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BARR LABORATORIES INC

Form 10-Q

November 14, 2001

UNITED STATES  
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 quarterly period ended September 30, 2001 or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 1-9860

BARR LABORATORIES, INC.  
(Exact name of Registrant as specified in its charter)

NEW YORK  
(State or Other Jurisdiction of  
Incorporation or Organization)

22-1927534  
(I.R.S. - Employer  
Identification No.)

TWO QUAKER ROAD, P. O. BOX 2900, POMONA, NEW YORK 10970-0519  
(Address of principal executive offices)

845-362-1100  
(Registrant's telephone number)

(Former name, former address and former fiscal year, if changed since last  
report)

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

Yes ☒ No

Number of shares of common stock, par value \$.01, outstanding as of September  
30, 2001: 35,507,864

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BARR LABORATORIES, INC.  
Consolidated Balance Sheets  
(in thousands, except share amounts)

SEPTEMBER  
2001  
(UNAUDITED)  
-----

Current assets:

ASSETS

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Cash and cash equivalents	\$ 299,
Accounts receivable, less allowances of \$34,145 and \$8,230 respectively	178,
Other receivables	24,
Inventories	116,
Deferred income taxes	2,
Prepaid expenses	8,
	-----
Total current assets	631,
Property, plant and equipment, net of accumulated depreciation of \$59,535 and \$56,770, respectively	104,
Other assets	4,
	-----
Total assets	\$ 740,
	=====
LIABILITIES AND SHAREHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	\$ 125,
Accrued liabilities	105,
Current portion of long-term debt	3,
Income taxes payable	44,
	-----
Total current liabilities	278,
Long-term debt	24,
Other liabilities	1,
Commitments & Contingencies	
Shareholders' equity:	
Preferred stock \$1 par value per share; authorized 2,000,000; none issued	
Common stock \$.01 par value per share; authorized 100,000,000; issued 35,694,796 and 35,581,369, respectively	
Additional paid-in capital	107,
Additional paid-in capital - warrants	16,
Retained earnings	311,
Accumulated other comprehensive income	
	-----
Treasury stock, shares at cost: 186,932 and 176,932, respectively	436,
	(
	-----
Total shareholders' equity	435,
	-----
Total liabilities and shareholders' equity	\$ 740,
	=====

SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS.

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	THREE MONTHS ENDED SEPTEMBER 30,	
	2001	2000
	-----	-----
Revenues:		
Product sales	\$309,766	\$ 99,680
Development and other revenue	5,563	3,456
	-----	-----
Total revenues	315,329	103,136
Costs and expenses:		
Cost of sales	186,404	68,384
Selling, general and administrative	16,402	12,112
Research and development	15,323	11,126
	-----	-----
Earnings from operations	97,200	11,514
Proceeds from patent challenge settlement	7,938	7,000
Interest income	1,837	2,248
Interest expense	377	521
Other expense	13	2,526
	-----	-----
Earnings before income taxes	106,585	17,715
Income tax expense	39,525	7,325
	-----	-----
Net earnings	\$ 67,060	\$ 10,390
	=====	=====
Earnings per common share	\$ 1.89	\$ 0.30
	=====	=====
Earnings per common share - assuming dilution	\$ 1.80	\$ 0.28
	=====	=====
Weighted average shares	35,465	35,059
	=====	=====
Weighted average shares - assuming dilution	37,348	37,613
	=====	=====

SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS.

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### CASH FLOWS FROM OPERATING ACTIVITIES:

Net earnings

Adjustments to reconcile net earnings to net cash provided by operating activities:

Depreciation and amortization

Deferred income tax benefit

Loss on sale of assets

Gain on sale of marketable securities

Write-off of investment

Changes in assets and liabilities:

(Increase) decrease in:

Accounts receivable and other receivables, net

Inventories

Prepaid expenses

Other assets

Increase (decrease) in:

Accounts payable, accrued liabilities and other liabilities

Income taxes payable

Net cash provided by operating activities

### CASH FLOWS FROM INVESTING ACTIVITIES:

Purchases of property, plant and equipment

Proceeds from sale of property, plant and equipment

Purchases of marketable securities, net

Net cash used in investing activities

### CASH FLOWS FROM FINANCING ACTIVITIES:

Principal payments on long-term debt and capital leases

Earnings from DuPont agreements applied to warrant receivable

Purchases of treasury stock

Proceeds from exercise of stock options and employee stock purchases

Net cash provided by financing activities

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Increase in cash and cash equivalents

Cash and cash equivalents at beginning of period

Cash and cash equivalents at end of period

### SUPPLEMENTAL CASH FLOW DATA:

Cash paid during the period:

Interest, net of portion capitalized

Income taxes

Non-cash transactions:

Equipment under capital lease

SEE ACCOMPANYING NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS.

