

BIOVAIL CORP INTERNATIONAL
Form 10-K
February 26, 2010

Table of Contents

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

FORM 10-K

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

For the fiscal year ended **December 31, 2009**

OR

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

For the transition period from _____ to _____
Commission file number 001-14956

BIOVAIL CORPORATION

(Exact Name of Registrant as Specified in its Charter)

CANADA

State or other jurisdiction of
incorporation or organization

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

**7150 Mississauga Road
Mississauga, Ontario
CANADA, L5N 8M5**

(Address of principal executive offices)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Shares, No Par Value	New York Stock Exchange, Toronto Stock Exchange

Securities registered pursuant to section 12(g) of the Act:

None
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Note Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Exchange Act from their obligations under those Sections.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted to Rule 405 of Regulations S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the common shares held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was \$2,128,166,465 based on the last reported sale price on the New York Stock Exchange on June 30, 2009.

Number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date:

158,372,110 common shares of Biovail Corporation issued and outstanding on February 24, 2010.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates certain information by reference from the registrant's proxy statement for the 2010 Annual Meeting of Shareholders expected to be held on May 18, 2010. Such proxy statement will be filed no later than 120 days after the close of the registrant's fiscal year ended December 31, 2009.

Table of Contents

TABLE OF CONTENTS
GENERAL INFORMATION

		Page
<u>PART I</u>		
<u>Item 1.</u>	<u>Business</u>	<u>1</u>
	<u>A. History and Development of the Company</u>	<u>1</u>
	<u>B. Business Overview</u>	<u>1</u>
	<u>C. Organizational Structure</u>	<u>28</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>28</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>46</u>
<u>Item 2.</u>	<u>Properties</u>	<u>47</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>48</u>
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	<u>57</u>
<u>PART II</u>		
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>60</u>
	<u>A. Market Information</u>	<u>60</u>
	<u>B. Holders</u>	<u>60</u>
	<u>C. Dividends</u>	<u>60</u>
	<u>D. Restrictions on Share Ownership by Non-Canadians</u>	<u>61</u>
	<u>E. Exchange Controls</u>	<u>64</u>
	<u>F. Taxation</u>	<u>64</u>
	<u>G. Sale of Unregistered Securities</u>	<u>65</u>
	<u>H. Purchases of Equity Securities by the Company and Affiliated Purchases</u>	<u>66</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>66</u>
	<u>A. Selected Financial Data</u>	<u>66</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operation</u>	<u>68</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>124</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>124</u>
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>124</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>124</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>124</u>
<u>PART III</u>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>125</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>125</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>125</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>125</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>125</u>
<u>PART IV</u>		
<u>Item 15.</u>	<u>Exhibits, Financial Statement Schedules</u>	<u>126</u>
<u>SIGNATURES</u>		<u>131</u>

Table of Contents

Basis of Presentation

General

Except where the context otherwise requires, all references in this Form 10-K to the "Company", "Biovail", "we", "us", "our" or similar words or phrases are to Biovail Corporation and its subsidiaries, taken together. In this Form 10-K, references to "\$" and "US\$" are to United States dollars and references to "C\$" are to Canadian dollars. Unless otherwise indicated, the statistical and financial data contained in this Form 10-K are presented as at December 31, 2009.

Unless otherwise noted, prescription and market data are derived from information provided by IMS Health Inc. ("IMS") and are as of its December 31, 2009 report. IMS is a provider of information solutions to the pharmaceutical and healthcare industries, including market intelligence and performance statistics.

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 United States of America (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 .

WELLBUTRIN®, WELLBUTRIN® SR, WELLBUTRIN® XL, WELLBUTRIN® XR, ZOVIRAX® and ZYBAN® are trademarks of The GlaxoSmithKline Group of Companies and are used by us under license. ULTRAM® is a trademark of Ortho-McNeil, Inc. (now known as PriCara, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.) and is used by us under license. STACCATO® is a trademark of Alexza Pharmaceuticals, Inc. and is used by us under license.

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-K contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and may be forward-looking information 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:

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;

Table of Contents

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) in the U.S.;

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;

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, including, but not limited to, the estimated costs and expected timing to complete the development of BVF-018 (tetrabenazine), efforts related to the development of BVF-036, BVF-040 and BVF-048 (pimavanserin), BVF-025 (fipamezole), BVF-324 (tramadol) and BVF-014 (GDNF), and efforts related to the development and regulatory approval of AZ-004 (Staccato® loxapine), including the expected potential milestone payments in connection with Staccato® loxapine, pimavanserin, fipamezole, GDNF and other research and development arrangements;

our ability to secure other development partners for, and to share development costs associated with, certain product development programs;

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 credit facility, to support future spending and business development requirements;

the expected future taxable income in determining any required deferred tax asset valuation allowance;

the impact of market conditions on our ability to access additional funding at reasonable rates, and 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 2014;

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

investment recovery, liquidity, valuation, impairment and other conclusions associated with our investment in auction rate securities;

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

expected timing and amount of principal and interest payments related to long-term obligations;

the impact of short-term fluctuations in our share price on the fair value of our Company's reporting unit for purposes of testing goodwill for impairment;

the availability of benefits under tax treaties and the continued availability of low effective tax rates for our operations;

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

Table of Contents

statements. Although we have indicated above certain of these statements set out herein, all of the statements in this Form 10-K that contain forward-looking statements are qualified by these cautionary statements. Although we believe that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Certain material factors or assumptions are applied in making forward-looking statements, including, but not limited to, factors and assumptions regarding 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 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 preclinical 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;

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;

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

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

our ability to repay or refinance the principal amount under our note 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-K, and in particular under Item 1A. "Risk Factors". 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.

Table of Contents

PART I

Item 1. Business.

A. History and Development of the Company

Biovail Corporation was formed under the *Business Corporations Act* (Ontario) on February 18, 2000, as a result of the amalgamation of TXM Corporation and Biovail Corporation International. Biovail Corporation was continued under the *Canada Business Corporations Act* (the "CBCA") effective June 29, 2005. For additional information with respect to material developments in our Company's business, including recent acquisitions and dispositions, see Item 1.B. "Business Overview Our Specialty CNS Strategy" and Item 2. "Properties".

Our principal executive office is located at 7150 Mississauga Road, Mississauga, Ontario, Canada, L5N 8M5, telephone (905) 286-3000. Our agent for service in the United States ("U.S.") is CT Corporation System, located at 111 Eighth Avenue, New York, New York, 10011, telephone number (212) 590-9331.

Descriptions of our principal capital expenditures and divestitures and descriptions of acquisitions of material assets are found in our Management's Discussion and Analysis of Financial Condition and Results of Operation ("MD&A") and in the notes to our consolidated financial statements included elsewhere in this annual report.

B. Business Overview

General Overview

We are 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.

The growth and development of our specialty CNS business is financially supported by our former base business model which focused on the development and large-scale manufacture of pharmaceutical products incorporating our oral drug-delivery technologies. While our strategy has transitioned to specialty CNS, this base business model continues to provide revenues and significant operating cash flow that can be used to support and fund licensing and acquisition opportunities in specialty CNS. Our drug delivery expertise also provides support for life cycle management of our specialty CNS products.

We also continue to identify and evaluate complementary acquisitions or business opportunities that support our specialty CNS strategy (such as our May 2009 acquisition of the full U.S. commercialization rights to Wellbutrin XL®).

Since adopting our specialty CNS strategy in May 2008, we have made significant progress in its implementation with the completion of two acquisitions and four in-licensing transactions for specialty CNS products. We believe that our continued ability to successfully implement our specialty CNS strategy will be driven by a number of factors, including (i) our strong balance sheet; (ii) ongoing cash flows generated by our former base business model; (iii) the in-licensing and acquisition opportunities currently available in the specialty CNS market; and (iv) our proven expertise in formulation, clinical development, regulatory affairs, manufacturing and marketing of prescription pharmaceutical products.

Transitioning Pharmaceutical Industry

Industry Overview

IMS Health Inc. ("IMS"), a provider of information solutions to the pharmaceutical and healthcare industries, including market intelligence and performance statistics, reported that the total U.S. prescription drug market was approximately \$291.5 billion in 2008 and is projecting 4% to 5% growth in the U.S. market for 2009. The Canadian pharmaceutical market was valued by IMS at C\$21.5 billion in 2009.

The pharmaceutical industry, and the companies that comprise it, have experienced significant changes over the past several years. For example, based on IMS data, during the 2009 to 2012 period, branded products with annual sales in excess of \$68.9 billion are expected to lose patent protection. To replace these revenues and

Table of Contents

reduce their dependence on internal development programs, large pharmaceutical companies often enter into strategic licensing arrangements with specialty pharmaceutical companies or augment their product pipelines by acquiring smaller pharmaceutical companies with development-stage pipeline products and technologies. Large pharmaceutical companies also employ strategies to extend brand life cycles and exclusivity periods and to establish product differentiation. We believe that this need to augment product pipelines was a key driver of merger and acquisition activity among certain large pharmaceutical companies in 2009.

In addition, factors such as increased enrollment in health maintenance organizations ("HMOs") in the U.S., growth in managed care, an aging and more health-aware population, introduction of several major new drugs that bring significant therapeutic benefits, and increased use of new marketing approaches such as direct-to-patient advertising, have forced many pharmaceutical companies to adjust their strategies. There has also been an industry-wide slowdown in the approval of new drugs in the U.S., particularly those providing only advances in convenience and patient compliance. Furthermore, the pharmaceutical industry is subject to ongoing political pressure to contain the growth in spending on drugs and to expedite and facilitate bioequivalent (generic) competition to branded products. In the U.S., health care reform remains a focal issue, and there are increasing financial pressures on the reimbursement policies of third-party payors, including incentives to pharmacies to substitute generics for branded products when available. A number of legislative and regulatory proposals aimed at changing the U.S. healthcare system, and changes in the levels at which pharmaceutical companies are reimbursed for sales of their products or pricing of drugs, have been proposed. In addition, as a result of the focus on healthcare reform in connection with the current presidential administration in the U.S., Congress may implement changes in laws and regulations governing healthcare service providers, including measures to control costs or reductions in reimbursement levels or price controls.

Transitioning of the Company's Business

The changing environment in the pharmaceutical industry required us to reassess our base business model, which culminated in a comprehensive review in early 2008 of all aspects of our business in an effort to identify and evaluate alternatives to enhance shareholder value. The result of that review was the development of our specialty CNS strategy — one that targets the development and commercialization of products that address unmet medical needs in specialty CNS disorders.

According to the latest available IMS data, CNS disorders represent an approximately \$70 billion market globally (approximately \$45 billion in the U.S.), with growth expected to be in the low- to mid-double digits in many niche specialty CNS markets, such as those within the markets of Parkinson's disease and multiple sclerosis.

By focusing our development and commercialization efforts on products that address unmet medical needs in specialty CNS disorders, we believe our products are likely to receive favourable formulary coverage, which will facilitate higher prescription volumes, favourable pricing and reimbursement acceptance and, consequently, higher revenues. By targeting unmet medical needs in niche markets, we believe we may also enhance the intellectual property protection or market exclusivity for our products; our strategy is to obtain market exclusivity of at least five years.

Our specialty CNS strategy also provides us with an opportunity to leverage our existing technologies and capabilities associated with our former base business model, including formulation, clinical development, regulatory affairs, manufacturing and marketing of prescription pharmaceutical products, both to assist with regulatory approvals and to effect life-cycle management.

Our Specialty CNS Strategy

2009 was a year of decisive action for Biovail as we transformed our Company with the aggressive, rapid and successful execution of our specialty CNS strategy. During the year, we substantially advanced our specialty CNS strategy with the acquisition of the worldwide development and commercialization rights to tetrabenazine and we completed three strategic in-licensing agreements in specialty CNS. Further, we enhanced our CNS expertise with the appointment of an External Advisory Board to provide medical, scientific and commercial input into our specialty CNS product development pipeline efforts and plans.

Table of Contents

Our long-term goal is to become the premier pharmaceutical company in specialty CNS disorders and the partner of choice for biotechnology and emerging pharmaceutical companies with active development programs in the specialty CNS therapeutic area.

Product Development

Specialty CNS spans several sub areas. Our primary focus has been on specialty neurology, which includes epilepsy, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis (ALS, or Lou Gehrig's disease), Alzheimer's disease and multiple sclerosis. We are also pursuing opportunities for unmet medical needs in specialty psychiatry disorders, as an example, pimavanserin as adjunctive therapy for schizophrenia. Both of these areas are serviced by small and generally overlapping prescribing communities of specialists, either neurologists or psychiatrists, thereby providing efficiency in commercialisation efforts. Since unmet medical needs are high in these areas we believe financial pressures on pricing, reimbursement and reliance on third-party payers is less intense; in addition, greater periods of protection for intellectual property (generally in excess of 5 years) are available.

We also review opportunities in therapeutic areas adjacent to specialty CNS, particularly as supportive care indications (e.g. fatigue associated with multiple sclerosis). We will also continue to review and consider opportunities supportive of our specialty CNS strategy such as the acquisition in May 2009 of the full US rights to Wellbutrin® XL.

Our product development strategy targets the in-licensing or acquisition of specialty CNS products with peak annual sales of \$75 million to \$300 million. We believe this range will result in less competition from large pharmaceutical companies. We are also targeting products with at least five years of market exclusivity. While focused on the U.S. and Canadian markets, our business development efforts cover broad geographies and include public, private and academic sources.

To mitigate the risk of product development, our business development efforts are focused on: (a) late-stage (post-Phase 2) drugs; (b) drugs approved for indications in countries other than the U.S. or Canada; (c) medical compounds already approved by the U.S. Food and Drug Administration (the "FDA") that can be repurposed for a different indication; and (d) in-market drugs. We may selectively pursue earlier-stage opportunities. Our goal is to build a robust and sustainable pipeline of products at varying stages of development that will create sustainable revenue growth.

Whenever an opportunity is identified, we apply rigorous financial, commercial and scientific analysis prior to making an investment decision. The majority of the capital we have deployed to date under our specialty CNS strategy has been targeted at near-term revenue opportunities. Where clinical or regulatory risk exists, as is the case with all development-stage compounds, our preference will be to in-license those products minimizing the upfront payment and structuring the agreement such that additional acquisition-related funds are only paid upon the attainment of development, regulatory or commercial milestones.

Execution of our Strategy

Since the adoption of our specialty CNS strategy in May 2008, we have completed six specialty CNS transactions, consisting of two acquisitions relating to tetrabenazine and four in-licensing agreements. Collectively, these transactions have significantly strengthened our product development pipeline, enhanced our reputation in the specialty CNS market and substantially accelerated the timeline for implementation of our five-year financial plan. Each of these transactions is described below:

Acquisition of Prestwick Pharmaceuticals, Inc.

On September 16, 2008, we acquired Prestwick Pharmaceuticals, Inc. ("Prestwick"), a privately held U.S.-based pharmaceutical company, for a total net cash purchase price of approximately \$101.9 million. Prestwick held the U.S. and Canadian licensing rights to tetrabenazine tablets (known as Xenazine® in the U.S. and Nitoman® in Canada). Prestwick had acquired those licensing rights from Cambridge Laboratories (Ireland) Ltd. ("Cambridge"), which, at the time, held the worldwide license for tetrabenazine (as described

Table of Contents

below, we acquired the worldwide development and commercialization rights to the entire portfolio of tetrabenazine products from Cambridge in June 2009).

On August 15, 2008, a U.S. new drug application ("NDA") for Xenazine® received FDA approval for the treatment of chorea associated with Huntington's disease. Xenazine® has been granted orphan drug designation by the FDA, which provides this product with seven years of market exclusivity in the U.S. from the date of approval. Xenazine® is the first and only FDA-approved treatment for any Huntington's disease-related symptom. Upon approval of Xenazine®, the FDA determined that a Risk Evaluation and Mitigation Strategy ("REMS") was necessary to ensure that the benefits of the drug outweigh its associated risks, to promote the informed prescribing and proper titration and dosing of Xenazine®, and to minimize the risk of drug-drug interactions. As part of the program associated with the REMS, our marketing partner Ovation Pharmaceuticals, Inc. ("Ovation") (now Lundbeck Inc. ("Lundbeck")) has begun the process of educating physicians, pharmacists, patients and their caregivers about the safe and effective use of Xenazine®.

In November 2008, Xenazine® tablets became commercially available in 12.5 mg and 25 mg strengths throughout the U.S. under an exclusive marketing, distribution and supply agreement entered into between Prestwick and Ovation prior to our acquisition of Prestwick. Through the end of 2009, 2,738 patients had enrolled, or were in the process of enrolling, with the Xenazine® distribution center. Nitoman® had previously been approved for sale in Canada by the Canadian Therapeutic Products Directorate ("TPD") in 1995. Nitoman® is marketed to Canadian physicians through the Biovail Pharmaceuticals Canada ("BPC") sales force.

Acquisition of Worldwide Development and Commercialization Rights to Tetrabenazine

In June 2009, we acquired the worldwide development and commercialization rights to the entire portfolio of tetrabenazine products, including Xenazine® and Nitoman®, held by Cambridge. By means of this acquisition, we obtained Cambridge's economic interest in the supply of tetrabenazine for the U.S. and Canadian markets, as well as for a number of other countries in Europe and around the world through existing distribution agreements. We also assumed Cambridge's royalty obligations to third parties on the worldwide sales of tetrabenazine. The total purchase price comprised cash consideration of \$200.0 million paid on closing and additional payments of \$12.5 million and \$17.5 million due to Cambridge on the first and second anniversaries of the closing date, respectively. Pursuant to the acquisition, we also acquired the rights to a modified-release formulation of tetrabenazine under development initially for the treatment of Tourette's Syndrome (BVF-018) and to the development of an isomer of tetrabenazine (RUS-350).

License of Pimavanserin

In May 2009, we entered into a collaboration and license agreement with ACADIA Pharmaceuticals Inc. ("ACADIA") to acquire the U.S. and Canadian rights to develop, manufacture and commercialize pimavanserin in a number of neurological and psychiatric conditions, including Parkinson's disease psychosis ("PDP"), and Alzheimer's disease psychosis ("ADP"). Pursuant to the terms of the collaboration and license agreement, we paid an upfront fee of \$30.0 million to ACADIA, with contingent obligations to pay developmental milestone payments associated with the successful completion of clinical trials, regulatory submissions and approvals for pimavanserin in the PDP, ADP and schizophrenia indications. Subject to certain limited exceptions, the agreement provides that we will be responsible for funding all development expenses for pimavanserin for PDP, ADP and schizophrenia.

A Phase 3 PDP study conducted by ACADIA in 2009 did not meet its primary endpoint of antipsychotic efficacy, but did meet the secondary endpoint of motoric tolerability. As a result, ACADIA and Biovail agreed to conclude a second Phase 3 PDP study at its current enrollment level to allow for the analysis of the study data as soon as practicable, and to use the data from these two Phase 3 studies to arrive at an enhanced study design that may be used in new Phase 3 studies for PDP. In October 2009, Biovail and ACADIA amended the collaboration and license agreement to provide that we will fund this third Phase 3 clinical trial for PDP; provided, however, that if the trial does not meet the primary endpoint, then ACADIA will reimburse the Company for 50% of the cost of the trial. Similarly, if the trial is successful, the related milestone payment will be reduced by 50% of the cost of the trial.

Table of Contents

The amendment also provides that ACADIA may elect to pursue an initial clinical trial in ADP at its own expense. If the ADP trial meets its clinical endpoint, we would reimburse ACADIA 100% of the cost of the trial.

License of Fipamezole

In August 2009, we entered into a collaboration and license agreement with Santhera Pharmaceuticals (Switzerland) Ltd. ("Santhera"), a subsidiary of Santhera Pharmaceuticals Holding AG, to acquire the U.S. and Canadian rights to develop, manufacture and commercialize fipamezole for the treatment of a number of neurological and psychiatric conditions, including levodopa-induced dyskinesia, also known as Parkinson's disease dyskinesia ("PDD").

