

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-Q

(MARK ONE)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934.

For the quarterly period ended September 30, 2001

OR

☐ TRANSACTION 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 11-0853640  
(State or other Jurisdiction of (I.R.S. Employer Identification No.)  
incorporation or organization)

695 N. Perryville Rd.  
Rockford, IL 61107  
(Address of Principal executive offices) (Zip Code)

(815) 399 - 2060  
(Registrant's telephone number, including area code)

Not Applicable  
(Former name, former address and former fiscal year, if changed since last  
report.)

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 50 days.

YES ☒ NO ☐

As of October 31, 2001 the registrant had 15,059,740 Shares of Common Stock,  
\$.01 par value, outstanding.

HALSEY DRUG CO., INC. AND SUBSIDIARIES

INDEX

PAGE #

-----

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

Condensed Consolidated Balance Sheets- 3  
September 30, 2001 and December 31, 2000

Condensed Consolidated Statements of 5  
Operations - Three and nine months ended  
September 30, 2001 and September 30, 2000

Consolidated Statements of Cash 6  
Flows - Nine months ended September 30, 2001  
and September 30, 2000

Consolidated Statements of Stockholders' 7  
Equity - Nine months ended September 30, 2001

Notes to Condensed Consolidated Financial 8  
Statements

Item 2. Management's Discussion and Analysis of Financial 12  
Condition and Results of Operations

PART II. OTHER INFORMATION

Item 2. Changes in Securities 16

Item 6. Exhibits and Reports on Form 8-K 16

SIGNATURES 17

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(Amounts in thousands)	2001 SEPTEMBER 30 -----	2000 DECEMBER 31 -----
CURRENT ASSETS		
Cash and cash equivalents	\$ 1,633	\$ 697
Accounts Receivable - trade, net of allowances for doubtful accounts of \$403 and \$315 at September 30, 2001 and December 31, 2000, respectively	239	3,487
Other receivables	10	645
Inventories	2,426	2,769
Prepaid insurance and other current assets	243 -----	545 -----
Total current assets	4,551	8,143
PROPERTY PLANT & EQUIPMENT, NET	5,462	5,332
DEFERRED PRIVATE OFFERING COSTS	779	1,138
OTHER ASSETS AND DEPOSITS	882 -----	596 -----
	\$11,674 =====	\$15,209 =====

The accompanying notes are an integral part of these statements

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(Amounts in thousands except share data)

	2001 SEPTEMBER 30 -----	2000 DECEMBER 31 -----
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Notes payable	\$ 2,376	\$ 1,844
Accounts payable	1,446	2,671
Accrued expenses	5,484	5,889
Convertible Subordinated Debentures	--	2,500
Department of Justice Settlement	300	300
	-----	-----
Total current liabilities	9,606	13,204
CONVERTIBLE SENIOR SECURED DEBENTURES, NET	45,206	42,279
TERM NOTES PAYABLE	15,500	12,000
DEPARTMENT OF JUSTICE SETTLEMENT	850	1,075
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock - \$.01 par value; authorized 80,000,000 shares; issued 15,059,740 shares at September 30, 2001 and 14,961,316 shares at December 31, 2000	151	149
Additional paid-in capital	35,905	35,440
Accumulated deficit	(95,544)	(88,938)
	-----	-----
	(59,488)	(53,349)
	-----	-----
	\$ 11,674	\$ 15,209
	=====	=====

The accompanying notes are an integral part of these statements

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(Amounts in thousands except per share data)

	SEPTEMBER 30			
	FOR THE NINE MONTHS ENDED		FOR THE THREE MONTHS ENDED	
	2001	2000	2001	2000
Product Sales	\$ 6,754	\$ 11,903	\$ 1,826	\$ 4,686
Product Development Revenues	8,500	5,000	3,500	--
Net Product Revenues	15,254	16,903	5,326	4,686
Cost of Manufacturing	11,504	13,965	3,657	5,173
Research & Development	926	1,243	306	573
Selling, General and Administrative Expenses	4,666	4,614	1,655	1,414
Loss from Operations	(1,842)	(2,919)	(292)	(2,474)
Amortization of Deferred Debt Discount and Private Offering Costs	1,834	1,834	673	612
Interest Expense, net	2,890	2,860	925	966
Other Income (Expense)	(34)	56	(12)	(72)
Loss before Income Taxes	(6,600)	(7,557)	(1,902)	(4,124)
Income Tax (Expense) Benefit	(6)	296	(1)	--
Net Loss	\$ (6,606)	\$ (7,261)	\$ (1,903)	\$ (4,124)
Net Loss Per Share (Basic and Diluted)	\$ (0.44)	\$ (0.50)	\$ (0.13)	\$ (0.28)
Average Number of Outstanding Shares	14,951,285	14,469,121	15,043,378	14,503,985