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BARR LABORATORIES, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF DOLLARS, EXCEPT PER SHARE AMOUNTS)  
(UNAUDITED)

#### 1. BASIS OF PRESENTATION

The consolidated financial statements include the accounts of Barr Laboratories, Inc. and its wholly-owned subsidiaries (the "Company" or "Barr") (See Note 12).

In the opinion of the Management of the Company, the interim consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods. Interim results are not necessarily indicative of the results that may be expected for a full year. These financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended June 30, 2001.

Certain amounts in the prior year's financial statements have been reclassified to conform with the current year presentation.

#### 2. CASH AND CASH EQUIVALENTS

Cash equivalents consist of short-term, highly liquid investments, including market auction securities with interest rates that are re-set in intervals of 7 to 49 days, which are readily convertible into cash at par value, which approximates cost.

As of September 30, 2001 and June 30, 2001, approximately \$101,621 and \$96,820, respectively, of the Company's cash was held in an interest bearing escrow account. Such amounts represent the portion of the Company's payable balance with AstraZeneca Pharmaceuticals LP

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("AstraZeneca"), which the Company has decided to secure in connection with its cash management policy. The Company pays AstraZeneca a monthly fee based on a rate multiplied by the average unsecured monthly Tamoxifen payable balance.

### 3. OTHER RECEIVABLES

Other receivables consist primarily of patent challenge settlement receivables and receivables related to development and other revenue (See Note 5).

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### 4. INVENTORIES

Inventories consisted of the following:

	September 30, 2001 -----	June 30, 2001 -----
Raw materials and supplies	\$ 24,171	\$ 22,656
Work-in-process	4,964	5,825
Finished goods	87,630	87,134
	-----	-----
	\$116,765	\$115,615
	=====	=====

Tamoxifen Citrate, purchased as a finished product, accounted for approximately \$69,378 and \$66,890 of finished goods inventory as of September 30, 2001 and June 30, 2001, respectively.

### 5. DEVELOPMENT AND OTHER REVENUE

Development and other revenue consists primarily of amounts received from DuPont Pharmaceuticals Company ("DuPont"), which has since been acquired by Bristol-Myers Squibb Company, for various development and co-marketing agreements entered into in March 2000. As the Company incurs research and other development activity costs, Barr records such expenses as research and development and invoices and records the related revenue from DuPont as development and other revenue.

Development and other revenue also includes royalty income earned under licensing agreements with other third parties.

### 6. EARNINGS PER SHARE

The following is a reconciliation of the numerators and denominators used to calculate earnings per common share ("EPS") on the Consolidated Statements of Earnings:

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	THREE MONTHS ENDED SEPTEMBER 30,	
	2001	2000
	-----	-----
EARNINGS PER COMMON SHARE:		
Net earnings (numerator)	\$67,060	\$10,000
Weighted average shares (denominator)	35,465	35,465
Net earnings	\$ 1.89	\$ 0.28
	=====	=====
EARNINGS PER COMMON SHARE - ASSUMING DILUTION:		
Net earnings (numerator)	\$67,060	\$10,000
Weighted average shares	35,465	35,465
Effect of dilutive options	1,883	2,000
	-----	-----
Weighted average shares - assuming dilution (denominator)	37,348	37,465
Net earnings	\$ 1.80	\$ 0.27
	=====	=====

Share amounts in thousands

During the three months ended September 30, 2001 and 2000, there were 295,855 and 1,500, respectively, of outstanding options and warrants that were not included in the computation of diluted EPS, because the securities' exercise prices were greater than the average market price of the common stock for the period.

## 7. COMPREHENSIVE INCOME

Comprehensive income is defined as the total change in shareholders' equity during the period other than from transactions with shareholders. For the Company, comprehensive income is comprised of net income and the net changes in unrealized gains and losses on securities classified for Statement of Financial Accounting Standards ("SFAS") No. 115 purposes as "available for sale". Total comprehensive income for the three months ended September 30, 2001 and 2000 was \$66,990 and \$12,002, respectively.