Pursuant to the terms of the collaboration and license agreement, we made an upfront payment of \$8.0 million to Santhera upon execution of the agreement, and made a further payment of \$4.0 million to Santhera on October 5, 2009, upon the closing of Santhera's acquisition of Oy Juvantia Pharma Ltd. We will have milestone payment obligations to Santhera for the initiation of a Phase 3 study, regulatory submissions and approvals of fipamezole in PDD and in the event we pursue a second indication for the compound.

We will be responsible for the development programs and associated costs in the U.S. and Canada for fipamezole for both PDD and a second indication should we pursue one.

License of GDNF

In December 2009, we entered into a license agreement with Amgen Inc. ("Amgen") and MedGenesis Therapeutix Inc. ("MedGenesis"), pursuant to which we were granted a license to exploit glial cell line derived neurotrophic factor ("GDNF") in certain CNS indications in certain countries (including in North America, Japan and a number of European countries). MedGenesis was also granted a license from Amgen to exploit GDNF in certain CNS indications in certain countries and for non-CNS indications. At the same time, we entered into a collaboration agreement with MedGenesis to develop and commercialize GDNF, initially for the treatment of Parkinson's disease in the United States, Japan and certain European countries and, potentially, in other countries and other CNS indications. Pursuant to the collaboration agreement, we were granted a license to MedGenesis' Convection Enhanced Delivery ("CED") platform for use with GDNF in CNS indications.

In connection with the collaboration agreement, we made upfront payments to MedGenesis totalling \$6.0 million. We have certain funding obligations towards the development of GDNF in Parkinson's disease in the U.S. and we could make development milestones payments related to regulatory approvals and sales to each of MedGenesis and Amgen. MedGenesis and Biovail intend to share development costs associated with Phase 3 clinical trials in the United States and with the development programs in other countries.

We will pay Medgenesis a royalty in respect of the sale of GDNF products in those countries in which we have license rights. We will be responsible for the supply of GDNF to MedGenesis in the countries in which it has license rights and MedGenesis will pay us a supply price. We and MedGenesis will pay royalties to Amgen based on net sales of GDNF products and could make milestone payments to Amgen related to sales of GDNF products.

License of 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 Staccato® loxapine (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. Staccato® loxapine combines Alexza's proprietary Staccato® single dose inhaler drug delivery system with the antipsychotic drug loxapine. In December 2009, Alexza submitted an 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.

Under the terms of the 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

Table of Contents

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 the 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 upon annual product volume. We intend to deploy a sales force to commercialize Staccato® loxapine in the U.S.

Acquisition of Full U.S. Commercialization Rights to Wellbutrin XL®

In May 2009, we acquired the full U.S. commercialization rights to Wellbutrin XL® from The GlaxoSmithKline Group of Companies ("GSK"). We had supplied Wellbutrin XL® to GSK for marketing or distribution in the U.S. since September 2003. The Wellbutrin XL® product formulation was developed, and is manufactured, by us under our own patents and proprietary technology.

Pursuant to the terms of the asset purchase agreement, we paid \$510.0 million to GSK to acquire the NDA for Wellbutrin XL®. Pursuant to the terms of a trademark license agreement with GSK, we also obtained an exclusive, royalty-free license to the Wellbutrin XL® trademark for use in the U.S.

The acquisition of Wellbutrin XL® complements our specialty CNS strategy as we expect Wellbutrin XL® to generate significant cash flows in the near, mid and long-term that can be used to finance our specialty CNS product development pipeline.

Other Acquisition Opportunities

We regularly review other in-market products as potential acquisition candidates. These products would provide immediate revenues and cash flows that we would leverage in pursuit of building long-term growth within specialty CNS markets. Our acquisition of the full U.S. commercialization rights to Wellbutrin XL® in May 2009 is an example of this type of transaction.

We believe that we are well-positioned to successfully capitalize on the unmet medical needs in specialty CNS. As we identify in-licensing or acquisition opportunities in the specialty CNS market, we believe we can successfully execute our growth strategy because of:

our strong balance sheet and significant financial resources (including operating cash flows);

our demonstrated track record with six specialty CNS transactions completed since September 2008; and

our in-house specialty CNS expertise, with proven capabilities in drug regulatory approval, medical affairs and clinical research.

In the long term, we believe we must create growth and long-term value by building and developing our specialty CNS pipeline, and establishing efficient commercialization pathways through which to bring products to market, including through the development or acquisition of our own specialty U.S. sales force.

Table of Contents

Product Development Pipeline

The chart below lists the various products within our development pipeline.

Since adopting our specialty CNS strategy in May 2008, we have made significant progress in building a specialty CNS product development pipeline. Today, as described in more detail below, we have five compounds in development: Staccato® loxapine, pimavanserin; BVF-018 (modified-release formulation of tetrabenazine); fipamezole; and GDNF. In addition to our specialty CNS development programs, we also continue to develop certain legacy products, as further described below.

Staccato® loxapine. In December 2009, Alexza submitted an NDA to the FDA for Staccato® loxapine. The FDA has accepted the NDA for filing and has indicated a PDUFA goal date of October 11, 2010. The NDA contains efficacy and safety data from more than 1,600 patients and subjects who have been studied in thirteen different clinical trials. Alexza has initiated and completed two pivotal Phase 3 clinical trials in connection with Staccato® loxapine and has indicated that both doses of Staccato® loxapine (5mg and 10mg) met the primary and key secondary endpoints of the studies with statistically significant reductions in agitation, as compared to placebo. In these studies, the administration of Staccato® loxapine was generally safe and well tolerated.

Pimavanserin. Pimavanserin is currently in Phase 3 development for PDP. Data from the first of two Phase 3 studies initiated by our partner, ACADIA, announced in September 2009, did not meet the study's primary endpoint. However, a signal of antipsychotic efficacy, most prominent in the U.S. centres involved in the study, was seen at the 40mg dose. We intend to use the findings from this study, in addition to those of a recent trial, to develop an enhanced study design for a new Phase 3 program.

Table of Contents

We are also pursuing the development of pimavanserin as adjunctive therapy in schizophrenia. In 2007, ACADIA released data from a Phase 2 study that showed that a 20mg dose of pimavanserin in conjunction with a low dose (2mg) of risperidone was as efficacious as 6mg of risperidone, but with a better side effect profile, including a statistically significant reduction in weight gain. We intend to initiate a Phase 3 program for pimavanserin as adjunctive therapy in schizophrenia in the middle of 2010. Schizophrenia is estimated by the U.S. National Institute of Mental Health to occur in 1% of the population in North America. In 2009, according to IMS over 12 million prescriptions were written for risperidone in the U.S.

BVF-018. BVF-018 is a modified-release formulation of tetrabenazine in development for Tourette's Syndrome in 5-16 year old children. BVF-018 has been designated an orphan drug by the FDA, which provides seven years of U.S. market exclusivity following approval. Contingent on successful safety assessments, which are ongoing, we expect to initiate a Phase 2 study on pediatric patients with Tourette's Syndrome in the third quarter of 2010.

Following review and preclinical assessments, a formal decision was made to discontinue development efforts in connection with RUS-350, a tetrabenazine-derived new chemical entity ("NCE") (an isomer) the rights to which we had acquired in June 2009 in our transaction with Cambridge.

Fipamezole. Fipamezole is a first-in-class compound that, in a Phase 2b study, displayed the potential to reduce levodopa-induced dyskinesia (also known as PDD). Levodopa is among the most effective drugs for treating Parkinson's disease. However, long-term use of levodopa is often complicated by significantly disabling dyskinesia, which largely negates the drug's beneficial effects. There are no FDA-approved drugs currently available for the treatment of PDD. We currently anticipate the initiation of the Phase 3 program in the U.S. for fipamezole in 2011.

GDNF. The GDNF protein is a naturally-occurring growth factor capable of protecting and promoting the survival of dopamine producing nerve cells, to which we licensed the rights from Amgen in certain CNS indications in certain territories in December 2009. We have also entered into an agreement with MedGenesis to collaborate on the development of GDNF, initially in Parkinson's disease and potentially other CNS indications. We are currently undertaking non-clinical studies in support of our application for an investigational new drug ("IND") for GDNF from the FDA and anticipate scheduling an IND meeting with the FDA in the second quarter of 2010.

Legacy Development Products. We also have a number of legacy development programs based on our former base business model. These include BVF-324 tramadol hydrochloride for the treatment of premature ejaculation, a sexual dysfunction believed to affect up to 30% of men of all ages. The Phase 3 program for BVF-324 in Europe, which is evaluating non-commercially available doses of tramadol, was initiated in the third quarter of 2009 and is expected to conclude in 2011. In due course, we intend to engage a development and commercialization partner for the European market.

With respect to generic pharmaceuticals, our historic research and development ("R&D") efforts have focused on difficult-to-manufacture products, where competition is more limited (relative to immediate-release products) and, consequently, commercial pricing and gross margins are potentially higher. In 2008 we submitted three abbreviated new drug applications (each, an "ANDA") to the FDA for approval. These include a generic formulation of 145 mg and 48 mg tablets of fenofibrate (marketed in the U.S. under the Tricor® brand name). We believe we are the first-to-file on the 48 mg strength, which generated revenues of approximately \$76.0 million in the twelve months ended December 31, 2009, according to IMS; and second on the 145 mg strength, which generated revenues of approximately \$1.5 billion over the same period. In addition, in December 2008 we announced the FDA's acceptance of our ANDA filing for 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). Seroquel® XR is an atypical antipsychotic agent indicated for the treatment of schizophrenia and bipolar disorder. The product is available in 150 mg, 200 mg, 300 mg and 400 mg strengths. According to IMS, Seroquel® XR generated U.S. revenues of approximately \$458.0 million in the twelve-month period ended December 31, 2009. In addition, in 2008 we filed an ANDA with the FDA seeking approval to market venlafaxine hydrochloride extended-release capsules equivalent to the 37.5 mg, 75 mg and 150 mg doses

Table of Contents

of Effexor® XR. According to IMS, Effexor® XR generated U.S. revenues of approximately \$2.8 billion in the twelve-month period ended December 31, 2009.

We do not currently have any other ANDA programs in our product development pipeline.

Our product development efforts are subject to the process and regulatory requirements of the FDA in the U.S., the TPD in Canada and applicable European regulatory agencies.

Research and Development

We devote significant resources to research and development for our speciality CNS strategy. Our objective is to identify, develop and bring to market products that address unmet medical needs, and to develop new or repurposed uses for existing compounds and medicines. We primarily conduct research through contracts with external service providers, contract research organizations ("CROs"), and in collaboration with other pharmaceutical companies. The research and development process from the time that we in-license or acquire a product to the time that a product is brought to market takes many years and is costly and unpredictable. See Item 1A. "Risk Factors – Company Specific Risks – Ability to In-License, Acquire and Develop Products" and "Preclinical and Clinical Trials".

In 2009, our R&D expenses were \$106.9 million, a 53% increase as compared to 2008. This increase reflects upfront payments, including costs of acquisition, of \$30.4 million, \$12.1 million and \$8.8 million in respect of the pimavanserin, fipamezole and GDNF, in-licensing transactions, respectively. Also included in R&D expenses in 2009 is \$8.0 million representing the write-off of the purchase price allocated to RUS-350 in the Cambridge transaction. Given the anticipated and significant increase in clinical-trial activity within our drug development pipeline, we expect R&D expenses in respect of our internal research and development programs to increase significantly in 2010 and 2011, compared with 2009. In 2008, our R&D expenses were \$69.8 million, a 31% decrease as compared to 2007. In 2007, during which time we pursued a number of reformulation-type opportunities related to our former base business model, our internal research and development programs expenses were \$100.6 million.

Primary Markets

Our primary markets, for both our specialty CNS products and those products related to our former base business model, are the U.S. and Canada. Our products which relate to our former base business model address CNS disorders, cardiovascular disease, pain management and antiviral conditions. In the U.S., such products are sold through marketing arrangements with third parties.

For our in-market specialty CNS products, in the U.S., until we develop a specialty sales force, we will continue to distribute our specialty CNS products through third party commercialization relationships. We intend to deploy a sales force to commercialize Staccato® loxapine in the U.S.

BPC markets our products in Canada.

While our business focus is primarily to develop products for the U.S. and Canadian markets, we have pursued opportunities to more fully exploit the commercial potential of our products by having them launched in new geographic markets through strategic marketing partners with expertise in their local markets. Our acquisition of the worldwide rights to tetrabenazine and our license to pursue GDNF indications in Japan and a number of European countries are evidence of this more global strategy.

Table of Contents**Current Product Portfolio and Product Revenues**

The following table summarizes our product revenues by category for the fiscal years of 2009, 2008 and 2007:

Product/Product Line	Revenues (\$000)			Change % for 2008/2009	% of Product Revenues		
	2009	2008	2007		2009	2008	2007
United States							
Wellbutrin XL® ⁽¹⁾	173,288 ⁽²⁾	120,745	212,325	44	22	17	27
Xenazine® ⁽³⁾	48,433	3,736		NM	6	1	
Aplenzin®	11,150			NM	1		
Zovirax®	146,267	150,613	147,120	(3)	19	21	18
Ultram® ER	53,986	81,875	86,714	(34)	7	11	11
Cardizem® LA	42,002	48,002	69,300	(12)	5	7	9
Legacy Products	165,679	154,206	136,855	7	21	22	17
Generic Products	67,035	83,246	86,843	(19)	8	12	11
Glumetza® (U.S. market)	1,250	1,545		(19)			
Canada							
BPC ⁽⁴⁾	79,936	70,580	61,889	13	10	10	8
Total Product Revenues	789,026	714,548	801,046	10	100⁽⁵⁾	100⁽⁵⁾	100⁽⁵⁾

NM: not meaningful.

- (1) Includes Wellbutrin XL® sales to GSK for marketing and distribution in Europe and elsewhere.
- (2) Includes sales following the acquisition of full U.S. commercialization rights in May 2009.
- (3) Includes Xenazine® sales in Europe and elsewhere from June 2009 and Nitoman® sales made in Canada prior to December 1, 2008.
- (4) Effective December 1, 2008, BPC assumed the marketing and distribution of Nitoman®.
- (5) Percentages may not add up to 100% due to rounding.

Each of these categories, and the products or product lines they include, is described in more detail below:

Wellbutrin® XL (bupropion hydrochloride extended release tablets)

Wellbutrin XL®, an extended-release formulation of bupropion indicated for the treatment of depression in adults, was launched in the U.S. in September 2003 by an affiliate of GSK. Pursuant to a manufacturing-and-supply agreement then in effect with GSK, we received a tiered supply price based on GSK's net sales of Wellbutrin XL®. In May 2009, we acquired the full U.S. commercialization rights to Wellbutrin XL® from GSK. With the 150 mg dosage strength genericized in late-2006 and the 300 mg dosage strength genericized in mid-2008, Wellbutrin XL® continues to hold a higher-than-anticipated share of the bupropion prescription market, despite no active sales force promotion since 2006. We believe this performance suggests the potential for continuation of the product's strong earnings and cash-flow contribution. In the fourth quarter of 2009, we announced two initiatives intended to support the brand: the supply of sample quantities to interested physicians and the introduction of coupons to reduce the out-of-pocket costs for patients. Shipment of coupons and samples will take place in the first quarter of 2010.

Xenazine® (tetrabenazine)

Approved by the FDA in August 2008, Xenazine® is indicated for the treatment of chorea associated with Huntington's disease. Huntington's disease is a rare, inherited neurological disorder that is passed from parent to child through a gene mutation. The disease causes a

degeneration of specific brain cells that most frequently

Table of Contents

leads to problems associated with loss of motor control, psychiatric and behavioral symptoms, and cognitive impairment.

Tetrabenazine has also been approved for use in a number of countries in Europe and around the world. Through our acquisition of the worldwide development and commercialization rights to tetrabenazine in June 2009, we have distribution arrangements for tetrabenazine in a number of countries outside North America, including Australia, Denmark, France, Germany, Ireland, Israel, Italy, New Zealand, Portugal, Spain, Switzerland and the United Kingdom.

Aplenzin® (bupropion hydrobromide)

Launched in the U.S. in April 2009 by sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), Aplenzin® is an extended-release formulation of bupropion hydrobromide for the treatment of major depressive disorder. Aplenzin® was approved by the FDA in April 2008 at dosage strengths of 174mg, 348mg and 522mg. The 522mg dosage strength of Aplenzin® represents the only FDA-approved single-tablet, once-daily treatment option equivalent to 450mg of bupropion hydrochloride (the active ingredient in Wellbutrin XL®) therapy.

In December 2008, we entered into a supply-and-distribution agreement with sanofi-aventis U.S., which is now marketing the product in the U.S. Under the terms of the agreement, we manufacture, supply and sell Aplenzin® to sanofi-aventis U.S. at contractually determined prices, which will be based on sanofi-aventis U.S.' net selling price. Our supply price will range from 25% to 35% of net sales, depending on the level of net sales of Aplenzin®.

Zovirax® Ointment/Zovirax® Cream (acyclovir)

Zovirax® Ointment is a topical formulation of a synthetic nucleoside analogue which is active against herpes viruses. Each gram of Zovirax® Ointment contains 50 mg of acyclovir in a polyethylene glycol base. This product is indicated for the management of initial genital herpes and in limited non-life threatening mucocutaneous herpes simplex infections in immuno-compromised patients. Zovirax® Ointment was originally launched in 1982 by Burroughs Wellcome and although it has not been promoted by Glaxo Wellcome, and subsequently GSK, since 1997, Zovirax® Ointment remains the market leader with approximately a 47% share of total prescriptions in the U.S. for topical anti-herpes products in 2009.

Zovirax® Cream was approved by the FDA in December 2002 and launched by us in July 2003. Zovirax® Cream is a topical antiviral medication used for the treatment of herpes labialis (cold sores). According to IMS, Zovirax® Cream held a 27% share of the total prescriptions in the U.S. for topical anti-herpes products at the end of 2009.

Pursuant to a distribution rights agreement, GSK provides us with Zovirax® products for the U.S. Since October 2002, we have been entitled to purchase a pre-determined quantity of Zovirax® inventory from GSK at reduced prices under a price allowance. The remaining inventory acquired at the reduced supply prices is expected to be sold in the first quarter of 2010, after which time the significantly higher supply price will have a material impact on the earnings contribution from Zovirax® product sales in 2010 and beyond.

Ultram® ER (tramadol hydrochloride extended-release tablets)

Ultram® ER is an extended-release formulation of tramadol hydrochloride indicated for the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time. Ultram® ER is available in 100mg, 200mg and 300mg tablet strengths. According to IMS, over 25 million prescriptions were dispensed for tramadol-based medicines in the U.S. in 2009. In November 2009, a generic formulation of the 100mg and 200mg strengths of Ultram® ER was launched in the U.S.

In November 2005, we entered into a 10-year supply agreement with Ortho-McNeil, Inc. ("OMI") (now known as PriCara, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("PriCara")) for the distribution of our extended release formulation of tramadol in the U.S. and Puerto Rico. Pursuant to the agreement, we are entitled to a supply price based on OMI's net selling price for Ultram® ER. In 2007 and 2008,

Table of Contents

our supply price was 37.5% of OMI's net selling price for Ultram® ER. In 2009, prior to the introduction of generic competition in December, our supply price was 35% of Ultram® ER's net selling price. The introduction of generic competition resulted in a 50% reduction in our contractual supply price for branded Ultram® ER tablets in the 100mg and 200mg strengths. In April 2009, we entered into a five-year supply agreement with Patriot Pharmaceuticals LLC ("Patriot") (a wholly owned subsidiary of Ortho-McNeil-Janssen Pharmaceuticals, Inc.) for the distribution of our authorized generic formulation of Ultram® ER and, concurrently with the November 2009 generic launch of the 100mg and 200mg strengths of Ultram® ER in the U.S., Patriot launched our authorized generic formulation of these two strengths of Ultram® ER. Pursuant to the agreement, we are entitled to a supply price based on Patriot's net selling price of the authorized generic formulations of Ultram® ER.

Cardizem® LA (diltiazem)

Cardizem® branded products have been the leading calcium channel blockers ("CCBs") for more than 20 years. In 2009, the U.S. CCBs market was valued by IMS at approximately \$2.0 billion, of which once-daily diltiazem products represented approximately \$576.0 million. These once-daily products generated 16 million prescriptions in the U.S. in 2009, of which 11 million were written for all Cardizem® products.

