

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, 2002

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
incorporation or organization)

(I.R.S. Employer Identification No.)

695 N. Perryville Rd.

Rockford, IL

(Address of Principal executive offices)

61107

(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 November 13, 2002 the registrant had 15,065,240 Shares of Common Stock,
\$.01 par value, outstanding.

HALSEY DRUG CO., INC. AND SUBSIDIARIES

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands)

| | SEPTEMBER 30, 2002 | DECEMBER 31, 2001 |
|--|-----------------------|----------------------|
| | ----- | ----- |
| CURRENT ASSETS | | |
| Cash | \$ 8 | \$ 442 |
| Accounts Receivable - trade, net of allowance for doubtful accounts of \$24 and \$347 at September 30, 2002 and December 31, 2001, respectively | 749 | 367 |
| Inventories | 2,425 | 2,729 |
| Prepaid expenses and other current assets | 691 | 238 |
| | ----- | ----- |
| Total current assets | 3,873 | 3,776 |
| PROPERTY PLANT & EQUIPMENT, NET | 5,522 | 5,998 |
| DEFERRED PRIVATE OFFERING COSTS | 214 | 672 |
| OTHER ASSETS AND DEPOSITS | 486 | 623 |
| | ----- | ----- |
| | \$10,095 | \$11,069 |
| | ===== | ===== |

The accompanying notes are an integral part of these statements.

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share data)

| | SEPTEMBER 30, 2002 | DECEMBER 31, 2001 |
|---|-----------------------|----------------------|
| | ----- | ----- |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| CURRENT LIABILITIES | | |
| Notes payable, net | \$ 27,442 | \$ 2,568 |
| Convertible subordinated debentures, net | 49,247 | -- |
| Accounts payable | 2,981 | 2,979 |
| Accrued expenses | 7,123 | 6,205 |
| Department of Justice settlement | 300 | 300 |
| | ----- | ----- |
| Total current liabilities | 87,093 | 12,052 |
| CONVERTIBLE SUBORDINATED DEBENTURES, NET | -- | 46,179 |
| TERM NOTE PAYABLE | -- | 17,500 |
| DEPARTMENT OF JUSTICE SETTLEMENT | 541 | 774 |
| COMMITMENTS AND CONTINGENCIES | | |
| STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Common stock - \$.01 par value; authorized 80,000,000 shares; 15,065,240 shares issued and outstanding at September 30, 2002 and December 31, 2001 | 151 | 151 |
| Additional paid-in capital | 44,499 | 35,914 |
| Accumulated deficit | (122,189) | (101,501) |
| | ----- | ----- |
| | (77,539) | (65,436) |
| | ----- | ----- |
| | \$ 10,095 | \$ 11,069 |
| | ===== | ===== |

The accompanying notes are an integral part of these statements.

HALSEY DRUG CO., INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(In thousands except, share data)

| | FOR THE NINE MONTHS ENDED | | FOR THE THREE MONTHS ENDED | |
|--|---------------------------|------------|----------------------------|------------|
| | ----- | | | |
| | SEPTEMBER 30, | | | |
| | 2002 | 2001 | 2002 | 2001 |
| | ----- | ----- | ----- | ----- |
| Product sales | \$ 6,152 | \$ 6,754 | \$ 2,013 | \$ 1,826 |
| Product development revenues | -- | 8,500 | -- | 3,500 |
| | ----- | ----- | ----- | ----- |
| Net product revenues | 6,152 | 15,254 | 2,013 | 5,326 |
| Cost of manufacturing | 9,372 | 11,504 | 3,118 | 3,657 |
| Research & development | 1,161 | 926 | 404 | 306 |
| Selling, general and administrative expenses | 5,472 | 4,672 | 1,957 | 1,656 |
| Plant shutdown costs | (120) | -- | -- | -- |
| | ----- | ----- | ----- | ----- |
| Loss from operations | (9,733) | (1,848) | (3,466) | (293) |
| Other income (expense) | | | | |
| ----- | | | | |
| Interest expense, net | (3,398) | (2,890) | (1,232) | (925) |
| Amortization of deferred debt discount and private offering costs | (7,562) | (1,834) | (3,187) | (673) |
| Investment in joint venture | -- | (45) | -- | (14) |
| Other | 5 | 11 | 16 | 2 |
| | ----- | ----- | ----- | ----- |
| NET LOSS | \$ (20,688) | \$ (6,606) | \$ (7,869) | \$ (1,903) |
| | ===== | ===== | ===== | ===== |
| Basic and diluted loss per share | \$ (1.37) | \$ (0.44) | \$ (0.52) | \$ (0.13) |
| | ===== | ===== | ===== | ===== |
| Weighted average number of outstanding shares | 15,065,240 | 14,951,285 | 15,065,240 | 15,043,378 |
| | ===== | ===== | ===== | ===== |

The accompanying notes are an integral part of these statements.

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(In thousands)

| | NINE MONTHS ENDED SEPTEMBER 30 | |
|--|-----------------------------------|-----------|
| | 2002 | 2001 |
| | ----- | ----- |
| Cash flows from operating activities | | |
| Net loss | \$(20,688) | \$(6,606) |
| | ----- | ----- |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities | | |
| Depreciation and amortization | 641 | 868 |
| Amortization of deferred debt discount and private offering costs | 7,562 | 1,834 |
| Amortization of deferred product acquisition costs | 27 | 35 |
| Provision for losses on accounts receivable | -- | 89 |
| Loss on sale of assets | 12 | -- |
| Debentures issued for interest | 1,633 | 1,623 |
| Changes in assets and liabilities | | |
| Accounts receivable | (1,739) | 3,160 |
| Inventories | 304 | 344 |
| Prepaid expenses and other current assets | (453) | 938 |
| Other assets and deposits | 140 | (245) |
| Accounts payable | 531 | (1,225) |
| Accrued expenses | 2,080 | (405) |
| | ----- | ----- |
| Total adjustments | 10,738 | 7,016 |
| | ----- | ----- |
| Net cash (used in) provided by operating activities | (9,950) | 410 |
| | ----- | ----- |
| Cash flows from investing activities | | |
| Capital expenditures | (267) | (1,034) |
| Net proceeds from sale of assets | 16 | -- |
| Investment in joint venture | -- | (41) |
| | ----- | ----- |
| Net cash used in investing activities | (251) | (1,075) |
| | ----- | ----- |
| Cash flows from financing activities | | |
| Proceeds from issuance of notes payable | 10,000 | 6,000 |
| Payments on notes payable | -- | (1,761) |
| Payments on convertible debentures | -- | (2,500) |
| Proceeds from exercise of stock options | -- | 87 |
| Payments to Department of Justice | (233) | (225) |
| | ----- | ----- |
| Net cash provided by financing activities | 9,767 | 1,601 |
| | ----- | ----- |
| NET (DECREASE) INCREASE IN CASH | (434) | 936 |
| Cash at beginning of period | 442 | 697 |
| | ----- | ----- |
| Cash at end of period | \$ 8 | \$ 1,633 |
| | ===== | ===== |

Supplemental disclosure of noncash investing and financing activities

For the nine months ended September 30, 2002

The Company issued approximately \$1,633 of debentures as payment for like amount of accrued debenture interest.

The Company issued approximately 2,120,000 warrants with an estimated relative fair value of \$2,412 in connection with the refinancing of existing bridge loans in January and May 2002.

