BIOVAIL Corp Form 10-Q May 07, 2010

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

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

For the Quarterly Period Ended March 31, 2010

OR

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

For the transition period from _	to
Commission File	Number: 001-14956

# **BIOVAIL CORPORATION**

(Exact name of registrant as specified in its charter)

Canada

98-0448205

(State or other jurisdiction of incorporation or organization)

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

7150 Mississauga Road, Mississauga, Ontario

L5N 8M5

(Address of principal executive offices)

(Zip Code)

(905) 286-3000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\circ$  No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ý

Accelerated filer o

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller

reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ý

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Common shares, no par value 158,478,375 shares issued and outstanding at May 4, 2010

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### **BIOVAIL CORPORATION**

### FORM 10-Q

# FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2010

### **BASIS OF PRESENTATION**

#### General

Except where the context otherwise requires, all references in this Form 10-Q 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 INTERNATIONAL®, BIOVAIL & SWOOSH DESIGN®, BPI®, BVF®, CARDISENSE , CARDIZEM®, CEFORM®, CRYSTAAL CORPORATION & DESIGN®, DITECH , FLASHDOSE®, GLUMETZA®, INSTATAB , ISORDIL®, JOVOLA , JUBLIA , MIVURA , NITOMAN®, ONELZA , ONEXTEN , ORAMELT , PALVATA , RALIVIA®, SHEARFORM , SMARTCOAT , SOLBRI , TESIVEE , TIAZAC®, TITRADOSE®, TOVALT , UPZIMIA , VASERETIC®, VASOTEC®, VEMRETA , VOLZELO , XENAZINE®, XENAZINA®, and ZILERAN .

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In addition, we have filed trademark applications for many of our other trademarks in Barbados, the U.S., Canada and in other jurisdictions 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 10-Q 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 within the meaning defined under applicable Canadian 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 impact of healthcare reform in the U.S. and elsewhere;

our intent and ability to implement and effectively execute plans and initiatives associated with our strategic focus on products targeting specialty central nervous system ("CNS") disorders and the anticipated impact of such strategy including, but not limited to, the amount and timing of expected contribution(s), from our product development pipeline;

our intent to complete in-license agreements and acquisitions and to successfully integrate such in-license agreements and acquisitions into our business and operations and to achieve the anticipated benefits of such in-license agreements and acquisitions;

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our intent to deploy a specialty U.S. sales force to support our specialty CNS strategy, including our intent to develop a sales force to commercialize AZ-004 (Staccato® loxapine) and BVF-007 (AMPAKINE®) in the U.S., and the timing and amount of costs associated with establishing such sales force;

the competitive landscape in the markets in which we compete, including, but not limited to, the prescription trends, pricing and the formulary or Medicare/Medicaid utilization and positioning for our products, the opportunities present in the market for therapies for specialty CNS disorders, the anticipated level of demand for our products and the availability or introduction of generic formulations of our products;

expected timing and/or impact on revenues and earnings of the introduction of generic versions of Ultram® ER (300mg dosage strength), Glumetza® (500mg dosage strength), Cardizem® LA and Cardizem® CD products;

our intent, timing and ability to complete the planned disposals of certain non-core assets, including, but not limited to, our Carolina, Puerto Rico manufacturing facility and operations and the anticipated costs, impacts and proceeds of such disposition;

our intent and related success or failure regarding the defence of our intellectual property against infringement;

our views, beliefs and positions related to, results of, and costs associated with, certain litigation and regulatory proceedings and the timing, costs and expected impact of the resolution of certain litigation and regulatory proceedings;

the timing, results, and progress of research and development and regulatory approval efforts;

our intent and ability to make future dividend payments or to repurchase our common shares under our share repurchase program;

the sufficiency of cash resources, including those under the accordion feature of our senior secured revolving credit facility, to support future spending and business development requirements;

the impact of market conditions on our ability to access additional funding at reasonable rates;

our ability to manage exposure to foreign currency exchange rate changes and interest rate changes;

our intent and ability to use a net share settlement approach upon conversion of our 5.375% Senior Convertible Notes due August 1, 2014 ("Convertible Notes");

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

our expected capital expenditures; and

expected impact of the adoption of new accounting guidance.

Forward-looking statements can generally be identified by the use of words such as "believe", "anticipate", "expect", "intend", "plan", "will", "may", "target", "potential" 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 10-Q 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 the items outlined above. 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 uncertainties associated with the specific determinations necessary to implement certain provisions under the healthcare reform legislation enacted in the U.S;

the successful execution of our specialty CNS strategy, including our ability to successfully identify, evaluate, acquire, obtain regulatory approval for, develop, manufacture and commercialize pipeline products;

the success of pre-clinical and clinical trials for our drug development pipeline or delays in clinical trials which adversely impact the timely commercialization of our pipeline products;

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the results of continuing safety and efficacy studies by industry and government agencies;

the uncertainties associated with the development, acquisition and launch of new products, including, but not limited to, the acceptance and demand for new pharmaceutical products, and the impact of competitive products and pricing;

our reliance on key strategic alliances, our ability to secure and maintain third-party research, development, manufacturing, marketing or distribution arrangements and securing other development partners for, and to share development costs associated with, certain product development programs;

the availability of capital and our ability to generate operating cash flows to support our growth strategy;

the continuation of the recent market turmoil, which could result in fluctuations in currency exchange rates and interest rates;

our eligibility for benefits under tax treaties and the continued availability of low effective tax rates for the business profits of our principal operating subsidiary;

the difficulty of predicting the expense, timing and outcome within our legal and regulatory environment, including, but not limited to, U.S. Food and Drug Administration, Canadian Therapeutic Products Directorate and European regulatory approvals, legal and regulatory proceedings and settlements thereof, the protection afforded by our patents and other intellectual and proprietary property, successful challenges to our generic products, and infringement or alleged infringement of the intellectual property rights of others;

our ability to establish or acquire a specialty U.S. sales force to support our specialty CNS strategy;

our ability to attract and retain key personnel;

the reduction in the level of reimbursement for, or acceptance of, pharmaceutical products by governmental authorities, health maintenance organizations or other third-party payors;

our ability to satisfy the financial and non-financial covenants of our credit facility and Convertible Notes indenture;

our ability to repay or refinance the principal amount under the Convertible Notes indenture at maturity;

the disruption of delivery of our products and the routine flow of manufactured goods across the U.S. border; 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 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 Form 10-Q, as well as under Item 1A "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2009. 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, except as may be required by law.

# PART I. FINANCIAL INFORMATION

# **Item 1. Financial 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)

	At March 31 2010	At December 31 2009
ASSETS		
Current		
Cash and cash equivalents	\$ 102,892	\$ 114,463
Marketable securities	8,231	9,566
Accounts receivable	105,025	119,919
Inventories	97,523	82,773
Prepaid expenses and other current assets	13,103	15,377
Deferred tax assets, net of valuation allowance	12,400	
Assets held for sale		8,542
	339,174	350,640
Marketable securities	11,543	11,516
Property, plant and equipment, net	106,896	103,848
Intangible assets, net	1,299,768	1,335,222
Goodwill	100,294	100,294
Deferred tax assets, net of valuation allowance	116,100	132,800
Other long-term assets, net	31,261	32,724
Care long term assets, not	21,201	52,72.
	\$ 2,005,036	\$ 2,067,044
LIABILITIES		
Current		
Accounts payable	\$ 42,480	
Dividends payable	14,255	14,246
Accrued liabilities	107,940	121,898
Accrued legal settlements	2,000	7,950
Income taxes payable	8,232	6,846
Deferred revenue	20,489	21,834
Current portion of long-term obligations	12,316	12,110
	207,712	256,906
Deferred revenue	64,346	69,247
Income taxes payable	66,200	66,200
Long-term obligations	316,570	313,975
Other long-term liabilities	5,905	6,344
	660,733	712,672
SHAREHOLDERS' EQUITY		
	1,466,720	1,465,004

Common shares, no par value, unlimited shares authorized, 158,466,361 and 158,310,884 issued and outstanding at March 31, 2010 and December 31, 2009, respectively

Additional paid-in capital	93,339	91,768
Accumulated deficit	(263,464)	(245,974)
Accumulated other comprehensive income	47,708	43,574
	1,344,303	1,354,372
	\$ 2,005,036	\$ 2,067,044

Commitments and contingencies (note 14)

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

# CONSOLIDATED STATEMENTS OF INCOME (LOSS)

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 March 31			
		2010		2009
REVENUE				
Product sales	\$	212,033	\$	165,393
Research and development		2,924		3,715
Royalty and other		4,678		4,211
		219,635		173,319
EXPENSES				
Cost of goods sold (exclusive of amortization of intangible assets shown separately below)		58,955		44,840
Research and development		66,887		14,528
Selling, general and administrative		43,513		43,244
Amortization of intangible assets		33,300		15,503
Restructuring costs		613		1,348
Legal settlements				241
		203,268		119,704
Operating income		16,367		53,615
Interest income		188		334
Interest expense		(9,827)		(340)
Foreign exchange gain (loss)		(623)		407
Impairment loss on debt securities		(155)		(2,707)
Loss on disposal of investments		Ì		(6)
•				, ,
Income before provision for income taxes		5,950		51,303
Provision for income taxes		9,100		12,300
110 vision for moonic taxes		,,100		12,300
Net income (loss)	\$	(3,150)	\$	39,003
Basic and diluted earnings (loss) per share	\$	(0.02)	\$	0.25
Weighted-average number of common shares outstanding (000s)		150 207		150.010
Basic		158,387		158,218
Diluted		158,387		158,270
Cash dividends declared per share	\$	0.090	\$	0.375

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

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# BIOVAIL CORPORATION

# CONSOLIDATED STATEMENTS OF ACCUMULATED DEFICIT

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

Three Months Ended March 31

	2010	2009
Accumulated deficit, beginning of period	\$ (245,974) \$	(319,909)
Net income (loss)	(3,150)	39,003
Cash dividends declared and dividend equivalents	(14,340)	(59,450)
Accumulated deficit, end of period	\$ (263,464) \$	(340,356)

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

# 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 1	Months	Ended
N	Aarch 3	1

	2010	2009
CASH FLOWS FROM OPERATING		
ACTIVITIES		
Net income (loss)	\$ (3,150)	\$ 39,003
Adjustments to reconcile net income (loss) to net		
cash provided by operating activities		
Depreciation and amortization	40,048	26,691
Amortization of deferred revenue	(4,775)	(5,300)
Amortization of discounts on long-term obligations	2,801	
Amortization of deferred financing costs	1,312	130
Acquired in-process research and development	51,003	
Deferred income taxes	4,300	7,800
Payment of accrued legal settlements	(5,950)	(6,158)
Addition to accrued legal settlements		241
Stock-based compensation	1,657	1,757
Impairment charges	155	2,707
Loss on sale of investments		6
Other	(522)	(23)
Changes in operating assets and liabilities:		
Accounts receivable	15,059	6,839
Insurance recoveries receivable		770
Inventories	(14,858)	1,226
Prepaid expenses and other current assets	2,275	3,210
Accounts payable	(29,730)	(16,334)
Accrued liabilities	(14,803)	(8,776)
Income taxes payable	1,401	1,010
Deferred revenue	(1,470)	(7,827)
Not each manifold by anaucting activities	11.752	46,972
Net cash provided by operating activities	44,753	40,972
CASH FLOWS FROM INVESTING		
ACTIVITIES		
Acquisition of in-process research and development		
intangible assets	(50,003)	
Proceeds from sale of property, plant and equipment	8,542	
Additions to property, plant and equipment	(3,634)	(786)
Proceeds from sales and maturities of marketable		
securities	1,215	13
Transfer to restricted cash		(5,250)
Additions to marketable securities		(1,019)
Net cash used in investing activities	(43,880)	(7,042)
CASH FLOWS FROM FINANCING		
ACTIVITIES		
Cash dividends paid	(14,246)	(59,331)
Proceeds from exercise of stock options	1,544	
•		

Net cash used in financing activities		(12,702)		(59,331)	
Effect of exchange rate changes on cash and cash					
equivalents		258		(452)	
				(40.050)	
Net decrease in cash and cash equivalents		(11,571)		(19,853)	
Cash and cash equivalents, beginning of period		114,463		317,547	
Cash and cash equivalents, end of period	\$	102,892	\$	297,694	
NON-CASH INVESTING AND FINANCING ACTIVITIES					
	Ф	(14.255)	¢	(59.331)	
Cash dividends declared but unpaid	\$	(14,255)	Ф	(39,331)	
Accrued acquisition of in-process research and					
development intangible assets		(1,000)			
The accompanying note		an interne	1	aut of the com	salidated financ

 ${\it The\ accompanying\ notes\ are\ an\ integral\ part\ of\ the\ consolidated\ financial\ statements}.$ 

### 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 formed under the *Business Corporations Act (Ontario)* on February 18, 2000, and was continued under the *Canada Business Corporations Act* on June 29, 2005. The Company is a specialty pharmaceutical company with a strategic focus on developing and commercializing products that address unmet medical needs in specialty central nervous system ("CNS") disorders.

### 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 10-K for the fiscal year ended December 31, 2009. 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, 2009. There have been no material changes to the Company's significant accounting policies since December 31, 2009, except as described below under "Adoption of New Accounting Guidance". The consolidated financial statements reflect all normal and recurring adjustments necessary for the fair presentation of the Company's financial position and results of operations for the interim periods presented.

Certain of the amounts in the three-month period ended March 31, 2009 have been reclassified to conform to the presentation adopted in the three-month period ended March 31, 2010.

### **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 Guidance**

Effective January 1, 2010, the Company adopted the following new accounting guidance:

Authoritative guidance requiring additional disclosure about the amounts of and reasons for significant transfers in and out of Level 1 and Level 2 fair value measurements. This guidance also clarifies existing disclosure requirements related to the level of disaggregation of fair value

### 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)

measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring Level 2 and Level 3 measurements. As the guidance only requires new disclosures, the adoption of this guidance did not impact the Company's financial position or results of operations. In addition, effective for interim and annual periods beginning after December 15, 2010, this guidance will require additional disclosure and require an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis.

Authoritative guidance for determining whether an entity is a variable interest entity ("VIE"). Under this guidance, an enterprise has a controlling financial interest when it has the power to direct the activities of a VIE that most significantly impact the entity's economic performance, and the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. Upon adoption of this guidance, the Company determined that none of its existing collaboration and license arrangements with other entities for various products under development represented arrangements with VIEs. Accordingly, the adoption of this guidance did not have any impact on the Company's consolidated financial statements.

### Recently Issued Accounting Guidance, Not Adopted as of March 31, 2010

In March 2010, new authoritative guidance was issued recognizing the milestone method of revenue recognition as a valid application of the proportional performance model when applied to research and development arrangements. An entity may make an accounting policy election to recognize the receipt of a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The guidance is effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The Company is currently evaluating the effect that the adoption of this guidance will have on its consolidated financial statements.

### 3. ASSET ACQUISITIONS

#### **AMPAKINE®**

On March 25, 2010, the Company acquired certain AMPAKINE® compounds, including associated intellectual property, from Cortex Pharmaceuticals, Inc. ("Cortex") for use in the field of respiratory depression, a brain-mediated breathing disorder. The acquired compounds include the Phase 2 compound CX717, the pre-clinical compounds CX1763 and CX1942, and the injectable dosage form of CX1739.

Under the terms of the asset purchase agreement, the Company paid an upfront fee of \$9,000,000 and expects to pay an additional \$1,000,000 upon the completion of a six-month transition period. In addition, the Company could pay up to \$15,000,000 in potential milestones contingent on the successful demonstration of the utility of an intravenous formulation of CX717 in treating respiratory depression (BVF-007), the successful completion of a Phase 3 clinical program using an AMPAKINE® compound, and approval from the U.S. Food and Drug Administration ("FDA") of an AMPAKINE® compound. The Company may also owe certain development milestones and/or royalties on net sales to third parties of an AMPAKINE® compound.

