

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 March 31, 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 Road, Crimson Building No. 2, Unit 4
Rockford, Illinois

61107

(Address of Principal Executive Offices)

(Zip Code)

(815) 399-2060

(Registrant's telephone number, including area code)

(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 90 days.

YES ☒ NO ☐

As of May 11, 2001 the registrant had 14,995,932 shares of Common Stock, \$.01
par value, outstanding.

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ITEM 1. FINANCIAL STATEMENTS
HALSEY DRUG CO., INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

(Amounts in thousands)	(UNAUDITED)	
	2001 MARCH 31 -----	2000 DECEMBER 31 -----
CURRENT ASSETS		
Cash and cash equivalents	\$ 1,263	\$ 697
Accounts Receivable - trade, net of allowances for doubtful accounts of \$281 at March 31, 2001 and \$315 at December 31, 2000, respectively	5,795	3,487
Other receivables	56	645
Inventories	2,655	2,769
Prepaid insurance and other current assets	181	545
	-----	-----
Total current assets	9,950	8,143
PROPERTY PLANT & EQUIPMENT, NET	5,480	5,332
DEFERRED PRIVATE OFFERING COSTS	1,016	1,138
OTHER ASSETS AND DEPOSITS	583	596
	-----	-----
	\$17,029	\$15,209
	=====	=====

The accompanying notes are an integral part of these statements

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Amounts in thousands)	(UNAUDITED)	
	2001 MARCH 31 -----	2000 DECEMBER 31 -----
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Notes payable	436	1,844
Accounts payable	3,280	2,671
Accrued expenses	5,706	5,889
Department of Justice Settlement	300	300
	-----	-----
Total current liabilities	9,722	10,704
CONVERTIBLE SUBORDINATED DEBENTURES, NET	45,750	44,779
TERM NOTES PAYABLE	14,000	12,000
DEPARTMENT OF JUSTICE SETTLEMENT	1,000	1,075
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY (DEFICIT)		
Common stock - \$.01 par value; authorized 80,000,000, shares; issued and outstanding 14,978,624 shares at March 31, 2001 and 14,961,316 shares at December 31, 2000	150	149
Additional paid-in capital	35,452	35,440
Accumulated deficit	(89,045)	(88,938)
	-----	-----
	(53,443)	(53,349)
	-----	-----
	\$ 17,029	\$ 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	For the Three months ended	
	March 31	
	2001	2000
Product sales	\$ 2,966	\$ 3,151
Product development revenues	5,000	--
Net product revenues	7,966	3,151
Cost of manufacturing	4,569	3,715
Research and development	306	393
Selling, general and administrative expenses ..	1,660	1,628
Income (loss) from operations	1,431	(2,585)
Amortization of deferred debt discount and private offering costs	(581)	(606)
Interest expense, net	(946)	(901)
Other income (expense)	(10)	10
Loss before income taxes	(106)	(4,082)
Income tax expense	--	--
Net loss	(106)	(4,082)
Net loss per share (basic and diluted)	\$ (0.01)	\$ (0.28)
Average number of outstanding shares	14,978,432	14,639,372

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

Three months ended

March 31

2001

2000

Cash flows from operating activities

Net loss	\$ (106)	\$ (4,082)
----------------	----------	------------

Adjustments to reconcile net loss to net cash provided by (used in) operating activities

Depreciation and amortization	247	191
Amortization of deferred debt discount and private offering costs	581	606
Provision (recovery) for losses on accounts receivable.....	(34)	279
Debentures and stock issued for interest	525	443

Changes in assets and liabilities

Accounts receivable	(2,274)	44
Other receivable	589	(10)
Inventories	114	476
Prepaid insurance and other current assets.	203	(133)
Other assets and deposits	169	(4)
Accounts payable	610	328
Accrued expenses	(185)	(210)

Total adjustments	545	2,010
-------------------------	-----	-------

Net cash provided by (used) in operating activities.....	439	(2,072)
--	-----	---------

