

# ACURA PHARMACEUTICALS, INC

## FORM 10-K405 (Annual Report (Regulation S-K, item 405))

Filed 04/02/01 for the Period Ending 12/31/00

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Symbol	ACUR
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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

**FORM 10-K**

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

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

**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000**

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

**FOR THE TRANSITION PERIOD FROM TO .**

*COMMISSION FILE NUMBER 1-10113*

**HALSEY DRUG CO., INC.**

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

NEW YORK  
(STATE OR OTHER JURISDICTION  
OF INCORPORATION OR ORGANIZATION)

11-0853640  
(I.R.S. EMPLOYER  
IDENTIFICATION NO.)

695 NORTH PERRYVILLE ROAD, CRIMSON BUILDING NO.  
2  
ROCKFORD, ILLINOIS  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

61107  
(ZIP CODE)

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

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

**TITLE OF CLASS**

NONE

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

(TITLE OF CLASS)

**COMMON STOCK, PAR VALUE \$0.01**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

As of March 23, 2001, the registrant had 14,961,316 shares of Common Stock, par value \$0.01, outstanding. Based on the average closing bid

and asked prices of the Common Stock on March 23, 2001 (\$1.02), the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$14,568,864.

**DOCUMENTS INCORPORATED BY REFERENCE**

DOCUMENT -----	WHERE INCORPORATED -----
Proxy Statement for the 2001 Annual Meeting of Shareholders	Part III

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## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Certain statements in this Report under the captions Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," Item 1, "Business", Item 3, "Legal Proceedings" and elsewhere in this Report constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"). Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Halsey Drug Co., Inc. ("Halsey" or the "Company"), or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: changes in general economic and business conditions; loss of market share through competition; introduction of competing products by other companies; the timing of regulatory approval and the introduction of new products by the Company; changes in industry capacity; pressure on prices from competition or from purchasers of the Company's products; regulatory changes in the generic pharmaceutical manufacturing industry; difficulties encountered in the development of novel product synthesis and manufacturing techniques; regulatory obstacles to the introduction of new technologies or products that are important to the Company's growth; availability of qualified personnel; the loss of any significant customers; and other factors both referenced and not referenced in this Report. When used in this Report, the words "estimate," "project," "anticipate," "expect," "intend," "believe," and similar expressions are intended to identify forward-looking statements.

## PART I

### ITEM 1. BUSINESS.

#### GENERAL

The Company, a New York corporation established in 1935, and its subsidiaries, are engaged in the development, manufacture, sale and distribution of generic drugs and active pharmaceutical ingredients ("API"s). A generic drug is the chemical and therapeutic equivalent of a brand-name drug for which patent protection has expired. A generic drug may only be manufactured and sold if patents (and any additional government-granted exclusivity periods) relating to the brand-name equivalent of the generic drug have expired. A generic drug is usually marketed under its generic chemical name or under a brand name developed by the generic manufacturer. Through its strategic alliance with Watson Pharmaceuticals, as described below, the Company sells its generic drug products under the Watson name for distribution by Watson to 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.

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

The Company manufactures its products at facilities in New York and Indiana. During the last several years, the Company has sought to diversify its businesses through strategic acquisitions and alliances and through the development and manufacture of APIs used by others as raw materials in the manufacture of finished drug forms. In this regard, the Company has acquired exclusive licenses to novel synthesis technologies which the Company expects to develop and use in the manufacture of APIs intended for use in pain management products.

#### RECENT EVENTS

##### Licensed Synthesis Technologies

On August 2, 2000, Halsey acquired an exclusive license to a patented technology for the efficient manufacture of codeine-based APIs used in pain management pharmaceuticals products (the "Codeine Technology"). The Codeine Technology was acquired from Biofine Pharmaceuticals, Inc. ("Biofine") and was developed in collaboration with the University of Nevada, Reno (the "University").

The license agreement with Biofine grants Halsey exclusive rights to the Codeine Technology in North America for twenty years, after which time Halsey will have a fully paid, non-exclusive license. The Codeine Technology license agreement further provides for milestone payments in the aggregate amount of up to \$2,675,000 tied to Halsey's receipt of required approvals and registrations from the U.S. Drug Enforcement Administration ("DEA"), the execution of acceptable raw material supply contracts and the launch of products developed with the Codeine Technology. In addition, Biofine and the University are to receive an aggregate royalty of up to five percent (5%) on net sales of APIs synthesized using the Codeine Technology.

On February 21, 2001, Halsey acquired an exclusive license to a technology providing for an efficient isolation of thebaine from raw poppy. The primary derivative of thebaine is oxycodone, an API used in pain management pharmaceutical products (the "Thebaine Technology" and collectively with the Codeine Technology, the "Licensed Technologies"). The Thebaine Technology, for which a provisional patent application has been filed with the U.S. Patent and Trademark Office, was acquired from Robert C. Corcoran ("Corcoran") and Biofine. The license agreement relating to the Thebaine Technology grants Halsey exclusive world-wide rights in the technology for twenty years, after which time Halsey will have a fully paid, non-exclusive license. The Thebaine Technology license agreement provides that Corcoran and Biofine are to receive an aggregate royalty of up to six percent (6%) on net sales of APIs synthesized using the Thebaine Technology.

Each of the Licensed Technologies are novel processes intended to be more efficient and cost effective methods of deriving APIs to be used in the manufacture of finished dosage pain management products by substantially reducing the time and steps required to produce the desired API. In the case of the Codeine Technology, two patents covering the synthesis processes have been issued in the United States and, to date, this technology has been successfully demonstrated under laboratory conditions. With respect to the Thebaine Technology, it is the Company's intention to file a definitive patent application with the U.S. Patent and Trademark Office prior to the one year anniversary of the date of filing of the provisional patent application by Corcoran. No assurance can be given that a patent will issue on the Thebaine Technology. Currently, the Thebaine Technology is in the process of being tested under laboratory conditions.

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

The development, marketing and sale of pain management products incorporating the Licensed Technologies is subject to extensive regulation by the DEA and the U.S. Food and Drug Administration ("FDA"). At present, the Company's API manufacturing facility located in Culver, Indiana is approved to manufacture Schedule III-N controlled substances. In order to continue the development and eventual commercialization of the Licensed Technologies, the Company will be required to obtain an amendment to its existing manufacturing registration and to obtain a raw material import registration from the DEA. The Company has filed an amendment to the Company's existing Schedule III-N manufacturing registration with the DEA to permit the Company to manufacture Schedule II to V controlled substances. In addition, the Company has started the application process with the DEA seeking approval to import raw poppy directly from India and Turkey to be used in the Company's API development and manufacturing efforts. At present, only two manufacturers in the United States possess such import registrations.

In order for the Company to receive the requested amendment to its existing Schedule III-N manufacturing registration, the Company has commenced the necessary security and related improvements to its Culver, Indiana manufacturing facility. As of December 31, 2000 the Company had expended \$100,000 on such capital improvements and has budgeted an additional \$250,000 to complete the necessary improvements.

As part of the DEA's analysis as to whether the issuance of an import registration to the Company is appropriate, the DEA will consider, among other things, whether adequate security safeguards and controls exist at the Company's Culver, Indiana facility and at all points in the chain of transfer of the raw poppy from suppliers in India and Turkey to the Company's Culver facility, whether the Licensed Technologies are viable and efficient processes, whether market demand for pain management products supports the approval of another import source, and whether the Company has established itself as an eligible party to source and obtain raw poppy supplies from foreign sources. The Company is currently making the necessary upgrades to its Culver, Indiana facility and establishing points of supply in foreign markets to meet these DEA requirements.

The Company anticipates that the existing manufacturers possessing import registrations will challenge any proposed issuance by the DEA of an import registration to the Company. In such event, a hearing on the merits of the DEA issuance of an import registration to the Company will be held before an administrative law judge and the ruling of the administrative law judge will be reviewed by the DEA Administrator. The Company estimates that if successful, of which no assurance can be given at this time, it will receive its

Schedule II to V manufacturing registration in the fourth quarter of 2001 (permitting it to manufacture Schedule II to V controlled substances and related APIs with raw materials sourced from third parties in the U.S.) and receive its import registration in the first quarter of 2004.

The development and commercialization of APIs and finished dosage products incorporating the Licensed Technologies are subject to various factors, many of which are outside the Company's control. Specifically, the Licensed Technologies have been tested only in laboratory or controlled pilot study settings and will need to be successfully "scaled up" in order to be commercially viable, of which no assurance can be given. Additionally, the Company must satisfy, and continue to maintain compliance with, the DEA's requirements for issuance of a Schedule II to V controlled substance manufacturing registration and import registration. Even assuming the Company can satisfy the DEA's requirements in this regard, no assurance can be given that the Company will prevail in any opposition proceeding anticipated to be brought by current manufacturers holding import registrations to prevent the issuance by the DEA of an import registration to the Company. The process of seeking a DEA import registration and contesting any opposition proceeding, as well as the continuing development of the Licensed Technologies, will continue through 2004. Although the Company believes it has sufficient working capital to fund operations for the next 12 months, the Company's cash flow and limited sources of available financing make it uncertain that the Company will have sufficient capital to complete the development of the Licensed Technologies, obtain required DEA approvals and fund the capital improvements necessary for the manufacture of API and finished dosage products incorporating the Licensed Technologies.

### **Strategic Alliance with Watson Pharmaceuticals**

On March 29, 2000, the Company completed various strategic alliance transactions with Watson Pharmaceuticals, Inc. ("Watson"). The transactions with Watson provided for Watson's purchase of the Company's then pending ANDA for doxycycline capsules USP, 50 mg and 100mg (the "doxycycline ANDA"), for Watson's rights to negotiate for Halsey to manufacture and supply certain identified future products to be developed by Halsey, for Watson's marketing and sale of the Company's core products and for Watson's extension of a \$17,500,000 term loan to the Company.

The product acquisition portion of the transactions with Watson provided for Halsey's sale of the pending doxycycline ANDA and related rights (the "Product") to Watson for aggregate consideration of \$13,500,000 (the "Product Acquisition Agreement"). Five million dollars of the purchase price for the Product was paid to the Company in May 2000 following the receipt of FDA approval of the doxycycline ANDA. Of the remaining \$8.5 million, \$5 million is payable within 30 days of Halsey's receipt of FDA approval to relocate manufacturing of the Product from its Brooklyn, New York facility to its Congers, New York facility, provided such approval is received by May 1, 2001, and the remaining \$3.5 million is payable within 10 days of Watson's receipt of notice from the FDA that Halsey is an approved source of the API for the Product, provided such notice is received by July 1, 2001. In view of prevailing market conditions for the Product, Watson has delayed obtaining FDA approval of Halsey as an approved source of the API but has indicated to the Company that the final \$3.5 million payment will be made by July 10, 2001. As part of the execution of the Product Acquisition Agreement, the Company and Watson executed ten year supply agreements covering the API and finished dosage form of the Product pursuant to which Halsey, at Watson's discretion, will manufacture and supply Watson's requirements for the Product API and, where the Product API is sourced from the Company, finish dosage forms of the Product.

The Company and Watson also executed a right of first negotiation agreement providing Watson with a first right to negotiate the terms under which the Company would manufacture and supply certain specified APIs and finished dosage products to be developed by the Company. The right of first negotiation agreement provides that upon Watson's exercise of its right to negotiate for the supply of a particular product, the parties will negotiate the specific terms of the manufacturing and supply arrangement, including price, minimum purchase requirements, if any, territory and term. In the event Watson does not exercise its right of first negotiation upon notice from the Company, or in the event the parties are unable to reach agreement on the material terms of a supply arrangement relating to such product within sixty (60) days of Watson's exercise of its right to negotiate for such product, the Company may negotiate with third parties for the supply, marketing



and sale of the applicable product. The right of first negotiation agreement has a term of ten years, subject to extension in the absence of written notice from either party for two additional periods of five years each. The right of first negotiation agreement applies only to API and finished dosage products identified in the agreement and does not otherwise prohibit the Company from developing APIs or finished dosage products for itself or third parties.

The Company and Watson also executed a manufacturing and supply agreement providing for Watson's marketing and sale of the Company's existing core products portfolio (the "Core Products Supply Agreement"). The Core Products Supply Agreement obligates Watson to purchase a minimum amount of approximately \$18,363,000 (the "Minimum Purchase Agreement") in core products from the Company, in equal quarterly installments over a period of 18 months (the "Minimum Purchase Period"). Due to certain unanticipated raw material shortages, the Company has been unable to supply Watson with sufficient quantities to meet their purchase obligation. The Company and Watson are currently discussing reducing Watson's purchase obligation for the remaining nine month term of the Core Products Supply Agreement during which time adequate supplies of these raw materials are expected to be available. See "Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations -- Liquidity". At the expiration of the Minimum Purchase Period if Watson does not continue to satisfy the Minimum Purchase Amount, the Company may market and sell the core products on its own or through a third party. Pending the Company's development and receipt of regulatory approval for its APIs and finished dosage products currently under development, and the marketing and sale of same, of which there can be no assurance, substantially all the Company's revenues will be derived from the Core Products Supply Agreement with Watson.

The final component of the Company's strategic alliance with Watson provided for Watson's extension of a \$17,500,000 term loan to the Company. The loan is funded in installments upon the Company's request for advances and the provision to Watson of a supporting use of proceeds relating to each such advance. The loan is secured by a first lien on all of the Company's assets, senior to the lien securing all other Company indebtedness, carries a floating rate of interest equal to prime plus two percent and matures on March 31, 2003. As of March 23, 2001, \$13,000,000 had been advanced to the Company under the Watson term loan. The net proceeds from the term loan have, in large part, been used to upgrade and equip the API manufacturing facility of Houba, Inc. located in Culver, Indiana, the Company's wholly-owned subsidiary, to upgrade and equip the Company's Congers, New York leased facilities, to satisfy approximately \$3,300,000 in bridge financing provided by Galen Partners and for working capital to fund continued operations. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" for a more detailed discussion of the \$17,500,000 term loan from Watson.

#### **Cessation and Relocation of Brooklyn, New York Operations**

On March 22, 2000 the Company executed a Lease Termination and Settlement Agreement with the landlord of the Company's Brooklyn, New York manufacturing facility (the "Settlement Agreement"). The Settlement Agreement provides for the early termination of the lease covering the Brooklyn facility and provides the Company with the time necessary to transfer operations to the Company's Congers, New York facilities and cease all manufacturing, research and development and warehouse operations currently conducted in Brooklyn. The Settlement Agreement provides for the termination of the Brooklyn facility lease on March 31, 2001. The original lease provided for a term expiring December 31, 2005 with a rental payment obligation of \$6,715,000 during the period from September 1, 2000 through December 31, 2005.

