

BIOVAIL CORP INTERNATIONAL  
Form 6-K  
November 10, 2008

[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, 2008**

**Commission File Number 001-14956**

**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**

**FORM 6-K**

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2008**

This Report of Foreign Private Issuer on Form 6-K ("Form 6-K") is incorporated by reference into the registration statements on Form S-8 (Registration Nos. 333-92229 and 333-138697) of Biovail Corporation.

**INDEX**

**Part I Financial Information**

Financial Statements (unaudited)	
Consolidated Balance Sheets as at September 30, 2008 and December 31, 2007	1
Consolidated Statements of Income for the three months and nine months ended September 30, 2008 and 2007	2
Consolidated Statements of Deficit for the three months and nine months ended September 30, 2008 and 2007	3
Consolidated Statements of Cash Flows for the three months and nine months ended September 30, 2008 and 2007	4
Condensed Notes to the Consolidated Financial Statements	5
Management's Discussion and Analysis of Results of Operations and Financial Condition	31

**Part II Other Information**

Legal Proceedings	62
Exhibits	62

**BASIS OF PRESENTATION**

**General**

Except where the context otherwise requires, all references in this Form 6-K to the "Company", "Biovail", "we", "us", "our" or similar words or phrases are to Biovail Corporation and its subsidiaries, taken together.

All dollar amounts in this report are expressed in United States ("U.S.") dollars.

**Trademarks**

The following words are trademarks of our Company and are the subject of either registration, or application for registration, in one or more of Canada, the U.S. or certain other jurisdictions: ATTENADE , A TABLET DESIGN (APEX DOWN)®, A TABLET DESIGN (APEX UP)®, APLENZIN , ATIVAN®, ASOLZA , BIOVAIL®, BIOVAIL CORPORATION®, BIOVAIL & SWOOSH DESIGN®, BPI®, BVF®, CARDISENSE , CARDIZEM®, CEFORM®, CRYSTAAL PHARMACEUTICALS , DITECH , FLASHDOSE®, GLUMETZA®, INSTATAB , ISORDIL®, JOVOLA , JUBLIA , MIVURA , ONELZA , ONEXTEN , ORAMELT , PALVATA , RALIVIA , SHEARFORM , SMARTCOAT , SOLBRI , TESIVEE , TIAZAC®, TITRADOSE , TOVALT , UPZIMIA , VASERETIC®, VASOCARD , VASOTEC®, VEMRETA , VOLZELO and ZILERAN .

WELLBUTRIN®, WELLBUTRIN® SR, WELLBUTRIN XL® (a once daily formulation of bupropion developed by Biovail), WELLBUTRIN® XR, ZOVIRAX® and ZYBAN® are trademarks of The GlaxoSmithKline Group of Companies and are used by us under license. ULTRAM® is a trademark of Ortho-McNeil, Inc. and is used by us under license. XENAZINE® and NITOMAN® are trademarks of Cambridge Laboratories (Ireland) Ltd. and are used by us under license.

## Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

In addition, we have filed trademark applications for many of our other trademarks in the U.S. and Canada and have implemented, on an ongoing basis, a trademark protection program for new trademarks.

**FORWARD-LOOKING STATEMENTS**

Caution regarding forward-looking information and statements and "Safe Harbor" statement under the U.S. Private Securities Litigation Reform Act of 1995:

*To the extent any statements made in this Form 6-K 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, and may be forward-looking information under applicable Canadian provincial securities legislation (collectively, "forward-looking statements"). These forward-looking statements relate to, among other things, our objectives, goals, strategies, beliefs, intentions, plans, estimates and outlook, including, without limitation, the intent and ability to implement and effectively execute plans associated with our New Strategic Focus and the anticipated impact of the New Strategic Focus, our intention to complete acquisitions and to successfully integrate such acquisitions into our business and operations and to achieve the anticipated benefits of such acquisitions, the timing regarding the planned closure of our Puerto Rico and Ireland operations, the associated costs and anticipated impact of such closures and possible impact on our manufacturing processes, our manufacturing ability, the Company's intent and ability and the timing and anticipated impact of the proposed sale of the Company's non-core assets, the availability of benefits under tax treaties, the timing, results and progress of our research and development efforts, the anticipated manufacturing and commercializing of pipeline products that are successfully developed, the intent and ability to make future dividend payments, the intent to continue our share repurchase program and to repurchase our common shares, the intention to make additional filings to permit the Company to repurchase common shares on the Toronto Stock Exchange, the expected impact of the acquisition of Prestwick Pharmaceuticals, Inc. ("Prestwick") on earnings per share and cash flows, the timing of the launch of Xenazine® in the U.S., our intention regarding the development of Prestwick's non-tetrabenazine products, the intent and timing to engage a contract sales organization to promote Zovirax®, the expected impact of the introduction of generic competition to the 150mg Wellbutrin XL® product, the timing of the introduction of generic competition to Ultram® ER, the investment recovery, liquidity, valuation and impairment conclusions associated with our investment in auction rate securities, the timing, costs and expected results of certain litigation and regulatory proceedings and the outcome, amount and timing of the potential settlement of certain of these proceedings, the sufficiency of cash resources (including those available under the accordion feature of our credit facility) to support future spending requirements, expected capital expenditures and business development activities, the ability to manage exposure to foreign currency exchange rate changes, and the expected impact of the adoption of new accounting standards. Forward-looking statements can generally be identified by the use of 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. Although we have indicated above certain of these statements set out herein, all of the statements in this Form 6-K that contain forward-looking statements are qualified by these cautionary statements. Although we believe that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Certain material factors or assumptions are applied in making forward-looking statements, including, but not limited to, factors and assumptions regarding prescription trends, pricing and the formulary and/or Medicare/Medicaid positioning for our products; the competitive landscape in the markets in which we compete, including, but not limited to, the availability or introduction of generic formulations of our products; timelines associated with the development of, and receipt of regulatory approval for, our new products; and actual results may differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from these expectations include, among other things: 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, the results of continuing safety and efficacy studies by industry and government agencies, uncertainties associated with the development, acquisition and launch of new products, contractual disagreements with third parties, availability of capital and ability to generate operating cash flows and satisfaction of applicable laws for dividend payments, the continuation of the recent market turmoil, market liquidity for our common shares, our satisfaction of applicable laws for the acquisition of our common shares, impact of a decline in our market capitalization on the carrying value of goodwill, reliance on key strategic alliances, delay in or transition issues arising from the closure of our Puerto Rico facilities, the successful implementation of our New Strategic Focus, our eligibility for benefits under tax treaties, the availability of raw materials and finished products, the regulatory environment, the unpredictability of protection afforded by our patents, the mix of activities*

*and income in various jurisdictions in which we operate, successful challenges to our generic products, infringement or alleged infringement of the intellectual property rights of others, unanticipated interruptions in our manufacturing operations or transportation services, the expense, timing and uncertain outcome of legal and regulatory proceedings and settlements thereto, payment by insurers of insurance claims, currency fluctuations, consolidated tax rate assumptions, fluctuations in operating results, the market liquidity and amounts realized for auction rate securities held as investments, and other risks detailed from time to time in our filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, as well our ability to anticipate and manage the risks associated with the foregoing. Additional information about these factors and about the material factors or assumptions underlying such forward-looking statements may be found in the body of this Form 6-K (including under the heading "Additional Risk Factors"), and under the heading "Risk Factors" under Item 3, Sub-Part D of our Annual Report on Form 20-F for the fiscal year ended December 31, 2007, filed on March 17, 2008. We caution that the foregoing list of important factors that may affect future results is not exhaustive. When relying on our forward-looking statements to make decisions with respect to our Company, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. We undertake no obligation to update or revise any forward-looking statement.*

## BIOVAIL CORPORATION

## CONSOLIDATED BALANCE SHEETS

In accordance with United States Generally Accepted Accounting Principles  
(All dollar amounts are expressed in thousands of U.S. dollars)

(Unaudited)

	At September 30 2008	At December 31 2007
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents	\$ 219,005	\$ 433,641
Short-term investment	7,578	
Marketable securities		3,895
Accounts receivable	99,796	111,114
Insurance recoveries receivable	1,860	62,942
Assets held for sale	7,003	
Inventories	70,151	80,745
Prepaid expenses and other current assets	10,678	14,680
	416,071	707,017
Marketable securities	23,141	24,417
Long-term investments	192	24,834
Property, plant and equipment, net	167,507	238,457
Intangible assets, net	745,822	630,514
Goodwill	100,294	100,294
Deferred tax assets, net of valuation allowance	18,200	20,700
Other long-term assets, net	29,734	35,882
	\$ 1,500,961	\$ 1,782,115
<b>LIABILITIES</b>		
<b>Current</b>		
Accounts payable	\$ 30,976	\$ 50,415
Accrued liabilities	83,160	74,363
Accrued legal settlements	26,648	148,000
Accrued contract costs		45,065
Income taxes payable	10,924	647
Deferred revenue	36,582	49,088
	188,290	367,578
Deferred revenue	89,251	55,653
Income taxes payable	53,000	54,100
Other long-term liabilities	6,534	6,965
	337,075	484,296
<b>SHAREHOLDERS' EQUITY</b>		
Common shares, no par value, unlimited shares authorized, 158,715,752 and 161,023,729 issued and outstanding at September 30, 2008 and December 31, 2007, respectively	1,468,485	1,489,807
Additional paid-in capital	30,815	23,925
Deficit	(381,280)	(278,495)
Accumulated other comprehensive income	45,866	62,582
	1,163,886	1,297,819

\$ 1,500,961 \$ 1,782,115

Commitments and contingencies (note 19)

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

## BIOVAIL CORPORATION

## CONSOLIDATED STATEMENTS OF INCOME

In accordance with United States 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	
	2008	2007	2008	2007
<b>REVENUE</b>				
Product sales	\$ 170,530	\$ 178,321	\$ 543,110	\$ 607,089
Research and development	5,465	6,237	18,522	18,456
Royalty and other	5,094	4,332	14,050	13,377
	181,089	188,890	575,682	638,922
<b>EXPENSES</b>				
Cost of goods sold (exclusive of amortization of intangible assets shown separately below)	47,468	50,458	145,080	161,408
Research and development	18,668	30,674	76,759	88,843
Selling, general and administrative	44,661	33,660	144,891	129,583
Amortization of intangible assets	12,342	11,979	35,727	35,942
Restructuring costs (recovery)	7,587	(820)	59,347	712
Legal settlements	2,000	2,062	26,648	2,062
Contract recoveries		(123)		(1,735)
	132,726	127,890	488,452	416,815
Operating income	48,363	61,000	87,230	222,107
Interest income	1,783	3,789	8,663	19,620
Interest expense	(246)	(245)	(724)	(9,375)
Foreign exchange gain (loss)	204	5,255	(1,139)	5,730
Equity loss		(432)	(1,195)	(1,325)
Gain on disposal of investments	4,156		7,617	15,716
Loss on impairment of investments	(1,223)		(5,328)	
Loss on early extinguishment of debt				(12,463)
Income before provision for income taxes	53,037	69,367	95,124	240,010
Provision for income taxes	4,600	3,500	15,600	12,500
Net income	\$ 48,437	\$ 65,867	\$ 79,524	\$ 227,510
Basic and diluted earnings per share	\$ 0.31	\$ 0.41	\$ 0.50	\$ 1.41
<b>Weighted average number of common shares outstanding (000s)</b>				
Basic	158,715	161,020	160,144	160,777
Diluted	158,715	161,020	160,144	160,824
Cash dividends declared per share	\$ 0.375	\$ 0.375	\$ 1.125	\$ 1.125

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





**BIOVAIL CORPORATION**

**CONSOLIDATED STATEMENTS OF DEFICIT**

**In accordance with United States Generally Accepted Accounting Principles  
(All dollar amounts are expressed in thousands of U.S. dollars)**

**(Unaudited)**

	<b>Three Months Ended September 30</b>		<b>Nine Months Ended September 30</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Deficit, beginning of period	\$ (370,288)	\$ (191,623)	\$ (278,495)	\$ (232,733)
Cumulative effect of adoption of SFAS 159			2,343	
Net income	48,437	65,867	79,524	227,510
Cash dividends declared and dividend equivalents	(59,429)	(60,385)	(180,565)	(180,918)
Repurchase of common shares			(4,087)	
Deficit, end of period	\$ (381,280)	\$ (186,141)	\$ (381,280)	\$ (186,141)

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

## BIOVAIL CORPORATION

## CONSOLIDATED STATEMENTS OF CASH FLOWS

In accordance with United States 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	
	2008	2007	2008	2007
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>				
Net income	\$ 48,437	\$ 65,867	\$ 79,524	\$ 227,510
<b>Adjustments to reconcile net income to net cash provided by (used in) operating activities</b>				
Depreciation and amortization	24,781	21,220	75,199	67,481
Amortization and write-down of deferred financing costs	130	117	390	4,691
Amortization and write-down of discounts on long-term obligations				962
Payment of accrued legal settlements, net of insurance recoveries	(83,048)	(14,400)	(93,048)	(14,400)
Additions to accrued legal settlements	2,000		26,648	
Accrued contract costs	(45,065)	(8,000)	(45,065)	(8,000)
Stock-based compensation	1,567	1,734	6,740	8,771
Gain on disposal of investment	(4,156)		(7,617)	(15,716)
Impairment charges	1,465		57,055	
Equity loss		432	1,195	1,325
Premium paid on early extinguishment of debt				7,854
Contract recoveries		(123)		(1,735)
Other	429	1,737	(624)	2,816
Changes in operating assets and liabilities:				
Accounts receivable	(5,952)	4,094	12,564	32,904
Insurance recoveries receivable	44	3,509	6,130	(451)
Inventories	77	891	9,989	(6,641)
Prepaid expenses and other current assets	(3,306)	(4,326)	4,218	3,314
Accounts payable	(3,896)	(11,054)	(16,459)	(968)
Accrued liabilities	3,003	(22,757)	(397)	(22,743)
Income taxes payable	2,384	2,677	9,827	(871)
Deferred revenue	(1,264)	1,797	(28,907)	(24,583)
Net cash provided by (used in) operating activities	(62,370)	43,415	97,362	261,520
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>				
Acquisition of business, net of cash acquired	(99,630)		(99,630)	
Transfer from restricted cash	83,048		83,048	
Transfer to restricted cash			(83,048)	
Proceeds from the sale of short-term investments			79,735	
Addition to short-term investments			(79,725)	
Additions to property, plant and equipment, net	(3,931)	(10,561)	(21,316)	(23,640)
Proceeds from sale of long-term investments, net of costs	8,712		20,899	37,769
Additions to restricted assets	(16)		(4,931)	
Additions to marketable securities	(999)	(31,938)	(4,781)	(32,270)
Proceeds from sales and maturities of marketable securities		1,285	4,450	1,599
Net cash used in investing activities	(12,816)	(41,214)	(105,299)	(16,542)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>				
Cash dividends paid	(59,518)	(60,385)	(180,286)	(261,140)
Repurchase of common shares			(25,538)	

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

Repayment of deferred compensation obligation, net	(31)	(23)	(183)	(283)
Redemption of Senior Subordinated Notes				(406,756)
Repayments of other long-term obligations				(11,250)
Issuance of common shares		527		11,217
Net cash used in financing activities	(59,549)	(59,881)	(206,007)	(668,212)
Effect of exchange rate changes on cash and cash equivalents	(316)	128	(692)	600
Net decrease in cash and cash equivalents	(135,051)	(57,552)	(214,636)	(422,634)
Cash and cash equivalents, beginning of period	354,056	469,458	433,641	834,540
Cash and cash equivalents, end of period	\$ 219,005	\$ 411,906	\$ 219,005	\$ 411,906

**NON-CASH INVESTING ACTIVITIES**

Accrued but unpaid business acquisition costs	\$ (2,341)	\$	\$ (2,341)	\$
Proceeds receivable from sale of long-term investment	1,001		1,001	

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

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**1. DESCRIPTION OF BUSINESS**

The Company was established on March 29, 1994 and was continued under the *Canada Business Corporations Act* on June 29, 2005. The Company is engaged in the formulation, clinical testing, registration, manufacture, and commercialization of pharmaceutical products.

**2. SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The accompanying unaudited consolidated financial statements have been prepared by the Company in United States ("U.S.") dollars and in accordance with U.S. generally accepted accounting principles ("U.S. 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 condensed notes to the unaudited 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, 2007, filed on March 17, 2008 with the U.S. Securities and Exchange Commission ("SEC") and Canadian Securities Administrators (the "2007 Form 20-F"). 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, 2007. There have been no material changes to the Company's significant accounting policies since December 31, 2007, except as described below under "Adoption of New Accounting Standards".

**Use of Estimates**

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.

**Adoption of New Accounting Standards**

Effective January 1, 2008, the Company adopted Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurements" ("SFAS 157") for financial assets and financial liabilities. SFAS 157 establishes a framework for measuring fair value in U.S. GAAP, clarifies the definition of fair value within that framework, and expands disclosures about the use of fair value measurements. SFAS 157 applies to all other accounting pronouncements that require (or permit) fair value measurements, but does not require any new fair value measurements in U.S. GAAP. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (i.e., an exit price). In determining fair value, the Company uses various valuation techniques. SFAS 157 establishes

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

a hierarchy for inputs to valuation techniques used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that reflect assumptions market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. There are three levels to the hierarchy based on the reliability of inputs, as follows:

Level 1 Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets and liabilities in markets that are not active.

Level 3 Unobservable inputs for the asset or liability.

To the extent that the valuation technique is based on inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3.

The adoption of SFAS 157 for financial assets and financial liabilities did not have a material effect on the Company's consolidated financial statements, or result in any significant changes to its valuation techniques or key considerations used in valuations.

In October 2008, the FASB issued FASB Staff Position ("FSP") No. FAS 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active" ("FSP 157-3"), which clarifies the application of SFAS 157 in a market that is not active. FSP 157-3 was effective for the Company at September 30, 2008. The Company incorporated the additional guidance provided by FSP 157-3 in the measurement of fair value of the auction rate securities disclosed in note 5. The effect of the adoption of FSP 157-3 on the Company's consolidated financial statements was not material.

Effective January 1, 2008, the Company adopted SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS 159"). SFAS 159 provides companies with an option to report many financial instruments and certain other items at fair value. The Company elected the fair value option for available-for-sale securities owned by its equity method investee in order to conform to the classification of those investments as trading securities by that investee. At January 1, 2008, the cumulative effect of the adoption of SFAS 159 resulted in the reclassification of an unrealized holding gain on those investments of \$2,343,000 from accumulated other comprehensive income to opening deficit. The Company did not elect the fair value option for any other eligible financial assets and financial liabilities that were not previously recorded at fair value.

Emerging Issues Task Force ("EITF") Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3"), became effective for new contracts entered into on or after January 1, 2008. Under EITF 07-3, non-refundable advance payments for goods and services that will be used in future research and development activities

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

should be recognized as an expense as the goods are delivered or the services are performed rather than when the payment is made. The adoption of EITF Issue No. 07-3 did not have any impact on the Company's consolidated financial statements.

**Recently Issued Accounting Standards, Not Adopted as of September 30, 2008**

In June 2008, the FASB issued SFAS No. 162, "The Hierarchy of Generally Accepted Accounting Principles" ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements presented in conformity with U.S. GAAP. This Statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles". The adoption of SFAS 162 is not expected to have any impact on the Company's consolidated financial statements.

In April 2008, the FASB issued FSP No. FAS 142-3, "Determination of the Useful Life of Intangible Assets" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "Goodwill and Other Intangible Assets" and also requires expanded disclosure related to the determination of intangible asset useful lives. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. Accordingly, the Company is required to apply the guidance of FSP 142-3 for determining useful life to intangible assets acquired on or after January 1, 2009 and the disclosure requirements of FSP 142-3 to intangible assets recognized as of or after January 1, 2009.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133" ("SFAS 161"). SFAS 161 applies to all derivative instruments and related hedged items accounted for under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"). SFAS 161 requires disclosures about how and why an entity uses derivative instruments; how derivative instruments and related hedged items are accounted for under SFAS 133; and how derivative instruments and related hedged items affect an entity's financial position, results of operations, and cash flows. SFAS 161 is effective for fiscal years beginning after December 15, 2008, with early adoption permitted. Accordingly, the Company is required to adopt the disclosure requirements of this standard beginning January 1, 2009.

