSES

Accrued expenses are summarized as follows:

	December 31,	
	1995	1994
	-----	-----
	(in thousands)	
Payroll related	\$ 850	\$1,039
Professional fees	120	74
Interest	337	251
Other	560	459
	-----	-----
	\$1,867	\$1,823
	=====	=====

Halsey Drug Co., Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE H - INCOME TAXES

The benefit for income taxes for the year ended December 31, 1993 is composed of the following (in thousands):

Current - Federal	\$(1,606)
Deferred - Federal, state and local	(934)
	-----
	\$(2,540)
	=====

Deferred income tax (benefits) provisions, resulting from differences between accounting for financial statement purposes and tax purposes, were as follows for the year ended December 31, 1993 (in thousands):

Depreciation	\$ 50
Provision for stockholders' litigation settlement	(1,260)
Pension expense	(116)
Provision for product recall	417
Provision for doubtful accounts	(172)
Inventory reserve	(168)
	-----
Deferred benefit before net operating loss carrybacks	(1,249)
Limitation of net operating loss carrybacks	315
	-----
	\$ (934)
	=====

Halsey Drug Co., Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE H (continued)

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

	Year ended December 31,					
	1995		1994		1993	
	Amount	%	Amount	%	Amount	%
(in thousands)						
Federal statutory rate	\$(1,295)	(34.0)%	\$(1,961)	(34.0)	\$(4,497)	(34.0)%
Change in valuation allowance	296	7.8				
Loss of which no tax benefit was provided	280	7.4	1,223	21.2		
Losses of subsidiaries with no tax benefit	240	6.3	479	8.3	472	3.5
Goodwill amortization	77	2.0	77	1.3	77	.7
Department of Justice settlement					850	6.4
Gain on sale of assets	546	14.3				
Other	152	6.9	182	3.2	558	4.2
	---	---	---	---	---	---
Actual (benefit) tax expense	\$ 296	7.8%	\$ -	-	\$ (2,540)	(19.2)%
	=====	=====	=====	=====	=====	=====

The Company has net operating loss carryforwards aggregating approximately \$6,613,000, expiring during the years 2009 through 2010. In addition, certain of the Company's subsidiaries file separate Federal income tax returns and have separate net operating loss carryforwards aggregating approximately \$4,783,000, expiring during the years 1998 through 2010.

The Company's tax loss carryforwards could be limited by Section 382 of the Internal Revenue Code with respect to the amount utilizable each year. This limitation would reduce the Company's ability to utilize net operating loss carryforwards included above. The amount of the limitation has not been quantified by the Company.

Halsey Drug Co., Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE H (continued)

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

	December 31,	
	1995	1994
	(in thousands)	
Deferred tax assets		
Net operating loss carryforwards	\$ 4,792	\$ 3,543
Allowance for doubtful accounts	117	318
Research and development tax credit	212	
Reserve for inventory	65	92
Litigation settlement		1,260
Other	36	44
	-----	-----
Gross deferred tax assets	5,222	5,257
	-----	-----
Deferred tax liabilities		
Depreciation	(771)	(517)
Other	(165)	(17)
	-----	-----
	(936)	(534)
	-----	-----
Net deferred tax assets before valuation allowance	4,286	4,723
		-----
Valuation allowance	(4,286)	(4,427)
	-----	-----
Net deferred tax assets	\$ -	\$ 296
	=====	=====

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, 1995 primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards.

Halsey Drug Co., Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)  
December 31, 1995, 1994 and 1993

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 has been 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 will 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 decree dated June 29, 1993 (such \$1,000,000 will be recorded by the Company when general clearance is obtained from the FDA) and (ii) \$1,900,000 at the earlier of (a) Mallinckrodt receiving certain authorizations from the FDA or (b) September 21, 1997 ("Deferred Payments"). Mallinckrodt also agreed to defer \$1,200,000 of the Company's trade debt due to an affiliate of Mallinckrodt (Note E).