The Settlement Agreement provided for the Company's payment of a termination fee of \$1,150,000, the advance payment of rent through August 31, 2000 and the deposit of a restoration escrow of \$200,000 to be used for facility repairs. The Company also deposited \$390,600 in escrow with its counsel to cover rental payments for the period September 1, 2000 through March 31, 2001. The rent escrow amount was released to the landlord on September 1, 2000. The Company recorded a total charge against earnings of approximately \$3,273,000 resulting from the elimination of its Brooklyn, New York operations. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" for a more detailed discussion of this charge against earnings.

As of March 23, 2001, all Brooklyn manufacturing operations have ceased and, except for a small group of employees performing final moving and shutdown activities, all employees have been terminated.

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

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

As part of the execution of the Lease, the Company and Par entered into a certain Manufacturing and Supply Agreement (the "M&S Agreement") having a minimum term of twenty seven months. The M&S Agreement provides for the Company's contract manufacture of certain designated products manufactured by Par at the Brenner Drive Facility prior to the effective date of the Lease. The M&S Agreement also provides that Par will purchase a minimum of \$1,150,000 in product during the initial 18 months of the Agreement. The M&S Agreement further provides that the Company will not manufacture, supply, develop or distribute the designated products to be supplied by the Company to Par under the M&S Agreement to or for any other person for a period of three years.

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

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

#### **Acquisition of Product ANDAs**

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

The Barr Products acquired by the Company were previously marketed by Barr, prior to its decision to strategically refocus its generic product portfolio several years ago. While the Barr Products cover a broad range of therapeutic applications and are the subject of approved ANDAs, the Company will be required to obtain approval from the FDA to permit manufacture and sale of any of the Barr Products, including site specific approval. The Company initially has identified 8 of the products for which it will devote substantial effort in seeking approval from the FDA for manufacture and sale. The Company estimates that certain of these Barr Product will be available for sale in the fourth quarter of 2001, although no assurance can be given that any of the Barr Products will receive FDA approval or that if approved, that the Company will be successful in the manufacture and sale of the such products. It is the Company's intention to continue to

evaluate the remaining Barr Products on an ongoing basis to assess their prospects for commercialization and likelihood of obtaining regulatory approval.

## **PRODUCTS AND PRODUCT DEVELOPMENT**

### **Generic Drug Products**

The Company historically has manufactured and sold a broad range of prescription and over-the-counter drug products. The Company's pharmaceutical product list currently includes a total of approximately 24 products, consisting of 18 dosage forms and strengths of prescription drugs and 6 dosage forms and strengths of over-the-counter drugs. Each dosage form and strength of a particular drug is considered in the industry to be a separate drug product. The Company's drug products are sold in various forms, including liquid and powder preparations, compressed tablets and two-piece, hard-shelled capsules.

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

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

During fiscal 2000, sales of antibiotics and narcotic analgesics accounted for approximately 61% of total net sales during such year. The Company anticipates that sales of antibiotics and narcotic analgesics will continue to represent a significant portion of the Company's revenue.

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

During the fiscal year ended December 31, 2000, the Company received one ANDA approval consisting of the doxycycline ANDA sold to Watson Pharmaceuticals. During fiscal 2001, the Company anticipates the submission of 15 ANDA supplements or amendments to the FDA. The supplements and amendments relate to transfer of existing ANDAs from the Company's Brooklyn facility to its Congers facility as well as the transfer of certain ANDAs obtained from Barr Laboratories. Although the Company has been successful in receiving ANDA approvals since its release from the FDA's Application Integrity Policy list in December 1996, there can be no assurance that any newly submitted ANDAs, or supplements or amendments thereto or those contemplated to be submitted, will be approved by the FDA. The Company will not be permitted to market any new product unless and until the FDA approves the ANDA relating to such product. Failure to obtain FDA approval for the Company's pending ANDAs, or a significant delay in submitting for or obtaining such approval, would adversely affect the Company's business operations and financial condition.

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

While the Company will continue the development of its finished goods pharmaceutical business, including the rehabilitation of the product ANDAs acquired from Barr, the Company will dedicate increasing resources to the expansion and enhancement of its operations devoted to the development and manufacture of APIs for use in the Company's finished dosage products as well as for sale to third party pharmaceutical companies, including Watson, in the form of API and finished dosage products. See "Recent Events -- Licensed Synthesis Technologies".

### **Active Pharmaceutical Ingredients**

As discussed above under the caption "Licensed Synthesis Technologies", in the last few years, the Company has increased its efforts to develop and manufacture APIs, also known as bulk chemical products. The development and sale of APIs generally is not subject to the same level of regulation as is the development and sale of drug products. Accordingly, APIs may be brought to market substantially sooner than drug products. During fiscal 2000, all of the Company's revenues were derived from the sale of finished dosage products. It is the Company's expectation that in connection with a strategic alliance with Watson, the development of the Licensed Technologies and other API development efforts, in addition to assisting in the expansion of the Company's line of finished dosage products, the Company will generate revenues from the sale of APIs starting in the latter part of 2001 and such revenue segment will likely increase thereafter as a percentage of total revenue.

### **RESEARCH AND DEVELOPMENT**

The Company currently conducts research and development activities at each of its Congers, New York and Culver, Indiana facilities. The Company's research and development activities consist primarily of new generic drug product development efforts and manufacturing process improvements, the development for sale of new chemical products and the development of APIs. 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 2000, 1999 and 1998, total research and development expenditures were \$1,821,000, \$1,075,000 and \$651,000. During 2001, the Company's research and development efforts will cover finished dosage products and APIs in a variety of therapeutic applications, with an emphasis on pain management products.

As of March 23, 2001, the Company maintained a full-time staff of 8 in its Research and Development Departments.

### **MARKETING AND CUSTOMERS**

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

The strategic alliance with Watson entered into on March 29, 2000 provides for the Company's core products portfolio to be sold by Watson's sales force under Watson's label. Accordingly, the Company has discontinued its own sales efforts of these products. The Company continues to perform limited contract manufacturing of certain non-core products for other pharmaceutical companies.

During 2000, 60% of the Company's total sales were to Watson Pharmaceuticals pursuant to the Core Products Supply Agreement between the Company and Watson (See "Recent Events -- Strategic Alliance with Watson Pharmaceuticals"). The Company believes that the loss of this customer would have a material

adverse effect on the Company. During 1999 the Company had net sales to two customers, aggregating approximately 25.3% of total sales. During 1998, the Company had net sales to two customers aggregating approximately 19% of total sales.

The estimated dollar amount of the backlog of orders for future delivery as of March 23, 2001 was approximately \$4,000,000 as compared with approximately \$800,000 as of March 31, 2000. Although these orders are subject to cancellation, management expects to fill substantially all orders by the second and third quarter of 2001. The increase in the Company's backlog as of March 23, 2001 compared to that in 2000 is largely a function of an increase in market penetration from marketing efforts by Watson as well as delayed orders as a result of temporary shortages of certain raw materials.

## **GOVERNMENT REGULATION**

### **General**

All pharmaceutical manufacturers, including the Company, are subject to extensive regulation by the Federal government, principally by the FDA, and, to a lesser extent, by state and local governments. Additionally, the Company is subject to extensive regulation by the U.S. Drug Enforcement Agency ("DEA") as a manufacturer of controlled substances. The Company cannot predict the extent to which it may be affected by legislative and other regulatory developments concerning its products and the healthcare industry generally. The Federal Food, Drug, and Cosmetic Act, the Generic Drug Enforcement Act of 1992, the Controlled Substance Act and other Federal statutes and regulations govern or influence the testing, manufacture, safe labeling, storage, record keeping, approval, pricing, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, criminal proceedings, total or partial suspension of production, and refusal of the government to enter into supply contracts or to approve new drug applications. The FDA also has the authority to revoke approvals of new drug applications. The ANDA drug development and approval process now averages approximately eight months to two years. The approval procedures are generally costly and time consuming.

FDA approval is required before any "new drug," whether prescription or over-the-counter, can be marketed. A "new drug" is one not generally recognized by qualified experts as safe and effective for its intended use. Such general recognition must be based on published adequate and well controlled clinical investigations. No "new drug" may be introduced into commerce without FDA approval. A drug which is the "generic" equivalent of a previously approved prescription drug also will require FDA approval. Furthermore, each dosage form of a specific generic drug product requires separate approval by the FDA. In general, as discussed below, less costly and time consuming approval procedures may be used for generic equivalents as compared to the innovative products. Among the requirements for drug approval is that the prospective manufacturer's methods must conform to the CGMPs. CGMPs apply to the manufacture, receiving, holding and shipping of all drugs, whether or not approved by the FDA. CGMPs must be followed at all times during which the drug is manufactured. To ensure full compliance with standards, some of which are set forth in regulations, the Company must continue to expend time, money and effort in the areas of production and quality control. Failure to so comply risks delays in approval of drugs, disqualification from eligibility to sell to the government, and possible FDA enforcement actions, such as an injunction against shipment of the Company's products, the seizure of noncomplying drug products, and/or, in serious cases, criminal prosecution. The Company's manufacturing facilities are subject to periodic inspection by the FDA.

In addition to the regulatory approval process, the Company is subject to regulation under Federal, state and local laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, state, Federal and foreign regulations, including possible future regulations of the pharmaceutical industry.

### **Drug Approvals**

There are currently three ways to obtain FDA approval of a new drug.

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

2. Abbreviated New Drug Applications ("ANDA"). The Drug Price Competition and Patent Term Restoration Act of 1984 (the "1984 Act") established the ANDA procedure for obtaining FDA approval for those drugs that are off-patent or whose exclusivity has expired and that are bioequivalent to brand-name drugs. An ANDA is similar to an NDA, except that the FDA waives the requirement of conducting complete clinical studies of safety and efficacy, although it may require expanded clinical bioavailability and/or bioequivalence studies. "Bioavailability" means the rate of absorption and levels of concentration of a drug in the blood stream needed to produce a therapeutic effect. "Bioequivalence" means equivalence in bioavailability between two drug products. In general, an ANDA will be approved only upon a showing that the generic drug covered by the ANDA is bioequivalent to the previously approved version of the drug, i.e., that the rate of absorption and the levels of concentration of a generic drug in the body are substantially equivalent to those of a previously approved equivalent drug. The principle advantage of this approval mechanism is that an ANDA applicant is not required to conduct the same preclinical and clinical studies to demonstrate that the product is safe and effective for its intended use.

The 1984 Act, in addition to establishing the ANDA procedure, created new statutory protections for approved brand-name drugs. In general, under the 1984 Act, approval of an ANDA for a generic drug may not be made effective until all product and use patents listed with the FDA for the equivalent brand name drug have expired or have been determined to be invalid or unenforceable. The only exceptions are situations in which the ANDA applicant successfully challenges the validity or absence of infringement of the patent and either the patent holder does not file suit or litigation extends more than 30 months after notice of the challenge was received by the patent holder. Prior to enactment of the 1984 Act, the FDA gave no consideration to the patent status of a previously approved drug. Additionally, under the 1984 Act, if specific criteria are met, the term of a product or use patent covering a drug may be extended up to five years to compensate the patent holder for the reduction of the effective market life of that patent due to federal regulatory review. With respect to certain drugs not covered by patents, the 1984 Act sets specified time periods of two to ten years during which approvals of ANDAs for generic drugs cannot become effective or, under certain circumstances, ANDAs cannot be filed if the equivalent brand-name drug was approved after December 31, 1981.

3. "Paper" NDA. An alternative NDA procedure is provided by the 1984 Act whereby the applicant may rely on published literature and more limited testing requirements. While that alternative sometimes provides advantages over the ANDA procedure, it is not frequently used.

### **Generic Drug Enforcement Act**

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

The Generic Drug Act requires the mandatory debarment of companies or individuals convicted of a federal felony for conduct relating to the development or approval of any ANDA, and gives the FDA discretion to debar corporations or individuals for similar conduct resulting in a federal misdemeanor or state felony conviction. The FDA may not accept or review during the period of debarment (one to ten years in the case of mandatory, or up to five years in the case of permissive, debarment of a corporation) any ANDA submitted by or with the assistance of the debarred corporation or individual. The Generic Drug Act also provides for temporary denial of approval of generic drug applications during the investigation of crimes that

could lead to debarment. In addition, in more limited circumstances, the Generic Drug Act provides for suspension of the marketing of drugs under approved generic drug applications sponsored by affected companies. The Generic Drug Act also provides for fines and confers authority on the FDA to withdraw, under certain circumstances, approval of a previously granted ANDA if the FDA finds that the ANDA was obtained through false or misleading statements.

### **Healthcare Reform**

Several legislative proposals to address the rising costs of healthcare have been introduced in Congress and several state legislatures. Many of such proposals include various insurance market reforms, the requirement that businesses provide health insurance coverage for all their employees, significant reductions in the growth of future Medicare and Medicaid expenditures, and stringent government cost controls that would directly control insurance premiums and indirectly affect the fees of hospitals, physicians and other healthcare providers. Such proposals could adversely affect the Company's business by, among other things, reducing the demand, and the prices paid, for pharmaceutical products such as those produced and marketed by the Company. Additionally, other developments, such as (i) the adoption of a nationalized health insurance system or a single payor system, (ii) changes in needs-based medical assistance programs, or (iii) greater prevalence of capitated reimbursement of healthcare providers, could adversely affect the demand for the Company's products.

### **COMPETITION**

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

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

### **RAW MATERIALS**

The raw materials essential to the Company's business are APIs purchased from numerous sources. Raw materials are generally available from several sources. The Federal drug application process requires specification of raw material suppliers. If raw materials from a supplier specified in a drug application were to become unavailable on commercially acceptable terms, FDA supplemental approval of a new supplier would be required. During 2000 and 1999, the Company purchased approximately \$1,485,000 and \$1,107,000, respectively, of its raw materials (constituting 28% and 15%, respectively, of its aggregate purchases of raw materials) from Mallinckrodt. Although the Company is now able to submit supplements to the FDA in order to allow the Company to purchase raw materials from alternate sources, there can be no assurance that if the Company were unable to continue to purchase raw materials from this supplier, that the Company would be successful in receiving FDA approval to such supplement or that it would not face difficulties in obtaining raw materials on commercially acceptable terms. Failure to receive FDA approval for, and to locate, acceptable alternative sources of raw materials would have a material adverse effect on the Company. The Company experienced a shortage of two raw materials in the latter half of 2000. These shortages are expected to continue through the second quarter of 2001.

