BIOVAIL CORP INTERNATIONAL
Form 6-K/A
May 14, 2004

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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 6-K/A

**REPORT OF FOREIGN PRIVATE ISSUER**
**PURSUANT TO RULE 13a-16 OR 15d-16 OF**
**THE SECURITIES EXCHANGE ACT OF 1934**

**For the Quarterly Period Ended September 30, 2003**

**Commission File Number 001-11145**

# BIOVAIL CORPORATION

(Translation of Registrant's name into English)

**7150 Mississauga Road, Mississauga, Ontario, CANADA, L5N 8M5**
(Address of principal executive office and zip code)

**Registrant's telephone number, including area code: (905) 286-3000**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ý Form 40-F o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1).

Yes o No ý

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7).

Yes o No ý

Indicate by check mark whether by furnishing the information contained in this form the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g 3-2(b) under the Securities Exchange Act of 1934.

Yes o No ý

**BIOVAIL CORPORATION**

**QUARTERLY REPORT**

**This Report of Foreign Private Issuer on Form 6-K/A is incorporated by reference into the registration statements on Form S-8 (Registration No. 333-92229) and on Form F-10 (Registration No. 333-14048) of Biovail Corporation.**

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**PART I FINANCIAL INFORMATION**



**PART II OTHER INFORMATION**



All dollar amounts in this report are expressed in U.S. dollars.

As used in this report, unless the context otherwise indicates, the terms "we", "us", "our" and similar terms, as well as references to "Biovail" or the "Company", mean Biovail Corporation together with its subsidiaries.

The following words and logos are trademarks of the Company and may be registered in Canada, the United States and certain other jurisdictions: Biovail, Cardizem®, Tiazac®, Wellbutrin®, Zyban®, Wellbutrin XL®, Wellbutrin SR®, Ativan®, Isordil®, Teveten®, Vasotec®, Vaseretic®, CEFORM , Shearform , FlashDose®, Instatab , SportSafe , DrinkUp and Cardisense®.

**BIOVAIL CORPORATION**

**CONSOLIDATED BALANCE SHEETS**
**In accordance with U.S. generally accepted accounting principles**

**(All dollar amounts are expressed in thousands of U.S. dollars)**
**(Unaudited)**

| | September 30 2003 (Restated Note 2) | December 31 2002 |
|---|---|---|
| **ASSETS** | | |
| **Current** | | |
| Cash and cash equivalents | **$ 43,289** | $ 56,080 |
| Restricted cash | **30,060** | |
| Accounts receivable | **237,611** | 190,980 |
| Inventories | **82,563** | 53,047 |
| Deposits and prepaid expenses | **9,302** | 21,524 |
| | **402,825** | 321,631 |
| Long-term investments | **102,035** | 79,324 |
| Property, plant and equipment, net | **165,551** | 136,784 |
| Goodwill, net | **102,448** | 102,212 |
| Intangible assets, net | **1,116,580** | 1,080,503 |
| Other assets, net | **147,080** | 113,350 |
| | **$ 2,036,519** | $ 1,833,804 |
| **LIABILITIES** | | |
| **Current** | | |
| Accounts payable | **$ 87,806** | $ 71,641 |
| Accrued liabilities | **101,749** | 106,005 |
| Income taxes payable | **44,880** | 35,691 |
| Deferred revenue | **11,841** | 9,231 |
| Current portion of long-term obligations | **101,513** | 122,590 |
| | **347,789** | 345,158 |
| Deferred revenue | **15,350** | 18,200 |
| Minority interest | **15,346** | |
| Long-term obligations | **701,605** | 624,760 |
| | **1,080,090** | 988,118 |
| **SHAREHOLDERS' EQUITY** | | |
| Common shares, no par value, unlimited shares authorized, 158,749,960 and 158,120,144 issued and outstanding at September 30, 2003 and December 31, 2002, respectively | **1,445,043** | 1,433,624 |
| Stock options outstanding | **4,940** | 4,856 |
| Executive Stock Purchase Plan loans | **(9,988)** | (9,988) |
| Deficit | **(511,640)** | (580,413) |
| Accumulated other comprehensive income (loss) | **28,074** | (2,393) |
| | **956,429** | 845,686 |

| | September 30 2003 | December 31 2002 |
|---|---|---|
| | **$ 2,036,519** | $ 1,833,804 |

*The accompanying notes are an integral part of the consolidated financial statements.*

**BIOVAIL CORPORATION**

**CONSOLIDATED STATEMENTS OF INCOME**
**In accordance with U.S. generally accepted accounting principles**

**(All dollar amounts are expressed in thousands of U.S. dollars, except per share data)**
**(Unaudited)**

| | Three Months Ended September 30 | | Nine Months Ended September 30 | |
|---|---|---|---|---|
| | **2003** | **2002** | **2003** | **2002** |
| | **(Restated Note 2)** | | **(Restated Note 2)** | |
| **REVENUE** | | | | |
| Product sales | **$ 179,985** | $ 174,508 | **$ 464,629** | $ 462,150 |
| Research and development | **4,542** | 7,653 | **10,815** | 19,168 |
| Co-promotion, royalty and licensing | **30,787** | 26,783 | **148,543** | 68,010 |
| | **215,314** | 208,944 | **623,987** | 549,328 |
| **EXPENSES** | | | | |
| Cost of goods sold | **40,079** | 44,007 | **88,823** | 121,014 |
| Research and development | **20,608** | 14,626 | **60,427** | 39,547 |
| Selling, general and administrative | **74,135** | 44,533 | **176,436** | 122,871 |
| Amortization | **28,243** | 15,994 | **114,650** | 42,522 |
| Acquired research and development | **18,409** | | **102,609** | |
| Settlements | | | **(34,055)** | |
| Write-down of assets | | 1,369 | | 1,369 |
| | **181,474** | 120,529 | **508,890** | 327,323 |
| **Operating income** | **33,840** | 88,415 | **115,097** | 222,005 |
| Interest income | **1,191** | 298 | **5,893** | 2,859 |
| Interest expense | **(10,540)** | (10,956) | **(30,029)** | (22,753) |
| Foreign exchange gain (loss) | **531** | (389) | **(9,594)** | (369) |
| Other income (expense) | **(5,958)** | 3,309 | **706** | 3,243 |
| **Income before provision for income taxes** | **19,064** | 80,677 | **82,073** | 204,985 |
| Provision for income taxes | **2,950** | 5,700 | **13,300** | 14,400 |
| **Net income** | **$ 16,114** | $ 74,977 | **$ 68,773** | $ 190,585 |
| **Earnings per share** | | | | |
| Basic | **$ 0.10** | $ 0.52 | **$ 0.43** | $ 1.27 |
| Diluted | **$ 0.10** | $ 0.49 | **$ 0.43** | $ 1.18 |
| **Weighted average number of common shares outstanding (000s)** | | | | |
| Basic | **158,704** | 145,367 | **158,428** | 150,252 |

| | Three Months Ended September 30 | | Nine Months Ended September 30 | |
|---|---|---|---|---|
| Diluted | **160,426** | 154,016 | **160,115** | 161,235 |

*The accompanying notes are an integral part of the consolidated financial statements.*

**BIOVAIL CORPORATION**

**CONSOLIDATED STATEMENTS OF DEFICIT**
**In accordance with U.S. generally accepted accounting principles**

**(All dollar amounts are expressed in thousands of U.S. dollars)**
**(Unaudited)**

| | Three Months Ended September 30 | | Nine Months Ended September 30 | |
|---|---|---|---|---|
| | **2003** | **2002** | **2003** | **2002** |
| | **(Restated Note 2)** | | **(Restated Note 2)** | |
| Deficit, beginning of period | **$ (527,754)** | $ (522,928) | **$ (580,413)** | $ (280,004) |
| Net income | **16,114** | 74,977 | **68,773** | 190,585 |
| | **(511,640)** | (447,951) | **(511,640)** | (89,419) |
| Excess of cost of common shares acquired over the stated capital thereof | | (29,672) | | (388,204) |
| **Deficit, end of period** | **$ (511,640)** | $ (477,623) | **$ (511,640)** | $ (477,623) |

*The accompanying notes are an integral part of the consolidated financial statements.*

**BIOVAIL CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**In accordance with U.S. generally accepted accounting principles**

**(All dollar amounts are expressed in thousands of U.S. dollars)**
**(Unaudited)**

| | Nine Months Ended September 30 | |
|---|---|---|
| | **2003** | **2002** |
| | **(Restated Note 2)** | |
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | |
| Net income | **$ 68,773** | $ 190,585 |
| **Add (deduct) items not involving cash** | | |
| Depreciation and amortization | **126,645** | 50,385 |
| Amortization of deferred financing costs | **2,103** | 2,016 |
| Amortization of discounts on long-term obligations | **5,461** | 3,928 |
| Compensation cost for employee stock options | **1,262** | 1,499 |
| Acquired research and development | **102,609** | |
| Write-down of assets | | 1,369 |
| Other | **4,307** | (3,243) |
| | **311,160** | 246,539 |
| Net change in non-cash operating items | **(67,100)** | (4,638) |
| **Cash provided by operating activities** | **244,060** | 241,901 |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | |
| Acquisitions of intangible assets | **(203,052)** | (373,388) |
| Increase in loan receivable | **(40,000)** | |
| Acquisitions of long-term investments | **(34,596)** | (85,451) |
| Additions to property, plant and equipment | **(28,283)** | (39,284) |
| Proceeds on disposal of intangible asset | **10,000** | |
| **Cash used in investing activities** | **(295,931)** | (498,123) |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | |
| Issuance of common shares, net of issue costs | **11,419** | 5,528 |
| Repurchase of common shares | | (503,100) |
| Proceeds from the exercise of warrants | | 112,823 |
| Advances under revolving term credit facility, including financing costs | **114,800** | 8,795 |
| Repayments of other long-term obligations | **(88,261)** | (41,980) |
| Issuance of Senior Subordinated Notes, net of financing costs | | 384,280 |
| **Cash provided by (used in) financing activities** | **37,958** | (33,654) |
| Effect of exchange rate changes on cash and cash equivalents | **1,122** | 36 |

| | Nine Months Ended September 30 | |
|---|---|---|
| **Decrease in cash and cash equivalents** | **(12,791)** | (289,840) |
| Cash and cash equivalents, beginning of period | **56,080** | 434,891 |
| **Cash and cash equivalents, end of period** | **$ 43,289** | $ 145,051 |

*The accompanying notes are an integral part of the consolidated financial statements.*

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**In accordance with U.S. generally accepted accounting principles**

**(Tabular amounts are expressed in thousands of U.S. dollars, except number of shares and per share data)**
**(Unaudited)**

## 1. GOVERNING STATUTE AND NATURE OF OPERATIONS

Biovail is incorporated under the laws of the Province of Ontario, Canada. The Company is a full-service pharmaceutical company engaged in the formulation of pharmaceutical products utilizing advanced oral drug delivery technologies, clinical testing, registration, manufacturing, sale and promotion of pharmaceutical products targeting the cardiovascular (including Type II diabetes), central nervous system, pain management and niche therapeutic areas. The Company's common shares trade on the New York Stock Exchange ("NYSE") and the Toronto Stock Exchange ("TSX").

## 2. RESTATEMENT AND RECLASSIFICATION OF COMPARATIVE FIGURES

During the course of the preparation of its annual consolidated financial statements, the Company determined that it had applied an inappropriate exchange rate to a Canadian dollar denominated long-term obligation. In December 2002, the Company acquired the rights, through a subsidiary whose functional currency is the U.S. dollar, to Wellbutrin® SR and Zyban in Canada from GlaxoSmithKline plc ("GSK") in a transaction denominated in Canadian dollars. At the date of acquisition, the Company recorded the acquired assets and the related long-term obligation in U.S. dollars at the exchange rate existing at that date. However, in the previously issued interim financial statements for 2003, the Company did not adjust the Wellbutrin® obligation to reflect changes in the exchange rate except for payments made on that obligation when a foreign exchange loss ($2,474,000 and $5,147,000 for the three months and nine months ended September 30, 2003, respectively) was recorded on those transactions. U.S. generally accepted accounting principles ("GAAP") require monetary balances denominated in a currency other than an entity's functional currency be translated to reflect the exchange rates in existence at each balance sheet date. Consequently, the translation of the Wellbutrin® obligation, using the exchange rates existing at March 31, 2003, June 30, 2003 and September 30, 2003, had the following impact on the Company's previously reported results of operations for the three months and nine months ended September 30, 2003:

| | Three Months Ended September 30 2003 | Nine Months Ended September 30 2003 |
|---|---|---|
| Net income as previously reported | $ 12,985 | $ 74,964 |
| Foreign exchange adjustments | 3,129 | (6,191) |
| Net income as restated | $ 16,114 | $ 68,773 |
| **Basic earnings per share** | | |
| As previously reported | $ 0.08 | $ 0.47 |
| As restated | $ 0.10 | $ 0.43 |
| **Diluted earnings per share** | | |
| As previously reported | $ 0.08 | $ 0.47 |
| As restated | $ 0.10 | $ 0.43 |

| | September 30 2003 |
|---|---|
| Current portion of long-term obligations as previously reported | $ 95,322 |
| Foreign exchange adjustment | 6,191 |
| Current portion of long-term obligations as restated | $ 101,513 |

Prior to September 30, 2003, the Company included foreign exchange gains or losses as a component of selling, general and administrative expenses. During the course of the preparation of its annual consolidated financial statements, the Company

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decided to present foreign exchange gains or losses (including the adjustments above) as an individual line item below operating income. Comparative figures have been reclassified to conform to this new presentation.