Cash flows from investing activities

Capital expenditures	(389)	(77)
Investment in joint venture	(2)	--

Net cash used in investing activities	(391)	(77)
---	-------	------

Cash flows from financing activities

Proceeds from issuance of term notes payable ..	2,000	10,800
Payments to Department of Justice	(75)	(75)
Payments on notes payable	(1,407)	(3,523)
	-----	-----
Net cash provided by financing activities	518	7,202
	-----	-----
NET INCREASE IN CASH	566	5,053
Cash at beginning of period	697	786
	-----	-----
Cash at end of period	\$ 1,263	\$ 5,839
	=====	=====

Supplemental disclosure of noncash activities:

Quarter ended March 31, 2001

The Company issued 17,308 shares of common stock as payment for approximately \$13,000 in accrued interest.

The Company issued approximately \$512,000 of debentures as payment for like amount of accrued debenture interest.

The accompanying notes are an integral part of these statements

HALSEY DRUG CO., INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)
Three months ended March 31, 2001

Amounts in thousands except share data

(UNAUDITED)

	Common Stock \$.01 par value		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance January 1, 2001 ...	14,961,316	\$ 149	\$ 35,440	\$ (88,939)	\$ (53,350)
Net loss for the three months ended March 31, 2001				(106)	(106)
Issuance of shares as payment of interest	17,308	1	12		13
Balance at March 31, 2001 .	14,978,624	\$ 150	\$ 35,452	\$ (89,045)	\$ (53,443)

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 for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring amounts) considered necessary to present fairly the financial position, results of operations and changes in cash flows for the three months ended March 31, 2001 have been made. The results of operations for the three months period ended March 31, 2001 are not necessarily indicative of the results that may be expected for the full year ending 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.

The computation of share 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 2001 and 2000 quarterly computation are warrants and options outstanding which would be antidilutive.

NOTE 2 - Inventories

(Amounts in thousands)

Inventories consists of the following:

	March 31, 2001	December 31, 2000
	-----	-----
Finished Goods	\$ 126	\$ 225
Work in Process	1,271	1,146
Raw Materials	1,258	1,398
	-----	-----
	\$ 2,655	\$ 2,769
	=====	=====

NOTE 3 - Convertible Subordinated Debentures

Convertible Subordinated Debentures consist of the following:

	March 31, 2001	December 31, 2000
	-----	-----
Debentures - 5.0%	\$46,959	\$46,446
Debentures - 10.0%	2,500	2,500
	-----	-----
	49,459	48,946
Less unamortized debt discount	(3,709)	(4,167)
	-----	-----
	\$45,750	\$44,779
	=====	=====

NOTE 4 - Notes Payable

Notes payable consist of the following:

	March 31, 2001	December 31, 2000
	-----	-----
Unsecured promissory demand notes	\$ 436	\$ 1,844
Term notes payable	14,000	12,000
	-----	-----
	14,436	13,844
	=====	=====

NOTE 5 - 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 adjustment has been made to the consolidated financial statements.

HALSEY DRUG CO., INC. AND SUBSIDIARIES
ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND
RESULTS OF OPERATIONS

	Three months ended March 31		
	Percentage of		Percentage Change
	Net Product Revenues		Year-to-Year
			Increase (Decrease)
	2001	2000	2001 as Compared to
	-----	-----	-----
	%	%	%
	-----	-----	-----
Product sales	37.2	100.0	(5.9)
Product development revenues	62.8	0.0	n/a
	-----	-----	-----
Net product revenues	100.0	100.0	152.8
Cost of manufacturing	57.4	117.9	23.0
Research and development	3.8	12.5	(23.1)
Selling, general and administrative expenses	20.8	51.7	2.0
	-----	-----	-----
Income (loss) from operations	18.0	(82.0)	155.4
Amortization of deferred debt discount and private offering costs	7.3	19.2	(4.1)
Interest expense, net	11.9	28.6	5.0
Other income (expense)	(0.1)	0.3	(200.0)
	-----	-----	-----
Loss before income taxes	(1.3)	(129.5)	(97.4)
Provision for income taxes	--	--	--
	-----	-----	-----
Net loss	(1.3)	(129.5)	(97.4)
	=====	=====	=====

