

BIOVAIL CORP INTERNATIONAL
Form 6-K
November 14, 2005

[QuickLinks](#) -- Click here to rapidly navigate through this document

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**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, 2005

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 Form 40-F

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 No

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 No

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 No

BIOVAIL CORPORATION

This Report of Foreign Private Issuer on Form 6-K is incorporated by reference into the registration statement on Form S-8 (Registration No. 333-92229) of Biovail Corporation.

INDEX

Part I Financial Information

Financial Statements (unaudited)	
Consolidated Balance Sheets as at September 30, 2005 and December 31, 2004	1
Consolidated Statements of Income for the three months and nine months ended September 30, 2005 and 2004	2
Consolidated Statements of Deficit for the three months and nine months ended September 30, 2005 and 2004	3
Consolidated Statements of Cash Flows for the nine months ended September 30, 2005 and 2004	4
Condensed Notes to the Consolidated Financial Statements	5
Management's Discussion and Analysis of Results of Operations and Financial Condition	24

Part II Other Information

Legal Proceedings	44
Exhibits	44

BASIS OF PRESENTATION

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 are trademarks of the Company and may be registered in Canada, the United States and certain other jurisdictions: Ativan®, Biovail®, Cardisense®, Cardizem®, Cardizem® LA, CEFORM , DrinkUp , FlashDose®, Glumetza , Instatab , Isordil®, Ralivia , Shearform , Smartcoat , Tiazac®, Tiazac® XC, Vasotec® and Vaseretic®. Wellbutrin®, Wellbutrin SR®, Wellbutrin XL®, Zovirax® and Zyban® are trademarks of "The GlaxoSmithKline Group of Companies" and are used by the Company under license. Ultram® is a trademark of the "Johnson & Johnson Group of Companies".

FORWARD-LOOKING STATEMENTS

"Safe Harbor" statement under the United States Private Securities Litigation Reform Act of 1995:

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. These forward-looking statements are subject to various risks and uncertainties including, but not necessarily limited to, the difficulty of predicting U.S. Food and Drug Administration and Canadian Therapeutic Products Directorate 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, reliance on third parties to distribute, promote and price certain of our key products, availability of raw materials and finished products, the regulatory environment, the outcome of legal proceedings, consolidated tax rate assumptions, fluctuations in operating results and other risks detailed from time to time in our filings with the U.S. Securities and Exchange Commission, the Ontario Securities Commission, and other securities regulatory authorities in Canada. We undertake no obligation to update or revise any forward-looking statement.

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)

	At September 30, 2005	At December 31, 2004
ASSETS		
Current		
Cash and cash equivalents	\$ 326,727	\$ 34,324
Marketable securities	931	5,016
Accounts receivable	125,716	148,762
Inventories	88,103	110,154
Assets of discontinued operation held for sale	3,865	
Deposits and prepaid expenses	11,042	16,395
	<u>556,384</u>	<u>314,651</u>
Long-term assets of discontinued operation held for sale	375	
Long-term investments	76,014	68,046
Property, plant and equipment, net	187,678	186,556
Goodwill	100,294	100,294
Intangible assets, net	874,670	978,073
Other assets, net	117,309	63,440
	<u>\$ 1,912,724</u>	<u>\$ 1,711,060</u>
LIABILITIES		
Current		
Accounts payable	\$ 36,852	\$ 41,120
Accrued liabilities	89,728	82,917
Liabilities of discontinued operation held for sale	1,240	
Income taxes payable	30,431	24,594
Deferred revenue	23,367	8,141
Current portion of long-term obligations	24,691	33,465
	<u>206,309</u>	<u>190,237</u>
Deferred revenue	97,581	16,525
Deferred leasehold inducements	5,171	4,914
Long-term obligations	422,648	445,471
	<u>731,709</u>	<u>657,147</u>
SHAREHOLDERS' EQUITY		
Common shares, no par value, unlimited shares authorized, 159,467,602 and 159,383,402 issued and outstanding at September 30, 2005 and December 31, 2004, respectively	1,458,183	1,457,065
Stock options outstanding	1,450	1,450
Deficit	(330,182)	(446,684)

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

	At September 30, 2005	At December 31, 2004
Accumulated other comprehensive income	<u>51,564</u>	<u>42,082</u>
	<u>1,181,015</u>	<u>1,053,913</u>
	<u>\$ 1,912,724</u>	<u>\$ 1,711,060</u>
Commitments and contingencies (note 13)		

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	
	2005	2004	2005	2004
REVENUE				
Product sales	\$ 244,455	\$ 202,243	\$ 609,505	\$ 572,604
Research and development	7,647	5,432	21,216	12,162
Royalty and other	5,956	5,943	17,201	19,040
	<u>258,058</u>	<u>213,618</u>	<u>647,922</u>	<u>603,806</u>
EXPENSES				
Cost of goods sold	51,991	50,111	152,964	158,076
Research and development	19,913	16,979	62,135	49,929
Selling, general and administrative	42,402	68,273	174,263	181,538
Amortization	15,443	16,262	46,818	48,965
Restructuring costs	1,118		19,725	
Write-down (gain on disposal) of assets		(1,471)	26,560	(1,471)
Acquired research and development				8,640
	<u>130,867</u>	<u>150,154</u>	<u>482,465</u>	<u>445,677</u>
Operating income	127,191	63,464	165,457	158,129
Interest income	2,386	186	3,676	757
Interest expense	(9,450)	(10,103)	(27,921)	(30,467)
Foreign exchange loss	(1,462)	(802)	(2,153)	(1,158)
Other expense	(271)		(804)	(2,434)
	<u>118,394</u>	<u>52,745</u>	<u>138,255</u>	<u>124,827</u>
Income from continuing operations before provision for income taxes	118,394	52,745	138,255	124,827
Provision for income taxes	9,095	2,100	11,975	5,200
	<u>109,299</u>	<u>50,645</u>	<u>126,280</u>	<u>119,627</u>
Income from continuing operations	109,299	50,645	126,280	119,627
Loss from discontinued operation	(7,636)	(1,010)	(9,778)	(4,678)
	<u>\$ 101,663</u>	<u>\$ 49,635</u>	<u>\$ 116,502</u>	<u>\$ 114,949</u>
Basic and diluted earnings per share				
Income from continuing operations	\$ 0.69	\$ 0.32	\$ 0.79	\$ 0.75
Loss from discontinued operation	(0.05)	(0.01)	(0.06)	(0.03)
	<u>\$ 0.64</u>	<u>\$ 0.31</u>	<u>\$ 0.73</u>	<u>\$ 0.72</u>

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

	Three Months Ended September 30		Nine Months Ended September 30	
Weighted average number of common shares outstanding (000s)				
Basic	159,421	158,801	159,402	159,060
Diluted	159,583	158,904	159,491	159,227

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	
	2005	2004	2005	2004
Deficit, beginning of period	\$ (431,845)	\$ (542,364)	\$ (446,684)	\$ (607,678)
Net income	101,663	49,635	116,502	114,949
Deficit, end of period	\$ (330,182)	\$ (492,729)	\$ (330,182)	\$ (492,729)

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	
	2005	2004
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 116,502	\$ 114,949
Adjustments to reconcile net income to cash provided by continuing operating activities		
Loss from discontinued operation	3,665	4,678
Depreciation and amortization	74,984	64,223
Amortization and write-down of deferred financing costs	2,671	3,510
Amortization of discounts on long-term obligations	1,929	2,438
Write-down (gain on disposal) of assets	26,560	(1,471)
Write-down of assets of discontinued operation	6,113	
Acquired research and development		8,640
Other	652	(823)
Changes in operating assets and liabilities	45,413	(28,731)
Net cash provided by continuing operating activities	278,489	167,413
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds on disposal of intangible assets, net of withholding tax	98,127	3,000
Acquisitions of intangible assets	(26,000)	
Additions to property, plant and equipment, net	(24,121)	(20,178)
Purchases of marketable securities	(6,345)	
Proceeds from sales and maturities of marketable securities	5,317	
Acquisition of business, net of cash acquired		(9,319)
Acquisitions of long-term investments		(2,877)
Net cash provided by (used in) continuing investing activities	46,978	(29,374)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayments of other long-term obligations	(28,894)	(52,796)
Proceeds (payments) on termination of interest rate swaps	(1,419)	6,300
Repayments under revolving term credit facility, including financing costs	(1,300)	(182,550)
Issuance of common shares, net of issue costs	1,118	3,687
Net cash used in continuing financing activities	(30,495)	(225,359)
Net cash used in discontinued operation	(2,775)	(2,055)
Effect of exchange rate changes on cash and cash equivalents	206	157
Net increase (decrease) in cash and cash equivalents	292,403	(89,218)
Cash and cash equivalents, beginning of period	34,324	133,261
Cash and cash equivalents, end of period	\$ 326,727	\$ 44,043

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

On June 29, 2005, Biovail Corporation was continued under the *Canada Business Corporations Act*, as authorized by the Company's shareholders at the Company's Annual and Special Meeting of Shareholders on June 28, 2005. Prior to June 29, 2005, the Company was incorporated under the *Business Corporations Act* (Ontario).

The Company is primarily engaged in the formulation, clinical testing, registration, manufacture and commercialization of pharmaceutical products utilizing advanced drug-delivery technologies. The Company's main therapeutic areas of product development focus are cardiovascular (including Type II diabetes), central nervous system and pain management. The Company's common shares trade on the New York Stock Exchange and the Toronto Stock Exchange under the symbol "BVF".

2. 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. generally accepted accounting principles ("GAAP") for interim financial reporting, which do not conform in all respects to the requirements of U.S. GAAP for annual 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 prepared in accordance with U.S. GAAP that are contained in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2004. These interim consolidated financial statements have been prepared using accounting policies that are consistent with the policies used in preparing the Company's audited consolidated financial statements for the year ended December 31, 2004. There have been no material changes to the Company's significant accounting policies since December 31, 2004.

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. If historical experience and other factors used by management to make these estimates do not reasonably reflect future activity, the Company's results of operations and financial position could be materially impacted.

Impairment of long-lived assets

The Company tests long-lived assets, which include property, plant and equipment, goodwill and intangible assets with finite lives, for impairment whenever events or changes in circumstances indicate that the carrying values of these assets may not be recoverable. This evaluation is performed by comparing the carrying values of these assets to the related estimated undiscounted future cash flows expected to be derived from these assets. If these cash flows are less than the carrying value of the asset, then the carrying

value of the asset is written down to its estimated fair value, based on the related estimated discounted future cash flows.

An evaluation of the carrying value of long-lived assets is required if indicators of potential impairment are present, such as damage or obsolescence, plans to discontinue use or restructure, and poor financial performance compared with original plans. There were no significant indications of impairment of the carrying values of the Company's long-lived assets at September 30, 2005, with the exception of the long-lived assets associated with the Company's Nutravail division (as described in note 4 Discontinued Operation).

The Company's Board of Directors has reviewed a number of options to increase the value of its legacy products. These products comprise Ativan®, Isordil®, Tiazac®, Vasotec® and Vaseretic® that are sold in the United States and Puerto Rico and Cardizem® CD that is sold in the United States, Canada and Puerto Rico. These products are not considered strategic to the Company's business and are in decline (in terms of prescription volumes) due to generic competition. The primary option currently under consideration is a distribution to the Company's shareholders, which would involve the transfer of the legacy assets to a new entity and the distribution of the shares of that entity to the Company's shareholders either as a dividend in kind or as a return of capital. The Board is expected to make a decision shortly on whether or not to proceed with this option; however, if approved, the timing for completion of such a distribution cannot be determined at this time as it would be subject to a number of conditions including, but not limited to: the resolution of, or at least greater clarity in respect of, certain regulatory and litigation matters; the preparation and filing of a preliminary prospectus and registration statement; the review and approval of those documents by regulatory authorities prior to being finalized and authorized for use in connection with a distribution; receipt of lender and other third-party consents; and approval by the Company's shareholders, if required. The aggregate carrying value of the intangible assets associated with these legacy products was \$630,270,000 at September 30, 2005. A potential distribution could result in a write-down of the carrying values of certain of these intangible assets.