**3. SIGNIFICANT ACCOUNTING POLICIES**

**Basis of presentation**

The accompanying unaudited consolidated financial statements have been prepared by the Company in U.S. dollars and in accordance with U.S. GAAP. The interim financial statements have been prepared using accounting policies that are consistent with policies used in preparing the Company's 2002 annual audited consolidated financial statements. Accordingly, these unaudited condensed notes to the consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2002.

In preparing the Company's consolidated financial statements, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from these estimates and the operating results for the interim periods presented are not necessarily indicative of the results expected for the full year.

On an ongoing basis, management reviews its estimates to ensure that these estimates appropriately reflect changes in the Company's business and new information as it becomes available. During the third quarter of 2003, management determined that, based on trends in historical returns experience, the Company's reserves for product returns related to certain products should be reduced and, accordingly, the Company recorded a reduction in these reserves of approximately $4,000,000.

**Advertising**

Advertising costs related to new product launches are expensed on the first showing of the products. The Company had not deferred any advertising costs at September 30, 2003. Deferred advertising costs of $4,055,000, $15,103,000 and $8,866,000 were included in deposits and prepaid expenses at June 30, 2003, March 31, 2003 and December 31, 2002, respectively.

**Stock-based compensation**

Under the provisions of the Financial Accounting Standards Board's ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation", companies can either measure the compensation cost of equity instruments issued under employee compensation plans using a fair value-based method or can continue to recognize compensation cost using the intrinsic value-based method under the provisions of Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees" and related interpretations. However, if the provisions of APB No. 25 are applied, pro forma disclosure of net income and earnings per share must be presented in the financial statements as if the fair value-based method had been applied.

The Company recognizes employee stock-based compensation costs under the intrinsic value-based method of APB No. 25. Accordingly, no compensation expense for stock options granted to employees at fair market value has been included in the determination of net income in the three month and nine month periods ended September 30, 2003 and 2002; however, the Company recorded compensation expense in those periods for stock options granted to the employees of DJ Pharma, Inc. on

acquisition. The following table presents the Company's pro forma net income and earnings per share as if the fair value-based method of SFAS No. 123 had been applied for all stock options granted:

| | Three Months Ended September 30 | | Nine Months Ended September 30 | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| | (Restated Note 2) | | (Restated Note 2) | |
| Net income as reported | **$ 16,114** | $ 74,977 | **$ 68,773** | $ 190,585 |
| Total pro forma stock-based compensation expense determined under fair value-based method | **4,404** | 3,808 | **13,845** | 10,445 |
| Pro forma net income | **11,710** | 71,169 | **54,928** | 180,140 |
| **Basic earnings per share** | | | | |
| As reported | **$ 0.10** | $ 0.52 | **$ 0.43** | $ 1.27 |
| Pro forma | **$ 0.07** | $ 0.49 | **$ 0.35** | $ 1.20 |
| **Diluted earnings per share** | | | | |
| As reported | **$ 0.10** | $ 0.49 | **$ 0.43** | $ 1.18 |
| Pro forma | **$ 0.07** | $ 0.46 | **$ 0.34** | $ 1.12 |

The fair values of all stock options granted during the three months and nine months ended September 30, 2003 and 2002 were estimated as of the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

| | Three Months Ended September 30 | | Nine Months Ended September 30 | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| Expected option life (years) | **4.0** | 4.0 | **4.0** | 3.8 |
| Volatility | **44.3%** | 52.7% | **52.1%** | 46.8% |
| Risk-free interest rate | **3.7%** | 4.2% | **4.0%** | 4.5% |

The Black-Scholes option-pricing model used by the Company to calculate option values, as well as other currently accepted option valuation models, were developed to estimate the fair value of freely tradeable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. These models also require highly subjective assumptions, including future stock price volatility and expected time until exercise, which greatly affect the calculated values. Accordingly, the Company does not believe that these models necessarily provide a reliable single measure of the fair value of the Company's stock option awards.

**Recent accounting pronouncements**

In November 2002, the FASB issued FASB Interpretation ("FIN") No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others". FIN No. 45 clarifies and expands on existing disclosure requirements for a guarantor regarding its obligations under certain guarantees it has issued. FIN No. 45 also requires that the guarantor must recognize a liability for the fair value of its obligations under certain

guarantees. The provisions of FIN No. 45 are effective for guarantees entered into after December 31, 2002. At September 30, 2003, the Company had no outstanding guarantees.

In January 2003, the FASB issued FIN No. 46, "Consolidation of Variable Interest Entities". FIN No. 46 requires consolidation of a variable interest entity by the primary beneficiary of the entity's expected results of operations. FIN No. 46 also requires certain disclosures by all holders of a significant variable interest in a variable interest entity that are not the primary beneficiary. FIN No. 46 is effective immediately for variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, FIN No. 46 is effective in the first reporting period ending after December 15, 2003. The Company is performing a review to determine if it is the primary beneficiary of any variable interest entities created or acquired prior to February 1, 2003. The Company will complete this review in the fourth quarter of 2003. Provided that the Company is not the primary beneficiary, the maximum exposure to losses related to any entity that may be determined to be a variable interest entity is limited to the carrying amount of the Company's investment in that entity.

In May 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities". SFAS No. 149 amends and clarifies the accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities". SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The initial adoption of SFAS No. 149 had no effect on the Company's financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity". SFAS No. 150 establishes standards for the measurement and classification of certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003. The initial adoption of SFAS No. 150 had no effect on the Company's financial position or results of operations.

**4. ACQUISITIONS**

**Ethypharm transactions**

In April 2002, Biovail acquired a 15% equity interest in Ethypharm S.A. ("Ethypharm") and a three-year option to purchase an additional 5% equity interest in Ethypharm, and Biovail obtained the rights to market six products under development by Ethypharm (including Ethypharm's Flashtab version of tramadol ("Tramadol FT")). Biovail's investment in Ethypharm is accounted for under the cost method.

In September 2003, Biovail entered into several agreements with Ethypharm comprising: (i) the acquisition of the remaining rights to Tramadol FT, and the elimination of Biovail's obligation to make any future milestone payments (except as described below) or royalty payments to Ethypharm related to Tramadol FT, (ii) the grant to Ethypharm of a 15-year license to manufacture and market Biovail's controlled-release formulation of diltiazem hydrochloride ("Diltiazem CR"), which is marketed by Biovail in the United States under the trade name Cardizem® LA, in all the countries of the world excluding Canada and the United States, (iii) the supply to Ethypharm of a quantity of diltiazem beads to enable it to encapsulate Diltiazem CR until the necessary technology transfer to manufacture diltiazem beads has been effected, and (iv) the grant to Ethypharm of a right of first offer to market Wellbutrin XL® in all countries outside North America that GSK does not elect to exercise its option. Biovail has recorded these transactions on a net basis, reflecting that these agreements were negotiated and concluded almost simultaneously, and that Biovail has elected, based on its right of set-off, to offset its payment due to Ethypharm (related to Tramadol FT) against the payments due from Ethypharm to Biovail (related to Diltiazem CR). Biovail recorded a net charge to acquired research and development of $3,063,000 related to these agreements, reflecting the

following amounts that were contractually agreed to by the parties, as well as the cost of the diltiazem beads supplied to Ethypharm:

| | |
|---|---|
| Tramadol FT acquisition | $ 21,000 |
| Diltiazem CR proceeds | (20,000) |
| Cost of diltiazem beads supplied | 2,063 |
| Acquired research and development | $ 3,063 |

In addition, Biovail will pay Ethypharm $1,000,000 if Tramadol FT is approved by the U.S. Food and Drug Administration ("FDA").

Biovail also agreed, subject to certain conditions, to subscribe for up to $20,000,000 of convertible and/or exchangeable bonds of Ethypharm. Biovail is entitled to set-off the future milestone and royalty payments that it may be required to make to Ethypharm, under the terms of the April 2002 license agreement between the parties, against the outstanding principal and interest on the bonds. The bonds may be converted, at Biovail's option, into an additional 10% equity interest in Ethypharm if the principal amount of the bonds is $10,000,000, 12.5% if the principal amount of the bonds is $15,000,000, and 15% if the principal amount of the bonds is $20,000,000. If Ethypharm enters into a transaction that results in a change in control, Biovail would receive an increased equity interest pursuant to a formula based on the valuation of Ethypharm at the date of the transaction. The bonds may be redeemed, at Ethypharm's option, for cash or, if Ethypharm becomes a publicly traded company, for equity. The bonds will mature on December 31, 2010 unless redeemed or converted earlier. The bonds will bear interest at a rate of 5% per annum. Interest on the bonds up to December 31, 2005 will be capitalized and added to the principal amount of the bonds and will not be paid in cash. After January 1, 2006, all interest payments will be paid in cash.

Certain of the conditions precedent to the closing of the bond subscription agreement require third parties, independent of Ethypharm and Biovail, to agree to revisions to their existing agreements with Ethypharm. Accordingly, the bond facility is not yet available to Ethypharm. If the conditions precedent are resolved and the bond subscription agreement is closed, Biovail believes it may be able to exercise significant influence over the operating and financial policies of Ethypharm and, accordingly, Biovail may adopt the equity method of accounting for its investment in Ethypharm.

Biovail has also negotiated with Ethypharm for significant improvements to the shareholder agreement, providing price protection on Biovail's initial investment in Ethypharm in the event of any private or public financing undertaken by Ethypharm.

**BNC-PHARMAPASS**

In July 2003, Biovail and Pharma Pass II, LLC ("PPII") formed a limited liability company ("BNC-PHARMAPASS") to develop enhanced formulations of three products. The three products under development are Coreg (carvedilol), a beta-blocker indicated for the treatment of congestive heart failure, Flomax (tamsulosin), indicated for the treatment of benign prostatic hyperplasia, and Teveten® (eprosartan mesylate), an angiotensin-II receptor blocker for the treatment of hypertension. On the formation of BNC-PHARMAPASS, PPII contributed all of its intellectual property relating to these products for a 51% interest in this company and Biovail contributed cash in the amount of $30,060,000 for a 49% interest in this company. Biovail has also agreed to provide sufficient additional funds to BNC-PHARMAPASS to allow it to pay the cost of all clinical trials related to these products. Biovail has an option to acquire PPII's interest in BNC-PHARMAPASS including all of PPII's intellectual property rights to these products for cash consideration plus a royalty on the net sales of these products.

Biovail is evaluating the effects of FIN No. 46 on the accounting for its investment in BNC-PHARMAPASS. Biovail will complete this evaluation during the fourth quarter of 2003. BNC-PHARMAPASS has been included in Biovail's consolidated

financial statements from the date of formation, reflecting Biovail's ability to effectively control the operations of BNC-PHARMAPASS through its 49% interest in this company, its contractual arrangements with this company, its current and ongoing financing of the research and development activities, and its ability to acquire PPII's interest in this company. All research and development expenditures incurred by BNC-PHARMAPASS will be charged to Biovail's consolidated research and development expenses. Biovail's investment in BNC-PHARMAPASS was accounted for under the purchase method of accounting. Consideration was allocated based on the estimated fair values at the date of formation, as follows:

| | |
|---|---|
| Acquired research and development | $ 15,346 |
| Restricted cash | 30,060 |
| Minority interest | (15,346) |
| Consideration | $ 30,060 |

The three products under development were fair valued at an aggregate amount of $31,350,000 using an income approach. The discount rates used to present value the estimated cash flows related to each of these products were determined based on the relative risk of achieving each product's estimated cash flows and were in the range of 30% to 50%. At the date of formation, these products were in pre-clinical phases of development, had not reached technological feasibility and had no known alternative future uses. The research being undertaken on these products relates specifically to developing novel formulations of the associated molecules. The Company does not foresee any alternative future benefit from the acquired research and development other than specifically related to these products under development. There is significant technological and regulatory approval risk associated with these products under development. The completion of these products will require significant amounts of future time and effort, as well as additional development costs, which will be incurred by BNC-PHARMAPASS and the Company. The aggregate costs to complete these products are estimated to be $50,000,000. The efforts required to develop the acquired research and development into commercially viable products include the completion of the development stages of the products, clinical-trial testing, regulatory approval and commercialization. The principal risks relating to these products under development are the outcomes of the formulation development, clinical studies and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, the Company will not receive any benefits unless regulatory approval is obtained. Accordingly, the Company's share of the fair value of these products of $15,346,000 was allocated to acquired research and development, which was expensed at the date of formation.