The DEA limits the quantity of the Company's inventories of certain raw materials used in the production of controlled substances based on historical sales data. In view of the Company's recently

depressed sales volume, these DEA limitations could increase the likelihood of raw material shortages and of manufacturing delays in the event the Company experiences increased sales volume or is required to find new suppliers of these raw materials.

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

## **SUBSIDIARIES**

The Company's Culver, Indiana manufacturing operations are conducted by Houba, Inc., an Indiana corporation and wholly-owned subsidiary of the Company. Halsey Pharmaceuticals, Inc., a Delaware corporation, is a wholly-owned subsidiary which is currently inactive. The Company also has the following additional subsidiaries, each of which is currently inactive and anticipated to be dissolved during the remainder of the 2001 fiscal year: Indiana Fine Chemicals Corporation, a Delaware corporation, H.R. Cenci Laboratories, Inc., a California corporation, Cenci Powder Products, Inc., a Delaware corporation, Blue Cross Products, Inc., a New York corporation, and The Medi-Gum Corporation, a Delaware corporation.

## **EMPLOYEES**

As of March 23, 2001, the Company had approximately 110 full-time employees. Approximately 28 employees are administrative and professional personnel and the balance are in production and shipping. Among the professional personnel, 8 are engaged in research and product development. Management believes that its relations with its employees are satisfactory.

## **ITEM 2. PROPERTIES.**

Halsey leases, as sole tenant, a pharmaceutical manufacturing facility of approximately 35,000 square feet located at 77 Brenner Drive, Congers, New York. The Agreement of Lease, with an unaffiliated third party, contains a three year term with a two year renewal option and provides for annual fixed rent of \$500,000 per year during the primary term of the Lease and \$600,000 per year during the renewal period. The primary term of the Lease expires on March 21, 2002. The leased facility houses a portion of the Company's manufacturing operations and includes office and warehouse space. The Lease also contains an option pursuant to which the Company may purchase the leased premises and improvements (including certain production and related equipment) for a purchase price of \$5 million, exercisable at any time during the Lease term.

Halsey leases, as sole tenant, a facility located at 125 Wells Avenue, Congers, New York. The Facility contains office, warehouse and manufacturing space and is approximately 18,000 square feet. The Lease provides for a term of four years with an option to renew for an additional three years and provides for annual fixed rent of approximately \$127,000 per year during the first two years of the Lease and approximately \$135,000 per year during the last two years.

Halsey leases approximately 4,700 square feet of office space located at 695 North Perryville Road, Building No. 2, Rockford, Illinois. The lease is between the Company and an unaffiliated lessor. The original lease had a term of two years expiring August 31, 2000, allows annual renewals through August 31, 2003 and calls for annual rental, including maintenance and common area expense, of approximately \$46,000 per year. This leased facility houses the Company's principal executive offices, including its sales, administration and finance operations.

The Company's Houba, Inc. subsidiary owns approximately 45,000 square feet of building space on approximately 30 acres of land in Culver, Indiana, which includes a 15,000 square foot manufacturing facility.



This manufacturing facility houses separate plants for the production of certain raw materials as well as finished dosage products in capsule and tablet form.

### **ITEM 3. LEGAL PROCEEDINGS.**

Beginning in 1992, actions were commenced against the Company and numerous other pharmaceutical manufacturers in the Pennsylvania Court of Common Pleas, Philadelphia Division, in connection with the alleged exposure to diethylstilbestrol ("DES"). The defense of all of such matters was assumed by the Company's insurance carrier, and a substantial number have been settled by the carrier. Currently, several actions remain pending with the Company as a defendant, and the insurance carrier is defending each action. Similar actions were brought in Ohio, and have been dismissed based on Ohio law. The Company does not believe any of such actions will have a material impact on the Company's financial condition.

The Company has been named as a defendant in one additional action which has been referred to the Company's insurance carrier and has been accepted for defense. The action, *Alonzo v. Halsey Drug Co., Inc. and K-Mart Corp.*, No. 64DOT-95111-CT-2736 (Indiana Superior Court, Porter County), was commenced on November 7, 1995 and involves a claim for unspecified damages relating to the alleged ingestion of "Doxycycline 100." The Company does not believe this action will have a material impact on the Company's financial condition.

### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

No matters were submitted to a vote of security holders during the fourth quarter of 2000.

## **PART II**

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

#### **MARKET AND MARKET PRICES OF COMMON STOCK**

On August 29, 2000, the Company was informed by the Adjudicatory Counsel of the American Stock Exchange ("Amex") that it had determined to delist the Common Stock of the Company for failure to meet the Amex's criteria for continued listing. The last day of trading of the Company's Common Stock on the Amex was September 7, 2000. The Company's Common Stock commenced trading on the NASDAQ sponsored Over the Counter Bulletin Board on September 8, 2000.

Set forth below for the periods indicated are (i) the high and low sales prices of the Company's Common Stock while listed on Amex as reported by the Exchange and (ii) the high and low bid price for the Company's Common Stock for trading in the Common Stock on the OTC Bulletin Board as reported by the OTC Bulletin Board.

## AMERICAN STOCK EXCHANGE

	PERIOD	SALES PRICE	
		HIGH	LOW
1999 Fiscal Year			
First Quarter.....		1 9/16	1
Second Quarter.....		3 3/16	1
Third Quarter.....		3 1/8	2
Fourth Quarter.....		2 3/4	3/4
2000 Fiscal Year			
First Quarter.....		2 3/8	1
Second Quarter.....		1.52	1.02
Third Quarter through September 7, 2000.....		1.375	.98

## OTC BULLETIN BOARD\*

	PERIOD	BID PRICE	
		HIGH	LOW
2000 Fiscal Year			
Third Quarter (commencing September 8, 2000).....		1.78	.3
Fourth Quarter.....		1.125	.41
2001 Fiscal Year			
First Quarter (through March 23, 2001).....		1.24	.69

\* Such over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

## **HOLDERS**

There were 750 holders of record of the Company's common stock on March 23, 2001. This number, however, does not reflect the ultimate number of beneficial holders of the Company's common stock.

## **DIVIDEND POLICY**

The payment of cash dividends from current earnings is subject to the discretion of the Board of Directors and is dependent upon many factors, including the Company's earnings, its capital needs and its general financial condition. The terms of the Company's 5% convertible senior secured debentures and the Loan Agreement with Watson Pharmaceuticals prohibit the Company from paying cash dividends. The Company does not intend to pay any cash dividends in the foreseeable future.

## **ITEM 6. SELECTED FINANCIAL DATA.**

The selected consolidated financial data presented on the following pages for the years ended December 31, 2000, 1999, 1998, 1997 and 1996 are derived from the Company's audited Consolidated Financial Statements. The Consolidated Financial Statements as of December 31, 2000 and December 31, 1999, and for each of the years in the three year period ended December 31, 2000, and the report thereon, are included elsewhere herein. The selected financial information as of and for the years ended December 31, 1998, 1997 and 1996 are derived from the audited Consolidated Financial Statements of the Company not presented herein.

The information set forth below is qualified by reference to, and should be read in conjunction with, the Consolidated Financial Statements and related notes thereto included elsewhere in this Report and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

	YEARS ENDED DECEMBER 31,				
	2000	1999	1998	1997	1996
	(IN THOUSANDS, EXCEPT PER SHARE DATA)				
OPERATING DATA:					
Net revenues.....	\$ 20,223	\$ 11,420	\$ 8,841	\$ 9,088	\$ 12,379
Costs and expenses					
Cost of revenues.....	18,743	15,316	12,712	15,407	16,826
Research and development.....	1,821	1,075	651	979	1,854
Selling, general and administrative.....	6,208	7,383	8,078	6,308	7,486
Plant shutdown costs.....	53	3,220	--	--	--
Interest expense.....	3,037	2,851	1,285	1,144	1,708
Amortization of deferred debt discount and private offering cost.....	2,448	1,825	661	--	--
Other (income) expense.....	(44)	(187)	(1,822)	264	(1,000)
Income (loss) before provision for income taxes.....	(12,043)	(20,063)	(12,724)	(15,014)	(14,495)
Provision (benefit) for income taxes.....	(389)	--	--	--	--
Net income (loss).....	\$ (11,654)	\$ (20,063)	\$ (12,724)	\$ (15,014)	\$ (14,495)
Net income (loss) per share.....	\$ (.80)	\$ (1.40)	\$ (.92)	\$ (1.12)	\$ (1.49)
Weighted average common shares outstanding.....	14,325,551	14,325,551	13,812,529	13,434,215	9,724,106

	DECEMBER 31,				
	2000	1999	1998	1997	1996
	(IN THOUSANDS, EXCEPT PER SHARE DATA)				
BALANCE SHEET DATA:					
Working capital (deficiency).....	\$ (2,561)	\$ (5,181)	\$ (6,665)	\$ (22,304)	\$ (12,201)
Total assets.....	15,209	12,495	16,413	7,667	11,982
Total liabilities.....	68,558	54,869	45,366	27,524	19,063
Retained earnings (accumulated deficit).....	(88,938)	(77,284)	(57,221)	(44,497)	(29,484)
Stockholders' equity (deficit).....	(53,349)	(42,374)	(28,953)	(19,857)	(7,081)

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

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

### OVERVIEW

The Company reported a net loss of \$11,654,000 or \$.80 per share for the year ended December 31, 2000 as compared with the net loss of \$20,063,000 or \$1.40 per share for 1999. Included in Net Revenues for 2000 was \$5.0 million of a total \$13.5 million due from Watson Laboratories as payment for a product ANDA sold to Watson in March, 2000. The remaining \$8.5 million is expected to be realized in 2001 as milestones are achieved. Included in the loss for 1999 is a one-time charge of \$3,220,000 resulting from the Company's decision to shutdown its Brooklyn operation. Net revenues for the year ended December 31, 2000, excluding the \$5.0 million referred to above, were approximately \$15,223,000 as compared to net revenues of approximately \$11,420,000 for 1999.

The Company reduced its loss before interest, depreciation and taxes to (\$5,958,000) for 2000 compared to (\$14,660,000) and (\$11,487,000) for 1999 and 1998, respectively. This was achieved even though the Company continued to operate the inefficient Brooklyn facility throughout 2000 as it awaited the FDA approval of its leased Congers facility. This approval was received in February, 2001 enabling the Company to close down its operations in Brooklyn in March, 2001 with an estimated annual operational savings of \$5,000,000.

The Company had the following achievements in 2000:

- Completed various strategic alliance transactions with Watson Pharmaceuticals, Inc. providing capital and guaranteed ongoing source of revenue from contract manufacturing.
- Received approval from the FDA of ANDA for doxycycline monohydrate.
- Acquired patented technology for the synthesis of codeine from morphine
- Subsequent to year end, the Company acquired technology for the efficient isolation of thebaine from raw opium.
- Subsequent to year end, received approval from the DEA to manufacture Schedule III-N controlled substances at the Company's Culver, Indiana facility .
- Subsequent to year end, completed the shutdown of the Brooklyn facility eliminating approximately \$5.0 million in annual operating costs.

## RESULTS OF OPERATIONS

The following chart reflects expenses, earnings, income, losses and profits expressed as a percentage of net revenues for the years 2000, 1999 and 1998.

	PERCENTAGE OF NET SALES YEAR ENDED DECEMBER 31,			PERCENTAGE CHANGE YEAR-TO-YEAR INCREASE (DECREASE) YEARS ENDED DECEMBER 31,	
	2000	1999	1998	1999 TO 2000	1998 TO 1999
Net product revenues.....	100%	100%	100%	77.1%	29.2%
Cost of Manufacturing.....	92.7	134.1	143.8	22.4	20.5
Research & Development.....	9.0	9.4	7.4	69.4	65.1
Selling, general and administrative expense.....	30.7	64.6	91.4	(15.9)	(8.6)
Plant shutdown costs.....	.3	28.2	--	(98.4)	--
(Loss) from operations.....	(32.6)	(136.4)	(142.5)	(57.6)	23.6
Interest expense.....	15.0	25.0	14.5	6.5	121.9
Amortization of deferred debt discount and private offering cost.....	12.1	16.0	7.5	34.1	176.1
Other (income) expenses.....	(.2)	(1.6)	(20.6)	(76.5)	(89.7)
(Loss) before income taxes.....	(59.6)	(175.7)	(143.9)	(40.0)	57.7
Net (loss).....	(57.6)	(175.7)	(143.9)	(41.9)	57.7

## NET PRODUCT REVENUES

Net product revenues for 2000 of \$20,223,000 represents an increase of \$8,803,000 as compared to net revenues for 1999. Net product revenues for 2000 are comprised of sales of products totaling \$15,223,000 and revenues from product development of \$5,000,000. The Company had no product development revenue in 1999 or prior years. The increase in sales of products is attributable primarily to the Core Products Supply Agreement with Watson dated, March, 2000 whereby Watson was obligated to purchase and pay for a minimum of \$9,180,000 of products in 2000.

Net product revenues for 1999 of \$11,420,000 represents an increase of \$2,579,000 as compared to net product revenues for 1998. The increase is attributable to greater market penetration as well as the introduction of additional products, primarily prednisolone, which accounted for approximately \$815,000 of new product revenues.

## **COST OF MANUFACTURING**

The Company's cost of manufacturing for 2000 improved to 92.7% versus 134.1% for 1999. The improvement in 2000 is due primarily to the addition of the \$5,000,000 of product development revenue. The development costs associated with this revenue were substantially incurred in prior years and were expensed at that time. The cost of manufacturing for 2000 on product sales alone was 123%.

The Company's cost of manufacturing for 1999 improved to 134.1% versus 143.8% for 1998. The improvement in 1999 is due primarily to the leveraging effect of greater sales over certain fixed manufacturing expenses.

## **RESEARCH & DEVELOPMENT EXPENSES**

For 2000, research and development expenses amounted to \$1,821,000 as compared to \$1,075,000 for 1999. The increase primarily reflects the costs associated with obtaining the codeine technology.

For 1999, research and development expenses amounted to \$1,075,000 as compared to \$651,000 for 1998. The increase primarily reflects the costs of additional regulatory personnel hired during 1999 to perform work in conjunction with new product development and the transfer of certain Barr ANDAs acquired during 1999.

The Company expects research and development expenses to increase in 2001 as compared to 2000 consistent with its plans to develop additional active pharmaceutical ingredients at its Culver, Indiana facility.

## **SELLING, GENERAL AND ADMINISTRATIVE EXPENSES**

Selling, general and administrative costs were \$6,208,000 (30.7% of net revenues) for 2000 compared to \$7,383,000 (64.6% of net revenues) for 1999. This decrease is primarily due to the elimination of the Company's outside sales force (approximately \$400,000) and reduced legal expenses (approximately \$750,000) in 2000 as compared to 1999.