Stock-based compensation

Stock options

Under the provisions of the Financial Accounting Standards Board ("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". 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 months and nine months ended September 30, 2005 or 2004. 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	
	2005	2004	2005	2004
Net income as reported	\$ 101,663	\$ 49,635	\$ 116,502	\$ 114,949
Pro forma stock-based compensation expense determined under fair value-based method	(1,485)	(5,020)	(3,757)	(16,398)
Pro forma net income	100,178	44,615	112,745	98,551
Basic and diluted earnings per share				
As reported	\$ 0.64	\$ 0.31	\$ 0.73	\$ 0.72
Pro forma	\$ 0.63	\$ 0.28	\$ 0.71	\$ 0.62

The fair values of all stock options granted during the three months and nine months ended September 30, 2005 and 2004 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	
	2005	2004	2005	2004
Expected option life (years)	4.2	4.0	4.0	3.8
Volatility	52.0%	55.7%	53.3%	56.0%
Risk-free interest rate	3.2%	3.8%	3.7%	3.6%
Dividend yield	%	%	%	%

The Black-Scholes option-pricing model used by the Company to calculate option values was 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. This model also requires highly subjective assumptions, including future stock price volatility and expected time until exercise, which greatly affect the calculated values.

Deferred Share Units ("DSU")

On May 4, 2005, the Company's Board of Directors adopted DSU plans for its Executive Chairman and non-employee directors, which entitles these directors to receive grants of DSUs. A DSU is a notional unit, equivalent in value to a common share. Each of these directors receives an annual grant of units under the DSU plans. In addition, these directors receive a portion of their annual compensation, and may elect to receive up to all of their annual retainer fees, in the form of DSUs. Directors may not receive any payment in respect of the DSUs until they withdraw from the Board.

The amount of compensation deferred is converted into DSUs based on the average trading price of the Company's common shares for the last five trading days prior to the date of grant. The Company recognizes compensation expense throughout the deferral period to the extent that the trading price of its common shares increases, and reduces compensation expense (but not below zero) throughout the deferral period to the extent that the trading price of its common shares decreases.

On August 3, 2005, the Board approved the grant of 85,960 DSUs to its Executive Chairman and 38,968 DSUs to its non-employee directors. As a result of an increase in the trading price of the Company's common shares between the grant date and September 30, 2005, the Company recorded \$2,500,000 of compensation expense related to these DSUs in the period ended September 30, 2005.

Recent accounting pronouncements

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"), which revises SFAS No. 123 and supersedes APB No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS No. 123 will no longer be an alternative to financial statement recognition. In April 2005, the U.S. Securities and Exchange Commission ("SEC") delayed the effective date of SFAS No. 123R. Under the SEC's rule, SFAS No. 123R is effective at the beginning of the first annual period commencing after June 15, 2005. Accordingly, the Company is required to adopt SFAS No. 123R beginning January 1, 2006. The Company is currently evaluating the requirements of SFAS No. 123R and expects that the adoption of this standard will have a material negative impact on its consolidated results of operations. The Company has not yet determined the method of adoption or other effects of adopting SFAS No. 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs - An Amendment of ARB No. 43, Chapter 4" ("SFAS No. 151"). SFAS No. 151 requires that items such as idle facility expense, excessive spoilage, double freight, and rehandling costs be excluded from the cost of inventory and expensed as incurred. Additionally, SFAS No. 151 requires that the allocation of fixed overheads be based on the normal capacity of the production facilities. SFAS No. 151 is effective for fiscal years commencing after June 15, 2005. Accordingly, the Company is required to adopt SFAS No. 151 beginning January 1, 2006. The Company is currently evaluating the effect that the adoption of SFAS No. 151 will have on its consolidated results of operations and financial position.

3. DISPOSITION AND RESTRUCTURING

Kos Pharmaceuticals, Inc. ("Kos")

On May 2, 2005, the Company sold all of its rights to Teveten and Teveten HCT, and the distribution rights to Cardizem® LA in the United States and Puerto Rico, to Kos. The Company will be the exclusive manufacturer and supplier of Cardizem® LA to Kos at contractually determined prices over an initial seven-year supply term. The Company and Kos will also collaborate on the development of up to three products, including a combination product comprising Cardizem® LA and Vasotec®. Subject to U.S. Food

and Drug Administration ("FDA") approval, the Company will be the exclusive manufacturer and supplier of the combination product to Kos.

In consideration for these transactions, Kos paid the Company \$105,477,000 in cash, less withholding tax of \$7,350,000. Kos may make additional payments to the Company related to the development of the combination product; however, the Company will only recognize these payments if the development milestones are achieved. Under the terms of the Cardizem® LA distribution agreement, the Company agreed to indemnify Kos (subject to certain conditions and limits) for lost profits in the event of generic competition to Cardizem® LA prior to December 31, 2008. The Company is aware that Andrx Corporation ("Andrx") is seeking FDA approval for a generic version of Cardizem® LA in multiple dosage formats (as described in note 13 Legal Proceedings).

The Kos transactions comprise multiple deliverables (sale of product and distribution rights, manufacturing and supply activities, and research and development services). In accordance with its revenue recognition accounting policy, the Company evaluated whether the deliverables represented separate units of accounting. The Company determined that it had objective and reliable evidence of the fair value of the delivered item (the Teveten and Teveten HCT product rights); however, it did not have sufficient evidence of the fair values of the undelivered items, and therefore the Kos transactions represented a single unit of accounting. As a result, the up-front cash consideration of \$105,477,000 was recorded in deferred revenue, and will be recognized in product sales on a straight-line basis over the seven-year Cardizem® LA supply term. Revenue and related costs associated with the sale of Cardizem® LA product to Kos will be recognized in earnings as title to the product transfers to Kos.

The disposal of Teveten and Teveten HCT to Kos resulted in a \$25,507,000 write-down of the carrying value of these product rights to reflect their fair value of \$53,700,000 (determined based on an independent valuation) at the date of disposition. The fair value of the Teveten and Teveten HCT product rights, as well as the cost of Teveten and Teveten HCT inventories of \$3,019,000 that were sold to Kos, were re-characterized as a deferred charge associated with the Cardizem® LA manufacturing and supply arrangement. The total deferred charge of \$56,719,000 and the withholding tax of \$7,350,000 were recorded in other assets, and will be amortized to cost of goods sold and income tax expense, respectively, on the same seven-year, straight-line basis as the deferred revenue described above. Inventories of Cardizem® LA, Teveten and Teveten HCT totaling \$4,862,000 that were not purchased by Kos were written off to cost of goods sold.

Restructuring

Concurrent with the Kos transactions, the Company restructured its U.S. commercial operations. As a result, the Company reduced its primary-care and specialty sales forces by 307 positions, and its general and administrative functions by 30 positions. The Company notified the affected employees on May 2, 2005. In addition, Kos offered employment to 186 of the Company's sales representatives, of which 164 accepted positions with Kos. The Company retained 85 specialty sales representatives who will initially focus exclusively on the promotion of Zovirax Ointment and Zovirax Cream to dermatologists and obstetricians/gynaecologists. In the three months and nine months ended September 30, 2005, the Company incurred restructuring charges of \$1,118,000 and \$19,725,000, respectively, which consisted of employee termination benefits, contract termination costs and professional fees. Employee termination costs include

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

severance and related benefits, as well as outplacement services. The Company did not pay termination benefits to those employees that were offered employment by Kos. Contract termination costs include facility and vehicle lease payments that the Company will continue to incur without economic benefit. A summary of accrued restructuring costs is as follows:

	At June 30 2005	Adjustments	Paid or Settled	At September 30 2005
Employee termination benefits	\$ 8,518	\$ 523	\$ (8,945)	\$ 96
Contract termination costs	4,473	198	(2,528)	2,143
Professional fees and other		397	(397)	
	\$ 12,991	\$ 1,118	\$ (11,870)	\$ 2,239

At September 30, 2005, the liability balance for contract termination costs includes \$1,598,000 related to a facility lease that will be settled over the remaining 10-year term of this lease. The Company expects that the remaining liability balance for contract termination costs will be paid or settled over the succeeding 12 months.

4. DISCONTINUED OPERATION

On September 28, 2005, the Board of Directors committed to a plan to sell the Company's Nutravail division. Nutravail develops and manufactures nutraceutical and food-ingredient products. This business is not considered strategic to the Company's core pharmaceutical operations. The Company has received an offer of \$3,000,000 from a third-party acquirer to purchase substantially all of the net assets of Nutravail, including intellectual property. Management believes that a sale transaction may be completed prior to December 31, 2005.

On the consolidated balance sheet at September 30, 2005, the net assets of Nutravail are reported as held for sale at their estimated fair value of \$3,000,000 based on the purchase offer received. Consequently, the

Company recorded a \$6,113,000 write-down of the carrying values of Nutravail's long-lived assets. The net assets held for sale are as follows:

	At September 30 2005
Assets	
Accounts receivable	\$ 1,390
Inventories	2,243
Deposits and prepaid expenses	232
	<hr/>
Current assets	3,865
Machinery and equipment	2,215
Other equipment and leasehold improvements	1,902
Technology	2,371
Less write-down of assets	(6,113)
	<hr/>
Long-term assets	375
	<hr/>
Total assets	4,240
	<hr/>
Liabilities	
Accounts payable	372
Accrued liabilities	451
Deferred revenue	417
	<hr/>
Current liabilities	1,240
	<hr/>
Net assets held for sale	\$ 3,000
	<hr/>

Because of the distinct nature of its business, Nutravail has identifiable operations and cash flows that are clearly distinguishable from the rest of the Company. Nutravail's operations and cash flows will be eliminated from the ongoing operations of the Company as a result of the sale transaction, and the Company will not have any significant continuing involvement in the operations of Nutravail after it is sold. Accordingly, Nutravail has been reported as a discontinued operation in the Company's consolidated statements of income for the current and prior periods.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

For the three months and nine months ended September 30, 2005 and 2004, the following revenue and expenses of Nutravail have been reclassified from continuing operations to loss from discontinued operation:

	Three Months Ended September 30		Nine Months Ended September 30	
	2005	2004	2005	2004
REVENUE				
Product sales	\$ 701	\$ 1,214	\$ 1,643	\$ 3,163
Research and development	162	510	824	669
Royalty and other	419	383	1,602	1,026
	1,282	2,107	4,069	4,858
EXPENSES				
Cost of goods sold	1,022	1,724	3,003	4,952
Research and development	495	669	1,512	1,540
Selling, general and administrative	1,220	656	3,015	2,840
Amortization	68	68	204	204
	2,805	3,117	7,734	9,536
Loss from discontinued operation before write-down of assets	(1,523)	(1,010)	(3,665)	(4,678)
Write-down of assets	(6,113)		(6,113)	
Loss from discontinued operation	\$ (7,636)	\$ (1,010)	\$ (9,778)	\$ (4,678)

5. INVENTORIES

	At September 30 2005	At December 31 2004
Raw materials	\$ 45,519	\$ 48,801
Work in process	12,705	14,862
Finished goods	29,879	46,491
	\$ 88,103	\$ 110,154

6. INTANGIBLE ASSETS

	At September 30, 2005		At December 31, 2004	
	Cost	Accumulated amortization	Cost	Accumulated amortization
Trademarks	\$ 703,698	\$ 142,765	\$ 703,698	\$ 116,453
Product rights	391,432	90,204	459,773	84,877
Technology	16,956	4,447	21,041	5,109
	1,112,086	\$ 237,416	1,184,512	\$ 206,439
Less accumulated amortization	237,416		206,439	
	\$ 874,670		\$ 978,073	

Amortization expense amounted to \$15,778,000 and \$16,598,000 in the three months ended September 30, 2005 and 2004, respectively, and \$47,825,000 and \$49,973,000 in the nine months ended September 30, 2005 and 2004, respectively.

Glumetza

In May 2002, the Company licensed from Depomed, Inc. ("Depomed") the rights to manufacture and market Glumetza (metformin hydrochloride ("HCl")) in the United States and Canada. Glumetza is indicated for the treatment of Type II diabetes. In May and June 2005, the Company and Depomed received approval from the Therapeutic Products Directorate in Canada and the FDA for Glumetza. In July 2005, the Company made a \$25,000,000 milestone payment to Depomed associated with the receipt of regulatory approval, and recorded a corresponding product right. This product right is being amortized using the straight-line method over its estimated useful life of 10 years.