BNC-PHARMAPASS's cash balance has been recorded as restricted cash in Biovail's consolidated financial statements, reflecting that it is to be used to partially fund the development of the three products by BNC-PHARMAPASS.

**Cardiovascular products**

In April 2003, Biovail entered into an agreement with Athpharma Limited ("Athpharma") to acquire four cardiovascular products under development for $44,200,000, including costs of acquisition, comprised of $21,210,000 paid on closing and $22,990,000 payable on October 15, 2003. The four products under development are Bisochron (bisoprolol), a beta-1 selective beta-blocker formulation for the treatment of hypertension, Isochron (isosorbide-5-mononitrate), a long-acting nitrate formulation for the treatment of angina, and Hepacol I (pravastatin) and Hepacol II (simvastatin), two liver-selective statin formulations for the treatment of high cholesterol. Athpharma will complete the development of these products. Biovail will pay a portion of the development costs, and may make aggregate payments of approximately $24,000,000 to Athpharma subject to the attainment of certain milestones. Biovail will also pay Athpharma royalties on the approval and commercialization of each product.

The cardiovascular products were fair valued using an income approach. The discount rates used to present value the estimated cash flows related to each of the cardiovascular products were determined based on the relative risk of achieving each product's estimated cash flows and were in the range of 45% to 70%. The following values were assigned to the

cardiovascular products: Bisochron $21,550,000, Isochron $13,100,000, Hepacol I $6,985,000, and Hepacol II $2,565,000. At the date of acquisition, these products were in various stages of completion, had not reached technological feasibility and had no known alternative future uses. Bisochron and Isochron were both entering Phase III clinical studies, and Hepacol I and Hepacol II were both in pre-clinical phases of development. In addition, none of these products had been submitted for approval by the FDA. Consequently, there is considerable uncertainty as to the technological feasibility of these products at the date of acquisition. The research being undertaken on these products relates specifically to developing novel formulations of the associated molecules. The Company does not foresee any alternative future benefit from the acquired research and development other than specifically related to these products under development. There is significant technological and regulatory approval risk associated with these products under development. The completion of these products will require significant amounts of future time and effort, as well as additional development costs, which will be incurred by Athpharma and the Company. The Company's share of the aggregate costs to complete these products is estimated to be $20,000,000. The efforts required to develop the acquired research and development into commercially viable products include the completion of the development stages of the products, clinical-trial testing, regulatory approval and commercialization. The principal risks relating to these products under development are the outcomes of the formulation development, clinical studies and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, the Company will not receive any benefits unless regulatory approval is obtained. Accordingly, the entire purchase price for these products was allocated to acquired research and development, which was expensed at the date of acquisition.

**Ativan® and Isordil®**

In May 2003, Biovail acquired the U.S. rights to Ativan® (lorazepam), indicated for the management of anxiety disorders, and Isordil® (isosorbide dinitrate), indicated for the prevention of angina pectoris due to coronary artery disease, from Wyeth Pharmaceuticals Inc. ("Wyeth"). Biovail also acquired a license to use certain technologies relating to Wyeth's Canadian sublingual version of Ativan® to develop new Ativan® sublingual products to be sold in the United States. Wyeth will manufacture and supply Ativan® and Isordil® to Biovail for three years and will temporarily provide distribution services. Biovail will make two fixed annual payments of $9,150,000 each to Wyeth under the manufacturing and supply agreement (regardless of the actual product supplied). Wyeth will also receive royalties on the future sales of any Ativan® line extension products that may be developed and marketed by Biovail, as well as a $20,000,000 milestone payment, increasing at 10% per annum, on the approval by the FDA of the first Ativan® line extension product that may be developed by Biovail.

The purchase price for Ativan® and Isordil® was $163,839,000 comprising cash consideration, including costs of acquisition, of $139,342,000, plus assumed current liabilities and the two remaining fixed annual payments. The remaining fixed annual payments were present valued using an imputed interest rate comparable to Biovail's available borrowing rate at the date of acquisition. Accordingly, the present value of the remaining fixed annual payments was determined to be $17,497,000.

As of September 30, 2003, the purchase price allocation for Ativan® and Isordil® was not finalized. The Company is in the process of obtaining a third party valuation of the acquired assets and expects to receive the final valuation report during the fourth quarter of 2003. Accordingly, the following allocation of the purchase price may be subject to adjustment. Total consideration was allocated based on the estimated fair values of the acquired assets as follows: (i) acquired research and development $40,000,000, (ii) trademarks $106,802,000, (iii) product rights $15,510,000, and (iv) technology $1,527,000. The fair values of the acquired assets were determined using an income approach. The discount rates used to present value the estimated cash flows related to each acquired asset were determined based on the relative risk of achieving each asset's estimated cash flows and were in the range of 10.5% to 45%.

The Ativan® sublingual products under development were fair valued using an income approach. The discount rates used to present value the estimated cash flows related to each of these products were determined based on the relative risk of achieving each product's estimated cash flows and were in the range of 30% to 35%. At the date of acquisition, the development of these products was not complete, had not reached technological feasibility and had no known alternative future uses. These products were in pre-clinical phases of development. In addition, none of these products had been

submitted for approval by the FDA. Consequently, there is considerable uncertainty as to the technological feasibility of these products at the date of acquisition. The research being undertaken on these products relates specifically to developing novel formulations of the associated molecules. The Company does not foresee any alternative future benefit from the acquired research and development other than specifically related to these products under development. There is significant technological and regulatory approval risk associated with these products under development. The completion of these products will require significant amounts of future time and effort, as well as additional development costs, which will be incurred by the Company. The costs to complete these products are estimated to be $23,500,000. The efforts required to develop the acquired research and development into commercially viable products include the completion of the development stages of the products, clinical-trial testing, regulatory approval and commercialization. The principal risks relating to these products under development are the outcomes of the formulation development, clinical studies and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, the Company will not receive any benefits unless regulatory approval is obtained. Accordingly, the portion of the purchase price related to these products under development was allocated to acquired research and development, which was expensed at the date of acquisition.

The trademarks will be amortized over their estimated useful lives of twenty years. The product rights and technology will be amortized over their estimated useful lives of fifteen years. The estimated weighted average useful life of the trademarks, product rights and technology is approximately nineteen years.

**Omeprazole**

In May 2003, Biovail made an additional payment of $33,000,000 to the prior owners of Pharma Pass LLC ("Pharma Pass") relative to Pharma Pass's participating interest in the gross profit on sales of a generic version of Prilosec (omeprazole). The additional payment will be amortized using a variable charge method to reflect the pattern in which the economic benefits of the asset are consumed.

**5. ACCOUNTS RECEIVABLE**

| | September 30 2003 | December 31 2002 |
|---|---|---|
| Trade | **$ 183,959** | $ 141,308 |
| Royalties | **20,767** | 30,104 |
| Other | **32,885** | 19,568 |
| | **$ 237,611** | $ 190,980 |

**6. INVENTORIES**

| | September 30 2003 | December 31 2002 |
|---|---|---|
| Raw materials | **$ 38,287** | $ 14,949 |
| Work in process | **13,233** | 11,901 |
| Finished goods | **31,043** | 26,197 |
| | **$ 82,563** | $ 53,047 |

**7. INTANGIBLE ASSETS**

| | September 30, 2003 | | December 31, 2002 | |
|---|---|---|---|---|
| | Cost | Accumulated amortization | Cost | Accumulated amortization |
| Brand names | **$ 702,958** | **$ 72,274** | $ 596,223 | $ 47,794 |
| Product rights | **612,646** | **143,796** | 571,105 | 55,531 |
| Core technology | **20,412** | **3,366** | 18,885 | 2,385 |
| | **1,336,016** | **$ 219,436** | 1,186,213 | $ 105,710 |
| less accumulated amortization | **219,436** | | 105,710 | |
| | **$ 1,116,580** | | $ 1,080,503 | |

Amortization expense amounted to $27,860,000 and $16,262,000 for the three months ended September 30, 2003 and 2002, respectively, and $113,498,000 and $43,328,000 for the nine months ended September 30, 2003 and 2002, respectively.

**8. OTHER ASSETS**

**Zovirax distribution agreement**

Effective October 1, 2002, the Company amended several terms of the original Zovirax distribution agreement with GSK, including a reduction in the supply price for this product. The Company has been paying the reduced supply price since the effective date; however, the reduced supply price was subject to repayment if Wellbutrin XL® was not approved by the FDA. Accordingly, the Company had been deferring the value of the reduced supply price pending the outcome of the Wellbutrin XL® approval. In June 2003, GSK received an approvable letter relating to Wellbutrin XL®, which raised only routine matters. As a result, the Company believed that the likelihood of repaying the reduced supply price was low and, accordingly, the Company reversed the liability for the deferred value of the reduced supply price. The reversal of the aggregate deferred value of $25,456,000, as of the date of the approvable letter, was recorded as a reduction to the cost of Zovirax sold in the three months ended June 30, 2003. On August 28, 2003, GSK received FDA approval for Wellbutrin XL®.

**Loan receivable**

In November 2002, in connection with a co-promotion agreement between Biovail and Reliant Pharmaceuticals, LLC ("Reliant"), as described in note 16 Co-Promotion Arrangement, Biovail, together with certain of Reliant's existing lenders, established an $85,000,000 secured credit facility in favour of Reliant. Biovail had committed to fund up to $40,000,000 of this credit facility. In June 2003, this credit facility was increased from $85,000,000 to $115,000,000 and Biovail agreed to increase its total commitment to this credit facility from $40,000,000 to $70,000,000. All other material terms and conditions of this credit facility were unchanged.

The secured credit facility is available to Reliant, subject to certain financial and non-financial covenants, for general corporate purposes. This credit facility is secured by a first charge over certain property and assets of Reliant. Interest is calculated daily on the outstanding advances at U.S. prime plus a margin of 2% and is payable in arrears on the first day of each calendar quarter. Prior to March 31, 2005, Reliant may elect to accrue but not make cash payments of interest. Such accrued interest will be added to the principal amount of the outstanding advances at March 31, 2005. Reliant is entitled to prepay any or all of the outstanding advances at any time without penalty. Commencing March 31, 2005, Reliant is to begin repayment of the outstanding advances in eight equal quarterly instalments, with the final instalment due on December 31, 2006.

At September 30, 2003 and December 31, 2002, Biovail had advanced a total of $70,000,000 and $30,000,000, respectively, to Reliant under the secured credit facility.

**9. LONG-TERM OBLIGATIONS**

| | September 30 2003 | December 31 2002 |
|---|---|---|
| | (Restated Note 2) | |
| Senior Subordinated Notes | **$ 400,000** | $ 400,000 |
| Unamortized discount | **(2,372)** | (2,646) |
| Fair value adjustment | **14,156** | 15,239 |
| | **411,784** | 412,593 |
| Revolving term credit facility | **225,000** | 110,000 |
| Vasotec® obligation | **57,622** | 67,942 |
| Wellbutrin® obligation | **42,494** | 69,961 |
| Zovirax obligation | **41,808** | 80,656 |
| Ativan® obligation | **17,673** | |
| Deferred compensation | **6,737** | 6,198 |
| | **803,118** | 747,350 |
| Less current portion | **101,513** | 122,590 |
| | **$ 701,605** | $ 624,760 |

Interest expense on long-term obligations amounted to $9,966,000 and $9,358,000 for the three months ended September 30, 2003 and 2002, respectively, and $28,120,000 and $20,318,000 for the nine months ended September 30, 2003 and 2002, respectively. Interest expense included the amortization of the discounts on long-term obligations of $1,483,000 and $1,854,000 for the three months ended September 30, 2003 and 2002, respectively, and $5,461,000 and $3,928,000 for the nine months ended September 30, 2003 and 2002, respectively.