The accompanying notes are an integral part of these statements

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(Amounts in thousands)

	NINE MONTHS ENDED SEPTEMBER 30	
	2001	2000
	----	----
Cash flows from operating activities		
Net loss	\$ (6,606)	\$ (7,261)
	-----	-----
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Depreciation and amortization	903	558
Amortization of deferred debt discount and deferred private offering costs	1,835	1,834
Provision for losses on accounts receivable	88	(255)
Gain on sale of assets	(--)	(93)
Debentures and stock issued for interest expense	1,623	1,537
Changes in assets and liabilities		
Accounts receivable	3,160	(2,502)
Other receivable	635	(57)
Inventories	344	390
Prepaid expenses and other current assets	303	(421)
Other assets and deposits	(245)	115
Accounts payable	(1,225)	88
Accrued expenses	(405)	750
	-----	-----
Total adjustments	7,016	1,944
	-----	-----
Net cash provide by (used in) operating activities	410	(5,317)
	-----	-----
Cash flows from investing activities		
Capital expenditures	(1,034)	(1,554)
Net proceeds from sale of assets	--	93
Investment in joint venture	(41)	(95)
	-----	-----
Net cash used in investing activities	(1,075)	(1,556)
	-----	-----
Cash flows from financing activities		
Proceeds from issuance of notes payable	6,000	9,769
Payments on notes payable	(1,761)	--
Payments on convertible subordinated debentures	(2,500)	--
Proceeds from exercise of stock options	87	--
Payments to Department of Justice	(225)	(225)
Deferred private offering costs	--	(124)
	-----	-----
Net cash provided by financing activities	1,601	9,420
	-----	-----
NET INCREASE IN CASH AND CASH EQUIVALENTS	936	2,547
Cash and cash equivalents at beginning of period	697	786
	-----	-----
Cash and cash equivalents at end of period	\$ 1,633	\$ 3,333
	=====	=====

Supplemental disclosure of noncash investing and financing activities For the nine months ended September 30, 2001

The Company issued 51,924 shares of common stock as payment for \$69,000 in debenture accrued interest.

\$1,554,000 of debentures was issued as payment for like amount of debenture accrued interest.

\$300,000 of senior secured notes was issued as payment for like amount of debentures.

The accompanying notes are an integral part of these statements

HALSEY DRUG CO., INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)  
(UNAUDITED)

(Amounts in thousands except per share data)

	Nine months ended September 30, 2001				
	Common Stock, \$.01 par value		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
	-----	-----	-----	-----	-----
Balance at January 1, 2001	14,961,316	\$ 149	\$ 35,440	(\$ 88,938)	(\$ 53,349)
Net Loss for the Nine Months Ended September 30, 2001				(6,606)	(6,606)
Issuance of Shares as Payment of Interest	51,924	1	69		70
Deferred Debt Discount on Issuance of Warrants			310		310
Exercise of Stock Options	46,500	1	86		87
	-----	-----	-----	-----	-----
Balance at September 30, 2001	15,059,740	\$ 151	\$ 35,905	(\$ 95,544)	(\$ 59,488)
	=====	=====	=====	=====	=====

The accompanying notes are an integral part of this statement

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of Halsey Drug Co., Inc. and subsidiaries (the "Company") have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles in the United States for complete financial statements. In the opinion of management, all adjustments considered necessary to present fairly the financial position, results of operations and changes in cash flows for the nine months ended September 30, 2001, assuming that the Company will continue as a going concern, have been made. The results of operations for the nine months period ended September 30, 2001 are not necessarily indicative of the results that may be expected for the full year ended December 31, 2001. The unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and footnotes thereto for the year ended December 31, 2000 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

As of September 30, 2001, the Company had working capital deficiency of approximately \$5,055,000 and an accumulated deficit of approximately \$95,544,000. The Company incurred a loss of approximately \$6,606,000 during the nine months ended September 30, 2001.