The Company issued 600,000 warrants with an estimated relative fair value of \$948 for the lending commitment of a bridge loan.

The Company issued approximately 1,367,000 warrants with an estimated relative fair value of \$1,569 in connection with the issuance of bridge loans.

The Company issued 25,000 warrants with an estimated relative fair value of \$30 for acquisition of product ANDAs.

The Company's convertible debt contained beneficial conversion features which were valued at \$3,626.

The accompanying notes are an integral part of these statements.

HALSEY DRUG CO., INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

(UNAUDITED)

(In thousands, except share data)

| | Nine months ended September 30, 2002 | | | | |
|--|--------------------------------------|--------------------------|--------------------------------------|---------------------------|-------------------------|
| | Common Stock, \$.01 par value | | Additional | Accumulated | Total |
| | ----- Shares ----- | ----- Amount ----- | ----- Paid-in Capital ----- | ----- Deficit ----- | ----- Total ----- |
| Balance at January 1, 2002 | 15,065,240 | \$ 151 | \$35,914 | \$(101,501) | \$(65,436) |
| Net loss for the nine months ended September 30, 2002 | | | | (20,688) | (20,688) |
| Issuance of warrants and beneficial conversion features in connection with convertible debt | | | 8,555 | | 8,555 |
| Issuance of warrant for the acquisition of product ANDAs | | | 30 | | 30 |
| | ----- | ----- | ----- | ----- | ----- |
| Balance at September 30, 2002 | 15,065,240 | \$ 151 | \$44,499 | \$(122,189) | \$(77,539) |
| | ===== | ===== | ===== | ===== | ===== |

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, consisting of normal recurring accrual adjustments, considered necessary to present fairly the financial position, results of operations and cash flows for the nine months ended September 30, 2002, assuming that the Company will continue as a going concern, have been made. The results of operations for the nine month period ended September 30, 2002 are not necessarily indicative of the results that may be expected for the full year ended December 31, 2002. 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, 2001 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

At September 30, 2002 the Company had cash of \$8,000 as compared to \$442,000 at December 31, 2001. The Company had a working capital deficiency at September 30, 2002 of \$(83,220,000) and an accumulated deficit of approximately \$(122,189,000). The Company incurred a loss of approximately \$(20,688,000) during the nine months ended September 30, 2002. The working capital deficiency of \$(83,220,000) includes the reclassification of \$66,747,000 of outstanding indebtedness to current liabilities comprising a \$17,500,000 term loan with Watson Pharmaceuticals, Inc. (the "Watson Term Loan") and the Company's \$49,247,000 net outstanding 5% net convertible debentures (the "Debentures") each of which are due in March 2003.

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. As of November 13, 2002, cash on hand was \$200,000 and \$1,100,000 remained available for advance to the Company under the 2002 Galen Bridge Loan Commitment. The Company estimates that the balance of the 2002 Galen Bridge Loan Commitment will fund the Company's working capital requirements only until mid-December 2002. The Company is in need of immediate additional financing in order to fund its working capital requirements and to continue to develop its opiate synthesis technologies. Although the Company is a party to a non-binding term sheet with Care Capital LLC and Essex Woodlands Health Ventures providing the terms of a private offering pursuant to which the Company would receive gross proceeds of \$10 million from the issuance of 5% convertible senior secured debentures (the "2002 Debentures") due March 31, 2006 (the "2002 Debentures Offering"), no assurance can be given that the 2002 Debenture Offering will be completed or that the amount of such financing, if any, will be sufficient to meet the Company's working capital requirements and provide adequate funding to provide for the development of the Company's opiate synthesis technologies. The failure of the Company to complete the 2002 Debenture Offering by mid-December 2002 will require the Company to significantly scale back or terminate operations and possibly seek relief under applicable bankruptcy laws.

The Company has funded operations by securing bridge financing from Galen Partners III, L.P. ("Galen"), certain of Galen's affiliates and certain investors in the Company's Debentures (collectively, "Galen Group") in the aggregate amount of approximately \$7,000,000 advanced in five (5) separate bridge loan transactions during the period from August 15, 2001 through April 5, 2002 (collectively, the "2001/2002 Galen Bridge Loans"). On May 8, 2002, the Company and the Galen Group completed an amendment to the 2001/2002 Galen Bridge Loan Agreement to (i) extend the maturity date of the \$7,000,000 principal

amount of the 2001/2002 Galen Bridge Loans, plus accrued and unpaid interest, to January 1, 2003, (ii) provide for the commitment of Galen to advance up to \$8,000,000 to the Company in the form of additional bridge loans to fund the Company's working capital requirements through December 31, 2002, (the "2002 Galen Bridge Loan Commitment"), and (iii) provide for the advance by Galen to the Company of a bridge loan of \$1,000,000 under the 2002 Galen Bridge Loan Commitment. All advances made by Galen to the Company under the 2002 Galen Bridge Loan Commitment have a maturity date of January 1, 2003.

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 Company's obligations under the 2001/2002 Galen Bridge Loans and advances made to the Company under the 2002 Galen Bridge Loan Commitment, 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 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 \$10 million. The Company is currently seeking such financing through transactions related to its business lines as well as private financings. On November 13, 2002, the Company signed a non-binding term sheet with Care Capital LLC and Essex Woodlands Health Ventures providing the terms of a private offering pursuant to which the Company would receive gross proceeds of \$10 million from the issuance of 5% convertible senior secured debentures (the "2002 Debentures") due March 31, 2006 (the "2002 Debenture Offering"). The closing of the 2002 Debenture Offering is subject to a number of conditions, including receipt of the agreement of each of Watson Pharmaceuticals and the holders of the Company's outstanding debentures to extend the maturity date of the indebtedness under the Watson Term Loan and the Company's outstanding debentures to March 31, 2006. In addition, it is a condition to the completion of the 2002 Debenture Offering that the 2001/2002 Galen Bridge Loans and advances made under the 2002 Galen Bridge Loan Commitment shall be satisfied by the Company's issuance of 2002 Debentures under the 2002 Debenture Offering. The Company has been advised by the Galen Group that it is agreeable to convert the outstanding indebtedness under the 2001/2002 Galen Bridge Loans and advances made under the 2002 Galen Bridge Loan Commitment to 2002 Debentures. In addition, the Company and Watson have agreed in principle to (i) transfer to the Watson Term Loan the Company's payment obligation to Watson of approximately \$3.9 million under the Core Products Supply Agreement between the parties, and (ii) extend the maturity date of the Watson Term Loan to March 31, 2006. In consideration of the amendments to the Watson Term Loan Agreement, the Company will issue to Watson common stock purchase warrants to purchase approximately 10,750,000 shares of the Company's common stock. The Company expects to negotiate with the holders of the Company's Debentures to extend the maturity date of the Debentures. No assurance can be given, however, that the Company will be successful in converting the Company's outstanding bridge loans to 2002 Debentures, in finalizing the amendments to the Watson Term Loan, in extending the maturity dates of the Debentures, or in completing the 2002 Debenture Offering.