In connection with the agreement, the Company agreed to manufacture Tablets for Mallinckrodt for a period of three years through March 31, 1998 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. 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, and 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.

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.

In connection with the filing of a Registration Statement with the Securities and Exchange Commission, the Company has revised the gain recorded on the sale of assets to Mallinckrodt and will not recognize the Deferred Payment until the earlier of (a) Mallinckrodt receiving certain authorizations from the FDA or (b) March 31, 1998. The effect of the adjustments on the accompanying financial statements is as follows (In thousands, except per share amounts):

As of December 31, 1995:

	As Previously	
	Reported	As Restated
	-----	-----
Net loss	\$(2,203)	\$(4,103)
Net loss per common share	(.28)	(.52)
Long Term Receivable	1,900	--

Accumulated deficit	(13,089)	(14,989)
---------------------	----------	----------

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

## 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, 1995, the Company has not funded its 1994 ERISA obligation of approximately \$116,000 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. During 1993, the Company (i) amended the Plan to reduce employee benefits, (ii) terminated certain employees sooner than expected, and (iii) reduced the discount rate used to determine the projected benefit obligations, all of which did not have a material effect on the Company's 1993 consolidated results of operations.

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.

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

	1995	December 31, 1994	1993
	----	----	----
	(in thousands)		
Normal service cost	\$ 49	\$ 50	\$ 45
Interest cost	25	27	38
Actual return on plan assets	(19)	(18)	(36)
Net amortization and deferral	(9)	(10)	(10)
	----	-----	-----
Net pension cost	\$ 46	\$ 49	\$ 37
	===	===	===

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

## 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 December 31,	
	1995	1994
	----	----
	(in thousands)	
Actuarial present value of benefit obligations		
at November 30, 1995 and 1994		
Estimated present value of vested benefits	\$405	\$307
Estimated present value of nonvested benefits	44	36
	----	-----
Accumulated benefit obligation	449	343
Value of future pay increases	22	17
	----	-----
Projected benefit obligation	471	360
Estimated market value of plan assets at November 30, 1995 and 1994	456	402
	---	-----
(Deficiency) excess of plan assets over projected benefit obligation	(15)	42
Unrecognized net gain	33	23
Unrecognized net asset at December 1, 1987 being amortized over 24 years	(9)	(9)
	----	-----
Prepaid pension cost	\$ 9	\$ 56
	=====	=====

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

## NOTE J (continued)

The assumptions used as of November 30, 1995 and 1994 in determining pension expense and funded status shown above were as follows:

	1995	1994
	-----	-----
Discount rate	7.00%	7.00%
Rate of salary progression	4.00	4.00
Long-term rate of return on assets	7.00	7.00

## 2. Employees' Pension Plan

The Company contributed approximately \$450,000, \$462,000 and \$515,000 in 1995, 1994 and 1993, 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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

## NOTE K (continued)

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.

A summary of activity of all options is as follows:

	December 31,		
	1995	1994	1993
	----	----	----
Outstanding at beginning of year	222,150	413,881	794,857
Granted	471,600	10,000	66,000
Cancelled	(54,070)	(201,731)	(132,656)
Exercised	(39,180)		(314,320)
	-----	-----	-----
Outstanding at end of year	600,500	222,150	413,881
	=====	=====	=====
Shares exercisable	183,900	144,742	239,610
	=====	=====	=====
Option prices per share			
Granted	\$1.94 - \$3.19	\$2.00	\$4.00-\$6.25
Cancelled	2.50 - 6.25	2.01 - 6.25	2.14- 6.25
Exercised	2.50		2.01- 5.50
Exercisable	2.50 - 6.25	2.50 - 6.25	2.01- 6.25

## 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, 51% H.R. Cenci

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

## NOTE L (continued)

Laboratories, Inc. and Cenci Powder Products, Inc., lease plant and office facilities on a month-to-month basis from an officer of the subsidiaries. Rent expense relating to these leases amounted to approximately \$86,000, \$99,000 and \$91,000 in 1995, 1994 and 1993, 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, 1995, 1994 and 1993 was approximately \$659,000, \$582,000 and \$502,000, respectively.