Selling, general and administrative costs were \$7,383,000 (64.6% of net sales) for 1999 compared to \$8,078,000 (91.4% of net sales) for 1998. This decrease is primarily due to the reduced legal expenses in 1999 as compared to 1998.

## **PLANT SHUTDOWN COSTS**

In the fourth quarter of 1999, the Company decided to discontinue its Brooklyn operations. The total charge against earnings in 1999 of approximately \$3,220,000 resulting from eliminating the Brooklyn operation includes the lease termination payment of \$1,150,000, a provision of \$200,000 for plant repairs, the write-off of leasehold improvements of \$1,778,000, severance and other costs for terminated employees of \$730,000, less deferred rent previously expensed of \$638,000.

## **INTEREST EXPENSE**

Interest expense for 2000 increased by 6.5% over that of 1999 reflecting interest on borrowings under the Watson term loan.

Interest expense for 1999 increased by 121.9% over that of 1998 reflecting the issuance of an additional \$17,800,000 of convertible debentures in 1999.

## **AMORTIZATION OF DEFERRED DEBT DISCOUNT AND DEBT ISSUANCE COSTS**

In 2000, 1999 and 1998 the Company issued warrants and incurred costs associated with private placements and bridge financings. The value of warrants issued in 2000, 1999 and 1998, as determined by use of the Black-Scholes valuation model, was \$124,750, \$5,234,000 and \$2,618,000, respectively. Additionally, the Company incurred approximately \$907,000 and \$1,516,000 of debt issuance costs in 1999 and 1998, respectively. These amounts are being amortized over the life of the underlying debentures which expire in March, 2003. Accordingly, the Company amortized \$2,509,000, \$1,825,000 and \$661,000 in 2000, 1999 and 1998, respectively.

## **OTHER INCOME**

Included in other income for 1998 is \$1,900,000 realized from the sale of certain assets to Mallinckrodt. This transaction was entered into in 1997 but the conditions for realization of the gain from the sale were not met until 1998.

## **LIQUIDITY AND CAPITAL RESOURCES**

At December 31, 2000, the Company had cash and cash equivalents of \$697,000 as compared to \$786,000 at December 31, 1999. The Company had a working capital deficit at December 31, 2000 of \$(2,561,000).

During the period from May 1997 through July 1997, the Company borrowed approximately \$3 million from Mylan Laboratories, Inc. pursuant to five unsecured, demand promissory notes. The advances made by Mylan Laboratories, Inc. were part of a proposed investment by Mylan Laboratories, Inc. in the Company, including the proposed purchase of the Company's Culver, Indiana facility as well as a partial tender offer for the Company's common stock. The Company used the proceeds of these borrowings for working capital. As of March 23, 2001, \$2,216,428 has been paid by the Company to Mylan against such indebtedness in the form of product deliveries to Mylan. Pursuant to an agreement reached between the parties, the Company is required to satisfy interest on the outstanding indebtedness on an annual basis while the indebtedness remains outstanding and to satisfy the principal amount of such indebtedness in the form of product deliveries to Mylan until such time as the indebtedness is satisfied in full.

The Company secured bridge financing from Galen Partners III, L.P. Galen Partners International III, L.P. and Galen Employee Fund III, L.P. (collectively, "Galen") in the aggregate amount of approximately \$3,300,000, funded through six separate bridge loan transactions during the period from December 8, 1999 through March 29, 2000 (collectively, the "2000 Galen Bridge Loans"). The principal amount of the 2000 Galen Bridge Loans and accrued and unpaid interest were satisfied in full with a portion of the proceeds of the Watson Term Loan (as described below). Prior to repayment, the 2000 Galen Bridge Loans accrued interest at the rate of 18% per annum and were secured by a first lien on all of the Company's assets. In consideration for the extension of the 2000 Galen Bridge Loans, the Company issued common stock purchase warrants to Galen to purchase an aggregate of 150,000 shares of the Company's common stock (representing warrants to purchase 50,000 shares of common stock for each \$1,000,000 in principal amount of the 2000 Galen Bridge Loans). The warrants issued pursuant to the 2000 Galen Bridge Loans have an exercise price equal to the fair market value of the Company's common stock on the date of issuance and are substantially identical to those issued by the Company in the Galen Offering completed in March 1998. The 2000 Galen Bridge Loans were obtained by the Company in order to provide necessary working capital prior to the completion of the Watson Term Loan as described below.

On March 22, 2000, the Company executed a Lease Termination and Settlement Agreement with the landlord of the Company's Brooklyn, New York manufacturing facility (the "Settlement Agreement"). The Settlement Agreement accelerates the termination of the lease covering the Company's Brooklyn facility and provides the Company with the time necessary to transfer operations to the Company's Congers, New York facilities and cease all manufacturing, research and development and warehouse operations currently conducted in Brooklyn. The Settlement Agreement provides for the termination of the Brooklyn lease on March 31, 2001. The original lease provided for a term expiring December 31, 2005 with a rental payment

obligation of \$6,715,000 during the period from September 1, 2000 through December 31, 2005. The Settlement Agreement provided for the Company's payment of a lease termination fee of \$1,150,000, the advance payment of rent through August 31, 2000 and a restoration escrow deposit of \$200,000 for plant repairs. The Company also deposited in escrow with its counsel \$390,600 which represents rental payments for the period September 1, 2000 through March 31, 2001. The rent escrow amount was released to the landlord on September 1, 2000. The Company funded the termination fee payment, the advance rental payment obligations and restoration amount required pursuant to the Settlement Agreement with the proceeds received from the Watson Term Loan described below.

In addition to the lease termination and escrow payments described above, the Company incurred severance and other costs for terminated employees of approximately \$730,000 which were paid in the second quarter of 2000. Also, the Company incurred capital costs of approximately \$2,000,000 in 2000 associated with the transfer of certain operations from Brooklyn to the Congers facility.

In addition to the other strategic alliance transactions with Watson Pharmaceuticals, Inc. ("Watson") completed on March 29, 2000 (see "Item 1. Business -- Recent Events -- Strategic Alliance with Watson Pharmaceuticals"), the Company and Watson executed a Loan Agreement providing for Watson's extension of a \$17,500,000 term loan to the Company (the "Watson Term Loan"). The Watson Term Loan will be funded in installments upon the Company's request for advances and the provision to Watson of a supporting use of proceeds relating to each such advance. As of March 23, 2001, \$13,000,000 had been advanced by Watson to the Company under the Watson Term Loan. The Watson Term Loan is secured by a first lien on all of the Company's assets, senior to the liens securing all other Company indebtedness, carries a floating rate of interest equal to prime plus two percent and matures on March 31, 2003. As of March 23, 2001, a portion of the net proceeds of the Watson Term Loan were used to satisfy in full the 2000 Galen Bridge Loans, to satisfy the Company's payment obligations under the Settlement Agreement with the landlord of its Brooklyn, New York facility, to fund capital improvements and for working capital. The remaining net proceeds of the Watson Term Loan will, in large part, be used to complete the upgrades to the API manufacturing facility of Houba, Inc., the Company's wholly-owned subsidiary, to complete the upgrades to the Company's Congers, New York leased facilities, to fund the relocation of the Company's research and development and manufacturing operations from its Brooklyn, New York facilities to its Congers, New York facility and for working capital to fund continued operations.

Pursuant to the terms of the Core Products Supply Agreement with Watson, Watson is required to purchase and pay for on a quarterly basis a minimum of \$3,060,000 for products supplied by the Company under such Agreement. As of March 23, 2001, Watson had made an advance payment of \$3,795,000 as required under the terms of the Core Products Supply Agreement to be applied against future product purchases under such Agreement. The advance payments and any additional advance payments made by Watson under the Core Products Supply Agreement will require that the Company supply Watson with a like amount of products without additional payments from Watson at such time.

Until such time as the Company successfully develops and commercializes new finished dosage products and APIs, of which there can be no assurance, the Company will continue to incur operating losses and negative cash flow. As discussed under the caption "Recent Events -- Strategic Alliance with Watson Pharmaceuticals", an additional \$8.5 million is payable by Watson to the Company under the terms of the Product Purchase Agreement completed in March, 2000 relating to the doxycycline ANDA (the "Remaining Doxycycline Payments"). The Company estimates that it will receive \$5 million of the Remaining Doxycycline Payments in the second quarter of 2001 and the remaining \$3.5 million of the Remaining Doxycycline Payments in the third quarter of 2001. The Remaining Doxycycline Payments combined with the \$4.5 million balance available under the Watson Term Loan will be sufficient to satisfy the Company's working capital requirements for the next 12 months. In the event of any delay in the receipt of funding from Watson, the Company's ability to operate could be hampered.

The process of obtaining the required DEA approvals, including contesting any resulting opposition proceeding, and the continuing development of the Licensed Technologies will continue through 2004. In order to fund the continued development of the Licensed Technologies, to complete the planned capital

improvements to the Company's Culver, Indiana and Congers, NY facilities, and to process the registrations and approvals required from the DEA (including funding the legal fees and related expenses in connection with any opposition proceeding relating to the Company's request for a raw material import registration), during the period from fiscal 2002 through and including fiscal 2004 the Company estimates that it will be required to obtain additional sources of financing or a third party equity investment of approximately \$7.5 million. There can be no assurance, however, that such financing or equity investment will be available to the Company at such time on acceptable terms, if at all. Failure to obtain such financing or equity investment will require the Company to delay or cease the continued development of the Licensed Technologies and the completion of the capital improvements discussed under the caption "Recent Events -- Licensed Synthesis Technologies." An extended delay or a cessation of the Company's continuing development efforts relating to the Licensed Technologies or delays in obtaining required DEA approvals, will have a material adverse effect on the Company's financial condition and results of operations.

## **CAPITAL EXPENDITURES**

The Company's capital expenditures during 2000, 1999, and 1998 were \$2,962,000, \$918,000 and \$1,545,000, respectively. The increase in capital expenditures in 2000 as compared to prior years is attributable to capital improvements to the Company's Congers, NY and Culver, Indiana facilities. Specific improvement were made to improve the laboratories at both Congers, NY and Culver, Indiana as well as to significantly improve and expand the manufacturing capabilities of both locations. The Company has budgeted for capital expenditures approximately \$2,000,000 in fiscal 2001. Such amounts will be funded from the net proceeds of the Watson Term Loan and the payments to be received by the Company pursuant to each of the Product Acquisition Agreement and Core Products Supply Agreement with Watson.

## **IMPACT OF INFLATION**

The Company believes that inflation did not have a material impact on its operations for the periods reported. Significant increases in labor, employee benefits and other expenses could have a material adverse effect on the Company's performance.

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

The response to this item is submitted as a separate section of this Report commencing on page F-1.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

Not Applicable.

## **PART III**

## **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.**

The information required by Item 10 will be included in the Company's Proxy Statement for the 2001 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 2000, and is hereby incorporated herein by reference to such Proxy Statement.

## **ITEM 11. EXECUTIVE COMPENSATION.**

The information required by Item 11 will be included in the Company's Proxy Statement for the 2001 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 2000, and is hereby incorporated herein by reference to such Proxy Statement.



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

The information required by Item 12 will be included in the Company's Proxy Statement for the 2001 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 2000, and is hereby incorporated herein by reference to such Proxy Statement.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information required by Item 13 will be included in the Company's Proxy Statement for the 2001 Annual Meeting of Shareholders, which will be filed within 120 days after the close of the Company's fiscal year ended December 31, 2000, and is hereby incorporated herein by reference to such Proxy Statement.

## PART IV

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

(a) Financial Statements -- See Index to Financial Statements.

(b) Reports on Form 8-K

No reports on Form 8-K were filed during the last quarter of the fiscal year covered by this Annual Report on Form 10-K.

(c) Exhibits

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

EXHIBIT NUMBER -----	DOCUMENT -----
3.1	Certificate of Incorporation and amendments (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on 10-K for the year ended December 31, 1999).
3.2	Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1993).
3.3	Restated By-Laws (incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report Form 10-K for the year ended December 31, 1998 (the "1998 Form 10-K")).
10.1	Credit Agreement, dated as of December 22, 1992, among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1992 (the "1992 Form 10-K")).
10.2	Amendment Two, dated as of January 12, 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A., together with forms of Stock Warrant and Registration Rights Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1993 (the "1993 Form 10-K")).
10.3	Amendment Three, dated as of May 31, 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1994).
10.4	Amendment Four, dated as of July 1994, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1994).
10.5	Amendment Five, dated as of March 21, 1995, to Credit Agreement among the Registrant and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K dated March 21, 1995 (the "March 8-K")).

EXHIBIT  
NUMBER  
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DOCUMENT  
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- 10.5(1) Form of Warrants issued to The Bank of New York, The Chase Manhattan Bank, N.A. and the Israel Discount Bank (incorporated by reference to Exhibit 10.5(i) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K")).
- 10.5(2) Letter Agreement, dated July 10, 1995, among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 6(a) to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995 (the "June 10-Q")).
- 10.5(3) Letter Agreement, dated November 16, 1995, among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.25(iv) to the 1995 10-K).
- 10.5(4) Amendment 6, dated as of August 6, 1996, to Credit Agreement among Halsey Drug Co., Inc., The Chase Manhattan Bank, N.A., The Bank of New York and Israel Discount Bank of New York (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996 (the "June 1996 10-Q")).
- 10.5(5) Letter Agreement, dated March 25, 1997 among Halsey Drug Co., Inc., The Chase Manhattan Bank, as successor in interest to The Chase Manhattan Bank (National Association), The Bank of New York and Israel Discount Bank.
- 10.6 Agreement Regarding Release of Security Interests dated as of March 21, 1995 by and among the Company, Mallinckrodt Chemical Acquisition, Inc. and The Chase Manhattan Bank, N.A. (incorporated by reference to Exhibit 10.9 of the March 8-K).
- 10.7 Consulting Agreement dated as of September, 1993 between the Registrant and Joseph F. Limongelli (incorporated by reference to Exhibit 10.6 to the 1993 Form 10-K).
- 10.8 Employment Agreement, dated as of January 1, 1993, between the Registrant and Rosendo Ferran (incorporated by reference to Exhibit 10.2 to the 1992 Form 10-K).
- 10.10(1) Halsey Drug Co., Inc. 1984 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.3 to the 1992 Form 10-K).
- 10.10(2) Halsey Drug Co., Inc. 1995 Stock Option and Restricted Stock Purchase Plan (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8, File No. 33-98396).
- 10.10(3) Halsey Drug Co., Inc. Non-Employee Director Stock Option Plan.
- 10.11 Leases, effective February 13, 1989 and January 1, 1990, respectively, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss (incorporated by reference to Exhibits 10.6 and 10.7, respectively, to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1989).
- 10.12 Lease, effective as of April 15, 1988, among the Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, and Rider thereto (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1987).
- 10.12(1) Lease, as of October 31, 1994, among Registrant and Milton J. Ackerman, Sue Ackerman, Lee Hinderstein, Thelma Hinderstein and Marilyn Weiss, together with Modification, Consolidation and Extension Agreement (incorporated by reference to Exhibit 10.12(i) to the 1995 Form 10-K).
- 10.13 Asset Purchase Agreement dated as of March 21, 1995 among Mallinckrodt Chemical Acquisition, Inc. ("Acquisition"), Mallinckrodt Chemical, Inc., as guarantor and the Registrant (incorporated by reference to Exhibit 10.1 to the March 8-K).