**Revolving term credit facility**

The Company maintains a $600,000,000 revolving term credit facility, which may be used for general corporate purposes, including acquisitions. At September 30, 2003, the Company had advances of $225,000,000 borrowed under this credit facility and a letter of credit of $77,189,000 issued under this credit facility. The letter of credit secures the remaining semi-annual payments the Company is required to make under the Vasotec® and Vaseretic® agreement.

**Ativan® obligation**

The obligation reflects the two remaining fixed annual payments related to the acquisition of Ativan® and Isordil®. This non-interest bearing obligation was discounted based on an imputed interest rate of 3%. The payments of $9,150,000 each are due on May 31, 2004 and May 31, 2005.

**Interest rate swap contracts**

The fair value of the fixed rate $7^{7}/_{8}$% Senior Subordinated Notes due April 1, 2010 ("Notes") is affected by changes in interest rates. The Company manages this exposure to interest rate changes through the use of interest rate swap contracts, which are recorded at fair value in the Company's consolidated balance sheets. In June 2002, the Company entered into

three interest rate swaps of aggregate $200,000,000 notional amount, which were designated as a hedge of the Notes. The interest rate swaps involve the receipt of amounts based on a fixed rate of 7 7/8% in exchange for floating rate interest payments, based on six-month London Interbank Offering Rate plus a spread of 2.69% to 2.99%, without an exchange of the underlying principal amount. Net receipts or payments relating to the interest rate swaps are recorded as an adjustment to interest expense.

Prior to April 1, 2003, the interest rate swaps effectively modified the Company's exposure to interest rate fluctuations by converting the interest payable on one-half of the fixed rate Notes to a floating rate. The changes in the fair values of the interest rate swaps and the offsetting changes in the fair value of the portion of the Notes being hedged were recognized in other income and expense. Accordingly, the net gain or loss recognized prior to April 1, 2003 related to the ineffective portion of the fair value hedge.

Effective April 1, 2003, the Company determined that the interest rate swaps no longer qualified as a highly effective hedge and, accordingly, the Company discontinued the application of hedge accounting as of that date. As a result, for the period from April 1, 2003 to September 30, 2003, the interest rate swaps continued to be adjusted for changes in their fair values; however, the Notes were not adjusted for the changes in their fair value during that period. In addition, the fair value adjustment to the Notes of $15,129,000, as at March 31, 2003, is being accreted to net income over the remaining term of the Notes.

At September 30, 2003, the fair values of the interest rate swaps of aggregate $18,699,000 were included in other assets. For the three months and nine months ended September 30, 2003, the Company recorded other expense of $5,958,000 and other income of $706,000, respectively, related to the changes in the fair values of the interest rate swaps, as well as the changes in the fair value of the Notes recognized prior to the termination of hedge accounting.

**10. COMMON SHARES**

During the nine months ended September 30, 2003, the Company issued 629,816 common shares on the exercise of stock options for proceeds of $11,419,000. The number of stock options outstanding at September 30, 2003 and December 31, 2002 were 6,684,362 and 5,924,615, respectively. During the nine months ended September 30, 2003, 1,434,706 stock options were granted, 629,816 stock options were exercised and 45,143 stock options were forfeited.

**11. EXECUTIVE STOCK PURCHASE PLAN ("ESPP") LOANS**

In October 2001, the Company made ESPP loans in aggregate amount of $9,988,000 to certain executive officers in order to finance the acquisition of common shares of the Company on the open market. The ESPP loans were due and payable on September 30, 2003. Subsequent to September 30, 2003, Mr. Melnyk repaid his loan. The remaining officers are finalizing arrangements to repay their loans.

**12. SETTLEMENTS**

**Pfizer Inc. ("Pfizer"), Bayer AG, Bayer Corporation, Teva Pharmaceuticals USA, Inc. ("Teva"), Mylan Pharmaceuticals Inc. ("Mylan"), Mylan Laboratories Inc.**

In June 2003, the Company negotiated an overall settlement with the above captioned entities through which all pending actions relating to generic versions of Procardia XL ("Nifedical XL") and Adalat CC, including actions alleging patent infringement and antitrust breaches, were dismissed. The settlement payment comprised the following amounts: (i) a recovery for the profit lost by the Company on sales of Nifedical XL, (ii) compensation for the value of dated Nifedical XL in inventory, (iii) a reimbursement of legal and other expenses incurred by the Company during the six months ended June 30, 2003, and (iv) interest. In connection with the settlement, the Company was granted a royalty-free, non-exclusive sub-license to U.S. Patent No. 4,264,446.

**Elan Corporation, plc ("Elan")**

In June 2003, the Company settled with Elan with respect to the termination of its rights to Elan's 30mg and 60mg generic versions of Adalat CC. In consideration, the parties agreed to settle certain amounts that were owed between them. The net settlement payment from Elan comprised a reimbursement for certain charges related to the supply of these products.

**Eli Lilly and Company ("Lilly")**

In March 2003, the Company negotiated a full and final settlement with Lilly with respect to Lilly's breach of contract due to its inability to supply Keftab to the Company and, as a result, the Company returned all of its right, title and interest in Keftab to Lilly. The settlement payment comprised the following amounts: (i) a recovery of the gross profit lost by the Company on account of Lilly's recall of Keftab and a share of the value of the Keftab product right that was written-off by the Company in December 2001, (ii) the recoverable value of the Keftab product right recorded in intangible assets, (iii) compensation for the value of the destroyed Keftab inventory recorded as a long-term receivable from Lilly, (iv) a reimbursement for legal and other expenses incurred by the Company during the three months ended March 31, 2003, and (v) interest.

**Mylan**

In March 2003, an arbitration tribunal awarded the Company damages with respect to Mylan's breach of contract relating to its failure to supply its generic version of Verelan ("Verapamil") to the Company. The settlement payment comprised the following amounts: (i) a recovery of the profit lost by the Company on sales of Verapamil, (ii) a reimbursement for legal expenses incurred by the Company during the three months ended March 31, 2003, and (iii) interest.

During the six months ended June 30, 2003, in relation to the matters described above, the Company recorded settlement payments of $34,055,000, mainly related to the Company's lost profits on sales of Nifedical XL, Keftab and Verapamil, and additional payments of $16,229,000, mainly related to a reduction in cost of goods sold, a reimbursement of legal and other expenses, and interest income. The Company recorded a $3,500,000 increase in its provision for income taxes related to these items. In addition, the Company recorded a $14,554,000 reduction to assets related to the recoverable value of the Keftab product right and the long-term receivable from Lilly.

## 13. EARNINGS PER SHARE

Earnings per share were computed as follows:

| | Three Months Ended September 30 | | Nine Months Ended September 30 | |
|---|---|---|---|---|
| | **2003** | **2002** | **2003** | **2002** |
| | **(Restated Note 2)** | | **(Restated Note 2)** | |
| Net income | **$ 16,114** | $ 74,977 | **$ 68,773** | $ 190,585 |
| Basic weighted average number of common shares outstanding (000s) | **158,704** | 145,367 | **158,428** | 150,252 |
| Dilutive effect of stock options (000s) | **1,722** | 1,939 | **1,687** | 2,994 |
| Dilutive effect of warrants (000s) | | 6,710 | | 7,989 |
| Diluted weighted average number of common shares outstanding (000s) | **160,426** | 154,016 | **160,115** | 161,235 |
| Basic earnings per share | **$ 0.10** | $ 0.52 | **$ 0.43** | $ 1.27 |
| Diluted earnings per share | **$ 0.10** | $ 0.49 | **$ 0.43** | $ 1.18 |

**14. COMPREHENSIVE INCOME**

Comprehensive income comprised the following:

| | Three Months Ended September 30 | | Nine Months Ended September 30 | |
|---|---|---|---|---|
| | **2003** | **2002** | **2003** | **2002** |
| | **(Restated Note 2)** | | **(Restated Note 2)** | |
| Net income | **$ 16,114** | $ 74,977 | **$ 68,773** | $ 190,585 |
| **Other comprehensive income (loss)** | | | | |
| Foreign currency translation adjustment | **(1,890)** | (1,351) | **12,789** | 221 |
| Unrealized holding gain (loss) on long-term investments | **6,367** | (6,604) | **17,678** | (7,175) |
| Reclassification adjustment for loss on long-term investment included in net income | | 554 | | 554 |
| Other comprehensive income (loss) | **4,477** | (7,401) | **30,467** | (6,400) |
| Comprehensive income | **$ 20,591** | $ 67,576 | **$ 99,240** | $ 184,185 |

**15. CASH FLOW INFORMATION**

**Net change in non-cash operating items**

| | Nine Months Ended September 30 | |
|---|---|---|
| | **2003** | **2002** |
| Accounts receivable | **$ (23,254)** | $ (41,510) |
| Inventories | **(31,864)** | (4,780) |
| Deposits and prepaid expenses | **10,483** | (2,089) |
| Accounts payable and accrued liabilities | **(31,320)** | 48,414 |
| Income taxes payable | **9,095** | 11,964 |
| Deferred revenue | **(240)** | (16,637) |
| | **$ (67,100)** | $ (4,638) |

**Non-cash investing and financing activities**

For the nine months ended September 30, 2003, non-cash investing and financing activities included a $22,990,000 payable related to the acquisition of the Athpharma cardiovascular products, a $21,000,000 payable to Ethypharm related to Tramadol FT (offset by a $20,000,000 receivable from Ethypharm related to Diltiazem CR), and a $17,497,000 discounted long-term obligation related to the acquisition of Ativan® and Isordil®.

**16. LEGAL PROCEEDINGS**

From time to time, the Company becomes involved in various legal and administrative proceedings, which it considers to be in the ordinary course of business. These proceedings include product liability, intellectual property, antitrust, governmental investigations and related private litigation. There are also ordinary course employment dismissal and related employment issues and other types of claims in which the Company routinely becomes involved but which individually and collectively are not material.

**Intellectual property**

RhoxalPharma Inc. ("RhoxalPharma") has filed an Abbreviated New Drug Submission ("ANDS") in Canada, seeking approval of a generic version of Tiazac®. In an attempt to comply with the Patented Medicines (Notice of Compliance) Regulations, RhoxalPharma has alleged to Health Canada that Canadian Patent No. 2,111,085, of which Biovail is the exclusive licensee, would not be infringed by the sale in Canada of RhoxalPharma's generic version of Tiazac®. RhoxalPharma served a Notice of Allegation on Biovail. In response to that Notice, Biovail instituted proceedings in the Federal Court of Canada in March 2002, to prohibit the issue of a Notice of Compliance (which is needed before RhoxalPharma can market its product in Canada) to RhoxalPharma until the merits of RhoxalPharma's allegations can be determined by the Federal Court. Until those proceedings are concluded, or until the expiry of 24 months after March 2002, whichever is earlier, no Notice of Compliance will be issued to RhoxalPharma.

A Certificate of Non-Infringement was served by Torpharm, Inc. ("Torpharm") on Aventis in October 2001, in respect of its filed Abbreviated New Drug Application ("ANDA") of a generic version of Cardizem® CD (120 mg, 180 mg and 300 mg) with the FDA. The patents against which Torpharm certified were acquired by the Company as part of the Company's acquisition of the Cardizem® family of products. Biovail has determined that Torpharm's ANDA infringes its patents and a legal suit has been commenced against Torpharm, the effect of which was to trigger the Hatch-Waxman provisions. As a result, the FDA is statutorily and automatically precluded from granting approval to Torpharm until the earlier of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity or a court decision to abbreviate the 30-month stay.

A Certificate of Non-Infringement was served by Torpharm on the Company in July 2002 in respect of Torpharm's filed ANDA for a generic version of Tiazac® as marketed in the United States. Biovail has made a determination that Torpharm's formulation infringes its Tiazac® patents and has therefore instituted a patent infringement suit against Torpharm, pursuant to the provisions of the Hatch-Waxman Act. As a result of Biovail's suit, the FDA is statutorily and automatically precluded from granting approval to Torpharm until the earlier of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

Glaxo Group Limited and the Company entered into a Rights Agreement, dated December 1, 2002, wherein the Company acquired the exclusive marketing rights to Zyban® and Wellbutrin® SR in Canada. Novopharm Limited ("Novopharm") has filed an ANDS in Canada, seeking approval of a generic version of Wellbutrin® SR. In an attempt to comply with the Patented Medicines (Notice of Compliance) Regulations, Novopharm has alleged to Health Canada that Canadian Patent Nos. 1,321,754, 2,142,320 and 2,168,364 are invalid, and alternatively, that they would not be infringed by the sale in Canada of Novopharm's generic version of Wellbutrin® SR. Novopharm served a Notice of Allegation on GlaxoSmithKline Inc. ("Glaxo") on February 18, 2003. The Company has the exclusive right to institute, and have carriage of, patent infringement proceedings and has pursued a legal challenge through a Notice of Application proceeding against Novopharm. Until these legal proceedings are concluded, or until the expiry of 24 months after March 31, 2003, the date of the Notice, whichever is earlier, no Notice of Compliance will be issued to Novopharm.