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

Twelve months ending December 31,	
	(in thousands)
1996	\$ 884
1997	928
1998	975
1999	1,023
2000	1,075
2001 and thereafter	6,234
	-----
Total minimum payments required	\$11,119
	=====

On January 1, 1993, the Company entered into an employment agreement with an officer having an initial term of five years. On July 1, 1994, the Company entered into an employment agreement with another officer having an initial term of three years. These employment agreements contain change in control provisions that would entitle each 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, 1995 under these agreements are approximately \$1,027,000.

## 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE M (continued)

In April and May of 1990, the FDA conducted a pre-approval inspection of the Company's facilities, certain pending approval applications and its manufacturing procedures. The FDA issued "Inspectional Observations" and made further investigations of the Company's recordkeeping practices and the accuracy of certain records maintained by the Company

during the research and development stage for a single drug entity not being marketed by the Company. On July 29, 1991, the Company received a Federal grand jury subpoena for documents relating to approved and unapproved ANDAs for various products and other documents relating to the Company's operations.

The Company received a letter dated October 25, 1991 from the FDA advising that the FDA, under its fraud policy, had undertaken a validity assessment with respect to the Company's ANDAs, including four pending ANDAs and various ANDA supplements, pursuant to which all reviews are suspended. The Company voluntarily undertook an internal audit and retained an outside consultant to review pending and various filed and approved ANDAs. As part of that process, the Company withdrew its ANDAs for the drug product, fenoprofen calcium.

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 FDA that resulted from the FDA's investigation. 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 Company's facilities 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 the FDA's Current Good Manufacturing Practice regulations. As part of satisfying the foregoing requirements, the Company is required to validate the manufacturing processes for each solid dosage drug product prior to manufacturing and shipping the drug product, except that the Company is permitted under the terms of the consent decree to manufacture and ship from its facilities six identified drug products at its own risk provided that: (i) at least twice per month, the Company's independent expert certifies that each batch of drug product upon validation will have been manufactured in accordance with the FDA Regulations and the formulation described in the drug products approved NDA ("New Drug Application") or ANDA, until such time as validation is completed for these products; and (ii) for any batches of these products that have already been manufactured, such certification will include certification by a company representative with personal

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE M (continued)

knowledge of the records relating to such drug that they are accurate and complete and a certification signed by an independent expert that he has personally reviewed the records provided and that in his professional opinion, the foregoing requirement concerning validation has been met. The Company commenced shipments of five of the six solid dosage products under the foregoing certification

process. After review by the Company and its consultants of one of the Company's six core products, a hydrocone bitartrate 5mg and acetaminophen 500mg tablet, discrepancies were discovered with some of the data in the Company's ANDA. This resulted in a voluntary recall of this product and the withdrawal of the ANDA. For the fiscal years ended December 31, 1995, 1994 and 1993, the remaining five products accounted for approximately 61%, 63% and 49% of the total sales of the Company, respectively.

During 1992, the Company understood that the Department of Justice ("DOJ") was continuing to conduct an ongoing criminal investigation into the Company's ANDAs, and related manufacturing and recordkeeping practices. In March of 1993, the Company received a second Federal grand jury subpoena for documents relating to two specific products and any other products manufactured by the Company for which improper records may have been kept. As a result of the government's investigation, the Company discovered certain product adulterations and recordkeeping problems with five products manufactured at the Company's Brooklyn plant. As a result of the above, for certain products, the Company indefinitely ceased production, initiated a product recall and recorded a charge to operations of approximately \$5,935,000 for the year ended December 31, 1993, consisting of inventory write-offs (\$2,925,000), a recall of products sold (\$950,000) and the DOJ settlement of \$2,060,000, as discussed below. Included in 1993 net sales are sales of discontinued products of approximately \$4,806,000.