In February 2008, the FASB issued FSP No. FAS 157-2, "Effective Date of FASB Statement No. 157", which defers the effective date of SFAS 157 for one year for certain nonfinancial assets and liabilities, except those that are recognized or disclosed at fair value on a recurring basis (at least annually). Accordingly, the Company is required to adopt SFAS 157 for nonfinancial assets and liabilities beginning January 1, 2009. The Company is currently evaluating the effect that the adoption of SFAS 157 for nonfinancial assets and liabilities will have on its consolidated financial statements.

In December 2007, the EITF issued EITF Issue No. 07-1, "Accounting for Collaborative Arrangements" ("EITF 07-1"). EITF 07-1 provides guidance for determining if a collaborative arrangement exists and establishes reporting requirements for revenues and costs generated from transactions between parties within a collaborative arrangement, as well as between the parties in a collaborative arrangement and third parties, and provides guidance for financial statement disclosures of collaborative arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and is required to be applied retrospectively to all prior periods where collaborative arrangements existed as of the effective date.

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**2. SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Accordingly, the Company is required to adopt EITF 07-1 beginning January 1, 2009. The Company is currently evaluating the effect that the adoption of EITF 07-1 will have on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS 141R") and SFAS 160, "Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51" ("SFAS 160"). These standards significantly change the accounting for, and reporting of, business combination transactions and noncontrolling (minority) interests in consolidated financial statements, including requirements to recognize noncontrolling interests at fair value; capitalize in-process research and development assets acquired; and expense acquisition related costs as incurred. SFAS 141R and SFAS 160 are required to be adopted simultaneously, and are effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. Accordingly, the Company is required to adopt SFAS 141R for business combinations occurring on or after January 1, 2009. As the Company currently has no minority interests, the adoption of SFAS 160 beginning January 1, 2009 is not expected to have a material effect on its consolidated financial statements.

**3. ACQUISITION OF PRESTWICK PHARMACEUTICALS, INC.**

On September 16, 2008, the Company acquired 100% of Prestwick Pharmaceuticals, Inc. ("Prestwick"). The acquisition of Prestwick was accounted for as a business combination under the purchase method of accounting. Accordingly, the results of Prestwick's operations have been included in the Company's consolidated financial statements since September 16, 2008. Prestwick is a U.S.-based pharmaceutical company that holds the U.S. and Canadian licensing rights to tetrabenazine tablets (known as Xenazine® in the U.S. and Nitoman® in Canada). Prestwick acquired those licensing rights from Cambridge Laboratories (Ireland) Ltd. ("Cambridge"), the worldwide license holder of tetrabenazine. On August 15, 2008, a New Drug Application for Xenazine® received U.S. Food and Drug Administration ("FDA") approval for the treatment of chorea associated with Huntington's disease and was granted Orphan Drug designation by the FDA, which provides the product with seven years of market exclusivity in the U.S. Nitoman® has been available in Canada since 1996. The acquisition of Prestwick is aligned with the Company's new strategic focus on specialty products targeting central nervous system ("CNS") disorders.

Prior to the Company's acquisition of Prestwick, Prestwick entered into a supply and distribution agreement with Ovation Pharmaceuticals, Inc. ("Ovation") for Xenazine® in the U.S. Ovation paid Prestwick \$50,000,000 for the exclusive rights to market and distribute Xenazine® for an initial term of 15 years. Following its acquisition of Prestwick, the Company will supply Xenazine® product to Ovation for a variable percentage of Ovation's annual net sales of the product. For annual net sales up to \$125,000,000, the Company's supply price will be 72% of net sales. Beyond \$125,000,000, the Company's supply price will be 65% of net sales. At both tiers, the Company will acquire Xenazine® product from Cambridge at a supply price of 50% of Ovation's net sales.



## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 3. ACQUISITION OF PRESTWICK PHARMACEUTICALS, INC. (Continued)

The total purchase price, including estimated acquisition costs of \$3,160,000, less cash acquired of \$1,067,000, was \$101,971,000. The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the date of acquisition.

Current assets (excluding cash acquired)	\$ 2,164
Intangible assets	157,916
Current liabilities (excluding deferred revenue)	(8,109)
Deferred revenue:	
Current	(3,000)
Long-term	(47,000)
Net assets acquired	\$ 101,971

The preceding purchase price allocation is preliminary and is based on information that was available as of the acquisition date to estimate the fair value of the assets acquired and liabilities assumed. Management believes that the information provides a reasonable basis for allocating the purchase price, but the Company is awaiting Prestwick's closing balance sheet and other additional information necessary to complete the purchase price allocation. The Company expects to receive the information to complete the purchase price allocation prior to the end of 2008.

**Intangible Assets**

The identifiable intangible assets have an estimated useful life of approximately 10 years based on the preliminary purchase price allocation.

**Severance Benefits**

The current liabilities assumed at the date of acquisition include \$3,477,000 related to severance benefits payable to 12 employees of Prestwick who were terminated as a result of the acquisition. The affected employees were notified prior to September 30, 2008 and the related benefits substantially paid out prior to the end of October 2008.

**Research and Development**

At the date of acquisition, Prestwick had a number of other CNS products in early-stage development, including Lisuride Sub Q (advanced Parkinson's disease), Lisuride Patch (Parkinson's disease) and D-Serine (schizophrenia). The Company does not intend to pursue the development of those products based on its assessment of their technical feasibility and/or commercial viability. In addition, Prestwick obtained options from Cambridge to participate in the development of future tetrabenazine products. As of the date of acquisition, Prestwick had not undertaken any development efforts related to those tetrabenazine products. As a result, no amount was allocated to any of these products in the purchase price allocation.

## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 3. ACQUISITION OF PRESTWICK PHARMACEUTICALS, INC. (Continued)

## Pro Forma Information

The following table presents pro forma results of operations as if the acquisition of Prestwick had occurred as of January 1, 2007, and includes amortization of the identifiable intangible assets and excludes Prestwick stock-based compensation expense. Prestwick's results of operations for the periods presented reflected the cost of research and development activities conducted for purposes of obtaining FDA approval for Xenazine®. This pro forma information is not necessarily indicative of the Company's results of operations had Prestwick been acquired as of January 1, 2007, nor necessarily indicative of the future results of operations of the Company.

	Three Months Ended September 30		Nine Months Ended September 30	
	2008	2007	2008	2007
Revenue	\$ 182,219	\$ 190,226	\$ 579,638	\$ 642,529
Net income	42,324	56,544	58,606	200,346
Basic and diluted earnings per share	\$ 0.27	\$ 0.35	\$ 0.37	\$ 1.25

## 4. RESTRUCTURING

The following table summarizes the major components of the restructuring costs recognized in the three months and nine months ended September 30, 2008:

	Asset Impairments		Employee Termination Benefits		Operating Lease Obligation	Contract Termination and Other Costs	Total
	Puerto Rico	Ireland	Puerto Rico	Ireland	Bridgewater		
Balance, January 1, 2008	\$	\$	\$	\$	\$	\$	\$
Costs incurred and charged to expense	42,275	9,000	275			210	51,760
Cash payments						(210)	(210)
Non-cash adjustments	(42,275)	(9,000)					(51,275)
Balance, June 30, 2008			275				275
Costs incurred and charged to expense		242	1,718	2,896	2,533	198	7,587
Cash payments						(198)	(198)
Non-cash adjustments		(242)		(65)	(769)		(1,076)
Balance, September 30, 2008	\$	\$	\$ 1,993	\$ 2,831	\$ 1,764	\$	\$ 6,588

## Puerto Rico Manufacturing Facilities

On May 8, 2008, the Company announced its intention to close its two manufacturing facilities located in Puerto Rico over the succeeding 18 to 24 months (the "shutdown period"). The Company is in the early stages of closing down these facilities and transferring certain manufacturing processes to its Steinbach, Manitoba manufacturing facility. The closure of the Puerto Rico facilities is intended to reduce the Company's cost infrastructure and improve the capacity utilization of its manufacturing operations.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

The Company conducted an impairment review of the property, plant and equipment located in Puerto Rico to determine if the carrying value of those assets was recoverable based on the expected cash flows

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**4. RESTRUCTURING (Continued)**

from their remaining use during the shutdown period and their eventual disposition. That review indicated that the cash flows were not sufficient to recover the carrying value of the property, plant and equipment, and, as a result, an impairment charge of \$42,275,000 was required to write down the carrying value of those assets to their estimated fair value. Fair value was determined based on market values for comparable assets.

The Company also expects to incur employee termination costs of approximately \$9,600,000 for severance and related benefits payable to the approximately 255 employees who will be terminated as a result of the planned closure of the Puerto Rico facilities. Those employees will be required to provide service to the Company during the shutdown period in order to be eligible for termination benefits. Accordingly, the Company will recognize the cost of those employee termination benefits ratably over the required future service period, including \$1,718,000 and \$1,993,000 recognized in the three months and nine months ended September 30, 2008, respectively.

**Ireland Research and Development Facility**

As of June 30, 2008, the Company had concluded that it was more-likely-than-not that it would close its research and development facility in Dublin, Ireland, as part of its plans to rationalize its pharmaceutical sciences operations. As a result, the Company recorded impairment charges of \$242,000 and \$9,242,000 in the three months and nine months ended September 30, 2008, respectively, related to the write-down of the carrying value of the building and equipment located in Ireland to their estimated fair value. Fair value was determined based on market values for comparable assets.

As of September 1, 2008, the Company committed to a plan to sell the Ireland facility (which comprises land, building and equipment) and has initiated a program to locate a buyer. The Company expects a sale transaction to be completed within the next 12 months subject to market conditions. Accordingly, the Ireland facility has been reclassified as held for sale on the consolidated balance sheet at September 30, 2008.

In August 2008, the Company concluded a 30-day consultation process with an employee representative group to discuss matters associated with the closure of the Ireland facility, including support for the approximately 50 employees who would be affected by this closure. Based on the outcome of that consultation process, the Company recognized costs related to employee terminations of \$2,896,000 in the three months ended September 30, 2008. The termination of the affected employees and closure of the Ireland facility is expected to be completed prior to the end of 2008.

**Bridgewater Facility**

In connection with the May 2005 restructuring of its U.S. commercial operations, the Company vacated a portion of its Bridgewater, New Jersey facility. The Company recognized a restructuring charge at that time for a gross operating lease obligation related to the vacant space offset by estimated sublease rentals that could be reasonably obtained. The Company's evaluation of current and expected general economic and commercial real estate market conditions as of September 30, 2008 indicated that an additional charge of \$2,533,000 was required to reflect lower estimated future sublease rentals, based on the expected time required to locate and contract a suitable sublease and the expected market rates for such a sublease. The Company will continue to assess the need to update the original restructuring charge related to this

## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 4. RESTRUCTURING (Continued)

operating lease obligation based on changes in the expected time it will take to sublease the vacant space and the expected sublease terms.

## 5. FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company's financial assets recorded at fair value have been categorized based on the fair value hierarchy in accordance with SFAS 157 (as described in note 2). The following fair value hierarchy table presents the components and classification of the Company's financial assets measured at fair value at September 30, 2008:

	Carrying Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale debt securities	\$ 128,777	\$ 114,928	\$ 13,849	\$
Available-for-sale equity securities	7,770	7,770		
Auction rate securities	12,499			12,499
Total financial assets	\$ 149,046	\$ 122,698	\$ 13,849	\$ 12,499
Cash and cash equivalents	\$ 118,135	\$ 114,928	\$ 3,207	\$
Short-term investment	7,578	7,578		
Marketable securities	23,141		10,642	12,499
Long-term investments	192	192		
Total financial assets	\$ 149,046	\$ 122,698	\$ 13,849	\$ 12,499

Available-for-sale debt securities using Level 1 inputs include U.S. treasury bills and money market funds that are actively traded or have quoted prices. Available-for-sale debt securities using Level 2 inputs include corporate bonds and government bonds that have quoted prices in markets that are not active. Available-for-sale equity securities include publicly traded securities for which quoted market prices are available.

The Company did not have any financial liabilities at September 30, 2008 that were subject to fair value measurements under SFAS 157.

## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 5. FAIR VALUE OF FINANCIAL INSTRUMENTS (Continued)

The following table presents a reconciliation of auction rate securities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months and nine months ended September 30, 2008:

	Three Months Ended September 30 2008	Nine Months Ended September 30 2008
Balance, beginning of period	\$ 13,459	\$ 18,000
Total unrealized losses:		
Included in net income <sup>(1)</sup> :		
Arising during period		(2,920)
Reclassification from other comprehensive income (loss)	(960)	(1,230)
Included in other comprehensive income (loss):		
Arising during period	(960)	(2,531)
Reclassification to net income	960	1,230
Settlements		(50)
Balance, end of period	\$ 12,499	\$ 12,499
Total amount of unrealized losses for the period included in net income relating to securities still held at September 30, 2008	\$ (960)	\$ (4,150)

(1)

Included in loss on impairment of investments in the consolidated statement of income.

**Auction Rate Securities**

At September 30, 2008 and December 31, 2007, the Company had \$26,775,000 and \$26,825,000, respectively, of principal invested in nine individual auction rate securities. These securities have long-term maturities for which the interest rates are reset through a dutch auction typically each month. Those auctions historically have provided a liquid market for these securities. These securities represent interests in collateralized debt obligations supported by pools of residential and commercial mortgages or credit cards, insurance securitizations, and other structured credits, including corporate bonds. Some of the underlying collateral for these securities consists of sub-prime mortgages. With the liquidity issues experienced in global credit and capital markets, these securities have experienced multiple failed auctions as the amount of auction rate securities submitted for sale has exceeded the amount of purchase orders.

The estimated fair values of the auction rate securities at September 30, 2008 and December 31, 2007 were \$12,499,000 and \$18,000,000, respectively, which reflected write-downs of \$14,276,000 and \$8,825,000, respectively, to the cost bases at those dates. Although these securities continue to pay interest according to their stated terms, the Company recorded impairment charges of \$4,150,000 in the nine months ended September 30, 2008 and \$6,000,000 in the year ended December 31, 2007, reflecting the portion of the auction rate securities that the Company has concluded has an other-than-temporary decline in estimated fair value due to a shortfall in the underlying collateral value for those securities.

In addition, the Company recorded unrealized losses in other comprehensive income of \$1,301,000 in the nine months ended September 30, 2008 and \$2,825,000 in the year ended December 31, 2007, reflecting



## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 5. FAIR VALUE OF FINANCIAL INSTRUMENTS (Continued)

adjustments to the portion of the auction rate securities that the Company has concluded has a temporary decline in estimated fair value. The Company does not consider this decline in estimated fair value to be other-than-temporary based on the adequacy of the underlying collateral value for those securities. In addition, it is the Company's intent to hold those securities until a recovery in market value occurs (or until maturity if necessary), and based on its existing cash resources, together with cash expected to be generated by operations, the Company does not expect to be required to sell those securities at a loss.

Due to the lack of Level 1 or Level 2 observable market quotes for the auction rate securities, the Company utilized valuation models based on Level 3 unobservable inputs in order to estimate the fair value of these securities at September 30, 2008 and December 31, 2007, including models that consider the expected cash flow streams, and collateral values as reported in the Trustee Reports for the respective securities, which include adjustments for defaulted securities and further adjustments for purposes of collateralization tests as outlined in Trust Indentures. The key assumptions used in those models relate to the timing of cash flows, discount rates, estimated amount of recovery, and probabilities assigned to various liquidation scenarios. The valuation of the auction rates securities is subject to uncertainties that are difficult to predict. Factors that may impact the Company's valuation include changes to the credit ratings of these securities, the underlying assets supporting these securities, the rates of default of the underlying assets, the underlying collateral value, and overall market liquidity.

As there is uncertainty as to when or if market liquidity will return to normal, the Company has classified the auction rate securities as long-term marketable securities on the consolidated balance sheets at September 30, 2008 and December 31, 2007.

The Company has commenced arbitration proceedings in the State of New York against Credit Suisse Securities (USA) LLC ("Credit Suisse") in respect of these securities, as described in note 19.

## 6. SHORT-TERM INVESTMENT

In the three months ended September 30, 2008, the Company realized a gain of \$4,156,000 on the sale of 2,326,394 common shares of Depomed Inc. ("Depomed") for cash proceeds of \$9,713,000. The cost basis of the shares sold was determined using the average cost method. The Company intends to dispose of the remaining 2,076,114 common shares of Depomed it held as of September 30, 2008 within the next 12 months subject to market conditions. Consequently, the Company reclassified the \$7,578,000 estimated fair value of its remaining investment in Depomed as a short-term investment on the consolidated balance sheet at September 30, 2008.

## 7. INVENTORIES

	At September 30 2008	At December 31 2007
Raw materials	\$ 20,659	\$ 32,577
Work in process	19,480	14,748
Finished goods	30,012	33,420
	\$ 70,151	\$ 80,745



## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 8. ASSETS HELD FOR SALE

In addition to its Ireland facility classified as held for sale (as described in note 4), the Company has identified certain non-core assets for divestiture including a vacant parcel of land adjacent to its corporate office with a carrying value of \$1,051,000. As of September 30, 2008, the Company had received a conditional offer to purchase the property. The Company expects to complete the sale of the land prior to the end of 2008 subject to satisfaction of the closing conditions. Accordingly, the Company has reclassified the land as held for sale on the consolidated balance sheet at September 30, 2008. At December 31, 2007, the carrying value of the Ireland facility and land held for sale of \$17,480,000 in the aggregate was included in property, plant and equipment on the comparative consolidated balance sheet.

## 9. LONG-TERM INVESTMENTS

On June 24, 2008, the Company sold its entire investment in common shares and convertible debt of Financière Verdi ("Verdi") for cash consideration of \$12,187,000, resulting in a gain on disposal of \$3,461,000.

## 10. INTANGIBLE ASSETS

	At September 30, 2008		At December 31, 2007	
	Cost	Accumulated Amortization	Cost	Accumulated Amortization
Trademarks	\$ 573,751	\$ 199,010	\$ 573,751	\$ 177,210
Product rights	502,845	139,469	344,929	119,402
Technology	14,800	7,095	14,800	6,354
	1,091,396	\$ 345,574	933,480	\$ 302,966
Less accumulated amortization	345,574		302,966	
	\$ 745,822		\$ 630,514	

## Amortization Expense

Amortization expense related to intangible assets that contribute to multiple business activities, including research and development, manufacturing and supply, royalty and licensing, and/or sales, marketing and distribution, is included in amortization expense. Amortization expense related to intangible assets that are associated with a single business activity is included in cost of goods sold, or other income statement line item, as appropriate.

Amortization expense related to intangible assets was recorded as follows:

	Three Months Ended September 30		Nine Months Ended September 30	
	2008	2007	2008	2007
Royalty and other revenue	\$ 268	\$ 268	\$ 804	\$ 804
Cost of goods sold	2,026	2,026	6,077	6,077
Amortization expense	12,342	11,979	35,727	35,942

\$ 14,636 \$ 14,273 \$ 42,608 \$ 42,823

## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 11. RESTRICTED ASSETS

In March 2008, under the terms of its reinsurance agreement, the Company provided security in trust in the amount of \$4,900,000, which has been recorded in other long-term assets on the consolidated balance sheet.

## 12. ACCRUED LEGAL SETTLEMENTS

	At September 30 2008	At December 31 2007
U.S. Department of Justice investigation	\$ 24,648	\$
U.S. securities class action		138,000
SEC investigation		10,000
Other	2,000	
	\$ 26,648	\$ 148,000

**U.S. Department of Justice Investigation**

As of May 16, 2008, the Company accrued \$24,648,000 relating to an agreement in principle to settle the U.S. Department of Justice ("DOJ") investigation into activities surrounding the 2003 commercial launch of Cardizem® LA (as described in note 19). Payment of that amount is pending final Court approval of this agreement.