## 8. NEW ACCOUNTING PRONOUNCEMENTS

### Business Combinations/Goodwill and Other Intangible Assets

In July 2001, the FASB issued SFAS No. 141, "Business Combinations," and No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 supercedes APB opinion No. 16, "Business Combinations" and amends or supercedes a number of related interpretations of APB 16. SFAS No. 141 eliminates the pooling-of-interests method of accounting for business combinations, and changes the criteria to recognize intangible assets apart from goodwill. SFAS No. 142 supercedes APB opinion No. 17, "Intangible Assets." Under SFAS No. 142, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually, or more frequently if impairment indicators arise, for impairment. The Company plans to adopt



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the provisions of SFAS No. 141 for any business combination that is initiated after June 30, 2001. The provisions of SFAS No. 142 are effective for fiscal years beginning after December 15, 2001. The Company will adopt SFAS No. 142 beginning in the first fiscal quarter of fiscal 2003.

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The Company does not believe that the adoption of SFAS No's. 141 and 142 will have a material impact on its results of operations or financial position.

### 9. COMMITMENTS AND CONTINGENCIES

#### Class Action Lawsuits

As of November 12, 2001, 38 class action complaints have been filed by direct and/or indirect purchasers of Ciprofloxacin (Cipro(R)) from 1997 to present against the Company, Bayer Corporation, The Rugby Group, Inc. and others. The complaints allege that the 1997 Bayer-Barr patent litigation settlement agreement was in violation of federal antitrust laws and/or state antitrust and consumer protection laws on the grounds that the agreement was allegedly anti-competitive.

As of November 12, 2001 30 consumer or third party payor class action complaints have been filed against Zeneca, Inc., AstraZeneca Pharmaceuticals LP and the Company. The complaints allege, among other things, that the 1993 settlement of patent litigation between Zeneca, Inc. and the Company insulates Zeneca, Inc. and the Company from generic competition and enables Zeneca, Inc. and Barr to charge artificially inflated prices for Tamoxifen citrate.

The Company believes that each of its agreements with Bayer Corporation and Zeneca, Inc., respectively, is a valid settlement to a patent suit and cannot form the basis of an antitrust claim. Although it is not possible to forecast the outcome of these matters, the Company intends to vigorously defend itself. It is anticipated that these matters may take several years to be resolved but an adverse judgement could have a material adverse impact on the Company's consolidated financial statements.

#### Invamed, Inc./Apothecon, Inc. Lawsuit

In February 1998 and May 1999, Invamed, Inc., which has since been acquired by Geneva Pharmaceuticals, Inc. and Apothecon, Inc., both of which are subsidiaries of Novartis AG, respectively, named the Company and several others as defendants in lawsuits filed in the United States District Court for the Southern District of New York, charging that the Company unlawfully blocked access to the raw material source for Warfarin Sodium. The two actions have been consolidated. The Company believes that these suits are without merit and intends to vigorously defend its position, but an adverse judgement could have a material impact on the Company's consolidated financial statements. These actions have gone through the discovery stage and a motion for summary judgement is pending. If this motion is denied this matter may take several years to be resolved.

#### Fluoxetine Hydrochloride Patent Challenge

As disclosed in the Company's Form 10-K, on July 23, 2001, the Court of appeals denied Eli Lilly & Company's ("Lilly") request for another

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rehearing and on July 27, 2001 issued its mandate to the District Court in Indianapolis instructing the District Court to enter a final order invalidating the Prozac(R) patent. On July 30, 2001, the District Court entered its order invalidating the Prozac patent and lifted the injunction preventing Barr from launching Fluoxetine, its generic version of Lilly's 20mg capsule Prozac product. On August 2, 2001, Barr launched its generic version. Lilly has petitioned the U.S. Supreme Court to review the Court of Appeals decision. The Supreme Court is not expected to make a decision on the Prozac matter

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for several months. If the Supreme Court overturns the Court of Appeals decision, which Barr believes is unlikely, and reinstates the Prozac patent, Barr may be liable for substantial damages which could have a material adverse effect on Barr's operations and financial condition.

On August 1, October 31 and November 6, 2001, aaiPharma Inc. ("AAI") filed lawsuits in the United States District Court for the Eastern District of North Carolina against Barr and others claiming that the generic versions of Prozac manufactured by those companies infringe AAI's patents. If Barr is found to infringe the AAI patents, Barr may be liable to AAI for damages that may reduce Barr's profits from its generic Prozac product. The Company believes that the suits filed against it by AAI are without merit and intends to defend its position vigorously. It is anticipated that these matters may take several years to be resolved but an adverse judgment could have a material adverse impact on the Company's consolidated financial statements.