In April 2003, we launched Cardizem® LA. Cardizem® LA is a graded, extended-release formulation of diltiazem hydrochloride that provides 24-hour blood pressure control with a single daily dose and offers physicians a flexible dosing range from 120 mg to 540 mg. Cardizem® LA is the only diltiazem product labeled to allow administration in either the morning or evening. With evening administration, clinical trials have shown Cardizem® LA improves reduction in blood pressure in the early morning hours, which is when patients are at the greatest risk of significant cardiovascular events, such as heart attack, stroke and death. We have arranged to have Kos Pharmaceuticals ("Kos") (a subsidiary of Abbott Laboratories ("Abbott")) promote Cardizem® LA in the U.S. and, pursuant to our arrangement with Kos, we manufacture, supply and sell Cardizem® LA to Kos for prices based on Kos' net selling price.

Legacy Products

This category includes branded products that we distribute in the U.S., but do not actively promote. In general, these are products that have been genericized and generate revenue streams that are relatively stable as a result of small and predictable declines in prescription volumes, generally offset by increases in pricing. The products in this reporting category are Cardizem® CD, Ativan®, Tiazac®, Vasotec®, Vaseretic® and Isordil®. Despite the availability of generic competition, these products continue to generate significant cash flow.

Cardizem® CD (diltiazem)

Cardizem® branded products have been leading medications in the CCB category of cardiovascular drugs for more than 20 years. sanofi-aventis Inc. ("sanofi-aventis") supplies Cardizem® CD to us.

Ativan® (lorazepam)

Ativan® is benzodiazepine lorazepam, indicated for the management of anxiety disorders or for the short-term relief of anxiety or anxiety associated with symptoms of depression. We acquired U.S. marketing rights to Ativan® from Wyeth Pharmaceuticals Inc. ("Wyeth") (now part of Pfizer Inc.) in June 2003. Wyeth provided us with Ativan® until 2007. Since August 2007, Meda Manufacturing GmbH ("Meda") has supplied us with Ativan® tablets for the U.S. market. Ativan® and its generics generated 26.4 million prescriptions in the U.S. during 2009.

Tiazac® (diltiazem)

Tiazac® belongs to the CCB class of drugs, used in the treatment of hypertension and angina. In 1995, Forest Laboratories Inc. ("Forest") acquired the right to market Tiazac® in the U.S. The formal product launch took place in February 1996. We act as the exclusive manufacturer of the product and receive a contractually determined supply price and a royalty payment from Forest on net sales of Tiazac®. Upon the onset of generic

Table of Contents

competition for Tiazac® in the U.S. in April 2003, we launched a competing authorized generic version through Forest under a variable supply price arrangement, following which Forest ceased promotional support for branded Tiazac®. Forest now distributes a Tiazac® authorized generic manufactured by us.

Vasotec® (enalapril maleate)/Vaseretic® (enalapril maleate/hydrochlorothiazide)

Vasotec® and Vaseretic® have been highly recognized in the treatment of hypertension, symptomatic congestive heart failure, and asymptomatic left ventricular dysfunction for nearly 20 years. Enalapril is a pro-drug; following oral administration, it is bio-activated by hydrolysis of the ethyl ester to enalaprilat, which is the active angiotensin converting enzyme ("ACE") inhibitor. Vasotec® is the maleate salt of enalapril. Vaseretic® combines Vasotec® and a diuretic, hydrochlorothiazide. The product is also indicated for the treatment of hypertension. Vasotec® (branded and generic) is one of the most widely prescribed ACE inhibitors. Vasotec® lost its market exclusivity in August 2000 and its prescription volumes have since been eroded by generic competition. Nevertheless, in 2009, there were 12.4 million prescriptions written for enalapril maleate in the U.S.

Isordil® (isosorbide dinitrate)

Isordil®, a coronary vasodilator, is indicated for the prophylaxis of ischemic heart pain associated with coronary insufficiency (angina pectoris). Isordil® dilates the blood vessels by relaxing the muscles in their walls. Oxygen flow improves as the vessels relax, and chest pain subsides. Isordil® helps to increase the amount of exercise that may occur prior to the onset of chest pain, and can help relieve chest pain that has already started, or prevent pain expected from a strenuous activity, such as walking up a hill or climbing stairs. We acquired U.S. marketing rights to Isordil® from Wyeth in June 2003. We purchase Isordil® tablets from Meda pursuant to a supply agreement.

In 2009, there were 1.7 million prescriptions written for isosorbide dinitrate in the U.S., according to IMS.

Generic Products

Our generic product portfolio currently consists of products that are distributed in the U.S. for us by Teva Pharmaceuticals Industries Ltd. ("Teva") and an authorized generic formulation of Tiazac® which is distributed in the U.S. by Forest. In 2009, the products distributed by Teva included bioequivalent formulations of Cardizem® CD, Adalat® CC, Procardia® XL, Tiazac®, Voltaren® XR and Trental®. Generic Tiazac® and generic Cardizem® CD are distributed by Teva Canada Limited (formerly Novopharm Limited) ("Teva Canada"), a subsidiary of Teva, in Canada.

Our portfolio of generic formulations of branded controlled release products, such as Cardizem® CD, Adalat® CC and Procardia® XL, represents technically challenging products to formulate. These technological barriers may limit the number of generic versions of the products. This competitive landscape allows for some pricing flexibility, and may mitigate, to some extent, the price discounting that can often reach 90% in the generic pharmaceuticals industry. However, beginning in 2007, a number of new competitor products became available, which resulted in a significant decline in our revenues relating to these products. In 2009, as a result of the withdrawal of two competing diltiazem-based products, prescription volume for our portfolio of generic products increased 13% compared with 2008.

Glumetza® (U.S. Market)

Glumetza® is a once-daily formulation of metformin indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Glumetza® 500 mg and 1,000 mg were approved by the FDA in June 2005. Pursuant to an agreement with Depomed Inc. ("Depomed") we manufacture and supply the 1,000 mg tablet to Depomed. In the U.S., Santarus, Inc. promotes Glumetza® to U.S. physicians for Depomed. Glumetza® competes against several other metformin products, including a number of generic formulations, in the oral diabetes market.

Table of Contents

For additional information with respect to these products, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operation - Product Sales".

Biovail Pharmaceuticals Canada

BPC is our Canadian marketing and sales division. The following products are promoted and/or distributed by BPC:

Tiazac®/Tiazac® XC (diltiazem)

Tiazac® is a CCB used in the treatment of hypertension and angina. Tiazac® is a once-daily formulation of diltiazem that delivers smooth blood pressure control over a 24-hour period. As a non-dihydropyridine CCB, Tiazac® provides specific renal protective benefits as well as blood pressure reduction, which is particularly important for diabetic hypertensive patients. At December 2009, according to IMS Tiazac® and Tiazac® XC held a 31.0% share of the once-daily diltiazem market (measured as a percentage of total prescriptions for once-daily diltiazem products). In August 2004, we received TPD approval for Tiazac® XC for the treatment of hypertension and, in July 2007, we received TPD approval for Tiazac® XC for the treatment of angina. Tiazac® XC is a novel formulation of diltiazem taken at bedtime and specifically formulated to provide peak drug-plasma levels during the early morning hours when cardiac events are most likely to occur. In January 2005, the BPC sales force launched Tiazac® XC to Canadian physicians. Tiazac® XC is listed on all provincial formularies.

Our generic version of Tiazac® is distributed in Canada by Teva Canada.

Wellbutrin® XL (extended-release bupropion hydrochloride)

In February 2005, we submitted a supplemental new drug submission ("sNDS") to the TPD for Wellbutrin® XL, a once-daily formulation of bupropion developed by us. The submission received TPD approval in January 2006. Wellbutrin® XL was formally launched in April 2006 by the BPC sales force. In February 2008, Wellbutrin® XL received TPD approval for a new indication for the prevention of seasonal major depressive illness. By December 2009, according to IMS Wellbutrin® XL had captured 58.5% share of the Canadian bupropion market (measured as a percentage of total prescriptions for bupropion products).

Wellbutrin® SR (bupropion)/Zyban® (sustained-release bupropion hydrochloride)

We acquired the Canadian rights to Wellbutrin® SR and Zyban® from GSK in December 2002. Wellbutrin® SR is indicated as a first-line therapy for the treatment of depression. Wellbutrin® SR's anti-depressant activity appears to be mediated by noradrenergic and dopaminergic mechanisms that differentiate it from SSRIs and other known anti-depressant agents. In addition to anti-depressant efficacy, Wellbutrin® SR has a low propensity to cause sexual dysfunction, a common side effect of some other anti-depressant therapies. Zyban®, the same chemical entity as Wellbutrin® SR, is indicated as an aid to smoking cessation treatment. Generic competition for Wellbutrin® SR in Canada commenced in 2005. Zyban® is marketed through non-sales force mediated, direct marketing activities.

Glumetza® (extended-release metformin hydrochloride)

Glumetza® is a once-daily formulation of metformin, indicated for the control of hyperglycemia in adult patients with type 2 (non-insulin dependent, mature onset) diabetes, as an adjunct to dietary management, exercise, and weight reduction, or when insulin therapy is not appropriate. Glumetza® (500 mg and 1,000 mg) received TPD approval in May 2005, and the 500 mg tablet was formally launched by the BPC sales force in Canada in November 2005. Glumetza® is the first and only once-daily metformin formulation available in Canada. A second application for a once-daily formulation of Glumetza® 1,000 mg tablets was filed with the TPD in February 2007 and received a Notice of Compliance ("NOC") in October 2007. The BPC sales force formally launched Glumetza® 1,000 mg tablets to Canadian physicians in January 2008. See Item 3. "Legal Proceedings - Intellectual Property".

Table of Contents

Ralivia® (extended-release tramadol hydrochloride)

Ralivia®, which competes with two other once-daily tramadol formulations in Canada, is indicated for the management of pain of moderate severity in patients who require continuous treatment for several days or more. In July 2008 we received approval for the broader indication of treatment of moderate to moderately severe pain. Ralivia® is produced using our proprietary Smartcoat® technology, which provides 24-hour delivery for more constant plasma concentration and clinical effects with less peak-to-trough fluctuation. Ralivia® is identical to Ultram® ER.

Nitoman® (tetrabenazine)

Nitoman® was approved by the TPD in 1995. It is indicated for the treatment of hyperkinetic movement disorders such as Huntington's chorea, Hemiballismus, Senile Chorea, Tic and Gilles de la Tourette Syndrome and Tardive Dyskinesia. Through the September 2008 acquisition of Prestwick, we acquired commercial responsibility for Nitoman® in Canada. Nitoman® is marketed to Canadian physicians through the BPC sales force.

Cardizem® CD (diltiazem)

Cardizem® branded products have been leading medications in the CCB category of cardiovascular drugs for more than 20 years. sanofi-aventis supplies Cardizem® CD to us.

Former Base Business Model

Our former base business model comprised numerous proprietary drug-delivery technologies that we used to develop controlled-release, enhanced/modified absorption and rapid-dissolve products. These technologies enabled us to develop both branded and generic pharmaceutical products. With our focus now on specialty CNS disorders, the products and technologies associated with our former base business model remain assets of the Company and a source of revenue and cash flow that has and will be used to support the growth and development of our specialty CNS business.

Oral controlled release technologies permit the development of specialized oral delivery systems that improve the absorption and utilization of drugs by the human body. These systems offer a number of advantages, in particular allowing the patient to take only one or two doses of the drug per day. This makes controlled release drug products ideally suited for the treatment of chronic conditions.

The following describes some of our proprietary drug-delivery technologies associated with our former base business model:

Technology	Description
Dimatrix	Diffusion-controlled matrix technology for water soluble drugs.
Macrocap	Immediate release beads for first order or zero order release.
Consurf	Zero order drug-delivery system for hydrophilic and hydrophobic drugs.
Multipart	Tablet carrier for the delivery of controlled release beads that preserves the integrity and release properties of the beads.
FlashDose	Oral disintegrating tablet ("ODT") technology for sustained release ODTs, rapid-onset ODTs, enhanced absorption ODTs, combination ODT s and taste-masking ODTs.
Shearform	Used to produce carrier materials used to produce rapid dissolve formulations.
Smartcoat®	Allows for the manufacturing of very high potency controlled release tablets, allowing for smaller- sized tablets while controlling the release over a 24-hour period.

Table of Contents

Technology	Description
Smartcoat® AQ	Aqueous-based, proprietary version of Smartcoat®.
Chronotabs	Made of Multipart or Smartcoat® tablets particularly adapted to the science of treating diseases that follow the body's circadian rhythms.
Zero Order Release Systems ("ZORS ")	Technology used to develop zero order kinetic systems, based on a proprietary controlled release matrix coating.
CEFORM	Technology used to produce uniformly sized and shaped microspheres of a wide range of pharmaceutical compounds. CEFORM can be used to formulate drugs that are generally thermally unstable and can be formulated for controlled release, enhanced absorption, delayed release, rapid absorption or taste masking.

Manufacturing

Our plant in Steinbach, Manitoba is our principal manufacturing facility. Certain of our Puerto Rico manufacturing activities were transferred to our Steinbach, Manitoba facility in 2009, with much of the remainder anticipated to be transferred in 2010. Our Carolina, Puerto Rico facility will now remain open indefinitely in order to meet higher than anticipated demand for generic Tiazac® and Cardizem® CD products. See Item 2. "Properties Manufacturing Facilities".

Through our manufacturing facilities in Manitoba and Puerto Rico, we manufacture branded products (including Wellbutrin® XL, Ultram® ER and Cardizem® LA) that are commercialized by third parties, and several other branded products that are distributed by BTA Pharmaceuticals, Inc. ("BTA") and BPC. We also manufacture generic products that are distributed by Teva and Forest in the U.S. and by Teva Canada in Canada.

Our manufacturing facilities are audited periodically by various regulatory agencies and are compliant with current Good Manufacturing Practices ("cGMP"). All technical operations are executed in accordance with the requirements as mandated by the FDA, Health Canada Health Products & Food Branch Inspectorate and other regulatory agencies around the world.

Certain of our products may be manufactured by third parties.

Raw Materials

We source raw materials for our manufacturing operations from various FDA-approved and TPD-approved companies worldwide. Whenever reasonably practicable, we have a minimum of two suppliers for all major active pharmaceutical ingredients ("APIs") for our manufactured products. This facilitates both the continuity of supply of raw materials and best pricing from suppliers based on volume and time period. However, the pricing of the raw materials needed for the development or manufacture of our products has fluctuated, from time to time, as a result of a number of factors, including the acts of governments outside the U.S. and Canada.

Marketing and Commercialization

Given the vast differences between the two markets, we employ different marketing and commercialization strategies in Canada and the U.S. In Canada, we commercialize our products directly through BPC. In the U.S. and other global markets, since the elimination of our U.S. sales force in December 2006, our products are marketed through strategic alliances with commercial counterparties that have established sales and marketing infrastructures in those regions. As we progress with our specialty CNS strategy, we expect to build or acquire a specialty U.S. sales force, which will allow us to promote our products directly. In addition to maintaining a greater share of the economics of our product portfolio, an in-house sales force will provide strategic flexibility with respect to commercialization.

Table of Contents

United States

Throughout our history, we have entered into a number of supply-and-distribution arrangements for the U.S. market with several respected pharmaceutical companies, including GSK, Johnson & Johnson, Forest, Teva, Abbott and, most recently, sanofi-aventis and Lundbeck (formerly Ovation). As described above under "Business Overview Our Specialty CNS Strategy Execution of Our Strategy", on September 16, 2008 we acquired Prestwick, which held the Canadian and U.S. licensing rights to tetrabenazine tablets (known as Xenazine® in the U.S. and Nitoman® in Canada) and, in June 2009, we acquired the worldwide development and commercialization rights to the entire portfolio of tetrabenazine products from Cambridge. In November 2008, Xenazine® tablets became commercially available throughout the U.S. under an exclusive marketing, distribution and supply agreement entered into between Prestwick and Ovation (now known as Lundbeck) prior to our acquisition of Prestwick. In the U.S., Lundbeck also provides marketing and promotion for tetrabenazine.

In the first quarter of 2009, Publicis Selling Solutions, Inc. ("PSS"), a contract sales organization ("CSO"), assumed responsibility for detailing of Zovirax® to U.S. physicians under Biovail's management of the brand. By switching to a CSO, we retain a greater share of Zovirax®'s revenue, as we have a fixed fee arrangement in our agreement with PSS. PSS has formed a dedicated contractual sales force for detailing of Zovirax® to U.S. physicians.

BTA distributes a number of branded products for which there is no longer market exclusivity. These Legacy Products include the well-known brands Cardizem® CD, Ativan®, Vasoretic®, Vasotec® and Isordil®. These products represent non-core assets that are not actively promoted by us, but remain well respected by the medical community. Due to the availability of several competing generic formulations, their prescription volumes are declining at fairly predictable rates.

Canada

In Canada, where the market dynamics are much different than in the U.S., we have maintained a direct-selling commercial presence through BPC that targets both specialist and high-prescribing primary-care physicians. BPC has established itself as a leading, independent pharmaceutical marketing and sales operation in the Canadian market. BPC's therapeutic focus lies in the cardiovascular disease, pain management and depression markets valued at C\$2.4 billion, C\$948.0 million, and C\$868.0 million, respectively by IMS.

BPC currently promotes a portfolio of products to approximately 12,000 physicians across Canada. Products include Tiazac® XC, Wellbutrin® XL, Ralivia®, Glumetza® and, since December 2008, Nitoman®. During 2009, the Tiazac® and Wellbutrin® franchises were BPC's leading product lines, representing approximately 38% and 36%, respectively, of our total Canadian product revenues. We believe BPC is an important asset and we intend to continue to leverage our Canadian commercialization infrastructure to support our physician-targeted focus. We are also pursuing a number of product-marketing opportunities and acquisitions that have a strategic fit to further grow BPC's business.

Other Countries

While our business focus is primarily to develop products for the U.S. and Canadian markets, we have pursued opportunities to more fully exploit the commercial potential of our products by having them launched in new geographic markets by strategic marketing partners with expertise in their local markets. For example, in 2007 and 2008, GSK launched Wellbutrin® XR in several European countries for the treatment of adult patients with major depressive episodes. In addition, we have distribution arrangements for tetrabenazine in a number of countries outside North America, including Australia, Denmark, France, Germany, Ireland, Israel, Italy, New Zealand, Portugal, Spain, Switzerland and the United Kingdom.

Patents and Proprietary Rights

We protect the proprietary nature of our technology through a combination of patents, trade secrets, know-how and other methods. We have not routinely sought patents on our controlled-release technologies themselves because the filing of certain patents may provide competitors and potential competitors with

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Table of Contents

information relating to proprietary technology, which may enable such competitors to exploit information related to such technology that is not within the confines of the protection of the patent. However, we usually do seek patent protection for novel products arising from our development efforts, in order to obtain intellectual property rights and associated market protection.

Historically, we have relied on trade secrets, know-how and other proprietary information. Our ability to compete effectively with other companies will depend, in part, upon our ability to maintain the proprietary nature of our technology. To protect our rights in these areas, we require our licensors, licensees and significant employees to enter into confidentiality agreements. These agreements may not, however, provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of such trade secrets, know-how or other proprietary information.

The exclusivity afforded by patent protection is very important to the sustainability of our specialty CNS focus. Accordingly, we will aggressively seek patent protection for these patents either by filing our own patents, acquiring patents or licensing-in patents from potential partners in the U.S., Canada and internationally. When reasonably possible, we will also file for additional patent protection to cover any improvements to the compounds or products we market or intend to market as well as, when applicable, to the underlying technology used for developing the compounds and products. We may at times also rely on trade-secrets, know-how, and agreements with third parties to develop, maintain and protect currently marketed and pipeline products.

We currently own or otherwise have rights (e.g. by license agreements) to a number of patents and patent applications in the U.S., Canada and internationally relating to our marketed and pipeline products. These patents and pending applications cover new chemical compounds and their methods of use, pharmaceutical compositions, process(es) for the manufacture of the new chemical compounds or intermediates used in the manufacture of the new chemical compounds.