**U.S. Securities Class Action**

At December 31, 2007, the Company had accrued \$138,000,000 in connection with an agreement to settle a number of securities class actions in the U.S. (as described in note 19), and recognized a receivable for the portion of the settlement amount expected to be recovered through insurance claims. On May 9, 2008, the Company paid \$83,048,000 in escrow to fund the settlement amount and its insurance carriers funded the remaining \$54,952,000. The escrow amount was dispersed upon receipt of final Court approval of this settlement on August 8, 2008.

**SEC Investigation**

At December 31, 2007, the Company had accrued an amount of \$10,000,000 relating to a potential settlement of the SEC investigation (as described in note 19), which was paid on March 24, 2008 to fully settle this matter.

## 13. ACCRUED CONTRACT COSTS

At December 31, 2007, the Company had recognized a liability of \$45,065,000 for a contractual amount owed to GlaxoSmithKline plc ("GSK") under the terms of the Wellbutrin XL® agreement. The maximum amount of this liability was reduced by the total dollar amount of Wellbutrin XL® sample supplies purchased by GSK prior to the introduction of generic competition to Wellbutrin XL®. In July 2008, the Company settled this liability by means of a cash payment to GSK.

## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 14. SHARE REPURCHASE PROGRAM

On May 8, 2008, the Company announced that its Board of Directors had approved a share repurchase program of up to 14,000,000 common shares, representing approximately 9% of the Company's issued and outstanding common shares. On June 2, 2008, the Company commenced a share repurchase program to purchase initially up to 8,051,186 common shares through the facilities of the New York Stock Exchange, representing approximately 5% of the Company's issued and outstanding common shares at that date. Following additional filings, the Company may also purchase shares over the Toronto Stock Exchange.

As of June 30, 2008, a total of 2,318,400 common shares had been repurchased through open-market transactions on the New York Stock Exchange, at a weighted-average price of \$11.01 per share, for total consideration of \$25,538,000. The excess of the cost of the common shares repurchased over their assigned value, totaling \$4,087,000, was charged to deficit. No additional common shares were repurchased during the three-month period ended September 30, 2008. The share repurchase program will terminate on June 1, 2009, or upon such earlier time that the Company completes its purchases.

Under the terms of its credit facility, the Company is not permitted to repurchase common shares in excess of \$50,000,000 in the aggregate in any given calendar year without obtaining the lenders' prior consent. The Company has not requested or obtained such consent.

## 15. STOCK-BASED COMPENSATION

## Stock Options and Restricted Share Units

The Company recognizes stock-based compensation expense related to stock options and restricted share units ("RSUs") on a straight-line basis over the requisite service period of the individual stock option or RSU grant, which generally equals the vesting period. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The following table summarizes the components and classification of stock-based compensation expense related to stock options and RSUs:

	Three Months Ended September 30		Nine Months Ended September 30	
	2008	2007	2008	2007
Stock options	\$1,111	\$1,734	\$4,319	\$8,771
RSUs	456		2,421	
Stock-based compensation expense	\$1,567	\$1,734	\$6,740	\$8,771
Cost of goods sold	\$ 194	\$ 160	\$ 449	\$ 714
Research and development expenses	247	275	684	1,319
Selling, general and administrative expenses	1,126	1,299	5,607	6,738
Stock-based compensation expense	\$1,567	\$1,734	\$6,740	\$8,771

In the nine months ended September 30, 2008, stock-based compensation expense included \$2,131,000 related to previously unrecognized compensation expense recognized upon the cancellation in May 2008 of certain stock options and RSUs previously

granted to the Company's current Chairman of the Board of

## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 15. STOCK-BASED COMPENSATION (Continued)

Directors, Dr. Douglas Squires, following his ceasing to serve as the Company's Chief Executive Officer ("CEO").

The Company did not recognize any tax benefits for stock-based compensation expense in the three months or nine months ended September 30, 2008 and 2007.

The following table summarizes stock option activity during the nine months ended September 30, 2008:

	Options (000s)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2008	5,256	\$ 23.02		
Granted	1,059	10.71		
Expired or forfeited	(1,594)	26.89		
Cancelled	(37)	10.83		
Outstanding, September 30, 2008	4,684	\$ 19.07	2.7	\$
Vested and exercisable, September 30, 2008	3,086	\$ 20.44	2.1	\$

The weighted-average grant-date fair value of all stock options granted in the nine months ended September 30, 2008 was \$1.07. No stock options were exercised in the nine months ended September 30, 2008. At September 30, 2008, the total remaining unrecognized compensation expense related to non-vested stock options amounted to \$4,573,000, which will be amortized over the weighted-average remaining requisite service period of approximately 15 months.

The following table summarizes non-vested RSU activity during the nine months ended September 30, 2008:

	RSUs (000s)	Weighted-Average Grant-Date Fair Value
Outstanding, January 1, 2008	125	\$ 20.18
Granted	217	13.26
Reinvested dividend equivalents	25	11.38
Vested	(10)	13.20
Forfeited	(27)	13.16
Cancelled	(89)	19.75
Outstanding, September 30, 2008	241	\$ 14.25

At September 30, 2008, the total remaining unrecognized compensation expense related to non-vested RSUs amounted to \$2,414,000, which will be amortized over the weighted-average remaining requisite service period of approximately 35 months.

## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 15. STOCK-BASED COMPENSATION (Continued)

## Deferred Share Units

The following table summarizes Deferred Share Unit ("DSU") activity during the nine months ended September 30, 2008:

	DSUs (000s)	Weighted-Average Grant-Date Fair Value
Outstanding, January 1, 2008	244	\$ 20.49
Granted	130	9.97
Reinvested dividend equivalents	14	11.17
Settled for cash	(162)	20.46
Outstanding, September 30, 2008	226	\$ 13.86

In the three months ended June 30, 2008, a cash payment of \$1,754,000 was made to settle the 128,309 DSUs previously granted to Eugene Melnyk, following his resignation as an officer and director of Biovail Laboratories International SRL ("BLS"), and total cash payments of \$367,000 were made to settle the 33,422 DSUs previously granted to two directors of the Company, following their resignation from the Board of Directors.

The Company had a liability related to DSUs outstanding at September 30, 2008 and December 31, 2007 of \$2,209,000 and \$3,275,000, respectively, based on the trading price of the Company's common shares as of those dates. In the nine months ended September 30, 2008, the Company recorded compensation expense related to DSUs of \$899,000, compared with \$364,000 recorded in the nine months ended September 30, 2007.

## 16. INCOME TAXES

The increase in the Company's effective tax rates in the three months and nine months ended September 30, 2008, compared with the three months and nine months ended September 30, 2007, was primarily due to charges associated with the agreement in principle to settle the DOJ investigation (as described in note 19) and restructuring activities (as described in note 4) that are not deductible or do not affect the income tax provision because of unrecognized tax losses in the local jurisdictions. In addition, certain components of the provision for income taxes do not vary with pre-tax income, including withholding taxes and provisions for uncertain tax positions.

## BIOVAIL CORPORATION

## CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)

(Unaudited)

## 17. EARNINGS PER SHARE

Earnings per share were calculated as follows:

	Three Months Ended September 30		Nine Months Ended September 30	
	2008	2007	2008	2007
Net income	\$ 48,437	\$ 65,867	\$ 79,524	\$ 227,510
Basic weighted average number of common shares outstanding (000s)	158,715	161,020	160,144	160,777
Dilutive effect of stock options and RSUs (000s)				47
Diluted weighted average number of common shares outstanding (000s)	158,715	161,020	160,144	160,824
Basic and diluted earnings per share	\$ 0.31	\$ 0.41	\$ 0.50	\$ 1.41

In the three months and nine months ended September 30, 2008, stock options to purchase approximately 4,274,000 and 4,622,000 common shares of the Company, respectively, had exercise prices greater than the average trading price of the Company's common shares, and were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive, compared with 3,261,000 and 4,879,000 stock options in the three months and nine months ended September 30, 2007, respectively.

## 18. COMPREHENSIVE INCOME

Comprehensive income comprised the following:

	Three Months Ended September 30		Nine Months Ended September 30	
	2008	2007	2008	2007
Net income	\$ 48,437	\$ 65,867	\$ 79,524	\$ 227,510
<b>Comprehensive income</b>				
Foreign currency translation adjustment:				
Arising during period	(7,941)	6,874	(12,442)	20,017
Reclassification to net income <sup>(1)</sup>	(868)		828	
Unrealized holding loss on auction rate securities:				
Arising during period	(960)	(2,700)	(2,531)	(2,700)
Reclassification to net income	960		1,230	
Net unrealized holding loss on available-for-sale securities				
Arising during period	2,886	(10,516)	2,374	(6,904)
Reclassification to net income	(3,832)		(3,832)	
Cumulative effect of adoption of SFAS 159			(2,343)	
Other comprehensive income (loss)	(9,755)	(6,342)	(16,716)	10,413



Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

Comprehensive income \$ 38,682 \$ 59,525 \$ 62,808 \$ 237,923

---

(1)

The foreign currency translation adjustment reclassified to net income is included in foreign exchange gain (loss) in the consolidated statement of income and resulted from the substantially complete liquidation of the assets of the Company's Irish subsidiary group.

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. 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.

Unless otherwise indicated, the Company cannot reasonably predict the outcome of these legal proceedings, nor can it estimate the amount of loss, or range of loss, if any, that may result from these proceedings. An adverse outcome in certain of these proceedings could have a material adverse effect on the Company's business, financial condition and results of operations, and could cause the market value of the Company's common shares to decline.

From time to time, the Company also initiates actions or files counterclaims. The Company could be subject to counterclaims or other suits in response to actions it may initiate. The Company cannot reasonably predict the outcome of these proceedings, some of which may involve significant legal fees. The Company believes that the prosecution of these actions and counterclaims is important to preserve and protect the Company, its reputation and its assets.

**Governmental and Regulatory Inquiries**

In July 2003, the Company received a subpoena from the U.S. Attorney's Office ("USAO") for the District of Massachusetts requesting information related to the promotional and marketing activities surrounding the commercial launch of Cardizem® LA. In particular, the subpoena sought information relating to the Cardizem® LA Clinical Experience Program, titled P.L.A.C.E. (Proving L.A. Through Clinical Experience). In October 2007, the Company received an additional related subpoena.

On May 16, 2008, Biovail Pharmaceuticals, Inc. (now Biovail Pharmaceuticals LLC), a subsidiary of the Company, entered into a written plea agreement whereby it agreed to plead guilty to violating the U.S. Anti-Kickback Statute and pay a fine of \$22,243,590. A hearing before the United States District Court in Boston where the plea agreement must be approved has not yet been scheduled but is expected to take place in December 2008. On May 16, 2008, Biovail Corporation entered into a non-prosecution agreement with the USAO whereby the USAO agreed to decline prosecution of Biovail Corporation in exchange for Biovail Corporation's continuing cooperation and in exchange for the Company's agreement to finalize a civil settlement agreement and pay a civil penalty of \$2,404,286. The civil settlement agreement has not yet been finalized.

On November 20, 2003, the Company received notification from the SEC indicating that the SEC would be conducting an informal inquiry relating to the Company's accounting and disclosure practices for the fiscal year 2003. These issues included whether or not the Company improperly recognized revenue and expenses for accounting purposes in relation to its financial statements in certain periods, disclosure related to these statements, and whether the Company provided misleading disclosure concerning the reasons for its forecast of a revenue shortfall in respect of the three-month period ended September 30, 2003 and certain transactions associated with a corporate entity acquired by the Company in 2002. On March 3, 2005, the Company received a subpoena from the SEC reflecting the fact that the SEC had entered a formal order of investigation. The subpoena sought information about the Company's financial reporting for the fiscal year 2003. Also, the scope of the investigation became broader than initially, and the period under review was extended to encompass the period January 1, 2001 to May 2004.

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. LEGAL PROCEEDINGS (Continued)**

On May 14, 2007, the Company issued a press release acknowledging that it had received a "Wells Notice" from the staff of the SEC alleging violations of federal securities laws related to the investigation described above. Four former officers also received Wells Notices shortly thereafter. The Company is indemnifying those individuals for legal expenses.

On March 24, 2008, the SEC filed a civil complaint against the Company, Eugene Melnyk, former Chairman and CEO, Brian Crombie, former Chief Financial Officer ("CFO"), and two former officers, Kenneth Howling and John Miszuk. The Company has entered into a Consent Decree with the SEC in which the Company has not admitted to the civil charges contained in the complaint but has paid \$10,000,001 to the SEC to fully settle the matter. As part of the settlement, the Company has also agreed to an examination of its accounting and related functions by an independent consultant. The settlement does not include the four individuals.

The Company has been contacted by the United States Attorney's Office for the Eastern District of New York ("EDNY"), who informed the Company that the office is conducting an investigation into the same matters that the SEC is investigating. The EDNY conducted interviews of several current or former Biovail employees and has requested documents related to fiscal years 2002 and 2003. The Company intends to cooperate with the investigation. The Company cannot predict the outcome or timing of when this matter may be resolved.

Over the last number of years, the Company has received a number of communications from the OSC relating to its disclosure, and/or seeking information pertaining to certain financial periods. The OSC had advised the Company that it was investigating whether the Company had improperly recognized revenue for accounting purposes in relation to the interim financial statements filed by the Company for each of the four quarters in 2001, 2002 and 2003, and related disclosure issues. The OSC also investigated whether the Company provided misleading disclosure concerning the reasons for Biovail's forecast of a revenue shortfall in respect of the three-month period ending September 30, 2003 and certain transactions associated with a corporate entity acquired by the Company in 2002, as well as issues relating to trading in the Company's common shares. These issues include whether insiders of the Company complied with insider reporting requirements, whether persons in a special relationship with the Company may have traded in the Company's shares with knowledge of undisclosed material information, 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 former directors of Biovail) may have had conflicts of interest in relation to the trading of the Company's shares.

Pursuant to a notice of hearing dated July 28, 2006, the staff of the OSC gave notice that an administrative hearing pursuant to sections 127 and 127.1 of the *Securities Act* (Ontario), R.S.O. 1990, c. S.5 (the "Ontario Securities Act") would be held related to the issues surrounding the trading in the Company's shares. The respondents in the hearing include former Chairman and CEO Eugene Melnyk and a former director of the Company, among others. The Company was not a party to this proceeding. The proceeding as against Eugene Melnyk has been settled. The hearing against the former director has concluded.

In a decision released June 20, 2008 a panel of the Ontario Securities Commission found that the former director acted contrary to the public interest and breached section 107 of the Securities Act when he: (i) failed to provide Biovail with accurate information concerning shares over which he shared control and direction; (ii) failed to file insider reports in respect of certain trades in Biovail securities; and (iii) engaged

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. LEGAL PROCEEDINGS (Continued)**

in a high volume of discretionary trading in Biovail securities during blackout periods imposed by Biovail. A sanctions hearing has not yet taken place.

Pursuant to a notice of hearing dated March 24, 2008, the staff of the OSC gave notice that an administrative hearing would be held related to the other matters investigated. The notice named the Company, former Chairman and CEO Eugene Melnyk, former CFO Brian Crombie, and Kenneth Howling and John Miszuk, two former officers. The hearing is scheduled to commence in February 2009.

**Securities Class Actions**

In late 2003 and early 2004, 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 of its former officers and a former director as defendants. On or about June 18, 2004, the plaintiffs filed a Consolidated Amended Complaint (the "Complaint"), alleging among other matters, that the defendants violated Sections 10(b) and 20(a) of the *Securities Exchange Act of 1934* (the "Exchange Act") and Rule 10b-5 promulgated thereunder. The Company responded to the Complaint by filing a motion to dismiss, which the Court denied. Thereafter, the Company filed its Answer denying the allegations in the Complaint.

On August 25, 2006, the plaintiffs filed a Consolidated Second Amended Class Action Complaint ("Second Amended Complaint") under seal. The Second Amended Complaint alleged, among other matters, that the defendants violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. More specifically, the Second Amended Complaint alleged 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.

In December 2007, the Company and the named individual defendants entered into an agreement in principle to settle this matter. The settlement was subject to approval by the United States District Court for the Southern District of New York. The settlement class included, with certain exceptions, all persons or entities that purchased the common stock of Biovail during the period from February 7, 2003 to March 2, 2004.

Under the terms of the agreement, the total settlement amount was \$138,000,000, out of which the Court-approved legal fees to the plaintiffs' counsel will be paid. On May 9, 2008, Biovail paid \$83,048,000 in escrow to fund the settlement amount (pending final Court approval of the settlement) and its insurance carriers funded the remaining \$54,952,000. The agreement contained no admission of wrongdoing by Biovail or any of the named individual defendants, nor did Biovail or any of the named defendants acknowledge any liability or wrongdoing by entering into the agreement.

The settlement received final Court approval on August 8, 2008.

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 claim sought damages in excess of \$100,000,000 for misrepresentation and breaches of s. 134 of the Ontario Securities Act and ss. 36 and 52 of the *Competition Act*, R.S. 1985, c. C-34, as well as class-wide punitive and exemplary damages. The claim essentially relied on the same facts and allegations as those cited in the Second Amended Complaint. The claim was served



**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. LEGAL PROCEEDINGS (Continued)**

on the Company and the named officers on September 29, 2005. The plaintiffs had not taken any steps to certify the action as a class proceeding or otherwise to move it forward.

On April 22, 2008, the Company and the individuals entered into an agreement to settle this matter. Under the terms of the agreement, the parties have agreed that the sole source of compensation for the plaintiffs will be the U.S. settlement funds referenced above. The agreement has received final court approval. The only issue outstanding is Canadian class counsel's entitlement to legal fees.

On October 8, 2008, the Company learned of a proposed securities class action lawsuit that has been filed in the U.S. District Court Southern District of New York against the Company, its Chairman and two former officers. The complaint has been filed on behalf of all persons and entities that purchased Biovail securities from December 14, 2006 through July 19, 2007. The complaint relates to public statements alleged to have been made in respect of Aplenzin (bupropion hydrobromide tablets) during the product's U.S. regulatory approval process. The Company believes the claim is completely without merit and will defend itself vigorously. The Company has not yet been served with the complaint.

**Antitrust**

Several class action or representative action complaints in multiple U.S. jurisdictions have been filed against the Company in which the plaintiffs have alleged that the Company improperly impeded the approval of a generic form of Tiazac®. Those actions filed in U.S. federal courts were filed in, or transferred to, and in some cases consolidated or coordinated 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 under the *Hatch-Waxman Act* and applicable law. Moreover, the Company's position is that it is not responsible for the inability of Andrx Corporation and Andrx Pharmaceuticals Inc. (collectively, the "Andrx Group") to receive timely final marketing approval from the FDA for its generic Tiazac® because the Andrx Group 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 all of the federal actions, which the federal plaintiffs appealed. These appeals were consolidated by the Court of Appeals. On July 25, 2008, the Court of Appeals affirmed the dismissal of those actions.

The Company has brought the Court's decision on Biovail's motions for Summary Judgment to the attention of the Superior Court of the State of California for Los Angeles County, the Superior Court of the State 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 the Andrx Group'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. The Court granted the Company's motion and dismissed the complaint with leave for the plaintiffs to file an amended complaint, which they filed. The Company then moved to dismiss the amended complaint. The Court also granted that motion and dismissed the amended complaint with prejudice. The plaintiffs moved to have the Court reconsider its decision, which the Court denied. The plaintiffs appealed, but their appeal was dismissed after they failed to file an appellate brief. The actions in the other California courts have now been stayed pending the final disposition of the cases pending in the District of Columbia. Now that the Court of Appeals has affirmed the dismissal of the federal claims, the California plaintiffs must decide

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. LEGAL PROCEEDINGS (Continued)**

whether or not they will pursue their state court actions. To date they have not taken any steps to pursue these actions since the Court of Appeals decision upholding summary judgment.