EXHIBIT  
NUMBER

## DOCUMENT

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- 10.14 Toll Manufacturing Agreement for APAP/Oxycodone Tablets dated as of March 21, 1995 between Acquisition and the Registrant (incorporated by reference to Exhibit 10.2 to the March 8-K).
- 10.15 Capsule ANDA Option Agreement dated as of March 21, 1995 between Acquisition and the Registrant (incorporated by reference to Exhibit 10.3 to the March 8-K).
- 10.16 Tablet ANDA Noncompetition Agreement dated as of March 21, 1995 between the Registrant and Acquisition (incorporated by reference to Exhibit 10.4 to the March 8-K).
- 10.17 Subordinated Non-Negotiable Promissory Term Note in the amount of \$1,200,00 dated March 21, 1995 issued by the Registrant to Acquisition (incorporated by reference to Exhibit 10.5 to the March 8-K).
- 10.18 Term Note Security Agreement dated as of March 21, 1995 among the Company, Houba, Inc. and Acquisition (incorporated by reference to Exhibit 10.6 to the March 8-K).
- 10.19 Amendment dated March 21, 1995 to Subordination Agreement dated as of July 21, 1994 between Mallinckrodt Chemical, Inc., Mallinckrodt Chemical Acquisition, Inc., the Registrant, The Chase Manhattan Bank (National Association), Israel Discount Bank of New York, The Bank of New York, and The Chase Manhattan Bank (National Association) (incorporated by reference to Exhibit 10.8 to the March 8-K).
- 10.20 Agreement dated as of March 30, 1995 between the Registrant and Zatpack, Inc. (incorporated by reference to Exhibit 10.10 to the March 8-K).
- 10.21 Waiver and Termination Agreement dated as of March 30, 1995 between Zuellig Group, W.A., Inc. and Indiana Fine Chemicals Corporation (incorporated by reference to Exhibit 10.11 to the March 8-K).
- 10.22 Convertible Subordinated Note of the Registrant dated December 1, 1994 issued to Zatpack, Inc. (incorporated by reference to Exhibit 10.12 to the March 8-K).
- 10.23 Agreement dated as of March 30, 1995 among the Registrant, Indiana Fine Chemicals Corporation, Zuellig Group, N.A., Inc., Houba Inc., Zetapharm, Inc. and Zuellig Botanical, Inc. (incorporated by reference to Exhibit 10.13 to the March 8-K).
- 10.24 Supply Agreement dated as of March 30, 1995 between Houba, Inc. and ZetaPharm, Inc. (incorporated by reference to Exhibit 10.14 to the March 8-K).
- 10.25 Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 6(a) to the June 10-Q).
- 10.26 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 6(a) to the June 10-Q).
- 10.27 Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated December 4, 1995 (the "December 8-K")).
- 10.28 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the December 8-K).
- 10.29 Form of 10% Convertible Subordinated Debenture (incorporated by reference to Exhibit 99 to the June 1996 10-Q).
- 10.30 Form of Redeemable Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the June 1996 10-Q).
- 10.31 Form of 5% Convertible Senior Secured Debenture (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated March 24, 1998 (the "March 1998 8-K")).

EXHIBIT  
NUMBER

## DOCUMENT

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- 10.32 Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the March 1998 8-K).
- 10.33 Debenture and Warrant Purchase Agreement dated March 10, 1998, by and among the Registrant, Galen Partners III, L.P. and the other Purchasers listed on the Signature Page thereto (incorporated by reference to Exhibit 10.1 to the March 1998 8-K).
- 10.34 Form of General Security Agreement of Halsey Drug Co., Inc. dated March 10, 1998 (incorporated by reference to Exhibit 10.2 to the March 1998 8-K).
- 10.35 Form of Agreement of Guaranty of Subsidiaries of Halsey Drug Co., Inc. dated March 10, 1998 (incorporated by reference to Exhibit 10.3 to the March 1998 8-K).
- 10.36 Form of Guarantor General Security Agreement dated March 10, 1998 (incorporated by reference to Exhibit 10.4 to the March 1998 8-K).
- 10.37 Stock Pledge Agreement dated March 10, 1998 by and between the Registrant and Galen Partners III, L.P., as agent (incorporated by reference to Exhibit 10.5 to the March 1998 8-K).
- 10.38 Form of Irrevocable Proxy Agreement (incorporated by reference to Exhibit 10.6 to the March 1998 8-K).
- 10.39 Agency Letter Agreement dated March 10, 1998 by and among the Purchasers a party to the Debenture and Warrant Purchase Agreement, dated March 10, 1998 (incorporated by reference to Exhibit 10.7 to the March 1998 8-K).
- 10.40 Press Release of Registrant dated March 13, 1998 (incorporated by reference to Exhibit 99.1 to the March 1998 8-K).
- 10.41 Current Report on Form 8-K as filed by the Registrant with the Securities and Exchange Commission on March 24, 1998.
- 10.42 Letter Agreement between the Registrant and the U.S. Department of Justice dated March 27, 1998 relating to the restructuring of the fine assessed by the Department of Justice under the Plea Agreement dated June 21, 1993.
- 10.43 Employment Agreement dated as of March 10, 1998 between the Registrant and Michael K. Reicher (incorporated by reference to Exhibit 10.43 to the Registrant's Annual Report of Form 10-K for the year ended December 31, 1997 (the "1997 Form 10-K")).
- 10.44 Employment Agreement dated as of March 10, 1998 between the Registrant and Peter Clemens (incorporated by reference to Exhibit 10.44 to the 1997 Form 10-K).
- 10.45 Amended, Restated and Consolidated Bridge Loan Agreement dated as of December 2, 1998 between the Company, Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. and the other signatures thereto (incorporated by reference to Exhibit 10.45 to the 1998 Form 10-K).
- 10.46 First Amendment to Amended, Restated and Consolidated Bridge Loan Agreement dated December 7, 1998 between the Company and the lenders listed on the signature page thereto (incorporated by reference to Exhibit 10.46 to the 1998 Form 10-K).
- 10.47 Second Amendment to Amended, Restated and Consolidated Bridge Loan Agreement dated March 8, 1999 between the Company and the lenders listed on the signature page thereto (incorporated by reference to Exhibit 10.47 to the 1998 Form 10-K).
- 10.48 Form of 10% Convertible Secured Note due May 30, 1999 (incorporated by reference to Exhibit 10.48 to the 1998 Form 10-K).
- 10.49 Form of Common Stock Purchase Warrant issued pursuant to be Amended, Restated and Consolidated Bridge Loan Agreement (incorporated by reference to Exhibit 10.49 to the 1998 Form 10-K).

EXHIBIT  
NUMBER

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- 10.50 Amended and Restated General Security Agreement dated December 2, 1998 between the Company and Galen Partners III, L.P., as Agent (incorporated by reference to Exhibit 10.50 to the 1998 Form 10-K).
- 10.51 Subordination Agreement dated December 2, 1998 between the Registrant and Galen Partners III, L.P., as Agent (incorporated by reference to Exhibit 10.51 to the 1998 Form 10-K).
- 10.52 Agency Letter Agreement dated December 2, 1998 by and among the lenders a party to the Amended, Restated and Consolidated Bridge Loan Agreement, as amended (incorporated by reference to Exhibit 10.52 to the 1998 Form 10-K).
- 10.53 Lease Agreement dated March 17, 1999 between the Registrant and Par Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.53 to the 1998 Form 10-K).
- 10.54 Lease Agreement dated September 1, 1998 between the Registrant and Crimson Ridge Partners (incorporated by reference to Exhibit 10.54 to the 1998 Form 10-K).
- 10.55 Manufacturing and Supply Agreement dated March 17, 1999 between the Registrant and Par Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.55 to the 1998 Form 10-K).
- 10.56 Halsey Drug Co., Inc. 1998 Stock Option Plan (incorporated by reference to Exhibit 10.56 to the 1998 Form 10-K).
- 10.57 Loan Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.57 to the Registrant's Current Report on Form 8-K dated March 29, 2000 (the "March 2000 8-K")).+
- 10.58 Amendment to Loan Agreement dated March 31, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.58 to the March 2000 8-K).
- 10.59 Secured Promissory Note in the principal amount of \$17,500,000 issued by the Registrant, as the maker, in favor of Watson Pharmaceuticals, Inc. dated March 31, 2000 (incorporated by reference to Exhibit 10.59 to the March 2000 8-K).
- 10.60 Watson Security Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.60 to the March 2000 8-K).
- 10.61 Stock Pledge Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.61 to the March 2000 8-K).
- 10.62 Watson Guarantee dated March 29, 2000 between Houba, Inc. and Watson Pharmaceuticals, Inc., as the guarantors, in favor of Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.62 to the March 2000 8-K).
- 10.63 Watson's Guarantors Security Agreement dated March 29, 2000 between Halsey Pharmaceuticals, Inc., Houba, Inc. and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.63 to the March 2000 8-K).
- 10.64 Subordination Agreement dated March 29, 2000 by and among the Registrant, Watson Pharmaceuticals, Inc. and the holders of the Registrant's outstanding 5% convertible debentures due March 10, 2003. (incorporated by reference to Exhibit 10.64 to the March 2000 8-K).+
- 10.65 Real Estate Mortgage dated March 29, 2000 between Houba, Inc. and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.65 to the March 2000 8-K).
- 10.66 Subordination Agreement by and among Houba, Inc., Galen Partners, III, L.P., Oracle Strategic Partners, L.P. and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.66 to the March 2000 8-K).
- 10.67 Product Purchase Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.67 to the March, 2000 8-K).+

EXHIBIT NUMBER -----	DOCUMENT -----
10.68	Finished Goods Supply Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.68 to the March 2000 8-K).+
10.69	Active Ingredient Supply Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.69 to the March 2000 8-K).+
10.70	Right of First Negotiation Agreement dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.70 to the March 2000 8-K).+
10.71	Finished Goods Supply Agreement (Core Products) dated March 29, 2000 between the Registrant and Watson Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.71 to the March 2000 8-K).+
10.72	Debenture and Warrant Purchase Agreement dated May 26, 1999 by and among the Registrant, Oracle Strategic Partners, L.P. and the other purchasers listed on the signature page thereto (the "Oracle Purchase Agreement") (incorporated by reference to Exhibit 10.72 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
10.73	Form of 5% Convertible Senior Secured Debenture issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.73 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
10.74	Form of Common Stock Purchase Warrant issued pursuant to the Oracle Purchase Agreement (incorporated by reference to Exhibit 10.74 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
10.75	Lease Termination and Settlement Agreement dated March 20, 2000 between the Registrant and Atlantic Properties Company in respect of the Registrant's Brooklyn, New York leased facility (incorporated by reference to Exhibit 10.75 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1999).
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 22 to the 1993 Form 10-K).
*23.1	Consent of Grant Thornton LLP, independent certified public accountants.

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\* Filed herewith.

+ A portion of this exhibit has been omitted pursuant to an application for confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## SIGNATURES

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

### HALSEY DRUG CO., INC.

By: /s/ MICHAEL REICHER

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

Date: March 26, 2001

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ WILLIAM G. SKELLY ----- William G. Skelly	Director	March 26, 2001
/s/ MICHAEL REICHER ----- Michael Reicher	Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2001
/s/ GERALD F. PRICE ----- Gerald F. Price	President and Director	March 26, 2001
/s/ PETER CLEMENS ----- Peter Clemens	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer) and Director	March 26, 2001
/s/ ALAN J. SMITH ----- Alan J. Smith	Director	March 26, 2001
/s/ BRUCE F. WESSON ----- Bruce F. Wesson	Director	March 26, 2001
/s/ WILLIAM SUMNER ----- William Sumner	Director	March 26, 2001
/s/ SRINI CONJEEVARAM ----- Srini Conjeevaram	Director	March 26, 2001
/s/ ZUBEEN SHROFF ----- Zubeen Shroff	Director	March 26, 2001
/s/ JOEL LIFFMANN ----- Joel Liffmann	Director	March 26, 2001

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## REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors  
Halsey Drug Co., Inc.

We have audited the accompanying consolidated balance sheets of Halsey Drug Co., Inc. and Subsidiaries as of December 31, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Halsey Drug Co., Inc. and Subsidiaries as of December 31, 2000 and 1999, and the consolidated results of their operations and their consolidated cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States of America.

**GRANT THORNTON LLP**

New York, New York  
February 16, 2001

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**

	DECEMBER 31,	
	2000	1999
	(IN THOUSANDS)	
<b>CURRENT ASSETS</b>		
Cash.....	\$ 697	\$ 786
Accounts receivable -- trade, net of allowances for doubtful accounts of \$315 and \$425 in 2000 and 1999, respectively.....	4,132	2,716
Inventories.....	2,769	3,502
Prepaid expenses and other current assets.....	545	213
	-----	-----
Total current assets.....	8,143	7,217
PROPERTY, PLANT AND EQUIPMENT, NET.....	5,332	3,013
DEFERRED PRIVATE OFFERING COSTS.....	1,138	1,623
OTHER ASSETS AND DEPOSITS.....	596	642
	-----	-----
	\$15,209	\$12,495
	=====	=====
<b>CURRENT LIABILITIES</b>		
Notes payable.....	\$ 1,844	\$ 4,038
Accounts payable.....	2,671	2,283
Accrued expenses.....	5,889	5,777
Department of Justice Settlement.....	300	300
	-----	-----
Total current liabilities.....	10,704	12,398
CONVERTIBLE SUBORDINATED DEBENTURES, NET.....	44,779	41,096
TERM NOTE PAYABLE.....	12,000	--
DEPARTMENT OF JUSTICE SETTLEMENT.....	1,075	1,375
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Common stock -- \$.01 par value; authorized, 80,000,000 shares; issued 14,961,316 shares and 14,829,511 shares in 2000 and 1999, respectively.....	149	148
Additional paid-in capital.....	35,440	35,751
Accumulated deficit.....	(88,938)	(77,284)
	-----	-----
Less treasury stock -- at cost (439,603 shares).....	(53,349)	(41,385)
	-----	-----
	(53,349)	(42,374)
	-----	-----
	\$15,209	\$12,495
	=====	=====

The accompanying notes are an integral part of these statements.