The failure to complete the 2002 Debenture Offering and to extend the maturity dates of each of the Watson Term Loan and the Debentures will require the Company to (i) significantly curtail product development activities, (ii) if available, obtain funding through arrangements with collaborative partners or others on terms that may require the Company to relinquish certain rights to its products and technologies, which the Company could otherwise pursue on its own, or that would significantly dilute the Company's stockholders, (iii) significantly scale back or terminate operations, and/or (iv) seek relief under applicable bankruptcy laws. Any extended delay in completing the 2002 Debenture Offering or in obtaining the extension of the maturity dates of the Company's indebtedness will result in the cessation of the Company's continuing development efforts relating to its products and technologies and will have a material adverse effect on the Company's financial condition and results of operations.

NOTE 2 - NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 142 ("SFAS No. 142"), "Goodwill and Other Intangible Assets." SFAS No. 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also requires that intangible assets with definite useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," as amended.

The Company adopted the provisions of SFAS No. 142 effective January 1, 2002. The adoption of SFAS No. 142 had no effect on the financial position or results of operations of the Company.

In August 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS No. 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 modifies the rules for accounting for the impairment or disposal of long-lived assets.

The Company adopted the provisions of SFAS No. 144 effective January 1, 2002. The adoption of SFAS No. 144 had no effect on the financial position or results of operations of the Company.

On April 30, 2002, the FASB issued Statement of Financial Accounting Standard No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS No. 145"). SFAS No. 145 rescinds Statement No. 4, which required all gains and losses from extinguishments of debt to be aggregated and, if material, classified as an extraordinary item, net the related income tax effect. Upon adoption of SFAS No. 145, companies will be required to apply the criteria in APB Opinion No. 30, "Reporting the Results of Operations-reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions" in determining the classification of gains and losses resulting from the extinguishment of debt. SFAS No. 145 is effective for all financial statements issued on or after May 15, 2002.

The Company adopted the provisions of SFAS No. 145 effective May 15, 2002. The adoption of SFAS No. 145 had no effect on the financial position or results of operations of the Company.

On July 30, 2002, the FASB issued Statement of Financial Accounting Standard No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS No. 146"). The standard requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Examples of costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing, or other exit or disposal activity. SFAS No. 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. The Company is currently evaluating the requirements and impact of this statement on its consolidated results of operations and financial position.

NOTE 3 - STRATEGIC ALLIANCE WITH WATSON PHARMACEUTICALS

Pursuant to the terms of the Company's 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 ended 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 the Company 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) (the "Advance Payment Balance") in two (2) equal monthly installments on October 1, 2002 and November 1, 2002.

As of November 13, 2002, the Advance Payment Balance was \$3,901,000. The Company is in default of its obligation to satisfy the repayment of the Advance Payment Balance in equal installments on October 1, 2002 and November 1, 2002. The Core Products Supply Agreement provides that Watson may transfer the Advance Payment Balance to the principal amount of the Watson Term Loan. The Core Products Supply Agreement further provides that Watson may terminate the Agreement if the Company fails to satisfy its payment obligations within sixty (60) days of the receipt of written notice of breach from Watson. To date, Watson has not advised the Company that the Advance Payment Balance will be transferred to the Watson Term Loan nor has Watson provided to the Company a written notice of breach of the Company's payment obligations under the Core Products Supply Agreement. The Company and Watson have agreed in principle to allow the Company to satisfy the Advance Payment Balance by the transfer of such amount to the Watson Term Loan. Although the Company expects that it will be successful in finalizing amendments to the Watson Term Loan Agreement to satisfy its obligations under the Core Products Supply Agreement, no assurance can be given that this will be the case. There also can be no assurance that Watson will not provide to the Company a written notice of breach of the Company's payment obligations under the Core Products Supply Agreement.

Pending the Company's development and receipt of regulatory approval for its API's and finished dosage products currently under development, and the marketing and sale of the same, of which there can be no assurance, substantially all the Company's revenues are expected to be derived from the Core Products Supply Agreement with Watson. In the event Watson provides to the Company a written notice of breach of the Core Products Supply Agreement and the Company is unable to complete the 2002 Debenture Offering or obtain other sources of third-party financing to satisfy its payment obligations to Watson, Watson could elect to terminate the agreement. The Company's failure to satisfy its payment obligations to Watson within sixty (60) days of Watson's provision of a written notice of breach under the Core Products Supply Agreement would also constitute a default under the Watson Term Loan Agreement, permitting Watson to declare the Watson Term Loan due and payable. The termination of the Core Products Supply Agreement with Watson or the Company's default under the Watson Term Loan would have a material adverse effect on the Company's financial condition and could result in a significant scale back or termination of operations, or the Company's petition for relief under applicable bankruptcy laws.

NOTE 4 - 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 2002 and 2001 nine month ended computation are approximately 63,582,000 and 52,192,000, respectively, of outstanding

warrants and options and the effect of convertible debentures and bridge loans outstanding which would be antidilutive.

NOTE 5 - INVENTORIES

Inventories consist of the following:

| | (In thousands) | |
|-----------------|--------------------|-------------------|
| | September 30, 2002 | December 31, 2001 |
| | ----- | ----- |
| Finished Goods | \$ -- | \$ 38 |
| Work in Process | 515 | 1,076 |
| Raw Materials | 1,910 | 1,615 |
| | ----- | ----- |
| | \$2,425 | \$2,729 |
| | ===== | ===== |

NOTE 6 - CONVERTIBLE SUBORDINATED DEBENTURES

Convertible Subordinated Debentures consist of the following:

| | (In thousands) | |
|--------------------------|--------------------|-------------------|
| | September 30, 2002 | December 31, 2001 |
| | ----- | ----- |
| 1998 Debentures | \$ 29,894 | \$ 28,954 |
| 1999 Debentures | 20,273 | 19,580 |
| | ----- | ----- |
| | 50,167 | 48,534 |
| Less: Debt discount | (920) | (2,355) |
| | ----- | ----- |
| | 49,247 | 46,179 |
| Less: Current maturities | (49,247) | -- |
| | ----- | ----- |
| | \$ -- | \$ 46,179 |
| | ===== | ===== |

NOTE 7 - NOTES PAYABLE

Notes payable consist of the following:

| | (In thousands) | |
|--------------------------|--------------------|-------------------|
| | September 30, 2002 | December 31, 2001 |
| | ----- | ----- |
| Bridge loans | \$ 12,778 | \$ 2,500 |
| Capital lease obligation | 50 | 68 |
| | ----- | ----- |
| | \$ 12,828 | \$ 2,568 |
| Less: Debt discount | (2,886) | (--) |
| | ----- | ----- |
| | \$ 9,942 | \$ 2,568 |
| | ===== | ===== |
| Term note payable | \$ 17,500 | \$ 17,500 |
| | ===== | ===== |

On August 15, 2001, the Company and 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 "2001/2002 Galen Bridge Loans"). The proceeds of the 2001/2002 Galen Bridge Loans 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 2001/2002 Galen Bridge Loans bear 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 2001/2002 Galen Bridge Loans had an initial maturity date of December 31, 2001.

On January 9, 2002, the Company and Galen agreed to amend the 2001/2002 Galen Bridge Loans to (1) refinance existing Bridge Loans to April 30, 2002, (2) issue warrants expiring January 9, 2009 to purchase approximately 195,000 shares of the Company's common stock at an exercise price of \$1.837 per share in exchange for the extension of the maturity date, and (3) provide for \$3,000,000 of additional financing. The relative estimated fair value of the warrants of \$267,000 was recorded as additional debt discount and amortized over the life of the bridge loan.