A Certificate of Non-Infringement was served by KV Pharmaceutical Company ("KV") on the Company in March 2003, in respect of KV's filed ANDA for a generic version of Tiazac® 420 mg, exclusively, as marketed in the United States. On April 28, 2003 the Company had filed a Complaint in the United States District for the Eastern District of Missouri Eastern Division under 35 U.S.C. §271(e)(2), alleging that KV had infringed U.S. Patent No. 5,529,791, by filing an ANDA to market a generic version of Tiazac, 420 mg. The Court, at the request of both parties, entered an Order of Dismissal on September 23, 2003.

**Product liability**

On January 4, 2002 a Plaintiff commenced an action against Biovail Pharmaceuticals, Inc. ("BPI") alleging personal injuries arising from her use of Dura-Vent, a product containing Phenylpropanolamine ("PPA") and formerly marketed by BPI. The

Company believes that this claim is without merit and, in the event the case proceeds further, it will be vigorously defended. This action has been currently stayed pending the outcome of a larger class of PPA actions.

**Antitrust**

Several class action complaints have been filed against the Company in which these Plaintiffs have alleged that Biovail has improperly impeded the approval of a generic form of Tiazac®. The Company has filed an Answer denying any impropriety or illegality. The Company believes that the Complaints are without merit and that its actions were in accord with its rights as contained in the Hatch-Waxman Amendments and the law. Moreover, the Company's position is that none of its actions was responsible for the inability of that product to receive final marketing approval by the FDA since a generic version of Tiazac® did not receive FDA approval for a lengthy period following the removal of all legal or regulatory impediments by the Company. Indeed, that product's failure to receive timely approval was due to its own scientific issues unrelated to any regulatory action taken by the Company. The Company is vigorously defending these actions. One such action has been voluntarily discontinued.

Several consumer class action suits have been commenced jointly against Biovail and Elan and against Teva relating to an agreement between a Biovail subsidiary and Elan for Biovail's in-licensing of Adalat CC products from Elan. The agreement in question has since been dissolved as a result of a settlement agreement with the Federal Trade Commission ("FTC"). Biovail is vigorously defending these suits. Biovail believes these suits are without merit since the delay in the marketing or out-licensing of the Company's Adalat CC product was due to manufacturing difficulties the Company encountered and not because of any improper activity on its part.

The Company has received an informal enquiry from the FTC with respect to the Company's acquisition and listing of certain patents relating to its Teveten® and Teveten® HCT products. The Company has cooperated with the FTC and does not expect any action by the FTC in this matter.

**Securities class action**

The Company has received notification that a number of Securities Class Action Complaints have been recently filed naming Biovail and certain officers. The Complaints allege the Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. More specifically the Complaints allege that Biovail and certain of its officers and directors made materially false and misleading statements during certain specified periods of time. These filed Complaints have not been formally served on the Defendants. The Company believes these actions are without merit and will aggressively pursue defences.

**Restrictive covenants**

On November 22, 2002, the Company filed an action against Verum Pharmaceuticals Inc. ("Verum"), and a number of its officers and employees seeking injunctive relief and damages to enjoin these Defendants from illegally and unfairly competing with Biovail in violation of the Computer Fraud and Abuse Act, 18 U.S.C. § 1030, and Defendants' contractual, statutory and common law obligations. On June 25, 2003, the Fourth Circuit Court of Appeals stayed enforcement of portions of a preliminary injunction originally granted to the Company on February 14, 2003. The Company intends to pursue its action for damages against Verum and the personal Defendants.

**Defamation and tort**

On April 29, 2003, Jerry I. Treppel commenced an action naming as Defendants the Company and certain officers thereof, and against Michael Sitrick and Sitrick & Company, Inc. (in their capacities as consultants to the Company), in which the Plaintiff has alleged that he was defamed by the Defendants and that the Company's actions resulted in damages to him by way of lost employment and employment opportunities.

Defendants have filed a motion to dismiss the Complaint on various grounds. The Company plans to defend the action vigorously as it believes it is without merit.

**Government investigations**

The Company has received notification from the U.S. Attorney, District of Massachusetts, on behalf of the U.S. Office of the Inspector General ("OIG") of Health and Human Services that a preliminary administrative inquiry has been initiated into the Company's clinical experience and marketing programs related to Cardizem® LA. The Company is providing the government its full cooperation in this investigation. After initial consultation with its external legal counsel, the Company believes that its programs are fully compliant with the OIG Guidelines.

**17. CO-PROMOTION ARRANGEMENT**

In November 2002, Biovail and Reliant entered into an agreement to co-promote Biovail's Cardizem® LA, Zovirax, Teveten®, Teveten® HCT, Rondec and Cedax products. Biovail and Reliant will detail these products to physicians in the United States during the period from October 1, 2002 to December 31, 2005. In addition, Biovail will spend a minimum prescribed amount on advertising and sales promotion of these products. In consideration of Reliant's co-promotion activities under the agreement, Biovail will pay Reliant a tiered co-promotion fee based on a percentage of the quarterly net sales of the co-promoted products covered by the agreement.

Effective April 1, 2003, Biovail amended certain terms of the co-promotion agreement with Reliant, such that Reliant is responsible for its pro-rata share of the advertising and sales promotion costs incurred during 2003 related to the co-promoted products. Accordingly, Biovail's selling, general and administrative expenses in the three months and nine months ended September 30, 2003 were recorded net of reimbursements of $8,167,000 and $25,000,000, respectively, due from Reliant. The terms of the amended co-promotion agreement also increased the tiered co-promotion fee payable to Reliant.

**18. SEGMENTED INFORMATION**

The Company operates in one operating segment the development and commercialization of pharmaceutical products. Substantially all of the operations of the Company are directly engaged in or support this operating segment. Other operations are not material and share many of the same economic and operating characteristics as pharmaceutical products. Therefore, they are included with pharmaceutical products for purposes of segment reporting.

**19. SUBSEQUENT EVENTS**

On November 20, 2003, the Company received a letter from the U.S. Securities and Exchange Commission ("SEC") advising the Company that it has initiated an informal inquiry pertaining to Biovail's accounting and financial reporting practices for the fiscal year 2002 and quarterly periods to date for fiscal 2003. Biovail intends to fully comply with SEC requests for information.

On November 24, 2003, the Company received regulatory approval to make a normal course issuer bid through the NYSE and TSX. The Company is entitled to purchase up to 13,164,059 common shares on or before November 25, 2004. Any common shares purchased by the Company under this issuer bid will be cancelled.

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (RESTATED)**

**In accordance with U.S. generally accepted accounting principles (All dollar amounts are expressed in U.S. dollars)**

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") prepared in accordance with U.S. generally accepted accounting principles ("GAAP") should be read in conjunction with the accompanying unaudited consolidated financial statements and condensed notes thereto. This MD&A should also be read in conjunction with the MD&A and audited consolidated financial statements and notes thereto contained in our Annual Report on Form 20-F for the fiscal year ended December 31, 2002.

**RESTATEMENT AND RECLASSIFICATION OF COMPARATIVE FIGURES**

During the course of the preparation of our annual consolidated financial statements, we determined that we had applied an inappropriate exchange rate to a Canadian dollar denominated long-term obligation. In December 2002, we acquired the rights, through a subsidiary whose functional currency is the U.S. dollar, to Wellbutrin® SR and Zyban in Canada from GlaxoSmithKline plc ("GSK") in a transaction denominated in Canadian dollars. At the date of acquisition, we recorded the acquired assets and the related long-term obligation in U.S. dollars at the exchange rate existing at that date. However, in our previously issued interim financial statements for 2003, we did not adjust the Wellbutrin® obligation to reflect changes in the exchange rate except for payments made on that obligation when a foreign exchange loss ($2.4 million and $5.1 million in the third quarter and first nine months of 2003, respectively) was recorded on those transactions. U.S. GAAP requires monetary balances denominated in a currency other than an entity's functional currency be translated to reflect the exchange rates in existence at each balance sheet date. Consequently, the translation of the Wellbutrin® obligation, using the exchange rates existing at March 31, 2003, June 30, 2003 and September 30, 2003, resulted in an increase in net income in the third quarter of 2003 from $13.0 million (basic and diluted earnings per share of $0.08) as previously reported to $16.1 million (basic and diluted earnings per share of $0.10) as restated, and a decrease in net income in the first nine months of 2003 from $75.0 million (basic and diluted earnings per share of $0.47) as previously reported to $68.8 million (basic and diluted earnings per share of $0.43) as restated. In addition, the current portion of long-term obligations increased from $95.3 million as previously reported to $101.5 million as restated.

Prior to the fourth quarter of 2003, we included foreign exchange gains or losses as a component of selling, general and administrative expenses. During the course of the preparation of our annual consolidated financial statements, we decided to present foreign exchange gains or losses as an individual line item below operating income. Comparative figures have been reclassified to conform to this new presentation.

**RESULTS OF OPERATIONS**

Total revenue in the third quarter of 2003 was $215.3 million, an increase of $6.4 million or 3% from $208.9 million in the third quarter of 2002. Net income in the third quarter of 2003 was $16.1 million, or diluted earnings per share of $0.10, compared to net income of $75.0 million, or diluted earnings per share of $0.49, in the third quarter of 2002. Net income and diluted earnings per share decreased by $58.9 million or 79% and $0.39 or 80%, respectively, in the third quarter of 2003 compared to the third quarter of 2002.

Total revenue in the first nine months of 2003 was $624.0 million, an increase of $74.7 million or 14% from $549.3 million in the first nine months of 2002. Net income in the first nine months of 2003 was $68.8 million, or diluted earnings per share of $0.43, compared to net income of $190.6 million, or diluted earnings per share of $1.18, in the first nine months of 2002. Net income and diluted earnings per share decreased by $121.8 million or 64% and $0.75 or 64%, respectively, in the first nine months of 2003 compared to the first nine months of 2002.

**REVENUE**

Our revenue is derived from sales of pharmaceutical products, providing research and development services, the co-promotion of pharmaceutical products, and from royalties and license fees. Product sales include sales of products developed and manufactured by us for distribution by our licensees and through direct marketing to physicians in the United States and Canada of proprietary and in-licensed products. Research and development revenue relates to product development activities in collaboration with third parties and pharmaceutical contract research services. Fees for co-promotion services are earned on the sales of co-promoted products developed by other companies. Royalties primarily arise on the sales of products we developed or acquired and from our interests in certain licensed products. License fees are derived from the license of our technologies or product rights.

The following table displays, for each period indicated, the dollar amount of each source of revenue and the total, and the percentage change in the dollar amount of each source and the total as compared to the corresponding prior year period.

| | Three Months Ended September 30 | | | Nine Months Ended September 30 | | |
|---|---|---|---|---|---|---|
| *[Dollar amounts in 000s]* | **2003** | **2002** | **Percentage Change** | **2003** | **2002** | **Percentage Change** |
| Product sales | **$ 179,985** | $ 174,508 | 3% | **$ 464,629** | $ 462,150 | 1% |
| Research and development | **4,542** | 7,653 | (41%) | **10,815** | 19,168 | (44%) |
| Co-promotion, royalty and licensing | **30,787** | 26,783 | 15% | **148,543** | 68,010 | 118% |
| | **$ 215,314** | $ 208,944 | 3% | **$ 623,987** | $ 549,328 | 14% |

**Product sales**

Product sales revenue comprises sales of Core products, Wellbutrin XL®, Biovail Pharmaceuticals Canada ("BPC") products, Generic products and Legacy products. Core products include Cardizem® LA, Zovirax Ointment and Cream, and Teveten® and Teveten® HCT. We promote Core products in the United States in collaboration with our co-promotion partner Reliant Pharmaceuticals, LLC ("Reliant"). We manufacture and supply Wellbutrin XL® to our marketing partner, GSK. BPC products include Tiazac®, Cardizem®, Wellbutrin® SR, Zyban®, Monocor and Retavase. We promote BPC products in Canada directly to physicians through our own network of integrated sales representatives. Generic products comprise those products sold through our marketing

partner, Teva Pharmaceuticals USA, Inc. ("Teva"). We do not promote Legacy products as most of these products have been genericized.

| | Three Months Ended September 30 | | | Nine Months Ended September 30 | | |
|---|---|---|---|---|---|---|
| *[Dollar amounts in 000s]* | 2003 | 2002 | Percentage Change | 2003 | 2002 | Percentage Change |
| Core products | **$ 60,075** | $ 18,075 | 232% | **$ 138,571** | $ 74,157 | 87% |
| Wellbutrin XL® | **8,223** | | N/A | **16,296** | | N/A |
| BPC products | **23,078** | 9,070 | 154% | **61,770** | 22,861 | 170% |
| Generic products | **20,359** | 60,393 | (66%) | **75,545** | 129,048 | (41%) |
| Legacy products | **68,250** | 86,970 | (22%) | **172,447** | 236,084 | (27%) |
| | **$ 179,985** | $ 174,508 | 3% | **$ 464,629** | $ 462,150 | 1% |

Product sales were $180.0 million in the third quarter of 2003 compared to $174.5 million in the third quarter of 2002, an increase of $5.5 million or 3%. Product sales were $464.6 million in the first nine months of 2003 compared to $462.2 million in the first nine months of 2002, an increase of $2.4 million or 1%.