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. The Company believes these suits are without merit because, among other reasons, the Company believes 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 "indirect purchasers". The remainder of the federal action is proceeding on the merits through the normal legal process. A class certification took place on May 24, 2007 and, in November 2007, the Court approved certification of a class of alleged "direct purchasers". In December 2007, the Defendants moved for the Court to reconsider that decision. A hearing has not yet taken place. The case is in discovery.

On March 21, 2006, the Company was advised that an additional claim in respect of this fact situation was filed by Maxi Drug Inc. d/b/a Brooks Pharmacy in the United States District Court, District of Columbia. The Company has accepted service of this complaint, and the case will proceed on the merits according to the schedule set by the Court in the related federal cases pending in the District of Columbia.

On April 4, 2008, a direct purchaser plaintiff filed a class action antitrust complaint in the United States District Court for the District of Massachusetts against the Company and SmithKline Beecham Inc. alleging that the Company and SmithKline Beecham took actions to improperly delay FDA approval for generic forms of Wellbutrin XL®. The direct purchaser plaintiff in the Massachusetts federal court lawsuit voluntarily dismissed its complaint on May 27, 2008, and shortly thereafter refiled a virtually identical complaint in United States District Court for the Eastern District of Pennsylvania. In late May and early June 2008, a total of six additional direct and indirect purchaser class actions were also filed against the Company and SmithKline Beecham in the Eastern District of Pennsylvania, all making similar allegations.

The Company believes that each of these complaints lacks merit and that its challenged actions complied with all applicable laws and regulations, including federal and state antitrust laws, FDA regulations, U.S. patent law, and the Hatch-Waxman Act. The Company has not yet answered or otherwise responded to the complaints but has moved to dismiss all complaints. No decision has been rendered.

**Intellectual Property**

On February 3, 2006, the Company and Laboratoires Des Produits Éthiques Ethypharm instituted an action against Sandoz Canada Inc. ("Sandoz") and Andrx Group stating that certain patents applicable to Tiazac® have been infringed contrary to the *Patent Act* (Canada) by the defendants. In addition, the Company is seeking injunctive relief restraining the defendants from offering for sale and/or manufacturing in Canada any product covered by the Company's patents and/or procuring the infringement of the Company's patents.





**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. LEGAL PROCEEDINGS (Continued)**

The defendants served the Company with a Statement of Defence and Counterclaim on May 15, 2006. Biovail delivered its reply on May 30, 2006 and pleadings closed in June 2006. The matter is proceeding.

In August of 2006, Sandoz brought an action against the Company under section 8 of the Patented Medicine (NOC) Regulations demanding damages for having been kept off the market with its generic version of Tiazac® due to prohibition proceedings taken against Sandoz's predecessors RhoxalPharma Inc. by Biovail under the Patented Medicine (NOC) Regulations. The prohibition proceedings were subsequently dismissed in November of 2005. This action is at an early stage and the Company cannot assess the merits, if any, of the claim at this stage.

Apotex Inc. ("Apotex") has filed a submission with the Minister of Health in Canada, which seeks approval of APO-Metformin ER (500mg), a generic form of Glumetza®. In connection with that submission, Apotex has served the Company with a Notice of Allegation in respect of two patents listed in the Patent Register. Apotex alleges that APO-Metformin ER will not infringe the patents and, alternately, that the patents are invalid. On January 23, 2008, the Company instituted legal proceedings in the Federal Court of Canada that prevented the issuance of a Notice of Compliance to Apotex until these proceedings are concluded, or until the expiry of 24 months from the date that the Company's application in the Federal Court of Canada was issued, whichever is earlier. While a date for the hearing of the Company's application has not yet been established, it is anticipated that the matter will come to a hearing before a judge of the Federal Court of Canada by the end of 2009.

Par Pharmaceutical Companies, Inc. ("Par") filed an ANDA with the FDA seeking approval to market Tramadol Hydrochloride Extended Release Tablets, 200mg. On May 9, 2007, BLS, along with Purdue Pharma Products L.P., Napp Pharmaceutical Group Ltd. and Ortho-McNeil, Inc. ("OMI") filed a complaint in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 6,254,887 by the filing of that ANDA, thereby triggering a 30-month stay of FDA's approval of that application. Par has answered the complaint and asserted counterclaims of non-infringement and patent invalidity. The plaintiffs have denied the counterclaims. On May 22, 2007, Par informed the Company that it had filed a supplemental ANDA seeking approval to market Tramadol Hydrochloride Extended Release Tablets, 100mg. On June 28, 2007, the same plaintiffs filed another complaint in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 6,254,887 by the filing of that ANDA, thereby triggering a 30-month stay of FDA's approval of the 100mg strength formulation.

On July 23, 2007, Par answered the second complaint and asserted counterclaims of non-infringement and patent invalidity. A case schedule has now been set, pursuant to which trial is expected to commence on January 9, 2009. On September 24, 2007, Par informed the Company that it had filed another supplemental ANDA seeking approval to market Tramadol Hydrochloride Extended Release Tablets, 300mg. On October 24, 2007, the same plaintiffs filed another complaint in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 6,254,887 by the filing of that ANDA, thereby triggering a 30-month stay of FDA's approval of the 300mg strength formulation. A Markman hearing claims construction ruling was released on November 4, 2008.

BLS recently filed an unopposed motion for dismissal of BLS from the case. BLS expects that the motion will be granted. The case will continue between the remaining plaintiffs and Par. BLS's dismissal from the case is not expected to substantively impact the proceedings.

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. LEGAL PROCEEDINGS (Continued)**

On July 2, 2008, the Company received a Notice of Paragraph IV Certification for Tramadol Hydrochloride Extended-release Tablets, 100 mg, a generic version of Ultram® ER, from Impax. BLS has filed suit along with Purdue Pharma Products L.P., Napp Pharmaceutical Group Ltd. and OMI pursuant to the provisions of the Hatch-Waxman Act, therefore FDA approval of Impax's generic product will be automatically stayed until January 2, 2011. The case is now proceeding in the ordinary course.

On September 23, 2008, the Company received a Notice of Paragraph IV Certification for Tramadol Hydrochloride Extended-release Tablets, 200 mg and 300 mg, generic versions of Ultram® ER, from Impax. Purdue Pharma Products L.P., Napp Pharmaceutical Group Ltd. and OMI filed a complaint in the United States District Court for the District of Delaware alleging infringement of U.S. Patent No. 6,254,887 by the filing of that ANDA, thereby triggering a 30-month stay of the FDA's approval of that application.

BLS filed an ANDA with the FDA seeking approval to market Venlafaxine Hydrochloride Extended-Release capsules equivalent to the 37.5, 75 and 150 mg doses. On June 26, 2008, Wyeth filed a complaint against Biovail Corporation, Biovail Technologies Ltd. and BLS in the United States District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 6,274,171 B1 and 6,419,958 B2 by the filing of that ANDA, thereby triggering a 30-month stay of FDA's approval of that application. The case is in its preliminary stages and will proceed in the ordinary course. No trial date has been set.

On or about June 26, 2008, BLS received Notices of Paragraph IV Certification from Sun Pharmaceutical Industries, Ltd., India ("Sun India") for diltiazem hydrochloride extended-release capsules (120, 180, 240, 300, and 360 mg strengths), a generic version of Cardizem® CD. On August 8, 2008, BLS filed suit against Sun India in the U.S. District Court of New Jersey alleging patent infringement of U.S. Patent Nos. 5,470,584, 5,286,497 and 5,439,689 pursuant to the provisions of the Hatch-Waxman Act. BLS has also sought declaratory judgment of infringement for all three patents. These suits are expected to result in a 30-month stay of the FDA approval of the 120, 180, 240 and 300mg strengths, and may, subject to an appropriate finding by the trial court, result in a 30-month stay of approval on the 360mg strength. There are currently no unexpired patents listed against BLS's 360mg strength product listed in the FDA's Orange Book database. No trial date has been set.

BLS filed an ANDA with the FDA seeking approval to market Fenofibrate Tablets in 48 mg and 145 mg dosage sizes. On November 3, 2008, Abbott Laboratories and Laboratoires Fournier filed a complaint against Biovail Corporation and BLS in the United States District Court for the Northern District of Illinois alleging infringement of U.S. Patent Nos. 6,277,405, 7,037,529, and 7,041,319 by the filing of the ANDA, thereby triggering a 30-month stay of FDA's approval of that application. On November 3, 2008, Elan Pharma International Ltd and Fournier Laboratories Ireland Ltd also filed a complaint against Biovail Corporation and BLS in the United States District Court for the District of New Jersey alleging infringement of U.S. Patent Nos. 5,145,684, 7,276,249, and 7,320,802 by the filing of the ANDA. The answers of Biovail Corporation and BLS to these claims will be due 20 days after service of the complaints. These cases are in their preliminary stages and will proceed in the ordinary course. Case schedules have not yet been set.

**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 of its officers, and against Michael Sitrick and Sitrick & Company, Inc. (in their capacity as

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. LEGAL PROCEEDINGS (Continued)**

consultants to the Company), in which he 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 to dismiss this action, which, after rehearing, the Court granted in part and denied in part. In response, the plaintiff filed a second amended complaint on March 24, 2005, which generally repeated the allegations and asserted that all defendants acted in concert and participated in the defamatory and other alleged misconduct.

On May 27, 2005, Eugene Melnyk, the Company's former Chairman and CEO, filed an answer to the second amended complaint and a counterclaim against Mr. Treppel. This counterclaim alleges defamation, defamation per se, and civil conspiracy. Mr. Melnyk's claims relate to, among other things, written and oral communications made by Mr. Treppel that caused damage to Mr. Melnyk's professional and business reputation.

Biovail and the named defendants, including Mr. Melnyk, filed a motion to dismiss the second amended complaint. Mr. Treppel also moved to dismiss the counterclaim brought by Mr. Melnyk.

On August 30, 2005, the Court granted in part and denied in part the motion to dismiss Mr. Treppel's claims, and dismissed the case with prejudice against three of the five defendants. In the Order the Court further noted that the remaining claims against Biovail and the only remaining individual defendant, Mr. Melnyk, were 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 denied in part and granted in part Mr. Treppel's motion to dismiss Mr. Melnyk's counterclaims against Mr. Treppel. This counterclaim is therefore proceeding on certain of the claims of defamation and defamation per se made by Mr. Melnyk.

Discovery in this case is nearing completion.

**Biovail Action Against S.A.C. and Others**

On February 22, 2006, the Company filed a lawsuit in Superior Court, Essex County, New Jersey, seeking \$4.6 billion in damages from 22 defendants (the "S.A.C. Complaint"). The S.A.C. Complaint alleges that the defendants participated in a stock market manipulation scheme that negatively affected the market price of Biovail shares and alleges violations of various state laws, including the *New Jersey Racketeer Influenced and Corrupt Organizations Act* (RICO), pursuant to which treble damages may be available.

The original defendants included: S.A.C. Capital Management, LLC, S.A.C. Capital Advisors, LLC, S.A.C. Capital Associates, LLC, S.A.C. Healthco Funds, LLC, Sigma Capital Management, LLC, Steven A. Cohen, Arthur Cohen, Joseph Healey, Timothy McCarthy, David Maris, Gradient Analytics, Inc., Camelback Research Alliance, Inc., James Carr Bettis, Donn Vickrey, Pinnacle Investment Advisors, LLC, Helios Equity Fund, LLC, Hallmark Funds, Gerson Lehrman Group, Gerson Lehrman Group Brokerage Services, LLC, Thomas Lehrman, Patrick Duff, and James Lyle. The defendants Hallmark Funds and David Maris have been voluntarily dismissed from the action by the Company.

The lawsuit is in its early stages. No discovery has been conducted. All defendants have moved to dismiss the complaint. These motions have yet to be heard by the Court.

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. LEGAL PROCEEDINGS (Continued)**

On January 26, 2007, United States District Judge Richard Owen issued an Order in a securities class action proceeding against the Company in the United States District Court for the Southern District of New York (described more fully above) that sanctioned the Company for its use in the S.A.C. Complaint of certain documents obtained in lawful discovery in the securities class action. Judge Owen ordered the return of the documents and the redaction of the S.A.C. Complaint. On February 22, 2007, the Company filed an Amended Complaint.

Pursuant to a March 16, 2007 Order, this case has been stayed pending the resolution of motions to dismiss in a factually similar class action that does not involve the Company. This stay currently remains in force. On September 10, 2007, the Company resolved in part a motion for sanctions previously pending in the United States District Court for the Southern District of New York. As part of that resolution, the Company dismissed defendant David Maris from this action and filed a Second Amended Complaint on October 3, 2007, removing the name of David Maris and his employer, Banc of America Securities LLC ("BAS"), from the S.A.C. Complaint. Pursuant to this settlement Maris and BAS will participate in depositions and will produce certain documents upon subpoena.

**General Civil Actions**

Complaints have been filed by the City of New York, the State of Alabama, the 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 City of New York and plaintiffs for all the counties in New York (other than Erie, Oswego and Schenectady) have voluntarily dismissed the Company and certain others of the named defendants on a without prejudice basis. Similarly, the State of Mississippi has voluntarily dismissed its claim against the Company and a number of defendants on a without prejudice basis.

In the case brought by the State of Alabama, the Company has answered the State's Amended Complaint and discovery is ongoing. The cases brought by the New York State counties of Oswego, Schenectady and Erie, each of which was originally brought in New York State court, were removed by defendants to federal court on October 11, 2006. The Company answered the complaint in each case after the removal to federal court. The cases were subsequently remanded and, following the remand, the defendants made an application to the New York State Litigation Coordinating Panel for pretrial coordination of the three actions. That application is pending.

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 are successful, any recovery against Biovail would likely not be significant.

On May 6, 2008, BLS commenced an arbitration under FINRA rules against Credit Suisse seeking \$26,775,000 in compensatory damages and \$53,550,000 in punitive damages. The Statement of Claim alleges that Credit Suisse, as non-discretionary manager of BLS's cash management account, fraudulently or negligently and in breach of the parties' customer agreement, invested BLS's assets in auction rate securities, which were not among BLS's approved investments. Credit Suisse has now delivered its Answer

**BIOVAIL CORPORATION**

**CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**In accordance with United States Generally Accepted Accounting Principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**(Unaudited)**

**19. LEGAL PROCEEDINGS (Continued)**

and Response. The matter is in its preliminary stages and the Company anticipates it will proceed in the ordinary course.

**20. SEGMENT INFORMATION**

The Company operates in one operating segment 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.

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS**

**(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") should be read in conjunction with the unaudited consolidated financial statements, and condensed notes thereto, prepared in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP") for the interim period ended September 30, 2008. This MD&A should also be read in conjunction with the annual 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, 2007, filed on March 17, 2008 with the U.S. Securities and Exchange Commission ("SEC") and the Canadian Securities Administrators ("CSA") (the "2007 Form 20-F").

Additional information relating to our Company, including the 2007 Form 20-F, is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on the SEC's website at [www.sec.gov](http://www.sec.gov).

The discussion and analysis contained in this MD&A are as of November 7, 2008.

**FORWARD-LOOKING STATEMENTS**

To the extent any statements made in this MD&A 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, and may be forward-looking information under applicable Canadian provincial securities legislation (collectively, "forward-looking statements"). These forward-looking statements relate to, among other things, our objectives, goals, strategies, beliefs, intentions, plans, estimates, and outlook, including, without limitation, statements concerning the following:

Intent and timing to engage a contract sales organization to promote Zovirax®;

Intent and ability to implement and effectively execute plans associated with our New Strategic Focus and the anticipated impact of such New Strategic Focus, including our ability to complete acquisitions and to successfully integrate such acquisitions and to achieve the anticipated benefits of such acquisitions;

Timing regarding the planned closures of our Puerto Rico and Ireland operations and the associated costs, the anticipated impact of such closures, as well as the possible impact on our manufacturing processes;

Intent regarding and timing of the planned disposals of non-core assets;

Intent and ability to continue the repurchase of our common shares under our share repurchase program and make additional filings thereunder;

Additional expected charges and anticipated annual savings related to ongoing or planned efficiency initiatives;

Expected declines in revenue due to the introduction of generic competition to the 150mg Wellbutrin XL® product;

Expected impact of the acquisition of Prestwick Pharmaceuticals, Inc. ("Prestwick") on earnings per share and cash flows;

Expected timing of the launch of Xenazine® in the U.S.;

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

Amount and timing of expected contribution from our product-development pipeline;

Amount and timing of investment in research and development efforts;

Outcome of business development efforts;

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

Beliefs and positions related to, results of, and costs associated with certain litigation and regulatory proceedings, including, but not limited to, the outcome of the court hearing to approve an agreement reached between a subsidiary of our Company and the U.S. Department of Justice ("DOJ") related to activities surrounding the 2003 commercial launch of Cardizem® LA;

Views and beliefs related to the outcome of patent infringement trial proceedings regarding, and the timing of the introduction of generic competition related to, Ultram® ER;

Expected timing of the introduction of a generic version of Cardizem® LA ;

Impact that generic competition to the 360mg strength of Cardizem® CD may have on our product sales and the carrying value of the associated intangible asset;

Regulatory approval and product commercialization timelines;

Timing, results, and progress of research and development efforts;

Expected impact of the resolution of certain legacy litigation and regulatory proceedings and the impact associated with recently announced litigation proceedings;

Sufficiency of cash resources, including those available under the accordion feature of our credit facility, to support future spending requirements;

Intent and ability to make future dividend payments;

Expected capital expenditures and business development activities;

Investment recovery, liquidity, valuation, and impairment conclusions associated with auction rate securities;

Intent and ability to hold auction rate securities until a recovery in market value occurs (or until maturity if necessary);

Ability to manage exposure to foreign currency exchange rate changes; and

Expected impact of the adoption of new accounting standards.

These forward-looking statements may not be appropriate for other purposes.



Forward-looking statements can generally be identified by the use of 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. Although we have indicated above certain of these statements set out herein, all of the statements in this MD&A that contain forward-looking statements are qualified by these cautionary statements. Although we believe that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Certain material factors or assumptions are applied in making forward-looking statements, including, but not limited to, factors and assumptions regarding prescription trends, pricing and the formulary and/or Medicare/Medicaid positioning for our products; the competitive landscape in the markets in which we compete, including, but not limited to, the availability or introduction of generic formulations of our products; timelines associated with the development of, and receipt of regulatory approval for, our new products; and actual results may differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from these expectations include, among other things: the difficulty of predicting U.S. Food and Drug Administration ("FDA") and Canadian Therapeutic Products Directorate approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the results of continuing safety and efficacy studies by industry and government agencies, uncertainties associated with the development, acquisition and launch of new products, contractual disagreements with third parties, availability

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

of capital and ability to generate operating cash flows and satisfaction of applicable laws for dividend payments, the continuation of the recent market turmoil, market liquidity for our common shares, our satisfaction of applicable laws for the acquisition of our common shares, impact of a decline in our market capitalization on the carrying value of goodwill, reliance on key strategic alliances, delay in or transition issues arising from the closure of our Puerto Rico facilities, the successful implementation of our New Strategic Focus, our eligibility for benefits under tax treaties, the availability of raw materials and finished products, the regulatory environment, the unpredictability of protection afforded by our patents, the mix of activities and income in the various jurisdictions in which we operate, successful challenges to our generic products, infringement or alleged infringement of the intellectual property rights of others, unanticipated interruptions in our manufacturing operations or transportation services, the expense, timing and uncertain outcome of legal and regulatory proceedings and settlements thereto, payment by insurers of insurance claims, currency fluctuations, consolidated tax rate assumptions, fluctuations in operating results, the market liquidity and amounts realized for auction rate securities held as investments, and other risks detailed from time to time in our filings with the SEC and the CSA, as well as our ability to anticipate and manage the risks associated with the foregoing. Additional information about these factors and about the material factors or assumptions underlying such forward-looking statements may be found in the body of this MD&A (including below under the heading "Additional Risk Factors"), as well as under the heading "Risk Factors" under Item 3, Sub-Part D of the 2007 Form 20-F. We caution that the foregoing list of important factors that may affect future results is not exhaustive. When relying on our forward-looking statements to make decisions with respect to our Company, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. We undertake no obligation to update or revise any forward-looking statement.