### Other Litigation

As of September 30, 2001, the Company was involved with other lawsuits incidental to its business, including patent infringement actions. Management of the Company, based on the advice of legal counsel, believes that the ultimate disposition of such other lawsuits will not have any significant adverse effect on the Company's consolidated financial statements.

## 10. SUBSEQUENT EVENT

On October 24, 2001, the Company completed its merger with Duramed Pharmaceuticals, Inc. The merger is intended to be treated as a tax-free reorganization and is being accounted for using the pooling-of-interest method. Under the terms of the merger agreement, Barr could issue up to a total of 8,696,786 shares of its common stock including shares needed to cover options and warrants outstanding at the effective date of the merger. Duramed common shareholders received a fixed exchange ratio of 0.2562 shares of Barr common stock for each share of Duramed common stock. As a result of the merger, Duramed Pharmaceuticals, Inc. became a wholly owned subsidiary of Barr Laboratories. These financial statements do not reflect the effect of the merger.

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

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### Results of Operations:

Comparison of the Three Months Ended September 30, 2001 to the Three Months Ended September 30, 2000 - (thousands of dollars)

Total revenues increased from \$103,136 to \$315,329 driven mainly by increased product sales as well as increased development and other revenue.

Product sales increased \$210,086 from \$99,680 to \$309,766 due mainly to the launch of Fluoxetine 20mg capsules ("Fluoxetine"), as well as other new products such as Norethindrone Acetate and Trexall and increased sales of Tamoxifen.

Tamoxifen sales increased 43.8% from \$62,494 to \$89,884. The increase was mainly attributable to an increase in units sold as well as higher prices. The increase in units sold was primarily due to changes in the timing of customers' purchases due to the timing of last year's Tamoxifen price increase. In fiscal 2000, the price increase occurred in May 2000 while in fiscal 2001, it occurred in February 2001. As a result, the decline in Tamoxifen sales the Company has seen historically between the fourth and first fiscal quarters did not occur. Tamoxifen is a patent protected product manufactured for the Company by AstraZeneca, the innovator. Currently, Barr is the only distributor of Tamoxifen in the U.S. other than AstraZeneca, whose product is sold under the brand name Nolvadex. The Company currently has a tentatively approved Abbreviated New Drug Application ("ANDA") to manufacture the 10 mg tablet of Tamoxifen and is awaiting approval of the 20 mg tablet application. After the patent expires in August 2002, the Company expects that it will either continue to sell Tamoxifen as a distributed product or as its own manufactured product. The Company expects that additional competitors will enter the market upon patent expiry. Whenever this occurs, Barr believes that while its revenues and market share will be negatively affected, its gross margins on the sales of Tamoxifen will exceed those it currently earns as a distributor.

Other product sales increased from \$37,186 to \$219,882. The increase was mainly attributable to the August 2001 launch of the Company's Fluoxetine 20 mg capsule, the generic equivalent of Eli Lilly's Prozac. Sales of Fluoxetine during the quarter were approximately \$175,000. The increase was also due to sales of Norethindrone Acetate, which the Company launched in June 2001 and revenues recognized from the previous launch of Trexall. Currently, Barr is the only manufacturer of the generic 20mg Fluoxetine capsule. Barr does not expect other generic competitors to launch competing products until late January 2002, when Barr's exclusivity period ends. When that occurs, the Company expects numerous additional generic equivalents to be launched, which should substantially reduce Barr's sales and profits from Fluoxetine compared to those earned during the exclusivity period.

Development and other revenue consists primarily of amounts received from DuPont Pharmaceuticals Company ("DuPont") for various development and co-marketing agreements entered into in March 2000. As the Company incurs research and other development activity costs, Barr records such expenses as research and development and invoices and records the related revenue from DuPont as development and other revenue (See Note 5 to the Consolidated Financial Statements). In the prior year \$1,835 was recorded as an offset to shareholders' equity, with the balance recorded as development and other revenue. Development and other revenue also includes royalty income earned under licensing agreements with other third parties.

Cost of sales increased to \$186,404 from \$68,384, primarily related to the increase in product sales. Cost of sales includes the profit split due Apotex,

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Inc., the Company's partner in the fluoxetine patent challenge. As a percentage of product sales, cost of sales declined from 68.6% to 60.2%. The decrease in cost of sales as a percentage of product sales was due to an improved mix in product sales as lower margin products like Tamoxifen made up a smaller percentage of sales, than in the prior year, due to new product launches such as Fluoxetine.

Selling, general and administrative expenses increased from \$12,112 to \$16,402. The increase was primarily due to higher insurance, freight and other costs associated with the launch of Fluoxetine, as well as increased legal costs related to ongoing patent challenges and the development of potential patent challenge cases, higher personnel costs and higher advertising and promotions costs.