In October 2005, Depomed informed the Company that the Company was in breach of its obligation to begin marketing Glumetza in the United States and Canada within 120 days following the grant of regulatory approval. If the breach is not cured within 60 days, Depomed may terminate the license agreement and request the Company to assign Depomed certain regulatory approvals for Glumetza. Depomed would be required to reimburse the Company for costs incurred by the Company to develop and obtain regulatory approval for Glumetza; however, this reimbursement would not include the \$25,000,000 milestone payment the Company made to Depomed.

The Company does not believe that it is in breach of its obligations and is currently in negotiations with Depomed to amend the license agreement. The Company fully intends on launching Glumetza in Canada in November 2005, which is within the 60-day time frame allowed to cure the breach. The Company believes an agreement can be reached with Depomed that will allow the Company to continue with its marketing plans for Glumetza in Canada. Accordingly, the Company believes that the carrying value of the Glumetza product right at September 30, 2005 is fully recoverable, based on the estimated undiscounted future cash flows related to forecasted sales of Glumetza in Canada.

Tramadol ODT

In April 2002, the Company obtained from Ethypharm S.A. ("Ethypharm") the rights to manufacture and market an orally disintegrating tablet ("ODT") formulation of the analgesic tramadol HCl in the United States, Canada and Mexico. In May 2005, the Company received FDA approval for Tramadol ODT. In July 2005, the Company made a \$1,000,000 milestone payment to Ethypharm associated with the receipt of FDA approval, and recorded a corresponding product right. This product right is being amortized using the straight-line method over its estimated useful life of eight years.

Teveten and Teveten HCT

On May 2, 2005, the Company disposed of the product rights to Teveten and Teveten HCT to Kos (as described in note 3 Disposition and Restructuring). At the date of disposition, the cost and related accumulated amortization of these product rights were \$94,341,000 and \$15,134,000, respectively.

7. LONG-TERM OBLIGATIONS

	At September 30 2005	At December 31 2004
7 ⁷ / ₈ % Senior Subordinated Notes due April 1, 2010	\$ 400,000	\$ 400,000
Unamortized discount	(1,642)	(1,916)
Fair value adjustment	2,208	7,443
	400,566	405,527
Zovirax obligation	21,681	32,230
Vasotec® and Vaseretic® obligation	21,057	27,704
Ativan® and Isordil® obligation		9,037
Deferred compensation	4,035	4,438
	447,339	478,936
Less current portion	24,691	33,465
	\$ 422,648	\$ 445,471

Interest expense on long-term obligations amounted to \$8,704,000 and \$9,349,000 in the three months ended September 30, 2005 and 2004, respectively, and \$25,251,000 and \$28,008,000 in the nine months ended September 30, 2005 and 2004, respectively.

Revolving Term Credit Facility

At September 30, 2005 and December 31, 2004, the Company had no outstanding borrowings under its revolving term credit facility. On May 25, 2005, the Company renewed this credit facility at \$250,000,000 for a term of 364 days. The revolving period of this credit facility is renewable for additional 364-day terms. If the lenders elect not to further extend the revolving period of this credit facility, the Company may elect to convert amounts then outstanding into a one-year term facility, repayable in four equal quarterly instalments. The interest rates charged under this credit facility and the financial covenants remain

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

unchanged. In May 2005, the reduction in the borrowing capacity under this facility from \$400,000,000 to \$250,000,000 resulted in write-down of the related deferred financing costs of \$536,000.

8. STOCK OPTIONS OUTSTANDING

The number of stock options outstanding at September 30, 2005 and December 31, 2004 were 8,290,080 and 7,712,262, respectively. During the nine months ended September 30, 2005, 2,100,245 stock options were granted, 66,891 stock options were exercised and 1,455,536 stock options were forfeited.

9. INCOME TAXES

The Company's provision for income taxes is based on a number of estimates and assumptions made by management. The Company's consolidated income tax rate is affected by the amount of net income earned in its various operating jurisdictions and the rate of taxes payable in respect of that income. The Company and its subsidiaries enter into many transactions and arrangements in the ordinary course of business in which the tax treatment is not entirely certain. In particular, certain countries in which the Company and its subsidiaries operate could seek to tax a greater share of income than has been provided for by the Company. The final outcome of any audits by taxation authorities may differ from the estimates and assumptions the Company has used in determining its consolidated tax provisions and accruals. This could result in a material effect on the Company's consolidated income tax provision and the net income for the period in which such determinations are made.

10. EARNINGS PER SHARE

Earnings per share were calculated as follows:

	Three Months Ended September 30		Nine Months Ended September 30	
	2005	2004	2005	2004
Net income	\$ 101,663	\$ 49,635	\$ 116,502	\$ 114,949
Basic weighted average number of common shares outstanding (000s)	159,421	158,801	159,402	159,060
Dilutive effect of stock options (000s)	162	103	89	167
Diluted weighted average number of common shares outstanding (000s)	159,583	158,904	159,491	159,227
Basic and diluted earnings per share	\$ 0.64	\$ 0.31	\$ 0.73	\$ 0.72

11. COMPREHENSIVE INCOME

Comprehensive income comprised the following:

	Three Months Ended September 30		Nine Months Ended September 30	
	2005	2004	2005	2004
Net income	\$ 101,663	\$ 49,635	\$ 116,502	\$ 114,949
Comprehensive income				
Foreign currency translation adjustment	8,198	6,790	5,120	3,957
Unrealized holding gain (loss) on long-term investments	8,585	849	4,362	(7,612)
Other comprehensive income (loss)	16,783	7,639	9,482	(3,655)
Comprehensive income	\$ 118,446	\$ 57,274	\$ 125,984	\$ 111,294

12. CHANGES IN OPERATING ASSETS AND LIABILITIES

Increases (decreases) in cash flows from operations as a result of changes in operating assets and liabilities were as follows:

	Nine Months Ended September 30	
	2005	2004
Accounts receivable	\$ 21,321	\$ 11,034
Inventories	18,261	(14,898)
Deposits and prepaid expenses	4,804	6,132
Accounts payable	(3,779)	(21,041)
Accrued liabilities	5,418	(14,258)
Income taxes payable	8,333	(724)
Deferred revenue	(8,945)	5,024
	\$ 45,413	\$ (28,731)

13. LEGAL PROCEEDINGS

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

The Company cannot currently predict or foresee the outcome of the legal proceedings it is involved in, or reasonably estimate the amount of any losses that may result from these proceedings. Accordingly, the Company has not accrued for any loss contingencies related to these proceedings at September 30, 2005. An adverse outcome in certain of these proceedings could have a material adverse effect on the Company's results of operations, financial position and cash flows.

Intellectual property

RhoxalPharma Inc. ("RhoxalPharma") has filed an Abbreviated New Drug Submission ("ANDS") in Canada, seeking approval of a generic version of Tiazac® (120mg, 180mg, 240mg, 300mg and 360mg). The Company has two patents listed in the Patent Registry and on April 1, 2004, instituted legal proceedings in the Federal Court of Canada that will prohibit the issuance of a Notice of Compliance ("NOC") to RhoxalPharma until these proceedings are concluded, or until the expiry of 24 months from the date of the Notice of Allegation, whichever is earlier. This matter was tried on September 21 and 22, 2005. On October 19, 2005, the Court dismissed the Company's application. The Company is considering its options to appeal; however, the appeal process does not prevent the issuance of an NOC to RhoxalPharma.

RhoxalPharma has filed an ANDS in Canada, seeking approval of a generic version of Wellbutrin® SR (100mg and 150mg). The Company has three patents listed in the Patent Registry and on January 6, 2005, instituted legal proceedings in the Federal Court of Canada that will prohibit the issuance of an NOC to RhoxalPharma until these proceedings are concluded, or until the expiry of 24 months after the date of the Notice of Allegation, whichever is earlier. A trial date has been tentatively scheduled for the beginning of April 2006.

Novopharm Limited ("Novopharm") has filed an ANDS in Canada, seeking approval of a generic version of Wellbutrin® SR (100mg and 150mg). The Company has three patents listed in the Patent Registry and on March 31, 2003, instituted legal proceedings in the Federal Court of Canada with respect to two of the three listed patents. On January 6, 2005, the Court issued a decision finding that Novopharm's formulations do not infringe the listed patents. The decision has been appealed, but that appeal process does not prevent the issuance of an NOC to Novopharm.

PharmaScience Inc. ("PharmaScience") has filed an ANDS in Canada, seeking approval of a generic version of Wellbutrin® SR (100mg and 150mg). The Company has three patents listed in the Patent Registry and on September 22, 2004, instituted legal proceedings in the Federal Court of Canada that will prohibit the issuance of an NOC to PharmaScience until these proceedings are concluded, or until the expiry of 24 months after the date of the Notice of Allegation, whichever is earlier.

Apotex Inc. ("Apotex") has filed an ANDS in Canada, seeking approval of a generic version of Tiazac® (120mg, 180mg, 240mg, 300mg and 360mg). In accordance with the Patented Medicines (NOC) Regulations, Apotex served the Company with a Notice of Allegation dated June 7, 2005 claiming that Canadian Patent Nos. 2,211,085 and 2,242,224 would not be infringed by the sale in Canada of Apotex's generic version of Tiazac®. On July 21, 2005, the Company instituted legal proceedings in the Federal Court of Canada that will prohibit the issuance of an NOC to Apotex until these proceedings are concluded, or until the expiry of 24 months after the date of the Notice of Allegation, whichever is earlier.

Anchen Pharmaceuticals Inc. ("Anchen") has filed an Abbreviated New Drug Application ("ANDA") in the United States, seeking approval for a generic version of Wellbutrin XL® (150mg and 300mg). On December 21, 2004, the Company instituted legal proceedings pursuant in the United States District Court for the Central District of California to the Hatch Waxman Act that preclude the FDA from granting approval to Anchen until the earliest 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.

Abrika Pharmaceuticals LLLP ("Abrika") has filed an ANDA in the United States, seeking approval for a generic version of Wellbutrin XL® (150mg and 300mg). On December 21, 2004, the Company instituted legal proceedings in the United States District Court for the Southern District of Florida pursuant to the Hatch Waxman Act that preclude the FDA from granting approval to Abrika until the earliest 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. Abrika brought a Motion for Summary Judgment that was heard on November 2, 2005. Following oral arguments, the Court reserved its decision. If the court denies Abrika's Motion, the case will continue in its ordinary course.

Impax Laboratories Inc. ("Impax") has filed an ANDA in the United States, seeking approval for a generic version of Wellbutrin XL® (150mg). On March 7, 2005, the Company instituted legal proceedings in the United States District Court for the Eastern District of Pennsylvania pursuant to the Hatch Waxman Act that preclude the FDA from granting approval to Impax until the earliest 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.

Watson Laboratories Inc. ("Watson") has filed an ANDA in the United States, seeking approval for a generic version of Wellbutrin XL® (150mg and 300mg). On September 8, 2005, the Company instituted legal proceedings in the United States District Court for the Southern District of New York pursuant to the Hatch Waxman Act that preclude the FDA from granting approval to Watson until the earliest 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.

On June 27, 2005 and September 2, 2005, Biovail received separate notice letters regarding Paragraph IV certification under the Hatch Waxman Act from Andrx alleging that their FDA filings for generic formulations of Cardizem® LA 420mg and Cardizem® LA 120mg, 180mg, 240mg, 300mg and 360mg, respectively, do not infringe the listed patents, U.S. Patent Nos. 5,529,791 and 5,288,505.

Upon receipt of the notices from Andrx, Biovail informed Kos pursuant to the provisions of Paragraph 6.13 of the Distribution and Product Acquisition Agreement (the "Kos Agreement") that it would not be instituting any legal proceedings, and that it therefore deferred to Kos the right to take legal action.

On August 10, 2005, Kos initiated a patent infringement lawsuit against Andrx for the 420mg strength in the U.S. District Court for the District of Delaware. On October 14, 2005, Kos initiated a second patent infringement lawsuit on the remaining strengths. Since Biovail is the holder of the New Drug Application for Cardizem® LA, it was legally required for these suits to name Biovail as Plaintiff.