**COMPANY PROFILE**

We are a specialty pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture and commercialization of pharmaceutical products. Our core competency lies in our expertise in the development and large-scale manufacture of pharmaceutical products incorporating oral drug-delivery technologies. We have a portfolio of products that includes the following brand names:

Wellbutrin® (bupropion) for the treatment of depression;

Ultram®/Ralivia (tramadol) for the treatment of moderate to moderately severe chronic pain;

Zovirax® (acyclovir) for the treatment of herpes; and

Cardizem®/Tiazac® (diltiazem) for the treatments of hypertension and angina.

We market and/or distribute our products in the U.S. principally through supply and distribution agreements with third-party strategic partners. Under those agreements, we manufacture and supply Wellbutrin XL® to GlaxoSmithKline plc ("GSK"); Ultram® ER to Ortho-McNeil, Inc. ("OMI"); Cardizem® LA to Kos Pharmaceuticals, Inc. ("Kos") (a subsidiary of Abbott Laboratories); Tiazac® branded and generic products to Forest Laboratories, Inc. ("Forest"); and bioequivalent (Generic) products to Teva Pharmaceuticals Industries Ltd. ("Teva").

Our Zovirax® products are distributed in the U.S. by our subsidiary BTA Pharmaceuticals, Inc., and were promoted by Sciele Pharma, Inc. ("Sciele") until October 10, 2008 under an exclusive promotional services agreement. On October 10, 2008, we terminated that agreement with Sciele as a result of Sciele's merger with Shionogi & Co., Ltd. effective October 9, 2008. We intend to engage a contract sales organization to take up the promotion of Zovirax® beginning in early 2009.

In Canada, we market and/or distribute a number of products, including Tiazac® XC, Wellbutrin® XL, Ralivia and Glumetza®, directly through our internal sales organization, Biovail Pharmaceuticals Canada ("BPC").



## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

## NEW STRATEGIC FOCUS

On May 8, 2008, we announced a new strategic focus (our "New Strategic Focus") on developing products targeted towards specialty central nervous system ("CNS") disorders. We also announced our intention to rationalize our manufacturing operations, pharmaceutical sciences operations, and general and administrative expenses. In addition, we announced our intention to commence a share repurchase program of up to 14,000,000 common shares.

## Acquisition of Prestwick

On September 16, 2008, we acquired 100% of Prestwick for a total net purchase price of approximately \$102.0 million (as described in note 3 to the unaudited consolidated financial statements for the interim period ended September 30, 2008). The acquisition of Prestwick was accounted for as a business combination under the purchase method of accounting. Accordingly, the results of Prestwick's operations have been included in our consolidated financial statements since September 16, 2008.

Prestwick holds the Canadian and U.S. licensing rights to tetrabenazine tablets (known as Xenazine® in the U.S. and Nitoman® in Canada). Prestwick acquired those licensing rights from Cambridge Laboratories (Ireland) Ltd. ("Cambridge"), the worldwide license holder of tetrabenazine. On August 15, 2008, a New Drug Application ("NDA") for Xenazine® received FDA approval for the treatment of chorea associated with Huntington's disease and was granted Orphan Drug designation by the FDA, which provides this product with seven years of market exclusivity in the U.S. Nitoman® has been available in Canada since 1996.

Xenazine® will be commercialized in the U.S. by Ovation Pharmaceuticals, Inc. ("Ovation") under an exclusive supply and marketing agreement entered into between Prestwick and Ovation prior to our acquisition of Prestwick. Ovation paid Prestwick \$50.0 million for the exclusive rights to market and distribute Xenazine® for an initial term of 15 years. We will supply Xenazine® product to Ovation for a variable percentage of Ovation's annual net sales of the product. For annual net sales up to \$125 million, our supply price will be 72% of net sales. Beyond \$125 million, our supply price will be 65% of net sales. At both tiers, we will acquire Xenazine® product from Cambridge at a supply price of 50% of Ovation's net sales. In addition, Prestwick held options to develop future related products with Ovation for the U.S. market in conjunction with Cambridge.

## Restructuring

The following table summarizes the major components of the restructuring costs recognized in the third quarter and first nine months of 2008:

(\$ in 000s)	Asset Impairments		Employee Termination Benefits		Operating Lease Obligation	Contract Termination and Other Costs	Total
	Puerto Rico	Ireland	Puerto Rico	Ireland	Bridgewater		
Balance, January 1, 2008	\$	\$	\$	\$	\$	\$	\$
Costs incurred and charged to expense	42,275	9,000	275			210	51,760
Cash payments						(210)	(210)
Non-cash adjustments	(42,275)	(9,000)					(51,275)
Balance, June 30, 2008			275				275
Costs incurred and charged to expense		242	1,718	2,896	2,533	198	7,587
Cash payments						(198)	(198)
Non-cash adjustments		(242)		(65)	(769)		(1,076)
Balance, September 30, 2008	\$	\$	\$ 1,993	\$ 2,831	\$ 1,764	\$	\$ 6,588



**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

***Puerto Rico Manufacturing Facilities***

In May 2008, we announced our intention to close our two Puerto Rico manufacturing facilities, and transfer certain manufacturing processes to our Steinbach, Manitoba facility, over a period of 18 to 24 months (the "shutdown period"). We believe the closure of the Puerto Rico facilities will reduce our cost infrastructure and improve the capacity utilization of our manufacturing operations.

We conducted an impairment review of the property, plant and equipment located in Puerto Rico to determine if the carrying value of those assets was recoverable based on the expected cash flows from their remaining use during the shutdown period and their eventual disposition. That review indicated that the cash flows were not sufficient to recover the carrying value of the property, plant and equipment, and, as a result, an impairment charge of \$42.3 million was required in the second quarter of 2008 to write down the carrying value of those assets to their estimated fair value. Fair value was determined based on market values for comparable assets.

We also expect to incur employee termination costs of approximately \$9.6 million for severance and related benefits payable to the approximately 255 employees who will be terminated as a result of the planned closure of the Puerto Rico facilities. Those employees will be required to provide service during the shutdown period in order to be eligible for termination benefits. Accordingly, we will recognize the cost of those employee termination benefits ratably over the required future service period, including \$1.7 million and \$2.0 million recognized in the third quarter and first nine months of 2008, respectively.

***Ireland Research and Development Facility***

As part of our plans to rationalize our pharmaceutical sciences operations, we have decided to close our research and development facility in Dublin, Ireland. As a result, we recorded impairment charges of \$242,000 and \$9.2 million in the third quarter and first nine months of 2008, respectively, to write down the carrying value of the building and equipment located in Ireland to their estimated fair value. Fair value was determined based on market values for comparable assets. We have initiated a program to locate a buyer for the Ireland facility and expect to complete a sale transaction within the next 12 months subject to market conditions.

In August 2008, we concluded a 30-day consultation process with an employee representative group to discuss matters associated with the closure of the Ireland facility, including support for the approximately 50 employees who would be affected by this closure. Based on the outcome of that consultation process, we recognized costs related to employee terminations of \$2.9 million in the third quarter of 2008. The termination of the affected employees and closure of the Ireland facility is expected to be completed prior to the end of 2008.

***Bridgewater Facility***

In connection with the May 2005 restructuring of our U.S. commercial operations, we vacated a portion of our Bridgewater, New Jersey facility. We recognized a restructuring charge at that time for a gross operating lease obligation related to the vacant space offset by estimated sublease rentals that could be reasonably obtained. Our evaluation of general economic and commercial real estate market conditions indicated that an additional charge of \$2.5 million was required in the third quarter of 2008 to reflect lower estimated future sublease rentals, based on the expected time required to locate and contract a suitable sublease and the expected market rates for such a sublease.

**Sale of Non-Core Assets**

We have identified certain non-core assets for divestiture including our equity investments in Depomed Inc. ("Depomed") and Financière Verdi ("Verdi"). In the third quarter of 2008, we realized a gain of \$4.2 million on the sale of 2,326,394 common shares of Depomed for cash proceeds of \$9.7 million. In October 2008, we received cash proceeds of \$1.2 million on the sale of a further 556,943 common shares of Depomed. Subject to

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

market conditions, we intend to dispose of our remaining 1,519,171 common shares of Depomed within the next 12 months. Those remaining shares had an estimated fair value of \$3.3 million as of October 31, 2008.

In the second quarter of 2008, we sold our entire investment in common shares and convertible debt of Verdi for cash proceeds of \$12.2 million, resulting in a gain on disposal of \$3.5 million.

In addition, we have received a conditional offer to purchase a vacant parcel of land adjacent to our corporate office with a carrying value of \$1.1 million. We expect to complete the sale of this property prior to the end of 2008, subject to satisfaction of the closing conditions.

**Share Repurchase Program**

In the second quarter of 2008, we repurchased a total of 2,318,400 common shares under our share repurchase program, at a weighted-average price of \$11.01 per share, for total consideration of \$25.5 million. The excess of the cost of the common shares repurchased over their assigned value totaled \$4.1 million. Since the second quarter of 2008, we have not repurchased any additional common shares; however, we intend to resume purchases in the fourth quarter of 2008. The share repurchase program will terminate on June 1, 2009, or upon such earlier time that we complete our purchases.

The terms of our credit facility require lenders' consent for share repurchases in excess of \$50 million in the aggregate per calendar year. To date, we have not requested or obtained such consent from the lenders.

**OUTLOOK**

We are currently reviewing procurement levels and practices and the structure of our support functions to ensure they are appropriately aligned with our Company's size and revenue base. We also remain focused on the resolution of legacy litigation matters, many of which have been resolved in the current year.

Over the next several quarters, our ongoing and planned efficiency initiatives are expected to result in additional charges to earnings as our Company repositions itself. Cumulatively, these charges, including \$56.8 million recorded in the first nine months of 2008, are expected to be in the range of \$80 million to \$100 million, of which the cash component is expected to be \$30 million to \$40 million. We anticipate that these efficiency initiatives, including the closures of our Puerto Rico and Ireland facilities, once fully implemented, will result in annual savings of \$30 million to \$40 million.

We expect to record period-over-period declines in sales of our existing portfolio of products for the next several quarters, mainly as a result of the introduction of generic competition to the 150mg Wellbutrin XL® product on May 30, 2008. We do not anticipate any meaningful contribution from our product-development pipeline until the 2010-2011 timeframe. We expect the acquisition of Prestwick to be accretive to both earnings per share and cash flows in 2009 based on our expectation that Ovation will launch Xenazine® in the U.S. prior to the end of 2008.

We continue to target an investment of over \$600 million in research and development through 2012, targeting unmet medical needs in specialty CNS markets. In this regard, business development efforts to in-license or acquire products targeting specialty CNS markets are active with a number of U.S. and international companies.

**CHANGES IN DIRECTORS AND OFFICERS**

At our reconvened 2008 annual meeting of shareholders held on August 8, 2008, the following new members were elected to our Board of Directors: Serge Gouin, Chairman of Quebecor Media Inc.; David Laidley, retired partner and former Chairman of Deloitte & Touche Canada; Spencer Lanthier, retired partner and former Chairman and Chief Executive of KPMG Canada; Mark Parrish, President of the International Association of Pharmaceutical Wholesalers and Senior Advisor, Frazer Healthcare Ventures; and Robert Power,





**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

former Executive Vice-President of Global Business Operations of Wyeth. In addition, Dr. Douglas Squires, Laurence Paul, Lloyd Segal, Michael Van Every, and William Wells were re-elected to our Board of Directors at the reconvened meeting of shareholders.

Following the 2008 annual meeting of shareholders, the independent members of our Board of Directors appointed Mr. Lanthier as Lead Director.

Effective May 1, 2008, our Board of Directors appointed Dr. Squires as Chairman of the Board of Directors. Dr. Squires was previously our Interim Chairman and CEO. Also effective May 1, 2008, our Board of Directors appointed Mr. Wells as our new CEO. Mr. Wells joined our Board of Directors in 2005, and had been Lead Director since June 30, 2007. As CEO, Mr. Wells remains on our Board of Directors. Consistent with our historical practice and our Company's corporate, operational and tax structure, Mr. Wells, as our key decision maker, will be based in Barbados, where he will also serve as President of Biovail Laboratories International SRL, our Company's principal operating subsidiary.

Effective September 3, 2008, Margaret Mulligan, FCA was appointed as our new Chief Financial Officer ("CFO"). Mrs. Mulligan succeeds Adrian de Saldanha, who had served as our Interim CFO since March 24, 2008.

On November 6, 2008, we announced the appointment of Dr. Christian Fibiger to the newly created role of Chief Scientific Officer ("CSO"). As CSO, Dr. Fibiger will be based in Barbados and will oversee the development of our Company's product pipeline.

**GOVERNMENTAL AND REGULATORY INQUIRIES**

**DOJ Agreement**

On May 16, 2008, we announced that a subsidiary of our Company, had reached an agreement with the DOJ in respect of criminal allegations related to activities surrounding the 2003 commercial launch of Cardizem® LA. In particular, the allegations relate to prior management's actions in 2002 and 2003 in respect of the Cardizem® LA clinical experience program, titled P.L.A.C.E. (Proving L.A. Through Clinical Experience). The agreement eliminates any criminal liability for Biovail Corporation and its subsidiaries, other than Biovail Pharmaceuticals LLC arising from this matter.

Under the terms of the agreement, Biovail Pharmaceuticals, Inc. (now Biovail Pharmaceuticals LLC) would plead guilty to charges relating to making payments to induce purchasing or ordering of Cardizem® LA in 2003 and would pay \$24.6 million to fully settle this matter, which we accrued in the second quarter of 2008. As part of the agreement, Biovail Corporation and its subsidiaries, other than Biovail Pharmaceuticals LLC, expect to receive full releases for all matters related to the DOJ's investigation. The agreement is subject to approval at a Court hearing that is expected to take place in December 2008.

**SEC Consent Decree**

On March 24, 2008, we announced we had reached a settlement with the SEC in respect of an investigation of our Company and certain former officers. The investigation related to specific accounting and financial disclosure practices, as previously disclosed, that occurred between 2001 and 2003 and resulted in a civil complaint filed by the SEC. We have entered into a Consent Decree with the SEC in which we have not admitted to the civil charges contained in the complaint; we paid \$10.0 million on March 24, 2008 to fully settle this matter. As part of the settlement, we also agreed to an examination of our accounting and related functions by an independent Consultant.

The settlement does not include four former officers who were also named in the complaint: Eugene Melnyk (then Chairman and CEO); Brian Crombie (then CFO); Kenneth Howling (then responsible for Corporate Communications, and later CFO until March 24, 2008); and John Miszuk (Vice-President, Controller)

## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

and Assistant Corporate Secretary until March 24, 2008). To our knowledge, the allegations against these individuals have not been resolved. Effective March 24, 2008, Mr. Howling and Mr. Miszuk were reassigned to different non-officer positions within our Company. Mr. Miszuk left our Company on September 30, 2008.

**OSC Notice of Hearing**

On March 24, 2008, the OSC issued a Notice of Hearing against our Company and the four former officers referred to above under "SEC Consent Decree" in respect of substantially the same matters as are described in the SEC complaint. The Notice of Hearing was accompanied by a Statement of Allegations setting out OSC staff's allegations concerning certain accounting and financial disclosure items dating from 2001 to 2003. On April 16, 2008, the hearing was adjourned on consent of all parties until February 2, 2009.

**OVERVIEW**

(\$ in 000s, except per share data)	Three Months Ended September 30		Nine Months Ended September 30	
	2008	2007	2008	2007
Revenue	\$ 181,089	\$ 188,890	\$ 575,682	\$ 638,922
Net income	48,437	65,867	79,524	227,510
Basic and diluted earnings per share	\$ 0.31	\$ 0.41	\$ 0.50	\$ 1.41
Cash dividends declared per share	\$ 0.375	\$ 0.375	\$ 1.125	\$ 1.125

	At September 30 2008	At December 31 2007
Cash and cash equivalents	\$ 219,005	\$ 433,641

**Revenue**

Total revenue declined \$7.8 million, or 4%, to \$181.1 million in the third quarter of 2008, compared with \$188.9 million in the third quarter of 2007, and declined \$63.2 million, or 10%, to \$575.7 million in the first nine months of 2008, compared with \$638.9 million in the first nine months of 2007. A significant factor in those declines was lower revenue from Wellbutrin XL® as a result of the launch of a generic version of the 150mg product on May 30, 2008. In the third quarter of 2008, that factor was partially offset by higher quarter-over-quarter sales of Ultram® ER reflecting the impact of price increases and a change in product mix in 2008, and lower shipments in third quarter of 2007 due to a backorder situation. Also partially offsetting the decline in Wellbutrin XL® revenue in the third quarter of 2008 was the impact of higher pricing of our Legacy products, which more than offset declining prescription volumes for those products.

In addition to the factors above, the decline in total revenue year-to-date also reflected a reduction in Cardizem® LA product sales, due to lower prescription volumes in the first nine months of 2008, and higher shipments of 120mg and 180mg strengths in the first quarter of 2007 as a result of addressing a backorder that existed at the end of 2006.

Changes in foreign currency exchange rates increased total revenue by approximately \$136,000 and \$5.5 million, or 0.1% and 1.0%, in the third quarter and first nine months of 2008, respectively, compared with the corresponding periods of 2007, due to the strengthening of the Canadian dollar relative to the U.S. dollar.

## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

## Results of Operations

Net income declined \$17.4 million, or 26%, to \$48.4 million (basic and diluted earnings per share of \$0.31) in the third quarter of 2008, compared with \$65.9 million (basic and diluted earnings per share of \$0.41) in the third quarter of 2007, and net income declined \$148.0 million, or 65%, to \$79.5 million (basic and diluted earnings per share of \$0.50) in the first nine months of 2008, compared with \$227.5 million (basic and diluted earnings per share of \$1.41) in the first nine months of 2007.

The following table displays specific items that impacted net income in the third quarters and first nine months of 2008 and 2007, and the impact of those items (individually and in the aggregate) on basic and diluted earnings per share ("EPS"). EPS figures may not add due to rounding.

(\$ in 000s, except per share data; Income (Expense))	Three Months Ended September 30				Nine Months Ended September 30			
	2008		2007		2008		2007	
	Amount	EPS Impact	Amount	EPS Impact	Amount	EPS Impact	Amount	EPS Impact
Restructuring costs	\$ (7,587)	\$ (0.05)	\$ 820	\$ 0.01	\$ (59,347)	\$ (0.37)	\$ (712)	\$
Legal settlements	(2,000)	(0.01)	(2,062)	(0.01)	(26,648)	(0.17)	(2,062)	(0.01)
Gain on disposal of investments	4,156	0.03			7,617	0.05	15,716	0.10
Proxy contest costs	(728)				(6,142)	(0.04)		
Management succession costs					(6,052)	(0.04)		
Loss on impairment of investments	(1,223)	(0.01)			(5,328)	(0.03)		
Equity loss			(432)		(1,195)	(0.01)	(1,325)	(0.01)
Loss on early extinguishment of debt							(12,463)	(0.08)
Contract recoveries			123				1,735	0.01
Total	\$ (7,382)	\$ (0.05)	\$ (1,551)	\$ (0.01)	\$ (97,095)	\$ (0.61)	\$ 889	\$ 0.01

## Cash Dividends

Cash dividends declared per share were \$0.375 in each of the first three quarters of 2008 and 2007. In November 2008, our Board of Directors declared a quarterly cash dividend of \$0.375 per share, payable on January 5, 2009. Upon payment of this dividend, we will have distributed \$4.50 per share to our shareholders since implementing our dividend program in December 2005.