The Company borrowed \$3,000,000 of the additional financing in \$1,000,000 installments on January 9, February 1, and March 1, 2002. Common stock purchase warrants to purchase 75,000 shares of the Company's common stock were issued on January 9, February 1, and March 1, 2002, at exercise prices of \$1.837, \$1.87 and \$2.087, respectively. The relative estimated fair value of the warrants of \$103,000, \$119,000, and \$112,000, respectively, was recorded as additional debt discount and amortized over the remaining life of the bridge loans.

The Galen Bridge Loans are convertible into shares of the Company's common stock at \$1.837 to \$2.087 per share. The estimated value of the conversion feature of \$754,000, was recorded as additional debt discount and amortized over the life of the Galen Bridge Loans.

On April 5, 2002, the Company further amended the 2001/2002 Galen Bridge Loans to provide \$1,500,000 of additional financing with a maturity date of April 30, 2002. The April 5, 2002 bridge loan is convertible into shares of the Company's common stock at \$2.01 per share. Common stock purchase warrants to purchase 50,000 shares of the Company's common stock were issued on April 5, 2002, at an exercise price of \$2.01. The relative estimated fair value of the warrants of \$98,000 and the estimated value of the conversion feature of \$464,000 was recorded as additional debt discount and amortized over the life of the Galen Bridge Loans.

On May 8, 2002, the Company and the Galen Group completed an amendment to the 2001/2002 Galen Bridge Loan Agreement to (i) extend the maturity date of a \$7,000,000 principal amount of the 2001/2002 Galen Bridge Loans, plus accrued and unpaid interest, to January 1, 2003, (ii) provide for the commitment of Galen to advance up to \$8,000,000 to the Company in the form of additional bridge loans to fund the Company's working capital requirements through December 31, 2002 (the "2002 Galen Bridge Loan Commitment") and (iii) provide for the advance by Galen to the Company of a bridge loan of \$1,000,000 under the 2002 Galen Bridge Loan Commitment.

In consideration for the extension of the maturity date on the 2001/2002 Galen Bridge Loan to January 1, 2003, the Company issued common stock purchase warrants to the Galen Group to purchase an aggregate of approximately 1,925,000 shares of the Company's common stock, representing 33,000 shares of the Company's common stock for each \$1,000,000 in bridge financing provided under the 2001/2002 Galen Bridge Loans having a term of thirty

(30) days, subject to anti-dilution protection. In consideration for Galen's agreement to provide the 2002 Galen Bridge Loan Commitment, the Company issued to Galen a common stock purchase warrant exercisable for 600,000 shares of the Company's common stock at an exercise price of \$2.16. In addition, the Company will issue additional common stock purchase warrants to Galen exercisable for up to 1,200,000 shares of the Company's common stock, issued in installments as advances are made to the Company under the 2002 Galen Bridge Loan Commitment. The number of warrants issuable by the Company for each advance will equal 33,000 shares of the Company's common stock for each \$1,000,000 in additional bridge financing having a term of thirty (30) days. Such additional warrants will have an exercise price equal to the average trading price of the Company's common stock for the twenty (20) trading days preceding the issuance of each such warrant, subject to anti-dilution protection.

The May 8, 2002 bridge loan is convertible into shares of the Company's common stock at \$2.16 per share. Common stock purchase warrants to purchase approximately an aggregate of 2,789,000 shares of the Company's common stock were issued at an exercise price of \$2.16. The relative estimated fair value of the warrants of \$3,387,000 and the estimated value of the conversion feature of \$1,635,000 was recorded as additional debt discount and amortized over the life of the Galen Bridge Loans.

On June 3, 2002, \$1.0 million was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.90 per share. Common stock purchase warrants to purchase approximately 236,000 shares of the Company's common stock were issued at an exercise price of \$1.90. The relative estimated fair value of the warrants of \$234,000 and the estimated value of the conversion feature of \$87,000 was recorded as additional debt discount and amortized over the remaining life of the bridge loan.

During the month of July 2002, \$1.5 million was advanced by Galen to the Company in the form of bridge loans under the 2002 Galen Bridge Loan Commitment. The bridge loans are convertible into shares of the Company's common stock at \$1.72 and \$1.45 per share. Common stock purchase warrants to purchase 204,000, and 90,000 shares of the Company's common stock were issued on July 1, and July 23, at exercise prices of \$1.72, and \$1.45, respectively. The relative estimated fair value of the warrants of approximately \$206,000, and \$81,000, respectively, and the estimated value of the conversion feature of \$136,000 and \$46,000, respectively was recorded as additional debt discount and amortized over the remaining life of the bridge loans.

On August 5, 2002, \$1.0 million was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.42 per share. Common stock purchase warrants to purchase approximately 166,000 shares of the Company's common stock were issued at an exercise price of \$1.42. The relative estimated fair value of the warrants of \$167,000 and the estimated value of the conversion feature of \$223,000 was recorded as additional debt discount and amortized over the remaining life of the bridge loan.

On September 3, 2002, \$1.0 million was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.51 per share. Common stock purchase warrants to purchase approximately 132,000 shares of the Company's common stock were issued at an exercise price of \$1.51. The relative estimated fair value of the warrants of approximately \$154,000 and the estimated value of the conversion feature of approximately \$280,000 was recorded as additional debt discount and amortized over the remaining life of the bridge loan.

On October 1, 2002, \$1.0 million was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.75 per share. Common stock purchase warrants to purchase approximately 102,000 shares of the Company's common stock were issued at an exercise price of \$1.75. The relative estimated fair value of the warrants of approximately \$121,000 and the estimated value of the conversion feature of

approximately \$90,000 will be recorded as additional debt discount in the Fourth Quarter and amortized over the remaining life of the bridge loan.

On November 4, 2002, \$200,000 was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.76 per share. Common stock purchase warrants to purchase approximately 13,000 shares of the Company's common stock was issued at an exercise price of \$1.76. The relative estimated fair value of the warrants of approximately \$18,000 and the estimated value of the conversion feature of approximately \$29,000 will be recorded as additional debt discount in the Fourth Quarter and amortized over the remaining life of the bridge loan.

On November 12, 2002, \$200,000 was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.77 per share. Common stock purchase warrants to purchase approximately 11,000 shares of the Company's common stock was issued at an exercise price of \$1.77. The relative estimated fair value of the warrants and the estimated value of the conversion feature will be recorded as additional debt discount in the Fourth Quarter and amortized over the remaining life of the bridge loan.

All advances made by Galen to the Company under the 2002 Galen Bridge Loan Commitment have a maturity date of January 1, 2003.

As of September 30, 2002 Watson Pharmaceuticals, Inc. had advanced \$17,500,000 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 in March 2003. (See Note 3)

NOTE 8 - 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 condensed consolidated financial statements.

NOTE 9 - RECLASSIFICATIONS

Certain reclassifications have been made to prior period amounts to conform to the current year's presentation. Such reclassifications have had no effect on reported net loss.

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

NINE MONTHS ENDED SEPTEMBER 30, 2002 VS NINE MONTHS ENDED SEPTEMBER 30, 2001

NET PRODUCT REVENUES

The Company's net product revenues for the nine months ended September 30, 2002 of \$6,152,000 represents a decrease of \$9,102,000 (59.7%) as compared to net product revenues for the nine months ended September 30, 2001 of \$15,254,000. During the nine month period ended September 30, 2001, the Company recognized \$8,500,000 of product development revenues associated with the sale of certain product rights to Watson Pharmaceuticals, Inc. The \$602,000 or (8.9%) decrease in product sales was due to the inability of the Company to obtain certain raw materials during the nine months ended September 30, 2002. The Company believes that these raw materials may become available in the Fourth Quarter of 2002. 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 partner with others for the marketing and distribution of these products.