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
	-----		
	(IN THOUSANDS, EXCEPT PER SHARE DATA)		
Net product revenues.....	\$ 20,223	\$ 11,420	\$ 8,841
Operating costs			
Cost of manufacturing.....	18,743	15,316	12,712
Research and development.....	1,821	1,075	651
Selling, general and administrative expenses.....	6,208	7,383	8,078
Plant shutdown costs.....	53	3,220	--
	-----		
Loss from operations.....	(6,602)	(15,574)	(12,600)
Other income(expense)			
Interest expense, net.....	(3,037)	(2,851)	(1,285)
Amortization of deferred debt discount and private offering costs.....	(2,448)	(1,825)	(661)
Other.....	44	187	1,822
	-----		
Loss before income tax benefit.....	(12,043)	(20,063)	(12,724)
Income tax benefit.....	389	--	--
	-----		
NET LOSS.....	\$(11,654)	\$(20,063)	\$(12,724)
	=====		
Basic and diluted loss per common share.....	\$ (.80)	\$ (1.40)	\$ (.92)
	=====		
Weighted average number of outstanding shares.....	14,503	14,326	13,813
	=====		

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, 2000, 1999 AND 1998**

	COMMON STOCK, \$.01 PAR VALUE		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TREASURY STOCK, AT COST		TOTAL
	SHARES	AMOUNT			SHARES	AMOUNT	
				(IN THOUSANDS)			
Balance at December 31, 1997.....	14,030	\$140	\$25,489	\$(44,497)	(440)	\$(989)	\$(19,857)
Issuance of shares -- conversion of notes payable.....	110	1	213				214
Issuance of shares as payment of interest.....	263	3	592				595
Issuance of shares -- settlement of trade payables.....	40		55				55
Deferred debt discount on warrants issued with convertible debentures....			2,764				2,764
Net loss for the year ended December 31, 1998.....				(12,724)			(12,724)
Balance at December 31, 1998 (carried forward).....	14,443	144	29,113	(57,221)	(440)	(989)	(28,953)
Balance at December 31, 1998 (brought forward).....	14,443	144	29,113	(57,221)	(440)	(989)	(28,953)
Issuance of shares as payment of interest.....	322	3	524				527
Deferred debt discount on warrants and private issuance costs.....			5,641				5,641
Warrants issued for acquisition of ANDA.....			350				350
Exercise of warrants.....	29	1	49				50
Issuance of shares as payment of legal fees.....	26		50				50
Issuance of shares as payment of payables.....	10		24				24
Net loss for the year ended December 31, 1999.....				(20,063)			(20,063)
Balance at December 31, 1999 (carried forward).....	14,830	148	35,751	(77,284)	(440)	(989)	(42,374)
Balance at December 31, 1999 (brought forward).....	14,830	148	35,751	(77,284)	(440)	(989)	(42,374)
Issuance of shares as payment of Interest.....	90	1	251				252
Conversion of debentures.....	9	--	12				12
Deferred private issuance costs.....			125				125
Issuance of shares as payment of legal fees.....	12	--	15				15
Issuance of shares as payment of payables.....	20	--	23				23
Reissuance of treasury stock.....			(737)		440	989	252
Net loss for the year ended December 31, 2000.....				(11,654)			(11,654)
<b>BALANCE AT DECEMBER 31, 2000.....</b>	<b>14,961</b>	<b>\$149</b>	<b>\$35,440</b>	<b>\$(88,938)</b>	<b>--</b>	<b>\$ --</b>	<b>\$(53,349)</b>

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,		
	2000	1999	1998
(IN THOUSANDS)			
Cash flows from operating activities			
Net loss.....	\$(11,654)	\$(20,063)	\$(12,724)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization.....	644	914	1,113
Amortization of deferred debt discount and private offering costs.....	2,509	1,825	661
Provision for losses on accounts receivable.....	(110)	145	(262)
(Gain) loss on disposal of assets.....	(93)	1,709	--
Stock issued for legal expense.....	15	50	--
Stock issued for trade payables.....	23	24	--
Debentures and stock issued for interest expense.....	1,858	939	170
Changes in assets and liabilities			
Accounts receivable.....	(1,306)	(1,422)	(1,115)
Inventories.....	732	2,852	(3,898)
Prepaid expenses and other current assets.....	(170)	(65)	126
Other assets and deposits.....	(38)	(157)	--
Accounts payable.....	388	399	(4,197)
Deferred gain.....	--	--	(1,900)
Other liabilities.....	--	(549)	--
Accrued expenses.....	474	1,444	(2,665)
Total adjustments.....	4,926	8,108	(11,967)
Net cash used in operating activities.....	(6,728)	(11,955)	(24,691)
Cash flows from investing activities			
Capital expenditures.....	(2,962)	(918)	(1,545)
Investment in joint venture.....	(113)	--	--
Net proceeds from sale of assets.....	93	69	96
Net cash provided by (used in) investing activities....	(2,982)	(849)	(1,449)
Cash flows from financing activities			
Proceeds from issuance of notes payable.....	13,800	4,000	6,495
Payments to Department of Justice.....	(300)	(300)	(178)
Bank overdraft.....	--	--	(159)
Due to banks.....	--	--	(2,476)
Payments on notes payable.....	(4,006)	(9,464)	--
Proceeds from issuance of convertible subordinated Debentures.....	--	17,862	25,800
Proceeds from exercise of stock warrants.....	--	49	--
Reissuance of treasury stock.....	252	--	--
Deferred private offering costs.....	(125)	(407)	(1,518)
Net cash provided by financing activities.....	9,621	11,740	27,964
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS...	(89)	(1,064)	1,824
Cash and cash equivalents at beginning of year.....	786	1,850	26
Cash and cash equivalents at end of year.....	\$ 697	\$ 786	\$ 1,850

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS -- (CONTINUED)**  
**YEAR ENDED DECEMBER 31,**  
**(IN THOUSANDS)**

Supplemental disclosures of noncash investing and financing activities:

**YEAR ENDED DECEMBER 31, 2000**

1. The Company issued 89,638 and 32,000 shares of common stock as payment for \$252,113 in debenture accrued interest and \$38,000 in trade payables and legal expenses.
2. The Company issued warrants to purchase 125,000 shares of common stock for the extension of the 2000 Galen Bridge Loan(s) maturity dates and recorded \$124,750 as deferred private issuance costs. The issuance costs were fully expensed during 2000.
3. The Company issued \$1,858,190 of debentures as payment for like amounts of debenture accrued interest.
4. Debentures of \$12,403 were converted into 8,834 shares of the Company's common stock.
5. The Company has paid \$1,002,845 of indebtedness in the form of product deliveries.

**YEAR ENDED DECEMBER 31, 1999**

1. The Company issued 321,777 shares of common stock as payment for \$526,779 in accrued interest.
2. The Company issued 26,106 shares of common stock as payment for \$50,500 in legal fees and 9,846 shares of common stock as payment for \$24,000 in trade payables.
3. The Company issued approximately 3,608,604 warrants (Note H) valued and recorded in the aggregate as \$5,234,000 of unamortized debt discount and a reduction in the amount of the related obligation.
4. The Company converted approximately \$6,609,000 of notes payable and approximately \$428,000 of accrued interest on notes payable into convertible subordinated debentures.
5. The Company converted approximately \$939,000 of accrued interest due from convertible subordinated debentures into additional debentures.
6. The Company issued 1,022,284 warrants for funding fees valued and recorded as \$907,000 in deferred private issuance costs.
7. The Company issued 500,000 warrants to Barr Laboratories, Inc. valued and recorded as \$350,000 for the acquisition of certain product rights.

**YEAR ENDED DECEMBER 31, 1998**

1. The Company issued 262,836 shares of common stock as payment for \$593,313 in accrued interest.
2. The Company reissued 20,000 shares of common stock as payment for \$25,000 in legal fees and 20,000 shares of common stock as payment for \$30,000 in trade payables.
3. The Company issued 110,658 shares of common stock as payment of outstanding notes payable in amounts of \$214,000 and \$1,782 in accrued interest.
4. The Company issued approximately 5,500,086 warrants (Note H) valued and recorded in the aggregate as \$2,263,434 of unamortized debt discount and a reduction in the amount of the related obligation.

The accompanying notes are an integral part of these statements.

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2000, 1999 AND 1998**

**NOTE A -- SUMMARY OF ACCOUNTING POLICIES**

Halsey Drug Co., Inc. (the "Company" or "Halsey"), a New York corporation established in 1935, and its subsidiaries, are engaged in the development, manufacture, sale, and distribution of generic drugs and active pharmaceutical ingredients ("APIs"). The Company is an emerging pharmaceutical company specializing in innovative drug development.

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., Indiana Fine Chemicals Corporation, Cenci Powder Products, Inc., H.R. Cenci Laboratories, Inc., and The Medi-Gum Corporation. Except for Houba, Inc., all of the other subsidiaries are inactive. All material intercompany accounts and transactions have been eliminated.

**2. Inventories**

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

**3. Property, Plant and Equipment**

Property, plant and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization are provided for in amounts sufficient to relate the cost of depreciable assets to operations over their estimated service lives, principally on a straight-line basis. The estimated lives used in determining depreciation and amortization are:

Buildings.....	25 years
Machinery and equipment.....	5-10 years

**4. Deferred Debt Discount and Private Issuance Costs**

Debt discount resulting from the issuance of stock warrants in connection with the issuance of subordinated debt (Note H) is recorded as a reduction of the related obligations and is amortized over the remaining life of the related obligations. Debt discount is determined by a calculation which is based, in part, by the relative fair values ascribed to such warrants determined by an independent valuation or management's use of the Black-Scholes valuation model. Deferred private issuance costs resulting from the issuance of warrants in connection with the extension of bridge loan maturity dates are recorded as deferred assets and amortized over the remaining life of the related obligations.

**5. Income Taxes**

The Company accounts for income taxes under the liability method in accordance with Statement of Financial Accounting Standards ("SFAS") No. 109, "Accounting for Income Taxes." Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

## HALSEY DRUG CO., INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

#### 6. Statements of Cash Flows

For purposes of the statements of cash flows, the Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. The Company paid no substantial income taxes for the years ended December 31, 2000, 1999 and 1998. In addition, the Company paid interest of approximately \$1,253,000, \$720,000 and \$1,946,000, respectively, for the years ended December 31, 2000, 1999 and 1998.

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

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

#### 8. Research and Development Costs

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

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

The Company reviews long-lived assets and certain identifiable intangibles held and used for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. See Note K for the impairment charge related to the write-off of leasehold improvements of the Company's Brooklyn, New York Plant.

#### 10. Stock-Based Compensation

The Company has elected to follow Accounting Principles Board Opinion No. 25 ("APB No. 25") "Accounting for Stock Issued to Employees," and related interpretations in accounting for its stock options issued to employees. Under APB No. 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized. However, Statement of Financial Accounting Standards No. 123 ("SFAS No. 123"), "Accounting for Stock-Based Compensation," requires presentation of pro forma net income as if the Company had accounted for its employees stock options under the fair value method of that statement.

Equity instruments issued to nonemployees in exchange for goods, fees and services are accounted for under the fair value method of SFAS No. 123.

#### 11. Earnings (Loss) Per Share

The computation of basic earnings (loss) per share of common stock is based upon the weighted average number of common shares outstanding during the period. Diluted earnings per share is based on basic earnings per share adjusted for the effect of other potentially dilutive securities. Excluded from the 2000, 1999 and 1998 computation are warrants and options outstanding which would be antidilutive.

#### 12. Revenue Recognition

The Company recognizes revenue, net of sales discounts and allowances, when title to product passes to customers. Revenue on contractual product sales is recognized on the higher of the minimum amounts required to be purchased or products shipped.



## HALSEY DRUG CO., INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

#### 13. New Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133 ("SFAS No. 133"), "Accounting for Derivative Instruments and Hedging Activities," which establishes accounting and reporting standards for derivative instruments and for hedging activities. SFAS No. 133, as amended by SFAS No. 138, is effective for all fiscal quarters of fiscal years beginning after June 15, 2000. The Company does not anticipate that the adoption of the statement will have a material impact on its financial statements.

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

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

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

The Company and Watson also executed a right of first negotiation agreement providing Watson with a first right to negotiate the terms under which the Company would manufacture and supply certain specified APIs and finished dosage products to be developed by the Company. The right of first negotiation agreement provides that upon Watson's exercise of its right to negotiate for the supply of a particular product, the parties will negotiate the specific terms of the manufacturing and supply arrangement, including price, minimum purchase requirements, if any, territory and term. In the event Watson does not exercise its right of first negotiation upon receipt of written notice from the Company as to its receipt of applicable governmental approval relating to a covered product, or in the event the parties are unable to reach agreement on the material terms of a supply arrangement relating to such product within sixty days of Watson's exercise of its right to negotiate for such product, the Company may negotiate with third parties for the supply, marketing and sale of the applicable product. The right of first negotiation agreement has a term of ten years, subject to extension in the absence of written notice from either party for two additional periods of five years each. The right of first negotiation agreement applies only to API and finished dosage products identified in the agreement and does not otherwise prohibit the Company from developing other APIs or finished dosage products for itself or third parties.

The Company and Watson also completed a manufacturing and supply agreement providing for Watson's marketing and sale of the Company's existing core products portfolio (the "Core Products Supply Agreement"). The Core Products Supply Agreement obligates Watson to purchase a minimum amount of approximately \$18,363,000 (the "Minimum Purchase Amount") in core products from the Company, in equal quarterly installments over a period of 18 months (the "Minimum Purchase Period"). At the expiration of the Minimum Purchase Period, if Watson does not continue to satisfy the Minimum Purchase Amount, the Company may market and sell the core products on its own or through a third party. Pending the Company's development and receipt of regulatory approval for its APIs and finished dosage products currently under

# HALSEY DRUG CO., INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

development, including, without limitation, the Product sold to Watson, and the marketing and sale of same, of which there can be no assurance, substantially all the Company's revenues expect to be derived from the Core Products Supply Agreement with Watson.

The final component of the Company's strategic alliance with Watson provided for Watson's extension of a \$17,500,000 term loan to the Company. The loan will be funded in installments upon the Company's request for advances and the provision to Watson of a supporting use of proceeds relating to each such advance. The loan is secured by a first lien on all of the Company's assets, senior to the lien securing all other Company indebtedness, carries a floating rate of interest equal to prime plus two percent and matures on March 31, 2003. As of December 31, 2000, Watson advanced \$12,000,000 to the Company (Note I).