## Financial Condition

At September 30, 2008 and December 31, 2007, we had cash and cash equivalents of \$219.0 million and \$433.6 million, respectively, and there were no borrowings outstanding under our \$250 million credit facility, or other long-term debt. The decline in cash and cash equivalents was primarily related to the following amounts paid during the first nine months of 2008:

\$99.6 million related to the acquisition of Prestwick;

\$83.0 million to fund the settlement of the U.S. securities class action (as described in note 19 to the unaudited consolidated financial statements for the interim period ended September 30, 2008);

\$45.1 million to GSK in settlement of the accrued contract costs associated with the introduction of generic competition to Wellbutrin XL®; and

\$10.0 million to settle the SEC investigation.



## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

## RESULTS OF OPERATIONS

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

## Revenue

The following table displays the dollar amount of each source of revenue in the third quarters and first nine months of 2008 and 2007; 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						Nine Months Ended September 30					
	2008		2007		Change		2008		2007		Change	
	\$	%	\$	%	\$	%	\$	%	\$	%	\$	%
Product sales	170,530	94	178,321	94	(7,791)	(4)	543,110	94	607,089	95	(63,979)	(11)
Research and development	5,465	3	6,237	3	(772)	(12)	18,522	3	18,456	3	66	
Royalty and other	5,094	3	4,332	2	762	18	14,050	2	13,377	2	673	5
	181,089	100	188,890	100	(7,801)	(4)	575,682	100	638,922	100	(63,240)	(10)

## Product Sales

The following table displays product sales by internal reporting category in the third quarters and first nine months of 2008 and 2007; 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						Nine Months Ended September 30					
	2008		2007		Change		2008		2007		Change	
	\$	%	\$	%	\$	%	\$	%	\$	%	\$	%
Wellbutrin XL®	16,587	10	53,516	30	(36,929)	(69)	105,863	19	167,969	28	(62,106)	(37)
Ultram® ER	20,837	12	13,765	8	7,072	51	64,107	12	63,346	10	761	1
Nitoman®	466				466	NM	466				466	NM
Zovirax®	32,767	19	31,017	17	1,750	6	107,422	20	103,517	17	3,905	4
Biovail Pharmaceuticals												
Canada	18,246	11	14,654	8	3,592	25	52,899	10	42,551	7	10,348	24
Cardizem® LA	13,191	8	14,429	8	(1,238)	(9)	33,883	6	61,064	10	(27,181)	(45)
Legacy	42,139	25	30,606	17	11,533	38	115,477	21	101,163	17	14,314	14
Generic	25,669	15	20,334	11	5,335	26	61,836	11	67,479	11	(5,643)	(8)
Glumetza® (U.S.)	628				628	NM	1,157				1,157	NM
	170,530	100	178,321	100	(7,791)	(4)	543,110	100	607,089	100	(63,979)	(11)

---

NM Not meaningful

## Wholesaler Inventory Levels

Three drug wholesale customers account for the majority of our Zovirax® and off-patent branded pharmaceutical (Legacy) product sales in the U.S. Our distribution agreements with those wholesalers limit the amount of inventory they can own to between 1/2 and 1 1/2 months of supply of our products. As indicated in the following table, at September 30, 2008, those wholesalers owned overall 1.2 months of supply of our products



## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

(compared with 1.5 months at December 31, 2007), of which only \$197,000 of inventory had less than 12 months remaining shelf life.

(\$ in 000s)	At September 30, 2008				At December 31, 2007		
	Original Shelf Life (In Months)	Total Inventory	Months On Hand (In Months)	Inventory With Less Than 12 Months Remaining Shelf Life	Total Inventory	Months On Hand (In Months)	Inventory With Less Than 12 Months Remaining Shelf Life
Zovirax®	36-48	\$ 12,608	1.2	\$ 103	\$ 15,863	1.5	\$ 93
Cardizem®	36-48	7,530	1.2	22	8,437	1.6	12
Ativan®	24	2,399	1.1	66	2,425	1.0	9
Vasotec® and Vaseretic®	24	2,085	1.4	5	1,705	1.2	17
Isordil®	36-60	229	1.3	1	376	2.4	4
Total	24-60	\$ 24,851	1.2	\$ 197	\$ 28,806	1.5	\$ 135

*Wellbutrin XL®*

Wellbutrin XL® product sales declined \$36.9 million, or 69%, to \$16.6 million in the third quarter of 2008, compared with \$53.5 million in the third quarter of 2007, and declined \$62.1 million, or 37%, to \$105.9 million in the first nine months of 2008, compared with \$168.0 million in the first nine months of 2007. Those declines reflected the adverse impact on volumes resulting from the introduction of generic competition to the 150mg product on May 30, 2008, as well as the continuing generic erosion of the 300mg product. Those factors were partially offset by the positive effect on our supply prices for the 300mg and 150mg products of price increases implemented by GSK over the last 12 months.

As a result of the introduction of generic competition to the 150mg product, GSK total sales of Wellbutrin XL® are not expected to meet the sales dollar-threshold to increase our supply price above the first tier in 2008, or thereafter.

*Ultram® ER*

Ultram® ER product sales increased \$7.1 million, or 51%, to \$20.8 million in the third quarter of 2008, compared with \$13.8 million in the third quarter of 2007, and increased \$761,000, or 1%, to \$64.1 million in the first nine months of 2008, compared with \$63.3 million in the first nine months of 2007. Those increases reflected the positive effect on our supply price of price increases implemented by OMI over the last 12 months and a change in prescription mix from the 100mg product to the higher 200mg and 300mg strengths. In addition, Ultram® ER product sales in the third quarter of 2007 were negatively impacted by the backorder of certain lots. Those factors were partially offset by lower sales of sample supplies to OMI in the third quarter and first nine months of 2008.

Effective January 1, 2009, our contractual supply price to OMI (which is determined based on a percentage of OMI's net selling price for Ultram® ER) will decline by 2.5 percentage points.

Par Pharmaceuticals Companies, Inc. ("Par") is seeking FDA approval for 100mg, 200mg and 300mg generic versions of Ultram® ER (as described in note 19 to the unaudited consolidated financial statements for the interim period ended September 30, 2008). Patent infringement trial proceedings are expected to commence in January 2009. In our view, we believe a Court ruling of non-infringement in favour of Par could result in the introduction of generic competition to Ultram® ER in the second quarter of 2009, at the earliest, should Par obtain FDA approval of its generic formulation and should it decide to launch at risk pending appeal.

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

*Nitoman®*

In the period following our acquisition of Prestwick on September 16, 2008, we recognized \$466,000 of revenue related to Nitoman® product sales in Canada.

*Zovirax®*

Zovirax® product sales increased \$1.8 million, or 6%, to \$32.8 million in the third quarter of 2008, compared with \$31.0 million in the third quarter of 2007, and increased \$3.9 million, or 4%, to \$107.4 million in the first nine months of 2008, compared with \$103.5 million in the first nine months of 2007. Those increases reflected price increases implemented for these products over the last 12 months, which more than offset lower prescription volumes.

*BPC*

Sales of BPC products increased \$3.6 million, or 25%, to \$18.2 million in the third quarter of 2008, compared with \$14.7 million in the third quarter of 2007, and increased \$10.3 million, or 24%, to \$52.9 million in the first nine months of 2008, compared with \$42.6 million in the first nine months of 2007. Excluding the positive effect on our Canadian dollar-denominated revenue of the strengthening of the Canadian dollar relative to the U.S. dollar, BPC product sales increased 24% and 15% in the third quarter and first nine months of 2008, respectively, compared with corresponding periods of 2007. Those increases reflected that higher sales of our promoted Wellbutrin® XL, Tiazac® XC, Ralivia (launched in November 2007) and Glumetza® products more than offset lower sales of our genericized Tiazac® and Wellbutrin® SR products.

*Cardizem® LA*

Cardizem® LA product sales include the amortization of deferred revenue associated with the cash consideration received from the sale to Kos of the distribution rights to Cardizem® LA in May 2005. That amortization amounted to \$3.8 million and \$11.3 million in each of the third quarters and first nine months of 2008 and 2007, respectively.

Revenue from sales of Cardizem® LA declined \$1.2 million, or 9%, to \$13.2 million in the third quarter of 2008, compared with \$14.4 million in the third quarter of 2007, and declined \$27.2 million, or 45%, to \$33.9 million in the first nine months of 2008, compared with \$61.1 million in the first nine months of 2007. Those declines reflected lower prescription volumes in the third quarter and first nine months of 2008, and higher shipments of 120mg and 180mg Cardizem® LA products to Kos in the first quarter of 2007 as a result of addressing the backorder for those strengths that existed at the end of 2006. Those factors were partially offset by the positive effect on our supply price of price increases implemented by Kos over the last 12 months.

Under the terms of a settlement agreement entered into in December 2007, Watson Pharmaceuticals, Inc. may commence the marketing and sales of a generic version of Cardizem® LA no earlier than April 1, 2009, at which time royalty payments to us will begin.

*Legacy*

Sales of Legacy products increased \$11.5 million, or 38%, to \$42.1 million in the third quarter of 2008, compared with \$30.6 million in the third quarter of 2007, and increased \$14.3 million, or 14%, to \$115.5 million in the first nine months of 2008, compared with \$101.2 million in the first nine months of 2007. Those increases reflected price increases implemented for these products (other than Tiazac®) over the last 12 months that more than offset declining prescription volumes.

In June 2008, we received notice that Sun Pharmaceutical Industries, Ltd., India ("Sun India") is seeking FDA approval for generic versions of Cardizem® CD (as described in note 19 to the unaudited consolidated



**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

financial statements for the interim period ended September 30, 2008), including the 360mg strength which currently is not subject to generic competition. There are currently no unexpired patents listed against our 360mg Cardizem® CD product listed in the FDA's Orange Book database. FDA approval of Sun India's 360mg product could have a material adverse impact on the overall sales of our Cardizem® CD branded product, and on the carrying value of the intangible asset associated with the Cardizem® trademark.

*Generic*

Sales of Generic products increased \$5.3 million, or 26%, to \$25.7 million in the third quarter of 2008, compared with \$20.3 million in the third quarter of 2007, due mainly to the recognition of a \$4.5 million adjustment made by Teva in the third quarter of 2008 to reduce its chargeback provision related to past sales of our Generic products. Despite the recognition of that amount in the third quarter of 2008, sales of Generic products declined \$5.6 million, or 8%, to \$61.8 million in the first nine months of 2008, compared with \$67.5 million in the first nine months of 2007, primarily due to lower prescription volumes and pricing for these products because of increased competition and changes in Teva's customer base.

*Glumetza® (U.S.)*

In the third quarter and first nine months of 2008, we recognized revenue of \$628,000 and \$1.2 million, respectively, related to our initial supply of 1000mg Glumetza® product and samples to Depomed for the U.S. market.

***Research and Development Revenue***

Research and development revenue from clinical research and laboratory testing services provided to external customers by our contract research division declined \$772,000, or 12%, to \$5.5 million in the third quarter of 2008, compared with \$6.2 million in the third quarter of 2007, and increased \$2.0 million, or 12%, to \$18.5 million in the first nine months of 2008, compared with \$16.5 million in the first nine months of 2007. Research and development revenue in the first nine months of 2007 included \$1.9 million from Kos related to development activities completed on Vasocard prior to the termination of that project.

***Royalty and Other Revenue***

Royalties from third parties on sales of products we developed or acquired and other revenue increased \$762,000, or 18%, to \$5.1 million in the third quarter of 2008, compared with \$4.3 million in the third quarter of 2007, and increased \$673,000, or 5%, to \$14.1 million in the first nine months of 2008, compared with \$13.4 million in the first nine months of 2007.

**Operating Expenses**

The following table displays the dollar amount of each operating expense category in the third quarters and first nine months of 2008 and 2007; the percentage of each category compared with total revenue in the

## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

respective period; and the dollar and percentage change in the dollar amount of each category. Percentages may not add due to rounding.

(\$ in 000s)	Three Months Ended September 30						Nine Months Ended September 30					
	2008		2007		Change		2008		2007		Change	
	\$	%	\$	%	\$	%	\$	%	\$	%	\$	%
Cost of goods sold	47,468	26	50,458	27	(2,990)	(6)	145,080	25	161,408	25	(16,328)	(10)
Research and development	18,668	10	30,674	16	(12,006)	(39)	76,759	13	88,843	14	(12,084)	(14)
Selling, general and administrative	44,661	25	33,660	18	11,001	33	144,891	25	129,583	20	15,308	12
Amortization of intangible assets	12,342	7	11,979	6	363	3	35,727	6	35,942	6	(215)	(1)
Restructuring costs (recovery)	7,587	4	(820)		8,407	NM	59,347	10	712		58,635	NM
Legal settlements	2,000	1	2,062	1	(62)	(3)	26,648	5	2,062		24,586	NM
Contract recoveries			(123)		123	(100)			(1,735)		1,735	(100)
	132,726	73	127,890	68	4,836	4	488,452	85	416,815	65	71,637	17

NM Not meaningful

**Cost of Goods Sold and Gross Margins**

Gross margins based on product sales were 72% in each of the third quarters of 2008 and 2007 and 73% in each of the first nine months of 2008 and 2007. The following factors had an unfavourable impact on gross margins in the third quarter and first nine months of 2008, compared with the corresponding periods of 2007:

Lower absorption of overhead costs due mainly to excess manufacturing capacity associated with decreased production volumes for Wellbutrin XL®, Cardizem® LA and Generic products;

The reduced contribution from higher margin 150mg Wellbutrin XL® product sales as a result of the introduction of generic competition; and

An increase in amortization expense of \$4.5 million and \$6.8 million in the third quarter and first nine months of 2008, respectively, compared with the corresponding periods of 2007, related to the Zovirax® deferred charge.

Those factors were offset by:

The positive impact of price increases we implemented for Zovirax® and certain Legacy products over the last 12 months;

The positive effect on our supply prices for Wellbutrin XL®, Ultram® ER and Cardizem® LA of the price increases implemented by our strategic partners over the last 12 months;

## Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

A lower proportion of lower margin Cardizem® LA product sales;

The inclusion of the \$4.5 million chargeback adjustment from Teva in the third quarter of 2008;

Lower charges for obsolescence related to inventories of certain of our products that are in excess of anticipated demand, and a recovery from OMI in the second quarter of 2008 related to the cost of Ultram® ODT inventory that had been previously written-off; and

A reduction in depreciation expense of \$1.7 million in the third quarter of 2008, as a result of the write down of the manufacturing plant and equipment located in Puerto Rico.

## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

*Research and Development Expenses*

The following table displays the dollar amount of each research and development expense category for the third quarters and first nine months of 2008 and 2007; the percentage of each category compared with total revenue in the respective period; and the percentage changes in the dollar amount of each category. Percentages may not add due to rounding.

(\$ in 000s)	Three Months Ended September 30						Nine Months Ended September 30					
	2008		2007		Change		2008		2007		Change	
	\$	%	\$	%	\$	%	\$	%	\$	%	\$	%
Internal research and development	13,141	7	25,773	14	(12,632)	(49)	59,359	10	75,857	12	(16,498)	(22)
Contract research services provided to external customers	5,527	3	4,901	3	626	13	17,400	3	12,986	2	4,414	34
Total research and development expenses	18,668	10	30,674	16	(12,006)	(39)	76,759	13	88,843	14	(12,084)	(14)

Internal research and development expenses declined \$12.6 million, or 49%, to \$13.1 million in the third quarter of 2008, compared with \$25.8 million in the third quarter of 2007, and declined \$16.5 million, or 22%, to \$59.4 million in the first nine months of 2008, compared with \$75.9 million in the first nine months of 2007. Those declines reflected reduced direct project spending as we are currently in the process of reviewing and optimizing the projects in our development portfolio to reflect our New Strategic Focus on specialty CNS products. Those declines also reflected the cost of clinical trial and scale-up activities conducted in the third quarter and first nine months of 2007 related to Aplenin and the BVF-146 program.

On April 23, 2008, the FDA approved our NDA for Aplenin (formerly known as BVF-033) for the treatment of depression. Aplenin is an alcohol-resistant formulation of a new bupropion salt and has been approved in 174mg, 348mg, and 522mg extended-release tablets. We are currently reviewing our commercial options for Aplenin including ongoing discussions with potential commercialization partners.

The BVF-146 program was terminated in March 2008 following a reassessment of the commercial opportunity for a once-daily combination product consisting of tramadol and a non-steroidal anti-inflammatory drug. In the first quarter of 2008, we accrued \$7.9 million for the estimated contractual obligations to wind down and close out a long-term safety study that was underway for BVF-146. Those obligations primarily consisted of fees and other costs that we are contractually obligated to pay to the contract research organization and investigators conducting this study. We expect to substantially settle those obligations prior to the end of 2008. The anticipated findings from this study were determined to have no alternative future use in other identifiable projects.

In the first nine months of 2008, we filed Abbreviated New Drug Applications for BVF-065 (venlafaxine) for the treatment of depression and BVF-203 (fenofibrate) for the treatment of high cholesterol. As previously disclosed, we terminated the BVF-239 program (for the treatment of a cardiovascular disease) as a consequence of our New Strategic Focus.

Costs associated with providing contract research services to external customers increased \$626,000, or 13%, to \$5.5 million in the third quarter of 2008, compared with \$4.9 million in the third quarter of 2007, and increased \$4.4 million, or 34%, to \$17.4 million in the first nine months of 2008, compared with \$13.0 million in the first nine months of 2007. Those increases reflected a higher volume of clinical research and laboratory testing services provided to external customers by our contract research division, as well as unabsorbed overhead costs at that division due to the decline in activity related to internal product-development programs.

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses increased \$11.0 million, or 33%, to \$44.7 million in the third quarter of 2008, compared with \$33.7 million in the third quarter of 2007, and increased \$15.3 million, or 12%, to \$144.9 million in the first nine months of 2008, compared with \$129.6 million in the first nine months of 2007, primarily due to:

An increase in compensation expense related to deferred share units ("DSUs") of \$3.0 million and \$535,000 in the third quarter and first nine months of 2008, respectively, compared with the corresponding periods of 2007, primarily as a result of the relative timing of the annual grant of DSUs to directors (which occurs following their election at the annual meeting of shareholders) that occurred in the third quarter of 2008, compared with the second quarter of 2007, and the impact of a decline in the underlying trading price of our common shares in the third quarter of 2007;

An increase in legal costs of \$2.8 million in the third quarter of 2008, reflecting the impact of insurance recoveries in the third quarter of 2007 (as described below);

The inclusion of consulting costs of \$1.8 million and \$4.4 million in the third quarter and first nine months of 2008, respectively, related to the development and implementation of our New Strategic Focus;

The inclusion of proxy contest costs of \$728,000 and \$6.1 million in the third quarter and first nine months of 2008, respectively, and management succession costs of \$6.1 million in the first nine months of 2008 (as described below);

An increase in promotional spending related to the launch of Ralivia in Canada of \$595,000 and \$3.9 million in the third quarter and first nine months of 2008, respectively, compared with the corresponding periods of 2007; and

An increase in fees earned by Sciele for its promotional services related to Zovirax® of \$87,000 and \$5.1 million in the third quarter and first nine months of 2008, respectively, compared with the corresponding periods of 2007.

Those factors were partially offset by:

A decrease in legal costs of \$10.0 million in the first nine months of 2008, compared with the first nine months of 2007, reflecting, in part, the recent settlement of certain legacy litigation and regulatory matters (as described below); and

A decrease in stock-based compensation (excluding the amount of cancelled stock options and RSUs included in management succession costs as described below) of \$173,000 and \$3.3 million in the third quarter and first nine months of 2008, respectively, compared with the corresponding periods of 2007, primarily due to a reduction in the overall number of stock options granted to employees, together with a lower estimated grant-date fair value for those options, and lower compensation expense related to stock options granted in prior years with higher grant-date fair values that have now vested.

The aforementioned proxy contest costs were incurred in connection with the contested election of our nominees to the Board of Directors at our 2008 annual meeting of shareholders.