Research and development expenses increased from \$11,126 to \$15,323. The increase was primarily due to an increased investment in outside clinical studies related to the development of SEASONALE(TM) and CyPat(TM). In addition, the increase reflected headcount and related costs associated with proprietary development.

Interest income decreased by \$411 primarily due to a decrease in market rates on the Company's short-term investments, which was partially offset by an increase in the average cash and cash equivalents balance.

Interest expense decreased \$144 primarily due to a decrease in variable interest rates, as well as a decrease in the Company's debt balances.

Other expense decreased by \$2,513 primarily due to the prior year including a loss of approximately \$2,500 resulting from the write-off of the Company's investment in Gynetics, Inc.

### Liquidity and Capital Resources

The Company's cash and cash equivalents increased from \$222,339 at June 30, 2001 to \$299,806 at September 30, 2001. In connection with an Alternative Collateral Agreement between the Company and the Innovator of Tamoxifen, the Company increased the cash held in its interest-bearing escrow account from \$96,820 at June 30, 2001 to \$101,621 at September 30, 2001 (See Note 2 to the Consolidated Financial Statements).

Cash provided by operating activities was \$79,719 for the three months ended September 30, 2001, driven by net earnings of \$67,060 and a decrease in working capital. The working capital decrease was led by increases in accounts payable, accrued liabilities and income taxes payable partially offset by an increase in accounts receivable. The increase in accounts payable and accrued liabilities was primarily the result of amounts accrued for the Fluoxetine profit split as well as increased Tamoxifen purchases. Income taxes payable increased as a result of increased taxable earnings and the timing of estimated tax payments. Accounts receivable at September 30, 2001 were \$178,974 or \$105,924 higher than those at June 30, 2000 primarily attributable to the launch of Fluoxetine. As Barr's sales and profits from Fluoxetine decline for example, when other generic manufacturers launch competing products at the end of Barr's exclusivity period, operating cash flows from Fluoxetine are also expected to decline.

Approximately \$7.9 million of the Company's quarterly cash flows from operations relates to payments from its contingent non-exclusive supply agreement with Bayer Corporation ("Bayer") related to its 1997 Cipro patent challenge. Under that agreement, Bayer has, at its option, the right to allow Barr and its partner (collectively Barr) to purchase Cipro at a predetermined discount or to

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provide Barr quarterly cash payments. This contingent supply agreement expires in December 2003. If Bayer does not elect to supply Barr with product, Barr would receive approximately \$31 million per calendar year for the remainder of the agreement, which are not related to sales of Cipro. However, there is no guarantee that Bayer will continue to make such payments. If Bayer elected to supply product to Barr for resale, the earnings and related cash flows, if any, Barr could earn from the sale of Cipro would be entirely dependent upon market conditions. The supply agreement also provides that, six months prior to patent expiry, if Barr is not already distributing the product, Barr will have the right to begin distributing ciprofloxacin product manufactured by Bayer.

A portion of the Company's spending on proprietary product development is being reimbursed by DuPont Pharmaceuticals Company, which has since been acquired by Bristol-Myers Squibb Company, in accordance with the development agreement entered into in March 2000. During the quarter ended September 30, 2001, the Company earned approximately \$5.3 million under the terms of the agreement. Payments under the Proprietary Product Development Agreement are reimbursements of Barr's spending up to an aggregate of \$45 million on three of its proprietary products. This agreement provides for reimbursement of up to \$4 to \$5 million per quarter through December 2003. As of September 30, 2001 the Company had received approximately \$25.3 million of the \$45 million maximum.

During the first three months of fiscal 2002, the Company invested approximately \$5 million in capital assets, primarily related to upgrades and new equipment for its facilities. The Company believes it may invest an additional \$21 to \$26 million in capital assets in fiscal 2002 primarily on investments in management information systems and expansion in its distribution, research and development, manufacturing and packaging capabilities. Over the past two years, capital projects have been funded from cash flows provided by operations. Given the extent and the long-term nature of some of the planned expenditures, the Company may consider financing a portion of the expansion and believes it has the capital structure and cash flow to take on additional debt.

Debt balances declined slightly during the quarter due to scheduled repayments on the Company's debt. Scheduled principal repayments on the Company's existing debt will be \$1,552 during the quarter ending December 31, 2001. The Company did not use any funds available to it under its \$20 million Revolving Credit Facility during the current quarter. The facility expires in December 2001 and the Company is currently evaluating an extension and/or expansion of such facility.