### NOTE C -- LIQUIDITY MATTERS

At December 31, 2000, the Company had a working capital deficiency of approximately \$2,561,000, had an accumulated deficit of approximately \$88,938,000 and had incurred a loss of approximately \$11,654,000 for the year then ended.

The net proceeds from the Watson Term Loan have permitted the Company to satisfy its current liabilities and accounts payable. In addition, management believes that additional proceeds from the Watson Term Loan combined with the payments to be received by the Company from Watson under each of the Product Acquisition Agreement and the Core Products Supply Agreement will provide the Company with sufficient working capital to fund operations for at least the next twelve months. However, any delay in the receipt of funds from Watson could hamper the Company's ability to operate.

### NOTE D -- CARRYING AMOUNT AND FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying amount of cash and cash equivalents, accounts receivable and accounts payable approximates fair value due to the short-term maturities of the instruments. The fair value of the Company's long-term and short-term debt cannot be determined without incurring excessive costs.

### NOTE E -- INVENTORIES

Inventories consist of the following:

	DECEMBER 31,	
	2000	1999
	(IN THOUSANDS)	
Finished goods.....	\$ 225	\$ 725
Work-in-process.....	1,146	720
Raw materials.....	1,398	2,057
	\$2,769	\$3,502
	=====	=====

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)**

**NOTE F -- PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment are summarized as follows:

	DECEMBER 31,	
	2000	1999
	(IN THOUSANDS)	
Machinery and equipment.....	\$11,411	\$12,806
Construction in progress.....	2,694	87
Leasehold improvements.....	106	82
Building and building improvements.....	1,000	990
Land.....	44	44
	-----	-----
	15,255	14,009
Less accumulated depreciation and amortization.....	9,923	10,996
	-----	-----
	\$ 5,332	\$ 3,013
	=====	=====

Depreciation and amortization expense for the years ended December 31, 2000, 1999 and 1998 was approximately \$643,000, \$914,000 and \$1,113,000, respectively.

**NOTE G -- ACCRUED EXPENSES**

Accrued expenses are summarized as follows:

	DECEMBER 31,	
	2000	1999
	(IN THOUSANDS)	
Payroll taxes payable.....	--	\$1,503
Rent.....	--	1,454
Interest.....	\$1,041	764
Accrued payroll.....	323	736
Professional fees.....	195	362
Deferred product obligation.....	2,846	--
Other.....	1,484	958
	-----	-----
	\$5,889	\$5,777
	=====	=====

At December 31, 1999, payroll taxes payable included approximately \$1,467,000 and \$31,000 of delinquent payroll taxes (including penalties and interest) due to the Internal Revenue Service and the State of New York, respectively, all of which liability was incurred in 1997 and 1996. Pursuant to an NOL carryback claim, the Company applied to the IRS for a refund of past taxes paid. During the year, the Company settled all claims owed to the IRS for delinquent payroll taxes net of any amounts due to the Company for NOL carryback claims. The claims resulted in \$723,534 of back taxes paid to be credited to the Company, of which \$334,838 was refunded in January 2001.

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)**

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

At December 31, 2000 and 1999 convertible subordinated debentures outstanding and related debt discount related to the following issuances are discussed below:

	DECEMBER 31,	
	2000	1999
ISSUANCE OF DEBENTURES	(IN THOUSANDS)	
Debentures -- August 1996(a).....	\$ 2,500	\$ 2,500
Debentures -- March 1998(b).....	20,790	20,800
Debentures -- issued in lieu of interest for March 1998(b).....	1,587	667
Debentures -- June 1998(c).....	4,998	5,000
Debentures -- issued in lieu of interest for June 1998(c).....	378	158
Debentures -- May 1999(d) and (e).....	12,862	12,862
Debentures -- issued in lieu of interest for May 1999(d) and (e).....	642	114
Debentures -- July 1999(d) and (e).....	5,000	5,000
Debentures -- issued in lieu of interest for July 1999(d) and (e).....	189	--
	48,946	47,101
Less: Debt discount.....	(4,167)	(6,005)
	\$44,779	\$41,096

(a) On August 6, 1996, the Company issued 250 units, at \$10,000 per unit, in a private placement of its securities ("August Private Placement"). Each unit consisted of: (i) a 10% convertible subordinated debenture due August 6, 2001 in the principal amount of \$10,000, interest payable quarterly, and convertible into shares of the Company's common stock at a conversion price of \$3.25 per share, subject to dilution, and (ii) 461 redeemable common stock purchase warrants ("warrants"). Each warrant entitled the holder to purchase one share of common stock for \$3.25, subject to adjustment during the five-year period commencing August 6, 1996.

(b) On March 10, 1998, the Company completed a private offering (the "Galen Offering") of securities to an investor group ("Galen") consisting of 5% convertible senior secured debentures due March 15, 2003, and common stock purchase warrants (with a seven-year life) exercisable for 2,244,667 shares of the Company's common stock at an exercise price of \$1.404 and 2,189,511 shares at an exercise price of \$2.279. The debentures are convertible into shares of the Company's common stock at a conversion price of \$1.404. The net proceeds to the Company from the Offering, after the deduction of related offering expenses of \$1,518,000 for legal and investment banker fees, was approximately \$19,300,000. These related offering costs are being amortized over the remaining five-year life of the related debentures.

(c) In June of 1998, Galen invested an additional \$5,000,000 in the Company in exchange for debentures and warrants having terms identical to those issued in the Galen Offering (539,583 and 526,325 common stock purchase warrants with an exercise price of \$1.404 and \$2.279, respectively).

(d) On May 26, 1999, the Company consummated a private offering of securities for an aggregate purchase price of up to \$22,800,000 (the "Oracle Offering"). The securities issued in the Oracle Offering consisted of 5% convertible senior secured debentures (the "1999 Debentures") and common stock purchase warrants (the "1999 Warrants"), each of which are substantially similar to the debentures and warrants issued by the Company in the Galen Offering completed in March, 1998. Of the \$22,800,000 to be invested pursuant to the Oracle Offering, \$5,000,000 was funded by Oracle Strategic Partners, L.P. ("Oracle") on May 26, 1999, the closing date of the Oracle Offering, with an additional \$10,000,000 to be funded by Oracle in two installments of \$5,000,000 each. The first \$5,000,000 installment of the additional \$10,000,000 Oracle investment was

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)**

funded on July 27, 1999. Pursuant to an agreement reached between the Company and Oracle on March 20, 2000, the final \$5,000,000 investment has been waived.

The 1999 Debentures were issued at par and will become due and payable as to principal on March 15, 2003. Approximately \$12,800,000 in principal amount of the 1999 Debentures were issued on May 26, 1999. Interest on the principal of the 1999 Debentures is accrued at the rate of 5% per annum and is payable on a quarterly basis.

The 1999 Debentures are convertible into shares of the Company's common stock at a conversion price of \$1.404 per share, for an aggregate of up to approximately 12,678,063 shares of the Company's common stock. The 1999 Warrants are exercisable for an aggregate of approximately 4,618,702 shares of the Company's common stock. Of such warrants, 2,309,351 warrants are exercisable at \$1.404 per share and the remaining 2,309,351 warrants are exercisable at \$2.279 per share. The 1999 Debentures and 1999 Warrants are convertible and exercisable, respectively, for an aggregate of approximately 17,296,765 shares of the Company's common stock.

(e) Approximately \$7,037,000 of the 1999 Debentures issued pursuant to the Oracle Offering were issued in exchange for the surrender of a like amount of principal and accrued interest outstanding under the Company's convertible promissory notes issued pursuant to various bridge loan transactions with Galen Partners III, L.P., Galen Partners International III, L.P., Galen Employee Fund III, L.P. (collectively, "Galen") and certain other investors in the aggregate amount of \$10,104,110 during the period from August 1998 through and including May 1999 (the "1999 Galen Bridge Loans"). In exchange for Galen and other investors granting extensions on maturity dates of the Company's convertible promissory notes, the Company issued 1,022,284 common stock purchase warrants at exercise prices ranging from \$1.18 to \$2.32. These warrants resulted in deferred private offering costs which are being amortized over the remaining five-year life of the related obligations. All amounts outstanding under the Galen Bridge Loans were repaid in 2000.

(f) In connection with certain 1995 amendments to a line of credit agreement then existing with a bank, the Company issued stock warrants to the bank, which expired July 17, 2000, to purchase shares of the Company's common stock at various exercise prices per share, subject to certain antidilution provisions. At December 31, 1999, the number of common stock warrants, as adjusted, equal 955,509 shares at exercise prices ranging from \$1.48 to \$1.51 per share. In March 1998, the Company completely satisfied its bank indebtedness and terminated the line of credit agreement.

Debt discount resulting from the issuance of stock warrants in connection with the issuance of subordinated debt is recorded as a reduction of the related obligations at the warrants relative fair value and is amortized as additional expense over the remaining life of the related obligations. At December 31, 2000 outstanding warrants giving rise to debt discount for related debentures are as follows:

WARRANTS RELATED TO DEBENTURES ABOVE	EXERCISE PRICES	NUMBER OF WARRANTS	ORIGINAL DEBT DISCOUNT	ACCUMULATED AMORTIZATION AT DECEMBER 31, 2000	UNAMORTIZED DEBT DISCOUNT AT DECEMBER 31, 2000	REMAINING LIFE (MONTHS)
(IN THOUSANDS)						
(a)	\$ 3.25	115,250	\$ 355	\$ 308	\$ 47	8
(b)	\$1.404 and \$2.279	4,434,178	2,263	1,245	1,018	27
(c)	\$1.404 and \$2.279	1,065,908	1,200	497	703	34
(d)	\$1.404 and \$2.279	3,608,604	4,034	1,635	2,399	27
(f)	\$ 1.48 to \$1.51	955,509	200	200	--	--
		10,179,449	\$8,052	\$3,885	\$4,167	

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)**

At December 31, 2000 outstanding warrants giving rise to deferred private offering costs are as follows:

WARRANTS	EXERCISE PRICES	NUMBER OF WARRANTS	ORIGINAL DEFERRED PRIVATE ISSUANCE COSTS	ACCUMULATED AMORTIZATION AT DECEMBER 31, 2000	UNAMORTIZED PRIVATE ISSUANCE COSTS AT DECEMBER 31, 2000	REMAINING LIFE (MONTHS)
(e)	\$ 1.18 to \$2.32	1,022,284	\$ 907	\$ 363	\$ 544	36

**NOTE I -- NOTES PAYABLE**

At December 31, 2000 and 1999, notes payable consisted of the following:

	DECEMBER 31,	
	2000	1999
	(IN THOUSANDS)	
Unsecured promissory demand notes(a).....	\$ 1,844	\$2,529
Bridge Loans(b).....	--	1,509
	\$ 1,844	\$4,038
Term note payable(c).....	\$12,000	\$ --

(a) At December 31, 2000, unsecured promissory demand notes consisted of \$1,376,000 due to Mylan, \$400,000 unsecured promissory demand notes due to Wastson and \$68,000 due to a former employee. During the period from May 1997 through June 1997, the Company borrowed approximately \$3 million from Mylan Laboratories, Inc. ("Mylan") pursuant to five unsecured, demand promissory notes. The advances made by Mylan Laboratories, Inc. were part of a proposed investment by Mylan in the Company, including the proposed purchase of the Company's Indiana facility as well as a partial tender offer for the Company's common stock. To date, \$1,624,000 has been paid by the Company to Mylan against such indebtedness in the form of product deliveries to Mylan. Pursuant to an agreement reached between the parties, the Company is required to satisfy interest on the outstanding indebtedness on an annual basis while the indebtedness remains outstanding and to satisfy the principal amount of such indebtedness in the form of product deliveries to Mylan until such time as the indebtedness is satisfied in full.

(b) In addition to the 1999 Galen Bridge Loans discussed in Note H, the Company secured bridge financing from Galen in order to provide necessary working capital prior to the completion of the Watson Term Loan as described in Note B. These bridge loans aggregated approximately \$3,300,000 and were funded through six separate bridge loan transactions during the period from December 8, 1999 through March 29, 2000 (collectively, the "2000 Galen Bridge Loans"). At December 31, 1999, \$1,509,000 relating to such bridge loans was outstanding. On March 31, 2000, the total principal amount of the 2000 Galen Bridge Loans and accrued and unpaid interest were satisfied in full with a portion of the proceeds of the Watson Term. Prior to repayment, the 2000 Galen Bridge Loans accrued interest at the rate of 18% per annum and were secured by a first lien on all of the Company's assets. In consideration for the extension of the 2000 Galen Bridge Loans, the Company issued common stock purchase warrants to Galen to purchase an aggregate of 125,000 shares of the Company's common stock. All amounts outstanding under the 1999 and 2000 Galen Bridge Loans were repaid in 2000.

The warrants issued pursuant to the 2000 Galen Bridge Loans have an exercise price equal to the fair market value of the Company's common stock on the date of issuance and are substantially identical to those issued by the Company in the Oracle Offering (Note H).

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)**

(c) In connection with various strategic alliance transactions, Watson Pharmaceuticals advanced \$12,000,000 to the Company under a term loan. The loan is secured by a first lien on all of the Company's assets, senior to the lien securing all other Company indebtedness, and carries a floating rate of interest equal to prime plus two percent and matures on March 31, 2003.

**NOTE J -- INCOME TAXES**

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

	YEAR ENDED DECEMBER 31,					
	2000		1999		1998	
	AMOUNT	%	AMOUNT	%	AMOUNT	%
	(DOLLARS IN THOUSANDS)					
Federal statutory rate.....	\$(4,095)	(34.0)%	\$(6,116)	(34.0)%	\$(4,326)	(34.0)%
Loss for which no tax benefit was provided.....	4,045	33.6	5,997	33.8	4,247	33.8
Federal tax carryback refund.....	(389)	(3.4)				
Department of Justice settlement.....	26	.2	31	.1	42	.1
Other.....	24	.2	88	.1	37	.1
Actual tax benefit.....	\$ (389)	(3.4)%	\$ --	--%	\$ --	--%
	=====	=====	=====	=====	=====	=====

The Company has net operating loss carryforwards aggregating approximately \$73,549,425, expiring during the years 2011 through 2020. In addition, certain of the Company's subsidiaries filed separate Federal income tax returns in prior years and have separate net operating loss carryforwards aggregating approximately \$5,296,385 expiring during the years 2001 through 2018.