This acquisition was accounted for as a purchase of in-process research and development ("IPR&D") intangible assets with no alternative future use. Accordingly, the \$9,000,000 upfront payment and the

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### BIOVAIL CORPORATION

### 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. ASSET ACQUISITIONS (Continued)

\$1,000,000 accrued transition payment, together with \$686,000 of acquisition costs, were charged to research and development expenses at the acquisition date.

### Staccato® Loxapine

On February 9, 2010, the Company entered into a collaboration and license agreement with Alexza Pharmaceuticals, Inc. ("Alexza") to acquire the U.S. and Canadian development and commercialization rights to AZ-004 for the treatment of psychiatric and/or neurological indications and the symptoms associated with these indications, including the initial indication of treating agitation in schizophrenia and bipolar patients. AZ-004 combines Alexza's proprietary Staccato® drug-delivery system with the antipsychotic drug loxapine. In December 2009, Alexza submitted a New Drug Application ("NDA") to the FDA for Staccato® loxapine. The FDA has accepted the NDA for filing and has indicated a Prescription Drug User Fee Act goal date of October 11, 2010.

Under the terms of the agreement, the Company paid an upfront fee of \$40,000,000, and could pay up to \$90,000,000 in potential milestones in connection with the initial indication contingent on the successful approval of the first AZ-004 NDA, successful commercial manufacturing scale-up, and the first commercial sale on an inpatient and on an outpatient basis, which may require the successful completion of additional clinical trials, regulatory submissions, and/or approval of a supplemental NDA. The Company will also make tiered royalty payments of 10% to 25% on net commercial sales of Staccato® loxapine. Alexza will supply Staccato® loxapine to the Company for commercialization and will receive a per-unit transfer price, based on annual product volume.

This acquisition was accounted for as a purchase of IPR&D intangible assets with no alternative future use. Accordingly, the \$40,000,000 upfront payment, together with \$317,000 of acquisition costs, was charged to research and development expenses at the acquisition date.

### 4. RESTRUCTURING

In May 2008, the Company initiated restructuring measures that were intended to rationalize its manufacturing operations, pharmaceutical sciences operations, and general and administrative expenses.

On January 15, 2010, the Company completed the sale of its Dorado, Puerto Rico manufacturing facility for net cash proceeds of \$8,542,000. The related property, plant and equipment was classified as assets held for sale on the consolidated balance sheet at December 31, 2009. The Company continued to occupy the Dorado facility until March 31, 2010, pursuant to a short-term lease agreement with the buyer. The Company is continuing to actively market its manufacturing facility located in Carolina, Puerto Rico.

The Company expects to incur employee termination costs of approximately \$9,600,000 in total for severance and related benefits payable to the approximately 240 employees who have been, or will be, terminated as a result of the closure of the Dorado and Carolina facilities. As these employees are required to provide service during the shutdown period in order to be eligible for termination benefits, the Company is recognizing the cost of those termination benefits ratably over the estimated future service period.

Prior to December 31, 2009, the Company completed the closure of its research and development facilities in Dublin, Ireland and Mississauga, Ontario, and the consolidation of its research and development operations in Chantilly, Virginia.

# 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)

The following table summarizes the major components of restructuring costs recognized through March 31, 2010:

	Asset Impai	irments	Employee T Ben	Contract Termination		
	Pl Manufacturing	narmaceutical Sciences	Manufacturing	Pharmaceutical Sciences	Costs	Total
Balance, January 1, 2008	\$		\$	\$	\$	\$
Costs incurred and charged						
to expense	42,602	16,702	3,309	2,724	4,865	70,202
Cash payments				(2,724)	(333)	(3,057)
Non-cash adjustments	(42,602)	(16,702)			(1,186)	(60,490)
Balance, December 31, 2008			3,309		3,346	6,655
Costs incurred and charged to expense Cash payments Non-cash adjustments	7,591 (7,591)	2,784		1,441 (1,278) 71	2,307 (1,321)	19,065 (4,640) (10,304)
Balance, December 31, 2009  Costs incurred and charged			6,210	234	4,332	10,776
to expense			333		280	613
Cash payments			(2,703)	(195)	(429)	(3,327)
Non-cash adjustments				6		6
Balance, March 31, 2010	\$		\$ 3,840	\$ 45	\$ 4,183	\$ 8,068

# 5. FAIR VALUE MEASUREMENTS

### Assets Measured at Fair Value on a Recurring Basis

The following fair value hierarchy table presents the components and classification of the Company's financial assets measured at fair value:

	nrrying Value	At Marc Quoted Prices in Active Markets for Identical Assets (Level 1)	Sign C Obs In	olionificant other ervable iputs evel 2)	Significant Unobservable Inputs (Level 3)	:
Money market funds	\$ 8,694	\$ 8,694	\$		\$	
Available-for-sale debt securities:						
Corporate bonds	9,589			9,589		
Government-sponsored enterprise securities	4,149			4,149		
Auction rate securities	6,036				6,03	6

Total financial assets	\$ 28,468	\$	8,694	\$ 13,738	\$ 6,036
Cash and cash equivalents	\$ 8,694	\$	8,694	\$	\$
Marketable securities	19,774			13,738	6,036
Total financial assets	\$ 28,468	\$	8,694	\$ 13,738	\$ 6,036
		8			

### 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 MEASUREMENTS (Continued)

	arrying Value	•	At Decemb quoted Prices in Active Markets for Identical Assets (Level 1)	Si	gnificant Other bservable Inputs Level 2)	Une	ignificant observable Inputs Level 3)
Money market funds	\$ 7,994	\$	7,994	\$		\$	
Available-for-sale debt securities:							
Corporate bonds	10,880				10,880		
Government-sponsored enterprise securities	4,193				4,193		
Auction rate securities	6,009						6,009
Total financial assets	\$ 29,076	\$	7,994	\$	15,073	\$	6,009
Cash and cash equivalents	\$ 7,994	\$	7,994	\$	15.050	\$	6.000
Marketable securities	21,082				15,073		6,009
Total financial assets	\$ 29,076	\$	7,994	\$	15,073	\$	6,009

Fair value measurements are estimated based on valuation techniques and inputs categorized as follows:

Level 1 Quoted prices (unadjusted) for identical securities in active markets.

Level 2 Quoted prices (unadjusted) for identical securities in markets that are not active.

Level 3 Discounted cash flow method (income approach) using significant inputs not observable in the market. These inputs include the estimated amount and timing of projected cash flows based on the underlying collateral coverage for each auction rate security, ranging from zero to 220%, after taking into account the priority sequence and liquidation preference of the tranches of the securities, and a weighted-average discount rate of 11.0%. These securities have a weighted-average coupon rate of 0.8% and a weighted-average maturity of 31 years. 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, with a weighted-average maturity of 25 years. Some of the underlying collateral for these securities consists of sub-prime mortgages. All of these securities are currently rated below investment grade.

At March 31, 2010 and December 31, 2009, the Company did not have any financial liabilities that were subject to fair value measurements.

### 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 MEASUREMENTS (Continued)

### Assets Measured at Fair Value on a Recurring Basis Using Significant Unobservable Inputs (Level 3)

The following table presents a reconciliation of auction rate securities measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

	Three Mo	nths E ch 31	inded
	2010		2009
Balance, beginning of period	\$ 6,009	\$	10,333
Total unrealized gains (losses):			
Included in net income (loss) <sup>(1)</sup> :			
Arising during period	(155)		(2,735)
Reclassification from other comprehensive income			28
Included in other comprehensive income:			
Arising during period	182		(146)
Reclassification to net income (loss)			(28)
Balance, end of period	\$ 6,036	\$	7,452
Total amount of unrealized losses for the period included in net			
income (loss) relating to securities still held at end of period	\$ (155)	\$	(2,707)

(1) Included in impairment loss on debt securities in the consolidated statements of income (loss).

### Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

The Company did not have any non-financial assets or non-financial liabilities that were measured at fair value on a recurring or non-recurring basis in the three-month period ended March 31, 2010.

# 6. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following table summarizes the estimated fair values of the Company's financial instruments:

	At March 31, 2010				
		rrying Value		Fair Value	
Cash equivalents	\$	8,694	\$	8,694	
Marketable securities		19,774		19,774	
Long-term obligations (as described in note 9)		(328,886)		(480,291)	

	Carrying Value		Fair Value
Cash equivalents	\$ 7,99	4 \$	7,994
Marketable securities	21,08	2	21,082
Long-term obligations (as described in note 9)	(326,08	5)	(434,518)
	10		

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### **BIOVAIL CORPORATION**

### 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)

# 6. FAIR VALUE OF FINANCIAL INSTRUMENTS (Continued)

The following table summarizes the Company's marketable securities by major security type:

### At March 31, 2010

	Cost			Fair		Gross	Unr	ealized
		Basis		Value	G	Sains		Losses
Corporate bonds	\$	9,390	\$	9,589	\$	199	\$	
Government-sponsored enterprise securities		4,095		4,149		54		
Auction rate securities <sup>(1)</sup>		26,775		6,036				(20,739)
	\$	40,260	\$	19,774	\$	253	\$	(20.739)

# At December 31, 2009

	Cost		Cost Fair			Gross	Unr	ealized
		Basis		Value	G	ains		Losses
Corporate bonds	\$	10,626	\$	10,880	\$	254	\$	
Government-sponsored enterprise securities		4,100		4,193		93		
Auction rate securities <sup>(1)</sup>		26,775		6,009				(20,766)
	\$	41,501	\$	21,082	\$	347	\$	(20,766)

(1)

The auction rate securities have been in a continuous loss position for at least 12 months. In May 2009, the Company received \$22,000,000 in a settlement with an investment bank in respect of these securities. The Company retained ownership of the securities under the terms of the settlement.

The contractual maturities of marketable securities held at March 31, 2010 were as follows:

		Carrying Value		Fair Value
Within one year	\$	8,231	\$	8,231
One to three years		5,507		5,507
After three years		6,036		6,036
	¢	10.774	¢	10.774

Gross gains and losses realized on the sale of marketable securities were not material in the three-month periods ended March 31, 2010 and 2009. The cost of securities sold, and the amount reclassified out of accumulated other comprehensive income into earnings, is

calculated using the specific identification method, if determinable, otherwise the average cost method is applied.

# 7. INVENTORIES

	 At arch 31 2010	De	At cember 31 2009
Raw materials	\$ 15,993	\$	14,290
Work in process	27,220		25,012
Finished goods	54,310		43,471
	\$ 97,523	\$	82,773

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# BIOVAIL CORPORATION

# 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. INTANGIBLE ASSETS

	At March 31, 2010			At Decemb	er 31,	, 2009
	Cost		ccumulated nortization	Cost		cumulated nortization
Trademarks	\$ 1,084,226	\$	287,278	\$ 1,084,226	\$	267,249
Product rights	693,286		218,466	693,126		202,881
IPR&D	28,000			28,000		
	1,805,512	\$	505,744	1,805,352	\$	470,130
Less accumulated amortization	505,744			470,130		
	\$ 1,299,768			\$ 1,335,222		

# **Amortization of Intangible Assets**

Amortization expense related to intangible assets was recorded as follows:

,			
	2010		2009
\$	268	\$	268
	2,026		2,026
	33,300		15,503
¢	25 504	Φ.	17.707
		2010 \$ 268 2,026	\$ 268 \$ 2,026 33,300

# 9. LONG-TERM OBLIGATIONS

	N	At March 31 2010	De	At ecember 31 2009
Convertible Notes, net of unamortized debt discount (March 31, 2010 \$49,415; December 31, 2009 \$51,715)	\$	300,585	\$	298,285
Cambridge obligation, net of unamortized debt discount (March 31, 2010 \$1,699; December 31, 2009 \$2,200)		28,301		27,800
		328,886		326,085
Less current portion		12,316		12,110
	\$	316,570	\$	313,975

# **Convertible Notes**

On June 10, 2009, the Company issued \$350,000,000 principal amount of 5.375% Senior Convertible Notes due August 1, 2014 ("Convertible Notes"). The Convertible Notes were issued at par and pay interest semi-annually on February 1 and August 1 of each year. The Convertible Notes may be converted based on a conversion rate of 67.0880 common shares per \$1,000 principal amount of Convertible Notes (which represents a conversion price of approximately \$14.91 per share).

### 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)

### 9. LONG-TERM OBLIGATIONS (Continued)

Upon conversion, the Convertible Notes may be settled in cash, common shares, or a combination of cash and common shares, at the Company's option. The Company's current intent and policy is to settle the Convertible Notes using a net share settlement approach, such that the principal amount of any Convertible Notes tendered for conversion would be settled in cash, and any excess conversion value settled in common shares.

Interest expense of \$7,502,000 was recognized on the Convertible Notes in the three-month period ended March 31, 2010, which comprised accrued cash interest of \$4,703,000, non-cash amortization of debt discount of \$2,300,000 and deferred financing costs of \$499,000.

At March 31, 2010 and December 31, 2009, the estimated fair value of the Convertible Notes in the secondary market was determined to be approximately \$451,990,000 and \$406,718,000, respectively, based on changes in the underlying trading price of the Company's common shares and market interest rates.

### **Cambridge Obligation**

In connection with the acquisition of the worldwide development and commercialization rights to tetrabenazine on June 19, 2009, the Company will make payments of \$12,500,000 and \$17,500,000 to Cambridge Laboratories (Ireland) Ltd. ("Cambridge") on June 21, 2010 and June 20, 2011, respectively. These payments were discounted based on imputed interest rates of 6.9% and 7.7%, respectively.

Non-cash amortization of the debt discount on the Cambridge obligation of \$501,000 was recognized in interest expense in the three-month period ended March 31,2010.

At March 31, 2010, the fair value of the Cambridge obligation approximated its carrying value based on current borrowing rates available to the Company.

### **Credit Facility**

On June 9, 2009, the Company established a \$410,000,000 senior secured revolving credit facility maturing on June 9, 2012. This facility contains an accordion feature that, subject to certain conditions, allows it to be increased to up to \$550,000,000. Borrowings under the facility are guaranteed by the Company's material subsidiaries and are secured by charges over substantially all of the assets of the Company and the assets of its material subsidiaries.

At March 31, 2010 and December 31, 2009, the Company had no outstanding borrowings under this facility.

### 10. STOCK-BASED COMPENSATION

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 these estimates.

### 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)

### 10. STOCK-BASED COMPENSATION (Continued)

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

	Three Months Ended March 31				
	2010		2009		
Stock options	\$ 623	\$	1,028		
RSUs	1,034		729		
Stock-based compensation expense	\$ 1,657	\$	1,757		
Cost of goods sold	\$ 138	\$	153		
Research and development expenses	192		244		
Selling, general and administrative expenses	1,327		1,360		
Stock-based compensation expense	\$ 1,657	\$	1,757		

The Company did not recognize any tax benefits for stock-based compensation expense in the three-month periods ended March 31, 2010 and 2009.

### **Stock Options**

The following table summarizes stock option activity during the three-month period ended March 31, 2010:

	Options (000s)			Weighted- Average Remaining Contractual Term (Years)		Aggregate Intrinsic Value	
Outstanding, January 1, 2010	3,988	\$	17.02				
Granted	905		15.33				
Exercised	(142)		10.86				
Expired or forfeited	(197)		18.13				
Outstanding, March 31, 2010	4,554	\$	16.83	2.9	\$	11,152	
Vested and exercisable, March 31, 2010	2,537	\$	19.87	1.8	\$	3,304	

The weighted-average grant-date fair value of stock options granted in the three-month period ended March 31, 2010 was \$4.59. The total intrinsic value of stock options exercised in the three-month period ended March 31, 2010 was \$587,000. Proceeds received on the exercise of stock options in the three-month period ended March 31, 2010 amounted to \$1,544,000. At March 31, 2010, the total remaining unrecognized compensation expense related to non-vested stock options amounted to \$4,663,000, which will be amortized over the weighted-average remaining requisite service period of approximately 22 months.