On September 17, 2001, the Securities and Exchange Commission ("SEC") issued an Emergency Order permitting companies to initiate common stock repurchase programs without impacting pooling-of-interest accounting. As a result, the Company's board of directors authorized the Company to spend up to \$100 million for such a common stock repurchase program. Such authorization was limited to the time periods established by the SEC. On October 12, 2001, the SEC's order expired and the Company's repurchase program ended. During the period the Company repurchased 10,000 shares of its common stock at a total cost of approximately \$695. The Company does not intend to initiate for at least two years another stock repurchase program that could jeopardize its pooling-of-interest accounting for the Duramed merger.

On October 24, 2001, the Company completed its merger with Duramed Pharmaceuticals, Inc. Barr expects to incur approximately \$40 to \$45 million in costs related to this merger, the majority of which will be incurred in fiscal 2002. These costs include amounts to satisfy existing employment contracts, estimated severance costs, duplicate facility expenses, as well as investment banking, legal, accounting, regulatory agency filings, financial printing and other related costs. In addition, at closing, Barr assumed approximately \$37 million in debt. The Company may either refinance or retire

all or a portion of the debt assumed through existing cash balances, its Revolving Credit Facility Agreement or other means that the Company may deem appropriate.

As a result of the merger, Barr expects to earn taxable income sufficient to utilize federal net operating losses of approximately \$100 million generated by Duramed over the past several years. The portion of the net operating loss Barr can utilize to reduce federal income tax payments each year is limited in accordance with IRS guidelines. The Company believes that it will be able to utilize the net operating loss over the next several years and expects to lower the amount of federal income taxes it pays by approximately \$35 million over that period.

The working capital costs associated with selling Tamoxifen are expected to increase after Barr begins to manufacture and sell its own version of Tamoxifen. For example, the Company's accounts payable are expected to decline significantly due to lower costs to manufacture and shorter payment terms to the Company's suppliers compared to those contained in Barr's distribution agreement with AstraZeneca. In addition, inventory costs for Tamoxifen are expected to decline significantly, as the cost to manufacture will be well below Barr's current purchase price. Accounts receivable balances will be affected by lower sales due to the launch of other generics and by longer payment terms offered to customers. The exact amount of such an increase in working capital is dependent upon several factors, some of which are outside Barr's control.

To expand its growth opportunities, the Company has and will continue to evaluate and enter into various strategic collaborations or acquisitions. The timing and amount of cash required to enter into these collaborations may be significant, but are difficult to predict because they are dependent on several factors, many of which are outside of the Company's control. The Company believes that its current cash balances, cash flows from operations and borrowing capacity, including unused amounts under its existing \$20 million Revolving Credit Facility, will be adequate to meet the operations described above and to take advantage of strategic opportunities as they occur. To the extent that additional capital resources are required, such capital may be raised by additional bank borrowings, equity offerings or other means.

#### Outlook -----

The following section contains a number of forward-looking statements, all of which are based on current expectations. Actual results may differ materially. The generic pharmaceutical industry is characterized by relatively short product lives and declining prices and margins as competitors launch competing products. The Company's strategy has been to develop generic products with some barrier to entry to limit competition and extend product lives and margins. The Company's expanded efforts in developing and launching proprietary products is also driven by the desire to market products that will have limited competition and longer product lives. The Company's future operating results are dependent upon several factors that impact its stated strategies. These factors include timing of product approval and launches, the ability to introduce new products, patient acceptance of new products and new indications of existing products, customer purchasing practices, pricing practices of competitors, spending levels

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including research and development and patent activities as well as risk factors contained in the Company's Registration Statement on Forms S-3 and S-4 as filed with the Securities and Exchange Commission in May 2001 and August 2001, respectively. In addition, the ability to receive sufficient quantities of raw materials to maintain its production is critical. While the Company has not experienced any interruption in sales due to lack of raw materials, the Company is continually identifying alternate raw material suppliers for many of its key products in the event that raw material shortages were to occur.

The following forward-looking statements of forecasted results for the quarter ending December 31, 2001 include the effect of the merger between Barr and Duramed Pharmaceuticals, Inc. The merger was approved by the shareholders of both companies and became effective on October 24, 2001. The merger is intended to be treated as a tax-free reorganization pursuant to section 368 of the Internal Revenue Code of 1986, as amended, and is being accounted for using the pooling-of-interest method. Comments included in this Outlook section exclude the impact of expensing costs associated with the merger including severance costs, transaction fees and other related costs, which are not expected to recur in future periods. However, such costs will be reflected in reported earnings. The forecasted results are compared to the unaudited combined results from the prior year quarter. A table of the prior year combined results is presented below.