A third Paragraph IV certification and notice letter has been received from Andrx relating to the newly listed patent covering Cardizem® LA, U.S. Patent No. 6,923,984. The notice letter has in similar fashion been brought to the attention of Kos. The Company does not intend to initiate legal proceedings against Andrx with respect to this recent notice letter and has instead again deferred that right to Kos, pursuant to the terms of Kos Agreement.

Product liability

Biovail Pharmaceuticals, Inc. ("BPI") has been named in two complaints Superior Court of the State of California for the County of Los Angeles (January 4, 2002) and United States District Court of the Western

District of Washington at Seattle (October 23, 2003) alleging personal injuries arising from Plaintiffs' use of Dura-Vent, a product containing phenylpropanolamine and formerly marketed by BPI. The California case has been dismissed without prejudice. The Company has never been served with a summons in the second case. The Plaintiff in the second case has agreed to stay the action pending the outcome of the multi district litigation involving other parties.

Antitrust

Several class action or representative action complaints in multiple jurisdictions have been filed against the Company in which the Plaintiffs have alleged that the Company has improperly impeded the approval of a generic form of Tiazac®. Those actions filed in federal courts have been transferred to, and in some cases consolidated in, the United States District Court for the District of Columbia. The Company believes that the complaints are without merit and that the Company's actions were in accordance with its rights as contained in the Hatch Waxman Amendments and the law. Moreover, the Company's position is that it is not responsible for Andrx's inability to receive timely final marketing approval from the FDA for its generic Tiazac® considering that the Andrx product did not receive FDA approval for a lengthy period following the removal of all legal or regulatory impediments by the Company. The Court granted the Company's Motion for Summary Judgment seeking to dismiss several of those actions, which the Federal Plaintiffs have appealed. The Company has brought the Federal decision to the attention of the Superior Court of the State of California for Los Angeles County, the Superior Court of California for the County of San Diego and the Superior Court of the State of California for the County of Alameda, where several State Court actions are pending. The Superior Court for the County of San Diego directed that certain discovery concerning Andrx's regulatory problems that was already produced to the Federal Plaintiffs be made available to the plaintiffs in that case. The Company complied with the Court's direction and then moved to dismiss the amended complaint in the case, but the Court has not yet ruled. The actions in the other California courts are stayed pending the final disposition of the cases pending in the District of Columbia.

Several class action and individual action complaints in multiple jurisdictions have been commenced jointly against the Company, Elan Corporation, plc ("Elan") and Teva Pharmaceuticals Industries Ltd. ("Teva") relating to an agreement between the Company and Elan for the licensing of Adalat CC products from Elan. These actions were transferred to the United States District Court for the District of Columbia. The agreement in question has since been dissolved as a result of a consent decree with the U.S. Federal Trade Commission ("FTC"). The Company believes these suits are without merit because, among other reasons, it is the Company's position that any 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 filed a motion for the summary dismissal of these actions. The Court has denied the Company's motion to dismiss the damage claims brought on behalf of a purported class of so-called "direct purchasers", generally consisting of distributors and large chain drug stores, but dismissed the claims of a class of consumers and "end-payors". The consumer and "end-payor" claims were re-filed in Superior Court of the State of California. The actions are proceeding on their merits through normal legal process.

Securities class actions

In the fourth quarter of 2003, a number of securities class action complaints were filed in the United States District Court for the Southern District of New York naming Biovail and certain Officers as Defendants. On or about June 18, 2004, the Plaintiffs filed a Consolidated Amended Complaint (the "Complaint"). The Complaint alleges, among other matters, that 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 Complaint alleges that the Defendants made materially false and misleading statements that inflated the price of the Company's stock between February 7, 2003 and March 2, 2004. The Plaintiffs seek to represent a class consisting of all persons other than the Defendants and their affiliates who purchased the Company's stock during that period. The Defendants responded to the Complaint by filing a motion to dismiss. The Court denied the motion to dismiss. The action is now proceeding on its merits through normal legal process.

On September 21, 2005, the Canadian Commercial Workers Industry Pension Plan commenced a securities class action in Canada against Biovail and several of its Officers. The action is purportedly prosecuted on behalf of all individuals other than the defendants who purchased Biovail's common stock between February 7, 2003 and March 2, 2004. The Complaint seeks damages in excess of \$100,000,000 for misrepresentation and breaches of s. 134 of the Securities Act, R.S.O. 1990, c. S.5, and ss. 36 and 52 of the Competition Act, R.S. 1985, c. C-34. The Complaint relies on the same facts and allegations as those cited in the U.S. Consolidated Securities Complaint. The Complaint was served on the Company and named Officers on September 29, 2005. The Company has not yet filed its response.

Defamation and tort

On April 29, 2003, Jerry I. Treppel, a former analyst at Banc of America Securities, commenced an action in the United States District Court for the Southern District of New York naming as Defendants the Company and certain Officers thereof, and against Michael Sitrick and Sitrick & Company, Inc. (in their capacities as consultants of 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.

The Company filed a motion for summary dismissal of this action, which the Court granted in substantial part. In response, the Plaintiff filed a Second Amended Complaint on March 24, 2005 adding allegations that all Defendants, through their concerted efforts, participated in the defamatory and other alleged misconduct. The Company filed a second motion to dismiss, directed at some of the claims. On August 30, 2005, the Court affirmatively dismissed a number of the Defendants. In the Order, the Judge further noted that the remaining claims against Biovail and the remaining personal defendant are limited to the defamation, tortious interference and civil conspiracy claims arising out of three statements he found to be susceptible of a defamatory meaning. The Court also granted in part (without prejudice) and denied in part Plaintiff's motion to dismiss the claims against the Company's Executive Chairman, Eugene Melnyk. In this regard, Mr. Melnyk has issued a counterclaim against the Plaintiff, claiming defamation, defamation per se, and civil conspiracy. Mr. Treppel filed a motion seeking to dismiss Mr. Melnyk's counterclaims, which has subsequently been granted in part and denied in part.

Mr. Treppel has claimed \$100,000,000 in damages but has provided no basis for the calculation of his claim. The case is proceeding through the normal legal process.

General civil actions

Complaints have been filed by the City of New York, the State of Alabama, State of Mississippi and a number of counties within the State of New York, claiming that the Company, and numerous other pharmaceutical companies, made fraudulent misstatements concerning the "average wholesale price" of their prescription drugs, resulting in alleged overpayments by the plaintiffs for pharmaceutical products sold by the companies. The United States Judicial Panel on Multi District Litigation has ordered that all the New York cases be consolidated and coordinated with similar class action litigation and lawsuits brought by other governmental entities pending in the United States District Court for the District of Massachusetts. Counsel for the City of New York and for all the counties in New York (other than Erie) that have sued Biovail has voluntarily dismissed the Company and certain others of the named defendants on a without prejudice basis. Activity in the Erie County case has largely been stayed pending the resolution of certain procedural matters. The Company and other named defendants filed a pre-answer motion to dismiss the Amended Complaint brought by the State of Alabama. The motion was denied but the Court has requested for the State to name the products on which it is suing. The Company has not yet been served with the complaint filed by the State of Mississippi and there has otherwise not been any activity in this case to date. Based on the information currently available, and given the small number of Biovail products at issue and the limited time frame in respect of such sales, the Company anticipates that even if these actions were successful, any recovery against Biovail would likely not be material.

Governmental and regulatory inquiries

In July 2003, the Company received notification from the U.S. Attorney, District of Massachusetts, on behalf of the U.S. Office of the Inspector General ("OIG") that a preliminary administrative inquiry has been initiated into the Company's clinical experience program related to the commercialization of Cardizem® LA. The OIG has indicated, through the issuance of subpoenas, its desire to interview certain persons (employees and non-employees) in order to confirm the Company's position as presented to the OIG. The Company is working diligently to resolve this matter, although it cannot predict the outcome or the timing of when this matter may be resolved.

On November 20, 2003, the Company received notification from the SEC indicating that the Commission would be conducting an informal inquiry relating to the Company's financial performance for the fiscal year 2003. On March 3, 2005, the Company received a subpoena from the SEC. The subpoena reflects the fact that the Commission has entered a formal order of investigation. The subpoena seeks information about the Company's financial performance for the fiscal year 2003, but the scope of the investigation is broader, and the period under review now goes back to January 2001. The Company continues to cooperate fully with the SEC by providing responsive documents and making Company representatives available for interviews by the Commission. The Company cannot predict either the outcome or the timing when this matter may be resolved.

The SEC has advised Biovail that it has reviewed the Company's Form 20-F for the fiscal year ended December 31, 2004 and its Form 6-K, filed August 12, 2005, for the fiscal quarter ended June 30, 2005. The SEC limited its review to the financial statements and related disclosures. It has provided comments and questions regarding certain accounting disclosures and methods as a result of this review and has made requests for certain additional disclosure in Biovail's filings. These matters are subject to interpretation and

the SEC review process is not complete. The ultimate resolution of these comments is uncertain, however is expected to result in certain modifications to disclosure in previously filed SEC filings. The Company will provide an update when these matters are resolved, and will revise the Form 20-F and Form 6-K as necessary.

In the course of the last three years, the Company has received a number of communications from the Ontario Securities Commission ("OSC") relating to its disclosure practice and or seeking information pertaining to certain financial periods. The OSC had advised the Company that it is investigating, among other things, two issues relating to Biovail's accounting and disclosure in 2003. The first is whether the Company improperly recognized revenue for accounting purposes in relation to its interim financial statements for each of the four quarters in 2003. The second is whether the Company provided misleading disclosure in its press release dated October 3, 2003 concerning the reasons for Biovail's forecast of a revenue shortfall in respect of the three-month period ending September 30, 2003. The OSC had also advised that it is investigating four issues relating to trading in the Company's common shares. These issues include whether insiders of the Company complied with insider reporting requirements, and whether persons in a special relationship with the Company may have traded in the Company's shares with knowledge of undisclosed material information. The OSC is also investigating whether certain transactions may have resulted in, or contributed to, a misleading appearance of trading activity in the Company's securities during 2003 and 2004, and whether certain registrants (who are past, or present, directors of Biovail) may have been in a conflict of interest in relation to trading of the Company's shares. More recently the OSC advised the Company that it is investigating whether the Company has improperly recognized revenue for accounting purposes in relation to the financial statements filed by the Company for each of the four quarters in 2001 and 2002 and related disclosure issues. In addition, the OSC has also indicated that it is investigating whether there has been improper trading and/or non-compliance with reporting and disclosure requirements in relation to trading of Biovail common shares held in several accounts in which the Company's Executive Chairman, Eugene Melnyk, may have direct or indirect beneficial ownership of or control or direction over, contrary to requirements of Ontario securities law. The Company cannot predict the outcome or the timing of when this matter may be resolved.

Although the Company is co-operating with these inquiries, it is unable at this point to predict the scope or outcome of these inquiries, and it is possible that one or more of them could result in the institution of administrative, civil injunctive or criminal proceedings, the imposition of fines and penalties, and/or other remedies and sanctions. The conduct of these proceedings could negatively impact the market price of the Company's securities. In addition, the Company expects to continue to incur expenses associated with responding to these agencies, regardless of the outcome, and these pending inquiries may divert the efforts and attention of the Company's management team from normal business operations.

14. SEGMENT 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.

15. SUBSEQUENT EVENTS

Tramadol products

In November 2005, the Company entered into an agreement with Ortho-McNeil, Inc. ("Ortho-McNeil"), a Johnson & Johnson company, for the marketing and distribution of the Company's once-daily, extended-release ("ER") and ODT formulations of tramadol HCl in the United States and Puerto Rico. Pending approval, the products will be known by the trade names Ultram® ER and Ultram® ODT. This agreement is subject to Hart-Scott-Rodino regulatory clearance in the United States. Ortho-McNeil anticipates launching Ultram® ER and Ultram® ODT in the United States and Puerto Rico in early 2006, and has retained an option for Ultram® ER for other jurisdictions, excluding Canada and Europe.