The aforementioned management succession costs were associated with the contractual obligations related to Dr. Squires ceasing to serve as our CEO and the ensuing appointment of Mr. Wells to that role, as well as previously unrecognized compensation expense in the amount of \$2.1 million recognized upon the cancellation in May 2008 of certain stock options and RSUs previously granted to Dr. Squires.

Legal costs comprised a significant portion of our selling, general and administrative expenses in the periods presented. In the third quarter and first nine months of 2008, those costs amounted to \$10.8 million and

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

\$26.8 million respectively, compared with \$8.0 million and \$36.8 million, respectively, in the corresponding periods of 2007. Legal costs in the third quarter and first nine months of 2007 were reported net of insurance recoveries of \$5.4 million and \$12.6 million, respectively. Legal costs included amounts related to matters we do not consider to be in the ordinary course of business, such as the S.A.C. complaint; governmental and regulatory inquiries; securities class actions; and defamation claims (as described in note 19 to the unaudited consolidated financial statements for the interim period ended September 30, 2008). As we have settled the SEC investigation and the U.S. and Canadian securities class action complaints, and have entered into an agreement in principle to settle the DOJ investigation in respect of the Cardizem® LA clinical experience program, we do not expect to incur additional significant legal costs related to those matters. However, we may continue to incur considerable legal costs related to new litigation proceedings and to the remaining unresolved legacy matters (including the cost of legal representation of certain former officers and directors pursuant to indemnification agreements) for an indefinite period, as we cannot predict the outcome or timing of when each of those matters may be resolved. In addition, we have exhausted our Director and Officer liability insurance for claims related to the litigation and regulatory matters in respect of our 2002 to 2004 policy period.

***Amortization Expense***

Amortization expense increased \$363,000, or 3%, to \$12.3 million in the third quarter of 2008, compared with \$12.0 million in the third quarter of 2007, and declined \$215,000, or 1%, to \$35.7 million in the first nine months of 2008, compared with \$35.9 million in the first nine months of 2007. In the third quarter and first nine months of 2008, amortization expense reflected the amortization of Prestwick's identifiable intangible assets in the period following our acquisition of Prestwick on September 16, 2008, offset by reduced amortization related to certain intangible assets written-down in December 2007.

***Restructuring Costs***

In the third quarter and first nine months of 2008, we incurred restructuring charges of \$7.6 million and \$59.3 million, respectively, as described above under "New Strategic Focus Restructuring".

***Legal Settlements***

In the third quarter and first nine months of 2008, we recorded charges for potential legal settlements of \$2.0 million and \$26.6 million, respectively, of which \$24.6 million related to the agreement in principle to settle with the DOJ (as described above under "Governmental and Regulatory Inquiries DOJ Agreement").

***Non-Operating Items***

***Interest Income and Expense***

Interest income declined \$2.0 million, or 53%, to \$1.8 million in the third quarter of 2008, compared with \$3.8 million in the third quarter of 2007, and declined \$11.0 million, or 56%, to \$8.7 million in the first nine months of 2008, compared with \$19.6 million in the first nine months of 2007, reflecting a decline in our cash balances following the redemption of our 7<sup>7</sup>/<sub>8</sub>% Senior Subordinated Notes ("Notes") effective April 1, 2007 and legal settlement and other payments made in the first nine months of 2008, together with lower prevailing interest rates.

Interest expense declined \$8.7 million, or 92%, to \$724,000 in the first nine months of 2008, compared with \$9.4 million in the first nine months of 2007. Interest expense in the first nine months of 2007 was mainly comprised of interest on our Notes prior to April 1, 2007.

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

***Foreign Exchange Gain or Loss***

We recognized a foreign exchange gain of \$204,000 and a foreign exchange loss of \$1.1 million in the third quarter and first nine months of 2008, respectively. In September 2007, the Canadian dollar was trading at a then 30-year high relative to the U.S. dollar, which contributed to foreign exchange gains of \$5.3 million and \$5.7 million recognized in the third quarter and first nine months of 2007, respectively.

***Equity Loss***

We recorded equity losses of \$1.2 million in the first nine months of 2008, and \$432,000 and \$1.3 million in the third quarter and first nine months of 2007, respectively, related to our investment in Western Life Sciences ("WLS"). As of the end of the first quarter of 2008, our cumulative share of the net losses of WLS exceeded our investment; as we are not committed to make further capital contributions to WLS, we did not recognize any additional equity losses related to this investment in the third quarter of 2008.

***Gain on Disposal of Investments***

In the third quarter of 2008, we recognized a gain of \$4.2 million on the sale of a portion of our investment in common shares of Depomed and, in the second quarter of 2008, we recognized a gain of \$3.5 million on the disposal of our investment in common shares and convertible debt of Verdi (as described above under "New Strategic Focus Sale of Non-Core Assets").

In the second quarter of 2007, we recorded a gain of \$15.7 million (net of costs) on the sale to Verdi of a portion of our investment in common shares of Ethypharm S.A. ("Ethypharm"). We received proceeds on disposal of \$39.4 million in cash and \$5.6 million in convertible bonds of Verdi. We exchanged the remaining portion of our Ethypharm investment for common shares of Verdi.

***Loss on Impairment of Investments***

In the third quarter and first nine months of 2008, we recorded losses of \$1.2 million and \$5.3 million, respectively, related primarily to other-than-temporary declines in the estimated fair value of a portion of our investment in auction rate securities (as described below under "Liquidity and Capital Resources Auction Rate Securities").

***Loss on Early Extinguishment of Debt***

In the second quarter of 2007, we recorded a charge of \$12.5 million on the early redemption of our Notes, which included a premium paid to Noteholders of \$7.9 million.

***Provision for Income Taxes***

We recorded provisions for income taxes of \$4.6 million and \$15.6 million in the third quarter and first nine months of 2008, respectively, compared with \$3.5 million and \$12.5 million, respectively, in the corresponding periods of 2007. Those provisions reflect the fact that most of our income was derived from a foreign subsidiary with lower statutory tax rates than those that apply in Canada. The increase in the effective tax rates in the third quarter and first nine months of 2008, compared with the corresponding periods of 2007, was primarily due to the charges associated with the agreement in principle to settle the DOJ investigation (as described above under "Governmental and Regulatory Inquiries DOJ Agreement") and restructuring activities (as described above under "New Strategic Focus Restructuring") that are not deductible or do not affect the income tax provision because of unrecognized tax losses in the local jurisdictions. In addition, certain components of the provision for income taxes do not vary with pre-tax income, including withholding taxes and provisions for uncertain tax positions.



## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

## SUMMARY OF QUARTERLY RESULTS

The following table displays a summary of our quarterly results of operations and cash flows for each of the eight most recently completed quarters:

(\$ in 000s, except per share data)	2008				2007			2006
	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
Revenue	\$ 181,089	\$ 186,095	\$ 208,498	\$ 203,896	\$ 188,890	\$ 203,027	\$ 247,005	\$ 307,648
Expenses	132,726	210,368	145,358	237,989	127,890	140,567	148,358	188,045
Operating income (loss)	48,363	(24,273)	63,140	(34,093)	61,000	62,460	98,647	119,603
Net income (loss)	48,437	(25,289)	56,376	(31,971)	65,867	67,824	93,819	117,976
Basic and diluted earnings (loss) per share	\$ 0.31	\$ (0.16)	\$ 0.35	\$ (0.20)	\$ 0.41	\$ 0.42	\$ 0.58	\$ 0.74
Net cash provided by (used in) operating activities	\$ (62,370)	\$ 67,056	\$ 92,676	\$ 79,333	\$ 43,415	\$ 98,277	\$ 119,828	\$ 235,637

## Third Quarter of 2008 Compared To Second Quarter of 2008

*Revenue*

Total revenue declined \$5.0 million, or 3%, to \$181.1 million in the third quarter of 2008, compared with \$186.1 million in the second quarter of 2008, primarily due to the decline in Wellbutrin XL® product sales as a result of the introduction of generic competition to the 150mg product on May 30, 2008.

*Results of Operations*

Net income increased \$73.7 million to \$48.4 million in the third quarter of 2008, compared with a net loss of \$25.3 million in the second quarter of 2008, primarily due to:

A decrease of \$44.2 million in restructuring costs recognized in the third quarter of 2008, compared with the second quarter of 2008 (as described above under "New Strategic Focus - Restructuring");

A decrease of \$22.6 million in legal settlements in the third quarter of 2008, related primarily to the agreement in principle to settle with the DOJ in the second quarter of 2008 (as described above under "Governmental and Regulatory Inquiries - DOJ Agreement"); and

A decrease of \$10.7 million in management succession and proxy contest costs in the third quarter of 2008, compared with the second quarter of 2008.

Those factors were partially offset by:

A decline in gross profit on product sales of \$8.7 million, or 7%, to \$123.1 million in the third quarter of 2008, compared with \$131.8 million in the second quarter of 2008, primarily due to the genericization of the 150mg Wellbutrin XL® product.

*Cash Flows*

Net cash provided by operating activities decreased \$129.4 million, or 193%, to net cash used of \$62.4 million in the third quarter of 2008, compared with net cash provided of \$67.1 million in the second quarter of 2008, primarily due to payments made in the third quarter of 2008 of \$83.0 million to fund the U.S. securities class action and \$45.1 million to GSK to settle the Wellbutrin XL® contract costs.

## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

## FINANCIAL CONDITION

The following table displays a summary of our financial condition at September 30, 2008 and December 31, 2007:

(\$ in 000s)	At September 30 2008	At December 31 2007
Working capital <sup>(1)</sup>	\$ 227,781	\$ 339,439
Long-lived assets <sup>(2)</sup>	1,013,623	969,265
Shareholders' equity	1,163,886	1,297,819

(1) Total current assets less total current liabilities.

(2) Property, plant and equipment; intangible assets; and goodwill.

**Working Capital**

Working capital declined \$111.7 million, or 33%, to \$227.8 million at September 30, 2008, compared with \$339.4 million at December 31, 2007, primarily due to:

A net decrease in cash and cash equivalents of \$214.6 million, which reflected the following amounts paid in the first nine months of 2008: \$99.6 million related to the acquisition of Prestwick; \$83.0 million to fund the settlement of the U.S. securities class action; \$45.1 million to GSK to settle the Wellbutrin XL® contract costs; and \$10.0 million to settle the SEC investigation;

A decrease in insurance recoveries receivables of \$61.1 million related primarily to the portion of the U.S. securities class action settlement funded by our insurance carriers;

A decrease in accounts receivable of \$11.3 million, mainly as a result of lower 150mg Wellbutrin XL® product sales; and

A decrease in inventories of \$10.6 million related primarily to reductions in raw material inventory reflecting lower production requirements for certain products.

Those factors were partially offset by:

A decrease in accrued legal settlements of \$148.0 million related to the settlements of the U.S. securities class action and SEC investigation, partially offset by an increase of \$26.6 million related primarily to the agreement in principle to settle with the DOJ (as described above under "Governmental and Regulatory Inquiries - DOJ Agreement");

A decrease in accrued contract costs of \$45.1 million related to the Wellbutrin XL® settlement with GSK;

## Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

A decrease in accounts payable of \$19.4 million, due mainly to the reduction in inventory purchases, lower legal costs, and a lower amount of promotional fees owing to Sciele; and

A decrease in the current portion of deferred revenue of \$12.5 million, due mainly to the amortization of the Ultram® ER supply prepayment and Cardizem® LA deferred revenue.

### **Long-Lived Assets**

Long-lived assets increased \$44.4 million, or 5%, to \$1,013.6 million at September 30, 2008, compared with \$969.3 million at December 31, 2007, primarily due to:

The addition of Prestwick's identifiable intangible assets of \$157.9 million; and

## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

Additions to property, plant and equipment of \$21.3 million, which included expenditures related to the expansion of our corporate office, the construction of a new facility in Barbados, and upgrades to our manufacturing facilities.

Those factors were partially offset by:

The impairment charge of \$51.5 million related to the write-downs of the carrying values of property, plant and equipment located in Puerto Rico and Ireland (as described above under "New Strategic Focus Restructuring");

The depreciation of plant and equipment of \$20.9 million and the amortization of intangible assets of \$42.6 million; and

The reclassification of \$7.0 million from property, plant and equipment to assets held for sale related to the aggregate carrying value of the Ireland facility and the vacant parcel of land adjacent to our corporate office.

**Shareholders' Equity**

Shareholders' equity declined \$133.9 million, or 10%, to \$1,163.9 million at September 30, 2008, compared with \$1,297.8 million at December 31, 2007, primarily due to:

Cash dividends declared and dividend equivalents on RSUs of \$180.6 million in the aggregate; and

The repurchase of \$25.5 million of common shares under our share repurchase program.

Those factors were partially offset by:

Net income of \$79.5 million (including \$6.7 million of stock-based compensation recorded in additional paid-in capital).

**CASH FLOWS**

The following table displays cash flow information for the third quarters and first nine months of 2008 and 2007:

(\$ in 000s)	Three Months Ended September		Nine Months Ended September 30	
	2008	2007	2008	2007
Net cash provided by (used in) operating activities	\$ (62,370)	\$ 43,415	\$ 97,362	\$ 261,520
Net cash used in investing activities	(12,816)	(41,214)	(105,299)	(16,542)
Net cash used in financing activities	(59,549)	(59,881)	(206,007)	(668,212)
Effect of exchange rate changes on cash and cash equivalents	(316)	128	(692)	600
Net decrease in cash and cash equivalents	(135,051)	(57,552)	(214,636)	(422,634)
Cash and cash equivalents, beginning of period	354,056	469,458	433,641	834,540
Cash and cash equivalents, end of period	\$ 219,005	\$ 411,906	\$ 219,005	\$ 411,906



**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

**Operating Activities**

Net cash provided by operating activities declined \$105.8 million, or 244%, to net cash used of \$62.4 million in the third quarter of 2008, compared with net cash provided of \$43.4 million in the third quarter of 2007, primarily due to:

A decrease of \$122.0 million related to income from operations before changes in operating assets and liabilities, due mainly to payments made in the third quarter of 2008 of \$83.0 million to fund the U.S. securities class action and \$45.1 million to GSK to settle the Wellbutrin XL® contract costs.

That factor was partially offset by:

An increase of \$25.8 million related to the change in accrued liabilities, due mainly to the amount and timing of payments to Teva related to wholesaler chargebacks and shelf-stock adjustments related to Generic product sales in the second and third quarters of 2007, partially offset by the inclusion of restructuring costs of \$6.6 million accrued in the third quarter of 2008.

Net cash provided by operating activities declined \$164.2 million, or 63%, to \$97.4 million in the first nine months of 2008, compared with \$261.5 million in the first nine months of 2007, primarily due to:

A decrease of \$181.2 million related to income from operations before changes in operating assets and liabilities, due mainly to the payments made in the first nine months of 2008 of \$83.0 million to fund the U.S. securities class action and \$45.1 million to settle the Wellbutrin XL® contract costs with GSK, as well as \$10.0 million paid to settle the SEC investigation; and a decline in gross profit on product sales of \$47.7 million, or 11%, to \$398.0 million in the first nine months of 2008, compared with \$445.7 million in the first nine months of 2007, reflecting lower sales of Wellbutrin XL® and Cardizem® LA, partially offset by higher Legacy product sales;

A decrease of \$20.3 million related to the change in accounts receivable, primarily as a result of lower net collections from GSK in the first nine months of 2008, compared with the first nine months of 2007; and

A decrease of \$15.5 million related to the change in accounts payable, due mainly to the amount and timing of payments related to raw material inventory purchases, as well as lower legal costs and a lower amount of promotional fees owing to Sciele.

Those factors were partially offset by:

An increase of \$22.3 million related to the change in accrued liabilities, due mainly the settlement of restructuring costs related to the December 2006 restructuring program and the elimination of interest payable on our Notes in the first nine months of 2007, partially offset by the accrued restructuring costs of \$6.6 million included in the third quarter of 2008;

An increase of \$16.6 million related to the change in inventories, due mainly to the reduction in raw material inventory purchases; and

An increase of \$10.7 million related to the change in income taxes payable, due mainly to the timing of payments.

**Investing Activities**

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

Net cash used in investing activities declined \$28.4 million, or 69%, to \$12.8 million in the third quarter of 2008, compared with \$41.2 million in the third quarter of 2007, primarily due to:

A transfer of \$83.0 million from restricted cash related to the amount paid to fund the U.S. securities class action settlement;



**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

A decrease in additions to marketable securities of \$30.9 million related primarily to \$27.0 million of auction rate securities added in the third quarter of 2007; and

An increase of \$8.7 million related to proceeds received as of September 30, 2008 from the sale of a portion of our investment in Depomed.

Those factors were partially offset by:

The \$99.6 million paid as of September 30, 2008 to acquire Prestwick (net of cash acquired).

Net cash used in investing activities increased \$88.8 million, or 537%, to \$105.3 million in the first nine months of 2008, compared with \$16.5 million in the first nine months of 2007, primarily due to:

The \$99.6 million net amount paid to acquire Prestwick; and

A \$16.9 million decrease in proceeds from the sale of investments related to the sale of our investments in Depomed and Verdi in the first nine months of 2008 for proceeds of \$20.9 million in the aggregate, and the disposal of a portion of our investment in Ethypharm to Verdi in the first nine months of 2007 for net proceeds of \$37.8 million.

Those factors were partially offset by:

A decrease in additions to marketable securities of \$27.5 million related primarily to the \$27.0 million of auction rate securities added in the third quarter of 2007.

**Financing Activities**

Net cash used in financing activities declined \$332,000, or 1%, to \$59.5 million in the third quarter of 2008, compared with \$59.9 million in the third quarter of 2007, primarily due to a reduction in cash dividends as a result of the repurchase of a portion of our common shares under our share repurchase program (as described above under "New Strategic Focus Share Repurchase Program").

Net cash used in financing activities declined \$462.2 million, or 69%, to \$206.0 million in the first nine months of 2008, compared with \$668.2 million in the first nine months of 2007, primarily due to:

The \$406.8 million decrease related to the redemption of our Notes in the second quarter of 2007;

A decrease of \$80.9 million in dividends paid in the first nine months of 2008 related primarily to a special dividend of \$0.50 per share paid in the first quarter of 2007; and

A decrease of \$11.2 million related to the final payment made to GSK in the third quarter of 2007 related to Zovirax®.

Those factors were partially offset by:

## Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 6-K

The repurchase of \$25.5 million of common shares in the second quarter of 2008 under our share repurchase program (as described above under "New Strategic Focus Share Repurchase Program"); and

A decrease of \$11.2 million in proceeds related to the issuance of common shares on the exercise of stock options in the first nine months of 2007.

## BIOVAIL CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

(All dollar amounts are expressed in U.S. dollars)

## LIQUIDITY AND CAPITAL RESOURCES

(\$ in 000s)	At September 30 2008	At December 31 2007
<b>Financial assets</b>		
Cash and cash equivalents	\$ 219,005	\$ 433,641
Short-term investment	7,578	
Marketable securities	23,141	28,312
<b>Total financial assets</b>	<b>\$ 249,724</b>	<b>\$ 461,953</b>

We had no long-term debt at September 30, 2008 or December 31, 2007.

**General**

We believe that our existing cash resources, together with cash expected to be generated by operations and from the potential sale of non-core assets (as described above under "New Strategic Focus - Sale of Non-Core Assets"), as well as funds available under our undrawn \$250 million credit facility, will be sufficient to meet our operational and capital expenditure requirements; support our current dividend policy and share repurchase program; cover the costs associated with our operating-efficiency initiatives; and meet our working capital needs, for at least the next 12 months, based on our current expectations. We anticipate total capital expenditures of approximately \$25 million in 2008. Major projects in 2008 include the expansion of our corporate office (now complete), the construction of a new facility in Barbados (now occupied), and ongoing upgrades to our manufacturing facilities.