### 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)

### 10. STOCK-BASED COMPENSATION (Continued)

#### **Time-Based RSUs**

Each vested RSU without performance goals ("Time-Based RSU") represents the right of a holder to receive one of the Company's common shares. The following table summarizes non-vested Time-Based RSU activity during the three-month period ended March 31, 2010:

	Time-Based RSUs (000s)	Weighted- Average Grant-Date Fair Value
Non-vested, January 1, 2010	379	\$ 11.71
Granted	209	14.95
Reinvested dividend equivalents	2	14.68
Vested	(14)	12.47
Forfeited	(8)	11.68
Non-vested, March 31, 2010	568	\$ 12.90

At March 31, 2010, the total remaining unrecognized compensation expense related to non-vested Time-Based RSUs amounted to \$4,346,000, which will be amortized over the weighted-average remaining requisite service period of approximately 20 months.

### Performance-Based RSUs

Each vested RSU with performance goals ("Performance-Based RSU") represents the right of a holder to receive a number of the Company's common shares, up to 200% of the RSUs granted, based on the Company's total shareholder return relative to an industry comparator group. If the Company's total shareholder return is below a specified performance level, no common shares will be paid. The following table summarizes non-vested Performance-Based RSU activity during the three-month period ended March 31, 2010:

	Performance- Based RSUs (000s)	Gı	eighted- Average rant-Date air Value
Non-vested, January 1, 2010	676	\$	18.94
Granted	107		22.29
Reinvested dividend equivalents	4		19.08
Non-vested, March 31, 2010	787	\$	19.57

At March 31, 2010, the total remaining unrecognized compensation expense related to the non-vested Performance-Based RSUs amounted to \$12,384,000, which will be amortized over the weighted-average remaining requisite service period of approximately 49 months. A maximum of 1,574,000 common shares could be issued upon vesting of the Performance-Based RSUs outstanding at March 31, 2010.

### 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)

### 10. STOCK-BASED COMPENSATION (Continued)

#### **Deferred Share Units**

The following table summarizes deferred share unit ("DSU") activity during the three-month period ended March 31, 2010:

	DSUs (000s)	Weighted- Average Grant-Date Fair Value	
Outstanding, January 1, 2010	343	\$ 12.82	
Reinvested dividend equivalents	2	14.68	
Outstanding, March 31, 2009	345	\$ 12.83	

The Company recorded compensation expense related to DSUs of \$824,000 and \$514,000 in the three months ended March 31, 2010 and 2009, respectively. At March 31, 2010 and December 31, 2009, the Company had a liability related to its DSU plans of \$5,796,000 and \$4,796,000, respectively, based on the trading price of the Company's common shares at those dates.

### 11. INCOME TAXES

In the three-month period ended March 31, 2010, the Company's effective tax rate was impacted by the non-deductible portion of the IPR&D charges associated with the acquisitions of the U.S. and Canadian development and commercialization rights to Staccato® loxapine and certain AMPAKINE® compounds (as described in note 3). In addition, these charges were recognized in a jurisdiction with lower statutory tax rates than those that apply in Canada.

# 12. EARNINGS (LOSS) PER SHARE

Earnings (loss) per share were calculated as follows:

	Three Months Ended March 31		
		2010	2009
Net income (loss)	\$	(3,150) \$	39,003
Basic weighted-average number of common shares outstanding (000s)		158,387	158,218
Dilutive effect of stock options and RSUs			52
Diluted weighted-average number of common shares outstanding (000s)		158,387	158,270
Basic and diluted earnings (loss) per share	\$	(0.02) \$	0.25

In the three-month period ended March 31, 2010, all stock options, RSUs and Convertible Notes were excluded from the calculation of diluted loss per share, as the effect of including them would have been

# 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)

## 12. EARNINGS (LOSS) PER SHARE (Continued)

anti-dilutive. The potential dilutive effect of stock options, RSUs and Convertible Notes on the weighted-average number of common shares outstanding was as follows:

Basic weighted-average number of common shares outstanding (000s)	158,387
Dilutive effect of stock options and RSUs	400
Dilutive effect of Convertible Notes	418
Diluted weighted-average number of common shares outstanding (000s)	159,205

In the three months ended March 31, 2010 and 2009, stock options to purchase approximately 2,555,000 and 3,088,000 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 (loss) per share because the effect would have been anti-dilutive.

## 13. COMPREHENSIVE INCOME

Comprehensive income comprised the following:

	Three Months Ended March 31			
	2010 2009			
Net income (loss)	\$	(3,150)	\$	39,003
Comprehensive income				
Foreign currency translation adjustment		4,041		(6,186)
Unrealized holding gain (loss) on auction rate				
securities:				
Arising in period		182		(146)
Reclassification to net income (loss) <sup>(1)</sup>				(28)
Net unrealized holding gain (loss) on				
available-for-sale securities				
Arising in period		(89)		118
Reclassification to net income (loss) <sup>(2)</sup>				2
Other comprehensive income (loss)		4,134		(6,240)
Comprehensive income	\$	984	\$	32,763

Included in impairment loss on debt securities in the consolidated statements of income (loss).

<sup>(2)</sup> Included in loss on disposal of investments in the consolidated statements of income (loss).

#### 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)

## 13. COMPREHENSIVE INCOME (Continued)

The components of accumulated other comprehensive income were as follows:

	Cı Tra	Foreign urrency anslation justment	]	let Unrealized Holding Gain on Available- For-Sale Securities	H	Unrealized olding Loss on Auction Rate Securities	Total
Balance, January 1, 2010	\$	44,286	\$	231	\$	(943) \$	43,574
Foreign currency translation adjustment		4,041					4,041
Net unrealized holding loss on available-for-sale securities				(89)			(89)
Unrealized holding gain on auction rate securities						182	182
Balance, March 31, 2010	\$	48,327	\$	142	\$	(761) \$	47,708

## 14. 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 its 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., the Company's former subsidiary, entered into a written plea agreement with the USAO whereby it agreed to plead guilty to violating the U.S. Anti-Kickback Statute and pay a fine of \$22.2 million.

In addition, 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

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#### BIOVAIL CORPORATION

## 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. LEGAL PROCEEDINGS (Continued)

Corporation's continuing cooperation and in exchange for its agreement to finalize a civil settlement agreement and pay a civil penalty of \$2.4 million. The civil settlement agreement has now been signed and the related fine has been paid. A hearing before the U.S. District Court in Boston took place on September 14, 2009 and the plea was approved.

In addition, as part of the overall settlement, the Company entered into a Corporate Integrity Agreement ("CIA") with the Office of the Inspector General and the Department of Health and Human Services on September 11, 2009. The CIA requires us to have a compliance program in place and to undertake a set of defined corporate integrity obligations for a five-year term. The CIA also includes requirements for an independent review of these obligations. Failure to comply with the obligations under the CIA could result in financial penalties.

#### **Antitrust**

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 two agreements: one between the Company and Elan for the licensing of Adalat CC products from Elan, and the other between the Company and Teva for the distribution of those products in the U.S. These actions were transferred to the U.S. District Court for the District of Columbia. The agreements in question have since been resolved as a result of a consent decree between Elan and Biovail and 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.

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 U.S. District Court for the District of Columbia. The Company has accepted service of this complaint, and the case is proceeding on the merits according to the schedule set by the Court in the related federal cases pending in the District of Columbia.

The Company and the other defendants filed motions to dismiss, and the Court denied the Company's motion to dismiss the damage claims brought on behalf of both a purported class of so-called "direct purchasers", generally consisting of distributors and large chain drug stores, and certain "direct purchasers" who have opted out of the class and sued the Company individually, but dismissed the claims of a class of consumers and so-called "indirect purchasers". The remainder of the federal action is proceeding on the merits through the normal legal process. The Court granted plaintiffs' motion for class certification on November 21, 2007 and certified a class of alleged "direct purchasers".

In December 2007, the Company and the other defendants moved for the Court to reconsider that decision and the Court denied that motion on November 3, 2008. On November 18, 2008, the Company and the other defendants filed a petition in the U.S. Court of Appeals for the District of Columbia Circuit pursuant to Fed. R. Civ. P. 23(f), requesting leave to appeal from the District Court's grant of class certification. The D.C. Circuit denied the defendants leave to appeal on February 23, 2009. On March 25, 2009, the defendants filed a petition in the D.C. Circuit for rehearing of their petition requesting leave to appeal. This request was denied.

#### 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. LEGAL PROCEEDINGS (Continued)

On December 23, 2008, the Company and the other defendants moved for summary judgment in the District Court to dismiss the entirety of the case. This motion was fully briefed in early June 2009 and a related hearing took place on October 7, 2009. A decision is pending. No trial date has been set.

On February 17, 2010, the Company entered into a settlement with the non-class or individual plaintiffs (the "Opt-outs"). Pursuant to the terms of the settlement, the Company paid a settlement amount, which was accrued through a charge to legal settlements expense as at December 31, 2009, and made no admission of wrongdoing. The Opt-out actions were dismissed on February 22, 2010.

On April 4, 2008, a direct purchaser plaintiff filed a class action antitrust complaint in the U.S. District Court for the District of Massachusetts against the Company, GlaxoSmithKline plc, and SmithKline Beecham Inc. (the latter two of which are referred to here as "GSK") seeking damages and alleging that the Company and GSK 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 re-filed a virtually identical complaint in the U.S. District Court for the Eastern District of Pennsylvania. In late May and early June 2008, additional direct and indirect purchaser class actions were also filed against the Company and GSK in the Eastern District of Pennsylvania, all making similar allegations, and these complaints were subsequently consolidated into separate direct and indirect purchaser actions.

On September 10, 2008, the Company and GSK filed motions to dismiss both the direct and indirect purchaser actions. Those motions were heard on February 26, 2009. In the direct purchaser case, on March 13, 2009, the Court granted in part and denied in part the motions, dismissing the Sherman Act Section 2 monopolization claim that had been made by the direct purchasers against the Company. The Company and GSK answered the remaining claims in the direct purchaser case on April 16, 2009. On March 26, 2009, before an order issued on the motions to dismiss the indirect purchaser plaintiffs' claims, the indirect purchaser plaintiffs filed an amended complaint. The pending motions were therefore denied as moot, and new motions to dismiss the indirect purchaser plaintiffs' claims were filed on April 30, 2009. On July 30, 2009, the court dismissed all indirect purchaser claims except for the antitrust claims (limited as to Biovail's concerted actions) in California, Nevada, Tennessee and Wisconsin and the consumer protection claims of California and Florida.

Discovery has now commenced. Briefing on the issue of class certification is underway. Under the current case timetable the class certification hearing will take place in August 2010.

The Company believes that each of these complaints lacks merit and that the Company's 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.

### **Intellectual Property**

In August 2006, Sandoz Canada Inc. ("Sandoz") brought an action against the Company under section 8 of the Canadian Patented Medicines Notice of Compliance Regulations ("PMNOC Regulations") demanding damages for having been kept off the market with its generic version of Tiazac® due to prohibition proceedings taken against Sandoz's predecessor RhoxalPharma Inc. by the Company under the PMNOC Regulations. The prohibition proceedings were subsequently dismissed in November of 2005. The Company defended against the action and discovery has been underway. The action was stayed pending a decision by the Supreme Court of Canada on whether to grant leave to appeal a decision on the measure of section 8

#### 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. LEGAL PROCEEDINGS (Continued)

damages in another unrelated action. The Supreme Court of Canada has now denied leave. A trial date has not been set as yet, but will likely be no earlier than October 2011.

On January 18, 2010, a Canadian Federal Court judge presiding over Biovail Corporation and Depomed, Inc. ("Depomed") v. Apotex Inc. ("Apotex") et al. issued a decision in a proceeding pursuant to the PMNOC Regulations in Canada to determine whether Apotex's allegations that a Depomed patent was invalid and/or not infringed was justified. This proceeding related to a Canadian application filed by Apotex to market a generic version of the 500mg formulation of Glumetza® (extended release metformin hydrochloride tablets) licensed in Canada by Depomed to Biovail Laboratories International SRL ("BLS"). Pursuant to the decision issued by the Court, Health Canada can authorize Apotex to market in Canada its generic version of the 500mg formulation of Glumetza®.

The decision, which was amended on January 20, 2010, found under Canadian law that Apotex's allegation was justified that the Depomed Canadian patent at issue in the matter (No. 2,290,624) (the "'624 Patent") is obvious. The judge found that the evidence presented by the parties was "evenly balanced" as to obviousness. The judge found in favour of Biovail and Depomed as to all other issues related to validity, enforceability and infringement of the '624 Patent under Canadian law. Apotex was authorized by Health Canada on February 4, 2010 to market its generic version of 500 mg Glumetza® in Canada. This decision, however, did not find the patent invalid and does not preclude the filing of a subsequent patent infringement suit against Apotex. The Company and Depomed commenced action for patent infringement against Apotex in Canadian Federal Court on February 8, 2010. Pleadings have now closed, but no further steps have yet been taken.

Par Pharmaceuticals Companies, Inc. ("Par") filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to market Tramadol Hydrochloride Extended Release Tablets, 200 mg. On May 9, 2007, BLS, along with Purdue Pharma Products L.P. ("Purdue"), Napp Pharmaceutical Group Ltd. ("Napp") and Ortho-McNeil, Inc. ("OMI") filed a complaint in the U.S. 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, 100 mg. On June 28, 2007, the same plaintiffs filed another complaint in the U.S. 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 100 mg strength formulation.

On July 23, 2007, Par answered the second complaint and asserted counterclaims of non-infringement and patent invalidity. On September 24, 2007, Par informed the Company that it had filed another supplemental ANDA seeking approval to market Tramadol Hydrochloride Extended Release Tablets, 300 mg. On October 24, 2007, the same plaintiffs filed another complaint in the U.S. 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 300 mg strength formulation. A Markman hearing claims construction ruling was released on November 4, 2008.

BLS filed a motion for dismissal of BLS from the cases, which the Court granted. Subsequently, OMI has also been dismissed from the case. The matter continues between the plaintiff and Par. BLS's and OMI's dismissals from the case are not expected to substantively impact the proceedings.

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#### BIOVAIL CORPORATION

#### 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. LEGAL PROCEEDINGS (Continued)

The hearing in this matter commenced and concluded in April 2009. Closing submissions were completed on June 15, 2009. On August 14, 2009, the District Court found in favour of Par, holding that, while Par infringed the patent claims, the patent claims at issue were invalid (there cannot be infringement of invalid claims). Purdue filed an appeal of the decision with the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") on September 3, 2009. OMI also appealed its dismissal at the same time, but the appeal has been withdrawn. Briefing in the appeal was completed in February, with oral argument before the Federal Circuit scheduled for May 7, 2010. A decision in the appeal is expected before the end of 2010. On November 16, 2009, Par announced that it had received final approval for its 100 mg and 200 mg products and began marketing the drug. Concurrently, Patriot Pharmaceuticals LLC ("Patriot") (a wholly owned subsidiary of Ortho-McNeil-Janssen Pharmaceuticals, Inc.), launched the Company's authorized generic formulation of these two strengths of Ultram® ER.

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 Laboratories, Inc ("Impax"). BLS filed suit along with Purdue, Napp and OMI in the U.S. District Court for the District of Delaware pursuant to the provisions of the Hatch-Waxman Act. As a result, FDA approval of Impax's generic product has been automatically stayed for 30 months until January 2, 2011. BLS filed a motion for dismissal from the case. OMI has also been dismissed from this case, which the Court granted. This matter is continuing between Par and Purdue and is currently in discovery.

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, Napp and OMI filed a complaint in the U.S. 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. OMI has been dismissed from this case. The matter is proceeding in the ordinary course between Impax and Purdue.