The Company will manufacture and supply Ultram® ER and Ultram® ODT to Ortho-McNeil for ten years at contractually determined supply prices. The supply price for Ultram® ER ranges from 27.5% to 37.5% of Ortho-McNeil's net selling price, depending on the year of sale. The supply price for Ultram® ODT is approximately equal to 30% of Ortho-McNeil's net selling price. Ortho-McNeil paid the Company a supply prepayment of \$60,000,000 to be credited against product purchases of Ultram® ER.

Generic Tiazac®

In November 2005, the Company entered into an agreement with Novopharm Limited ("Novopharm"), a subsidiary of Teva, for the distribution of a generic version of Tiazac® in Canada. The Company will manufacture and supply generic Tiazac® to Novopharm for five years at a supply price equal to 37.5% of the listed formulary price. Novopharm intends to immediately launch generic Tiazac® in Canada.

**BIOVAIL CORPORATION
MANAGEMENT'S DISCUSSION AND ANALYSIS
OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION**

**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 Results of Operations and Financial Condition ("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 prepared in accordance with U.S. GAAP that are contained in our Annual Report on Form 20-F for the fiscal year ended December 31, 2004.

The discussion and analysis contained in this MD&A are as of November 14, 2005.

STRATEGIC UPDATE

Tramadol products

In November 2005, we entered into a ten-year supply agreement with Ortho-McNeil, Inc. ("Ortho-McNeil"), a Johnson & Johnson company, for the distribution of our recently approved extended-release ("ER") and orally disintegrating tablet ("ODT") formulations of tramadol (see **Research and development expenses**). We will manufacture and supply these products to Ortho-McNeil for distribution in the United States and Puerto Rico under the trade names (pending approval) Ultram® ER and Ultram® ODT. Our contractually determined supply prices will be based on 27.5% to 37.5% of Ortho-McNeil's net selling price for Ultram® ER, depending on the year of sale, and approximately 30% of Ortho-McNeil's net selling price for Ultram® ODT.

Outlook

Ortho-McNeil anticipates launching Ultram® ER and Ultram® ODT in early 2006. We believe that a considerable market opportunity may exist for ER and ODT formulations of tramadol in the United States analgesia market and, accordingly, we anticipate that these products will have a material positive impact on our future results of operations, financial position and cash flows.

Legacy products

Our Board of Directors has reviewed a number of options to increase the value of our legacy products. These products comprise Ativan®, Isordil®, Tiazac®, Vasotec® and Vaseretic® that are sold in the United States and Puerto Rico and Cardizem® CD that is sold in the United States, Canada and Puerto Rico. These products are not considered strategic to our business and are in decline (in terms of prescription volumes) due to generic competition. The primary option currently under consideration is a distribution to our shareholders, which would involve the transfer of the legacy assets to a new entity and the distribution of the shares of that entity to our shareholders either as a dividend in kind or as a return of capital. Our Board is expected to make a decision shortly on whether or not to proceed with this option; however, if approved, the timing for completion of such a distribution cannot be determined at this time as it would be subject to a number of conditions including, but not limited to: the resolution of, or at least greater clarity in respect of, certain regulatory and litigation matters; the preparation and filing of a preliminary prospectus and registration statement; the review and approval of those documents by regulatory authorities prior to being finalized and authorized for use in connection with a distribution; receipt of lender and other third-party consents; and approval by our shareholders, if required. The aggregate carrying value of the intangible assets associated with these legacy products was \$630.3 million at September 30, 2005. A potential distribution could result in a write-down of the carrying values of certain of these intangible assets.

DISPOSITION AND RESTRUCTURING

Kos

On May 2, 2005, we sold all of our rights to Teveten and Teveten HCT, and the distribution rights to Cardizem® LA in the United States and Puerto Rico, to Kos Pharmaceuticals, Inc. ("Kos"). We will be the exclusive manufacturer and supplier of Cardizem® LA to Kos at contractually determined prices over an initial seven-year supply term. We will also collaborate with Kos on the development of up to three products, including a combination product comprising Cardizem® LA and Vasotec®. Subject to U.S. Food and Drug Administration ("FDA") approval, we will be the exclusive manufacturer and supplier of the combination product to Kos.

In consideration for these transactions, Kos paid us \$105.5 million in cash, less withholding tax of \$7.4 million. Kos may make additional payments to us related to the development of the combination product; however, we will only recognize these payments if the development milestones are achieved. Under the terms of the Cardizem® LA distribution agreement, we agreed to indemnify Kos (subject to certain conditions and limits) for lost profits in the event of generic competition to Cardizem® LA prior to December 31, 2008. We are aware that Andrx Corporation is seeking FDA approval for a generic version of Cardizem® LA in multiple dosage formats.

The Kos transactions comprise multiple deliverables (sale of product and distribution rights, manufacturing and supply activities, and research and development services). In accordance with our revenue recognition accounting policy, we evaluated whether the deliverables represented separate units of accounting. We determined that we had objective and reliable evidence of the fair value of the delivered item (the Teveten and Teveten HCT product rights); however, we did not have sufficient evidence of the fair values of the undelivered items, and therefore the Kos transactions represented a single unit of accounting. As a result, the up-front cash consideration of \$105.5 million was recorded in deferred revenue, and will be recognized in product sales on a straight-line basis over the seven-year Cardizem® LA supply term. Revenue and related costs associated with the sale of Cardizem® LA product to Kos will be recognized in earnings as title to the product transfers to Kos.

The disposal of Teveten and Teveten HCT to Kos resulted in a \$25.5 million write-down of the carrying value of these product rights to reflect their fair value of \$53.7 million (determined based on an independent valuation) at the date of disposition. The fair value of the Teveten and Teveten HCT product rights, as well as the cost of Teveten and Teveten HCT inventories of \$3.0 million that were sold to Kos, were re-characterized as a deferred charge associated with the Cardizem® LA manufacturing and supply arrangement. The total deferred charge of \$56.7 million and the withholding tax of \$7.4 million were recorded in other assets, and will be amortized to cost of goods sold and income tax expense, respectively, on the same seven-year, straight-line basis as the deferred revenue described above. Inventories of Cardizem® LA, Teveten and Teveten HCT totaling \$4.9 million that were not purchased by Kos were written off to cost of goods sold in the second quarter of 2005.

Restructuring

Concurrent with the Kos transactions, we restructured our U.S. commercial operations. As a result, we reduced our primary-care and specialty sales forces by 307 positions, and our general and administrative functions by 30 positions. We notified the affected employees on May 2, 2005. In addition, Kos offered employment to 186 of our sales representatives, of which 164 accepted positions with Kos. We retained 85 specialty sales representatives who will focus on the promotion of Zovirax Ointment and Zovirax Cream to dermatologists and obstetricians/gynaecologists, as well as provide co-promotion services for Ultram® ER and Ultram® ODT to women's health-care practitioners. In the third quarter and first nine months of 2005, we incurred restructuring charges of \$1.1 million and \$19.7 million, respectively, which consisted of employee termination benefits, contract termination costs and professional fees. Employee termination costs include

severance and related benefits, as well as outplacement services. We did not pay termination benefits to those employees that were offered employment by Kos. Contract termination costs include facility and vehicle lease payments that we will continue to incur without economic benefit.

Outlook

The Kos transactions and restructuring activities had a material positive impact on our results of operations, financial position and cash flows in the third quarter of 2005, due to the cost savings associated with the reduction in headcount in our U.S. commercial operations, as well as the discontinuance of spending on sales and marketing activities to support Cardizem® LA, Teveten and Teveten HCT. We anticipate that these cost savings will continue to have a material positive impact on our future results of operations, financial position and cash flows. In addition, the net amortization of the deferred revenue and other assets associated with the Kos transactions will positively impact our earnings by \$5.9 million annually over the seven-year Cardizem® LA supply term. All of the above factors are partly offset by lower revenue and gross profit on sales of Cardizem® LA product to Kos and the elimination of Teveten and Teveten HCT product sales.

DISCONTINUED OPERATION

On September 28, 2005, the Board of Directors committed to a plan to sell our Nutravail division. Nutravail develops and manufactures nutraceutical and food-ingredient products. This business is not considered strategic to our core pharmaceutical operations. We have received an offer of \$3.0 million from a third-party acquirer to purchase substantially all of the net assets of Nutravail, including intellectual property. Management believes that a sale transaction may be completed prior to December 31, 2005.

On the consolidated balance sheet at September 30, 2005, the net assets of Nutravail are reported as held for sale at their estimated fair value of \$3.0 million based on the purchase offer received. Consequently, we recorded a \$6.1 million write-down of the carrying values of Nutravail's long-lived assets.

Because of the distinct nature of its business, Nutravail has identifiable operations and cash flows that are clearly distinguishable from the rest of Biovail. Nutravail's operations and cash flows will be eliminated from our ongoing operations as a result of the sale transaction, and we will not have any significant continuing involvement in the operations of Nutravail after it is sold. Accordingly, Nutravail has been reported as a discontinued operation in our results of operations for the current and prior periods.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

For the third quarters and first nine months of 2005 and 2004, the following revenue and expenses of Nutravail have been reclassified from continuing operations to loss from discontinued operation:

	Three Months Ended September 30		Nine Months Ended September 30	
	2005	2004	2005	2004
REVENUE				
Product sales	\$ 701	\$ 1,214	\$ 1,643	\$ 3,163
Research and development	162	510	824	669
Royalty and other	419	383	1,602	1,026
	<u>1,282</u>	<u>2,107</u>	<u>4,069</u>	<u>4,858</u>
EXPENSES				
Cost of goods sold	1,022	1,724	3,003	4,952
Research and development	495	669	1,512	1,540
Selling, general and administrative	1,220	656	3,015	2,840
Amortization	68	68	204	204
	<u>2,805</u>	<u>3,117</u>	<u>7,734</u>	<u>9,536</u>
Loss from discontinued operation before write-down of assets	(1,523)	(1,010)	(3,665)	(4,678)
Write-down of assets	(6,113)		(6,113)	
Loss from discontinued operation	\$ (7,636)	\$ (1,010)	\$ (9,778)	\$ (4,678)

Outlook

Without significant capital investment, Nutravail was expected to continue to incur losses into the foreseeable future. As a result, we anticipate that the sale of Nutravail will have a material positive impact on our future results of operations and cash flows.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Critical accounting policies and estimates are those policies and estimates that are most important and material to the preparation of our consolidated financial statements, and which require management's most subjective and complex judgment due to the need to select policies from among alternatives available and make estimates about matters that are inherently uncertain. The nature of our critical accounting policies or estimates has not changed since December 31, 2004.

RESULTS OF OPERATIONS

We operate our business on the basis of a single reportable segment—the development and commercialization of pharmaceutical products. This basis reflects how management reviews the business, makes investing and resource allocation decisions, and assesses operating performance.

Revenue increased 21% from \$213.6 million in the third quarter of 2004 to \$258.1 million in the third quarter of 2005, and 7% from \$603.8 million in the first nine months of 2004 to \$647.9 million in the first nine months of 2005, due mainly to higher product sales.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

Income from continuing operations increased 116% from \$50.6 million (basic and diluted earnings per share of \$0.32) in the third quarter of 2004 to \$109.3 million (basic and diluted earnings per share of \$0.69) in the third quarter of 2005. There were no material events impacting our income from continuing operations in the third quarters of 2005 and 2004.

Net income increased 105% from \$49.6 million (basic and diluted earnings per share of \$0.31) in the third quarter of 2004 to \$101.7 million (basic and diluted earnings per share of \$0.64) in the third quarter of 2005.

Income from continuing operations increased 6% from \$119.6 million (basic and diluted earnings per share of \$0.75) in the first nine months of 2004 to \$126.3 million (basic and diluted earnings per share of \$0.79) in the first nine months of 2005. Our income from continuing operations in the first nine months of 2005 was impacted by the following events:

Write-off of \$4.9 million (basic and diluted impact per share of \$0.03) of Cardizem® LA, Teveten and Teveten HCT inventories that were not purchased by Kos;

Restructuring costs of \$19.7 million (basic and diluted impact per share of \$0.12); and

Write-down of assets of \$26.6 million (basic and diluted impact per share of \$0.17) primarily related to the Teveten and Teveten HCT product rights sold to Kos.