We cannot, however, predict the amount or timing of our need for additional funds under various circumstances, such as a significant future acquisition; new product development projects; changes to our capital structure; or other factors that may require us to raise additional funds through borrowings, or the issuance of debt or equity securities. In addition, certain contingent events, such as the resolution of certain legal proceedings (as described in note 19 to the unaudited consolidated financial statements for the interim period ended September 30, 2008), if realized, could have a material adverse impact on our liquidity and capital resources. The credit and capital markets have experienced unprecedented deterioration in 2008, including the failure of a number of significant and established financial institutions in the U.S. and abroad, all of which will have an impact on the availability of credit and capital in the near term. Accordingly, it is recognized that those existing market conditions may limit our access to additional funding at any reasonable rate.

**Cash and Cash Equivalents**

Our cash and cash equivalents are held in cash operating accounts, or are invested in securities such as treasury bills, money market funds, term deposits, or commercial paper with a minimum investment-grade credit rating of "A1/P1".

**Short-Term Investment**

We have classified our remaining investment in common shares of Depomed as a short-term investment based on our intent to dispose of those shares within the next 12 months (as described above under "New Strategic Focus - Sale of Non-Core Assets").

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

**Auction Rate Securities**

Our marketable securities portfolio currently includes \$26.8 million of principal invested in nine individual auction rate securities. These securities have long-term maturities for which the interest rates are reset through a dutch auction typically each month. Those auctions historically have provided a liquid market for these securities. These securities represent interests in collateralized debt obligations supported by pools of residential and commercial mortgages or credit cards, insurance securitizations, and other structured credits, including corporate bonds. Some of the underlying collateral for these securities consists of sub-prime mortgages. With the liquidity issues experienced in global credit and capital markets, these securities have experienced multiple failed auctions as the amount of auction rate securities submitted for sale has exceeded the amount of purchase orders.

The estimated fair values of the auction rate securities at September 30, 2008 and December 31, 2007 were \$12.5 million and \$18.0 million, respectively, which reflected write-downs of \$14.3 million and \$8.8 million, respectively, to the cost bases at those dates. Although these securities continue to pay interest according to their stated terms, we recorded impairment charges of \$4.2 million in the first nine months of 2008 and \$6.0 million in 2007, reflecting the portion of the auction rate securities that we have concluded has an other-than-temporary decline in estimated fair value due to a shortfall in the underlying collateral value for those securities. Those charges did not have a material impact on our liquidity.

In addition, we recorded unrealized losses in other comprehensive income of \$1.3 million in the first nine months of 2008 and \$2.8 million in 2007, reflecting adjustments to the portion of the auction rate securities that we have concluded have a temporary decline in estimated fair value. We do not consider this decline in estimated fair to be other-than-temporary based on the adequacy of the underlying collateral value for those securities. In addition, it is our intent to hold those securities until a recovery in market value occurs (or until maturity if necessary), and based on our existing cash resources, together with cash expected to be generated by operations, we do not expect to be required to sell those securities at a loss.

Due to the lack of observable market quotes for the auction rate securities, we utilized valuation models based on unobservable inputs in order to estimate the fair value of these securities at September 30, 2008 and December 31, 2007, including models that consider the expected cash flow streams, and collateral values as reported in the Trustee Reports for the respective securities, which include adjustments for defaulted securities and further adjustments for purposes of collateralization tests as outlined in Trust Indentures. The key assumptions used in those models relate to the timing of cash flows, discount rates, estimated amount of recovery, and probabilities assigned to various liquidation scenarios. The valuation of the auction rate securities is subject to uncertainties that are difficult to predict. Factors that may impact our valuation include changes to the credit ratings of these securities, the underlying assets supporting these securities, the rates of default of the underlying assets, the underlying collateral value, and overall market liquidity.

The credit and capital markets may continue to deteriorate in during the last quarter of 2008 and into 2009. If uncertainties in these markets continue, or these markets deteriorate further, or we experience any additional declines in underlying collateral values on the auction rate securities, we may incur additional write downs to these securities, which could have a material impact on our results of operations, financial condition and cash flows. We have discontinued additional investments in auction rate securities.

**Debt Capacity**

We currently do not have any outstanding borrowings under our \$250 million committed credit facility. In June 2007, we received lender consent, pursuant to our request under the annual extension option, to extend the maturity date of this facility for an additional year to June 2010. This facility may be used for general corporate purposes, including acquisitions. This facility includes an accordion feature which allows it to be increased up to \$400 million; however, in the current global credit environment, it is not expected that this feature would be

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

available at any reasonable terms. At September 30, 2008, we were in compliance with all financial and non-financial covenants associated with this facility.

**Credit Ratings**

On September 23, 2008, Standard and Poor's lowered our corporate credit rating from "BB" to "BB-" and our bank loan rating from "BBB-" to "BB+" with stable outlook, citing concerns that our New Strategic Focus and rationalization of our operations will involve a long time frame, significant investments and high execution risk, and that our share repurchase program could weaken our liquidity.

**CONTRACTUAL OBLIGATIONS**

As a result of the termination of our exclusive promotional services agreement with Sciele on October 10, 2008 (as described above under "Company Profile"), we are no longer obligated to pay Sciele the annual fee that would have otherwise been due under the terms of that agreement in fiscal years 2009 through 2011. With that exception, there have been no material changes outside the normal course of business to the items specified in the contractual obligations table and related disclosures under the heading "Contractual Obligations" in the annual MD&A contained in the 2007 Form 20-F.

**OFF-BALANCE SHEET ARRANGEMENTS**

In the normal course of business, we enter into agreements that include indemnification provisions for product liability and other matters. There have been no material changes to the indemnification provisions specified under the heading "Off-Balance Sheet Arrangements" in the annual MD&A contained in the 2007 Form 20-F.

**OUTSTANDING SHARE DATA**

Our common shares are listed on the Toronto Stock Exchange and New York Stock Exchange.

At October 31, 2008, we had 158,716,777 issued and outstanding common shares, as well as 4,625,468 stock options and 236,124 RSUs outstanding.

**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 short-term and long-term investments. We have used derivative financial instruments from time to time as a risk management tool and not for trading or speculative purposes.

**Inflation; Seasonality**

Our results of operations have not been materially impacted by inflation or seasonality.

**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 denominated in Canadian dollars or euros. 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. Where possible, we manage foreign currency risk by managing same currency assets in relation to same currency liabilities, and same currency revenue in relation to same currency expenses. As a result, both favourable and unfavourable foreign currency impacts to our non-U.S. dollar-denominated operating expenses are mitigated to a certain extent by the natural, opposite impact on our



**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

non-U.S. dollar-denominated revenue. At September 30, 2008, the effect of a hypothetical 10% immediate and adverse change in foreign currency exchange rates (relative to the U.S. dollar) on our foreign currency-denominated cash, cash equivalent, accounts receivable, accounts payable, and intercompany balances would not have a material impact on our net income. Currently, we do not utilize forward contracts to hedge against foreign currency risk.

**Interest Rate Risk**

The primary objective of our policy for the investment of temporary cash surpluses is the protection of principal, and, accordingly, we generally invest in investment-grade debt securities with varying maturities, but typically less than three months. As it is our intent and policy to hold these investments until maturity, we do not have a material exposure to interest rate risk, and, as a result, a hypothetical 10% immediate and adverse change in interest rates would not have a material impact on the realized value of these investments.

We are also exposed to interest rate risk on our investment in auction rate securities. Interest rates on these securities are typically reset every month; however, following the failure to complete successful auctions and reset of the interest rates, interest on these securities is being calculated and paid based on prescribed spreads to LIBOR. As we are guaranteed a fixed spread to market interest rates, our interest rate risk exposure is minimal, and, as a result, a hypothetical 10% immediate and adverse change in interest rates would not have a material impact on the fair value of these securities.

We do not currently have any long-term debt, nor do we currently utilize interest rate swap contracts to hedge against interest rate risk.

**Investment Risk**

We are exposed to investment risks primarily on our available-for-sale equity investments. The fair values of these investments are subject to significant fluctuations due to stock market volatility; changes in general economic conditions; and/or changes in the financial condition of each investee. 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. At September 30, 2008, a hypothetical 10% immediate and adverse change in the quoted market prices of our available-for-sale equity investments would not have a material impact on the fair value of those investments.

We are also exposed to investment risks on our investment in auction rate securities due to the current market liquidity issues (as described above under "Liquidity and Capital Resources - Auction Rate Securities").

**ADDITIONAL RISK FACTORS**

Investment in our common shares involves a degree of risk. The following risk factors and the risk factors set out under the heading "*Risk Factors*" in the 2007 Form 20-F should be carefully considered before any investment is made. These risk factors are some of the key risk factors generally associated with our business. However, the risk factors outlined below and in the 2007 Form 20-F are not the only ones that we face. Additional risks not currently known to us or that we currently deem immaterial may also impair our business operations.

**New Strategic Focus**

Under our New Strategic Focus, we anticipate investing over \$600 million in research and development in the 2008-2012 timeframe, which includes in-licensing and milestone payments, but excludes acquisition costs (as in the Prestwick transaction). Such investment is for the exploration of niche in-licensed and new chemical entities ("NCEs"), new indications and in-house reformulation opportunities in the specialty CNS market. Our

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

success in implementing this New Strategic Focus is subject to a number of risks, including: our ability to develop a commercial expertise in specialty neurology; our ability to develop in-house research and development expertise in specialty neurology; our ability to build and develop the necessary expertise to identify, evaluate and acquire high priority compounds; and our ability to successfully commercialize any CNS compounds that we develop or acquire. Over the next few years, if we are unable to commercialize new CNS products successfully, there could be a material adverse effect on our business, financial condition and results of operations and it could cause the market value of our common shares to decline.

The failure to successfully implement our New Strategic Focus, or parts of it, including our ability to realize the projected benefits of cost-reduction initiatives, may have an adverse impact on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

**Closure of our Puerto Rico Facilities**

As part of our New Strategic Focus, we are consolidating our manufacturing resources through the closure of our two Puerto Rico manufacturing facilities and the transfer of certain manufacturing processes to our Steinbach, Manitoba facility. If we experience a delay in transitioning such manufacturing processes to Steinbach, or if we experience other disruptions or issues in transitioning these manufacturing processes to Steinbach, we could fail to deliver our products in a timely manner, which could adversely affect our relationships with our customers and business partners, which, in turn, could adversely affect our business, financial condition and results of operations and could cause the market value of our common shares to decline.

**Integration of Acquisitions**

Should we complete an acquisition or license or acquire specialty CNS compounds in clinical development in accordance with our New Strategic Focus, we may be unable to successfully integrate the personnel and operations of a new business or achieve the operational synergies or other benefits that we had anticipated. Moreover, we might fail to discover liabilities of a business or operating or other problems prior to completing a transaction. We could experience adverse accounting and financial consequences, such as the need to make large provisions against the acquired assets or to write down acquired assets. We might also experience a dilutive effect on our earnings. Depending on how any such transaction is structured, there may be an adverse impact on our capital structure and on our ability to pay dividends in accordance with our current dividend policy. Further, an acquisition could disrupt our ongoing business, distract our management and employees or lead to increased expenses.

On September 16, 2008, we acquired Prestwick, a privately-held, U.S.-based pharmaceutical company that holds the Canadian and U.S. licensing rights to tetrabenazine tablets (known as Xenazine® in the U.S. and Nitoman® in Canada), a drug used in the treatment of chorea associated with Huntington's disease. In addition to the integration risks noted above, there are a number of risks associated with this acquisition, which include, but are not limited to the following:

The successful commercial launch of Xenazine® in the U.S. by our partner, Ovation;

Delays or additional regulatory compliance requirements imposed as a result of additional post-marketing preclinical studies; and

The risks of serious adverse effects such as depression and suicidal thoughts and actions associated with tetrabenazine and the impact of such risks on the successful commercialization of Xenazine® in the U.S. and Nitoman® in Canada.

If we are unable to successfully integrate the operations and manage these risks, the anticipated benefits of this acquisition may not be realized and we may experience material adverse consequences to our business, financial condition and results of operations.





**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

(All dollar amounts are expressed in U.S. dollars)

**Deterioration in the Global Credit and Capital Markets**

The credit and capital markets have experienced unprecedented deterioration in 2008, including the failure of a number of significant and established financial institutions in the U.S and abroad, all of which will have an impact on the availability of credit and capital in the near term. If uncertainties in these markets continue, or these markets deteriorate further, it could have a material adverse impact on our liquidity and capital resources.

**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. There have been no material changes to our critical accounting policies and estimates specified under the heading "Critical Accounting Policies and Estimates" in the annual MD&A contained in the 2007 Form 20-F.

**RECENT ACCOUNTING PRONOUNCEMENTS**

**Adoption of New Accounting Standards**

Effective January 1, 2008, we adopted Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurements" ("SFAS 157") for financial assets and financial liabilities. SFAS 157 establishes a framework for measuring fair value in U.S. GAAP, clarifies the definition of fair value within that framework, and expands disclosures about the use of fair value measurements. SFAS 157 applies to all other accounting pronouncements that require (or permit) fair value measurements, but does not require any new fair value measurements in U.S. GAAP. Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (i.e., an exit price). In determining fair value, we use various valuation techniques. SFAS 157 establishes a hierarchy for inputs to valuation techniques used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that reflect assumptions market participants would use in pricing the asset or liability developed based on market data obtained from independent sources. Unobservable inputs are inputs that reflect our own assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. To the extent that the valuation technique is based on inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. The adoption of SFAS 157 for financial assets and financial liabilities did not have a material effect on our consolidated financial statements, or result in any significant changes to our valuation techniques or key considerations used in valuations.

In October 2008, the FASB issued FASB Staff Position ("FSP") No. FAS 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active" ("FSP 157-3"), which clarifies the application of SFAS 157 in a market that is not active. FSP 157-3 was effective for us at September 30, 2008. The effect of the adoption of FSP 157-3 on our consolidated financial statements was not material.

Effective January 1, 2008, we adopted SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS 159"). SFAS 159 provides companies with an option to report many financial instruments and certain other items at fair value. We elected the fair value option for available-for-sale securities owned by Western Life Sciences ("WLS"), our equity method investee, in order to conform to the classification of those investments as trading securities by WLS. At January 1, 2008, the cumulative effect of the adoption of SFAS 159 resulted in the reclassification of an unrealized holding gain on those investments of \$2.3 million from

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

accumulated other comprehensive income to opening deficit. We did not elect the fair value option for any other eligible financial assets and financial liabilities that were not previously recorded at fair value.

Emerging Issues Task Force ("EITF") Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3"), became effective for new contracts entered into on or after January 1, 2008. Under EITF 07-3, non-refundable advance payments for goods and services that will be used in future research and development activities should be recognized as an expense as the goods are delivered or the services are performed rather than when the payment is made. The adoption of EITF Issue No. 07-3 did not have any impact on our consolidated financial statements.

**Recently Issued Accounting Standards, Not Adopted as of September 30, 2008**

In June 2008, the FASB issued SFAS No. 162, "The Hierarchy of Generally Accepted Accounting Principles" ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements presented in conformity with U.S. GAAP. This Statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles". The adoption of SFAS 162 is not expected to have any impact on our consolidated financial statements.

In April 2008, the FASB issued FSP No. FAS 142-3, "Determination of the Useful Life of Intangible Assets" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "Goodwill and Other Intangible Assets" and also requires expanded disclosure related to the determination of intangible asset useful lives. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. Accordingly, we are required to apply the guidance of FSP 142-3 for determining useful life to intangible assets acquired on or after January 1, 2009 and the disclosure requirements of FSP 142-3 to intangible assets recognized as of or after January 1, 2009.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133" ("SFAS 161"). SFAS 161 applies to all derivative instruments and related hedged items accounted for under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"). SFAS 161 requires disclosures about how and why an entity uses derivative instruments; how derivative instruments and related hedged items are accounted for under SFAS 133; and how derivative instruments and related hedged items affect an entity's financial position, results of operations, and cash flows. SFAS 161 is effective for fiscal years beginning after December 15, 2008, with early adoption permitted. Accordingly, we are required to adopt the disclosure requirements of this standard beginning January 1, 2009.

In February 2008, the FASB issued FSP No. FAS 157-2, "Effective Date of FASB Statement No. 157", which defers the effective date of SFAS 157 for one year for certain nonfinancial assets and liabilities, except those that are recognized or disclosed at fair value on a recurring basis (at least annually). Accordingly, we are required to adopt SFAS 157 beginning January 1, 2009 for nonfinancial assets and liabilities. We are currently evaluating the effect that the adoption of SFAS 157 for nonfinancial assets and liabilities will have on our consolidated financial statements.

In December 2007, the EITF issued EITF Issue No. 07-1, "Accounting for Collaborative Arrangements" ("EITF 07-1"). EITF 07-1 provides guidance for determining if a collaborative arrangement exists and establishes reporting requirements for revenues and costs generated from transactions between parties within a collaborative arrangement, as well as between the parties in a collaborative arrangement and third parties, and provides guidance for financial statement disclosures of collaborative arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and is required to be applied retrospectively to all prior periods

**BIOVAIL CORPORATION**

**MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**

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

where collaborative arrangements existed as of the effective date. Accordingly, we are required to adopt EITF 07-1 beginning January 1, 2009. We are currently evaluating the effect that the adoption of EITF 07-1 will have on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS 141R") and SFAS 160, "Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51" ("SFAS 160"). These standards significantly change the accounting for, and reporting of, business combination transactions and noncontrolling (minority) interests in consolidated financial statements, including requirements to recognize noncontrolling interests at fair value; capitalize in-process research and development assets acquired; and expense acquisition related costs as incurred. SFAS 141R and SFAS 160 are required to be adopted simultaneously, and are effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. Accordingly, we are required to adopt SFAS 141R for business combinations occurring on or after January 1, 2009. As we currently have no minority interests, the adoption of SFAS 160 beginning January 1, 2009 is not expected to have a material effect on our consolidated financial statements.

**UNRESOLVED SEC STAFF COMMENTS**

On May 2, 2008, we were advised by the staff of the SEC that they had completed their review of our 2007 Form 20-F.

**OSC CONTINUOUS DISCLOSURE REVIEW**

On July 18, 2008, we were advised that the OSC's Corporate Finance Branch had completed its most recent review of our continuous disclosure record.

**CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING**

There were no changes in our internal controls over financial reporting that occurred during the three-month period ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**BIOVAIL CORPORATION**  
**FORM 6-K**  
**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2008**

**PART II OTHER INFORMATION**

**1. LEGAL PROCEEDINGS**

For detailed information concerning legal proceedings, reference is made to note 19 to the consolidated financial statements included under Part I of this Form 6-K.

**2. EXHIBITS**

Exhibit 99.1 Certification of the Chief Executive Officer

Exhibit 99.2 Certification of the Chief Financial Officer

**BIOVAIL CORPORATION  
FORM 6-K  
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2008**

**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 7, 2008

By: /s/ MARGARET MULLIGAN

Margaret Mulligan  
Chief Financial Officer

63

---

QuickLinks

[BIOVAIL CORPORATION FORM 6-K FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2008](#)

[INDEX](#)

[BASIS OF PRESENTATION](#)

[FORWARD-LOOKING STATEMENTS](#)

[BIOVAIL CORPORATION CONSOLIDATED BALANCE SHEETS In accordance with United States 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 United States 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 United States Generally Accepted Accounting Principles \(All dollar amounts are expressed in thousands of U.S. dollars\) \(Unaudited\)](#)

[BIOVAIL CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS In accordance with United States Generally Accepted Accounting Principles \(All dollar amounts are expressed in thousands of U.S. dollars\) \(Unaudited\)](#)

[BIOVAIL CORPORATION CONDENSED NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS In accordance with United States Generally Accepted Accounting Principles \(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data\) \(Unaudited\)](#)

[BIOVAIL CORPORATION MANAGEMENT'S DISCUSSION AND ANALYSIS \(All dollar amounts are expressed in U.S. dollars\)](#)

[PART II OTHER INFORMATION](#)

[SIGNATURES](#)