On or about July 22, 2009 the Company received a Notice of Paragraph IV Certification from Paddock Laboratories Inc. ("Paddock") for tramadol hydrochloride extended release tablets in 100 mg, 200 mg and 300 mg dosage strengths, a generic version of Ultram® ER. Purdue filed substantially similar suits against Paddock on September 4, 2009, in the U.S. District Court for the District of Minnesota and in the U.S. District Court for the District of Delaware, thereby triggering a 30-month stay against the approval of Paddock's ANDA. Purdue has requested the Court to stay the litigation, pending resolution of its appeal in the Par case. The Company is not a party to this litigation.

The Company has also received a Notice of Paragraph IV Certification dated and mailed on September 15, 2009, from Cipher Pharmaceuticals, Inc. ("Cipher"), which has filed an NDA pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act for tramadol hydrochloride extended release tablets in 100, 200 and 300 mg dosage strengths, a generic version of Ultram® ER. Purdue filed suit against Cipher in the U.S. District Court for the Eastern District of Virginia on October 30, 2009, thereby triggering a 30-month stay. Purdue has indicated that it will seek a stay of its case against Cipher, pending resolution of its appeal in the Par case. The Company is not a party to this litigation.

Purdue has also requested a stay of the actions pending a decision from the Panel on Multidistrict Litigation ("MDL") to create an MDL for the various Ultram® ER cases that have been filed. Purdue is seeking to consolidate the cases.

#### 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. LEGAL PROCEEDINGS (Continued)

The Company received a further Notice of Paragraph IV Certification dated and mailed on December 8, 2009 from Lupin Ltd. ("Lupin") for Tramadol Hydrochloride Extended Release tablets in 100, 200 and 300mg dosages. Purdue filed suit against Lupin in the U.S. District Court for the District of Delaware on January 21, 2010. The Company is not a party to this litigation.

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 of Effexor® XR. On June 26, 2008, Wyeth Pharmaceuticals Inc. ("Wyeth") filed a complaint against the Company, Biovail Technologies Ltd. and BLS in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 6,274,171 B1, 6,403,120 and 6,419,958 B2 by the filing of the ANDA, thereby triggering a 30-month stay of the FDA's approval of that application. On September 25, 2008, the Company filed its Answer and Affirmative Defenses along with counterclaims of non-infringement and invalidity. The Company and Wyeth executed a Settlement and Release Agreement on November 12, 2009 and, subsequently, BLS and Wyeth executed a license agreement as of January 28, 2010, whereby BLS can manufacture, import and sell venlafaxine hydrochloride extended release capsules with an effective date expected to be on or about June 1, 2011, subject to earlier launch in limited circumstances, but in no event earlier than January 1, 2011. BLS will pay Wyeth a royalty fee on the sale of its venlafaxine hydrochloride extended release capsules under the license, computed as a percentage of net sales, as defined in the license agreement. The license royalty fee term begins with the license effective date and ends on the expiration of the Wyeth patents covered by the license agreement. BLS is solely responsible for manufacturing and marketing its venlafaxine hydrochloride extended release capsules. Through December 31, 2009, BLS has not commenced sales of its venlafaxine hydrochloride extended release capsules. The parties filed a Joint Motion to Enter Consent Judgment and to Enter Stipulated Order on March 9, 2010, which was entered by the Court on March 19, 2010.

On or about June 26, 2008, BLS received Notices of Paragraph IV Certification from Sun Pharmaceutical Industries, Ltd., India ("Sun") for diltiazem hydrochloride extended release capsules, 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg strengths, a generic version of Cardizem® CD. On August 8, 2008, BLS filed suit against Sun 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 mg, 180 mg, 240 mg and 300 mg strengths. The patents-in-suit were listed in the FDA's Orange Book against the 360 mg strength after the filing of the complaint in this action. On September 30, 2008, Sun delivered its Answer and Counterclaim, which include declarations of non-infringement, invalidity and unenforceability as well as certain antitrust allegations. In resolving this dispute, the Company and Sun executed a Settlement Agreement and a License Agreement on March 9, 2010. The parties filed a Stipulation and Proposed Order of Dismissal on April 16, 2010, which was entered as an Order of Dismissal by the Court on April 19, 2010. Under the terms of the settlement and license agreements, which were submitted to the U.S. Federal Trade Commission and U.S. Department of Justice pursuant to Section 1112(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003, Biovail has granted Sun, and its subsidiary Sun Pharma Global FZE, a non-exclusive license (without right to sublicense) to distribute various dosage strengths of Sun's generic formulation of Cardizem® CD in the U.S., upon receipt of regulatory approval from the FDA, subject to certain limitations on the sales quantities of the 360mg dosage strength, with reference to IMS Health prescription data. Sun will pay Biovail a royalty based on net sales of the various dosage strengths of its generic formulation. The license term ends August 8, 2012 the date the last Cardizem® CD patent expires.

#### 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. LEGAL PROCEEDINGS (Continued)

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 and Laboratoires Fournier S.A. filed a complaint against Biovail Corporation and BLS in the U.S. 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. This matter has now been transferred to the U.S. District Court for the District of New Jersey. On November 3, 2008, Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. also filed a complaint against Biovail Corporation and BLS in the U.S. 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 and Counterclaims of Biovail Corporation and BLS have been filed. These cases are proceeding in the ordinary course. No trial date has yet been set.

On or about December 1, 2008, the FDA accepted an ANDA filed by BLS seeking approval to market generic formulations of the 200 mg, 300 mg and 400 mg strengths of quetiapine fumarate extended release tablets (sold under the brand name Seroquel® XR by AstraZeneca Pharmaceuticals LP ("AstraZeneca")). On January 9, 2009, AstraZeneca and AstraZeneca UK Limited filed a complaint against Biovail Corporation, BLS, and BTA Pharmaceuticals, Inc. in the U.S. District Court for the District New Jersey alleging infringement of U.S. Patent Nos. 4,879,288 (the "'288 Patent") and 5,948,437 (the "'437 Patent") by the filing of that ANDA, thereby triggering a 30-month stay of the FDA's approval of that application. Answers and Counterclaims have been filed. Discovery relating to invalidity of the '288 Patent has been stayed pending a decision from the U.S. Court of Appeals for the Federal Circuit in a related case not involving the Company. That case has now been resolved and the Company is currently reviewing documents. The case, including discovery on the '437 Patent, is proceeding in the ordinary course. Claim construction briefing was completed in April 2010. A Markman (claim construction) hearing has not been scheduled, but is expected to take place before August 2010. Fact discovery remains ongoing.

On April 8, 2010, AstraZeneca filed suit against a fourth ANDA applicant, Anchen Pharmaceuticals ("Anchen"). According to the Complaint, Anchen's ANDA is for the 150, 200, 300 and 400 mg products, and Anchen filed Paragraph IV certifications against both the '288 and '437 patents. Anchen's Answer is due on May 10, 2010. It is unclear whether the Anchen case will be coordinated with the ongoing cases against Biovail and other unrelated parties.

On or about July 3, 2009, BLS received a Notice from Cary Pharmaceuticals Inc. ("Cary"), related to Cary's NDA pursuant to Section 505(B)(2) for bupropion hydrochloride 450 mg extended-release tablets. The Certification references U.S. Patent No. 6,096,341, which is listed in the FDA's Orange Book for the 150 mg and 300 mg dosage strength of Wellbutrin XL®, and No. 6,143,327, which is currently listed in the FDA's Orange Book for the 150 mg dosage strength of Wellbutrin XL®. On August 13, 2009, the Company filed suit in the U.S. District Court for the District of Delaware, thereby triggering a 30-month stay of the approval of Cary's NDA. The Complaint was served on Cary on August 24, 2009, and Cary served its Answer on September 24, 2009. Following a scheduling conference with the judge in mid-January 2010, a Markman (claim construction) hearing has been scheduled for June 1, 2010, with fact and expert discovery to follow. The case is proceeding in the ordinary course. No trial date has yet been set.

On or about January 5, 2010, BLS received a Notice of Paragraph IV Certification dated January 4, 2010 from Watson Laboratories, Inc. Florida ("Watson"), related to Watson's ANDA filing for Buproprion Hydrobromide Extended-release Tablets, 174 mg and 348 mg, which correspond to the Company's Aplenzin® Extended-release Tablets 174 mg and 348 mg products. Watson asserted that U.S. Patent

#### 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. LEGAL PROCEEDINGS (Continued)

Nos. 7,241,805, 7,569,610, 7,572,935 and 7,585,897 which are listed in the FDA's Orange Book for Aplenzin® are invalid or not infringed. BLS subsequently received from Watson a second Notice of Paragraph IV Certification for U.S. Patent Nos 7,645,802 and 7,649,019, which were listed in the FDA's Orange Book after Watson's initial certification. Watson has alleged these patents are not infringed or invalid. The Company filed suit pursuant to the Hatch-Waxman Act against Watson on February 18, 2010, in the U.S. District Court for the District of Delaware and on February 19, 2010, in the U.S. District Court for the Southern District of Florida, thereby triggering a 30-month stay of the approval of Watson's ANDA. The Delaware action has been dismissed without prejudice and the litigation will proceed in the Florida Court. The Company has received a third Notice of Paragraph IV Certification from Watson dated March 5, 2010, seeking to market its products prior to the expiration of U.S. Patent Nos. 7,662,407 and 7,671,094. The Company received a fourth Notice of Paragraph IV Certification from Watson on April 9, 2010. The Company filed a second Complaint against Watson in Florida Court on the third and fourth Notices on April 16, 2010. The Company is seeking to have the two actions consolidated before the same judge.

On or about January 27, 2010, BLS received a Notice of Paragraph IV Certification from Paddock dated January 22, 2010, relating to Paddock's ANDA filing for Buproprion Hydrobromide Extended-release Tablets, 174 mg and 522 mg, which correspond to the Company's Aplenzin® Extended-release Tablets 174 mg and 522 mg products. Paddock has certified that the six patents currently listed in the FDA's Orange Book for Aplenzin®, plus an additional unlisted BLS patent relating to buproprion hydrobromide, are not infringed and/or invalid. A Complaint was filed on March 9, 2010 against Paddock in the U.S. District Court for the District of Minnesota. A parallel suit in the U.S. District Court for the District of Delaware has been dismissed without prejudice. A second suit was filed in the U.S. District Court for the District of Minnesota on April 15, 2010 following a second Paragraph IV certification received from Paddock. Both cases, which are now consolidated before the same judge, are proceeding in the ordinary course.

### 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 the Company's common shares and alleges violations of various state laws, including the New Jersey Racketeer Influenced and Corrupt Organizations Act.

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 defendant Hallmark Funds was voluntarily dismissed from the action by the Company.

The case was subsequently stayed by an order of the Trial Judge, dated March 16, 2007, pending disposition of certain issues in a factually similar shareholder class action that did not involve the Company (the "New Jersey shareholder class action").

The stay of this action imposed by the Court's March 16, 2007 Order was lifted on March 20, 2009. On April 17, 2009, the Company filed a motion for leave to file a Second Amended Complaint, amending the

#### 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. LEGAL PROCEEDINGS (Continued)

allegations to assert trade libel and conspiracy, and seeking damages in excess of \$100.0 million. The proposed Second Amended Complaint names as defendants only the S.A.C. related entities, Timothy McCarthy and Gradient Analytics, LLC (formerly Camelback Research Alliance Inc.). All other remaining defendants were dismissed from the lawsuit.

The named defendants opposed the filing of the Second Amended Complaint and moved to dismiss it. The motion was heard on July 10, 2009. A decision was subsequently rendered in the defendants' favour on August 20, 2009. As a result, the matter was dismissed.

On February 17, 2010, SAC Capital Advisors, LLC commenced an action against the Company in the United States District Court for the District of Connecticut. The complaint alleges malicious prosecution related to the Company's complaint against it. A factually similar complaint was filed the same day by Gradient Analytics, Inc., Donn Vickery and James Carleton Carr Bettis in the United States Court for the District of Arizona. The Company believes that these complaints are without merit and will be filing motions to dismiss in May 2010 pursuant to the current case timetable.

# **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. On October 16, 2009, the Supreme Court of Alabama issued an opinion reversing judgments in favour of the State in the first three cases that were tried against co-defendant companies. The Alabama Supreme Court also rendered judgment in favour of those defendants, finding that the State's fraud-based theories failed as a matter of law. The Company's case is presently scheduled to proceed to trial in January 2011.

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 New York State Litigation Coordinating Panel granted the defendants' application to coordinate the three actions for pretrial purposes in Erie County. Discovery is ongoing with trial presently scheduled to commence in February 2011.

On December 15, 2009, Biovail was served with a Seventh Amended Complaint under the False Claims Act in an action captioned United States of America, ex rel. Constance A. Conrad v. Actavis Mid-Atlantic, LLC, et al., United States District Court, District of Massachusetts. This case was originally filed in 2002 and maintained under seal until shortly before Biovail was served. Twenty other companies are named as defendants. In the Seventh Amended Complaint, Conrad alleges that various formulations of Rondec, a

# 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. LEGAL PROCEEDINGS (Continued)

product formerly owned by Biovail, were not properly approved by the FDA and therefore not a "Covered Outpatient Drug" within the meaning of the Medicaid Rebate Statute. As such, Conrad alleges that Rondec was not eligible for reimbursement by federal healthcare programs, including Medicaid. Conrad seeks treble damages and civil penalties under the False Claims Act. According to the briefing schedule set by the court, motions to dismiss are due 30 days after the Complaint is unsealed in respect of each defendant. The Company intends to file a motion to dismiss.

## 15. SEGMENT INFORMATION

The Company operates in one operating segment pharmaceutical products. Management assesses performance and makes resource decisions based on the consolidated results of operations of this operating segment.

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## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

#### INTRODUCTION

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("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 March 31, 2010 (our "Consolidated Financial Statements"). 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 10-K for the fiscal year ended December 31, 2009, filed on February 26, 2010 with the U.S. Securities and Exchange Commission ("SEC") and the Canadian Securities Administrators ("CSA") (the "2009 Form 10-K").

Additional information relating to our Company, including the 2009 Form 10-K, is available on SEDAR at www.sedar.com and on the SEC's website at www.sec.gov.

Unless otherwise indicated herein, the discussion and analysis contained in this MD&A is as of May 7, 2010.

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

#### FORWARD-LOOKING STATEMENTS

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

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 within the meaning defined under applicable Canadian 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 impact of healthcare reform in the U.S. and elsewhere;

our intent and ability to implement and effectively execute plans and initiatives associated with our strategic focus on products targeting specialty central nervous system ("CNS") disorders and the anticipated impact of such strategy, including, but not limited to, the amount and timing of expected contribution(s) from our product development pipeline;

our intent to complete in-license agreements and acquisitions and to successfully integrate such in-license agreements and acquisitions into our business and operations and to achieve the anticipated benefits of such in-license agreements and acquisitions;

our intent to deploy a specialty U.S. sales force to support our specialty CNS strategy, including our intent to develop a sales force to commercialize AZ-004 (Staccato® loxapine) and BVF-007 (AMPAKINE®) in the U.S., and the timing and amount of costs associated with establishing such sales force;

the competitive landscape in the markets in which we compete, including, but not limited to, the prescription trends, pricing and the formulary or Medicare/Medicaid utilization and positioning for our products, the opportunities present in the market for therapies for specialty CNS disorders, the anticipated level of demand for our products and the availability or introduction of generic formulations of our products;

expected timing and/or impact on revenues and earnings of the introduction of generic versions of Ultram® ER (300mg dosage strength), Glumetza® (500mg dosage strength), Cardizem® LA and Cardizem® CD products;

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our intent, timing and ability to complete the planned disposals of certain non-core assets, including, but not limited to, our Carolina, Puerto Rico manufacturing facility and operations and the anticipated costs, impacts and proceeds of such disposition;

anticipated level of demand for generic Tiazac® and generic Cardizem® CD products;

our intent and related success or failure regarding the defence of our intellectual property against infringement;

our views, beliefs and positions related to, results of, and costs associated with, certain litigation and regulatory proceedings and the timing, costs and expected impact of the resolution of certain litigation and regulatory proceedings;

the timing, results, and progress of research and development and regulatory approval efforts;

our intent and ability to make future dividend payments or to repurchase our common shares under our share repurchase program;

the sufficiency of cash resources, including those available under the accordion feature of our senior secured revolving credit facility, to support future spending and business development requirements;

the impact of market conditions on our ability to access additional funding at reasonable rates;

our ability to manage exposure to foreign currency exchange rate changes and interest rate changes;

our intent and ability to use a net share settlement approach upon conversion of our 5.375% Senior Convertible Notes due August 1, 2014 ("Convertible Notes");

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

our expected capital expenditures; and

expected impact of the adoption of new accounting guidance.