The following table shows our products that have patent protection and the dates for the latest expiring patents listed on the FDA's Orange Book or the Canadian Patent Register, as applicable, for certain of our products marketed or distributed by us or on our behalf:

Products	U.S. Patent Expiration	Canadian Patent Expiration
Wellbutrin® XL	2018	2023
Wellbutrin® SR		2014
Cardizem® LA	2021	
Cardizem® CD (360mg)	2012	
Tiazac® XC		2020
Tiazac®		2016
Ultram® ER	2014	
Ralivia®		2023
Glumetza®	2021 (500mg)/2020 (1000mg)	2021 (500mg)/2023 (1000mg)
Zyban®		2014
Aplenzin®	2026	

Development pipeline products are not listed on this chart.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Although the patents for the above listed products remain in-force, several of the products have now been genericized. For example, in the U.S., Wellbutrin® XL (150mg and 300mg), Ativan®, Isordil®, Vasotec®, Vaseretic®, and Glumetza® 500 mg have been genericized, and in Canada, Wellbutrin® SR, Cardizem®, Tiazac® and Zyban® have been genericized. While there are no patents listed for Xenazine® in the U.S., it has received an orphan drug designation by the FDA, which expires in 2015. Additional patents may be listed with expiry dates that extend beyond the dates provided above as relevant patents become available and are deemed

Table of Contents

suitable for listing on the FDA's Orange Book within the bounds of the Hatch-Waxman Act provisions or the Canadian Patented Medicines Notice of Compliance Regulations ("PMNOC Regulations").

The patents covering Ultram® ER have recently been found to be invalid following a trial in the U.S. The invalidity decision has been appealed, with a further decision not expected until later in 2010. Nevertheless, Par Pharmaceuticals ("Par") has launched a 100 mg and 200 mg generic version of Ultram® ER. Concurrently, Patriot (a wholly owned subsidiary of Ortho-McNeil-Janssen Pharmaceuticals, Inc.) launched our authorized generic formulation of these two strengths of Ultram® ER.

On January 18, 2010, a Canadian Federal Court judge presiding over Biovail Corporation and Depomed, Inc. v. Apotex Inc. 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 Inc. ("Apotex") to market a generic version of the 500 mg formulation of Glumetza® (extended release metformin hydrochloride tablets) licensed in Canada by Depomed to BLS. Pursuant to the decision issued by the Court, Health Canada authorized Apotex to market in Canada its generic version of the 500 mg formulation of Glumetza® on February 4, 2010.

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 to market in Canada its generic version of 500 mg Glumetza® by Health Canada on February 4, 2010. 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 filed a Claim for infringement against Apotex in Canadian Federal Court on February 8, 2010.

Our legacy products include Cardizem® CD, Ativan®, Tiazac®, Vasotec®, Vaseretic® and Isordil®. With the exception of Cardizem® CD and Tiazac®, the other legacy products have no unexpired patent-related exclusivity for the purposes of the Hatch-Waxman Act provisions.

Since adopting our specialty CNS strategy in May 2008, we have made significant progress in building a specialty CNS product-development pipeline. To support this strategy, we have created, acquired or licensed-in intellectual property related to the various products currently under development. For example, we have obtained exclusive U.S. and Canadian intellectual property rights for pimavanserin from ACADIA for the prevention or treatment of any psychiatric and neurological indication, including but not limited to PDP and ADP. Patents to pimavanserin have been granted in the U.S. The expiry dates of the last patent or patent applications, if it issues to patent, is in 2028.

As a result of the acquisition of the worldwide development and commercialization rights to the entire portfolio of tetrabenazine products from Cambridge in June 2009, we acquired the U.S. and worldwide intellectual property rights to a controlled-release formulation of tetrabenazine (currently marketed in immediate-release form as Xenazine® in the U.S. and Nitoman® in Canada) in development for Tourette's Syndrome (BVF-018). A patent application relating to BVF-018 was filed as both an International PCT and U.S. utility application in August, 2009. The U.S. patent application, if issued, will expire in 2029.

We have also obtained from Santhera, in August 2009, exclusive U.S. and Canadian intellectual property rights to develop and commercialize fipamezole hydrochloride for the treatment and prevention of any psychiatric and neurological disease, including but not limited to PDD. In the U.S. and Canada, the last patent or patent application, if it issues to patent, will expire in 2024.

In December 2009, we entered into a license agreement with Amgen, pursuant to which we were granted rights to use GDNF protein in CNS indications in the U.S. and in certain other countries. The GDNF protein is a naturally-occurring growth factor capable of protecting and promoting the survival of dopamine producing nerve cells. We have obtained a co-exclusive license from Amgen to patents related to GDNF in the U.S. and in certain other countries. The expiry date of the last U.S. patent licensed from Amgen is in 2017. The expiry date of the last pending U.S. patent application licensed from Amgen, if issued, is in 2024. In addition, we entered into an agreement with MedGenesis to collaborate on the development of GDNF, initially in Parkinson's

Table of Contents

disease, and potentially in other CNS indications. We have obtained an exclusive license from MedGenesis to patent applications related to their CED platform for use with GDNF for CNS indications in the US and in certain other countries. The expiry date of the last pending U.S. patent application licensed from MedGenesis, if it issues to patent, is in 2029.

We have also obtained from Alexza, in February 2010, exclusive U.S. and Canadian intellectual property rights to develop and commercialize Staccato® loxapine for the treatment and prevention of any psychiatric and/or neurological indication and the symptoms associated with these indications, including but not limited to the rapid treatment of agitation associated with schizophrenia or bipolar disorder. Alexza has several issued patents and pending patent applications relating to its Staccato® platform technology as well as to the Staccato® loxapine product. In the US, the last patent will expire in 2024 and the last patent application, if it issues to patent, will expire in 2023. In Canada, the last patent and patent application, if it issues to patent, will expire in 2023.

We also have a number of legacy development programs in place based on our former business focus, which include BVF-324. BVF-324 comprises tramadol hydrochloride as the active ingredient for the treatment of premature ejaculation, a sexual dysfunction. The Phase 3 program for BVF-324 in Europe, which is evaluating non-commercially available doses of tramadol, was initiated in the third quarter of 2009 and is expected to conclude in 2011. We have obtained worldwide exclusive rights to the intellectual property relating to BVF-324. At least one patent for BVF-324 has been granted in the U.S. and will expire in 2022.

Not all of the patents relating to our pipeline products may be listable in the FDA's Orange Book. Also, the expiry dates for any one or more patents may be extended due to delays during prosecution of the patent applications under 35 U.S.C. §154(b) or due to delays in the FDA approval process under 35 U.S.C. §156. On the other hand, the patent term for any one or more of the patents currently listed or to be listed in the FDA's Orange Book for our pipeline products may be limited due to an earlier decision of invalidity or unenforceability by a U.S. court from which no appeal can be taken.

Significant Customers

The following table identifies external customers that accounted for 10% or more of our total revenue during the year ended December 31, 2009:

	Percentage of Total Revenue 2009 %
McKesson Corporation	25
Cardinal Health, Inc.	21
AmerisourceBergen Corporation	10

Contract Research Division

Our Contract Research Division ("CRD") provides pharmaceutical companies with a broad range of early stage clinical-research services. This involves conducting first-in-man and pharmacokinetic first-in-human and early phase clinical studies, along with bioanalytical laboratory testing to establish a drug's safety and tolerance or a drug's bioavailability or its bioequivalence to another drug moiety. Clinical studies are reviewed by an independent ethics review board that assures that all studies are conducted in an ethical and safe manner, without compromising the safety or well-being of the human subjects participating in these studies. As well, all clinical studies are designed and conducted in accordance with strict guidelines regulated under the FDA in the U.S., the TPD in Canada and the European Medicines Agency ("EMA") in Europe, and executed under Good Laboratory Practices and Good Clinical Practices.

In prior years, we were CRD's primary customer. However, beginning in 2008, as we shifted our focus away from reformulation programs associated with our former base business model, our activity level dropped significantly at CRD. Although we contemplate continuing to use CRD's services for internal activities, the division continues to aggressively pursue new external customers.

Table of Contents

Regulation

The R&D, manufacture and marketing of pharmaceuticals are subject to regulation by U.S., Canadian and foreign health authorities. Such national agencies and other federal, state, provincial and local entities regulate the testing, manufacturing, safety, pricing and promotion of our products.

U.S. Regulation

New Drug Application

We are required by the FDA to comply with regulations governing our products prior to commencement of marketing by us or by our commercial partners. New chemical entities and new formulations for existing drug compounds which cannot be filed as ANDAs are subject to NDA requirements. These requirements include: (a) preclinical laboratory and animal toxicology tests; (b) submission in certain cases of an IND, and its required acceptance by the FDA before human clinical trials can commence; (c) adequate and well-controlled replicate human clinical trials to establish the safety and efficacy of a drug for its intended indication; (d) the submission of an NDA to the FDA; and (e) FDA approval of an NDA prior to any commercial sale or shipment of the product, including pre-approval and post-approval inspections of its manufacturing and testing facilities.

Preclinical laboratory and animal toxicology tests must be performed to assess the safety and potential efficacy of a product. The results of these preclinical tests, together with information regarding the methods of manufacture of the products and quality control testing, are then submitted to the FDA as part of an IND requesting authorization to initiate human clinical trials. Additionally, an independent Institutional Review Board ("IRB") at each medical site proposing to conduct the clinical trials must review and approve each study protocol and oversee conduct of the trial. An IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. If the FDA imposes a clinical hold, the IND sponsor must resolve the FDA's concerns before clinical trials can begin. Preclinical tests and studies can take several years to complete, and there is no guarantee that an IND we submit based on such tests and studies will become effective within any specific time period, or if at all.

Clinical trials involve the administration of a pharmaceutical product to individuals under the supervision of qualified medical investigators that are experienced in conducting studies under "Good Clinical Practice" guidelines. Clinical studies are conducted in accordance with protocols that detail the objectives of a study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA and to an IRB prior to the commencement of each clinical trial. Clinical studies are typically conducted in three sequential phases, which may overlap. In Phase 1, first-in-man, the initial introduction of the product into healthy human subjects, the compound is tested for absorption, safety, tolerability, metabolic interaction, distribution and excretion. Phase 2 involves studies in a limited patient population with the disease to be treated to (a) determine the preliminary or potential effectiveness of the product for specific targeted indications; (b) determine optimal dosage; and (c) identify possible adverse effects and safety risks. If Phase 2 evaluations demonstrate that a pharmaceutical product is potentially effective, has acceptable data to show an appropriate clinical dose and has an acceptable safety profile, Phase 3 clinical trials are undertaken to further evaluate clinical efficacy of the product and to further test its safety within an expanded patient population at geographically dispersed clinical study sites. Periodic reports to the FDA and IRBs on the clinical investigations are required. We, as a sponsor of the study, the IRB or the FDA may suspend clinical trials at any time if any such party believes the clinical subjects are being exposed to unacceptable health risks. The results of the product development, analytical laboratory studies, toxicology studies and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing of a pharmaceutical product.

The above-described NDA requirements are predicated on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove safety and efficacy. However, for those NDAs containing some data which the applicant neither owns nor has a right-of-reference, the FDA's ability to grant approval is limited when there are exclusivity periods or infringed patent rights that are accorded to others. These NDAs are governed by 21 U.S.C. § 355(b)(1), also known as Section 505(b)(2) of the U.S. *Food, Drug and Cosmetic Act* (the "FD&C Act") (referred to as "505(b)(2) NDAs").

Table of Contents

Abbreviated New Drug Application

In certain cases, where the objective is to develop a generic (bioequivalent formulation) of an approved product already on the market, an ANDA is required. Under the ANDA procedure, the FDA waives the requirement to submit complete reports of preclinical and clinical studies of safety and efficacy, and instead, requires the submission of bioequivalence data, which is a demonstration that the generic drug produces the statistically equivalent blood levels of active ingredient in the body as its brand-name counterpart. It is mandatory that the generic products have a comparable rate and extent of absorption as measured by plasma drug levels as a function of time. In certain cases, an ANDA applicant may submit a suitability petition to the FDA requesting permission to submit an ANDA for a drug product that differs from a previously approved reference drug product (the "Listed Drug") when the change is one authorized by statute. Permitted variations from the Listed Drug may include changes in: (a) route of administration; (b) dosage form; (c) strength; and (d) one of the active ingredients of the Listed Drug when the Listed Drug is a combination product. The FDA must approve the petition before the ANDA may be submitted. An applicant is not permitted to petition for any changes from Listed Drugs which are not authorized by statute. The information in a suitability petition must demonstrate that the change may be adequately evaluated for approval without data from investigations to show the product's safety or effectiveness. The advantages of an ANDA over an NDA include reduced R&D costs associated with bringing a product to market, potentially shorter review and approval periods and potentially quicker time to market. The disadvantages include the lack of market exclusivity unless the ANDA is the first substantially complete file to challenge innovator patents (see " Patent Certification and Exclusivity Issues").

505(b)(2) Application Process

In certain cases, pharmaceutical companies may submit an application for marketing approval of a drug product under Section 505(b)(2) of the FD&C Act (referred to as "505(b)(2) NDAs"). This mechanism essentially relies upon the same FDA conclusions that would support the approval of an ANDA available to an applicant who develops a modification of a Listed Drug that is not supported by a suitability petition. Relative to more extensive regulatory requirements for full 505(b)(1) NDAs, the Section 505(b)(2) regulations permit applicants to forego costly and time-consuming drug development studies by relying on the FDA's finding of safety and efficacy for a previously approved drug product. Under some circumstances, the extent of the reliance on the approved drug product approaches that which is permitted under the generic drug approval provisions. This approach is intended to encourage innovation in drug development without requiring duplicative studies to demonstrate what is already known about a drug while protecting the patent and exclusivity rights for the approved drug. If clinical efficacy trials are required for approval, the 505(b)(2) NDAs product is generally entitled to three years of market exclusivity following approval.

Patent Certification and Exclusivity Issues

When submitting ANDAs and 505(b)(2) NDAs, a company must include certifications with respect to any patents that claim the Listed Drug or that claim a use for the Listed Drug for which the applicant is seeking approval. If applicable patents are in effect and the patent information has been submitted to the FDA and listed in the FDA's Orange Book, the FDA may be required to delay approval of the ANDAs or 505(b)(2) NDAs until the patents expire. If the applicant believes it will not infringe the patents or that the patents are invalid, it can make a patent certification to the owners of the patents and the holder of the original NDA approval for the drug product for which a generic drug approval is being sought. This may result in patent infringement litigation which could delay the FDA approval of the ANDA or 505(b)(2) NDA for up to 30 months. If the drug product covered by an ANDA or 505(b)(2) NDA were to be found by a court to infringe another company's patents, approval of the ANDA or 505(b)(2) NDAs could be delayed until the infringed patents expire.

Under the FD&C Act, the first filer of an ANDA with a certification of patent non-infringement or invalidity is generally entitled to receive 180 days of market exclusivity. Subsequent filers of generic products would be entitled to market their approved product after the 180-day exclusivity period expires. However, the first filer may be deemed to have forfeited its 180-day exclusivity period if, for example, it has not started marketing its generic product within certain time frames.

Table of Contents

Patent expiration refers to expiry of U.S. patents (inclusive of any extensions) on drug compounds, formulations and uses. Patents outside the U.S. may differ from those in the U.S. Under U.S. law, the expiration of a patent on a drug compound does not create a right to make, use or sell that compound. There may be additional patents relating to a person's proposed manufacture, use or sale of a product that could potentially prohibit such person's proposed commercialization of a drug formulation.

The FD&C Act contains non-patent market exclusivity provisions that offer additional protection to pioneer drug products and are independent of any patent coverage that might also apply. In the case of pioneer drugs, exclusivity refers to the fact that the effective date of approval of a potential competitor's ANDA or 505(b)(2) NDAs may be delayed or, in certain cases, an ANDA or 505(b)(2) NDA may not be submitted until the exclusivity period expires. Five-year exclusivity periods are granted to the first approval of a new chemical entity. Three-year exclusivity periods may apply to products which are not new chemical entities, but for which new clinical investigations are essential to the approval. For example, a new indication for use, or a new dosage strength of a previously approved product, may be entitled to an exclusivity period, but only with respect to that indication or dosage strength. In the case of pioneer drugs, exclusivity periods only offer protection against a competitor entering the market via the ANDA and 505(b)(2) NDA routes, and do not operate against a competitor that generates all of its own data and submits a full NDA under Section 505(b)(1) of the FD&C Act.

Other Issues That May Arise Prior to Approval

Satisfaction of FDA requirements typically takes several years. The actual time required varies substantially, based upon the type, complexity, and novelty of the pharmaceutical product, among other things. Government regulation imposes costly and time-consuming requirements and restrictions throughout the product life cycle and may delay product marketing for a considerable period of time, limit product marketing, or prevent marketing altogether. Success in preclinical or early stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit, or prevent marketing approval. Even if a product receives marketing approval, the approval is limited to specific clinical indications. Further, even after marketing approval is obtained, the discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

If applicable regulatory criteria are not satisfied, the FDA may deny approval of an 505(b)(2) NDA, full NDA or an ANDA or may require additional testing. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA may require further testing and surveillance programs to monitor the pharmaceutical product that has been commercialized. Non-compliance with applicable requirements can result in additional penalties, including product seizures, injunction actions and criminal prosecutions.

Issues Pertaining to Post-marketing Compliance

After product approval, there are continuing significant regulatory requirements imposed by the FDA, including record-keeping requirements, obligations to report adverse experiences, and restrictions on advertising and promotional activities. Quality control and manufacturing procedures must continue to conform to cGMPs, and the FDA periodically inspects facilities to assess cGMP compliance. Additionally, post-approval changes in manufacturing processes or facilities, product labeling, or other areas require FDA review and approval. Failure to comply with FDA regulatory requirements may result in enforcement action by the FDA, including product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, impositions of injunctions prohibiting product manufacture or distribution, and civil and criminal penalties. Maintaining compliance is costly and time-consuming. Nonetheless, we cannot be certain that we, or our present or future suppliers or third-party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of noncompliance could have a material adverse impact on our business.

The FDA's policies may change, and additional government regulations may be enacted that could delay, limit, or prevent marketing approval of our products or affect our ability to manufacture, market, or distribute our products after approval. Moreover, increased attention to the containment of healthcare costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on

Table of Contents

our business. Our failure to obtain coverage, an adequate level of reimbursement, or acceptable prices for our future products could diminish any revenues we may be able to generate. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payors. U.S. government and other third-party payors increasingly are attempting to contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Our activities also may be subject to state laws and regulations that affect our ability to develop and sell our products. We are also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, clinical, laboratory, and manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future, and the failure to comply may have a material adverse impact on our business.

The labeling, advertising and distribution of a drug or biologic product also must be in compliance with FDA requirements, which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the internet. The FDA has very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing a company to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions and criminal prosecutions. Each NDA must be accompanied by a user fee, pursuant to the requirements of the PDUFA, and its amendments. According to the FDA's fee schedule, effective on October 1, 2009 for the fiscal year 2010, the user fee for an application requiring clinical data, such as a NDA, is \$1,405,500, and \$702,250 for an application not requiring clinical data or a supplement requiring clinical data. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs and biologics (\$77,720), and an annual establishment fee (\$457,200) on facilities used to manufacture prescription drugs and biologics. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that we expect to incur in the future and will need to be paid at the time of application submission to FDA.

The marketing, promotional, and pricing practices of pharmaceutical manufacturers, as well as the manner in which manufacturers interact with purchasers and prescribers, are subject to various other federal and state laws, including the federal anti-kickback statute and the False Claims Act and state laws governing kickbacks, false claims, unfair trade practices, and consumer protection. Over the past several years, the FDA, the Department of Justice, and various other agencies have increased their enforcement activities with respect to pharmaceutical companies. Over this period, claims brought by these agencies against Biovail and various other companies under these and other laws have resulted in corporate criminal sanctions and substantial civil settlements. See Item 3. "Legal Proceedings," for information about the recently resolved marketing and promotional practices investigation involving Biovail, including information regarding a Corporate Integrity Agreement ("CIA") entered into by Biovail in connection with the resolution of the U.S. federal marketing practices investigation involving Cardizem® LA.