Until such time as the Company successfully develops and commercializes new finished dosage products and active pharmaceutical ingredients, of which there can be no assurance, the Company will continue to incur operating losses and negative cash flow. The Company believes that the final payment under the Product Purchase Agreement of \$3.5 million received on July 10, 2001 combined with the \$700,000 balance available under the Watson Term Loan will be sufficient to satisfy the Company's working capital requirements only through the end of 2001.

The Company's efforts to obtain the approval of the U.S. Drug Enforcement Administration ("DEA") for a registration to import raw materials for use in production, including contesting pending third-party opposition proceedings, and the continuing development of the Company's licensed technologies will continue through 2004. In order to fund continued operations, satisfy the Senior Secured Notes and to fund the continued development of the Company's licensed technologies during the period from fiscal 2002 through and including 2004, which includes the completion of planned capital improvements to the Company's Indiana and New York facilities and the processing of the registrations and approvals required from the DEA (including funding the legal fees and related expenses in connection pending opposition proceedings relating to the Company's request for a raw material import registration, the Company estimates that it will be required to obtain additional sources of financing or a third party equity investment of approximately \$15.0 million. The Company is currently seeking additional funds through transactions related to its business lines as well as private financings. There can be no assurance, however, that such additional financing will be available to the Company on acceptable terms, if at all. Failure to obtain such financing or equity investment may require the Company (i) to delay or cease the continued development of its licensed technologies and the completion of planned capital expenditures, (ii) to obtain funds through arrangements with third parties on terms that may require the Company to relinquish rights to its licensed technologies which the Company would otherwise pursue on its own or that would dilute the Company's stockholders and/or (iii) to significantly scale back or terminate operations. An extended delay or a cessation of the Company's continuing development efforts relating to its 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. The accompanying consolidated financial statements do not include any adjustments relating to the preceding uncertainties.

#### NOTE 2 - STRATEGIC ALLIANCE WITH WATSON PHARMACEUTICALS

Pursuant to the terms of the Core Products Supply Agreement with Watson, Watson was required to purchase and pay for on a quarterly basis a minimum of \$3,060,000 for products supplied by the Company under such Agreement. For the three quarters ending December 31, 2000, Watson had made an advance payment of approximately \$4,402,000 as required under the terms of the Core Products Supply Agreement to be applied against future product purchases under such Agreement. The advance payments and any additional advance payments made by Watson under the Core Products Supply Agreement will require that the Company supply Watson with a like amount of products without additional payments from Watson at such time. On August 8, 2001, the Company and Watson executed an amendment to the Core Products Supply Agreement (the "Core Products Amendment") providing (i) for a reduction of Watson's minimum purchase requirements from \$3,060,000 to \$1,500,000 per quarter, (ii) for an extension of Watson's minimum purchase requirements from the quarter ending September 30, 2001 to quarter ending September 30, 2002, (iii) for Watson to recover previous advance payments made under the Core Products Supply Agreement in the form of the Company's provision of products having a purchase price of up to \$750,000 per quarter (such credit amount to be in excess of Watson's \$1,500,000 minimum quarterly purchase obligation), and (iv) for the Company's repayment to Watson of any remaining advance payments made by Watson under the Core Products Supply Agreement (and which amount has not been recovered by product deliveries by the Company to Watson as provided in Subsection (iii) above) in two (2) equal monthly installments on October 1, 2002 and November 1, 2002. As of September 30, 2001, Watson's advance payments were \$4,147,000. The Company currently anticipates that it will supply Watson with sufficient product to satisfy Watson's advance payment and has provided for such costs.