### SELECTED PRO-FORMA COMBINED FINANCIAL RESULTS QUARTER ENDED DECEMBER 31, 2000 (IN THOUSANDS)

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(UNAUDITED)

Product sales	\$145,516
Development and other revenue	6,480
	-----
Total revenues	151,996
Research and development	15,721
Selling, general and administrative	18,577
Operating income	16,165
Income before tax and preferred stock dividends	28,261
Income taxes	10,564
Income before preferred stock dividends	299
Net income	\$ 17,399
Earnings per common share - assuming dilution	0.39
Weighted average shares	44,581

#### Revenues

#### Product sales:

Product sales are expected to be dramatically higher in the quarter ending

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December 31, 2001 compared to the prior year driven by sales of Fluoxetine, which Barr launched in August 2001 as well as higher sales of Tamoxifen, higher sales of other products such as Cenestin, a hormone replacement product, and generic oral contraceptives including Aviane and Apri.

Tamoxifen increases are expected to be driven primarily by the timing of customer purchases in anticipation of a price increase. Barr increases its selling price at the time the innovator initiates a price increase. Last fiscal year, the innovator raised Tamoxifen prices in February 2001, which was two to three months earlier than in prior years. As a result, Barr's customers who historically increase their purchases in advance of the price increase, did not purchase the same quantities as in the past. This year, customers appear to be anticipating an earlier price increase and may increase purchases accordingly.

Fluctuations in quarterly Tamoxifen sales based on the timing of price increases are not unusual and have occurred over the past several years. Tamoxifen sales tend to be lower in the quarter following a price increase as customer purchases decline.

Sales of Cenestin, Apri and Aviane are expected to increase significantly versus the prior year due to increasing market shares for each product.

### Development and other revenue:

Development and other revenue is expected to range from \$3 to \$5 million in the quarter ending December 31, 2001 down from nearly \$6.5 million last year. The decline is primarily due to the prior year including \$2 million related to Trexall, which was completed at the end of March 2001.

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### Margins:

Overall margins on product sales are expected to be up significantly compared to the prior year, primarily due to a lower percentage of Tamoxifen sales in the current year compared to the prior year. Tamoxifen, which the Company distributes, has a margin of approximately 14-15% per year, which is substantially lower than the margin Barr earns on products it manufactures.

### Research and development:

Research and development spending in the quarter is expected to be in the \$18 to \$20 million range compared to \$15.7 million in the prior year. A portion of this increase is related to expected spending on the products in the DuPont proprietary drug development agreement. The balance of the expected increase is due mainly to anticipated increases in clinical trial costs associated with the Company's generic drug development effort.

### Selling, general and administrative:

Selling, general and administrative is expected to be up significantly from the prior year to \$30 to \$32 million range compared to approximately \$19 million in the prior year. The largest component of the year over year increase is due to the increased marketing expenses related to higher Cenestin sales. Under the terms of the Company's agreement with Solvay Pharmaceuticals ("Solvay"), Solvay receives 80% of the gross profits on Cenestin sales. Solvay's share of Cenestin gross profits is included in marketing costs. Also contributing to the expected increase will be higher sales and marketing costs associated with supporting the Company's recently launched products such as Trexall and Fluoxetine as well as supporting expected product launches in the quarter. Other selling, general and administrative expense increases are expected to include higher distribution



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costs due to higher sales volumes and higher legal costs related primarily to patent challenge activities.

### Interest income:

Interest income is expected to increase slightly from the prior year quarter as significantly higher cash balances are nearly offset by significantly lower interest rates.

### Interest expense:

Interest expense is expected to be lower than in the prior year quarter due to lower debt balances and lower interest rates.

### Other income:

Other income is expected to be down substantially compared to the prior year. The prior year's quarter included the gain on the sale of a portion of the Company's investment in Galen Holdings, PLC.

### Preferred stock dividends:

No preferred stock dividends are expected in the quarter as the previously outstanding preferred stock was converted to common stock in late September 2001.

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### Tax rate:

The prior year's tax expense has been recast to reflect the removal of a portion of Duramed's valuation allowance that the Company believes is no longer necessary on a combined basis. After adjusting for the valuation allowance, the combined prior year tax rate was approximately 37%, which is consistent with expectations for the current year. As a result of the combination, the future cash benefit attributable to the utilization of the remaining net operating losses on a prospective basis will be accounted for as an increase to shareholders' equity in accordance with SFAS No. 109, "Accounting for Income Taxes."