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 has recorded a provision of \$2,060,000 (net of imputed interest). As of December 31, 1995, the Company has only paid two quarterly installments and additional partial payments of \$90,000. 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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE M (continued)

reclassified as a current liability in the 1995 and 1994 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.

On March 31, 1993, and April 1, 1993, five lawsuits were filed by shareholders against the Company and three or more of the Company's directors. Each of the actions alleged that the Company and its directors 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 the Department of Justice and FDA investigations. Each of the actions purported to be brought on behalf of a class of the Company's shareholders. Also, on May 20, 1993 and October 14, 1993, two separate shareholders derivative lawsuits were filed against the Company and three or more of the Company's directors. Each of these lawsuits alleged that the Company and its directors concealed certain government investigations by the FDA and the Department of Justice. These actions also alleged that the directors breached their fiduciary duty in connection with their dispositions of their share of the Company's common stock on the basis of material information which was not publicly known. In June 1994, the plaintiffs of the five lawsuits and the two shareholder-derivative lawsuits and the Company agreed to a settlement of these lawsuits. The Company agreed to pay to the plaintiffs \$1,000,000 in cash, which has been paid by the Company's insurance carrier and, at the Company's option, either (i) the issuance of shares of the Company's common stock having a value, as of the date of distribution, of \$3,000,000 or (ii) the payment by the Company of \$3,000,000 in cash or (iii) any combination of issuance of shares or payment of cash by the Company having a combined value as of the date of distribution of \$3,000,000. 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 November 12, 1993, the Securities and Exchange Commission ("SEC") requested that the Company provide to the SEC, on a voluntary basis, information and documents regarding the ingredients and filings relating to the following drugs: quinidine gluconate, propylthiouracil, acetaminophen and codeine phosphate, metronidazole, quinidine sulfate, and hydralazine hydrochloride. The SEC 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 SEC and has made available various

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE M (continued)

documents. These documents relate to the testing, formulations and sale of these drugs which were maintained by the Company at the offices of its counsel in Maryland. In April 1994, the SEC 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 SEC and outlined the parameters of a proposed settlement. An additional submission was made on January 31, 1995 to bring additional information to the SEC. In May 1995, a formal Order of Investigation was issued by the SEC covering the foregoing matters. In June 1995, additional documents were submitted. Officers and directors of the Company have also testified before the SEC. On October 24, 1995, the SEC staff informed the Company that it would recommend that the Commission authorize the institution of an administrative proceeding pursuant to Section 21C of the Securities Exchange Act of 1934 (the "Exchange Act") against the Company. Specifically the staff indicated it would seek an Order after filing 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 proposed action would allege 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 staff proposal conforms in large part to the settlement proposal submitted by the Company. Under this proposal, the Company, without admitting the allegations would then enter into a Consent Decree not to violate the law in the future. The Company is unable to predict the ultimate outcome of the SEC adopting the staff proposal although the SEC has indicated that it anticipates such action. An adverse determination in this regard could have a material adverse effect on the Company's financial condition. The Company is unable to predict the likelihood of an unfavorable outcome as a result of this inquiry and, accordingly, no provision has been made for any potential costs.

A lawsuit has been 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 alleges 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 seeks unspecified compensatory damages, as well as punitive damages, rescission, specific performance, reformation and a declaration as to what amount, if any, is owed to plaintiff. Because of the early stage of this action, it is not possible at this time to predict with reasonable certainty the ultimate outcome of this matter and, accordingly, no provision has been made for any potential costs relating to this matter.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 1995, 1994 and 1993

NOTE N - SALE OF COMMON STOCK

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

On October 27, 1994, the Company sold 500,000 shares of its common stock in exchange for \$1,000,000 from Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"). In connection with these shares, Ranbaxy had the right to have its shares of the Company's common stock registered under the Securities Act of 1993. In July 1995, the Company repurchased the 500,000 shares from Ranbaxy for \$1,100,000.