Our income from operations in the first nine months of 2004 was impacted by a charge of \$8.6 million (basic and diluted impact per share of \$0.05) to acquired research and development expense, associated with our acquisition of Pharma Pass II's ("PPII") remaining interest in BNC-PHARMAPASS, LLC ("BNC-PHARMAPASS").

Net income increased 1% from \$114.9 million (basic and diluted earnings per share of \$0.72) in the first nine months of 2004 to \$116.5 million (basic and diluted earnings per share of \$0.73) in the first nine months of 2005.

REVENUE

Our revenue is derived primarily from the following sources:

Sales of pharmaceutical products developed and manufactured by us, as well as sales of proprietary and in-licensed products.

Pharmaceutical clinical research and laboratory testing services, and product development activities in collaboration with third parties.

Royalties from the sale of products we developed or acquired and from our interests in certain licensed products.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

The following tables display the dollar amount of each source of revenue in the third quarters and first nine months of 2005 and 2004, the percentage of each source of revenue compared with total revenue in the respective period, and the dollar and percentage change in the dollar amount of each source of revenue. Percentages may not add due to rounding.

(\$ in 000s)	Three Months Ended September 30					
	2005		2004		Change	
Product sales	\$ 244,455	95%	\$ 202,243	95%	\$ 42,212	21%
Research and development	7,647	3	5,432	3	2,215	41
Royalty and other	5,956	2	5,943	3	13	
	\$ 258,058	100%	\$ 213,618	100%	\$ 44,440	21%

(\$ in 000s)	Nine Months Ended September 30					
	2005		2004		Change	
Product sales	\$ 609,505	94%	\$ 572,604	95%	\$ 36,901	6%
Research and development	21,216	3	12,162	2	9,054	74
Royalty and other	17,201	3	19,040	3	(1,839)	(10)
	\$ 647,922	100%	\$ 603,806	100%	\$ 44,116	7%

Product sales

The following tables display product sales by reporting category in the third quarters and first nine months of 2005 and 2004, the percentage of each category compared with total product sales in the respective period, and the dollar and percentage changes in the dollar amount of each category. Percentages may not add due to rounding.

(\$ in 000s)	Three Months Ended September 30					
	2005		2004		Change	
Wellbutrin XL	\$ 109,261	45%	\$ 86,423	43%	\$ 22,838	26%
Zovirax	22,770	9	9,747	5	13,023	134
Cardizem® LA	17,292	7	5,243	3	12,049	230
Teveten			5,261	3	(5,261)	(100)
Biovail Pharmaceuticals Canada	23,354	10	25,350	13	(1,996)	(8)
Legacy	29,517	12	31,856	16	(2,339)	(7)
Generic	42,261	17	38,363	19	3,898	10
	\$ 244,455	100%	\$ 202,243	100%	\$ 42,212	21%

Nine Months Ended September 30

(\$ in 000s)	2005		2004		Change	
Wellbutrin XL	\$ 216,486	36%	\$ 207,583	36%	\$ 8,903	4%
Zovirax	68,175	11	44,664	8	23,511	53
Cardizem® LA	46,271	8	43,301	8	2,970	7
Teveten	6,534	1	12,377	2	(5,843)	(47)
Biovail Pharmaceuticals Canada	72,076	12	72,192	13	(116)	
Legacy	98,441	16	85,916	15	12,525	15
Generic	101,522	17	106,571	19	(5,049)	(5)
	\$ 609,505	100%	\$ 572,604	100%	\$ 36,901	6%

Wellbutrin XL

Our bupropion ER tablets ("Wellbutrin XL") are sold by GlaxoSmithKline plc ("GSK") in the United States. Our revenue from sales of Wellbutrin XL increased 26% and 4% in the third quarter and first nine months of 2005, respectively, compared with the corresponding periods of 2004. In the third quarter of 2005, GSK's net sales of Wellbutrin XL exceeded the sales-dollar threshold to increase our supply price to GSK from the second to third and highest tier.

Wellbutrin XL revenue increased at a higher rate of growth in the third quarter of 2005, relative to the first nine months of 2005, due to a reduction in the level of GSK's safety stock of trade product in the first quarter of 2005. During 2004, GSK had increased its safety stock of trade product in anticipation of our need to shift production in 2005 from Wellbutrin XL to scale-up activities for various products under development, including our Tramadol ER product.

Zovirax products

Combined sales of Zovirax Ointment and Zovirax Cream increased 134% and 53% in the third quarter and first nine months of 2005, respectively, compared with the corresponding periods of 2004. The increases in Zovirax sales reflected higher prescription volumes in the third quarter and first nine months of 2005, and reductions in inventory levels of Zovirax at the wholesale level in the corresponding periods of 2004. These reductions related to the transition to distribution service agreements with our three major U.S. wholesalers in late 2004 and early 2005. These agreements generally establish limits on inventory levels held by these wholesalers and eliminates investment buying by these wholesalers, which can result in sales fluctuations unrelated to end-customer demand.

In the first quarters of 2005 and 2004, we effected price increases for Zovirax. In the first quarter of 2004, this event had a significant effect on our Zovirax sales levels, as wholesalers purchased additional quantities of Zovirax in anticipation of the price increase. This resulted in significantly lower sales of Zovirax in the second and third quarters of 2004, compared with the first quarter of 2004. In the first quarter of 2005, the distribution service agreements reduced investment buying by our three major wholesalers and, as a result, the fluctuations in the sales levels of Zovirax between the first quarter and the second and third quarters of 2005 were not nearly as significant as those in the corresponding periods of 2004.

Cardizem® LA

After May 2, 2005 (the date of the Kos transactions), we sell Cardizem® LA to Kos at contractual prices that are lower than what we historically charged for this product when selling direct to wholesalers; however, Cardizem® LA sales included \$3.8 million and \$6.3 million in the third quarter and first nine months of 2005,

respectively, related to the amortization of the deferred revenue associated with Kos transactions. Sales of Cardizem® LA increased 230% and 7% in the third quarter and first nine months of 2005, respectively, compared with the corresponding periods of 2004. The increases in Cardizem® LA sales reflected reductions in inventories of this product at the wholesale level during the last three quarters of 2004, which were related to the transition to wholesaler distribution services agreements, and were not related to end-customer demand for this product.

Cardizem® LA revenue increased at a higher rate of growth in the third quarter of 2005, relative to the first nine months of 2005, due to unanticipated returns of expired product in the first quarter of 2005, primarily related to low end-customer demand for one package size of this product.

Teveten products

Sales of Teveten and Teveten HCT reflected only those sales made prior to May 2, 2005 (the date of the Kos transactions).

Biovail Pharmaceuticals Canada ("BPC") products

BPC products are Tiazac® XC, Tiazac®, Wellbutrin® SR, Zyban®, Monocor and Retavase, which are sold in Canada. Sales of BPC products declined 8% in the third quarter of 2005, compared with the third quarter of 2004, and were unchanged in the first nine months of 2005, compared with the first nine months of 2004. BPC product sales reflected a decline in sales of Wellbutrin® SR due to the introduction of generic competition, offset partly by growth in Tiazac® sales and the launch of Tiazac® XC in January 2005.

In October 2005, the Federal Court of Canada issued a decision finding that RhoxalPharma Inc.'s ("RhoxalPharma") formulation for a generic version of Tiazac® did not infringe on our patents. This decision allowed the Therapeutic Products Directorate ("TPD") in Canada to issue a Notice of Compliance to RhoxalPharma in October 2005. As a result, we expect that RhoxalPharma will introduce its generic version of Tiazac® into the Canadian marketplace in late 2005. We anticipate that this introduction will result in a significant decline in BPC's sales of Tiazac®, which were \$13.8 million and \$39.8 million in the third quarter and first nine months of 2005, respectively. However, in November 2005, we entered into an agreement with Novopharm Limited ("Novopharm"), a subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva"), for the distribution in Canada of our own generic version of Tiazac® to compete with RhoxalPharma's product. We will manufacture and supply generic Tiazac® to Novopharm for five years at a supply price equal to 37.5% of the listed formulary price. Novopharm intends to immediately launch generic Tiazac® in Canada. The introduction of generic formulations of Tiazac® does not affect our ongoing conversion strategy for Tiazac® XC.

Legacy products

Our legacy products are Ativan®, Cardizem® CD, Isordil®, Tiazac®, Vasotec® and Vaseretic®, which are sold primarily in the United States. We sell Tiazac® (brand and generic) to Forest Laboratories, Inc. ("Forest") for distribution in the United States. Our other legacy products are primarily sold directly to wholesalers in the United States. Sales of our legacy products declined 7% overall in the third quarter of 2005, compared with the third quarter of 2004, and increased 15% overall in the first nine months of 2005, compared with the first nine months of 2004. The decrease in legacy product sales in the third quarter of 2005 was due to lower sales of both brand and generic Tiazac®, offset partly by higher sales of our other legacy products. The increase in the legacy product sales in the first nine months of 2005 reflected lower sales of brand Tiazac®, which were more than offset by higher sales of our other legacy products.

The increases in overall sales of our other legacy products in the third quarter and first nine months of 2005, reflected reductions in inventories of these products at the wholesale level during the last three quarters of 2004, which were related to the transition to wholesaler distribution service agreements.

Generic products

Our generic products are bioequivalent versions of Adalat CC, Cardizem® CD, Procardia XL, Trental and Voltaren XR, which we manufacture and sell to a subsidiary of Teva for distribution in the United States. Sales of our generic products increased 10% overall in the third quarter of 2005, compared with the third quarter of 2004, and declined 5% overall in the first nine months of 2005, compared with the first nine months of 2004. The increase in generic product sales in the third quarter of 2005 was mainly due to stronger sales of generic Procardia XL. The decline in generic product sales in the first nine months of 2005 was mainly due to weaker sales of generic Adalat CC.

Research and development revenue

Research and development revenue increased 41% and 74% in the third quarter and first nine months of 2005, compared with the corresponding periods of 2004. The increases in research and development revenue reflected a higher level of clinical research and laboratory testing services provided to external customers by our contract research operation.

Royalty and other revenue

Royalty and other revenue were unchanged in the third quarter of 2005, compared with the third quarter of 2004, and declined 10% in the first nine months of 2005, compared with the first nine months of 2004. Royalty and other revenue reflected a decrease in royalty income on Tiazac® brand sales by Forest, due to generic competition that resulted in lower end-customer demand for this product, offset by an increase in royalty income from our interest in Tricor (fenofibrate).

OPERATING EXPENSES

The following tables display the dollar amount of each operating expense item in the third quarters and first nine months of 2005 and 2004, the percentage of each item compared with total revenue in the respective period, and the dollar and percentage change in the dollar amount of each item. Percentages may not add due to rounding.

(\$ in 000s)	Three Months Ended September 30					
	2005		2004		Change	
Cost of goods sold	\$ 51,991	20%	\$ 50,111	23%	\$ 1,880	4%
Research and development	19,913	8	16,979	8	2,934	17
Selling, general and administrative	42,402	16	68,273	32	(25,871)	(38)
Amortization	15,443	6	16,262	8	(819)	(5)
Restructuring costs	1,118				1,118	N/A
Gain on disposal of assets			(1,471)	(1)	1,471	(100)
	\$ 130,867	51%	\$ 150,154	70%	\$ (19,287)	(13)%

(\$ in 000s)	Nine Months Ended September 30					
	2005		2004		Change	
Cost of goods sold	\$ 152,964	24%	\$ 158,076	26%	\$ (5,112)	(3)%
Research and development	62,135	10	49,929	8	12,206	24
Selling, general and administrative	174,263	27	181,538	30	(7,275)	(4)
Amortization	46,818	7	48,965	8	(2,147)	(4)
Restructuring costs	19,725	3			19,725	N/A
Write-down (gain on disposal) of assets	26,560	4	(1,471)		28,031	N/A
Acquired research and development			8,640	1	(8,640)	(100)
	\$ 482,465	74%	\$ 445,677	74%	\$ 36,788	8%

Cost of goods sold and gross margins

Cost of goods sold increased 4% in the third quarter of 2005, compared with the third quarter of 2004, and declined 3% in the first nine months of 2005, compared with the first nine months of 2004. Cost of goods sold included \$2.0 million and \$3.4 million in the third quarter and first nine months of 2005, respectively, related to the amortization of the deferred charge associated with Kos transactions. In addition, cost of goods sold included \$1.6 million and \$1.8 million in the third quarter and first nine months of 2005, respectively, related to the amortization of the deferred charge related to a reduction in the Zovirax supply price to be paid to GSK.