Core product sales were $60.1 million and $138.6 million in the third quarter and first nine months of 2003, respectively, compared to $18.1 million and $74.2 million in the third quarter and first nine months of 2002, respectively. The increases in Core product sales in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 reflected the launches of Teveten® HCT, Cardizem® LA and Zovirax Cream. In February 2003, we received U.S. Food and Drug Administration ("FDA") approvals for Teveten® HCT and Cardizem® LA, each indicated for the treatment of hypertension. We began to actively promote Teveten® HCT and Cardizem® LA in March 2003 and April 2003, respectively. In July 2003, we launched Zovirax Cream, indicated for the treatment of cold sores.

Wellbutrin XL® product sales were $8.2 million and $16.3 million in the third quarter and first nine months of 2003, respectively. In August 2003, GSK received FDA approval for Wellbutrin XL®. We receive a share of the revenue generated on sales of Wellbutrin XL® trade product by GSK, and we sell sample product to them at contractually agreed prices.

BPC product sales were $23.1 million and $61.8 million in the third quarter and first nine months of 2003, respectively, compared to $9.1 million and $22.9 million in the third quarter and first nine months of 2002, respectively. The increases in BPC product sales in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 were due to higher Tiazac® shipments in Canada and the added contribution from Wellbutrin® SR and Zyban®, which were acquired from GSK in December 2002.

Generic product sales were $20.4 million and $75.5 million in the third quarter and first nine months of 2003, respectively, compared to $60.4 million and $129.0 million in the third quarter and first nine months of 2002, respectively. The decreases in Generic products sales in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 were partly due to increased competition and lower pricing, as well as a reduction in inventory levels by Teva.

We also determined that Teva had deducted certain amounts in the computation of net sales of our Generic products that resulted in lower than expected revenue. In the third quarter of 2003, Teva issued to us an $8.5 million credit note related to these deductions, which we recorded as an adjustment to Generic product sales. We are continuing to work with Teva to address other reasons for the declines in Generic product sales.

Legacy product sales were $68.3 million and $172.4 million in the third quarter and first nine months of 2003, respectively, compared to $87.0 million and $236.1 million in the third quarter and first nine months of 2002, respectively. Legacy product sales included the added contribution from Ativan® (lorazepam), indicated for the management of anxiety disorders, and Isordil® (isosorbide dinitrate), indicated for the prevention of angina pectoris due to coronary artery disease. In May 2003, we acquired the U.S. rights to Ativan® and Isordil® from Wyeth Pharmaceuticals Inc. ("Wyeth"). During the third quarter of 2003, management determined that, based on trends in historical returns experience, the reserves for product returns related to certain Legacy products should be reduced and, accordingly, we recorded a reduction in these reserves of approximately $4 million.

The decreases in Legacy product sales in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 were mainly due to a decline in sales of Cardizem® CD and Tiazac® in the United States. Sales of Cardizem® CD were impacted by a backlog in the supply of the product from the manufacturer, Aventis Pharmaceuticals, Inc. Sales of Tiazac® in the United States were impacted by the introduction of a generic version of the product by Andrx Corporation ("Andrx"). We have launched our own generic version of Tiazac® through our marketing partner, Forest Laboratories Inc., to compete with Andrx's product. In addition, we are entitled to receive a royalty from Andrx based on the net sales of its product.

**Research and development**

Research and development activities generated revenue of $4.5 million in the third quarter of 2003 compared to $7.7 million in the third quarter of 2002, a decrease of $3.2 million or 41%. Research and development activities generated revenue of $10.8 million in the first nine months of 2003 compared to $19.2 million in the first nine months of 2002, a decrease of $8.4 million or 44%.

In the third quarter and first nine months of 2002, research and development revenue included revenue associated with the development of Wellbutrin XL® in collaboration with GSK. During 2002, we completed the development of Wellbutrin XL®.

**Co-promotion, royalty and licensing**

Co-promotion, royalty and licensing activities generated revenue of $30.8 million in the third quarter of 2003 compared to $26.8 million in the third quarter of 2002, an increase of $4.0 million or 15%. Co-promotion, royalty and licensing activities generated revenue of $148.5 million in the first nine months of 2003 compared to $68.0 million in the first nine months of 2002, an increase of $80.5 million or 118%.

In the first quarter of 2003, we concluded our co-promotion of Wellbutrin SR® in the United States and we earned the final quarterly increment of $10 million from GSK. In the third quarter and first nine months of 2002, we earned $10 million and $30 million, respectively, related to

the co-promotion of Wellbutrin SR®. Our remaining co-promotion revenue was related to the co-promotion of H. Lundbeck A/S' Celexa in Canada. We will discontinue the promotion of Celexa effective December 31, 2003.

Royalty revenue increased in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 due to the added contribution from our participating interest in the gross profit on sales by a third party of a generic version of Prilosec (omeprazole). In May 2003, we made an additional payment relative to our interest in omeprazole. The future contribution from our interest in omeprazole will be affected by additional generic competition and over-the-counter competition.

**OPERATING EXPENSES**

The following table displays, for each period indicated, the dollar amount of each operating expense item and the total, and the percentage change in the dollar amount of each item and the total as compared to the corresponding prior year period.

| | Three Months Ended September 30 | | | Nine Months Ended September 30 | | |
|---|---|---|---|---|---|---|
| *[Dollar amounts in 000s]* | **2003** | **2002** | **Percentage Change** | **2003** | **2002** | **Percentage Change** |
| Cost of goods sold | **$ 40,079** | $ 44,007 | (9%) | **$ 88,823** | $ 121,014 | (27%) |
| Research and development | **20,608** | 14,626 | 41% | **60,427** | 39,547 | 53% |
| Selling, general and administrative | **74,135** | 44,533 | 66% | **176,436** | 122,871 | 44% |
| Amortization | **28,243** | 15,994 | 77% | **114,650** | 42,522 | 170% |
| Acquired research and development | **18,409** | | N/A | **102,609** | | N/A |
| Settlements | | | N/A | **(34,055)** | | N/A |
| Write-down of assets | | 1,369 | (100%) | | 1,369 | (100%) |
| | **$ 181,474** | $ 120,529 | 51% | **$ 508,890** | $ 327,323 | 55% |

**Cost of goods sold and gross margins**

Cost of goods sold was $40.1 million in the third quarter of 2003 compared to $44.0 million in the third quarter of 2002, a decrease of $3.9 million or 9%. Cost of goods sold was $88.8 million in the first nine months of 2003 compared to $121.0 million in the first nine months of 2002, a decrease of $32.2 million or 27%. Gross margins based on product sales were 78% and 81% in the third quarter and first nine months of 2003, respectively, compared to 75% and 74% in the third quarter and first nine months of 2002, respectively.

The decreases in cost of goods sold, and the related increases in the gross margins, in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 were mainly related to a lower Zovirax supply price. Effective October 1, 2002, we amended several terms of the original Zovirax distribution agreement with GSK, including a reduction in the supply price for the product. We have been paying the reduced supply price since the effective date; however, the reduced supply price was subject to repayment if Wellbutrin XL® was not approved by the FDA. Accordingly, prior to the second quarter of 2003, we had been deferring the value of the reduced supply price

pending the outcome of the product approval. In the second quarter of 2003, we reversed the liability for the deferred value of the reduced supply price. The reversal of the aggregate deferred value of $25.5 million, as of the date of the approvable letter, was recorded as a reduction to the cost of Zovirax sold in the second quarter of 2003.

Gross margins in the third quarter and first nine months of 2003 were also favourably impacted by the inclusion of Cardizem® LA in the product mix, partially offset by lower gross margins associated with Wellbutrin XL® due to higher initial mix of sample versus trade product sales.

**Research and development**

Research and development expenses were $20.6 million in the third quarter of 2003 compared to $14.6 million in the third quarter of 2002, an increase of $6.0 million or 41%. Research and development expenses were $60.4 million in the first nine months of 2003 compared to $39.5 million in the first nine months of 2002, an increase of $20.9 million or 53%. As a percentage of total revenue, research and development expenses were 10% in both the third quarter and first nine months of 2003 compared to 7% in both the third quarter and first nine months of 2002.

Research and development expenses reflect direct spending on the development of products utilizing advanced oral drug delivery technologies. In the ordinary course of business, we enter into research and development collaborations with third parties to provide formulation and other services for our products under development. These third party developers are typically compensated through a combination of fees for service, milestone payments and/or royalty payments from future sales of the products under development.

The increase in research and development expenses in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 reflected an increase in clinical activity to support the upcoming New Drug Application ("NDA") submissions for our once-daily formulations of tramadol, for the signs and symptoms of osteoarthritis, and metformin, for the treatment of Type II diabetes. Two Phase III clinical trials have been completed on tramadol and the results of these trials are being analyzed. In the first half of 2003, we also competed the clinical activity to support the June 2003 submission of a supplemental NDA for an angina indication for Cardizem® LA.

Additional products under development in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 include clinically enhanced versions of venlafaxine, fenofibrate, acyclovir, simvastatin, sumatriptan and lorazepam, as well as four cardiovascular products being developed by us in collaboration with Athpharma Limited ("Athpharma"). In addition, research and development expenses in the second and third quarters of 2003 included the costs associated with a clinical experience program designed to evaluate the use of Cardizem® LA in a clinical practice setting.

**Selling, general and administrative**

Selling, general and administrative expenses were $74.1 million in the third quarter of 2003 compared to $44.5 million in the third quarter of 2002, an increase of $29.6 million or 66%. Selling, general and administrative expenses were $176.4 million in the first nine months of 2003 compared to $122.9 million in the first nine months of 2002, an increase of $53.5 million or 44%. As a percentage of total revenue, selling, general and administrative expenses were 34% and 28% in the third quarter and

first nine months of 2003, respectively, compared to 21% and 22% in the third quarter and first nine months of 2002, respectively.

The increases in selling, general and administrative expenses in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 reflected an increase in costs associated with our expanded U.S. commercial operations, as well as costs associated with the transition of that group from Raleigh, NC, as well as certain research and development personnel from Chantilly, VA, to our new U.S. head office in Bridgewater, NJ.

Also contributing to the increases in selling, general and administrative expenses were advertising and promotional expenses related to the launches of Cardizem® LA, Teveten® HCT and Zovirax Cream. All previously deferred advertising costs related to Cardizem® LA and Zovirax Cream were expensed on the launches of these products in the second and third quarters of 2003, respectively. Advertising costs related to Teveten® and Teveten® HCT were recorded net of a $8.5 million marketing allowance paid by Solvay Pharmaceuticals Marketing & Licensing AG in the first half of 2003.

Effective April 1, 2003, we amended certain terms of our co-promotion agreement with Reliant such that Reliant is responsible for its pro-rata share of the advertising and promotion costs incurred during 2003 related to the co-promoted products. Accordingly, selling, general and administrative expenses in the third quarter of and first nine months of 2003 were recorded net of reimbursements of $8.2 million and $25 million, respectively, due from Reliant. As a result, we are able to increase the level of spending on advertising and promotion related to the co-promoted products during 2003. The terms of the amended co-promotion agreement also increased Reliant's interest in the net sales of the co-promoted products, which resulted in higher co-promotion fees payable to them.

**Amortization**

Amortization expense was $28.2 million in the third quarter of 2003 compared to $16.0 million in the third quarter of 2002, an increase of $12.2 million or 77%. Amortization expense was $114.7 million in the first nine months of 2003 compared to $42.5 million in the first nine months of 2002, an increase of $72.2 million or 170%. As a percentage of total revenue, amortization expense was 13% and 16% in the third quarter and first nine months of 2003, respectively, compared to 8% in both the third quarter and first nine months of 2002.