Three months ended March 31, 2001 vs. three months ended March 31, 2000

Net Product Revenues

The Company's net product revenues for the three months ended March 31, 2001 of \$7,966,000 represents an increase of \$4,815,000 (152.8%) as compared to net sales for the three months ended March 31, 2000 of \$3,151,000. This increase is a result of the recognition of \$5,000,000 of product development revenues associated with the sale of certain product rights to Watson Pharmaceuticals, Inc. 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 March 31, 2001, cost of manufacturing increased by approximately \$854,000 as compared to the three months ended March 31, 2000. The increase for 2001 is attributable to lower margins realized from contract manufacturing revenues and higher manufacturing overhead associated with the addition of the leased facilities at Congers, NY. Product revenues for the same three month period ended March 31, 2000 consisted of Halsey labeled products carrying higher margins.

Selling, General and Administrative Expenses

Selling, general and administrative expenses as a percentage of sales for the three months ended March 31, 2001 and 2000 were 20.8% and 51.7%, respectively. Overall these expenses in the first three months of 2001 increased \$32,000 over the same period in 2000.

Research and Development Expenses

Research and development expenses as a percentage of sales for the three months ended March 31, 2001 and 2000 was 3.8% and 12.5%, 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 7 ANDA supplements or amendments to the FDA during 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 effect the transfer of the products obtained from Barr Laboratories in April 1999 to the

Company. 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 Products will be available for sale in the fourth quarter of 2001.

Net Income (Loss)

For the three months ended March 31, 2001, the Company had net loss of \$106,000 as compared to a net loss of \$4,082,000 for the three months ended March 31, 2000. Included in the results for the three months ended March 31, 2001 was interest expense of \$946,000 and amortization of deferred debt discount and private offering costs of \$581,000 as compared to \$901,000 and \$606,000, respectively, over the same period in 2000.

Liquidity and Capital Resources

At March 31, 2001, the Company had cash and cash equivalents of \$1,263,000 as compared to \$697,000 at December 31, 2000. The Company had working capital of \$228,000 at March 31, 2001 and a working capital deficiency of \$2,561,000 at December 31, 2000.

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 partial tender offer for the Company's common stock. The Company used the proceeds of these borrowings for working capital. As of May 8, 2001, approximately \$2,611,000 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.

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 provided 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 for 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 represented 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 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 May 8, 2001, \$14 million 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 May 8, 2001, a portion of the net proceeds of the Watson Term Loan were used to satisfy in full 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 April 20, 2001 Watson remitted \$5,000,000 to the Company representing the second installment for the doxycycline monohydrate product purchased by Watson from the Company. The proceeds of this installment as well as 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 facility 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 May 8, 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. The Company and Watson are currently discussing reducing Watson's purchase obligation to \$1,500,000 per quarter.

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. An additional \$3.5 million is payable by Watson to the Company under the terms of the Product Purchase Agreement. The Company estimates that it will receive the remaining \$3.5 million in the third quarter of 2001. The Company believes that the final payment to be received under the Product Purchase Agreement combined with the \$3.5 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 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 any resulting third-party opposition proceeding, and the continuing development of the Company's 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 its licensed technologies and the completion of planned capital improvements. 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

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

During the quarter ended March 31, 2001, the Company issued an aggregate of 17,398 shares of Common Stock and 5% Convertible Senior Secured Debenture in the principal amount of approximately \$525,000 in satisfaction of accrued interest on both the Company's outstanding 10% convertible debentures issued in August 1996 and 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 Exhibit Index.
- (b) Reports on Form 8-K. None.

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.

HALSEY DRUG CO., INC.

Date: May 11, 2001

BY:s/s Michael K. Reicher

Michael K. Reicher
Chairman and Chief
Executive Officer

Date: May 11, 2001

BY:s/s Peter A. Clemens

Peter A. Clemens
VP & Chief Financial
Officer