COST OF MANUFACTURING

For the nine months ended September 30, 2002, cost of manufacturing decreased \$2,132,000 to \$9,372,000 as compared to the nine months ended September 30, 2001 of \$11,504,000. This decrease is primarily attributable to reduced costs associated with the decreased net product revenues as noted above as well as the elimination of manufacturing overhead expenses from the closure of the Company's Brooklyn, New York facility in March 2001. During 2001, the Company's Congers, New York facility utilized both third party packaging operations and laboratory services. The decrease also reflects the transitioning of both outside packaging and laboratory functions to internal departments.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses as a percentage of net product revenues for the nine months ended September 30, 2002 and 2001 were 88.9% and 30.6%, respectively. Overall these expenses in the first nine months of 2002 increased \$800,000 over the same period in 2001. The increase is primarily attributable to legal expenses incurred for patent research and regulatory matters associated with the DEA manufacturing and import license registrations and increases in product marketing expenses and corporate insurance premiums.

RESEARCH AND DEVELOPMENT EXPENSES

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 the development of the Company's Opiate Synthesis Technologies, including the development for sale of new chemical products and the development of APIs, as well as new generic drug product development efforts and manufacturing process improvements. 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 bio-availability, bio-equivalence and shelf-life. During 2002, 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. Research and development expenses increased \$235,000 over the same period in 2001 and as a percentage of net product revenues for the nine months ended September 30, 2002 and 2001 was 18.9% and 6.1%, respectively.

The Company is proceeding with the development of products, apart from those obtained from Barr Laboratories, for submission to the FDA. During fiscal 2002, the Company

anticipates the submission of four ANDA supplements or amendments to the FDA. The supplements and amendments relate to the 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 is performing the necessary regulatory steps to effect the transfer of certain 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 mid-2003, 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 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.

The Company is continuing development efforts relating to certain API's. 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. Although the Company did not generate revenues from the sale of API's in fiscal 2001 or in the nine months ended September 30, 2002, it is the Company's expectation that its strategic alliance with Watson Pharmaceuticals, Inc. and the continued development of the Opiate Synthesis Technologies and other API development efforts, in addition to assisting in the expansion of the Company's line of finished dosage products, will generate revenues from the sale of products using internally produced APIs starting in the Fourth Quarter of 2003 and such revenue segment will likely increase thereafter as a percentage of total revenue. The Company currently manufactures two API's and has seven others under development.

NET LOSS

For the nine months ended September 30, 2002, the Company had a net loss of \$(20,688,000) as compared to a net loss of \$(6,606,000) for the nine months ended September 30, 2001. Included in the results for the nine months ended September 30, 2002 was net interest expense of \$3,398,000 and amortization of deferred debt discount and private offering costs of \$7,562,000 as compared to \$2,890,000 and \$1,834,000, respectively, for the nine months ended September 30, 2001.

THREE MONTHS ENDED SEPTEMBER 30, 2002 VS THREE MONTHS ENDED SEPTEMBER 30, 2001

NET PRODUCT REVENUES

The Company's net product revenues for the three months ended September 30, 2002 of \$2,013,000 represents a decrease of \$3,313,000 or (62.2%) as compared to net product revenues for the three months ended September 30, 2001 of \$5,326,000. During the three month period ending September 30, 2001, the Company recognized \$3,500,000 of product development revenues associated with the sale of certain product rights to Watson Pharmaceuticals, Inc. The increase in product sales of \$187,000, or 10.2%, reflects some limited availability of raw material which had been in short supply throughout 2002. The Company believes that these raw materials may become available in the Fourth Quarter of 2002.

On an ongoing basis, the Company expects to generate revenues from the development

and manufacture of both finished dosage and API's and then partner with others for the marketing and distribution of these products.

COST OF MANUFACTURING

For the three months ended September 30, 2002 cost of manufacturing decreased by \$539,000 as compared to the three months ended September 30, 2001. During this three month period in 2001, the Company's Congers, New York facility utilized both third party packaging operations and laboratory services. The decrease reflects the transitioning of both outside packaging and laboratory functions to internal departments.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses as a percentage of net product revenues for the three months ended September 30, 2002 and 2001 were 97.2% and 31.1%, respectively. Overall these expenses in the three months ended September 30, 2002 increased \$301,000 over the same period in 2001. The increase is primarily attributable to legal expense incurred for patent research and regulatory matters associated with the DEA manufacturing and import license registrations, and increases in product marketing expenses and corporate insurance premiums.

RESEARCH AND DEVELOPMENT EXPENSES

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 the development of the Opiate Synthesis Technologies, including the development for sale of new chemical products and the development of APIs, as well as new generic drug product development efforts and manufacturing process improvements. 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. During 2002, 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. Research and development expenses for the three months ended September 30, 2002 increased \$98,000 over the same period in 2001 and as a percentage of net product revenues for the three months ended September 30, 2002 and 2001 was 20.1% and 5.7%, respectively.

NET LOSS

For the three months ended September 30, 2002, the Company had a net loss of \$7,869,000 as compared to a net loss of \$1,903,000 for the three months ended September 30, 2001. Included in the results for the three months ended September 30, 2002 was interest expense of \$1,232,000 and amortization of deferred debt discount and private offering costs of \$3,187,000 as compared to \$925,000 and \$673,000 respectively, over the same period in 2001.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2002, the Company had cash of \$8,000 as compared to \$422,000 at December 31, 2001. The Company had a working capital deficiency at September 30, 2002 of \$(83,220,000) and an accumulated deficit of approximately \$(122,189,000). The Company incurred a loss of approximately \$(20,688,000) during the nine months ended September 30, 2002.

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. As of November 13, 2002, cash on hand was \$200,000 and \$1,100,000 remained available for advance to the Company under the 2002 Galen Bridge Loan Commitment. The Company estimates that the balance of the 2002 Galen Bridge Loan Commitment will fund the

Company's working capital requirements only until mid-December 2002. The Company is in need of immediate additional financing in order to fund its working capital requirements and to continue to develop its opiate synthesis technologies. Although the Company is a party to a non-binding term sheet with Care Capital LLC and Essex Woodlands Health Ventures providing the terms of a private offering pursuant to which the Company would receive gross proceeds of \$10 million from the issuance of 5% convertible senior secured debentures (the "2002 Debentures") due March 31, 2006 (the "2002 Debentures Offering"), no assurance can be given that the 2002 Debenture Offering will be completed or that the amount of such financing, if any, will be sufficient to meet the Company's working capital requirements and provide adequate funding to provide for the development of the Company's opiate synthesis technologies. The failure of the Company to complete the 2002 Debenture Offering by mid-December 2002 will require the Company to significantly scale back or terminate operations and possibly seek relief under applicable bankruptcy laws.

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 provides for funding 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 September 30, 2002, Watson had advanced the full \$17.5 million available 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 in March 2003. The net proceeds of the Watson Term Loan were used in part to satisfy certain bridge loans made by Galen Partners III, L.P. ("Galen") 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 to fund the Company's working capital requirements.