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", "target", "potential", 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 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 the items outlined above. 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 uncertainties associated with the specific determinations necessary to implement certain provisions under the healthcare reform legislation enacted in the U.S.;

the successful execution of our specialty CNS strategy, including our ability to successfully identify, evaluate, acquire, obtain regulatory approval for, develop, manufacture and commercialize pipeline products;

the success of pre-clinical and clinical trials for our drug development pipeline or delays in clinical trials which adversely impact the timely commercialization of our pipeline products;

the results of continuing safety and efficacy studies by industry and government agencies;

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the uncertainties associated with the development, acquisition and launch of new products, including, but not limited to, the acceptance and demand for new pharmaceutical products, and the impact of competitive products and pricing;

our reliance on key strategic alliances, our ability to secure and maintain third-party research, development, manufacturing, marketing or distribution arrangements and securing other development partners for, and to share development costs associated with, certain product development programs;

the availability of capital and our ability to generate operating cash flows to support our growth strategy;

the continuation of the recent market turmoil, which could result in fluctuations in currency exchange rates and interest rates;

our eligibility for benefits under tax treaties and the continued availability of low effective tax rates for the business profits of our principal operating subsidiary;

the difficulty of predicting the expense, timing and outcome within our legal and regulatory environment, including, but not limited to, U.S. Food and Drug Administration ("FDA"), Canadian Therapeutic Products Directorate and European regulatory approvals, legal and regulatory proceedings and settlements thereof, the protection afforded by our patents and other intellectual and proprietary property, successful challenges to our generic products, and infringement or alleged infringement of the intellectual property rights of others;

our ability to establish or acquire a specialty U.S. sales force to support our specialty CNS strategy;

our ability to attract and retain key personnel;

the reduction in the level of reimbursement for, or acceptance of, pharmaceutical products by governmental authorities, health maintenance organizations or other third-party payors;

our ability to satisfy the financial and non-financial covenants of our credit facility and the Convertible Notes indenture;

our ability to repay or refinance the principal amount under the Convertible Notes indenture at maturity;

the disruption of delivery of our products and the routine flow of manufactured goods across the U.S. border; 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, as well as under Item 1A "Risk Factors" of our 2009 Form 10-K. 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, except as may be required by law.

# **OVERVIEW**

# **Company Profile**

We are a specialty pharmaceutical company with a strategic focus on developing and commercializing products that address unmet medical needs in specialty CNS disorders. We have various research and development, clinical research, manufacturing and commercial operations located in Barbados, Canada, the U.S., Ireland and Puerto Rico.

## **U.S. Healthcare Reform**

In March 2010, healthcare reform legislation was enacted in the U.S. This legislation contains several provisions that may impact our business.

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Although many provisions of the new legislation do not take effect immediately, several provisions became effective in the first quarter of 2010. These provisions include: (i) an increase in the minimum Medicaid rebate to states participating in the Medicaid program from 15.1% to 23.1% on branded prescription drugs; (ii) the extension of the Medicaid rebate to Managed Care Organizations that dispense drugs to Medicaid beneficiaries; and (iii) the expansion of the 340(B) Public Health Services drug pricing program, which provides outpatient drugs at reduced rates, to include additional hospitals, clinics, and healthcare centres.

Beginning in 2011, the new legislation requires that drug manufacturers provide a 50% discount to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e., the "donut hole"). Also, beginning in 2011, a new fee will be assessed on prescription drug manufacturers and importers that sell branded prescription drugs to specified U.S. government programs (e.g., Medicare and Medicaid). This fee will be calculated based upon each entity's relative share of total applicable branded prescription drug sales for the preceding calendar year. The aggregate industry wide fee is expected to total \$28 billion through 2019, ranging from \$2.5 billion to \$4.1 billion annually.

Presently, uncertainty exists as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. For example, we do not yet know when and how discounts will be provided to the additional hospitals eligible to participate under the 340(B) program. In addition, determinations as to how the Medicare Part D coverage gap will operate and how the annual fee on branded prescription drugs will be calculated and allocated remain to be clarified, though, as noted above, these programs will not be effective until 2011. We have made several estimates with regard to important assumptions relevant to determining the financial impact of this legislation on our business due to the lack of availability of both certain information and complete understanding of how the process of applying the legislation will be implemented. Based on these estimates and assumptions, this new legislation did not have a material impact on our financial condition or results of operations in the first quarter of 2010.

#### **Business Development**

#### **AMPAKINE®**

On March 25, 2010, we acquired certain AMPAKINE® compounds, including associated intellectual property, from Cortex Pharmaceuticals, Inc. ("Cortex") for use in the field of respiratory depression, a brain-mediated breathing disorder. The acquired compounds include the Phase 2 compound CX717, the pre-clinical compounds CX1763 and CX1942, and the injectable dosage form of CX1739. AMPAKINE® is directly aligned with our specialty CNS strategy and has the potential to address a significant unmet medical need. In addition, AMPAKINE® aligns with the specialty sales force we intend to deploy in the U.S. for Staccato® loxapine (as described below under "Staccato® Loxapine").

Under the terms of the asset purchase agreement, we paid an upfront fee of \$9.0 million and expect to pay an additional \$1.0 million upon the completion of a six-month transition period. In addition, we could pay up to \$15.0 million in potential milestones contingent on the successful demonstration of the utility of an intravenous formulation of CX717 in treating respiratory depression (BVF-007), the successful completion of a Phase 3 clinical program using an AMPAKINE® compound, and approval from the FDA of an AMPAKINE® compound. We may also owe certain development milestones and/or royalties on net sales to third parties of an AMPAKINE® compound.

This acquisition was accounted for as a purchase of in-process research and development ("IPR&D") intangible assets with no alternative future use. Accordingly, the \$9.0 million upfront payment and the \$1.0 million accrued transition payment, together with \$0.7 million of acquisition costs, were charged to research and development expenses at the acquisition date.

# Staccato® Loxapine

On February 9, 2010, we entered into a collaboration and license agreement with Alexza Pharmaceuticals, Inc. ("Alexza") to acquire the U.S. and Canadian development and commercialization rights to AZ-004 for the treatment of psychiatric and/or neurological indications and the symptoms associated with these indications, including the initial indication of treating agitation in schizophrenia and bipolar patients.

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AZ-004 combines Alexza's proprietary Staccato® drug-delivery system with the antipsychotic drug loxapine. Staccato® loxapine for the treatment of agitation in schizophrenia and bipolar patients is directly aligned with our specialty CNS strategy.

In December 2009, Alexza submitted a New Drug Application ("NDA") to the FDA for Staccato® loxapine. The FDA has accepted the NDA for filing and has indicated a Prescription Drug User Fee Act ("PDUFA") goal date of October 11, 2010.

Pursuant to the terms of the collaboration and license agreement, we paid an upfront fee of \$40.0 million, and could pay up to \$90.0 million in potential milestones in connection with the initial indication, contingent on the successful approval of the first AZ-004 NDA, successful commercial manufacturing scale-up, and the first commercial sale on an inpatient and on an outpatient basis, which may require the successful completion of additional clinical trials, regulatory submissions, and/or approval of a supplemental NDA. We will also make tiered royalty payments of 10% to 25% on net commercial sales of Staccato® loxapine. Alexza will supply the product to us for commercialization and will receive a per-unit transfer price, based on annual product volume.

We intend to deploy a specialty sales force to commercialize Staccato® loxapine in the U.S. We estimate the costs associated with establishing this sales force will amount to approximately \$10 million in the second half of 2010, and between \$40 million and \$70 million in 2011, depending on the breadth of the label approved by the FDA.

This acquisition was accounted for as a purchase of IPR&D intangible assets with no alternative future use. Accordingly, the \$40.0 million upfront payment, together with \$0.3 million of acquisition costs, was charged to research and development expenses at the acquisition date.

#### **Research and Development**

The following table displays selected information regarding our specialty CNS drug-development programs:

PROGRAM	COMPOUND	INDICATION(S)	DEVELOPMENT STATUS
AZ-004	Staccato® loxapine	Agitation in schizophrenia and bipolar patients	NDA filed; PDUFA goal date October 11, 2010
BVF-036	Pimavanserin	Parkinson's disease psychosis	Phase 3
BVF-048	Pimavanserin	Schizophrenia co-therapy	Phase 2
BVF-025	Fipamezole	Parkinson's disease dyskinesia	Phase 2
BVF-040	Pimavanserin	Alzheimer's disease psychosis	Pre-Phase 2
BVF-018	Tetrabenazine MR	Tourette's Syndrome	Phase 1
BVF-007	AMPAKINE®	Respiratory depression	Pre-clinical
BVF-014	GDNF	Parkinson's disease	Pre-Investigation New Drug

In addition to the programs outlined above, Phase 3 clinical trials continue in Europe for BVF-324 (the use of non-commercially available doses of tramadol for the treatment of premature ejaculation). Enrolment for these studies is occurring more slowly than we had anticipated, which will impact our original assumptions and timelines for the product.

# Restructuring

In May 2008, we initiated restructuring measures that were intended to rationalize our manufacturing operations, pharmaceutical sciences operations, and general and administrative expenses.

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On January 15, 2010, we completed the sale of our Dorado, Puerto Rico manufacturing facility for net cash proceeds of \$8.5 million. We continued to occupy the Dorado facility until March 31, 2010, pursuant to a short-term lease with the buyer, during which time remaining manufacturing and packaging processes were transferred to our Steinbach, Manitoba manufacturing facility. While we are continuing to actively market our manufacturing facility located in Carolina, Puerto Rico, this site is expected to remain open indefinitely in order to meet higher than anticipated demand for our generic Tiazac® and generic Cardizem® CD products, which is attributable to manufacturing issues involving competitors' products.

We expect to incur employee termination costs of approximately \$9.6 million in total for severance and related benefits payable to the approximately 240 employees who have been, or will be, terminated as a result of the closure of the Puerto Rico facilities. As these employees are required to provide service during the shutdown period in order to be eligible for termination benefits, we are recognizing the cost of those termination benefits ratably over the estimated future service period.

Prior to December 31, 2009, we completed the closure of our research and development facilities in Dublin, Ireland and Mississauga, Ontario, and the consolidation of our research and development operations in Chantilly, Virginia.

The following table summarizes the major components of restructuring costs recognized through March 31, 2010:

	Asset Impa	irments	Employee T Bene		Contract Termination	
	P	harmaceutical	I	Pharmaceutical	and Other	
(\$ in 000s)	Manufacturing	Sciences	Manufacturing	Sciences	Costs	Total
Balance, January 1, 2008	\$ \$	3	\$	\$	\$	\$
Costs incurred and charged to						
expense	42,602	16,702	3,309	2,724	4,865	70,202
Cash payments				(2,724)	(333)	(3,057)
Non-cash adjustments	(42,602)	(16,702)			(1,186)	(60,490)
Balance, December 31, 2008			3,309		3,346	6,655
Costs incurred and charged to						
expense	7,591	2,784	4,942	1,441	2,307	19,065
Cash payments			(2,041)	(1,278)	(1,321)	(4,640)
Non-cash adjustments	(7,591)	(2,784)		71		(10,304)
Balance, December 31, 2009			6,210	234	4,332	10,776
Costs incurred and charged to						
expense			333		280	613
Cash payments			(2,703)	(195)	(429)	(3,327)
Non-cash adjustments				6		6
Balance, March 31, 2010	\$ \$	ò	\$ 3,840	\$ 45	\$ 4,183	\$ 8,068

# **Results of Efficiency Initiatives**

Our ongoing and planned efficiency initiatives have resulted in cumulative charges to earnings of \$105.4 million recorded through March 31, 2010. These charges are expected to be up to \$120 million, of which the cash component is expected to be up to \$40 million, including \$32.5 million incurred through March 31, 2010. We expect that these initiatives, once fully implemented, may result in annual savings of \$40 million to \$60 million.

We are targeting in excess of \$70 million in total proceeds from the divestiture and monetization of non-core assets. To date, we have realized \$63.1 million of this goal.

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# **Major Products**

The following table displays selected information regarding our major brand name products by therapeutic area:

BRAND NAME(S)	INDICATION(S)	MARKET	COMMERCIALIZATION				
	:	Specialty CNS					
Xenazine®	Huntington's chorea	U.S.	Supply and distribution agreement with Lundbeck Inc. (as subsidiary of H. Lundbeck A/S).				
Nitoman®	Hyperkinetic movement disorders, including Huntington's chorea	Canada	Marketed and distributed by Biovail Pharmaceuticals Canada ("BPC").				
Xenazine®, Xenazina®, Nitoman®	Hyperkinetic movement disorders	Territories other than the U.S. and Canada	Supply and distribution arrangements with various third-party distributors.				
	Non-Specialty CNS						
Wellbutrin XL®	Major and seasonal depressive disorders	U.S.	Distributed by our subsidiary BTA Pharmaceuticals, Inc. ("BTA") $^{(1)}$ .				
Wellbutrin XL®	Major depressive disorder	Territories other than the U.S. and Canada	Supply and distribution agreement with affiliates of The GlaxoSmithKline Group of Companies ("GSK").				
Ativan®	Anxiety	U.S.	Distributed by BTA.				
Aplenzin®	Major depressive disorder	U.S.	Supply and distribution agreement with sanofi-aventis U.S. LLC ("sanofi-aventis").				
Wellbutrin® XL	Major and seasonal depressive disorders	Canada	Marketed by BPC.				
Wellbutrin® SR	Major depressive disorder	Canada	Distributed by BPC.				
Zyban®	Smoking cessation	Canada	Distributed by BPC.				
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BRAND NAME	INDICATION(S)	MARKET	COMMERCIALIZATION
	Pa	in Managemer	nt
Ultram® ER	Moderate to moderately severe chronic pain	U.S.	Supply and distribution agreement with PriCara (a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.).
Ralivia®	Moderate to moderately severe chronic pain	Canada	Marketed and distributed by BPC.
		Antiviral	
Zovirax® Cream, Zovirax® Ointment	Herpes	U.S.	Distributed by BTA and promoted by Publicis Selling Solutions, Inc. ("Publicis"), a contract sales organization.
	(	Cardiovascular	
Cardizem® LA	Hypertension and angina	U.S.	Supply and distribution agreement with Kos Pharmaceuticals, Inc. ("Kos") (now known as Abbott Laboratories).
Cardizem® CD	Hypertension and angina	U.S.	Distributed by BTA.
Vasotec®, Vaseretic®	Hypertension and congestive heart failure	U.S.	Distributed by BTA.
Tiazac®	Hypertension and angina	U.S.	Supply and distribution agreement with Forest Laboratories, Inc. ("Forest").
Isordil®	Angina	U.S.	Distributed by BTA.
Glumetza®	Type 2 diabetes	U.S.	Supply agreement with Depomed, Inc.
Tiazac® XC, Tiazac®	Hypertension and angina	Canada	Marketed and/or distributed by BPC.
Glumetza®	Type 2 diabetes	Canada	Marketed and distributed by BPC.
Cardizem® CD	Hypertension and angina	Canada	Distributed by BPC.

<sup>(1)</sup> Prior to the acquisition of the full U.S. commercialization rights on May 14, 2009, Wellbutrin XL® was manufactured and supplied to affiliates of GSK for distribution in the U.S.