#### NOTE 3 - INVENTORIES

(Amounts in thousands)

Inventories consists of the following:

	September 30, 2001	December 31, 2000
	-----	-----
Finished Goods	\$ --	\$ 225
Work in Process	1,104	1,146
Raw Materials	1,322	1,398
	-----	-----
	\$2,426	\$2,769
	=====	=====

## NOTE 4 - CONVERTIBLE DEBENTURES

Convertible Debentures consist of the following:

	September 30, 2001	December 31, 2000
	-----	-----
Senior Secured Debentures - 5.0%	\$ 48,002	\$ 46,446
Subordinated Debentures - 10.0%	--	2,500
	-----	-----
	48,002	48,946
Less Current Maturity	--	(2,500)
	-----	-----
	48,002	46,446
Less Unamortized Debt Discount	(2,796)	(4,167)
	-----	-----
	\$ 45,206	\$ 42,279
	=====	=====

## NOTE 5 - NOTES PAYABLE

Notes Payable consist of the following:

	September 30, 2001	December 31, 2000
	-----	-----
Unsecured Promissory Demand Notes	\$ 83	\$ 1,844
10% Convertible Senior Secured Notes	2,500	--
	-----	-----
	\$ 2,583	\$ 1,844
	-----	-----
Less Unamortized Debt Discount	(207)	--
	-----	-----
	\$ 2,376	\$ 1,844
	=====	=====
Term Note Payables	\$15,500	\$12,000

On August 15, 2001, the Company and Galen Partners III, L.P., certain of its Affiliates and certain investors in the Company's 5% convertible senior secured debentures (collectively, the "Galen Group") executed a certain Bridge Loan Agreement pursuant to which the Galen Group made a bridge loan to the Company in the principal amount of \$2,500,000 (the "Galen Bridge Loan"). The proceeds of the Galen Bridge Loan were used by the Company to satisfy in full the Company's 10% convertible subordinated debentures in the principal amount of \$2,500,000 issued in August 1996 and which matured on August 6, 2001. The Galen Bridge Loan bears interest at the rate of 10% per annum and is secured by a lien on all the Company's assets, junior to the security interest granted to Watson under the Watson Term Loan but senior to the security interest granted to the holders of the Company's 5% convertible subordinated debentures issued in March, 1998 and May, 1999. The Galen Bridge Loan Note is convertible into common stock at a conversion price of \$3.012 per share, which conversion price equals the average trading price of the Company's common stock for the 20 days preceding the closing date. In consideration for

the extension of the Galen Bridge Loan, the Company issued to the Galen Group common stock purchase warrants to purchase an aggregate of 187,500 shares of the Company's common stock at an exercise price of \$3.012 per share. The relative estimated fair value of the warrants, \$310,000, has been recorded as additional debt discount and will be amortized over the life of the bridge loan. The Galen Bridge Loan warrants are substantially identical to those issued in the Company's Debenture and Warrant Offerings completed in March, 1998 and May, 1999. The Galen Bridge Loan matures on December 31, 2001.

As of September 30, 2001, Watson Pharmaceuticals, Inc. had advanced \$15,500,000 to the Company under a term loan. The loan is secured by a first lien on all of the Company's assets, senior to the lien securing all other Company indebtedness, carries a floating rate of interest equal to prime plus two percent and matures on March 31, 2003.

#### NOTE 6 - CONTINGENCIES

The Company currently is a defendant in several lawsuits involving product liability claims. The Company's insurance carriers have assumed the defense for all product liability and other actions involving the Company. The final outcome of these lawsuits cannot be determined at this time, and accordingly, no provision has been provided for in the consolidated financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS  
OF OPERATIONS

.....  
NINE MONTHS ENDED SEPTEMBER 30, 2001 VS NINE MONTHS ENDED SEPTEMBER 30, 2000  
.....

NET PRODUCT REVENUES

The Company's net product revenues for the nine months ended September 30, 2001 of \$15,254,000 represents a decrease of \$1,649,000 (9.8%) as compared to net product revenues for the nine months ended September 30, 2000 of \$16,903,000. During the nine-month period ending September 30, 2001, the Company recognized an additional \$3,500,000 of product development revenues associated with the sale of certain product rights to Watson Pharmaceuticals, Inc. versus the same period ending September 30, 2000. Additionally, product sales decreased because of a modification to the Watson core products agreement and further, the Company was unable to obtain certain raw materials during the nine months ended September 30, 2001. The Company believes that these raw materials will become available in the later part of the fourth quarter of 2001. On an ongoing basis, the Company expects to generate revenues from the development and manufacture of both finished dosage and active pharmaceutical ingredients ("API's"), and then partnering with others for the marketing and distribution of these products.