Gross margins based on product sales were 79% and 75% in the third quarter and first nine months of 2005, respectively, compared with 75% and 72% in the third quarter and first nine months of 2004, respectively. The increases in gross margins reflected mainly manufacturing efficiencies that we are continuing to achieve in the production of Wellbutrin XL, as well as a decrease in the proportion of lower margin Wellbutrin XL sample supplies versus trade product sales in the third quarter and first nine months of 2005, compared with the corresponding periods of 2004.

In the second quarter of 2005, following a review of existing market conditions for Cardizem® CD, we recorded a provision of \$5.7 million for inventory of this product in excess of expected demand. We anticipate a continuing decline in Cardizem® CD prescriptions due to increasing competition from generics and Cardizem® LA. In addition, we wrote off the \$4.9 million of Cardizem® LA, Teveten and Teveten HCT inventories not purchased by Kos. Excluding these inventory charges, our normalized gross margins were 77% in the first nine months of 2005.

Research and development expenses

Research and development expenses increased 17% and 24% in the third quarter and first nine months of 2005, respectively, compared with the corresponding periods of 2004. We invested 8% and 10% of total revenue in research and development activities in the third quarter and first nine months of 2005, respectively, compared with 8% in both the third quarter and first nine months of 2004. The increases in research and development expenses were primarily due to increased spending on our late-stage product development programs, and costs associated with a higher level of contract research services provided to external customers. Research and development activities in the third quarter and first nine months of 2005 included line extension and enhanced formulation programs for tramadol, bupropion, and the anti-depressant venlafaxine.

We achieved a number of recent successes from our late-stage product-development pipeline, including the following milestones:

In May 2005, we received final approval from the FDA for our ODT formulation of tramadol. In July 2005, we made a \$1.0 million milestone payment to Ethypharm S.A. associated with the FDA approval of this product, and we recorded a corresponding addition to product rights.

In May 2005, we received tentative approval from the FDA for our New Drug Application for Zolpidem ODT, for the treatment of insomnia. Final approval for this product cannot be made effective until the expiration of Sanofi-Aventis's patent for Ambien in October 2006.

In May and June 2005, we received approval from the TPD and the FDA for Glumetza (metformin), for the treatment of Type II diabetes. Glumetza was developed in collaboration with Depomed, Inc. ("Depomed"). In July 2005, we made a \$25.0 million milestone payment to Depomed associated with the regulatory approval of this product, and we recorded a corresponding addition to product rights.

In October 2005, we were informed by Depomed that we were in breach of our obligation to begin marketing Glumetza in the United States and Canada within 120 days following the grant of regulatory approval. If the breach is not cured within 60 days, Depomed may terminate the license agreement and request that we assign Depomed certain regulatory approvals for Glumetza. Depomed would be required to reimburse us for costs we incurred to develop and obtain regulatory approval for Glumetza; however, this reimbursement would not include the \$25.0 million milestone payment we made to Depomed.

We do not believe that we are in breach of our obligations and we are currently in negotiations with Depomed to amend the license agreement. We fully intend to launch Glumetza in Canada in November 2005, which is within the 60-day time frame allowed to cure the breach. We believe an agreement can be reached with Depomed that will allow us to continue with our marketing plans for Glumetza in Canada. Accordingly, we believe that the carrying value of the Glumetza product right at September 30, 2005 is fully recoverable, based on the estimated undiscounted future cash flows related to forecasted sales of Glumetza in Canada.

In September 2005, we received approval from the FDA for Tramadol ER, for the treatment of moderate to moderately severe chronic pain. We are the first and only company to receive an approval for a once-daily tramadol formulation.

Selling, general and administrative expenses

Selling, general and administrative expenses declined 38% and 4% in the third quarter and first nine months of 2005, respectively, compared with the corresponding periods of 2004. As a percentage of total revenue, selling, general and administrative expenses were 16% and 27% in the third quarter and first nine months of 2005, respectively, compared with 32% and 30% in the third quarter and first nine months of 2004, respectively. The declines in selling, general and administrative expenses reflected the impact of the Kos transactions and concurrent restructuring of our U.S. commercial operations. These events resulted in immediate cost savings associated with a reduction in headcount in our primary-care and cardiovascular specialty sales forces and the discontinuance of spending on sales and marketing activities to support Cardizem® LA, Teveten and Teveten HCT. These factors were partially offset by higher corporate expenses resulting from our corporate governance and Sarbanes-Oxley compliance initiatives, as well as an expansion of our executive group and compensation expense related to Deferred Share Units granted in the third quarter of 2005.

Amortization expense

Amortization expense declined 5% and 4% in the third quarter and first nine months of 2005, respectively, compared with the corresponding periods of 2004. The declines in amortization expense reflected the final amortization of our interest in generic omeprazole in the first quarter of 2004, and the discontinuance of amortization of the Teveten and Teveten HCT product rights following the Kos transactions. As a result of the disposal of the Teveten and Teveten HCT product rights, amortization expense will be reduced by \$1.2 million per quarter or \$4.7 million annually.

Restructuring costs

In the third quarter and first nine months of 2005, we incurred charges of \$1.1 million and \$19.7 million, respectively, associated with the restructuring of our U.S. commercial operations. At September 30, 2005, there was a remaining liability balance of \$2.2 million for restructuring costs, which was mainly related to a facility lease that will be settled over the remaining 10-year term of this lease.

Write-down or gain on sale of assets

In the second quarter of 2005, the disposal of the Teveten and Teveten HCT product rights to Kos resulted in a \$25.8 million write-down (including costs to sell) of the carrying value of these product rights to reflect their fair value of \$53.7 million at the date of disposition. In addition, we wrote-off our \$0.7 million investment in convertible debentures of Procyon Biopharma Inc. ("Procyon"), as a result of our decision to terminate the Fibrostat licensing agreement with Procyon.

In the third quarter of 2004, we disposed of the product rights to Cedax for proceeds of \$3.0 million, which resulted in a gain on disposal of \$1.5 million.

Acquired research and development expense

In the first quarter of 2004, we acquired PPII's remaining interest in BNC-PHARMAPASS, a company that we formed in 2003 with PPII to advance the development of three products (carvedilol, eprosartan and tamsulosin). We subsequently agreed with PPII to terminate the development of tamsulosin, and the intellectual property related to this product was returned to PPII. We recorded a charge of \$8.6 million to acquired research and development expense related to the increase in our share of the fair values of the two remaining products (carvedilol and eprosartan). Both of these products are in early clinical phases of development.

OPERATING INCOME

We recorded operating income of \$127.2 million and \$165.5 million in the third quarter and first nine months of 2005, respectively, compared with \$63.5 million and \$158.1 million in the third quarter and first nine months of 2004, respectively. In the first nine months of 2005, charges related to the cost of inventories not purchased by Kos, the write-down of assets and restructuring activities reduced operating income by a total of \$51.1 million. In the first nine months of 2004, the charge to acquired research and development expense reduced operating income by \$8.6 million.

Operating income in the third quarter and first nine months of 2005, compared with the corresponding periods of 2004, reflected higher gross margins on product sales and lower sales force and marketing costs. These factors were partially offset by increased research and development spending and higher corporate expenses.

NON-OPERATING ITEMS

Interest expense

Interest expense was \$9.5 million and \$27.9 million in the third quarter and first nine months of 2005, respectively, compared with \$10.1 million and \$30.5 million in the third quarter and first nine months of 2004, respectively. Interest expense mainly comprised interest on our 7⁷/₈% Senior Subordinated Notes due April 1, 2010 ("Notes"). In July 2005, we terminated an interest rate swap of \$200.0 million notional amount that was designated as hedge of our Notes.

Provision for income taxes

Our 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. We recorded provisions for income taxes of \$9.1 million and \$12.0 million in the third quarter and first nine months of 2005, respectively, and \$2.1 million and \$5.2 million in the third quarter and first nine months of 2004, respectively. Our effective tax rate was affected by the availability of unrecognized tax loss carryforwards that can be used to offset taxable income in Canada and the United States, as well as losses that were incurred in the United States prior to the transactions with Kos and restructuring activities.

Our provision for income taxes is based on a number of estimates and assumptions made by management. Our consolidated income tax rate is affected by the amount of net income earned in our various operating jurisdictions and the rate of taxes payable in respect of that income. We enter into many transactions and arrangements in the ordinary course of business in which the tax treatment is not entirely certain. In particular, certain countries in which we operate could seek to tax a greater share of income than has been provided for by us. The final outcome of any audits by taxation authorities may differ from the estimates and assumptions we have used in determining our consolidated tax provisions and accruals. This could result in a material effect on our consolidated income tax provision and the net income for the period in which such determinations are made.

SUMMARY OF QUARTERLY RESULTS

The following tables present a summary of our quarterly results for each of the eight most recently completed quarters:

(\$ in 000s, except per share data)	2005			2004
	Q3	Q2	Q1	Q4
Revenue	\$ 258,058	\$ 216,178	\$ 173,686	\$ 275,350
Income from continuing operations	109,299	4,922	12,059	46,582
Net income	101,663	3,707	11,132	46,045

Basic and diluted earnings per share

Income from continuing operations	\$ 0.69	\$ 0.03	\$ 0.08	\$ 0.29
Net income	\$ 0.64	\$ 0.02	\$ 0.07	\$ 0.29

(\$ in 000s, except per share data)	2004			2003
	Q3	Q2	Q1	Q4
Revenue	\$ 213,618	\$ 204,886	\$ 185,302	\$ 195,394
Income (loss) from continuing operations	50,645	45,784	23,198	(96,621)
Net income (loss)	49,635	44,208	21,106	(96,038)

Basic and diluted earnings (loss) per share

Income (loss) from continuing operations	\$ 0.32	\$ 0.29	\$ 0.15	\$ (0.61)
Net income (loss)	\$ 0.31	\$ 0.28	\$ 0.13	\$ (0.60)

The increase in revenue in the third quarter of 2005, compared with the first and second quarters of 2005, was due mainly to higher revenue from sales of Wellbutrin XL to GSK. In the first quarter of 2005, GSK reduced the level of its safety stock of Wellbutrin XL, after ordering additional quantities of this product during 2004, in anticipation of our need to shift production from Wellbutrin XL to other of our products under development. In addition, the increase in revenue reflected the impact of the tiered supply price for Wellbutrin XL, which is reset to the lowest tier at the start of each calendar year. In the second and third quarters of 2005, GSK's net sales of Wellbutrin XL exceeded the sales-dollar threshold to increase the supply price from the first to second tier and from the second to third and highest tier, respectively.

The increase in net income in the third quarter of 2005, compared with the second quarter of 2005, reflected the lower sales force and marketing costs following the Kos transactions and restructuring activities in the second quarter. Also contributing to the increase in net income in the third quarter of 2005, compared with the second quarter of 2005, as well as the decline in net income in the second quarter of 2005, compared with the first quarter of 2005, were the charges related to the write-down of assets and restructuring activities recorded in the second quarter.

FINANCIAL CONDITION

The following table presents a summary of our financial condition at September 30, 2005 and December 31, 2004:

(\$ in 000s)	At September 30 2005	At December 31 2004
Working capital	\$ 350,075	\$ 124,414
Long-lived assets	1,279,951	1,328,363
Long-term obligations	447,339	478,936
Shareholders' equity	1,181,015	1,053,913

Working capital

The \$225.7 million increase in working capital from December 31, 2004 to September 30, 2005 was primarily due to:

Cash generated from continuing operations of \$278.5 million; and

Net proceeds of \$98.1 million from the transactions with Kos.