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In addition to the brand name products noted above, the following table displays selected information regarding our generic product portfolio by therapeutic area:

BRAND NAME	INDICATION(S)	MARKET	COMMERCIALIZATION				
	Aut	horized Gener	ics				
Ultram® ER	Moderate to moderately severe chronic pain	U.S.	Supply and distribution agreement with Patriot Pharmaceuticals LLC ("Patriot") (an affiliate of PriCara).				
Tiazac®	Hypertension and angina	U.S.	Supply and distribution agreement with Inwood Laboratories Incorporated (a subsidiary of Forest).				
Tiazac®	Hypertension and angina	Canada	Supply and distribution agreement with Teva Novapharm, a subsidiary of Teva Pharmaceuticals Industries Ltd. ("Teva").				
	ANDA Generics						
Adalat CC (nifedipine)	Hypertension and angina	U.S.	Supply and distribution agreement with affiliates of Teva.				
Cardizem® CD (diltiazem)	Hypertension and angina	U.S.	Supply and distribution agreement with affiliates of Teva.				
Cardizem® CD (diltiazem)	Hypertension and angina	Canada	Supply and distribution agreement with Teva Novapharm.				
Procardia XL (nifedipine)	Hypertension and angina	U.S.	Supply and distribution agreement with affiliates of Teva.				
Trental (pentoxifylline)	Peripheral vascular disease	U.S.	Supply and distribution arrangement with affiliates of Teva.				
Voltaren XR (diclofenac)	Arthritis	U.S.	Supply and distribution agreement with affiliates of Teva.				

# **Selected Financial Information**

Three	Months	Ended	March	31
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	2010	2009	Change	:
(\$ in 000s, except per share data)	\$	\$	\$	%
Revenue	219,635	173,319	46,316	27
Operating expenses	203,268	119,704	83,564	70
Net income (loss)	(3,150)	39,003	(42,153)	(108)
Basic and diluted earnings (loss) per share	(0.02)	0.25	(0.27)	(108)
Cash dividends declared per share	0.090	0.375	(0.285)	(76)

At	At	
March 31	December 31	
2010	2009	Change

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	\$	\$	\$	%
Total assets	2,005,036	2,067,044	(62,008)	(3)
Long-term obligations, including current portion	328,886	326,085	2,801	1

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#### **General Economic Conditions**

Beginning in late 2008 and continuing through the first quarter of 2010, foreign currency exchange rates between the U.S. dollar and the Canadian dollar have been experiencing significant volatility. Changes in foreign currency exchange rates increased total revenue by approximately \$4.5 million, or 2.0%, in the first quarter of 2010, compared with the first quarter of 2009, due to a strengthening of the Canadian dollar relative to the U.S. dollar on a year-over-year basis. A stronger Canadian dollar, while having a favourable impact on revenue, has a negative impact on our operating expenses. Where possible, we manage our exposure to foreign currency exchange rate changes through operational means, mainly by matching our cash flow exposures in foreign currencies. As a result, the positive impact of a stronger Canadian dollar on revenue generated in Canadian dollars, but reported in U.S. dollars, is largely counteracted by an opposing effect on operating expenses incurred in Canadian dollars. As our Canadian dollar-denominated expenses moderately exceeded our Canadian dollar-denominated revenues, the appreciation of the Canadian dollar in the first quarter of 2010 had the overall effect of marginally decreasing our net income as reported in U.S. dollars.

#### Financial Performance

#### Changes in Revenue

Total revenue increased \$46.3 million, or 27%, to \$219.6 million in the first quarter of 2010, compared with \$173.3 million in the first quarter of 2009, primarily due to:

incremental revenue from Wellbutrin XL®, following the acquisition of the full U.S. commercialization rights in May 2009;

higher sales of Xenazine® in the U.S. and the addition of rest-of-world sales following the acquisition of the worldwide development and commercialization rights to tetrabenazine in June 2009;

increased demand for our generic Tiazac® and generic Cardizem® CD products, which was attributable to competitors' manufacturing issues; and

the favourable impact of foreign exchange rate changes on Canadian-dollar denominated revenue.

Those factors were partially offset by:

a decline in Ultram® ER product sales, as a result of the introduction of generic competition to the 100mg and 200mg dosage strengths in the fourth quarter of 2009, partially offset by our supply of 100mg and 200mg authorized generic versions.

# Changes in Net Income

Net income declined \$42.2 million, or 108%, to a net loss of \$3.2 million (basic and diluted loss per share of \$0.02) in the first quarter of 2010, compared with net income of \$39.0 million (basic and diluted earnings per share ("EPS") of \$0.25) in the first quarter of 2009, primarily due to:

a \$51.0 million IPR&D charge in the first quarter of 2010 in connection with the acquisitions of the U.S. and Canadian development and commercialization rights to Staccato® loxapine and certain AMPAKINE® compounds;

a \$17.8 million increase in amortization expense due to the inclusion of amortization of the Wellbutrin XL® trademark intangible asset acquired in May 2009, and the tetrabenazine product rights intangible asset arising from the acquisition of the worldwide development and commercialization rights in June 2009; and

a \$9.5 million increase in interest expense, mainly related to the Convertible Notes issued in June 2009.

Those factors were partially offset by:

an increased contribution from product sales of \$32.5 million, mainly related to the incremental revenue from Wellbutrin XL®, following the May 2009 acquisition of the full U.S. commercialization rights, and reduced costs and improved capacity utilization of our manufacturing operations.

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## Specific Items Impacting Net Income

When assessing our financial performance, management utilizes an internal measure that excludes specific items from net income determined in accordance with U.S. GAAP. Management believes the identification of these items enhances an analysis of our financial performance when comparing our operating results between periods. These items consist of: acquisition-related costs (including IPR&D charges and transaction costs); restructuring costs; legal settlements; gains and losses on asset dispositions; investment gains and losses; and certain other unusual items that are evaluated on an individual basis based on their nature or size. The following are examples of how net income excluding specific items is utilized:

executive management receives a monthly analysis of our operating results which includes a measure of net income and EPS excluding specific items;

annual budgets are prepared on a specific item-adjusted basis; and

executive management's annual compensation is determined, in part, by reference to net income excluding specific items.

We believe that investors' understanding of our financial performance is enhanced by disclosing the specific items identified by management. However, any measure of net income excluding any or all of these items is not, and should not be viewed as, a substitute for net income prepared under U.S. GAAP. These items are presented solely to allow investors to more fully understand how management assesses our financial performance.

The following table displays the specific items identified by management that impacted net income in the first quarters of 2010 and 2009, and the impact of these items (individually and in the aggregate) on basic and diluted EPS. EPS figures may not add due to rounding.

#### **Three Months Ended March 31**

# 2010

				2009				
(\$ in 000s, except per share data; Income (Expense))		Amount	<b>EPS Impact</b>		Amount		EPS Impact	
$IPR\&D^{(1)}$	\$	(51,003)	\$	(0.32)	\$		\$	
SEC/OSC independent consultant and related costs <sup>(2)</sup>		(631)				(1,427)		(0.01)
Restructuring costs		(613)				(1,348)		(0.01)
Impairment losses on debt securities		(155)				(2,707)		(0.02)
Legal settlements						(241)		
Loss on disposal of investments						(6)		
Total	\$	(52,402)	\$	(0.33)	\$	(5,729)	\$	(0.04)

Included in research and development expenses.

Included in selling, general and administrative expenses.

The net impact of the preceding specific items on our provision for income taxes in each of the periods presented was not material.

### Cash Dividends

Cash dividends declared per share were \$0.09 and \$0.375 in the first quarters of 2010 and 2009, respectively.

On May 5, 2010, our Board of Directors approved a modification of our dividend policy, which now contemplates the payment of a quarterly dividend of \$0.095 per share, a 5.5% increase compared with \$0.09 per share payable under the former policy in place since May 2009. The declaration of future dividends pursuant to this new policy is always subject to the discretion of the Board of Directors, and is generally based on our business performance, operational results, future capital requirements, business development requirements and other requirements and applicable laws. Pursuant to the new policy, our Board of Directors declared a quarterly cash dividend of \$0.095 per share, payable on July 5, 2010.

Prior to May 2009, our dividend policy had contemplated the payment of a quarterly dividend of \$0.375 per share.

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## Changes in Financial Condition

At March 31, 2010, we had cash and cash equivalents of \$102.9 million (compared with \$114.5 million at December 31, 2009) and we had no borrowings outstanding under our \$410.0 million credit facility. At March 31, 2010, we had long-term obligations of \$300.6 million in respect of the Convertible Notes and \$28.3 million owed to Cambridge Laboratories (Ireland) Limited ("Cambridge") in connection with the tetrabenazine acquisition in June 2009, and we had dividends payable of \$14.3 million in respect of our fourth quarter 2009 results, which dividend was paid on April 5, 2010.

In the first quarter of 2010, operating cash flows of \$44.8 million were a significant source of liquidity. We paid total cash dividends of \$14.2 million and we utilized a portion of our available cash resources to fund the following acquisition activities (exclusive of acquisition costs) in the first quarter of 2010:

\$40.0 million upfront for the U.S. and Canadian development and commercialization rights to Staccato® loxapine; and

\$9.0 million upfront for certain AMPAKINE® compounds.

#### 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 amounts of each source of revenue for the first quarters of 2010 and 2009; 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.

	Three Months Ended March 31							
	2010		2009		Change			
(\$ in 000s)	\$	%	\$	%	\$	%		
Product sales	212,033	97	165,393	95	46,640	28		
Research and development	2,924	1	3,715	2	(791)	(21)		
Royalty and other	4,678	2	4,211	2	467	11		
Total revenue	219,635	100	173,319	100	46,316	27		

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#### **Product Sales**

The following table displays the dollar amounts of product sales by internal reporting category for the first quarters of 2010 and 2009; 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.

		Three Months Ended March 31						
	2010	2010			Change			
(\$ in 000s)	\$	%	\$	%	\$	%		
Wellbutrin XL®	49,790	23	20,120	12	29,670	147		
Aplenzin®	4,041	2	3,821	2	220	6		
Xenazine®	16,110	8	6,683	4	9,427	141		
Zovirax®	38,974	18	32,911	20	6,063	18		
BPC	23,347	11	15,308	9	8,039	53		
Ultram® ER	7,929	4	20,596	12	(12,667)	(62)		
Cardizem® LA	7,649	4	8,187	5	(538)	(7)		
Legacy	42,548	20	40,579	25	1,969	5		
Generic	21,073	10	16,871	10	4,202	25		
Glumetza® (U.S.)	572		317		255	80		
Total product sales	212,033	100	165,393	100	46,640	28		

Wholesaler Inventory Levels

Three drug wholesale customers account for the majority of our Zovirax®, off-patent branded pharmaceutical ("Legacy"), and, since May 14, 2009, Wellbutrin XL® product sales in the U.S. Our distribution agreements with these wholesalers limit the amount of inventory they can own to between ½ and ½ months of supply of our products. As indicated in the following table, at each of March 31, 2010 and December 31, 2009, these wholesalers owned overall 1.0 months of supply of our products, of which only \$0.2 million of inventory had less than 12 months remaining shelf life as at both March 31, 2010 and December 31, 2009.

		At	: March 31, 2	010	<b>At December 31, 2009</b>				
	Original Shelf Life	Total Inventory	Months On Hand	Inventory With Less Than 12 Months Remaining Shelf Life	Total Inventory	Months On Hand	Inventory With Less Than 12 Months Remaining Shelf Life		
(\$ in 000s)	(In Months)	\$	(In Months)	\$	\$	(In Months)	\$		
Wellbutrin XL®	18	12,952	0.8	57	15,389	1.0	34		
Zovirax®	36-48	12,054	0.9	124	14,689	1.1	93		
Cardizem®	36-48	7,057	1.0	33	8,380	1.1	21		
Ativan®	24	1,828	0.9	6	2,300	1.1	77		
Vasotec® and									
Vaseretic®	24	1,378	1.3	11	1,468	1.1	9		
Isordil®	36-60	213	1.0	1	265	1.2	1		
Total	18-60	35,482	1.0	232	42,491	1.0	235		

#### Wellbutrin XL®

Wellbutrin XL® product sales increased \$29.7 million, or 147%, to \$49.8 million in the first quarter of 2010, compared with \$20.1 million in the first quarter of 2009, reflecting incremental revenue of approximately \$35.4 million earned in the first quarter of 2010, as a result of the acquisition of the full U.S. commercialization rights in May 2009, and the positive effect of subsequent price increases. Those factors were partially offset by declines in prescription volumes due to generic competition, and a planned reduction of wholesaler inventories in anticipation of a change in the U.S. National Drug Code for this product in the second quarter of 2010.

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#### Aplenzin®

Aplenzin® product sales increased \$0.2 million, or 6%, to \$4.0 million in the first quarter of 2010, compared with \$3.8 million in the first quarter of 2009. Sanofi-aventis launched the 348mg and 522mg dosage strengths of Aplenzin in the U.S. in April 2009, and the 174mg dosage strength in July 2009. In April 2010, sanofi-aventis advised us that it had engaged an independent contract sales organization to promote Aplenzin®.

#### *Xenazine*®

Xenazine® product sales increased \$9.4 million, or 141%, to \$16.1 million in the first quarter of 2010, compared with \$6.7 million in the first quarter of 2009, reflecting a year-over-year increase in patient enrollment in the U.S., as well as the inclusion of sales of the product in other countries in Europe and around the world, following the acquisition of the worldwide development and commercialization rights to tetrabenazine in June 2009.

#### **Zovirax®**

Zovirax® product sales increased \$6.1 million, or 18%, to \$39.0 million in the first quarter of 2010, compared with \$32.9 million in the first quarter of 2009, reflecting price increases implemented for these products over the last 12 months, which more than offset lower prescription volumes. In addition, sales in the first quarter of 2009 were negatively impacted by a decline in promotional activities, as Publicis did not commence its detailing of Zovirax® until February 2009.

#### BPC

Sales of BPC products increased \$8.0 million, or 53%, to \$23.3 million in the first quarter of 2010, compared with \$15.3 million in the first quarter of 2009. Excluding the positive effect on BPC Canadian dollar-denominated revenue of the strengthening of the Canadian dollar relative to the U.S. dollar, BPC product sales increased 28% in the first quarter of 2010, compared with the corresponding period of 2009. The increase in BPC revenue reflected increased prescription volumes for our promoted Wellbutrin® XL, Tiazac® XC and Ralivia® products, as well as increased demand for our genericized Tiazac® and Cardizem® CD products, which was attributable to competitors' manufacturing issues. In addition, sales of Glumetza® in the first quarter of 2010 benefited from a delay in the introduction of a competing generic version of the 500mg dosage strength.

### Ultram® ER

Ultram® ER product sales declined \$12.7 million, or 62%, to \$7.9 million in the first quarter of 2010, compared with \$20.6 million in the first quarter of 2009, reflecting the impact on volumes of the introduction of generic competition to the 100mg and 200mg dosage strengths in November 2009 (which also had some negative impact on sales of the 300mg product). In addition, upon generic entry, our contractual supply price to PriCara for branded 100mg and 200mg product (which is determined based on a percentage of PriCara's net selling price) was reduced by 50%. As there is currently no generic equivalent to the 300mg product, our supply price to PriCara for that dosage strength remains unchanged. All of those factors were partially offset by revenue generated through our supply of 100mg and 200mg authorized generic versions of Ultram® ER to Patriot.

#### Cardizem® LA

Revenue from sales of Cardizem® LA declined \$0.5 million, or 7%, to \$7.6 million in the first quarter of 2010, compared with \$8.2 million in the first quarter of 2009, as a result of lower prescription volumes. In March 2010, a subsidiary of Watson Pharmaceuticals, Inc. ("Watson") introduced its generic version of Cardizem® LA in all dosage strengths except 120mg. Although we are entitled to a royalty from Watson based on net sales of its generic Cardizem® LA product, the introduction of generic competition could have a material adverse impact on our revenues and earnings.