Canadian Regulation

The requirements to sell pharmaceutical drugs in Canada are substantially similar to those in the U.S., which are described above, with the exception of the 505(b)(2) NDAs and 180-day marketing exclusivity period for a first filer of an ANDA under the FD&C Act in the U.S. and as otherwise noted below.

Clinical Trial Application

Before conducting clinical trials of a new drug in Canada, a Clinical Trial Application must be submitted to the TPD. Applications for Phase 1 trials include information about the proposed trial and the new drug as well as information on any previously executed clinical trials with the new drug. Phase 2 and 3 applications also include information on the methods of manufacture of the drug and controls, and preclinical laboratory and animal toxicology tests on the safety and potential efficacy of the drug. If, within 30 days of receiving the application, the TPD does not notify the applicant that its application is unsatisfactory, the applicant may proceed with clinical trials of the drug (although the TPD targets to review applications to conduct Phase 1 trials within 7 days). The phases of clinical trials are the same as those described above under "U.S. Regulation - New Drug Application".

Table of Contents

New Drug Submission ("NDS")

Before selling or advertising a new drug in Canada, the applicant must submit an NDS or sNDS to the TPD and receive a NOC from the TPD to sell the drug. The submission includes information describing the new drug, including its proper name, the proposed name under which the new drug will be sold, a quantitative list of ingredients in the new drug and the specifications for each of those ingredients, the plant and equipment to be used in manufacturing, preparation and packaging the new drug, the methods of manufacturing, preparation and packaging the new drug, the controls applicable to these operations, the tests to be applied to control the potency, purity, stability and safety of the new drug, pharmacology data and the results of non-clinical, biopharmaceutics, clinical trials, as appropriate, the intended indications for which the new drug may be prescribed, all representations to be made for the promotion of the new drug including route of administration, proposed dosage, claims, contra-indications and side effects, the effectiveness and safety of the new drug when used as intended and draft labels to be used. The TPD reviews the NDS or sNDS. If the submission meets the requirements of Canada's *Food and Drugs Act* (the "F&D Act") and regulations, the TPD will issue an NOC for the new drug.

The TPD may deny approval or may require additional information or testing of a proposed new drug if applicable regulatory criteria are not met. Product approvals may be suspended if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Contravention of the F&D Act and regulations can result in fines and other sanctions, including product seizures and criminal prosecutions.

Where the TPD has already approved a drug for sale, the applicant may seek approval from the TPD to sell an equivalent generic drug through an Abbreviated New Drug Submission ("ANDS"). The TPD does not require additional clinical trials to be conducted by the manufacturer of a proposed drug that is claimed to be equivalent to a drug that has already been approved for sale and marketed. Instead, the manufacturer must satisfy the TPD that the drug is bioequivalent to the drug that has already been approved and marketed.

The Canadian government has regulations which can prohibit the issuance of an NOC for a patented medicine to a generic competitor, provided that the patentee, exclusive licensee or a person who has obtained the consent of the owner of the patent (the "First Person") has filed a list of its Canadian patents covering that medicine with the Minister of Health. Generic competitors that are interested in marketing generic versions of medicines against which certain patents have been listed must either state that they will await expiry of such patents or, alternatively, serve a notice of allegation pursuant to the regulations ("Notice of Allegation") in which they outline the reasons that their products will not infringe the listed patents or that the listed patents are invalid. At that point, the First Person can commence a legal proceeding to obtain an order of prohibition directed to the Minister of Health prohibiting him or her from issuing an NOC to the generic competitor that has served a Notice of Allegation. The Minister of Health may be prohibited from issuing an NOC permitting the importation or sale of a patented medicine to a generic competitor until patents on the medicine expire or the allegation of non-infringement and/or invalidity of the patent(s) in question is resolved by litigation in the manner set out in such regulations. In contrast to the 30-month stay employed in U.S. proceedings, the Canadian regulations provide that the Minister of Health cannot issue a NOC to the generic competitor until the earlier of the expiry of 24 months from the start of the prohibition proceedings or the hearing of the proceedings on their merits. There may be additional patents relating to a company's proposed manufacture, use or sale of a product that could potentially prohibit a generic competitor's proposed commercialization of a drug compound. Unlike the situation in the U.S., prohibition proceedings commenced under the Canadian regulations are not technically patent infringement proceedings and so any ruling made by a judge in a prohibition proceeding would not be binding on another judge in the event that either party to the prohibition proceeding separately commences patent infringement or invalidity proceedings.

The regulations under the F&D Act also contain non-patent exclusivity provisions that offer additional protection to innovative drug products. The current regulations prohibit the Minister of Health from issuing an NOC to a manufacturer that makes a direct or indirect comparison to an "innovative drug" until at least eight years have passed from issuance of the innovator's NOC for the innovative drug. This eight-year Canadian period is extended by a further six months in the case of drugs that have been the subject of clinical trials designed and conducted for the purpose of increasing the knowledge of the behaviour of the drug in pediatric

Table of Contents

populations. "Innovative drug" is defined as "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister of Health and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph". Additionally, the regulations have introduced, with a limited exception for the export of certain drugs to least-developed countries, a six-year "no filing" period with respect to an NDS, sNDS, ANDS or sANDS within the eight-year term of data protection. The six-year and eight-year prohibitions do not apply where the innovator consents to the earlier filing by the second manufacturer of an application for an NOC or to the issuance of an NOC to the second manufacturer, as the case may be. This data protection will only apply where the innovative drug has received an NOC and is marketed in Canada. A register of innovative drugs has been created, listing for each such drug the dates on which the six-year, eight-year and, where applicable, the pediatric extension periods will expire.

Certain provincial regulatory authorities in Canada have the ability to determine whether and which consumers of a drug sold within such province will be reimbursed by a provincial government health plan. A determination that a drug is reimbursable in a particular province results in the listing of that drug on the relevant provincial formulary. The listing or non-listing of a drug on a provincial formulary may affect the price of the drug within that province and the volume of the drug sold within that province.

Additional Regulatory Considerations

Sales of our products by our commercial partners outside the U.S. and Canada are subject to local regulatory requirements governing the testing, registration, pricing and marketing of pharmaceutical products, which vary widely from country to country.

Our manufacturing facilities located in Steinbach, Manitoba and Carolina, Puerto Rico, operate according to FDA-mandated and TPD-mandated Good Manufacturing Practices ("GMP"). These manufacturing facilities are inspected on a regular basis by the FDA, the TPD and other regulatory authorities. Our internal quality auditing team monitors compliance on an ongoing basis with FDA-mandated and TPD-mandated GMP. From time to time, the FDA, the TPD or other regulatory agencies may adopt regulations that may significantly affect the manufacture and marketing of our products.

In addition to the regulatory approval process, pharmaceutical companies are subject to regulations under provincial, state and federal laws, including requirements regarding occupational safety, controlled substances, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, provincial, state, federal and foreign regulations, including possible future regulations governing the pharmaceutical industry. We believe that we are in compliance in all material respects with such regulations as are currently in effect.

Taxation

We have operations in various countries that have differing tax laws and rates. A significant portion of our revenue and income is earned in Barbados, a country with low domestic tax rates. Dividends from such after-tax business income are received tax-free in Canada. Our tax structure is supported by current domestic tax laws in the countries in which we operate and the application of tax treaties between the various countries in which we operate. Our effective tax rate may change from year to year based on changes in the mix of activities and income allocated or earned among the different jurisdictions in which we operate; changes in tax laws in these jurisdictions; changes in the tax treaties between various countries in which we operate; changes in our eligibility for benefits under those tax treaties; and changes in the estimated values of deferred tax assets and liabilities. Such changes could result in an increase in the effective tax rate on all or a portion of our income to a rate possibly exceeding the statutory income tax rate of Canada or the U.S. We conduct transfer pricing studies to support the pricing of transactions between the various entities in our structure. Our income tax reporting is subject to audit by domestic and foreign tax authorities.

Competition

The pharmaceutical industry is highly competitive. We compete with large pharmaceutical and chemical companies, specialized CROs, research and development firms, universities and other research institutions.

Table of Contents

In the specialty CNS market, we compete with specialty pharmaceutical companies, such as Lundbeck, UCB S.A., Teva and Valeant Pharmaceuticals International. Competing in the specialty CNS market requires us to (i) identify, evaluate and acquire high priority compounds, (ii) commercialize any CNS compounds that we develop, in-license or acquire and (iii) develop competitive in-house R&D expertise.

In the drug-delivery technology market associated with our former base business model, we compete with large pharmaceutical companies. This market is subject to rapid and significant technological change that could render certain of our products obsolete or uncompetitive. In addition, many of our competitors have (i) greater financial resources and sales and marketing capabilities, (ii) greater experience in clinical testing and human clinical trials of pharmaceutical products, and (iii) greater experience in obtaining FDA, TPD and other regulatory approvals.

BPC competes with sales and marketing organizations that commercialize pharmaceuticals in Canada, such as Paladin Labs Inc. Competing in this market requires us to identify innovative products and to leverage our sales and marketing capabilities.

Seasonality of Business

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

Employees

As of December 31, 2009, we employed 1,291 employees and 20 temporary employees who are hired on a contract basis. None of these employees is represented by a collective bargaining agreement.

Geographic Areas

See Note 26 to the Consolidated Financial Statements, "Segment Information", in Item 15. "Exhibits, Financial Statement Schedules".

A significant portion of our revenue and income is earned in Barbados, which has low domestic tax rates. See Item 1A. "Risk Factors - Income Tax - Our effective tax rates may increase".

Availability of Information

The Company's Internet address is www.biovail.com. Our annual report on Form 10-K is available, without charge, on our website, as soon as reasonably practicable after it is filed electronically with the U.S. Securities and Exchange Commission ("SEC"). We will make available, without charge, on our website, all of the quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practicable after they are electronically filed with the SEC. Copies are also available, without charge, and requests for such copies should be directed to us at the following address: Biovail Corporation, 7150 Mississauga Road, Mississauga, Ontario, Canada, L5N 8M5, Attention: Investor Relations; by telephone (905) 286-3000; by facsimile (905) 286-3050; or by email to ir@biovail.com. References to our website addressed in this report are provided as a convenience and do not constitute, nor should be viewed as, an incorporation by reference of the information contained on, or available through, the website. Therefore, such information should not be considered a part of this report.

Table of Contents**C. Organizational Structure**

Set out below are the Company's principal operating subsidiaries as at December 31, 2009 (all of which are wholly-owned).

Company	Jurisdiction of Incorporation	Nature of Business	Address
Biovail Laboratories International SRL	Barbados	Strategic planning and management of intellectual property, manufacture, sale, development, licensing of pharmaceutical products	Christ Church, Barbados
Biovail Laboratories International (Barbados) SRL	Barbados	Strategic planning and management of intellectual property, manufacture, sale, development, licensing of pharmaceutical products	Christ Church, Barbados
Biovail Distribution Corporation	Delaware	Distribution of pharmaceutical products	Bridgewater, New Jersey
BTA Pharmaceuticals, Inc.	Delaware	Distribution of pharmaceutical products	Bridgewater, New Jersey
Biovail Technologies Ltd.	Delaware	Contract development of pharmaceutical products	Chantilly, Virginia
Biovail Technologies (Ireland) Ltd.	Ireland	Distribution of pharmaceutical products and supply chain services	Dublin, Ireland

Item 1A. Risk Factors.

Investment in our common shares involves a degree of risk. These risks should be carefully considered before any investment is made. The following are some of the key risk factors generally associated with our business. However, the risks described below are not the only ones that we face. Additional risks not currently known to us or that we currently deem immaterial may also impair our business operations.

I. COMPANY-SPECIFIC RISKS**1. Ability to In-License, Acquire and Develop Products**

Our future revenue growth and profitability are dependent upon our ability to in-license or otherwise acquire new specialty CNS compounds or other commercially viable products and to further develop or enhance such products. Our failure to do so successfully could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Our future revenue growth, profitability and financial condition depend, to a significant extent, on our ability to successfully in-license or otherwise acquire new specialty CNS compounds or other commercially viable products and to further develop or enhance such products. Our success in implementing our specialty CNS strategy is subject to a number of risks, including our ability to identify, effectively evaluate, acquire and develop high priority compounds.

We rely on the acquisition, in-licensing or other access to products or technologies from third-party drug-development companies. Supplementing our product portfolio in this manner requires the commitment of substantial effort and expense in seeking out, evaluating and negotiating collaboration or acquisition agreements, which we may incur without achieving our desired results. In addition, product in-licensing involves inherent risks, including uncertainties due to matters that may affect the successful development or commercialization of the in-licensed product, as well as the possibility of contractual disagreements with regard to terms such as patent rights, license scope or termination rights. Competition for attractive product opportunities is intense and may require us to devote substantial resources, both human and financial, to an opportunity that may not result in a successfully developed, or commercialized, product.

In addition, our current structure, which is dependent in the U.S. on third-party marketing or distribution partners, may make us less attractive to third-party marketers, distributors and licensors of new products, and this may affect our ability to secure such partners.

Table of Contents

Product development is subject to a great deal of uncertainty, risk and expense. Development of pharmaceutical candidates may fail or be terminated at various stages of the R&D process, often after substantial financial and other resources have been invested in their exploration and development.

2. Preclinical and Clinical Trials

a. We will not be able to commercialize our pipeline products if preclinical studies do not produce successful results or if clinical trials do not demonstrate safety and efficacy in humans.

The Company and its development partners, as applicable, conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy in humans of our pipeline products in order to obtain regulatory approval for the sale of our pipeline products. Preclinical studies and clinical trials are expensive, can take many years and have uncertain outcomes.

In clinical trials for products for specialty CNS conditions, the number of patients that may have the relevant condition may be lower, making it more difficult to recruit the patients necessary to conduct a meaningful clinical trial. Although regulatory requirements may permit smaller-sized clinical trials for products for these types of conditions, demonstrating statistically significant efficacy with a smaller clinical trial population may be more difficult. Also, to the extent that the clinical endpoint for these types of conditions is more easily measured and well-defined, any negative clinical trial results are very apparent.

Our success will depend on the success of the preclinical and clinical trials conducted by us and our development partners. It can take several years to complete the preclinical and clinical trials of a product, and a failure of one or more of these preclinical or clinical trials can occur at any stage of testing. We believe that the development of each of our pipeline products involves significant risks at each stage of testing. If preclinical or clinical trial difficulties and failures arise, our pipeline products may never be approved for sale or become commercially viable.

The risk of preclinical or clinical trial failure is even greater where the pipeline product contains an NCE, or where the pipeline product uses a novel or not fully known mechanism of action. Likewise, the risk of discovering harmful side effects is greater where the pipeline product contains an NCE.

In addition, the possibility exists that:

the results from early preclinical or clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;

a pipeline product may not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved;

institutional review boards or regulators, including the FDA and TPD, may hold, suspend or terminate our preclinical or clinical research or the preclinical or clinical trials of our pipeline products for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

subjects may drop out of our clinical trials;

our preclinical or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical or clinical trials;

the cost of our preclinical or clinical trials may be greater than we currently anticipate; and

the difficulties and risks associated with preclinical and clinical trials may result in the failure to receive regulatory approval to continue to test or to sell our pipeline products or the inability to commercialize any of our pipeline products.

Table of Contents

b. If clinical trials for our pipeline products are delayed, we may be unable to commercialize our pipeline products on a timely basis, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Planned clinical trials may not begin on time, may take longer to complete than anticipated, or may need to be restructured after they have begun. Clinical trials can be delayed for a variety of reasons, including delays related to:

obtaining an effective investigational new drug application, or IND application, or regulatory approval to commence a clinical trial;

identifying and engaging a sufficient number of clinical trial sites;

negotiating acceptable clinical trial agreement terms with prospective trial sites;

obtaining institutional review board approval to conduct a clinical trial at a prospective site;

recruiting qualified subjects to participate in clinical trials in a timely manner;

competition in recruiting clinical investigators;

shortage or lack of availability of supplies of drugs for clinical trials;

the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;

the placement of a clinical hold on a study;

the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion; and

exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial.

Our pipeline products have significant milestones to reach, including the successful completion of clinical trials, before commercialization. If we experience significant delays in or termination of clinical trials, our financial results and the commercial prospects for our pipeline products or any other products that we may develop will be adversely impacted. In addition, our product development costs would increase and our ability to generate revenue could be impaired.

c. We rely on third parties to conduct, supervise and monitor our clinical trials, and those service providers may perform in an unsatisfactory manner, such as by failing to meet established deadlines for the completion of such trials.

We rely on third parties such as CROs, medical institutions and clinical investigators to enroll qualified patients and conduct, supervise and monitor our clinical trials. Our reliance on these service providers for clinical development activities reduces our control over these activities. Our reliance on these service providers, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with good clinical practice regulations, and the investigational plan and protocols contained in the relevant regulatory application, such as the IND application. In addition, they may not complete activities on schedule, or may not conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our trial design. If these service providers do not successfully carry out

their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or prevented.

3. Regulatory Approvals and Compliance

a. If we fail to obtain regulatory approval to sell our pipeline products we would not be able to generate related revenues in future periods, which could have a material adverse effect on our business and results of operations and could cause the market value of our common shares to decline.

FDA and TPD approval is required before any prescription drug product, including generic drug products, can be sold in the U.S. and Canada, respectively. Other countries may also have similar regulatory approval

Table of Contents

requirements before products can be sold in those countries. The process of obtaining FDA, TPD and other regulatory approvals to manufacture and market new and generic pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. The timing and cost of obtaining FDA, TPD and other regulatory approvals, or the failure to obtain such approvals, could adversely affect our product introduction plans, business, financial condition and results of operations and could cause the market value of our common shares to decline.

If we do not receive regulatory approval to sell our pipeline products, we will not be able to generate revenues in future periods for such products, which could have a material adverse effect on our business and results of operations and could cause the market value of our common shares to decline.

b. Our marketing, promotional and pricing practices, as well as the manner in which an in-house or third-party sales force interact with purchasers, prescribers and patients, are subject to extensive regulation and any material failure to comply could result in significant sanctions against the Company.

The marketing, promotional, and pricing practices of pharmaceutical companies, as well as the manner in which companies, in-house or third-party sales forces interact with purchasers, prescribers, and patients, are subject to extensive regulation. Regulatory enforcement by the applicable agency may result in the imposition of civil and/or criminal penalties, injunctions, and/or limitations on marketing practice for our products. Many companies, including Biovail, have been the subject of claims related to these practices asserted by federal authorities. These claims have resulted in fines and other consequences to the Company. We are now operating under a CIA that requires us to maintain a comprehensive compliance program governing our sales, marketing and government pricing and contracting functions. Material failures to comply with the CIA could result in significant sanctions to the Company. For example, enforcement actions could result in expansion of the existing restrictions on our sales and marketing activities under the CIA. See Item 3. "Legal Proceedings". Even in jurisdictions like Canada where certain types of marketing practices are regulated more through guidelines and codes of conduct than legislation, engaging in certain types of marketing practices can result in significant scrutiny, negative publicity and harm to business relationships even if the company is not breaching any legislation.

c. We may incur significant liability if it is determined that we are promoting the "off-label" use of drugs.

Companies may not promote drugs for "off-label" uses that is, uses that are not described in the product's labelling and that differ from those approved by the FDA, TPD or other applicable regulatory agencies. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across medical specialties. Although the FDA, TPD and other regulatory agencies do not regulate a physician's choice of treatments, the FDA, TPD and other regulatory agencies do restrict communications by pharmaceutical companies or their sales representatives on the subject of off-label use. The FDA, TPD and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Notwithstanding the regulatory restrictions on off-label promotion, the FDA, TPD and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. Although we believe that all of our communications regarding all of our products are in compliance with the relevant regulatory requirements, the FDA, TPD or another regulatory authority may disagree, and we may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged. Our distribution partners may also be the subject of regulatory investigations involving, or remedies or sanctions for, off-label uses of products we have licensed to them, which may have an adverse impact on sales of such licensed products, which may, in turn, have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Table of Contents

d. All products manufactured by us or for us by third-party manufacturers must be made in a manner consistent with FDA-mandated, TPD-mandated and ICH-mandated GMP which require substantial expenditures of time, money and effort.