COST OF MANUFACTURING

For the nine months ended September 30, 2001, cost of manufacturing decreased \$2,461,000 to \$11,504,000 as compared to the nine months ended September 30, 2000 of \$13,965,000. This is primarily attributable to the reduction of product sales partially offset by the addition of manufacturing overhead costs from the lease of the Congers manufacturing facility in March 2000.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses as a percentage of net product revenues for the nine months ended September 30, 2001 and 2000 were 30.6% and 27.3%, respectively. Overall these expenses in the first nine months of 2001 increased \$52,000 over the same period in 2000.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses as a percentage of net product revenues for the nine months ended September 30, 2001 and 2000 were 6.1% and 7.4%, respectively. The Company's research and development program is concentrating its efforts in three areas.

First, the Company is continuing development efforts relating to certain API's. The Company currently manufactures two API's and has seven others under development.

Second, the Company is proceeding with the development of products, apart from those obtained from Barr Laboratories, for submission to the FDA. The Company expects the submission of four ANDA supplements or amendments to the FDA during the balance of fiscal 2001, each of which relate to the site transfer of existing ANDAs from the Company's former Brooklyn, New York facility to its Congers, New York facility.

Third, the Company is performing the necessary regulatory steps to affect the regulatory transfer to the Company of the products obtained from Barr Laboratories in April, 1999. The Company initially has identified three of the products for which it will devote substantial effort in seeking approval from the FDA for manufacture and sale. The Company estimates that certain of these Barr Products will be available for sale in the fourth quarter of 2001.

NET INCOME (LOSS)

For the nine months ended September 30, 2001, the Company had net loss of \$6,606,000 as compared to a net loss of \$7,261,000 for the nine months ended September 30, 2000. Included in the results for the nine months ended September 30, 2001 was interest expense of \$2,890,000 and amortization of deferred debt discount and private offering costs of \$1,834,000 as compared to \$2,860,000 and \$1,834,000, respectively, for the year earlier period. Also, included in results for the nine months ended September 30, 2000 was a tax benefit of \$296,000 from the settlement of a income tax refund claim

originally submitted in 1996 and a \$93,000 gain recorded on the sale of assets.  
.....  
THREE MONTHS ENDED SEPTEMBER 30, 2001 VS THREE MONTHS ENDED SEPTEMBER 30, 2000  
.....  
NET PRODUCT REVENUES

The Company's net product revenues for the three months ended September 30, 2001 of \$5,326,000 represents an increase of \$640,000 (13.7%) as compared to net product revenues for the three months ended September 30, 2000 of \$4,686,000. This increase is primarily a result of the recognition in the three month period ended September 30, 2001 of \$3,500,000 in product development revenues associated with the sale of certain product rights to Watson Pharmaceuticals, Inc. Additionally, product sales decreased because of a modification to the Watson core products agreement and further, the Company was unable to obtain certain raw materials during the three months ending September 30, 2001. The Company believes that these raw materials will become available in the later part of the fourth quarter of 2001. On an ongoing basis, the Company expects to generate revenues from the development and manufacture of both finished dosage and active pharmaceutical ingredients ("API's"), and then partnering with others for the marketing and distribution of these products.

#### COST OF MANUFACTURING

For the three months ended September 30, 2001, cost of manufacturing decreased by approximately \$1,516,000 as compared to the three months ended September 30, 2000. The decrease for 2001 is attributable to the reduction of product revenues.

#### SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses as a percentage of net product revenues for the three months ended September 30, 2001 and 2000 were 31.1% and 30.2%, respectively. The increase of \$241,000 is due primarily to regulatory consulting services.

#### RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses as a percentage of net product revenues for the three months ended September 30, 2001 and 2000 was 5.7% and 12.2%, respectively. The Company's research and development program is concentrating its efforts in three areas.

First, the Company is continuing development efforts relating to certain API's. The Company currently manufactures two API's and has seven others under development.

Second, the Company is proceeding with the development of products, apart from those obtained from Barr Laboratories, for submission to the FDA. The Company expects the submission of four ANDA supplements or amendments to the FDA during the balance of fiscal 2001, each of which relate to the site transfer of existing ANDAs from the Company's former Brooklyn, New York facility to its Congers, New York facility.