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, which is

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being amortized over seven years on a straight-line basis. This amortization amounted to \$3.8 million in each of the first quarters of 2010 and 2009.

Legacy

Sales of our Legacy products increased \$2.0 million, or 5%, to \$42.5 million in the first quarter of 2010, compared with \$40.6 million in the first quarter of 2009, reflecting higher sales of generic Tiazac®, which was attributable to competitors' manufacturing issues. In addition, declining prescription volumes for our other Legacy brands were largely offset by price increases implemented over the last 12 months.

On March 9, 2010, we reached a settlement with Sun Pharmaceutical Industries, Ltd., India ("Sun"), with respect to patent litigation related to Sun's Abbreviated New Drug Application for a generic version of Cardizem® CD. Under the terms of the settlement and license agreements, which were submitted to the U.S. Federal Trade Commission and the U.S. Department of Justice pursuant to Section 1112(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003, we have granted Sun, and its subsidiary Sun Pharma Global FZE, a non-exclusive license (without right to sublicense) to distribute various dosage strengths of Sun's generic formulation of Cardizem® CD in the U.S., upon receipt of regulatory approval from the FDA, and subject to certain limitations on the sales quantities of the 360mg dosage strength. Nevertheless, the introduction of Sun's 360mg generic version (following FDA approval) could have a material adverse impact on our revenues and earnings. Sun will pay us a royalty based on net sales of the various dosage strengths of its generic formulation. The license term ends on August 8, 2012 the date the last Cardizem® CD patent expires. No amount was paid to Sun under the terms of this settlement.

Generic

Sales of our bioequivalent ("Generic") products increased \$4.2 million, or 25%, to \$21.1 million in the first quarter of 2010, compared with \$16.9 million in the first quarter of 2009, reflecting higher sales of generic Cardizem® CD, which was attributable to competitors' manufacturing issues, which more than offset lower overall prescription volumes and pricing for the remaining products.

### Research and Development Revenue

Research and development revenue declined \$0.8 million, or 21%, to \$2.9 million in the first quarter of 2010, compared with \$3.7 million in the first quarter of 2009, as a result of a lower level of clinical research and laboratory testing services provided to external customers by our contract research division, partially offset by the positive impact of the strengthening of the Canadian dollar relative to the U.S. dollar.

### Royalty and Other Revenue

Royalties from third parties on sales of products we developed or acquired and other revenue increased \$0.5 million, or 11%, to \$4.7 million in the first quarter of 2010, compared with \$4.2 million in the first quarter of 2009, due mainly to royalties earned on sales of generic Tiazac® by Forest and generic Cardizem® CD by other third parties.

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## **Operating Expenses**

The following table displays the dollar amounts of each operating expense category for the first quarters of 2010 and 2009; the percentage of each category compared with total revenue in the respective period; and the dollar and percentage changes in the dollar amount of each category. Percentages may not add due to rounding.

	<b>Three Months Ended March 31</b>					
	2010	2009		Change	е	
(\$ in 000s)	\$	%	\$	%	\$	%
Cost of goods sold (exclusive of amortization of intangible assets shown						
separately below)	58,955	27	44,840	26	14,115	31
Research and development	66,887	30	14,528	8	52,359	360
Selling, general and administrative	43,513	20	43,244	25	269	1
Amortization of intangible assets	33,300	15	15,503	9	17,797	115
Restructuring costs	613		1,348	1	(735)	(55)
Legal settlements			241		(241)	(100)
Total operating expenses	203,268	93	119,704	69	83,564	70

## Cost of Goods Sold

Cost of goods sold, which excludes the amortization of intangible assets described separately below under " Amortization of Intangible Assets", increased \$14.1 million, or 31%, to \$59.0 million in the first quarter of 2010, compared with \$44.8 million in the first quarter of 2009. The percentage increase in cost of goods sold was higher than the corresponding 28% increase in total product sales in the first quarter of 2010, primarily due to:

an increased supply price for Zovirax® inventory purchased from GSK, as a result of the conclusion of a price allowance that had entitled us to purchase a pre-determined quantity of Zovirax® inventory from GSK at reduced prices;

the increase in lower margin Xenazine® product sales;

the decline in volume of higher margin 150mg Wellbutrin XL® product sales, as a result of the introduction of generic competition in May 2008;

the negative impact on Ultram® ER product sales of the reduction in our contractual supply price for the 100mg and 200mg dosage strengths; and

the negative impact on labour and overhead costs at our Steinbach, Manitoba manufacturing facility, as a result of the strengthening of the Canadian dollar relative to the U.S. dollar.

Those factors were partially offset by:

lower labour and overhead costs at our Puerto Rico manufacturing facilities and higher absorption at the Steinbach facility, each of which was a result of the transfer of certain manufacturing activities from the Puerto Rico facilities to the Steinbach facility;

an increased contribution from higher margin Wellbutrin XL® product sales following the acquisition of the full U.S. commercialization rights in May 2009; and

the positive impact of price increases implemented over the last 12 months.

## Research and Development Expenses

The following table displays the dollar amounts of research and development expenses by internal reporting category for the first quarters of 2010 and 2009; the percentage of each category compared with total revenue in the respective period; and the dollar and percentage changes in the dollar amount of each category. Percentages may not add due to rounding.

	Three Months Ended March 31									
	2010		2009		Change	e				
(\$ in 000s)	\$	%	\$	%	\$	%				
IPR&D	51,003	23			51,003	NM				
Internal research and development										
programs	12,577	6	11,108	6	1,469	13				
Contract research services provided to external										
customers	3,307	2	3,420	2	(113)	(3)				
Total research and development	44 997	20	14.500	0	52.250	260				
expenses	66,887	30	14,528	8	52,359	360				

M 4 F 1 1 M 1 24

NM Not meaningful

As described above under "Overview Business Development", we recorded a total IPR&D charge of \$51.0 million in the first quarter of 2010, related to the acquisitions of the U.S. and Canadian development and commercialization rights to Staccato® loxapine and certain AMPAKINE® compounds.

Internal research and development expenses increased \$1.5 million, or 13%, to \$12.6 million in the first quarter of 2010, compared with \$11.1 million in the first quarter of 2009, reflecting higher direct project spending on our specialty CNS drug-development programs, partially offset by lower labour and overhead costs as a result of the closure of our Mississauga, Ontario research and development facility and consolidation of our research and development operations in Chantilly, Virginia. In addition, clinical trial costs for BVF-324 in the first quarter of 2010 were lower than expected due to the slow enrolment in these studies.

Costs associated with providing contract research services to external customers declined \$0.1 million, or 3%, to \$3.3 million in the first quarter of 2010, compared with \$3.4 million in the first quarter of 2009, reflecting the decline in activity levels at our contract research division, and lower labour costs as a result of headcount reductions in the second quarter of 2009, partially offset by the negative impact on labour and overhead costs as a result of the strengthening of the Canadian dollar relative to the U.S. dollar.

# Selling, General and Administrative Expenses

Selling, general and administrative expenses increased \$0.3 million, or 1%, to \$43.5 million in the first quarter of 2010, compared with \$43.2 million in the first quarter of 2009, primarily due to:

an increase in product promotional spending of \$2.9 million in support of key products; and

the negative impact of the strengthening of the Canadian dollar relative to the U.S. dollar.

Those factors were partially offset by:

a decrease in legal costs of \$3.4 million, primarily related to reduced indemnification obligations to certain former officers and directors. Total legal costs amounted to \$10.0 million and \$13.5 million in the first quarters of 2010 and 2009, respectively, which included indemnification obligations of \$0.8 million and \$5.8 million, respectively, in those periods.

# Amortization of Intangible Assets

Amortization expense increased \$17.8 million, or 115%, to \$33.3 million in the first quarter of 2010, compared with \$15.5 million in the first quarter of 2009, due to the inclusion of amortization of the Wellbutrin XL® trademark intangible asset acquired in May 2009, and the tetrabenazine product rights

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intangible assets arising from the acquisition of the worldwide development and commercialization rights in June 2009.

# Restructuring Costs

We recorded restructuring charges of \$0.6 million and \$1.3 million in the first quarters of 2010 and 2009, respectively, as described above under "Overview Restructuring".

## **Non-Operating Income (Expense)**

The following table displays the dollar amounts of each non-operating income or expense category for the first quarters of 2010 and 2009; and the dollar and percentage changes in the dollar amount of each category.

	Three Months Ended March 31					
	2010	2009	Chang	e		
(\$ in 000s; Income (Expense))	\$	\$	\$	%		
Interest income	188	334	(146)	(44)		
Interest expense	(9,827)	(340)	(9,487)	NM		
Foreign exchange gain (loss)	(623)	407	(1,030)	(253)		
Impairment loss on debt securities	(155)	(2,707)	2,552	(94)		
Loss on disposal of investment		(6)	6	(100)		
Total non-operating expense	(10,417)	(2,312)	(8,105)	351		

NM Not meaningful

#### Interest Expense

Interest expense increased \$9.5 million to \$9.8 million in the first quarter of 2010, compared with \$0.3 million in the first quarter of 2009, which included non-cash amortization of debt discounts on the Convertible Notes and the Cambridge obligation of \$2.8 million and the non-cash amortization of deferred financing costs associated with the Convertible Notes and our credit facility of \$1.3 million.

# Impairment Loss on Debt Securities

We recorded losses related to other-than-temporary declines in the estimated fair value of a portion of our investment in auction rate securities of \$0.2 million and \$2.7 million in the first quarters of 2010 and 2009, respectively, reflecting the portion of these securities that we concluded has an other-than-temporary decline in estimated fair value due to a shortfall in their underlying collateral value.

#### **Provision for Income Taxes**

The following table displays the dollar amounts of the current and deferred provisions for income taxes for the first quarters of 2010 and 2009; and the dollar and percentage changes in the dollar amount of each provision. Percentages may not add due to rounding.

	Three Months Ended March 31						
	2010	2009	Change	e			
(\$ in 000s)	\$	\$	\$	%			
Current income tax expense	4,800	4,500	300	7			
Deferred income tax expense	4,300	7,800	(3,500)	(45)			
Total provision for income taxes	9,100	12,300	(3,200)	(26)			

In the first quarter of 2010, our effective tax rate was primarily affected by the non-deductible portion of the IPR&D charges associated with the acquisitions of the U.S. and Canadian development and commercialization

rights to Staccato® loxapine and certain AMPAKINE® compounds. In addition, these charges were recognized in a jurisdiction with lower statutory tax rates than those that apply in Canada.

# SUMMARY OF QUARTERLY RESULTS

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

	2010		2009	9				2008	
(\$ in 000s, except per share data)	Q1	Q4	Q3		Q2	Q1	Q4	Q3	Q2
Revenue	\$ 219,635 \$	241,053	\$ 212,523 \$	3	193,535	\$ 173,319	\$ 181,496	\$ 181,089 \$	186,095
Expenses	203,268	182,405	154,179	1	182,988	119,704	144,617	132,726	210,368
Operating income (loss)	16,367	58,648	58,344		10,547	53,615	36,879	48,363	(24,273)
Net income (loss)	(3,150)	73,000	40,362		24,090	39,003	120,380	48,437	(25,289)
Basic and diluted earnings (loss) per									
share	\$ (0.02) \$	0.46	\$ 0.25 \$	6	0.15	\$ 0.25	\$ 0.76	\$ 0.31 \$	(0.16)
Net cash provided by (used in) operating activities	\$ 44,753 \$	127,647	\$ 89,197 \$	6	97,081	\$ 46,972	\$ 106,963	\$ (62,370) \$	67,056

The following table displays the specific items identified by management that impacted net income in each of the eight most recently completed quarters and the impact of these items in the aggregate on basic and diluted EPS. As described above under "Overview Selected Financial Information Specific Items Impacting Net Income", management believes the identification of these items enhances an analysis of our financial performance when comparing operating results between periods; however, excluding some or all of these items should not be viewed as a substitute for net income under U.S. GAAP.

	2010		2009				2008	
(\$ in 000s, except per share data; Income (Expense))	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2
IPR&D <sup>(1)</sup>	\$ (51,003)	\$ (20,814)\$	(8,126) \$	(30,414) \$	\$	\$	\$	
SEC/OSC independent consultant and related costs <sup>(2)</sup>	(631)	(83)	169	(1,546)	(1,427)			
Restructuring costs	(613)	(3,937)	(2,413)	(11,367)	(1,348)	(10,855)	(7,587)	(51,760)
Impairment losses on debt and equity securities	(155)	(501)	(385)	(1,617)	(2,707)	(4,541)	(1,223)	(489)
Reduction in valuation allowance on deferred tax assets		26,000				90,000		
Gain on auction rate security settlement				22,000				
Loss on sale and leaseback of assets		(10,968)						
Legal settlements, net of insurance recoveries		(5,950)			(241)	(5,917)	(2,000)	(24,648)
Acquisition-related costs				(5,596)				
Proxy contest costs			(399)	(629)		(50)	(728)	(5,414)
Gain (loss) on disposal of investments			466	344	(6)	(1,083)	4,156	3,461
Write-down of deferred financing costs				(537)				
Management succession costs						(1,362)		(6,052)
Total	\$ (52,402)	\$ (16.253)\$	(10,688) \$	(29,362) \$	(5.729) \$	66,192 \$	(7,382)\$	(84,902)
	\$ (02,102)	Ψ (10,200)Ψ	(10,300) ψ	(2),502) φ	(ε,. 2)) ψ	σσ,172 φ	(,,εο2) φ	(0.,702)
EPS impact	\$ (0.33)	\$ (0.10)\$	(0.07) \$	(0.19) \$	(0.04) \$	0.42 \$	(0.05)\$	(0.53)
EPS impact	\$ (0.33)	\$ (0.10)\$	(0.07) \$	(0.19) \$	(0.04) \$	0.42 \$	(0.05)\$	(0.53)

Included in research and development expenses.

Included in selling, general and administrative expenses.

# First Quarter of 2010 Compared To Fourth Quarter of 2009

# Results of Operations

Total revenue declined \$21.4 million, or 9%, to \$219.6 million in the first quarter of 2010, compared with \$241.1 million in the fourth quarter of 2009, mainly due to declines in product sales of Wellbutrin XL®, due to generic erosion, and Zovirax®, reflecting the partial seasonality of the product.

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Net income decreased \$76.2 million, or 104%, to a net loss of \$3.2 million in the first quarter of 2010, compared with net income of \$73.0 million in the fourth quarter of 2009, primarily due to:

a decrease of \$26.0 million in deferred income tax benefits, related to a reduction in the valuation allowance recorded against U.S. operating loss carryforwards in the fourth quarter of 2009;

an increase of \$30.2 million in IPR&D charges, related to the acquisitions of the U.S. and Canadian development and commercialization rights to Staccato® loxapine and certain AMPAKINE® compounds in the first quarter of 2010; and

a decreased contribution from product sales of \$19.8 million, mainly related to the declines in Wellbutrin XL® and Zovirax® product sales, combined with the increased supply price for Zovirax® inventory.

#### Cash Flows

Net cash provided by operating activities declined \$82.9 million, or 65%, to \$44.8 million in the first quarter of 2010, compared with \$127.6 million in the fourth quarter of 2009, primarily due to:

a decrease of \$63.8 million related to the change in accounts payable, mainly due to the settlement in the first quarter of 2010 of a \$10.7 million amount owing to Teva in respect of Generic product sales provisions (which was included in accounts payable in the fourth quarter of 2009), the increased supply price for Zovirax® inventory purchased from GSK after the conclusion of the price allowance, and net payments in respect of clinical trial costs associated with BVF-324 and a royalty obligation on worldwide sales of tetrabenazine;

a decrease of \$20.8 million related to the change in accrued liabilities, mainly due to the initial interest payment on the Convertible Notes and the disbursement of 2009 employee bonuses in the first quarter of 2010;

the decreased contribution from product sales of \$19.8 million; and

a payment of \$6.0 million in the first quarter of 2010 in connection with the settlement of a litigation matter.