All products manufactured by us or for us by third-party manufacturers must be made in a manner consistent with FDA-mandated, TPD-mandated and ICH-mandated GMP. Compliance with GMP regulations requires substantial expenditures of time, money and effort in such areas as production, quality control and quality assurance to ensure full technical, facility and system compliance. The FDA, TPD and other regulatory authorities inspect on a regular basis our and our third-party manufacturers' manufacturing facilities for compliance. Failure to comply with GMP regulations could occur for various reasons, including failure of a product to meet or maintain specifications, stability issues or unexpected trends in patient adverse drug reactions ("ADRs"). If the regulatory agencies were to require one of our or our third-party manufacturers' manufacturing facilities to cease or limit production, our business could be adversely affected, in part because regulatory approval to manufacture a drug is generally site-specific. As a result of ceasing manufacturing and packaging at the Dorado, Puerto Rico facility our in-house manufacturing will largely be concentrated at our Steinbach, Manitoba facility with the Carolina, Puerto Rico facility remaining open indefinitely in order to meet higher demand for generic Tiazac® and generic Cardizem® CD products. Delay and cost in obtaining regulatory approval to manufacture at a different facility also could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

In addition, if we or our third-party manufacturers fail to comply with applicable continuing regulatory requirements, our business could be seriously harmed because a regulatory agency may:

issue warning letters;

suspend or withdraw our regulatory approval for approved or in-market products;

seize or detain products or recommend a product recall;

refuse to approve pending applications or supplements to approved applications filed by us;

suspend any of our ongoing clinical trials;

impose restrictions or obligations on our operations, including costly new manufacturing requirements;

close our facilities or those of our contract manufacturers; or

impose civil or criminal penalties.

Under certain circumstances, regulatory agencies also have the authority to revoke previously granted drug approvals. These policies may change and additional U.S. or Canadian federal, provincial, state or local governmental regulations or foreign governmental regulations may be enacted that could affect our ability to maintain compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that may arise from future legislation or administrative action.

If we or our third-party manufacturers were deemed to be deficient regarding regulatory compliance in any significant way, it could have a material adverse effect on our business, financial condition and results of operations and it could cause the market value of our common shares to decline.

4. Manufacturing, Supply and Delivery

a. Manufacturing difficulties or delays may adversely affect our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Our manufacturing and other processes use complicated and sophisticated equipment, which sometimes requires a significant amount of time to obtain and install. In addition, the closure of our Dorado, Puerto Rico facility, which we intend to close in 2010, will concentrate the majority of our in-house manufacturing at our Steinbach, Manitoba facility and, as a result, we will face risks inherent in manufacturing our products largely at a single facility. Manufacturing complexity, testing requirements and safety and security processes combine to

Table of Contents

increase the overall difficulty of manufacturing these products and resolving manufacturing problems that we may encounter. Although we endeavour to properly maintain our equipment, including through on-site quality control and experienced manufacturing supervision, and have key spare parts on hand, our business could suffer if certain manufacturing or other equipment, or all or a portion of our remaining facility, were to become inoperable for a period of time. This could occur for various reasons, including catastrophic events, such as hurricanes, earthquakes or other natural disasters, explosions, environmental accidents, pandemics, quarantine, equipment failures or delays in obtaining components or replacements, construction delays or defects and other events, both within and outside of our control. We will not have a secondary or back-up manufacturing facility in place to assist with these manufacturing and other processes should any of these events occur. As a result, we could experience substantial production delays in the event of any such occurrence until we build or locate replacement equipment or a replacement facility, as applicable, and seek to obtain necessary regulatory approvals for such replacement. Any interruption in our manufacture of products could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

b. If we are unable to optimize the use of or expand our manufacturing facilities or secure cost-effective third-party manufacturing arrangements in a timely manner, we may be unable to meet market demand for our products, which could affect our business, financial condition and results of operations and could cause the market value of our common shares to decline.

We have, in past years, operated some of our manufacturing facilities on a 24-hour-a-day, seven-day-a-week production cycle to meet the market demand for current in-market products and anticipated product launches. Successfully operating on that basis and meeting the anticipated market demand requires minimal equipment failures and product rejections. In addition, we manufacture products that employ a variety of technology platforms. Some of our manufacturing facilities may, at times, be scheduled in excess of rated capacity, while others may be under-utilized. Unless our manufacturing processes are optimized or our manufacturing facilities are expanded where appropriate, or we secure cost-effective third-party manufacturing arrangements in a timely manner, we may have difficulty fulfilling all demand for new large volume products, which could adversely affect our results of operations, financial condition and cash flows. In addition, if we are required to expand any of our facilities, it may require significant capital investment. If we are unable to complete any expansion projects in a timely and cost-efficient manner or adequately equip the expanded facilities in a timely and cost-effective manner or we experience delays in receiving FDA and TPD approvals for these expanded facilities, it could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

c. Disruptions of delivery of our products and the routine flow of manufactured goods across the U.S. border could adversely impact our business, financial condition and results of operations and could cause the market value of our common shares to decline.

The supply of our products to our customers is subject to and dependent upon the use of transportation services. Disruption of transportation services could adversely impact our financial results. In addition, our manufacturing facilities are located outside the continental U.S. and most of our sales are within the U.S. A significant portion of our revenue is derived from products that are imported into the U.S. in finished dosage form from Canada or other countries and must undergo review by the Department of Homeland Security U.S. Customs and Border Protection ("DHS-CBP"). We also purchase products from third parties outside the U.S. Disruption to the routine flow of manufactured goods across the border could have a significant impact on when revenues are recognized and the willingness of customers to continue to purchase products that we import from outside of the U.S. As such, any change in policy or policy implementation relating to U.S. border controls may have an adverse impact on our access to the U.S. marketplace that, in turn, could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Over the past few years, pharmaceutical products manufactured outside of the U.S. have been associated with significant adverse health effects and/or as posing elevated risks even in the absence of adverse effects. As a result, there is increased interest in disclosure with regard to foreign sourcing of ingredients. Current practice

Table of Contents

within the pharmaceutical industry with respect to country of origin marking ("COOM") is in a period of transition toward more disclosure. Compliance determinations at U.S. border stations are complicated by the fact that the country of origin for tariff purposes may not be the same as for COOM purposes and may be different still from the FDA "manufactured by" statement. The result can be that DHS-CBP may issue a Notice to Mark and/or Notice to Redeliver incurring relabeling costs and delay that may or may not be well founded and/or penalties and fines for products deemed to be improperly presented for importation. Not all of our customers have adopted the same approach to COOM and instructions from border officials can vary. In addition, repeated presentation of goods with similar compliance deficiencies can result in fines. We may be exposed to such costs and disruption until we can establish and confirm agreement with our customers to accept a consistent set of labelling rules that are also acceptable to DHS-CBP.

d. If we are unable to obtain components or raw materials, or products supplied by third parties, our ability to manufacture and deliver our products to the market may be impeded, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Some components and raw materials used in our manufactured products, and some products sold by us, are currently available only from one or a limited number of domestic or foreign suppliers. Such suppliers must be qualified in accordance with applicable regulatory requirements and the process of qualifying a supplier can be costly and time consuming. In the event an existing supplier becomes unavailable through business interruption or financial insolvency or loses its regulatory status as an approved source and we do not have a second supplier, we will attempt to locate a qualified alternative; however, we may be unable to obtain the required components, raw materials or products on a timely basis or at commercially reasonable prices. A prolonged interruption in the supply of a single-sourced raw material, including the API, or finished product or the occurrence of quality deficiencies in the products which our suppliers provide, could have a material adverse effect on our business, financial condition and results of operations, and the market value of our common shares could decline.

Our arrangements with foreign suppliers are subject to certain additional risks, including the availability of government clearances, export duties, transport issues, political instability, currency fluctuations and restrictions on the transfer of funds. Arrangements with international raw material suppliers are subject to, among other things, FDA and TPD regulation, various import duties and required government clearances. Acts of governments outside the U.S. and Canada may affect the price or availability of raw materials needed for the development or manufacture of our products. The degree of impact such a situation could have would, in part, depend on the product affected.

In addition, we rely on third-party manufacturers to supply certain products that we market or distribute, including Cardizem® CD, Vasotec®, Vaseretic®, Zovirax®, Ativan®, Wellbutrin® SR, Zyban®, Glumetza® 500 mg, Isordil®, Xenazine® and Nitoman®. Our manufacturers may suffer an interruption, including due to manufacturing or shipping problems, financial insolvency, regulatory inspections or difficulty in sourcing components or raw materials. We are also vulnerable to a supply interruption should we be unable to renew or replace, or successfully transfer, such supply arrangements when our current agreements with our third-party manufacturers expire, in which case we may experience an interruption in our supply. Any such supply interruption could have an adverse impact on our operations.

e. Delays or transition issues arising from the closure of our Dorado, Puerto Rico manufacturing facility may adversely affect our business and results of operations and could cause the market value of our common shares to decline.

In support of the implementation of our specialty CNS strategy, we are consolidating our manufacturing resources through the closure of our Dorado, Puerto Rico manufacturing facility and the transfer of certain manufacturing processes to our Steinbach, Manitoba facility. We anticipate that the site in Dorado will be fully transitioned to Steinbach early in 2010. If we experience a delay in transitioning such manufacturing processes to Steinbach, or if we experience other disruptions or issues (including a delay in obtaining necessary regulatory approvals) in transitioning these manufacturing processes to Steinbach, we could fail to deliver our products in a timely manner, which could adversely affect our relationships with our customers and business partners, which,

Table of Contents

in turn, could adversely affect our business and results of operations and could cause the market value of our common shares to decline. The Carolina, Puerto Rico site is expected to remain open indefinitely due to increased demand for products manufactured in this plant.

5. Commercialization and Marketing

a. Our approved products may not achieve or maintain expected levels of market acceptance, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Even if we are able to obtain regulatory approvals for our new pharmaceutical products, generic or branded, the success of those products is dependent upon achieving and maintaining market acceptance. New product candidates that appear promising in development may fail to reach the market or may have only limited or no commercial success. Levels of market acceptance for our new products could be impacted by several factors, many of which are not within our control, including but not limited to:

safety, efficacy, convenience and cost-effectiveness of our products compared to products of our competitors;

scope of approved uses and marketing approval;

timing of market approvals and market entry;

availability of alternative products from our competitors;

acceptance of the price of our products; and

ability to market our products effectively at the retail level or in the appropriate setting of care.

Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of the affected products. Accordingly, new data about our products, or products similar to our products, could negatively impact demand for our products due to real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal.

These situations, should they occur, could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

b. We may not be able to establish or acquire a U.S. sales force to effectively support our specialty CNS strategy.

We currently do not have an in-house sales force to market our products in the U.S. In the U.S., our products are marketed through strategic alliances with commercial parties with established sales and marketing infrastructures. In order to support our specialty CNS strategy, we plan to create or acquire a specialized U.S. sales force to effectively support the CNS products in our pipeline or CNS products we acquire or develop in the future. To meet our objectives, we must attract and retain highly qualified personnel with specialized skill sets. Competition for qualified personnel can be intense, and we might not be successful in attracting and retaining them. Our ability to build and maintain a specialized U.S. sales force will depend on our ability to recruit, train and retain top quality people with advanced skills who understand sales to, and the specific needs of, our target customers. Developing a direct sales force is expensive and time consuming and could delay or limit the success of any product launch. The cost of establishing and maintaining a direct sales force may exceed its cost effectiveness. Additionally, we will compete with many companies that currently have extensive and well-funded sales operations. Our sales efforts may be unable to compete successfully against these companies, and we may not be able to develop an effective specialized U.S. sales force on a timely basis or at all. If we are unable to establish an appropriate U.S. sales force to execute our specialty CNS strategy or secure third-party marketing or distribution partners in the U.S., we may not be able to commercialize new products successfully which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Table of Contents

c. We may not be able to effectively establish third-party marketing or distribution arrangements.

The success of any new product will depend on our ability to secure third-party marketing or distribution arrangements in the U.S. and elsewhere in the absence of a specialty in-house sales force appropriate to the relevant subscribing community. Seeking out, evaluating and negotiating marketing partnership agreements may involve the commitment of substantial time and effort and may not ultimately result in a viable marketing or distribution relationship. If we enter into a marketing agreement whereby we outsource marketing and promotional activities, including creation and implementation of a sales force, to a third-party, our control over specific materials and tactics used by that sales force may be diminished as compared with a specialty in-house sales force. If we are unable to establish an appropriate U.S. sales force to execute our specialty CNS strategy or secure third-party marketing or distribution arrangements in the U.S., we may not be able to commercialize new products successfully which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

d. We may experience reductions in the levels of reimbursement for or acceptance of pharmaceutical products by governmental authorities, HMOs or other third-party payors. Any such reductions could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

A number of legislative and regulatory proposals aimed at changing the U.S. healthcare system, and changes in the levels at which pharmaceutical companies are reimbursed for sales of their products or pricing of drugs, have been proposed. In addition, as a result of the focus on healthcare reform in connection with the current presidential administration in the U.S., Congress may implement changes in laws and regulations governing healthcare service providers, including measures to control costs or reductions in reimbursement levels or price controls, which may have an adverse impact on our business. While we cannot predict when or whether any of these proposals will be adopted, or the effect these proposals may have on our business, the pending nature of these proposals, as well as the adoption of any proposal, may exacerbate industry-wide pricing pressures and could have a material adverse effect on our business, financial condition and results of operations.

Various governmental authorities and private health insurers and other organizations, such as HMOs, managed care organizations ("MCOs") and provincial formularies provide reimbursement to consumers for the cost of certain pharmaceutical products. Our ability to successfully commercialize our products and product candidates even if FDA or TPD approval is obtained and the demand for our products depend, in part, on the extent to which reimbursement is available from such third-party payors.

Third-party payors are increasingly becoming less willing to reimburse for medications which offer primarily convenience to and greater compliance among patients (such as once-daily formulations) and are focusing more on products that offer clinically meaningful benefits. If we are not able to execute our specialty CNS strategy, which we believe is designed to address this shift, it could have a material adverse effect on our business, financial condition and results of operations. Even if we continue to successfully execute our specialty CNS strategy, the products that will be commercialized are likely to be costly. Insurers may be reluctant to list such drugs on their formulary, thus limiting reimbursement of those products and having a material adverse affect on volume of sales.

Third-party payors increasingly challenge the pricing of pharmaceutical products. In addition, the trend toward managed healthcare in the U.S., the growth of organizations such as HMOs and MCOs and legislative proposals and other initiatives in the U.S. and Canada to reform healthcare and government insurance programs, could significantly influence the purchase of pharmaceutical products (both brand and generic drugs), resulting in lower prices and/or a reduction in product demand. For example, some of the provinces in Canada have implemented or are considering implementing cost saving measures such as requiring brand name drug companies to enter into "risk-sharing or listing agreements" with the province whereby the drug company pays "rebates" or other incentives to the province to list the drug on the provincial formulary. In addition, although currently this practice has been limited, some provinces are instituting tenders to determine which interchangeable product will be listed on the provincial formulary. Further, some provinces reimburse generic drugs based on a formula equal to a percentage of the price of the corresponding brand name drug and one

Table of Contents

recent trend has been to significantly lower the percentage at which generics will be reimbursed. Other provinces (the four western provinces and the territories) have announced that they will form a joint prescription drug buying plan to better leverage their buying power. These and other cost-containment measures and healthcare reforms could affect our ability to sell our products at viable prices, could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline. By way of further example, in the U.S., the Medicare Prescription Drug, Improvement and Modernization Act of 2003 established a voluntary outpatient prescription drug benefit under Part D of the Social Security Act. The program, which went into effect January 1, 2006, is administered by the Centers for Medicare & Medicaid Services within the Department of Health and Human Services and is implemented and operated by private sector Part D plan sponsors. Each participating drug plan is permitted by regulation to develop and establish its own unique drug formulary that may exclude certain drugs from coverage, impose prior authorization and other coverage restrictions, and negotiate payment levels for drugs which may be lower than reimbursement levels available through private health plans or other payors. Moreover, beneficiary co-insurance requirements could influence which products are recommended by physicians and selected by patients. To the extent that private insurers or managed care programs follow Medicare Part D coverage and payment developments, the adverse effects of lower Medicare payments may be magnified by private insurers adopting similar lower payments. New federal or state drug payment changes or healthcare reforms in the U.S. may be enacted or adopted in the future that could further lower payment for our products.

Uncertainty exists about the reimbursement status of newly approved pharmaceutical products. Reimbursement in the U.S., Canada or foreign countries may not be available for some of our products. Any reimbursement granted may not be maintained, or limits on reimbursement available from third parties may reduce the demand for, or negatively affect the price of, those products. We are also unable to predict if additional legislation or regulation or non-legislative initiatives impacting the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation or non-legislative initiatives would have on our business. Any reimbursement may be reduced in the future, perhaps to the point that market demand for our products declines. Such decline could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Changes to Medicare, Medicaid or similar governmental programs or the amounts paid by those programs for our services may adversely affect our business, financial condition and results of operations. These programs are highly regulated and subject to frequent and substantial changes and cost-containment measures. In recent years, changes in these programs have limited and reduced reimbursement to providers.

The prices of drugs sold or reimbursed in a particular jurisdiction can impact the prices at which such drug is sold or reimbursed in other jurisdictions. For example, the province of Quebec has a "most favoured nation" clause regarding the price at which it will reimburse drugs. The maximum price at which patented drugs can be sold in Canada is regulated by the Patented Medicine Prices Review Board and is dependent on the price at which the drug is sold in certain countries in the world. Therefore, decreases in prices in one jurisdiction can have repercussions in other jurisdictions.

e. A relatively small group of products represents a significant portion of our revenues, gross profit and earnings. If, due to genericization or otherwise, the volume or pricing of any of these products declines or the costs of related manufacturing, distribution or marketing increase, it could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Sales of a limited number of our products represent a significant portion of our revenues, gross profit and earnings. As the volume or pricing of our existing significant products declines in the future, our business, financial condition, and results of operations could be materially adversely affected and this could cause the market value of our common shares to decline.

The genericization of our existing products is one of the reasons for the current or continued decline in volume and pricing of our products. Following the initial pricing and volume impact of genericization, pricing

Table of Contents

and volume may either decrease further or increase dependent upon market and competitive conditions. In addition, if this or any of our other key products were to become subject to any other issues, such as material adverse changes in prescription growth rates, unexpected side effects, regulatory proceedings, material product liability litigation, publicity affecting doctor or patient confidence or pressure from competitive products, the adverse impact on our business, financial condition and results of operations and market value of our common shares could be significant.

f. The pharmaceutical industry is highly competitive and is subject to rapid and significant technological change, which could render our technologies and products obsolete or uncompetitive.

The pharmaceutical industry is highly competitive and is subject to rapid and significant technological change that could render certain of our products obsolete or uncompetitive. Many of our competitors are conducting R&D activities in therapeutic areas targeted by our products and our product development candidates. The introduction of competitive therapies as alternatives to our existing products may negatively impact our revenues from those products, and the introduction of products that directly compete with products in development could dramatically reduce the value of those development projects or chances of successfully commercializing those products, which could have a material adverse effect on our long-term financial success. For example, our Legacy Products (as described in Item 1.B., "Business Overview Current Product Portfolio and Product Revenues") face competition from conventional forms of drug delivery and from controlled release drug-delivery systems developed, or under development, by other companies.