Partially offset by:

Repayments of long-term obligations of \$28.9 million;

Acquisitions of intangible assets of \$26.0 million;

Net additions to property, plant and equipment of \$24.1 million;

A decrease in accounts receivable of \$23.0 million mainly related to the amount and timing of collections of revenue recognized on the sale of Wellbutrin XL and generic products;

A decrease in inventories of \$22.1 million mainly related to lower Cardizem® LA, Teveten and Teveten HCT inventory balances following the transactions with Kos, as well as an increase in the provision for inventory obsolescence of \$5.7 million related to Cardizem® CD; and

An increase in current deferred revenue of \$15.2 million primarily related to proceeds from the Kos transactions.

Long-lived assets

Long-lived assets comprise property, plant and equipment, goodwill, intangible and other assets, net of accumulated depreciation and amortization. The \$48.4 million decrease in long-lived assets from December 31, 2004 to September 30, 2005, reflected primarily the depreciation of plant and equipment of \$22.5 million and the amortization of intangible and other assets of \$53.5 million, as well as the write-downs of the carrying values of the Teveten and Teveten HCT product rights and Nutravail's long-lived assets of \$25.5 million and \$6.1 million, respectively. These factors were partially offset by the additions of the Glumetza and Tramadol ODT product rights of aggregate \$26.0 million and net capital expenditures on property, plant and equipment of \$24.1 million, which included expenditures related to the ongoing expansion of our Steinbach, Manitoba manufacturing facility.

Long-term obligations

The \$31.6 million decrease in long-term obligations, including the current portion thereof, from December 31, 2004 to September 30, 2005, reflected primarily the following instalments:

Payment of \$11.3 million to GSK related to the October 2002 amendments to the Zovirax distribution agreement;

Final payment of \$9.2 million to Wyeth Pharmaceuticals Inc. ("Wyeth") related to the acquisition of Ativan® and Isordil®; and

Payment of \$7.6 million to Merck & Co., Inc. ("Merck") related to the acquisition of Vasotec® and Vaseretic®.

Shareholders' equity

The \$127.1 million increase in shareholders' equity from December 31, 2004 to September 30, 2005, reflected primarily net income of \$116.5 million, as well as a \$4.4 million unrealized holding gain on our available-for-sale investments, mainly related to our equity investment in Depomed, and a \$5.1 million foreign currency translation gain due to a strengthening of the Canadian dollar relative to the U.S. dollar.

CASH FLOWS

At September 30, 2005, we had cash and cash equivalents of \$326.7 million, compared with \$34.3 million at December 31, 2004. The following table displays cash flow information for the first nine months of 2005 and 2004:

(\$ in 000s)	Nine Months Ended September 30	
	2005	2004
Net cash provided by continuing operating activities	\$ 278,489	\$ 167,413
Net cash provided by (used in) continuing investing activities	46,978	(29,374)
Net cash used in continuing financing activities	(30,495)	(225,359)
Net cash used in discontinued operation	(2,775)	(2,055)
Effect of exchange rate changes on cash and cash equivalents	206	157
Net increase (decrease) in cash and cash equivalents	\$ 292,403	\$ (89,218)

Operating activities

Net cash provided by continuing operating activities increased \$111.1 million from the first nine months of 2004 to the first nine months of 2005, primarily due to:

An increase of \$36.9 million in income from operations excluding non-cash items, mainly related to higher product sales and gross margins, and lower sales force and marketing costs;

An increase of \$10.3 million in net collections of accounts receivable;

A decrease of \$50.4 million in net purchases of inventories and payments of accounts payable; and

A decrease of \$19.7 million in net payments of accrued liabilities mainly related to lower product returns and rebates.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

In the first nine months of 2005, net cash provided by continuing operating activities was used to make the milestone payments related to Glumetza and Tramadol ODT, to fund the expansion of the Steinbach manufacturing facility and other capital expenditures, and to repay long-term obligations. In the first nine months of 2004, net cash provided by continuing operating activities was primarily used to repay our revolving term credit facility and other long-term obligations.

Investing activities

Net cash provided by continuing investing activities increased \$76.4 million from the first nine months of 2004 to the first nine months of 2005, primarily due to:

An increase of \$98.1 million related to the net proceeds from the Kos transactions; and

A decrease of \$9.3 million related to our acquisition of PPII's remaining interest in BNC-PHARMAPASS in the first quarter of 2004.

Partially offset by:

An increase of \$26.0 million related to the additions of the Glumetza and Tramadol ODT product rights.

Financing activities

Net cash used in continuing financing activities declined \$194.9 million from the first nine months of 2004 to the first nine months of 2005, primarily due to:

A decrease of \$180.0 million in repayments under our revolving term credit facility; and

A decrease of \$23.9 million in repayments of other long-term obligations mainly related to the final payment of \$21.8 million to GSK in the first quarter of 2004 for the Canadian rights to Wellbutrin® and Zyban®.

Outlook

We anticipate utilizing our existing cash resources and continuing cash flows from operations to support primarily our growth strategy through potential acquisitions of new products, technologies and/or businesses. We are also considering using part of these funds to redeem a portion of our Notes, repurchase a percentage of our common shares and/or pay a dividend to our shareholders.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2005, we had total long-term obligations of \$447.3 million, including the current portion thereof, which included the carrying value of our Notes of \$400.6 million and obligations related to the acquisitions of intangible assets of \$42.7 million. At September 30, 2005, we had no outstanding borrowings under our revolving term credit facility; however, we had a letter of credit of \$27.1 million issued under this facility, which secures the remaining semi-annual payments we are required to make to Merck related to our acquisition of Vasotec® and Vaseretic®. In May 2005, we renewed this credit facility for a one-year term at \$250.0 million. This facility is renewable for additional one-year revolving terms at the lenders' option, with a one-year term out at our option if the lenders do not renew. This facility may be used for general corporate purposes, including acquisitions. At September 30, 2005, we were in compliance with all financial and non-financial covenants associated with this facility. Our current corporate credit ratings from Standard & Poor's ("S&P") and Moody's Investors Service ("Moody's") are BB+ and Ba3, respectively, the current ratings

on our Notes from S&P and Moody's are BB- and B2, respectively, and S&P's current rate on our revolving term credit facility is BBB-.

We believe that our existing balance of cash and cash equivalents, together with cash expected to be generated by operations and existing funds available under our revolving term credit facility, will be sufficient to support our operational, capital expenditure and interest requirements, as well as to meet our obligations as they become due. However, in the event that we make significant future acquisitions or change our capital structure, we may be required to raise additional funds through additional borrowings or the issuance of additional debt or equity securities.

CONTRACTUAL OBLIGATIONS

The following table summarizes our fixed contractual obligations at September 30, 2005:

(\$ in 000s)	Payments Due by Period				
	Total	2005	2006 and 2007	2008 and 2009	Thereafter
Long-term obligations	\$ 444,139	\$ 7,628	\$ 36,511	\$	\$ 400,000
Operating lease obligations	44,325	1,725	12,600	9,900	20,100
Purchase obligations	30,694	14,505	16,189		
Total contractual obligations	\$ 519,158	\$ 23,858	\$ 65,300	\$ 9,900	\$ 420,100

The above purchase obligations are in connection with the manufacture and supply of Cardizem® products by Aventis Pharmaceuticals Inc. ("Aventis") and Vasotec® and Vaseretic® by Merck. We are obligated to purchase approximately \$12.6 million worth of Cardizem® products from Aventis in both 2005 and 2006. We are obligated to make semi-annual payments to Merck for minimum quantities of Vasotec® and Vaseretic® (regardless of the actual product supplied). The remaining payments to Merck are \$1.9 million in 2005 and \$3.6 million in 2006.

The above table does not reflect any milestone payments in connection with research and development collaborations with third parties, as these payments are contingent on the achievement of specific developmental, regulatory and/or commercial milestones. In addition, under certain arrangements, we may have to make royalty payments based on a percentage of future sales of the products in the event regulatory approval for marketing is obtained. From a business perspective, we view these payments favourably as they signify that the products are moving successfully through the development phase toward commercialization.

The above table also does not reflect a contingent purchase obligation in connection with the acquisition of Ativan® and Isordil®. On the approval by the FDA of the first Ativan® line extension product that may be developed by us, we will be obligated to pay Wyeth a \$20.0 million additional rights payment, increasing at 10% per annum from May 2003.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have any off-balance sheet arrangements at September 30, 2005, other than operating leases and purchase obligations in connection with the manufacture and supply of Cardizem® products, Vasotec® and Vaseretic®, which are disclosed above under contractual obligations.

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 use derivative financial instruments from time to time 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 denominated in U.S. dollars. Our only other significant transactions are in Canadian dollars, and we do not have any material non-U.S. dollar-denominated obligations. We also face foreign currency exposure on the translation of our operations in Canada and Ireland from their local currencies to the U.S. dollar. Currently, we do not utilize forward contracts to hedge against foreign currency risk; however, a 10% change in foreign currency exchange rates would not have a material impact on our consolidated results of operations, financial position or cash flows.

Interest rate risk

The primary objective of our policy for the investment of temporary cash surpluses is the protection of principal and, accordingly, we invest in investment-grade securities with varying maturities. External independent fund administrators manage our investments. As it is our general 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 revolving term credit facility. This credit facility bears interest based on London Interbank Offering Rate, 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, consequently, 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. Prior to July 5, 2005, we managed this exposure to interest rate changes through the use of an interest rate swap, which modified our exposure to interest rate fluctuations by converting one-half of our fixed rate Notes to floating rate. Effective July 5, 2005, we terminated this interest rate swap. Based on our overall interest rate exposure, a 10% change in interest rates would not have a material impact on our consolidated results of operations, financial position or cash flows.

Investment risk

We are exposed to investment risks on our investments in other companies. The fair values of our investments are subject to significant fluctuations due to stock market volatility and changes in general market conditions. We regularly review the carrying values of our investments and record losses whenever 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 impact on our consolidated results of operations; however, it would not have a material impact on our consolidated financial position or cash flows.

RECENT ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"), which revises SFAS No. 123, "Accounting for Stock-Based Compensation", and supersedes Accounting Principles Board Opinion ("APB")

No. 25, "Accounting for Stock Issued to Employees". SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS No. 123 will no longer be an alternative to financial statement recognition. In April 2005, the SEC delayed the effective date of SFAS No. 123R. Under the SEC's rule, SFAS No. 123R is effective at the beginning of the first annual period commencing after June 15, 2005. Accordingly, we are required to adopt SFAS No. 123R beginning January 1, 2006. We are currently evaluating the requirements of SFAS No. 123R and expect that the adoption of this standard will have a material negative impact on our consolidated results of operations. We have not yet determined the method of adoption or other effects of adopting SFAS No. 123R, and we have not determined whether the adoption will result in amounts that are similar to our current pro forma disclosures under SFAS No. 123.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs - An Amendment of ARB No. 43, Chapter 4" ("SFAS No. 151"). SFAS No. 151 requires that items such as idle facility expense, excessive spoilage, double freight, and rehandling costs be excluded from the cost of inventory and expensed as incurred. Additionally, SFAS No. 151 requires that the allocation of fixed overheads be based on the normal capacity of the production facilities. SFAS No. 151 is effective for fiscal years commencing after June 15, 2005. Accordingly, we are required to adopt SFAS No. 151 beginning January 1, 2006. We are currently evaluating the effect that the adoption of SFAS No. 151 will have on our consolidated results of operations and financial position.

BIOVAIL CORPORATION
PART II OTHER INFORMATION

1. LEGAL PROCEEDINGS

For detailed information concerning legal proceedings, reference is made to note 13 Legal Proceedings to the consolidated financial statements included under Part I of this Quarterly Report.

2. EXHIBITS

Exhibit 99.1 Third Quarter 2005 Interim Report For Canadian Regulatory Purposes
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: November 14, 2005

By: /s/ JOHN R. MISZUK

John R. Miszuk
Vice President, Controller and
Assistant Secretary

QuickLinks

BIOVAIL CORPORATION

INDEX Part I Financial Information

BASIS OF PRESENTATION

FORWARD-LOOKING STATEMENTS

CONSOLIDATED BALANCE SHEETS

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

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)

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)
Consolidated Statements of Cash Flows

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)

BIOVAIL CORPORATION PART II OTHER INFORMATION

SIGNATURES