Those factors were partially offset by:

an increase of \$35.9 million related to the change in accounts receivable, mainly due to the declines in Wellbutrin XL® and Zovirax® product sales in the first quarter of 2010 and the timing of receipts.

## FINANCIAL CONDITION, LIQUIDITY AND CAPITAL RESOURCES

#### **Selected Measures of Financial Condition**

The following table displays a summary of our financial condition at March 31, 2010 and December 31, 2009:

	At	At		
	March 31	December 31		
	2010	2009	Change	
(\$ in 000s; Asset (Liability))	\$	\$	\$	%
Working capital <sup>(1)</sup>	131,462	93,734	37,728	40
Long-lived assets <sup>(2)</sup>	1,506,958	1,539,364	(32,406)	(2)
Long-term obligations, including current portion	(328,886)	(326,085)	(2,801)	1
Shareholders' equity	(1,344,303)	(1,354,372)	10,069	(1)

- (1) Total current assets less total current liabilities.
- (2) Property, plant and equipment, intangible assets, and goodwill.

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## Working Capital

Working capital increased \$37.7 million, or 40%, to \$131.5 million at March 31, 2010, compared with \$93.7 million at December 31, 2009, primarily due to:

a decrease in accounts payable of \$29.5 million, mainly due to the settlement of the \$10.7 million amount owing to Teva in respect of Generic product sales provisions, and net payments in respect of clinical trial costs associated with BVF-324 and the royalty obligation on worldwide sales of tetrabenazine;

an increase in inventories of \$14.8 million, reflecting the higher cost base of Zovirax® inventory;

a decrease in accrued liabilities of \$14.0 million, mainly due to the initial interest payment on the Convertible Notes and the disbursement of 2009 employee bonuses; and

a decrease in accrued legal settlements of \$6.0 million related to the payment made to settle a litigation matter.

Those factors were partially offset by:

a decrease in accounts receivable of \$14.9 million, mainly due to the declines in Wellbutrin XL® and Zovirax® product sales in the first quarter of 2010 and the timing of receipts; and

a net decline in cash and cash equivalents of \$11.6 million, which primarily reflected: \$50.0 million paid in the aggregate to acquire the U.S. and Canadian development and commercialization rights to Staccato® loxapine and certain AMPAKINE® compounds, and \$14.2 million paid in dividends; partially offset by \$44.8 million in operating cash flows and proceeds of \$8.5 million on the sale of our Dorado, Puerto Rico manufacturing facility.

#### Long-Lived Assets

Long-lived assets declined \$32.4 million, or 2%, to \$1,507.0 million at March 31, 2010, compared with \$1,539.4 million at December 31, 2009, primarily due to:

the depreciation of plant and equipment of \$3.9 million and the amortization of intangible assets of \$35.6 million.

That factor was partially offset by:

additions to property, plant and equipment of \$3.6 million, primarily incurred at our Steinbach manufacturing facility in connection with the transfer of certain manufacturing and packaging processes from our Puerto Rico manufacturing facilities; and

an increase of \$2.8 million related to the impact of foreign exchange rate changes on the reported value in U.S. dollars of property, plant and equipment located in Canada, due to the impact of a stronger Canadian dollar relative to the U.S. dollar at March 31, 2010, compared with December 31, 2009.

# Long-term Obligations

Long-term obligations (including the current portion) increased \$2.8 million, or 1%, to \$328.9 million at March 31, 2010, compared with \$326.1 million at December 31, 2009, reflecting the amortization of debt discounts on the Convertible Notes and the Cambridge obligation.

# Shareholders' Equity

Shareholders' equity declined 10.1 million, or 1%, to 1344.3 million at March 31, 2010, compared with 1354.4 million at December 31, 2009, primarily due to:

cash dividends declared and dividend equivalents on restricted share units ("RSUs") of \$14.3 million in the aggregate; and

a net loss of \$3.2 million (including \$1.7 million of stock-based compensation recorded in additional paid-in capital).

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Those factors were partially offset by:

a positive foreign currency translation adjustment of \$4.0 million to other comprehensive income, due mainly to the impact of the strengthening of Canadian dollar relative to the U.S. dollar at March 31, 2010, compared with December 31, 2009, which increased the reported value of our Canadian dollar-denominated net assets.

#### **Cash Flows**

The following table displays cash flow information for the first quarters of 2010 and 2009:

	Three Months Ended March 31			
	2010	2009	Change	
(\$ in 000s)	\$	\$	\$	%
Net cash provided by operating activities	44,753	46,972	(2,219)	(5)
Net cash used in investing activities	(43,880)	(7,042)	(36,838)	523
Net cash used in financing activities	(12,702)	(59,331)	46,629	(79)
Effect of exchange rate changes on cash and cash equivalents	258	(452)	710	(157)
Net decrease in cash and cash equivalents	(11,571)	(19,853)	8,282	(42)
Cash and cash equivalents, beginning of period	114,463	317,547	(203,084)	(64)
Cash and cash equivalents, end of period	102,892	297,694	(194,802)	(65)

## **Operating Activities**

Net cash provided by operating activities declined \$2.2 million, or 5%, to \$44.8 million in the first quarter of 2010, compared with \$47.0 million in the first quarter of 2009, attributable to the net effect of the following factors:

a decrease related to the change in operating assets and liabilities of \$22.2 million, or 112%, to cash used of \$42.1 million in the first quarter of 2010, compared with cash used of \$19.9 million in the first quarter of 2009, primarily due to:

a decrease of \$16.1 million related to the change in inventories, reflecting the higher cost base of Zovirax® inventory; and

a decrease of \$13.4 million related to the change in accounts payable, mainly due to payments made in the first quarter of 2010 to settle the amount owing to Teva in respect of Generic product sales provisions, and in respect of clinical trial costs associated with BVF-324 and the royalty obligation on worldwide sales of tetrabenazine.

an increase in income from operations before changes in operating assets and liabilities of \$20.0 million, or 30%, to \$86.9 million in the first quarter of 2010, compared with \$66.9 million in the first quarter of 2009, primarily due to:

an increased contribution from product sales of \$32.5 million, mainly related to the incremental revenue from Wellbutrin XL ®, Xenazine®, generic Tiazac® and generic Cardizem® CD products (partially offset by lower Ultram® ER product sales), together with the reduced costs and improved capacity utilization of our manufacturing operations.

That factor was partially offset by:

the payment of \$6.0 million in the first quarter of 2010 in connection with the settlement of a litigation matter; and

the inclusion of cash interest expense of \$4.7 million on the Convertible Notes in the first quarter of 2010.

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#### **Investing Activities**

Net cash used in investing activities increased \$36.8 million, or 523%, to \$43.9 million in the first quarter of 2010, compared with \$7.0 million in the first quarter of 2009, primarily due to:

an increase of \$50.0 million related to the acquisitions of the U.S. and Canadian development and commercialization rights to Staccato® loxapine and certain AMPAKINE® compounds in the first quarter of 2010.

That factor was partially offset by:

a decrease related to the proceeds of \$8.5 million received on the sale of our Dorado, Puerto Rico manufacturing facility in the first quarter of 2010.

#### Financing Activities

Net cash used in financing activities declined \$46.6 million, or 79%, to \$12.7 million in the first quarter of 2010, compared with \$59.3 million in the first quarter of 2009, primarily due to a decrease in cash dividends paid of \$45.1 million, reflecting the reduction in our quarterly cash dividend policy to \$0.09 per share from \$0.375 per share commencing in May 2009.

#### **Net Financial Assets (Liabilities)**

	At March 31	At December 31	CI.	
	2010	2009	Change	
(\$ in 000s; Asset (Liability))	\$	\$	\$	%
Financial Assets				
Cash and cash equivalents	102,892	114,463	(11,571)	(10)
Marketable securities	19,774	21,082	(1,308)	(6)
Total financial assets	122,666	135,545	(12,879)	(10)
Financial Liabilities				
Convertible Notes	(300,585)	(298,285)	(2,300)	1
Cambridge obligation	(28,301)	(27,800)	(501)	2
Total financial liabilities	(328,886)	(326,085)	(2,801)	1
Net financial liabilities	(206,220)	(190,540)	(15,680)	8

We believe that cash expected to be generated by operations and from the potential sale of remaining non-core assets, as well as funds available under our \$410.0 million credit facility, and its \$140.0 million accordion feature, will be sufficient to meet our operational and capital expenditure requirements, support our 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 \$10 million in 2010, principally to maintain existing facilities and capacity.

We cannot, however, predict the amount or timing of our need for additional funds under various circumstances, such as: significant business development transactions; new product development projects or clinical studies; changes to our capital structure; or other factors that may require us to raise additional funds through borrowings, or the issuance of debt, equity or equity-linked securities. In addition, certain contingent events, such as the resolution of certain legal proceedings (as described in note 14 to our Consolidated Financial Statements), if realized, could have a material adverse impact on our liquidity and capital resources. The continuing uncertainty in the credit and capital markets may limit our access to additional funding or affect the pricing thereof.

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## Cash and Cash Equivalents

Our cash and cash equivalents are principally held in cash operating accounts, or are invested in securities such as treasury bills, certain money market funds, term deposits, or commercial paper with the highest investment-grade credit rating obtainable.

#### **Auction Rate Securities**

Our marketable securities portfolio currently includes \$26.8 million of principal invested in nine individual auction rate securities. In May 2009, we entered into a settlement with an investment bank in respect of our investment in these securities. Under the terms of this settlement, we received a payment of \$22.0 million in the second quarter of 2009, and retained ownership of the securities. The estimated fair value of these securities at each of March 31, 2010 and December 31, 2009 was \$6.0 million. We do not consider the remaining fair value of these securities to be material to our liquidity.

#### **Debt Capacity**

We currently have \$350.0 million principal amount of Convertible Notes issued and outstanding. We have no outstanding borrowings under our \$410.0 million credit facility. This facility, plus its \$140.0 million accordion feature, may be used for general corporate purposes, including acquisitions and capital expenditures. At March 31, 2010, we were in compliance with all covenants associated with this facility.

## Share Repurchase Program

On August 5, 2009, our Board of Directors approved the purchase of up to 15.8 million of our common shares on the open market under a share repurchase program or normal course issuer bid, subject to a maximum of \$75.0 million of common shares being repurchased during any fiscal year pursuant to a covenant in our credit facility (unless such condition is waived or varied by our lenders). We have not repurchased any of our common shares under this program.

#### OFF-BALANCE SHEET ARRANGEMENTS AND CONTRACTUAL OBLIGATIONS

We have no off-balance sheet arrangements that have a material current effect or that are reasonably likely to have a material future effect on our results of operations, financial condition, capital expenditures, liquidity, or capital resources.

We acquire and collaborate on products still in development and enter into research and development arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the products in development. As described above under "Overview Business Development", we may be required to make milestone payments of up to \$105.0 million in the aggregate pursuant to the terms of the collaboration and license agreement for Staccato® loxapine and the asset purchase agreement for AMPAKINE®. These payments are contingent on the achievement of specific developmental, regulatory, and commercial milestones. In addition, we may have to make royalty payments based on a percentage of future net sales of Staccato® loxapine and AMPAKINE® compounds in the event regulatory approval is obtained.

There have been no other material changes outside the normal course of business to the items specified in the contractual obligations table and related disclosures under the heading "Off-Balance Sheet Arrangements and Contractual Obligations" in the annual MD&A contained in the 2009 Form 10-K.

## **OUTSTANDING SHARE DATA**

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

At May 4, 2010, we had 158,478,375 issued and outstanding common shares, as well as 4,521,739 stock options, 564,874 RSUs without performance goals, and 790,916 RSUs with performance goals outstanding (which vest at up to 200% of the RSUs granted, depending on our performance relative to an industry comparator group).

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Assuming full share settlement, 23,480,800 common shares are issuable upon the conversion of the Convertible Notes (based on a conversion rate of 67.0880 common shares per \$1,000 principal amount of Convertible Notes, subject to adjustment); however, our intent and policy is to settle the Convertible Notes using a net share settlement approach.

#### QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes to our exposures to market risks as disclosed under the heading "Quantitative and Qualitative Disclosures About Market Risk" in the annual MD&A contained in the 2009 Form 10-K.

#### 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 disclosed under the heading "Critical Accounting Policies and Estimates" in the annual MD&A contained in the 2009 Form 10-K.

#### RECENT ACCOUNTING GUIDANCE

## **Adoption of New Accounting Guidance**

Effective January 1, 2010, we adopted the following new accounting guidance:

Authoritative guidance requiring additional disclosure about the amounts of and reasons for significant transfers in and out of Level 1 and Level 2 fair value measurements. This guidance also clarifies existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring Level 2 and Level 3 measurements. As the guidance only requires new disclosures, the adoption of this guidance did not impact our financial position or results of operations. In addition, effective for interim and annual periods beginning after December 15, 2010, this guidance will require additional disclosure and require an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis.

Authoritative guidance for determining whether an entity is a variable interest entity ("VIE"). Under this guidance, an enterprise has a controlling financial interest when it has the power to direct the activities of a VIE that most significantly impact the entity's economic performance, and the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. Upon adoption of this guidance, we determined that none of our existing collaboration and license arrangements with other entities for various products under development represented arrangements with VIEs. Accordingly, the adoption of this guidance did not have any impact on our Consolidated Financial Statements.

# Recently Issued Accounting Guidance, Not Adopted as of March 31, 2010

In March 2010, new authoritative guidance was issued recognizing the milestone method of revenue recognition as a valid application of the proportional performance model when applied to research and development arrangements. An entity may make an accounting policy election to recognize the receipt of a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The guidance is effective for fiscal years, including interim periods within those years, beginning on or after June 15, 2010. We are currently evaluating the effect that the adoption of this guidance will have on our financial condition and results of operations.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

Information relating to quantitative and qualitative disclosures about market risk is detailed in Item 2, and is incorporated herein by reference.

## Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2010. Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of March 31, 2010. There were no changes in our internal controls over financial reporting that occurred during the three-month period ended March 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

#### PART II. OTHER INFORMATION

## Item 1. Legal Proceedings

For information concerning legal proceedings, reference is made to note 14 to the condensed consolidated financial statements included under Part I, Item 1, of this Form 10-Q.

#### Item 1A. Risk Factors

Except as set forth below, there have been no material changes to the risk factors disclosed in Item 1A "Risk Factors" of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

#### The implementation of U.S. healthcare reform legislation could adversely affect our business.

In March 2010, healthcare reform legislation was enacted in the U.S. This new legislation imposes cost containment measures that adversely affect the amount of reimbursement for our products. These measures include increasing the minimum rebates for our drugs covered by Medicaid programs and extending such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations, as well as expansion of the 340(B) Public Health Services drug pricing program. This legislation also requires that drug manufacturers provide a specified discount to Medicare Part D beneficiaries, and imposes a new fee on drug manufacturers and importers that sell branded prescription drugs to specified U.S. government programs. A number of the provisions of the legislation require new and revised regulations and guidance by governmental agencies to implement, which has not yet occurred. Moreover, additional reforms to healthcare programs may be introduced in the coming years. Accordingly, while it is too early to predict the ultimate impact of this new legislation on our business, the legislation could have a material adverse effect on our business, cash flows, financial condition and results of operations.

## Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

## Item 3. Defaults Upon Senior Securities

None.

## Item 4. (Removed and Reserved)

#### Item 5. Other Information

None.

## Item 6. Exhibits

- Exhibit 31.1 Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 31.2 Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.1 Certification of the Chief Executive Officer pursuant to 18 U.S.C. § 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.2 Certification of the Chief Financial Officer pursuant to 18 U.S.C. § 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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Date: May 7, 2010

## **SIGNATURE**

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** (Registrant) /s/ MARGARET MULLIGAN Margaret Mulligan Senior Vice-President and Chief Financial Officer

(Principal Financial Officer and Duly Authorized Officer) 55