We compete with companies in North America and internationally, including major pharmaceutical and chemical companies, specialized CROs, research-and-development firms, universities and other research institutions. Many of our competitors have greater financial resources and selling and marketing capabilities, greater experience in clinical testing and human clinical trials of pharmaceutical products and greater experience in obtaining FDA, TPD and other regulatory approvals than we do. In addition, some of our competitors may have lower development and manufacturing costs. Our competitors may succeed in developing technologies and products that are more effective or less expensive to produce or use than any that we may develop or license. These developments could render our technologies and products obsolete or uncompetitive, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

g. We have entered into distribution agreements with other companies to distribute certain of our generic products at supply prices based on net sales. Declines in the pricing and/or volume, over which we have no control, of such generic products, and therefore the amounts paid to us, may have a material adverse effect on our business and results of operations and could cause the market value of our common shares to decline.

Our portfolio of generic products is the subject of various agreements, pursuant to which we manufacture and sell generic products to other companies, which distribute such products in the U.S. and Canada at a supply price typically based on net sales. These companies make all distribution and pricing decisions independently of Biovail. If the pricing and/or volume of such generic products declines, our revenues could be adversely impacted which could have a material adverse effect on our business and results of operations and could cause the market value of our common shares to decline.

6. Post-Approval and Post-Marketing Regulatory Impacts

a. Our marketed drugs will be subject to ongoing regulatory review. If we fail to comply with U.S. and Canadian regulatory requirements and those in other territories where our products are sold, we could lose our marketing approvals or be subject to fines or other sanctions, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Following initial regulatory approval of any drugs we or our partners may develop, we will be subject to continuing regulatory review by the FDA, the TPD and other regulatory authorities in territories where our products are marketed or intended to be marketed, including the review of adverse drug events and clinical

Table of Contents

results that are reported after product candidates become commercially available. This may include results from any post-marketing follow-up studies or other reporting required as a condition to approval. The manufacturing, labeling, packaging, storage, distribution, advertising, promotion, reporting and recordkeeping related to the product will also be subject to extensive ongoing regulatory requirements. In addition, incidents of ADRs, unintended side effects or misuse relating to our products could result in additional regulatory controls or restrictions, or even lead to withdrawal of a product from the market. Similarly, our CRD operations could suffer a loss of business or be subject to liability should a serious ADR occur during the course of their conduct of a study.

b. Our approved products may be subject to additional clinical trials which could result in the loss of marketing approval, changes in product labeling or new or increased concerns about side effects or efficacy.

As a condition to granting marketing approval of a product, the FDA and TPD may require a company to conduct additional clinical trials. The results generated in these trials could result in the subsequent loss of marketing approval, changes in product labeling or new or increased concerns about side effects or efficacy of a product. On September 27, 2007, the *Food and Drug Administration Amendments Act of 2007* ("FDAA") was enacted, giving the FDA enhanced post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with post-approval regulatory requirements and potential restrictions on sales of approved products. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or undertaken voluntarily, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our products. Such studies, which increasingly employ sophisticated methods and techniques, may call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies may result in the discontinuance of product marketing or the need for risk management programs. In addition, government agencies may determine that a product should be scheduled as a controlled substance under the *Controlled Drugs and Substances Act* (the "CDSA"), as has been proposed by Health Canada for our tramadol products. If one of our products is scheduled under the CDSA or a similar regulation, such regulation would reduce practitioner prescriptions for such product, which may lead to a reduction in revenues from such product. Such regulation may also increase the costs of manufacturing and distributing such product in order to meet the regulatory requirements applicable to controlled substances, such as process upgrades and renovations required at our facilities and changes to our manufacturing, storage and transportation practices.

7. Intellectual Property

a. We may be unable to effectively protect our intellectual and other proprietary property, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

The pharmaceutical industry historically has generated substantial litigation concerning the manufacture, use and sale of products and we expect this litigation activity to continue. Generic drug manufacturers seek to sell and, in a number of cases have sold generic versions of many of our most important products prior to the expiration of our patents, and have exhibited a readiness to do so for other products in the future. As a result, we expect that patents related to our products will be routinely challenged, and our patents may not be upheld. If we are not successful in defending an attack on our patents and maintaining exclusive rights to market one or more of our major products still under patent protection, we could lose a significant portion of sales in a very short period, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline. See Item 1.B. "Business Overview Patents and Proprietary Rights", for more information on our intellectual property rights and Item 3. "Legal Proceedings Intellectual Property", for a discussion of intellectual property-related proceedings in which we are involved.

Table of Contents

In addition, we rely on trade secrets, know-how and other proprietary information to provide additional legal protection to various aspects of our business, including information about our formulations, manufacturing methods and analytical procedures, as well as information contained in our Company documents and regulatory filings. Although we require our employees and other vendors and suppliers to sign confidentiality agreements, we may not have adequate remedies in the event of a breach of these confidentiality agreements. Furthermore, the trade secrets and proprietary technology upon which we rely may otherwise become known or be independently developed by our competitors without infringing upon any proprietary technology. Our success will depend, in part, on our ability in the future to protect those trade secrets and other proprietary information.

The cost of responding to challenges to our patents and the inherent costs to defend the validity of our patents, including the prosecution of infringements and the related litigation, and to protect our other intellectual property could be substantial and could preclude or delay commercialization of products. Such litigation could also require a substantial commitment of our management's time.

b. We may be subject to intellectual property litigation and infringement claims, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Our success will depend, in part, on our ability in the future to obtain patents and to operate without infringing on the proprietary rights of others. Our competitors may have filed patent applications, or hold issued patents, relating to products or processes competitive with those we are developing. The patents of our competitors may impair our ability to do business in a particular area.

In the event we discover that we may be infringing third-party patents or other intellectual property rights, we may not be able to obtain licenses from those third parties on commercially attractive terms or at all. We may have to defend against charges that we violated patents or the proprietary rights of third parties. Litigation is costly and time-consuming, and diverts the attention of our management and technical personnel. In addition, if we infringe the intellectual property rights of others, we could lose our right to develop, manufacture or sell products, including our generic products, or could be required to pay monetary damages or royalties to license proprietary rights from third parties. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products, which could have a material adverse effect on our business, financial condition, and results of operations and could cause the market value of our common shares to decline. See Item 3. "Legal Proceedings Intellectual Property", for a discussion of intellectual property-related proceedings in which we are involved.

8. Income Tax

a. Our effective tax rates may increase.

We have operations in various countries that have differing tax laws and rates. A significant portion of our revenue and income is earned in Barbados, a country with a low domestic tax rate. Dividends from such after-tax business income are received tax-free in Canada. Our tax structure is supported by current domestic tax laws in the countries in which we operate and the application of tax treaties between the various countries in which we operate. Our income tax reporting is subject to audit by domestic and foreign authorities. Our effective tax rate may change from year to year based on changes in the mix of activities and income allocated or earned among the different jurisdictions in which we operate; changes in tax laws in these jurisdictions; changes in the tax treaties between various countries in which we operate; changes in our eligibility for benefits under those tax treaties; and changes in the estimated values of deferred tax assets and liabilities. Such changes could result in an increase in the effective tax rate on all or a portion of our income to a rate possibly exceeding the statutory income tax rate of Canada or the U.S. See Item 1.B. "Business Business Overview Taxation".

Our provision for income taxes is based on certain estimates and assumptions made by management. Our consolidated income tax rate is affected by the amount of net income earned in our various operating jurisdictions, the availability of benefits under tax treaties, and the rates of taxes payable in respect of that income. We enter into many transactions and arrangements in the ordinary course of business in respect of which the tax treatment is not entirely certain. We must therefore make estimates and judgments based on our knowledge and understanding of applicable tax laws and tax treaties, and the application of those tax laws and

Table of Contents

tax treaties to our business, in determining our consolidated tax provision. For example, certain countries could seek to tax a greater share of income than has been provided for by us. The final outcome of any audits by taxation authorities may differ from the estimates and assumptions we have used in determining our consolidated tax provisions and accruals. This could result in a material adverse effect on our consolidated income tax provision, financial condition and the net income for the period in which such determinations are made.

We have recorded a valuation allowance on deferred tax assets relating to our Canadian operating losses, Scientific Research and Experimental Development pool, investment tax credit carryforward balances, provisions for legal settlements, and future tax depreciation. We have assumed that these deferred tax assets are more likely than not to remain unrealized.

Our deferred tax assets and related valuation allowances are affected by events and transactions arising in the ordinary course of business, acquisitions of assets and businesses, and non-recurring items. The assessment of the appropriate amount of the valuation allowance against the net deferred tax asset is dependent upon several factors, including estimates of the realization of deferred income tax assets, which realization is primarily based on forecasts of future taxable income. Significant judgment is applied to determine the appropriate amount of valuation allowance to record. Changes in the amount of the valuation allowance required could materially increase or decrease our provision for income taxes in a given period.

9. Litigation and Regulatory Investigations

a. We are involved in various legal proceedings in the U.S. and Canada and may experience unfavourable outcomes of such proceedings, or of future proceedings, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

We are a defendant in antitrust class actions in the U.S. related to our generic Adalat products as well as our Wellbutrin® XL product.

We are also a party to several other actions or may become a party to actions that could similarly impact our business. The above actions are more fully described at Item 3. "Legal Proceedings".

In all cases, the resolution of these actions could have a material adverse effect on our business, financial condition and results of operations or could cause the market price of our common shares to decline. In addition, we may continue to incur expenses associated with our defense of these actions, and the pending actions may divert the efforts and attention of our management team from normal business operations.

b. As a public company, we face risks related to class action lawsuits, including threatened litigation.

As with any other public company, we may become involved in legal proceedings, including class action securities litigation and derivative lawsuits, which may be brought against us. Court decisions and legislative activity may increase our exposure to any of these types of claims. In some cases, substantial non-economic or punitive damages may be sought against us. We currently maintain insurance coverage for some of these potential liabilities. Other potential liabilities may not be covered by insurance, insurers may dispute coverage or the amount of insurance may not be enough to cover damages awarded. In addition, certain types of damages may not be covered by insurance, and insurance coverage for all or certain forms of liability may become unavailable or prohibitively expensive in the future. Additionally, the outcome of litigation and other legal matters is always uncertain, and outcomes that are not justified by the evidence can occur. It is possible that an unfavourable resolution of one or more legal matters could result in a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

c. We are subject to exposure relating to product liability claims.

We face an inherent business risk of exposure to significant product liability and other claims in the event that the use of our products results, or is alleged to have resulted, in adverse effects. Furthermore, our products may cause, or may appear to have caused, adverse side effects (including death) or potentially dangerous drug interactions that we may not learn about or understand fully until the drug has been administered to patients for

Table of Contents

some time. As our products are used more widely and in patients with varying medical conditions, the likelihood of an adverse drug reaction, unintended side effect or incidence of misuse may increase. In addition, as part of our specialty CNS strategy, we have turned from a primarily reformulation focused business model to one where we are looking to in-license or acquire compounds, including NCEs. As a result, our product liability exposure is greater than when we focused primarily on reformulation of existing drugs. Product liability claims, regardless of their merits or their ultimate outcomes, are costly, divert management's attention and may adversely affect our reputation and demand for our products and may result in significant damages.

Our product liability insurance coverage may not be sufficient to cover our claims and we may not be able to obtain sufficient coverage at a reasonable cost in the future. An inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the growth of our business or the number of products we can successfully market. The withdrawal of a product following complaints, or a product liability claim could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

10. Senior Convertible Notes

On June 10, 2009, the Company issued \$350.0 million principal amount of senior convertible notes in a private placement (the "Notes"). See Item 5.G. "Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities - Sale of Unregistered Securities" for a description of the Notes.

a. We may not be able to refinance the Notes if required or if we so desire.

The Notes mature in 2014. We may need or desire to refinance all or a portion of the Notes or any other future indebtedness that we incur on or before the maturity of the Notes or such other indebtedness. We may not be able to refinance any of our indebtedness on commercially reasonable terms, if at all.

b. We may incur substantially more debt or take other actions which may affect our ability to satisfy our obligations under the Notes on a net-share settlement basis.

We may incur significant additional indebtedness in the future. We will not be restricted under the terms of the Notes or the indenture governing the Notes from incurring any such additional indebtedness, including any secured debt. In addition, the limited covenants applicable to the Notes do not require us to achieve or maintain any minimum financial results relating to our financial position or results of operations. The terms of the Notes do not limit our ability to recapitalize, incur additional debt or take a number of other actions, including repurchasing our common shares. Taking certain of these actions could diminish our ability to execute our stated intention to settle the Notes at maturity on a net-share settlement basis.

c. The issuance of a significant number of our common shares upon conversion of the Notes, or the perception of such issuance, could depress the market price of our common shares.

We have stated our intention to settle the Notes on a net share basis at their maturity. If we are not able to repay or refinance the principal amount of the Notes at maturity we would be required to settle in shares. The issuance of a substantial number of our common shares in connection with the conversion or settlement of the Notes could depress the market price of our common shares and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future issuances of our common shares would have on the market price of our common shares. Any transaction involving the issuance of common shares, or securities convertible into common shares, would result in dilution, which could be substantial, to holders of our common shares.

Table of Contents

11. Other Company Risks

a. If the companies in which we invest, or with which we partner or co-develop products, are not successful, it could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Actions by third parties who control the promotion, pricing, trade rebate levels, product availability or other items for products we supply to them could have a material adverse impact on our financial results.

Economic, governmental, industry and other factors outside our control affect companies with which we may partner or co-develop products. Some of the material risks relating to such companies include:

the ability of these companies to successfully develop, manufacture and obtain necessary governmental approvals for the products which serve as the basis for our investments in, or relationship with, such companies;

the ability of competitors of these companies to develop similar or more effective products, making the products developed by these companies difficult or impossible to market;

the ability of these companies to adequately secure patents for their products and protect their proprietary rights;

the ability of these companies to enter the marketplace without infringing upon competitors' patents or other intellectual property;

the ability of these companies to remain financially solvent;

the ability of these companies to remain technologically competitive; and

the dependence of these companies upon key scientific and managerial personnel.

We may have limited or no control over the resources that any such company may devote to develop the products for which we collaborate with them. Any such company may not perform as expected. These companies may breach or terminate their agreements with us or otherwise fail to conduct product discovery and development activities successfully, or in a timely manner. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

b. Our continued success is dependent on our continued ability to attract and retain key personnel. Any failure to attract and retain key personnel could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Much of our success to date has resulted from the particular scientific and management skills of personnel available to us. If these individuals are not available, we might not be able to attract or retain employees with similar skills. The continued availability of such individuals is important to our ongoing success. In addition, our success in implementing our specialty CNS strategy is also subject to our ability to further develop and retain competitive in-house R&D expertise in specialty CNS. If we are unsuccessful in attracting and retaining key employees, it could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

c. We may not have sufficient cash and may be limited in our ability to access financing for future expenditures, which may prevent us from executing on our CNS strategy and expanding our business and our portfolio of products.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

We may in the future need to incur additional debt or issue equity to fund acquisitions and other investments as contemplated by our specialty CNS strategy, to continue to pay dividends under our dividend policy, to fund working capital needs or to support our limited capital expenditure requirements. To the extent we are unable to renew our credit facility at its maturity in June 2012 or, in the interim, access new sources of capital at affordable rates, we may be unable to expand our business. If we raise funds through the issuance of new debt or equity, any debt securities or preferred shares issued may have rights and preferences and privileges

Table of Contents

senior to those of holders of our Notes and common shares. The terms of any new debt securities may impose restrictions on our operations that may have a material adverse effect on our financial condition. If we raise funds through the issuance of equity or convertible debt, the proportional ownership interests of our shareholders would be diluted.

In addition, we may choose to raise additional funds or, upon its maturity in June 2012, renew our credit facility in order to capitalize on perceived opportunities in the marketplace that may accelerate our growth objectives. Our ability to secure such financing in the future will depend in part on the prevailing capital market conditions as well as our business performance. We may not be successful in our efforts to secure financing, if needed, on terms satisfactory to us.

d. The general business and economic conditions in Canada, the U.S. and other countries in which we conduct business could have a material adverse impact on our liquidity and capital resources.

The market environment, the lack of liquidity in certain markets, the level of activity and volatility in capital markets and the stability of various financial markets may continue to have an impact on the availability of credit and capital in the near term. If uncertainties in these markets continue, or these markets deteriorate, it could have a material adverse impact on our liquidity, our ability to raise capital and interest costs.

e. The current business and economic conditions, coupled with the current regulatory environment, could have a negative impact on the pharmaceutical industry, which in turn could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

The current business and economic conditions in the national and global markets may negatively affect our operations in the future. Our revenues are contingent upon our ability to develop, license or otherwise acquire new commercially viable products and obtain associated regulatory approvals in multiple jurisdictions. Recently, companies globally have experienced volatility in the ability and cost to raise capital in the equity and debt markets or through traditional credit markets to fund business activities. In addition, the increased regulatory environment from the FDA has increased the costs of R&D for pharmaceutical companies. For example, on September 27, 2007, the FDAA was enacted, giving the FDA enhanced post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with post-approval regulatory requirements and potential restrictions on sales of approved products. Accordingly, faced with the uncertainty of the availability and cost of raising capital and the potential for increased costs due to regulatory changes, many pharmaceutical companies have recently cut costs, including canceling current clinical trials and not pursuing additional clinical trials. These changes in both the economic and regulatory environments directly affect our business, and, in the event we are unable to conduct necessary R&D activities, our ability to generate revenues could be hindered, which could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

f. We are exposed to risks relating to currency exchanges.

We operate internationally, but a majority of our revenue and expense activities and capital expenditures are denominated in U.S. dollars. Our only other significant transactions are denominated in Canadian dollars and our Canadian dollar expenses may not be entirely offset by our Canadian dollar revenues. We also face minor foreign currency exposure on the translation of our non-U.S. dollar functional operations from their local currencies to the U.S. dollar.

As of December 31, 2009, we do not have any outstanding forward foreign exchange contracts.

g. We are exposed to risks related to interest rates.

The primary objective of our policy for the investment of temporary cash surpluses is the protection of principal and, accordingly, we invest in investment grade securities with varying maturities, but typically less than

Table of Contents

90 days. Our credit facility bears interest based on U.S. Dollar London Interbank Offering Rates, U.S. dollar base rate, Canadian dollar prime rate or Canadian dollar bankers' acceptance rates. While we currently do not have any outstanding borrowings under this facility, to the extent we borrow material amounts under this facility in the future, a change in interest rates could have a material adverse effect on our results of operations, financial condition or cash flows.

As of December 31, 2009, we do not have any outstanding interest rate swap contracts.

h. Our securities are subject to price volatility.

Stock market trading prices for the securities of pharmaceutical and biotechnology companies, including our own, have historically been highly volatile, and such securities have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. For example, during the 12-month period ended December 31, 2009, the price of our common shares ranged from a low of \$9.26 to a high of \$15.50 on the New York Stock Exchange ("NYSE").

i. Our failure to comply with applicable environmental laws and regulations worldwide could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

We are subject to laws and regulations concerning the environment, safety matters, regulation of chemicals and product safety in the countries where we manufacture and sell our products or otherwise operate our business. These requirements include regulation of the handling, manufacture, transportation, use and disposal of materials, including the discharge of pollutants into the environment. In the normal course of our business, hazardous substances may be released into the environment, which could cause environmental or property damage or personal injuries, and which could subject us to remediation obligations regarding contaminated soil and groundwater or potential liability for damage claims. Under certain laws, we may be required to remediate contamination at certain of our properties regardless of whether the contamination was caused by us or by previous occupants of the property or by others.

In recent years, the operations of all companies have become subject to increasingly stringent legislation and regulation related to occupational safety and health, product registration and environmental protection. Such legislation and regulations are complex and constantly changing, and future changes in laws or regulations may require us to install additional controls for certain of our emission sources, to undertake changes in our manufacturing processes or to remediate soil or groundwater contamination at facilities where such cleanup is not currently required.

j. Rising insurance costs or our inability to obtain insurance could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

The cost of insurance, including insurance for directors and officers, workers' compensation, property, product liability and general liability insurance, may increase in future years. Such insurance may also become unavailable to us. For example, as a result of the recent settlements in a number of our legacy legal and regulatory proceedings, we will have exhausted our coverage under our Director and Officer liability insurance for claims reported in respect of our 2002-2004 policy period. Rising insurance costs or the inability to obtain insurance could have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline. In response to increased costs, we may increase deductibles or decrease certain coverages to mitigate cost increases. These increases, and our increased risk due to increased deductibles and reduced coverages, could have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

k. We are exposed to risks if we are unable to comply with laws and future changes to laws affecting public companies, including the Sarbanes-Oxley Act of 2002 ("SOX"), and also to increased costs associated with complying with such laws.