The increases in amortization expense in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 primarily reflected the incremental amortization of our interest in omeprazole, as well as the incremental amortization associated with other acquired intangible assets.

**Acquired research and development**

In September 2003, we entered into several agreements with Ethypharm S.A. ("Ethypharm") comprising: (i) the acquisition of the remaining rights to Ethypharm's Flashtab version of tramadol ("Tramadol FT"), which had been previously licensed from Ethypharm in April 2002, and the elimination of our obligation to make any future milestone payments (except as described below) or royalty payments to Ethypharm related to Tramadol FT, (ii) the grant to Ethypharm of a 15-year license to manufacture and market our controlled-release formulation of diltiazem hydrochloride ("Diltiazem CR"), which is marketed by us in the United States under the trade name Cardizem® LA,

in all the countries of the world excluding Canada and the United States, (iii) the supply to Ethypharm of a quantity of diltiazem beads to enable it to encapsulate Diltiazem CR until the necessary technology transfer to manufacture diltiazem beads has been effected, and (iv) the grant to Ethypharm of a right of first offer to market Wellbutrin XL® in all countries outside North America that GSK does not elect to exercise its option. We have recorded these transactions on a net basis, reflecting that these agreements were negotiated and concluded almost simultaneously, and that we have elected, based on our right of set-off, to offset our payment due to Ethypharm (related to Tramadol FT) against the payments due from Ethypharm to us (related to the Diltiazem CR). We recorded a net charge to acquired research and development of $3.1 million related to these agreements. In addition, we will pay Ethypharm $1 million if Tramadol FT is approved by the FDA.

In July 2003, we formed a limited liability company ("BNC-PHARMAPASS") with Pharma Pass II, LLC ("PPII") to develop enhanced formulations of three products. The three products under development are Coreg (carvedilol), a beta-blocker indicated for the treatment of congestive heart failure, Flomax (tamsulosin), indicated for the treatment of benign prostatic hyperplasia, and Teveten® (eprosartan mesylate), an angiotensin-II receptor blocker for the treatment of hypertension. On the formation of BNC-PHARMAPASS, PPII contributed all of its intellectual property relating to these products for a 51% interest in this company and we contributed cash in the amount of $30.1 million for a 49% interest in this company. We have also agreed to provide sufficient additional funds to BNC-PHARMAPASS to allow it to pay the cost of all clinical trials related to these products. We have an option to acquire PPII's interest in BNC-PHARMAPASS including all of PPII's intellectual property rights to these products for cash consideration plus a royalty on the net sales of these products.

At the date of formation, the three products were in pre-clinical phases of development, had not reached technological feasibility and had no known alternative future uses. The research being undertaken on these products relates specifically to developing novel formulations of the associated molecules. We do not foresee any alternative future benefit from the acquired research and development other than specifically related to these products under development. There is significant technological and regulatory approval risk associated with these products under development. The completion of these products will require significant amounts of future time and effort, as well as additional development costs, which will be incurred by BNC-PHARMAPASS and us. The aggregate costs to complete these products are estimated to be $50 million. The efforts required to develop the acquired research and development into commercially viable products include the completion of the development stages of the products, clinical-trial testing, regulatory approval and commercialization. The principal risks relating to these products under development are the outcomes of the formulation development, clinical studies and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, we will not receive any benefits unless regulatory approval is obtained. Accordingly, our share of the fair value of these products of $15.3 million was allocated to acquired research and development, which was expensed at the date of formation.

In May 2003, in connection with our acquisition of Ativan® and Isordil®, we also acquired a license to use certain technologies relating to Wyeth's Canadian sublingual version of Ativan® to develop new Ativan® sublingual products to be sold in the United States. The purchase price for Ativan® and Isordil® included $40 million allocated to the Ativan® sublingual products under development. As of November 28, 2003, the purchase price allocation for Ativan® and Isordil® has not been finalized. We are in the process of obtaining a third party valuation of the acquired assets and expect to receive the

final valuation report during the fourth quarter of 2003. Accordingly, the preceding purchase price allocated to the sublingual products may be subject to adjustment.

In April 2003, we entered into an agreement with Athpharma to acquire four cardiovascular products under development for $44.2 million. The four products under development are Bisochron (bisoprolol), a beta-1 selective beta-blocker formulation for the treatment of hypertension, Isochron (isosorbide-5-mononitrate), a long-acting nitrate formulation for the treatment of angina, and Hepacol I (pravastatin) and Hepacol II (simvastatin), two liver-selective statin formulations for the treatment of high cholesterol.

At the dates of acquisition, the acquired Ativan® sublingual and Athpharma cardiovascular products were in various stages of completion, had not reached technological feasibility and had no known alternative future uses. In addition, none of these products had been submitted for approval by the FDA. Consequently, there is considerable uncertainty as to the technological feasibility of these products at the dates of acquisition. The research being undertaken on these products relates specifically to developing novel formulations of the associated molecules. We do not foresee any alternative future benefit from the acquired research and development other than specifically related to these products under development. There is significant technological and regulatory approval risk associated with these products under development. The completion of these products will require significant amounts of future time and effort, as well as additional development costs, which we will incur. We estimate that our share of the aggregate costs to complete the cardiovascular products will be $20 million and that our costs to complete the sublingual products will be $23.5 million. The efforts required to develop the acquired research and development into commercially viable products include the completion of the development stages of the products, clinical-trial testing, regulatory approval and commercialization. The principal risks relating to these products under development are the outcomes of the formulation development, clinical studies and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, we will not receive any benefits unless regulatory approval is obtained. Accordingly, the consideration for these products was allocated to acquired research and development, which was expensed at the dates of acquisition.

**Settlements**

In the second quarter of 2003, we negotiated an overall settlement with Pfizer Inc. ("Pfizer"), Bayer AG, Bayer Corporation, Teva, Mylan Pharmaceuticals Inc. ("Mylan") and Mylan Laboratories Inc. through which all pending actions relating to generic versions of Procardia XL ("Nifedical XL") and Adalat CC, including actions alleging patent infringement and antitrust breaches, were dismissed. In addition, in the second quarter of 2003, we settled with Elan Corporation, plc ("Elan") with respect to the termination of our rights to Elan's 30mg and 60mg generic versions of Adalat CC. In the first quarter of 2003, we reached settlements with Eli Lilly and Company ("Lilly"), with respect to Lilly's breach of contract due to its inability to supply us with Keftab, and with Mylan, with respect to Mylan's breach of contract relating to its supply to us of its generic version of Verelan ("Verapamil").

During the first half 2003, in relation to the matters described above, we recorded settlement payments of $34.1 million, mainly related to our lost profits on sales of Nifedical XL, Keftab and Verapamil and additional payments of $16.2 million, mainly related to a reduction in cost of goods sold,

a reimbursement of legal and other expenses, and interest income. We recorded a $3.5 million increase in our provision for income taxes related to these items. In addition, we recorded a $14.6 million reduction to assets related to the recoverable value of the Keftab product right and the long-term receivable from Lilly.

**OPERATING INCOME**

Operating income was $33.8 million in the third quarter of 2003 compared to $88.4 million in the third quarter of 2002, a decrease of $54.6 million or 62%. Operating income was $115.1 million in the first nine months of 2003 compared to $222.0 million in the first nine months of 2002, a decrease of $106.9 million or 48%. As a percentage of total revenue, operating income was 16% and 18% in the third quarter and first nine months of 2003, respectively, compared to 42% and 40% in the third quarter and first nine months of 2002, respectively.

The decreases in operating income in the third quarter and first nine months of 2003 compared to the corresponding periods of 2002 were mainly due to a higher proportion of royalty revenue relative to product sales, charges for acquired research and development, and higher amortization expense relative to total revenue, partly offset by the recognition of the aggregate value of the lower Zovirax supply price, and our settlements with Pfizer et al, Elan, Lilly and Mylan.

**NON-OPERATING ITEMS**

**Interest income and expense**

Interest income was $1.2 million and $5.9 million in the third quarter and first nine months of 2003, respectively, compared to $0.3 million and $2.9 million in the third quarter and first nine months of 2002, respectively. Interest income comprised interest earned on our investment portfolio, which is comprised primarily of high-grade government and corporate securities, as well as interest on our settlements with Pfizer et al, Lilly and Mylan.

Interest expense was $10.5 million in the third quarter of 2003 compared to $11.0 million in the third quarter of 2002, a decrease of $0.5 million or 4%. Interest expense was $30.0 million in the first nine months of 2003 compared to $22.8 million in the first nine months of 2002, an increase of $7.2 million or 32%. Interest expense mainly comprised interest on our 7$^{7}/_{8}$% Senior Subordinated Notes due April 1, 2010 ("Notes"). In June 2002, we entered into three interest rate swap contracts, of aggregate $200 million notional amount, which involve the receipt of amounts based on a fixed rate of 7$^{7}/_{8}$% in exchange for floating rate interest payments based on six-month London Interbank Offering Rate ("LIBOR") plus a spread. Net receipts or payments relating to the interest rate swaps are recorded as an adjustment to interest expense.

**Foreign exchange gain or loss**

We recorded a foreign exchange gain of $0.5 million and a foreign exchange loss of $9.6 million in the third quarter and first nine months of 2003, respectively, compared to foreign exchange losses of $0.4 million in both the third quarter and first nine months of 2002. The foreign exchange gain and loss in the third quarter and first nine months of 2003, respectively, were primarily related to the translation to U.S. dollars of our Canadian dollar denominated obligation to GSK for the rights to Wellbutrin® SR

and Zyban in Canada, and were the result of a weakening of the Canadian dollar in the third quarter of 2003, and a strengthening of the Canadian dollar in the first nine months of 2003, relative to the U.S. dollar.

**Other income and expense**

Prior to April 1, 2003, the interest rate swaps effectively modified our exposure to interest rate fluctuations by converting the interest payable on one-half of our fixed rate Notes to a floating rate. The changes in the fair values of the interest rate swaps and the offsetting changes in the fair value of the portion of our Notes being hedged were recognized in other income and expense. Accordingly, the net gain or loss recognized prior to April 1, 2003 related to the ineffective portion of the fair value hedge.

Effective April 1, 2003, we determined that the interest rate swaps no longer qualified as a highly effective hedge and, accordingly, we discontinued the application of hedge accounting as of that date. As a result, for the period from April 1, 2003 to September 30, 2003, the changes in the fair values of the interest rate swaps were recognized in other income and expense; however, our Notes were not adjusted for the changes in their fair value during that period. In the third quarter and first nine months of 2003, we recorded other expense of $6.0 million and other income of $0.7 million, respectively, related to the changes in the fair values of the interest rate swaps, as well as the changes in the fair value of our Notes recognized prior to the termination of hedge accounting. We recorded other income of $3.3 million and $3.2 million in the third quarter and first nine months of 2002, respectively, related to the changes in the fair values of the interest rate swaps, as well as the changes in the fair value of our Notes.

**Provision for income taxes**

Our tax rate was affected by the relative profitability of our operations in various foreign tax jurisdictions. We recorded provisions for income taxes of $3.0 million and $13.3 million in the third quarter and first nine months of 2003, respectively, compared to $5.7 million and $14.4 million in the third quarter and first nine months of 2002, respectively. The low effective tax rate reflected the fact that most of our income was derived from foreign subsidiaries with lower statutory tax rates than those that apply in Canada. In addition, our effective tax rate was affected by the low profitability of our operations in the United States due to the expansion of our sales organization and sales and marketing expenses related to new product launches.

**LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2003, we had cash and cash equivalents of $43.3 million compared to cash and cash equivalents of $56.1 million at December 31, 2002. At September 30, 2003, we also had restricted cash of $30.1 million, which is to be used to partially fund the development of the three products by BNC-PHARMAPASS. We maintain a $600 million revolving term credit facility, which may be used for general corporate purposes, including acquisitions. At September 30, 2003, we were in compliance with all financial and non-financial covenants associated with our credit facility. At September 30, 2003, we had advances of $225 million borrowed under our credit facility and we had a letter of credit with a

balance of $77.2 million issued under our credit facility. The letter of credit secures the remaining semi-annual payments we are required to make under the Vasotec® and Vaseretic® agreement.