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 ended 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) (the "Advance Payment Balance") in two (2) equal monthly installments on October 1, 2002 and November 1, 2002.

As of November 13, 2002, the Advance Payment Balance was \$3,901,000. The Company is in default of its obligation to satisfy the repayment of the Advance Payment Balance in equal installments on October 1, 2002 and November 1, 2002. The Core Products Supply Agreement provides that Watson may transfer the Advance Payment Balance to the principal amount of the Watson Term Loan. The Core Products Supply Agreement further provides that Watson may terminate the Agreement if the Company fails to satisfy its payment obligations within sixty (60) days of the receipt of written notice of breach from Watson. To date, Watson has not advised the Company that the Advance Payment Balance will be transferred to the Watson Term Loan nor has Watson provided to the Company a

written notice of breach of the Company's payment obligations under the Core Products Supply Agreement. The Company and Watson have agreed in principle to allow the Company to satisfy the Advance Payment Balance by the transfer of such amount to the Watson Term Loan. Although the Company expects that it will be successful in finalizing amendments to the Watson Term Loan Agreement to satisfy its obligations under the Core Products Supply Agreement, no assurance can be given that this will be the case. There also can be no assurance that Watson will not provide to the Company a written notice of breach of the Company's payment obligations under the Core Products Supply Agreement.

Pending the Company's development and receipt of regulatory approval for its API's and finished dosage products currently under development, and the marketing and sale of the same, of which there can be no assurance, substantially all the Company's revenues are expected to be derived from the Core Products Supply Agreement with Watson. In the event Watson provides to the Company a written notice of breach of the Core Products Supply Agreement and the Company is unable to complete the 2002 Debenture Offering or obtain other sources of third-party financing to satisfy its payment obligations to Watson, Watson could elect to terminate the agreement. The Company's failure to satisfy its payment obligations to Watson within sixty (60) days of Watson's provision of a written notice of breach under the Core Products Supply Agreement would also constitute a default under the Watson Term Loan Agreement, permitting Watson to declare the Watson Term Loan due and payable. The termination of the Core Products Supply Agreement with Watson or the Company's default under the Watson Term Loan would have a material adverse effect on the Company's financial condition and could result in a significant scale back or termination of operations or the Company's petition for relief under applicable bankruptcy laws.

The Company secured bridge financing from Galen, certain of Galen's affiliates and certain investors in the Company's 5% convertible subordinated debentures (collectively, the "Galen Group") in the aggregate amount of approximately \$7,000,000 funded through five (5) separate bridge loan transactions during the period from August 15, 2001 through April 5, 2002 (collectively, the "2001/2002 Galen Bridge Loans"). \$2,500,000 of the 2001/2002 Galen Bridge Loans 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 remaining \$4,500,000 balance of the 2001/2002 Galen Bridge Loans was used for working capital to fund continuing operations. The Galen Bridge Loans bear interest at the rate of 10% per annum and are 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 promissory notes issued in the 2001/2002 Galen Bridge Loans are convertible into common stock at an average initial conversion price of \$2.33 per share, which conversion price equals the average trading price of the Company's common stock for the 20 days preceding the closing date of each bridge loan advance. The conversion price of the promissory notes is subject to full-ratchet dilution protection to equal the lower purchase price/conversion price of the Company's securities issued in a subsequent offering. In consideration for the extension of the 2001/2002 Galen Bridge Loans, the Company issued to the Galen Group common stock purchase warrants to purchase an aggregate of 657,461 shares of the Company's common stock at an average initial exercise price of \$2.22 per share. The exercise price of the Warrants is subject to full-ratchet dilution protection to equal the lower purchase price/conversion price of the Company's securities issued in a subsequent offering.

On May 8, 2002, the Company and the Galen Group completed an amendment to the 2001/2002 Galen Bridge Loan Agreement to (i) extend the maturity date of the \$7,000,000 principal amount of the 2001/2002 Galen Bridge Loans, plus accrued and unpaid interest, to January 1, 2003, (ii) provide for the commitment of Galen to advance up to \$8,000,000 to the Company in the form of additional bridge loans to fund the Company's working capital requirements through December 31, 2002 (the "2002 Galen Bridge Loan Commitment") and (iii) provide for the advance by Galen to the Company of a bridge loan of \$1,000,000 under the 2002 Galen Bridge Loan Commitment.

In consideration for the 2001/2002 Bridge Loans Maturity Date Extension, the Company issued common stock purchase warrants to the Galen Group to purchase an aggregate of approximately 1,925,000 shares of the Company's common stock, representing 33,000 shares of the Company's common stock for each \$1,000,000 in bridge financing provided under the 2001/2002 Galen Bridge Loans having a term of thirty (30) days. With respect to the 2002 Galen Bridge Loan Commitment, advances bear interest at the rate of ten percent (10%) per annum, are secured by a lien on all the Company's assets and have a maturity date of January 1, 2003. Promissory notes issued under the 2002 Galen Bridge Loan Commitment are convertible into the Company's common stock at a conversion price equal to the average of the trading price of the Company's common stock for the twenty (20) trading days preceding the issuance of each promissory note, subject to full-ratchet dilution protection to equal the lower purchase price/conversion price of the Company's securities issued in a subsequent offering. In consideration for Galen's agreement to provide the 2002 Galen Bridge Loan Commitment, the Company issued to Galen a common stock purchase warrant exercisable for 600,000 shares of the Company's common stock at an exercise price equal to the average trading price for the Company's common stock for the twenty (20) trading days preceding the issuance of such warrant, subject to the same full-ratchet dilution protections provided in the bridge loan promissory notes. In addition, the Company will issue additional common stock purchase warrants to Galen exercisable for up to 1,200,000 shares of the Company's common stock, issued in installments as advances are made to the Company under the 2002 Galen Bridge Loan Commitment. The number of warrants issuable by the Company for each advance will equal 33,000 shares of the Company's common stock for each \$1,000,000 in additional bridge financing having a term of thirty (30) days. Such additional warrants will have an exercise price equal to the average trading price of the Company's common stock for the twenty (20) trading days preceding the issuance of each such warrant, subject to the same full-ratchet dilution protections provided in the bridge loan promissory notes.

The May 8, 2002 bridge loan is convertible into shares of the Company's common stock at \$2.16 per share. Common stock purchase warrants to purchase approximately an aggregate of 2,789,000 shares of the Company's common stock were issued at an exercise price of \$2.16. The relative estimated fair value of the warrants of \$3,387,000 and the estimated value of the conversion feature of \$1,635,000 was recorded as additional debt discount and amortized over the life of the Galen Bridge Loan.

On June 3, 2002, \$1.0 million was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.90 per share. Common stock purchase warrants to purchase approximately 236,000 shares of the Company's common stock were issued at an exercise price of \$1.90. The relative estimated fair value of the warrants of \$234,000 and the estimated value of the conversion feature of \$87,000 was recorded as additional debt discount and amortized over the remaining life of the bridge loans.

During the month of July 2002, \$1.5 million was advanced by Galen to the Company in the form of bridge loans under the 2002 Galen Bridge Loan Commitment. The bridge loans are convertible into shares of the Company's common stock at \$1.72 and \$1.45 per share. Common stock purchase warrants to purchase 204,000, and 90,000 shares of the Company's common stock were issued on July 1, and July 23, at exercise prices of \$1.72, and \$1.45, respectively. The relative estimated fair value of the warrants of approximately \$206,000, and \$81,000, respectively, and the estimated value of the conversion feature of \$136,000 and 46,000, respectively, was recorded as additional debt discount and amortized over the remaining life of the bridge loans.