Third, the Company is performing the necessary regulatory steps to affect the regulatory transfer to the Company of the products obtained from Barr Laboratories in April, 1999. The Company initially has identified three of the products for which it will devote substantial effort in seeking approval from the FDA for manufacture and sale. The Company estimates that certain of these Barr Products will be available for sale in the fourth quarter of 2001.

#### NET INCOME (LOSS)

For the three months ended September 30, 2001, the Company had a net loss of \$1,903,000 as compared to a net loss of \$4,124,000 for the three months ended September 30, 2000. Included in the results for the three months ended September 30, 2001 was interest expense of \$925,000 and amortization of deferred debt discount and private offering costs of \$673,000 as compared to \$966,000 and \$612,000, respectively, for the year earlier period.

## LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2001, the Company had cash and cash equivalents of \$1,633,000 as compared to \$697,000 at December 31, 2000. The Company had working capital deficiency at September 30, 2001 of \$5,055,000 as compared to a working capital deficiency of \$5,061,000 at December 31, 2000.

In addition to the other strategic alliance transactions with Watson Pharmaceuticals, Inc. ("Watson") completed on March 29, 2000, the Company and Watson executed a Loan Agreement providing for Watson's extension of a \$17,500,000 term loan to the Company (the "Watson Term Loan"). The Watson Term 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. As of October 31, 2001, Watson had advanced \$16.8 million 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 October 31, 2001, a portion of the net proceeds of the Watson Term Loan were used to satisfy in full the bridge loans made by Galen Partners to the Company during 2000, 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. In addition, pursuant to the terms of the Product Purchase Agreement with Watson dated March 29, 2000 (the "Product Purchase Agreement"), on July 10, 2001 Watson remitted \$3,500,000 to the Company representing the final installment for the Doxycycline monohydrate product purchased by Watson from the Company. The proceeds of this installment as well as the \$700,000 balance available under the Watson Term Loan will, in large part, be used to fund the upgrades to the API manufacturing facility of Houba, Inc., the Company's wholly-owned subsidiary, to fund the upgrades to the Company's Congers, New York leased facilities, and for working capital to fund continued operations.

Pursuant to the terms of the Core Products Supply Agreement with Watson, Watson was required to purchase and pay for on a quarterly basis a minimum of \$3,060,000 for products supplied by the Company under such Agreement. For the three quarters ending December 31, 2000, Watson had made an advance payment of approximately \$4,402,000 as required under the terms of the Core Products Supply Agreement to be applied against future product purchases under such Agreement. The advance payments and any additional advance payments made by Watson under the Core Products Supply Agreement will require that the Company supply Watson with a like amount of products without additional payments from Watson at such time. On August 8, 2001, the Company and Watson executed an amendment to the Core Products Supply Agreement (the "Core Products Amendment") providing (i) for a reduction of Watson's minimum purchase requirements from \$3,060,000 to \$1,500,000 per quarter, (ii) for an extension of Watson's minimum purchase requirements from the quarter ending September 30, 2001 to quarter ending September 30, 2002, (iii) for Watson to recover previous advance payments made under the Core Products Supply Agreement in the form of the Company's provision of products having a purchase price of up to \$750,000 per quarter (such credit amount to be in excess of Watson's \$1,500,000 minimum quarterly purchase obligation), and (iv) for the Company's repayment to Watson of any remaining advance payments made by Watson under the Core Products Supply Agreement (and which amount has not been recovered by product deliveries by the Company to Watson as provided in Subsection (iii) above) in two (2) equal monthly installments on October 1, 2002 and November 1, 2002. As of September 30, 2001, Watson's advance payments were \$4,147,000. The Company currently anticipates that it will supply Watson with sufficient product to satisfy Watson's advance payment and has provided for such costs.

On August 15, 2001, the Company and Galen Partners III, L.P., certain of its Affiliates and certain investors in the Company's 5% convertible senior secured debentures (collectively, the "Galen Group") executed a certain Bridge Loan Agreement pursuant to which the Galen Group made a bridge loan to the Company in the principal amount of \$2,500,000 (the "Galen Bridge Loan"). The proceeds of the Galen Bridge Loan were used by the Company to satisfy in full the Company's 10% convertible subordinated