In the first nine months of 2003, cash provided by operating activities was $244.1 million comprising net income, after adjustments for items not involving cash, of $311.2 million and net changes in non-cash operating items that used cash of $67.1 million, mainly due to increases in accounts receivable and inventories, and decreases in accounts payable and accrued liabilities. In the first nine months of 2002, cash provided by operating activities was $241.9 million comprising net income, after adjustments for items not involving cash, of $246.5 million and net changes in non-cash operating items that used cash of $4.6 million, mainly due to an increase in accounts receivable and a decrease in deferred revenue, offset by increases in accounts payable and accrued liabilities.

Net cash used in investing activities was $295.9 million in the first nine months of 2003 compared to $498.1 million in the first nine months of 2002. In the first nine months of 2003, we acquired $203.1 million of intangible assets including initial payments of $146.3 million for Ativan® and Isordil®, $33 million relative to our interest in omeprazole and an initial payment of $21.2 million for the Athpharma cardiovascular products. In the first nine months of 2002, we acquired $373.4 million of intangible assets comprising initial payments of $145.7 million for Vasotec® and Vaseretic®, $133.4 million for Zovirax and $94.3 million for Teveten®. In the first nine months of 2003, we advanced an additional $40 million, for a total of $70 million, to Reliant under its secured credit facility with us. In the first nine months of 2003, we acquired long-term investments of $34.6 million including our $30.1 million investment in BNC-PHARMAPASS and an additional $3.5 million equity investment in Depomed, Inc. ("Depomed"). In the first nine months of 2002, we acquired long-term investments of $85.5 million including equity investments in Ethypharm and Depomed of $68.2 million and $13.7 million, respectively. Additions to property, plant and equipment were $28.3 million in the first nine months of 2003 compared to $39.3 million in the first nine months of 2002. In the first quarter of 2003, we recorded $10 million of the Lilly settlement payment, related to the recoverable value of the Keftab product rights, as proceeds on the disposal of intangible assets.

Net cash provided by financing activities was $38.0 million in the first nine months of 2003 compared to net cash used in financing activities of $33.7 million in the first nine months of 2002. Proceeds from the issuance of common shares on the exercise of stock options were $11.4 million in the first nine months of 2003 compared to $5.5 million in the first nine months of 2002. In the first nine months of 2002, we repurchased 12.9 million of our common shares on the open market, under our stock repurchase program, at an average purchase price of $39.08 per share for total consideration of $503.1 million. Proceeds from the exercise of warrants were $112.8 million in the first nine months of 2002. We borrowed $115 million under our credit facility in the first nine months of 2003 compared to $10 million in the first nine months of 2002. In the first nine months of 2003, we repaid $88.3 million of long-term obligations related to the acquisitions of intangible assets compared to $42.0 million repaid in the first nine months of 2002. In the first quarter of 2002, we received net proceeds of $384.3 million on the issue of our Notes.

Overall, our cash and cash equivalents decreased by $12.8 million and $289.8 million in the first nine months of 2003 and 2002, respectively.

**Obligations and other matters**

At September 30, 2003, we had total long-term obligations of $803.1 million, including the current portion thereof, which included the carrying value of our Notes of $411.8 million, borrowings under our credit facility of $225 million and obligations related to the acquisitions of intangible assets of aggregate $159.6 million.

On November 5, 2001, we filed a $1.5 billion base shelf prospectus with the Canadian provincial securities commissions covering the potential sale of any combination of common shares, debt securities or warrants. On the same date, we filed a registration statement on Form F-10 covering those securities with the U.S. Securities and Exchange Commission ("SEC") under the multijurisdictional disclosure system. We may offer one or more of these types of securities in one or more offerings during the succeeding 25 months. One or more shareholders may also sell common shares pursuant to the base shelf prospectus. We will not receive any of the proceeds from any sale of common shares by the selling shareholders.

At September 30, 2003, we had a balance of $424.4 million available under our base shelf prospectus to offer at our discretion. Our base shelf prospectus will expire in December 2003.

We believe that the cash expected to be generated by our operations during 2003 along with existing capital resources and sources of financing will be sufficient to support our remaining 2003 operational, capital expenditure and interest requirements, as well as to meet our obligations as they become due.

We agreed, subject to certain conditions, to subscribe for up to $20 million of convertible and/or exchangeable bonds of Ethypharm. We are entitled to set-off the future milestone and royalty payments that we may be required to make to Ethypharm, under the terms of the April 2002 license agreement between the parties, against the outstanding principal and interest on the bonds. The bonds may be converted, at our option, into an additional 10% equity interest in Ethypharm if the principal amount of the bonds is $10 million, 12.5% if the principal amount of the bonds is $15 million, and 15% if the principal amount of the bonds is $20 million. If Ethypharm enters into a transaction that results in a change of control, we would receive an increased equity interest pursuant to a formula based on the valuation of Ethypharm at the date of the transaction. The bonds may be redeemed, at Ethypharm's option, for cash or, if Ethypharm becomes a publicly traded company, for equity. The bonds will mature on December 31, 2010 unless redeemed or converted earlier. The bonds will bear interest at a rate of 5% per annum. Interest on the bonds up to December 31, 2005 will be capitalized and added to the principal amount of the bonds and will not be paid in cash. After January 1, 2006, all interest payments will be paid in cash.

Certain of the conditions precedent to the closing of the bond subscription agreement require third parties, independent of Ethypharm and us, to agree to revisions to their existing agreements with Ethypharm. Accordingly, the bond facility is not yet available to Ethypharm. If the conditions precedent are resolved and the bond subscription agreement is closed, we believe we may be able to exercise significant influence over the operating and financial policies of Ethypharm and, accordingly, we may adopt the equity method of accounting for our investment in Ethypharm.

We have also negotiated with Ethypharm for significant improvements to the shareholder agreement, providing price protection on our initial investment in Ethypharm in the event of any private or public financing undertaken by Ethypharm.

In October 2001, we made Executive Stock Purchase Plan ("ESPP") loans in aggregate amount of $10.0 million to certain executive officers in order to finance the acquisition of our common shares on the open market. The ESPP loans were due and payable on September 30, 2003. Subsequent to September 30, 2003, Mr. Melnyk repaid his loan. The remaining officers are finalizing arrangements to repay their loans.

On November 20, 2003, we received a letter from the SEC advising us that it has initiated an informal inquiry pertaining to our accounting and financial reporting practices for the fiscal year 2002 and quarterly periods to date for fiscal 2003. We intend to fully comply with SEC requests for information.

On November 24, 2003, we received regulatory approval to make a normal course issuer bid through the New York Stock Exchange and the Toronto Stock Exchange. We are entitled to purchase up to 13.2 million common shares on or before November 25, 2004. Any common shares purchased by us under the issuer bid will be cancelled.

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to financial market risks, including changes in foreign currency exchange rates, interest rates on investments and debt obligations and equity market prices on long-term investments. We currently use derivative financial instruments to manage our exposure to interest rate risk. We use derivative financial instruments as a risk management tool and not for trading or speculative purposes.

Inflation has not had a significant impact on our results of operations.

**Foreign currency risk**

We operate internationally but a majority of our revenue and expense activities and capital expenditures are transacted in U.S. dollars. Our only other significant transactions are in Canadian dollars. A 10% change in foreign currency exchange rates would have a material effect on our consolidated results of operations, financial position or cash flows.

**Interest rate risk**

The primary objective of our investment policy is the protection of principal and, accordingly, we invest in high-grade government and corporate securities with varying maturities, but typically less than 90 days. External independent fund administrators manage our investments. As it is our intent and policy to hold these investments until maturity, we do not have a material exposure to interest rate risk.

We are exposed to interest rate risk on borrowings under our credit facility. Our credit facility bears interest based on LIBOR, U.S. dollar base rate, Canadian dollar prime rate or Canadian dollar bankers' acceptance. At our option we may lock in a rate of interest for a period of up to one year.

The imputed rates of interest used to discount our long-term obligations related to the acquisitions of intangible assets are fixed and, therefore, the fair values of these obligations are affected by changes in interest rates.

The fair value of our fixed rate Notes is affected by changes in interest rates. We manage this exposure to interest rate changes through the use of interest rate swaps, which modify our exposure to interest rate fluctuations by converting one-half of our fixed rate Notes to floating rate.

Based on our overall interest rate exposure at September 30, 2003, a 10% change in interest rates would not have a material effect on our consolidated results of operations, financial position or cash flows.

**Investment risk**

We are exposed to investment risks on our cost method and available-for-sale investments in other companies. The fair values of our investments are subject to significant fluctuations due to stock market volatility and changes in general economic conditions. We regularly review the carrying values of our investments and record losses when events and circumstances indicate that there have been other than temporary declines in their fair values. A 10% change in the aggregate fair values of our investments would have a material effect on our consolidated results of operations; however, it would not have a material effect on our consolidated financial position or cash flows.

**RECENT ACCOUNTING PRONOUNCEMENTS**

In November 2002, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation ("FIN") No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others". FIN No. 45 clarifies and expands on existing disclosure requirements for a guarantor regarding its obligations under certain guarantees it has issued. FIN No. 45 also requires that the guarantor must recognize a liability for the fair value of its obligations under certain guarantees. The provisions of FIN No. 45 are effective for guarantees entered into after December 31, 2002. At September 30, 2003, we had no outstanding guarantees.

In January 2003, the FASB issued FIN No. 46, "Consolidation of Variable Interest Entities". FIN No. 46 requires consolidation of a variable interest entity by the primary beneficiary of the entity's expected results of operations. FIN No. 46 also requires certain disclosures by all holders of a significant variable interest in a variable interest entity that are not the primary beneficiary. FIN No. 46 is effective immediately for variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, FIN No. 46 is effective in the first reporting period ending after December 15, 2003. We are performing a review to determine if we are the primary beneficiary of any variable interest entities created or acquired prior to February 1, 2003. We will complete this review in the fourth quarter of 2003. Provided that we are not the primary beneficiary, the maximum exposure to losses related to any entity that may be determined to be a variable interest entity is limited to the carrying amount of our investment in that entity.

In May 2003, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities". SFAS No. 149 amends and clarifies the accounting for derivative instruments, including certain derivative instruments

embedded in other contracts, and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities". SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The initial adoption of SFAS No. 149 had no effect on our financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity". SFAS No. 150 establishes standards for the measurement and classification of certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003. The initial adoption of SFAS No. 150 had no effect on our financial position or results of operations.

**FORWARD-LOOKING STATEMENTS**

To the extent any statements made in this report contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe", "anticipate", "expect", "intend", "plan", "will", "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements include, but are not necessarily limited to risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials and finished products, third parties, the regulatory environment, fluctuations in operating results and other risks detailed from time to time in our filings with the SEC.

**BIOVAIL CORPORATION**

**PART II OTHER INFORMATION**

**1. OPERATIONAL INFORMATION**

The press releases issued by the Company subsequent to the filing of its Form 6-K on August 29, 2003 were as follows:

| | | |
|---|---|---|
| a) | October 3, 2003 | Biovail Provides Guidance on 2003 Third Quarter Results |
| b) | October 8, 2003 | Biovail Confirms Wellbutrin XL® Shipment Recovery |
| c) | October 16, 2003 | Biovail Announces Third Quarter 2003 Earnings Release Date |
| d) | October 23, 2003 | Biovail Announces Third Quarter 2003 Earnings Release Conference Call Details |
| e) | October 30, 2003 | Biovail Reports Third Quarter 2003 Financial Results |
| f) | October 30, 2003 | Biovail Provides 2004 Guidance |
| g) | November 7, 2003 | Biovail to Present at CIBC World Markets' Fourteenth Annual Healthcare Conference |
| h) | November 7, 2003 | Biovail to Present at Credit Suisse First Boston Health Care Conference in Phoenix |
| i) | November 13, 2003 | Biovail Comments on Class Action Complaint |
| j) | November 20, 2003 | Biovail Confirms Informal Inquiry by SEC |
| k) | November 21, 2003 | Biovail Announces Intention to Make a Normal Course Issuer Bid |
| l) | November 24, 2003 | Biovail Receives Regulatory Approval to Make Normal Course Issuer Bid |

**2. LEGAL PROCEEDINGS**

For detailed information concerning legal proceedings, reference is made to note 16 to the consolidated financial statements included under Part I of this report and to Item 8.A. of the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2002.

**3. EXHIBITS**

| | |
|---|---|
| Exhibit 99.1 | Third Quarter 2003 Interim Report For Canadian Regulatory Purposes (Restated) |
| Exhibit 99.2 | Certifications of the Chief Executive Officer and Chief Financial Officer |

**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.

Biovail Corporation

Date: May 14, 2004

By: /s/ JOHN R. MISZUK

John R. Miszuk
*Vice President, Controller and*
*Assistant Secretary*

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