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

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)**

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

	DECEMBER 31,	
	2000	1999
	( IN THOUSANDS )	
Deferred tax assets		
Net operating loss carryforwards.....	\$33,805	\$27,349
Allowance for doubtful accounts.....	133	50
Research and development tax credit.....	212	212
Reserve for inventory.....	235	218
Reserve for chargebacks.....	105	21
Shutdown costs.....	780	1,352
Severance package.....	45	242
Litigation settlement.....	135	44
Rent.....	--	44
Reserve for Medicaid.....	37	93
Capital loss carryforwards.....	210	210
Reserve for contingencies.....	--	14
Charitable contribution carryforwards.....	6	1
Other.....	49	26
	-----	-----
Gross deferred tax assets.....	35,752	29,876
	-----	-----
Deferred tax liabilities		
Depreciation.....	(559)	(430)
Other.....	(42)	(42)
	-----	-----
	(601)	(472)
	-----	-----
Net deferred tax assets before valuation allowance.....	35,151	29,404
Valuation allowance.....	(35,151)	(29,404)
	-----	-----
Net deferred tax assets.....	\$ --	\$ --
	=====	=====

SFAS No. 109 requires a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. The valuation allowance at December 31, 2000 primarily pertains to uncertainties with respect to future utilization of net operating loss carryforwards.

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

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

At December 31, 1999 the Company was obligated to pay rent through December 31, 2005 pursuant to a noncancellable lease obligation for its facility in Brooklyn, New York. Under a termination and settlement agreement consummated on March 22, 2000 (the "Settlement Agreement"), in exchange for a termination payment of \$1,150,000, the termination of the lease has been accelerated to August 31, 2000. The total base rent payments that would have been required from September 1, 2000 to December 31, 2005, were



## HALSEY DRUG CO., INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

approximately \$6,715,000. The agreement does allow the Company to continue to lease the facility beyond August 31, 2000, but requires the Company to vacate the premises no later than March 31, 2001, which is the date the Company will vacate the Brooklyn facility. In addition, the Settlement agreement provides for the advance payment of rent through August 31, 2000 and a restoration escrow deposit of \$200,000 for plant repairs. The Company also deposited in escrow with its counsel \$390,600 which represents rental payments for the period September 1, 2000 through March 31, 2001. The Company funded the termination fee payment, the advance rental payment obligations and restoration amount required pursuant to the Settlement Agreement with the proceeds received from the Watson Term Loan (Note B).

At December 31, 2000, the Company recorded a charge of approximately \$53,000 representing additional severance costs.

#### NOTE L -- SALE AND ACQUISITION OF ABBREVIATED NEW DRUG APPLICATIONS ("ANDA")

##### Sale of ANDA

On March 21, 1995, the Company sold its ANDA for 5mg Oxycodone HCL/325mg Acetaminophen Tablets ("Tablets") and certain equipment used in the production of the tablets. Pursuant to the agreement, the Company recognized the final portion of the gain, \$1,900,000, as other income in March 1998.

##### Acquisition of Barr Laboratories, Inc. ANDA

On April 16, 1999, the Company completed an acquisition agreement with Barr Laboratories, Inc. ("Barr") providing for the Company's purchase of the rights to 50 pharmaceutical products (the "Barr Products"). Under the terms of the acquisition agreement with Barr, the Company acquired all of Barr's rights in the Barr Products, including all related governmental approvals (including ANDAs) and related technical data and information. In consideration for the acquisition of the Barr Products, the Company issued to Barr a common stock purchase warrant exercisable for 500,000 shares of the Company's common stock having an exercise price of \$1.0625 per share (the fair value of the Common Stock on the date of issuance) and having a term of five years. The Company valued the warrants at \$350,000 using the Black Scholes option pricing model. Accordingly, the Company recorded a deferred charge to be amortized as an expense to the Company's operations over a ten-year period which is the estimated life of the related ANDA. The acquisition agreement with Barr also allows Barr to purchase any of the Barr Products manufactured by the Company for a period of five years.

#### NOTE M -- COMMERCIALIZATION AND LICENSE AGREEMENT

Effective September 27, 2000, the Company entered into an exclusive license for certain patented technology owned by Bio-Fine Pharmaceuticals, Inc. for the synthesis of codeine from morphine. The agreement provided for a fixed amount of \$3,175,000 to be paid out as certain milestones are achieved with a total of \$500,000 paid as of December 31, 2000. The agreement also provided for the grant of 50,000 warrants and an employment agreement, both contingent upon FDA approval and first commercial sale, which has not yet occurred.

#### NOTE N -- PENSION EXPENSE

##### 1. Management Pension Plan

The Company had maintained a defined benefit plan covering substantially all nonunion employees which was terminated in November 1996. Subsequently, all Plan assets were converted to cash and held in a money market fund (to continue the Trust) from which all vested participant interests were to be paid. In 1998, the Company received approval to terminate the Plan by the Pension Benefit Guarantee Corporation, all assets

## HALSEY DRUG CO., INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

were distributed to the vested participants, the Trust was terminated and a final filing was made with the Internal Revenue Service.

#### 2. Employees' Pension Plan

The Company contributed approximately \$55,512, \$67,872 and \$421,000, in 2000, 1999 and 1998, 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."

#### 3. 401(k) and Profit-sharing Plan

Effective October 1, 1998, the Company established a 401(k) and profit-sharing plan for all employees other than those covered under collective bargaining agreements. Eligible employees may elect to make a basic contribution of up to 1.5% of their annual earnings. The plan provides that the Company can make discretionary matching contributions equal to 25% of the first 6% of employee contributions for an aggregate employee contribution of 1.5%, along with a discretionary profit-sharing contribution. The Company's expense under the plan was \$0 in 2000, 1999, and 1998, respectively.

#### NOTE O -- STOCK OPTION PLAN

In June 1998, the stockholders of the Company approved the adoption of a stock option and restricted stock purchase plan (the "1998 Option Plan"). The 1998 Option Plan provides for the granting of (i) nonqualified options to purchase the Company's common stock at not less than the fair market value on the date of the option grant and (ii) incentive stock options to purchase the Company's common stock at not less than the fair market value on the date of the option grant. As of December 31, 2000, there was no exercise of any options to purchase any common stock under the 1998 Option Plan. The total number of shares which may be sold pursuant to options and rights granted under the 1998 Option Plan is 3,600,000, which vest over four years and have a ten-year life. No option can be granted under the 1998 Option Plan after April 2008 and no option can be outstanding for more than ten years after its grant.

The Company has adopted the disclosure provisions of Statement of Financial Accounting Standards No. 123 ("SFAS No. 123"), "Accounting for Stock-Based Compensation." It applies APB Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its plans and does not recognize compensation expense for its stock-based compensation plans. If the Company had elected to recognize compensation expense based upon the fair value at the grant date for awards under these plans

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)**

consistent with the methodology prescribed by SFAS No. 123, the Company's net income and earnings per share would be reduced to the pro forma amounts indicated below:

	YEAR ENDED DECEMBER 31,		
	2000	1999	1998
	(THOUSANDS, EXCEPT PER SHARE AMOUNTS)		
Net loss			
As reported.....	\$(11,654)	\$(20,063)	\$(12,724)
Pro forma.....	(13,753)	(20,954)	(13,663)
Loss per share			
As reported.....	\$ (.80)	\$ (1.40)	\$ (.92)
Pro forma.....	(.95)	(1.46)	(.98)

These pro forma amounts may not be representative of future disclosures because they do not take into effect pro forma compensation expenses related to grants made before 1995. The fair value of these options was estimated at the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions for the years ended December 31, 2000, 1999 and 1998, respectively: expected volatility of 73%, 73% and 67%; risk-free interest rates of 7.0%, 6.8% and 5.6%; and expected lives of 10 years, 10 years and 10 years. At the date of grant, all exercise prices equaled the market value of the stock.

Transactions involving stock options are summarized as follows:

	STOCK OPTIONS OUTSTANDING	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE FAIR VALUE
Balance at December 31, 1997.....	481,739	\$3.60	
Granted.....	2,254,850	2.37	\$1.71
Forfeited.....	(511,303)	3.16	
Balance at December 31, 1998.....	2,225,286	2.46	
Granted.....	503,500	1.19	.80
Forfeited.....	(118,567)	3.08	
Balance at December 31, 1999.....	2,610,219	2.19	
Granted.....	2,262,000	1.50	1.38
Forfeited.....	(350,902)	2.04	
Balance at December 31, 2000.....	4,521,317	1.86	

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

RANGES OF EXERCISE PRICES	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
	NUMBER OUTSTANDING AT DECEMBER 31, 2000	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER EXERCISABLE AT DECEMBER 31, 2000	WEIGHTED AVERAGE EXERCISE PRICE
\$ .64 - \$2.00	2,397,700	9.21	\$1.35	220,675	\$1.35
2.01 - 3.00	2,070,350	7.45	2.40	1,328,925	2.39
3.01 - 4.38	53,267	4.25	3.56	53,267	3.56
	4,521,317			1,602,867	

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)**

**NOTE P -- COMMITMENTS**

The Company occupies plant and office facilities under noncancellable operating leases which expire in July 2004. These 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. 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, 2000, 1999 and 1998 was approximately \$1,517,000, \$1,574,000 and \$1,243,000, respectively.

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

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

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

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

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

As of December 31, 2000, the approximate minimum rental commitments under these operating leases are as follows:

	( IN THOUSANDS )
	-----
Twelve months ending December 31,	
2001.....	\$ 833
2002.....	275
2003.....	149
2004 and thereafter.....	73
	-----
Total minimum payments required.....	\$1,330
	=====

## HALSEY DRUG CO., INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

#### Employment Contracts

During March 1998, the Company entered into employment contracts with each of two new officers/ employees of the Company which cover a five-year and a three-year period, respectively. The contracts provide for, among other things:

(i) annual salaries of \$175,000 and \$140,000 to be paid over the five-year and three-year periods, respectively, and (ii) an aggregate of 1,300,000 options (included in the 1998 grants -- Note O) to purchase the Company's stock at an exercise price of \$2.38 per common share that vest evenly over a three-to-five-year service period and expire in ten years. In April 2000, these contracts were extended to April 30, 2005.

#### NOTE Q -- CONTINGENCIES

##### Department of Justice ("DOJ") Settlement

On June 21, 1993, the Company entered into a Plea Agreement with the DOJ to resolve the DOJ's investigation into the manufacturing and record keeping practices of the Company's Brooklyn plant. The Plea Agreement required the Company to pay a fine of \$2,500,000 over five years in quarterly installments of \$125,000, commencing on or about September 15, 1993.

As of February 28, 1998, the Company was in default of the payment terms of the Plea Agreement and had made payments aggregating \$350,000. On March 27, 1998, the Company and the DOJ signed the Letter Agreement serving to amend the Plea Agreement relating to the terms of the Company's satisfaction of the fine assessed under the Plea Agreement. Specifically, the Letter Agreement provided that the Company will satisfy the remaining \$2,150,000 of the fine through the payment of \$25,000 on a monthly basis commencing June 1, 1998, plus interest on such outstanding balance (at the rate calculated pursuant to 28 U.S.C. Section 1961)(currently 5.319%). Such payment schedule will result in the full satisfaction of the DOJ fine in December 2005. The Letter Agreement also provides certain restrictions on the payment of salary or compensation to any individual in excess of \$150,000 without the written consent of the DOJ. In addition, the Letter Agreement requires the repayment of the outstanding fine to the extent of 25% of the Company's after-tax profit or the remaining balance owed and 25% of the net proceeds received by the Company on any sale of a capital asset for a sum in excess of \$10,000. At December 31, 2000, the Company is current in its payment obligations with a remaining obligation of \$1,375,000.

#### Other Legal Proceedings

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

The Company has been named as a defendant in one additional action which has been referred to the Company's carrier and has been accepted for defense. This action, *Alonzo v. Halsey Drug Co., Inc. and K-Mart Corp.* was commenced on November 5, 1995 and involves a claim for unspecified damages relating to the alleged ingestion of "Doxycycline 100." The ultimate outcome of these lawsuits cannot be determined at this time, and accordingly, no adjustment has been made to the consolidated financial statements.

**HALSEY DRUG CO., INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)**

**NOTE R -- SIGNIFICANT CUSTOMERS AND SUPPLIERS**

The Company sells its products to customers who are primarily drug distributors, drugstore chains and wholesalers and are not concentrated in any specific region. The Company performs ongoing credit evaluations of its customers and generally does not require collateral. During 2000, the Company had net sales to one customer in excess of 10% of total sales aggregating to 58.5% of total sales. During 1999, the Company had net sales to one customer in excess of 10% of total sales, aggregating 16.3% of total sales. During 1998, the Company had net sales to one customer in excess of 10% of total sales, accounting for 17.6% of total sales.

During 2000 and 1999, the Company purchased approximately \$1,485,000 and \$1,107,000 respectively, of its raw materials, representing approximately 28% and 15%, respectively, of total raw material purchases from one supplier.

**NOTE S -- QUARTERLY FINANCIAL DATA (UNAUDITED)**

**Quarterly Financial Data (amounts in thousands except per share amounts)**

	1ST QUARTER -----	2ND QUARTER -----	3RD QUARTER -----	4TH QUARTER -----	YEAR -----
2000					
Total product revenues.....	\$ 3,151	\$ 9,066	\$ 4,686	\$ 3,320	\$ 20,223
Operating income (loss).....	(2,585)	2,140	(2,474)	(3,683)	(6,602)
Net income (loss).....	(4,082)	945	(4,124)	(4,393)	(11,654)
Earnings (loss) per share -- basic and diluted.....	\$ (.28)	\$ .07	\$ (.28)	\$ (.30)	\$ (.80)
1999					
Total product revenues.....	\$ 3,224	\$ 2,567	\$ 2,468	\$ 3,161	\$ 11,420
Operating income (loss).....	(2,421)	(3,091)	(3,669)	(6,393)	(15,574)
Net income (loss).....	(3,282)	(4,010)	(4,672)	(8,099)	(20,063)
Earnings (loss) per share -- basic and diluted.....	\$ (.23)	\$ (.28)	\$ (.33)	\$ (.56)	\$ (1.40)

**Exhibit 23.1**

**CONSENT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS**

We have issued our report dated February 16, 2001, accompanying the consolidated financial statements included in the Annual Report of Halsey Drug Co., Inc. on Form 10-K for the year ended December 31, 2000. We hereby consent to the incorporation by reference of said report in the Registration Statement of Halsey Drug Co., Inc. on Form S-8 (File No. 33-98396, effective October 19, 1995).

*/s/ GRANT THORNTON LLP*

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*GRANT THORNTON LLP*

*New York, New York  
March 31, 2001*

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**End of Filing**

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