debentures in the principal amount of \$2,500,000 issued in August 1996 and which matured on August 6, 2001. The Galen Bridge Loan bears interest at the rate of 10% per annum and is secured by a lien on all the Company's assets, junior to the security interest granted to Watson under the Watson Term Loan but senior to the security interest granted to the holders of the Company's 5% convertible subordinated debentures issued in March, 1998 and May, 1999. The Galen Bridge Loan Note is convertible into common stock at a conversion price of \$3.012 per share, which conversion price equals the average trading price of the Company's common stock for the 20 days preceding the closing date. In consideration for the extension of the Galen Bridge Loan, the Company issued to the Galen Group common stock purchase warrants to purchase an aggregate of 187,500 shares of the Company's common stock at an exercise price of \$3.012 per share. The relative estimated fair value of the warrants, \$310,000, has been recorded as additional debt discount and will be amortized over the life of the bridge loan. The Galen Bridge Loan warrants are substantially identical to those issued in the Company's Debenture and Warrant Offerings completed in March, 1998 and May, 1999. The Galen Bridge Loan matures on December 31, 2001.

Until such time as the Company successfully develops and commercializes new finished dosage products and active pharmaceutical ingredients, of which there can be no assurance, the Company will continue to incur operating losses and negative cash flow. The Company believes that the cash on hand combined with the \$700,000 balance available under the Watson Term Loan will be sufficient to satisfy the Company's working capital requirements only through the end of 2001.

The Company's efforts to obtain the approval of the U.S. Drug Enforcement Administration ("DEA") for a registration to import raw materials for use in production, including contesting pending third-party opposition proceedings, and the continuing development of the Company's licensed technologies will continue through 2004. In order to fund continued operations, satisfy the Galen Bridge Loan and to fund the continued development of the Company's licensed technologies during the period from fiscal 2002 through and including 2004, which includes the completion of planned capital improvements to the Company's Culver, Indiana and Congers, NY facilities and the processing of the registrations and approvals required from the DEA (including funding the legal fees and related expenses in connection with pending opposition proceedings relating to the Company's request for a raw material import registration), the Company estimates that it will be required to obtain additional sources of financing or a third party equity investment of approximately \$15.0 million. The Company is currently seeking additional funds through transactions related to its business lines as well as private financings. There can be no assurance, however, that such additional financing will be available to the Company on acceptable terms, if at all. Failure to obtain such financing or equity investment may require the Company (i) to delay or cease the continued development of its licensed technologies and the completion of planned capital expenditures, (ii) to obtain funds through arrangements with third parties on terms that may require the Company to relinquish rights to its licensed technologies which the Company would otherwise pursue on its own or that would dilute the Company's stockholders and/or (iii) to significantly scale back or terminate operations. An extended delay or a cessation of the Company's continuing development efforts relating to its 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.

PART II OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

During the quarter ended September 30, 2001, the Company issued an aggregate of 17,308 shares of Common Stock and 5% Convertible Senior Secured Debenture in the principal amount of approximately \$524,000 in satisfaction of accrued interest on the Company's outstanding 5% convertible senior secured debentures issued in March and June 1998, and May and July 1999 (the "Convertible Debentures").

Each of the holders of the Convertible Debentures for which interest payments were made in Common Stock and 5% Convertible Senior Secured Debentures are accredited investors as defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended (the "Act"). The Common Stock and 5% Convertible Senior Secured Debentures issued in satisfaction of the interest payments under the Convertible Debentures were issued without registration under the Act in reliance upon Section 4(2) of the Act and Regulation D promulgated thereunder.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

- (a) The exhibits required to be filed as part of this report on form 10-Q are listed in the attached Index.
- (b) Reports on Form 8-K.

On September 7, 2001, the Company filed a Current Report on Form 8-K (the "Form 8-K"). Under Item 5 of the Form 8-K the Company indicated that the U.S. Drug Enforcement Administration ("DEA") had filed a notice in the Federal Register regarding the Company's application for registration to manufacture Schedule II controlled substances. The Company also indicated that the DEA had filed a notice in the Federal Register regarding the Company's application for registration to import certain controlled substances.

SIGNATURES

Pursuant to the requirements 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.

Date: November 12, 2001

HALSEY DRUG CO., INC.

By: /s/ Michael K. Reicher

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Michael K. Reicher  
Chairman and  
Chief Executive Officer

By: /s/ Peter A. Clemens

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Peter A. Clemens  
VP & Chief Financial Officer