### Earnings per share:

Previously, Barr indicated that it expected to earn approximately \$1.30 to \$1.40 per share in the second quarter ending December 31, 2001, excluding the effect of the merger and related non-recurring merger costs. The Company currently expects that earnings per share for the quarter ending December 31, 2001 will increase to \$1.40 to \$1.50 per share, excluding the effect of the merger and related non-recurring merger costs. The expected increase in earnings per share is attributable to higher than expected sales of Tamoxifen and other manufactured products as well as continued strong sales of Fluoxetine.

Based on the information provided above, the Company expects combined second quarter earnings per share to be \$1.25 to \$1.35, which includes approximately 8.6 million shares issued to complete the merger and excludes merger related costs of approximately \$40 to \$45 million. This expected combined earnings per share does not include potential earnings contributions of products pending approval at the U.S. Food and Drug Administration, which could be launched prior to the end of the second quarter.

### Forward-Looking Statements:

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Except for the historical information contained herein, this Form 10-Q contains forward-looking statements, all of which are subject to risks and uncertainties that cannot be predicted or quantified and, consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include: the timing and outcome of legal proceedings; the difficulty of predicting the timing of FDA approvals; the difficulty in predicting the timing and outcome of court decisions on patent challenges, including the Supreme Court; the court and FDA decisions on exclusivity periods; market and customer acceptance and demand for new pharmaceutical products; the ability to market proprietary products; the impact of competitive products and pricing; timing and success of product development and launch; availability of raw materials; the regulatory environment; fluctuations in operating results; and, other risks detailed from time-to-time in the Company's filings with the Securities and Exchange Commission. Forward-looking statements can be identified by their use of words such as "expects," "plans," "will," "should," "believes," "may," "estimates," "intends" and other words of similar meaning. Should known or unknown risks or uncertainties materialize, or should our assumptions prove inaccurate, actual results could vary materially from those anticipated.

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### ITEM 3.

#### QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As discussed in the 2001 Annual Report on Form 10-K, the Company's exposure to market risk from changes in interest rates, in general, is not material.

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## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

#### Class Action Lawsuits

#### Ciprofloxacin (Cipro) Class Action Suits

The Company has been named as a defendant in several actions related to its settlement of the Cipro patent challenge. The following are class action complaints on behalf of direct and/or indirect purchasers for Cipro from 1997 to present against the Company along with Bayer Corporation and the Rugby Group, Inc. and others alleging violation of federal antitrust laws and/or state antitrust and consumer protection laws. The following actions have been filed, on the date indicated, in state court: Donna Moore (California Superior Court, Sonoma County 10/25/01); Alan Moore (California Superior Court, Sonoma County 10/29/01); Senior Action Network, on behalf of the Citizens of the State of California (California Superior Court, San Francisco County 10/30/01).

#### Tamoxifen Citrate Class Action Suits

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The following complaints represent putative consumer or third-party payor class action complaints, brought under federal and state antitrust and/or consumer protection statutes, arising out of Zeneca's and Barr's 1993 settlement of a patent infringement action. The complaints allege that the 1993 settlement insulates Zeneca and the Company from generic competition and enables Zeneca and Barr to charge artificially high prices for Tamoxifen Citrate. Plaintiffs seek to recover both Barr's and Zeneca's profits and treble damages, where appropriate, for the alleged antitrust violations. The following actions have been filed in state courts: Cobalt (DC 10/5/01); Steward (KS 10/22/01). The following actions have been filed in or removed to United States District Courts: Platt (M.D. Fla. 7/27/01); Underwood (D. Minn. 8/1/01); Donega (D. Mass. 8/7/01); Teamsters Local 237 (E.D. NY 8/7/01); Lynch (E.D. NY 8/21/01); Callaway (D. KS 9/18/01); Maloney (S.D. Fla. 10/9/01); IBEW (E.D. NY 10/23/01); A.F. of L. (E.D. NY 10/23/01); Mechanical Contractors (E.D. NY 10/23/01); Sheet Metal Workers (E.D. NY 10/23/01); Local 1199 National Benefit Fund (E.D. NY 10/23/01).

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

(a)	Exhibit Number	Exhibit
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None

(b)	There were no reports filed on Form 8-K in the quarter ended September 30, 2001.
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### 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.

BARR LABORATORIES, INC.

Dated: November 14, 2001

/s/ William T. McKee

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William T. McKee  
Chief Financial Officer  
(Principal Financial Officer and  
Principal Accounting Officer)

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