On August 5, 2002, \$1.0 million was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.42 per share. Common stock purchase warrants to purchase approximately 166,000 shares of the Company's common stock were issued at an exercise price of \$1.42. The relative estimated fair value of the warrants of approximately \$167,000 and the estimated value of the conversion feature of \$223,000

was recorded as additional debt discount and amortized over the remaining life of the bridge loan.

On September 3, 2002, \$1.0 million was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.51 per share. Common stock purchase warrants to purchase approximately 132,000 shares of the Company's common stock were issued at an exercise price of \$1.51. The relative estimated fair value of the warrants of approximately \$154,000 and the estimated value of the conversion feature of approximately \$280,000 was recorded as additional debt discount and amortized over the remaining life of the bridge loan.

On October 1, 2002, \$1.0 million was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.75 per share. Common stock purchase warrants to purchase approximately 102,000 shares of the Company's common stock were issued at an exercise price of \$1.75. The relative estimated fair value of the warrants of approximately \$121,000 and the estimated value of the conversion feature of approximately \$90,000 will be recorded as additional debt discount in the Fourth Quarter and amortized over the remaining life of the bridge loan.

On November 4, 2002, \$200,000 was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.76 per share. Common stock purchase warrants to purchase approximately 13,000 shares of the Company's common stock was issued at an exercise price of \$1.76. The relative estimated fair value of the warrants of approximately \$18,000 and the estimated value of the conversion feature of approximately \$29,000 will be recorded as additional debt discount in the Fourth Quarter and amortized over the remaining life of the bridge loan.

On November 12, 2002, \$200,000 was advanced by Galen to the Company in the form of a bridge loan under the 2002 Galen Bridge Loan Commitment. The bridge loan is convertible into shares of the Company's common stock at \$1.77 per share. Common stock purchase warrants to purchase approximately 11,000 shares of the Company's common stock was issued at an exercise price of \$1.77. The relative estimated fair value of the warrants and the estimated value of the conversion feature will be recorded as additional debt discount in the Fourth Quarter and amortized over the remaining life of the bridge loan.

All advances made by Galen to the Company under the 2002 Galen Bridge Loan Commitment have a maturity date of January 1, 2003.

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 opiate synthesis technologies will continue through 2004. In order to fund continued operations, and to fund the continued development of the Company's opiate synthesis 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 \$10 million. The Company is seeking such financing through transactions related to its business lines as well as private financings and is currently in active negotiations with certain third parties. Although the Company is a party to a non-binding term sheet with Care Capital LLC and Essex Woodlands Health Ventures providing the terms of the 2002 Debenture Offering, the closing of the 2002 Debenture Offering is subject to a number of conditions, including receipt of the agreement of each of Watson Pharmaceuticals and the holders of the Company's outstanding debentures to

extend the maturity date of the indebtedness under the Watson Term Loan and the Company's outstanding debentures to March 31, 2006. In addition, it is a condition to the completion of the 2002 Debenture Offering that the 2001/2002 Galen Bridge Loans and advances made under the 2002 Galen Bridge Loan Commitment shall be satisfied by the Company's issuance of 2002 Debentures under the 2002 Debenture Offering. The Company has been advised by the Galen Group that it is agreeable to convert the outstanding indebtedness under the 2001/2002 Galen Bridge Loans and advances made under the 2002 Galen Bridge Loan Commitment to 2002 Debentures. In addition, the Company and Watson have agreed in principle to (i) transfer to the Watson Term Loan the Company's payment obligation to Watson of approximately \$3.9 million under the Core Products Supply Agreement between the parties, and (ii) extend the maturity date of the Watson Term Loan to March 31, 2006. In consideration the amendments to the Watson Term Loan Agreement, the Company will issue to Watson common stock purchase warrants to purchase approximately 10,750,000 shares of the Company's common stock. The Company expects to negotiate with the holders of the Company's Debentures to extend the maturity date of the Debentures. The Debentures have a maturity date of March 31, 2003. No assurance can be given, however, that the Company will be successful in converting the Company's outstanding bridge loans to 2002 Debentures, in finalizing the amendments to the Watson Term Loan Agreement, in extending the maturity dates for the Debentures, or in completing the 2002 Debenture Offering.

The failure of the Company to complete the 2002 Debenture Offering and to extend the maturity dates of each of the Watson Term Loan and the Debentures will require the Company to (i) significantly curtail product commercialization efforts, including the development and commercialization of the opiate synthesis technologies, (ii) if available, obtain funding through arrangements with collaborative partners or others on terms that may require the Company to relinquish certain rights in its opiate synthesis technologies, which the Company could otherwise pursue on its own, or that would significantly dilute the Company's stockholders, (iii) significantly scale back or terminate operations, and/or (iv) seek relief under applicable bankruptcy laws. Any extended delay in completing the 2002 Debenture Offering or in obtaining the extension of the maturity dates of the Company's indebtedness will result in the cessation of the Company's continuing development efforts relating to its opiate synthesis technologies and will have a material adverse effect on the Company's financial condition and results of operations.

The following table presents the Company's expected cash requirements for contractual obligations outstanding as of September 30, 2002:

| (in thousands) | Total | Due as of 9/30/03 | Due as of 9/30/04 and 9/30/05 | Due as of 9/30/06 and 9/30/07 | Due Thereafter |
|---|----------|----------------------|-------------------------------------|-------------------------------------|-------------------|
| | ----- | ----- | ----- | ----- | ----- |
| Convertible subordinated debentures (1) | \$50,167 | \$50,167 | -- | -- | -- |
| Bridge loans payable (1) | 12,778 | 12,778 | -- | -- | -- |
| Term loan payable (1) | 17,500 | 17,500 | -- | -- | -- |
| Department of justice settlement | 841 | 300 | \$ 541 | -- | -- |
| Capital leases | 50 | 26 | 24 | -- | -- |
| Operating leases | 1,254 | 725 | 517 | \$12 | -- |
| Employment agreements | 917 | 355 | 562 | -- | -- |
| | ----- | ----- | ----- | --- | --- |
| Total-Contractual Cash Obligations | \$83,507 | \$81,851 | \$1,644 | \$12 | \$-- |
| | ===== | ===== | ===== | === | === |

(1) As discussed in Note 1 - Basis of Presentation, if the Company is successful in completing the 2002 Debenture Offering, of which there can be no assurance, Galen has advised the Company that it is agreeable to convert the outstanding indebtedness under the 2001/2002 Galen Bridge Loans and advances made under the 2002 Galen Bridge Loan Commitment to 2002 Debentures. In addition, the Company and Watson have agreed in principle to (i) transfer to the Watson Term Loan the Company's payment obligations under the Core Products Supply Agreement between the parties, and (ii) extend the maturity date of Watson Term Loan to March 31, 2006. The Company expects to negotiate with the holders of the Company's Debentures to extend the maturity date of the Debentures. No assurance can be given, however, that the Company will be successful in converting the Company's outstanding bridge loans to 2002 Debentures, in finalizing the amendments to the Watson Term Loan Agreement, in extending the maturity dates for the Debentures, or in completing the 2002 Debenture Offering.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60, which was released by the Securities and Exchange Commission ("SEC") in December 2001, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note A of the Notes to Consolidated Financial Statements, as contained in the Company's Annual Report on Form 10-K, includes a summary of the Company's significant accounting policies and methods used in the preparation of the financial statements. In preparing these financial statements, the Company has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. The Company does not believe there is a great likelihood that materially different amounts would be reported under different conditions or using different assumptions. The Company's critical accounting policies are as follows:

REVENUE RECOGNITION

The Company recognizes revenue at the time a product is shipped to customers. The Company established sales provisions for estimated chargebacks, discounts, rebates, returns, pricing adjustments and other sales allowances concurrently with the recognition of revenue. The sales provisions are established based upon consideration of a variety of factors, including but not limited to, actual return and historical experience by product type, the number and timing of competitive products approved for sale, the expected market for the product, estimated customer inventory levels by product, price declines and current and projected economic conditions and levels of competition. Actual product return, chargebacks and other sales allowances incurred are, however, dependent upon future events. Management continually monitors the factors that influence sales allowance estimates and make adjustments to these provisions when allowances may differ from established allowances.

ALLOWANCE FOR DOUBTFUL ACCOUNTS

Estimates are used in determining the allowance for doubtful accounts based on the Company's historical collections experience, current trends, credit policy and a percentage of its accounts receivable by aging category. In determining these percentages, the Company looks at historical write-offs of its receivables. The Company also looks at the credit quality of its customer base as well as changes in its credit policies. The Company continuously monitors collections and payments from its customers. While credit losses have historically been within expectations and the provisions established, the Company cannot guarantee that it will continue to experience the same credit loss rates that it has in the past.

INVENTORIES

The Company's inventories are stated at the lower of cost or market, with cost determined on the first-in, first-out basis. In evaluating whether inventory is stated at

the lower of cost or market, management considers such factors as the amount of inventory on hand, remaining shelf life and current and expected market conditions, including levels of competition. As appropriate, the Company records provisions to reduce inventories to their net realizable value.

INCOME TAXES

Deferred income taxes are recognized for temporary differences between financial statement and income tax bases of assets and liabilities and loss carry-forwards for which income tax benefits are expected to be realized in future years. A valuation allowance is established, when necessary, to reduce deferred tax assets to the amount expected to be realized. In estimating future tax consequences, the Company generally considers all expected future events other than an enactment of changes in the tax laws or rates. The Company has recorded a full valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. While the Company has considered future taxable income in assessing the need for the valuation allowance, in the event the Company were to determine that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made.

STOCK COMPENSATION

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25") and comply with the disclosure provision of SFAS No. 123, "Accounting for Stock-based Compensation" ("SFAS No. 123"). If the Company were to include the cost of stock-based employee compensation in the financial statements, the Company's operating results would decline based on the fair value of the stock-based employee compensation.

DEFERRED DEBT DISCOUNT

Deferred debt discount results from the issuance of stock warrants in connection with the issuance of subordinated debt and other notes payable. The amount of the discount is recorded as a reduction of the related obligation and is amortized over the remaining life of the related obligations. Management determines the amount of the discount, based, in part, by the relative fair values ascribed to the warrants determined by an independent valuation or through the use of the Black-Scholes valuation model. Inherent in the Black-Scholes valuation model are assumptions made by management regarding the estimated life of the warrant, the estimated volatility of the Company's common stock and the expected dividend yield.

New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 142 ("SFAS No. 142"), "Goodwill and Other Intangible Assets". SFAS No. 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also requires that intangible assets with definite useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," as amended.

The Company adopted the provisions of SFAS No. 142 effective January 1, 2002. The adoption of SFAS No. 142 had no effect on the financial position or results of operations of the Company.

In August 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS No. 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 modifies the rules for accounting for the impairment or disposal of long-lived

assets.

The Company adopted the provisions of SFAS No. 144 effective January 1, 2002. The adoption of SFAS No. 144 had no effect on the financial position or results of operations of the Company.

On April 30, 2002 the FASB issued Statement of Financial Accounting Standard No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS No. 145"). SFAS No. 145 rescinds Statement No. 4, which required all gains and losses from extinguishments of debt to be aggregated and, if material, classified as an extraordinary item, net of related income tax effect. Upon adoption of SFAS No. 145, companies will be required to apply the criteria in APB Opinion No. 30, "Reporting the Results of Operations-reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions" in determining the classification of gains and losses resulting from the extinguishment of debt. SFAS No. 145 is effective for all financial statements issued on or after May 15, 2002.

The Company adopted the provisions of SFAS No. 145 effective May 15, 2002. The adoption of SFAS No. 145 had no effect on the financial position or results of operations of the Company.

On July 30, 2002, the FASB issued Statement of Financial Accounting Standard No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS No. 146"). The standard requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Examples of costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing, or other exit or disposal activity. SFAS No. 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. The Company is currently evaluating the requirements and impact of this statement on its consolidated results of operations and financial position.

ITEM 4. CONTROLS AND PROCEDURES

Within the 90 days prior to the date of this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including its consolidated subsidiaries) required to be included in the Company's periodic Securities and Exchange Commission filings. No significant changes were made in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

Disclosure controls and procedures are those controls and other procedures that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including the Company's principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

PART II OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

During the quarter ended September 30, 2002, the Company issued (i) 5% Convertible Debentures in the principal amount of approximately \$551,000 in satisfaction of accrued interest on the Company's outstanding 5% Convertible Subordinated Debentures issued in March and June 1998, and May and July 1999 (the "Convertible Debentures"), and (ii) convertible promissory notes and warrants pursuant to outstanding bridge loans (the "Bridge Loan Securities").

Each of the holders of the Convertible Debentures for which interest payments were made in 5% Convertible Subordinated Debentures, and the bridge lenders receiving the Bridge Loan Securities are accredited investors as defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended (the "Act"). The 5% Convertible Subordinated Debentures issued in satisfaction of the interest payments under the Convertible Debentures and the Bridge Loan Securities 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.

Date: November 13, 2002

HALSEY DRUG CO., INC.

By: s/s Michael K. Reicher

Michael K. Reicher
Chairman and
Chief Executive Officer

By: s/s Peter A. Clemens

Peter A. Clemens
VP & Chief Financial Officer

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Michael K. Reicher, the Chief Executive Officer of Halsey Drug Co.,
Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Halsey Drug Co., Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

s/s Michael K. Reicher

Michael K. Reicher
Chief Executive Officer

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Peter A. Clemens, the Chief Financial Officer of Halsey Drug Co., Inc.,
certify that:

1. I have reviewed this quarterly report on Form 10-Q of Halsey Drug Co., Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - d) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - e) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - f) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - c. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

s/s Peter A. Clemens

Peter A. Clemens
Chief Financial Officer

CERTIFICATION OF PERIODIC REPORT

I, Michael K. Reicher, the Chief Executive Officer of Halsey Drug Co., Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

- (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2002 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 13, 2002

/s/ Michael K. Reicher

Michael K. Reicher
Chief Executive Officer

CERTIFICATION OF PERIODIC REPORT

I, Peter A. Clemens, the Chief Financial Officer and Vice President of Halsey Drug Co., Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

- (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2002 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 13, 2002

/s/ Peter A. Clemens

Peter A. Clemens
Chief Financial Officer
and Vice President