NOTE O - 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 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. During 1993, the Company had net sales to two customers in excess of 10% of total sales, each aggregating 12% of total sales. Balances due from these customers were approximately 25% and 7% of total accounts receivable at December 31, 1995 and 1994, 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, 1995, 1994 and 1993

NOTE O (continued)

During 1995, the Company purchased approximately \$2,741,000 of its raw materials from Mallinckrodt and amounts due this supplier represented approximately 29.7% of accounts payable as of December 31, 1995. The federal drug application process requires specification of raw materials suppliers. If raw materials from a supplier specified in a drug application were to become unavailable on commercially acceptable credit terms, FDA supplemental approval of any new supplier would be required. In view of the FDA consent decree and the suspension of review of the Company's ANDA by the FDA, the Company would be unable to obtain FDA supplemental approval at the Brooklyn plant for a new supplier except in very limited circumstances. The Drug Enforcement Administration 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. There can be no assurance that the Company will not face difficulties in obtaining raw materials on commercially acceptable terms, which could have a material adverse effect on the Company.

NOTE P - TEMPORARY CLOSING COSTS OF FACILITY

As a result of irregularities identified in the manufacturing operations of its 51%-owned subsidiary, H.R. Cenci Laboratories, Inc. ("LABS"), the Company, in July 1994, ceased all manufacturing and sales activities at LABS. The Company, upon completion of its review and modifications at the facility, reopened LABS in January 1996. In connection with this temporary closure, the Company recorded costs of \$615,000 and \$427,000 for the years ending December 31, 1995 and 1994, respectively. These costs consist of inventory write-offs, utilities, security and rent.

## EXHIBIT INDEX

Exhibit Number	Description	Page No.
3.1	Certificate of Incorporation and	
3.2	Restated Bylaws (incorporated by reference to	
10.1	Credit Agreement, dated as of December 22,	
10.2	Amendment Two, dated as of January 12, 1994,	
10.3	Amendment Three, dated as of May 31, 1994, to	
10.4	Amendment Four, dated as of July 1994, to	
10.5	Amendment Five, dated as of March 21, 1995,	
10.5(i)	Form of Warrants issued to The Bank of New	
10.5(ii)	Letter Agreement, dated July 10, 1995, among	
10.6	Agreement Regarding Release of Security	
10.7	Consulting Agreement dated as of September,	
10.8	Employment Agreement, dated as of January 1,	
10.9	Employment Agreement, dated as of July 1,	
10.10(i)	Halsey Drug Co., Inc. 1984 Stock Option Plan,	
10.10(ii)	Halsey Drug Co., Inc. 1995 Stock Option and	
10.11	Leases, effective February 13, 1989 and	
10.12	Lease, effective as of April 15, 1988, among	
10.12(i)	Lease, as of October 31, 1994, among	
10.13	Asset Purchase Agreement dated as of March	
10.14	Toll Manufacturing Agreement for	
10.15	Capsule ANDA Option Agreement dated as of	
10.16	Tablets ANDA Noncompetition Agreement dated	
10.17	Subordinated Non-Negotiable Promissory Term	
10.18	Term Note Security Agreement dated as of	
10.19	Amendment dated March 21, 1995 to	
10.20	Agreement dated as of March 30, 1995 between	
10.21	Waiver and Termination Agreement dated as of	
10.22	Convertible Subordinated Note of the	
10.23	Agreement dated as of March 30, 1995 among	
10.24	Supply Agreement dated as of March 30, 1995	

10.25(i) Form of 10% Convertible Subordinated

10.25(ii) Form of Redeemable Common Stock Purchase

10.25(iii)Form of 10% Convertible Subordinated

10.25(iv) Form of Redeemable Common Stock Purchase

10.25(v) Letter Agreement dated November 16, 1995

22 Subsidiaries of the Registrant (incorporated

24 Consent of Grant Thornton LLP, independent

\*27 Financial Data Schedule

12-MOS

DEC-31-1995

DEC-31-1995

353

0

1,969

280

7,716

10,414

18,471

11,077

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0