Any future changes to the laws and regulations affecting public companies, as well as compliance with existing provisions of SOX in the U.S. and Part XXIII.1 of the *Securities Act* (Ontario), R.S.O. 1990, c. S.5 (the "Ontario Securities Act") and related rules and applicable stock exchange rules and regulations, may cause us to incur increased costs as we evaluate the implications of new rules and respond to new requirements. As we are no longer exempt from certain requirements under the U.S. securities laws and applicable U.S. stock exchange rules and regulations due to the cessation of our status as a foreign private issuer effective January 1, 2010, we are now subject to additional U.S. filing, disclosure and compliance requirements, which may also cause us to incur an increase in costs. Delays, or a failure to comply with any new laws, rules and regulations that apply to us, could result in enforcement actions, the assessment of other penalties and civil suits. New laws and regulations could make it more expensive for us under indemnities we provide to our officers and directors and could make it more difficult for us to obtain certain types of insurance, including liability insurance for directors and officers; as such, we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on the Board of Directors or as officers. We may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services all of which could cause our general and administrative costs to increase beyond what we currently have planned. We are continuing to evaluate and monitor developments with respect to these laws, rules and regulations, and we cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

We are required annually to review and report on the effectiveness of our internal control over financial reporting in accordance with applicable securities laws. The results of this review are reported in this Annual Report on Form 10-K and in our MD&A. Our registered public accounting firm is also required to report on the effectiveness of our internal control over financial reporting.

If we fail to maintain effective internal controls over our financial reporting, there is the possibility of errors or omissions occurring or misrepresentations in our disclosures which could have a material adverse effect on our business and financial condition and the value of our common shares.

Item 1B. Unresolved Staff Comments.

Not applicable.

Table of Contents**Item 2. Properties.**

We believe that we have sufficient facilities to conduct our operations during 2010. The following table lists the location, use, size and ownership interest of our principal properties:

Location	Use	Size	Ownership
Mississauga, Ontario, Canada	Corporate office, sales, marketing and administration	79,400 Sq. Ft.	Leased
Christ Church, Barbados	Strategic planning; oversight and management of product sales, product development, supply chain and logistics, contract management, licensing, intellectual property management and administration	23,275 Sq. Ft.	Owned
Toronto, Ontario, Canada	Contract research and development and administration	33,000 Sq. Ft.	Owned
	Contract research and development	13,000 Sq. Ft.	Leased
Steinbach, Manitoba, Canada	Manufacturing and warehousing	250,000 Sq. Ft.	Owned
Chantilly, VA, USA	Research and development services	80,000 Sq. Ft.	Leased
	Warehousing	10,000 Sq. Ft.	Leased
	Vacated and sublet	50,000 Sq. Ft.	Leased
Bridgewater, NJ, USA	Administration	110,000 Sq. Ft.	Leased
Dorado, Puerto Rico	Warehousing	145,000 Sq. Ft.	Leased ⁽¹⁾
Carolina, Puerto Rico	Manufacturing	25,000 Sq. Ft.	Owned
	Warehousing	10,000 Sq. Ft.	Leased
Dublin, Ireland	Distribution of pharmaceutical products and supply chain services	1,000 Sq. Ft.	Leased

(1) To be closed in 2010, with certain manufacturing processes to be transferred to the Steinbach, Manitoba facility.

Manufacturing Facilities

We own and lease space for manufacturing, warehousing, research, development, sales, marketing, and administrative purposes. We currently operate two modern, fully integrated pharmaceutical manufacturing facilities located in Steinbach, Manitoba and Carolina, Puerto Rico. These facilities meet FDA-mandated and TPD-mandated GMP. These facilities are inspected on a regular basis by regulatory authorities, and our own internal auditing team ensures compliance on an ongoing basis with such standards.

In May 2008, in connection with the introduction of our specialty CNS strategy, we announced our intention to close our Puerto Rico manufacturing facilities, and transfer certain manufacturing processes to our Steinbach, Manitoba facility, over a period of 18 to 24 months. The closure of the Puerto Rico facilities will reduce our cost infrastructure and improve the capacity utilization of our manufacturing operations. We completed the sale of the Dorado facility in January 2010, and have entered an agreement to lease back the premises until March 31, 2010. The Carolina site is expected to remain open indefinitely due to increased demand for products manufactured in this plant. We are continuing to actively market the Carolina facility. We do not anticipate any impact to our existing revenue base due to the consolidation of our manufacturing facilities.

We have owned our Steinbach, Manitoba facility since 1992. In 2006, we completed a \$31.0 million expansion at that facility which increased total size to 250,000 square feet, providing additional manufacturing capacity and capability. Among the products manufactured in Steinbach in 2008 were Wellbutrin® XL, Ultram® ER, Cardizem® LA, and Tiazac® XC.

Table of Contents

The Carolina, Puerto Rico facility totals 35,000 square feet, including a 25,000 square-foot owned manufacturing facility and a 10,000 square-foot leased warehouse space. This plant is specially constructed for the high volume production of controlled release beads.

Other Facilities

Our corporate headquarters is located in Mississauga, Ontario. In connection with our objective of monetizing our non-core assets, in November 2009, we completed a sale/leaseback transaction in respect of our corporate headquarters for net proceeds of \$17.8 million. Included in this transaction was a vacant parcel of land adjacent to this facility, which was sold but not leased back. We recognized a loss on disposal of \$11.0 million on the transaction date. We will continue to occupy the facility under a 20-year operating lease at market rental rates.

Our principal operating subsidiary, Biovail Laboratories International SRL ("BLS") is based in Barbados, West Indies. In 2008, we relocated from our previous leased facility to a newly constructed facility in Christ Church. This facility is used for strategic planning, and the oversight and management of product sales and related operations, product development, supply chain and logistics, contract management, licensing, intellectual property management and administration.

The Bridgewater, New Jersey facility, which we began leasing in 2003, is used for our U.S. operations including certain clinical and R&D administration.

The Chantilly, Virginia facility continues to perform primarily R&D services and to be a technology transfer site.

In July 2009, we completed the sale of our Dublin, Ireland R&D facility for net cash proceeds of \$5.2 million.

The Dublin, Ireland office, which we began leasing in August 2009, is used as an office for the management of product sales and distribution and the provision of supply chain services.

We believe our facilities are in satisfactory condition and are suitable for their intended use, although some limited investments to improve our manufacturing and other related facilities are contemplated, based on the needs and requirements of our business.

Item 3. 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

Table of Contents

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 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 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.

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

On March 24, 2008, the SEC filed a civil complaint against the Company, Eugene Melnyk, the Company's former Chairman and Chief Executive Officer ("CEO"), Brian Crombie, the Company's former Chief Financial Officer ("CFO"), and two former officers, Kenneth Howling and John Miszuk, related to the matters investigated by the SEC. The Company has entered into a Consent Decree with the SEC in which it has not admitted to the civil charges contained in the complaint but has paid \$10.0 million to the SEC to fully settle the matter. As part of the settlement, the Company has also agreed to an examination of its accounting and related functions by an independent consultant. The settlement does not include the four individuals although the Company understands Mr. Howling has also reached a settlement with the SEC. The matter is proceeding as against former officers Mr. Melnyk, Mr. Crombie and Mr. Miszuk in the ordinary course and no hearing date has been set. The Company is indemnifying these individuals for their legal costs.

In the Spring of 2007, the Company was contacted by the USAO for the Eastern District of New York ("EDNY"), which informed the Company that the office is conducting an investigation into the same matters that the SEC is investigating. The USAO for the EDNY conducted interviews of several of the Company's current or former employees and requested documents related to fiscal years 2002 and 2003. The Company cooperated with this request and has not been contacted further. The Company cannot predict the outcome or timing of when this matter may be resolved.

Over the last few years, the Company received a number of communications from the Ontario Securities Commission (the "OSC") relating to its disclosure, and/or seeking information pertaining to certain financial periods. Similar to the SEC, the OSC advised the Company that it had investigated whether the Company improperly recognized revenue for accounting purposes in relation to the interim financial statements filed by the Company for each of the four quarters in 2001, 2002 and 2003, and the first quarter of 2004, and related disclosure issues. The OSC also investigated whether the Company provided misleading disclosure concerning the reasons for its forecast of a revenue shortfall in respect of the three-month period ending September 30,

Table of Contents

2003, and certain transactions associated with a corporate entity that the Company acquired in 2002, as well as issues relating to trading in its common shares. These issues included whether the Company's insiders complied with insider reporting requirements, whether persons in a special relationship with the Company may have traded in its common shares with knowledge of undisclosed material information, whether certain transactions may have resulted in, or contributed to, a misleading appearance of trading activity in the Company's securities during 2003 and 2004 and whether certain registrants (who are the Company's former directors) may have had conflicts of interest in relation to the trading of the Company's common shares.

Pursuant to a Notice of Hearing dated July 28, 2006, the staff of the OSC gave notice that an administrative hearing pursuant to sections 127 and 127.1 of the Ontario Securities Act would be held related to the issues surrounding the trading in the Company's common shares. The respondents in the hearing included former Chairman and CEO Eugene Melnyk and a former director of the Company, among others. The Company was not a party to this proceeding. The proceeding as against Eugene Melnyk has been settled. In a decision released June 20, 2008, a panel of the OSC found that the former director acted contrary to the public interest and breached section 107 of the Ontario Securities Act when he (a) failed to provide the Company with accurate information concerning common shares over which he shared control and direction, (b) failed to file insider reports in respect of certain trades in the Company's securities and (c) engaged in a high volume of discretionary trading in its securities during blackout periods imposed by the Company.

Pursuant to a Notice of Hearing dated March 24, 2008, the staff of the OSC gave notice that an administrative hearing would be held related to the other matters investigated. The notice named the Company, former Chairman and CEO Eugene Melnyk, former CFO Brian Crombie, and Kenneth Howling and John Miszuk, two former officers. On January 9, 2009, the OSC approved a settlement reached with the Company. Pursuant to the terms of this settlement, the Company paid approximately \$5.3 million in costs and sanctions and agreed to the appointment of an independent consultant to examine and report on the Company's training of its personnel concerning compliance with financial and other reporting requirements under applicable securities laws in Ontario. On January 27, 2009, the OSC approved a settlement with Messrs. Howling and Miszuk and on February 10, 2009, the OSC approved a settlement with Mr. Crombie. The Company understands that the matter is proceeding against Mr. Melnyk. The hearing has now concluded and a decision is under reserve.

Securities Class Action

On October 8, 2008, a proposed securities class action lawsuit was filed in the U.S. District Court Southern District of New York against the Company, its current Chairman, one current officer and two former officers. The complaint was filed on behalf of all persons and entities that purchased the Company's securities from December 14, 2006 through July 19, 2007. The complaint related to public statements alleged to have been made in respect of Aplenzin® (bupropion hydrobromide tablets) during the product's U.S. regulatory approval process. The Company believed the claim was without merit and filed a motion to dismiss this action in its entirety. The motion was granted and the action was dismissed with prejudice on May 8, 2009. Sanctions were thereafter sought by the Company. The decision granting the motion to dismiss was appealed by the plaintiffs. Pursuant to an agreement reached between the parties, the plaintiffs agreed to dismiss the appeal in exchange for the Company withdrawing its request for sanctions. On June 26, 2009, the appeal was dismissed. This matter has concluded.

Antitrust

Several class action and individual action complaints in multiple jurisdictions have been commenced jointly against the Company, Elan Corporation plc ("Elan") and 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.

Table of Contents

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 D.C. 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.

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.

The Company has now reached 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 and made no admission of wrong doing. The Opt-out actions will be dismissed.

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.

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.

Table of Contents

Intellectual Property

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

The defendants served the Company with a Statement of Defence and Counterclaim on May 15, 2006. The Company delivered its reply on May 30, 2006, and pleadings closed in June 2006. Pursuant to an agreement by the parties, the claim and counterclaim have been dismissed.

In August 2006, Sandoz brought an action against the Company under section 8 of the 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 damages in another unrelated action. The Supreme Court of Canada has now denied leave. A trial will likely occur in the later half of 2010 or early 2011, depending on the court's schedule.

On November 7, 2008, Novopharm Limited (now Teva Canada) brought an action against the Company under section 8 of the PMNOC Regulations demanding damages for having been kept off the market with its generic version of Wellbutrin® SR due to prohibition proceedings taken against them by the Company under the PMNOC Regulations. The prohibition proceedings were subsequently dismissed in January 2005. The parties reached an agreement to resolve this matter. The action has now been dismissed.

On January 18, 2010, a Canadian Federal Court judge presiding over Biovail Corporation and Depomed, Inc. v. Apotex Inc. 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 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 to market in Canada its generic version of 500 mg Glumetza® by Health Canada on February 4, 2010. 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 filed a Claim for infringement against Apotex in Canadian Federal Court on February 8, 2010.

Par filed an 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 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

Table of Contents

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, and was granted, a motion for dismissal of BLS from the cases. 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.

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 Court of Appeals for the Federal Circuit on September 3, 2009. OMI also appealed its dismissal at the same time, but the appeal has been withdrawn. 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 (a wholly owned subsidiary of Ortho-McNeil-Janssen Pharmaceuticals, Inc.), launched our 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, and was granted, a motion for dismissal from the case. OMI has also been dismissed from this case. 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"), who have 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.

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.

Table of Contents

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 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 that 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 agreement in November, 2009 and, subsequently, BLS and Wyeth have 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.

On or about June 26, 2008, BLS received Notices of Paragraph IV Certification from Sun Pharmaceutical Industries, Ltd., India ("Sun India") for diltiazem hydrochloride extended release capsules, 120 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 India in the U.S. District Court of New Jersey alleging patent infringement of U.S. Patent Nos. 5,470,584, 5,286,497 and 5,439,689 pursuant to the provisions of the Hatch-Waxman Act. BLS has also sought declaratory judgment of infringement for all three patents. These suits are expected to result in a 30-month stay of the FDA approval of the 120 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 India delivered its Answer and Counterclaim, which include declarations of non-infringement, invalidity and unenforceability as well as certain antitrust allegations. This case is currently stayed, pending settlement discussions.

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 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 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. No Markman hearing to determine claim scope and meaning nor a trial date have yet been set.

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

Table of Contents

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 hearing has been scheduled for late May 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 Bupropion 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 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 and/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 and/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.

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 Bupropion 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 bupropion hydrobromide are not infringed and/or invalid. The Company will be filing suit against Paddock no later than March 8, 2010.

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.

On January 26, 2007, the Company was found to have breached the terms of a protective order in a securities class action then proceeding against it and certain of its former officers in New York Federal Court (the "New York class action"). The New York class action was settled in December 2008. Specifically, the Company was found to have breached the terms of the protective order by using documents obtained from a non-party in the S.A.C. Complaint. The Court ordered that the Company and its counsel return copies of the documents and redact the S.A.C. Complaint accordingly. On February 22, 2007, the Company filed an Amended Complaint. On September 10, 2007, the Company resolved a motion for sanctions previously pending in the New York class action in connection with the breach of the protective order referred to above. As part of that resolution, the Company dismissed defendant Maris from this action and filed a First Amended Complaint on October 3, 2007.

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").

Table of Contents

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 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 defend once served.

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 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 product formerly owned by Biovail, was 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 on or before April 19, 2010.

On May 6, 2008, BLS commenced an arbitration under Financial Industry Regulatory Authority rules against an investment institution at which it held a cash management account seeking \$26.8 million in compensatory damages and \$53.6 million in punitive damages. The Statement of Claim alleged that the investment institution, as non-discretionary manager of BLS's cash management account, fraudulently or

Table of Contents

negligently, and in breach of the parties' customer agreement, invested BLS's assets in auction rate securities, which were not among BLS's approved investments. The investment institution subsequently delivered its Answer and Response. A hearing was scheduled to commence on July 8, 2009. The matter has now been settled as between the parties for payment to BLS in the amount of \$22.0 million. BLS continues to hold the auction rate securities.

Item 4. Submission of Matters to a Vote of Security Holders.

Not applicable.

Executive Officers of the Registrant

The name and age as of February 24, 2010 and position with us of each of the members of senior management are set forth below.

Name	Age	Position
Biovail Corporation		
William (Bill) Wells	49	Chief Executive Officer
Margaret (Peggy) Mulligan	51	Senior Vice-President, Chief Financial Officer
Gilbert Godin	51	Executive Vice-President and Chief Operating Officer
Mark Durham	50	Senior Vice-President, Human Resources and Shared Services
Gregory Gubitz	52	Senior Vice-President, Corporate Development and General Counsel
Biovail Laboratories International SRL		
William (Bill) Wells	49	President
Michel Chouinard	53	Chief Operating Officer
Dr. H. Christian Fibiger	66	Senior Vice-President, Chief Scientific Officer
BTA Pharmaceuticals, Inc.		
Christine C. Mayer	51	Senior Vice-President, Business Development Services

Mr. Wells was appointed the Chief Executive Officer of Biovail Corporation and the President of BLS effective May 1, 2008. Mr. Wells was originally elected to the Board of Directors in June 2005. Mr. Wells served as the Lead Director of the Board from June 30, 2007 to April 18, 2008. Mr. Wells is responsible for the operational and general management of our Company and has accountability for all aspects of our business, including marketing, sales, R&D, and manufacturing. As President of BLS, the Company's key operating subsidiary, Mr. Wells is responsible for all strategic and executive operating decisions relating to BLS' business, including its R&D strategies, budgets, priorities and programs. Mr. Wells' responsibilities as President of BLS also includes the review and the decision-making authority over all significant product and technology acquisitions and development and BLS' supply and distribution agreements. Mr. Wells is also responsible for developing and maintaining strategic alliances and important customer relationships. Prior to joining us on May 1, 2008, Mr. Wells was the Chief Financial Officer of Loblaw Companies Limited ("Loblaw"), Canada's largest food distributor and a leading provider of general merchandise products, drugstore products, and financial products and services, a position from which he resigned immediately prior to joining Biovail as our Chief Executive Officer and President of BLS. Mr. Wells also served as a director or officer of a number of subsidiaries of Loblaw. Prior to his position at Loblaw, Mr. Wells served as Chief Financial Officer of Bunge Limited ("Bunge"), a U.S.-headquartered company, whose shares are listed on the NYSE, in the global agribusiness, fertilizer and food product industries, and also served as a director or officer of a number of other subsidiaries and joint ventures of Bunge since January 2000. Mr. Wells is versed in corporate governance matters, having led Bunge's initial public offering on the NYSE, managed its SOX compliance process and overseen its investor relations program. Prior to joining Bunge, Mr. Wells spent 10 years in senior financial management at McDonald's Corporation in the U.S. and Brazil. Mr. Wells is currently a Trustee and a member of the audit committee of the Lakefield College School Foundation, a member of the investment committee of

Table of Contents

the Uruguay International Venture Capital Fund and formerly a member of the Standard & Poor's Corporate Issuer Advisory Board. Mr. Wells holds a Masters degree in International Business from the University of South Carolina and a Bachelor's degree in Philosophy and English from the University of Western Ontario.

Mrs. Mulligan was appointed Senior Vice-President and Chief Financial Officer of Biovail Corporation effective September 3, 2008. Mrs. Mulligan has responsibility for finance, including consolidated financial planning and reporting, information technology, risk and financial operations. Her responsibilities also include the development of strategies and programs to proactively position our Company and business to disparate groups of external stakeholders, including the investment community, media, governments, the medical community and the general public. Mrs. Mulligan was most recently a Principal at Priiva Consulting Corporation, a leading game theory consulting practice. Prior to that, she served as Executive Vice-President, Chief Financial Officer and Treasurer of Linamar Corporation, a publicly traded auto components supplier, from 2005 to 2007. Prior to Linamar, Mrs. Mulligan spent more than 11 years with The Bank of Nova Scotia (Scotiabank), most recently as Executive Vice-President, Systems and Operations, where she was responsible for operational processes and technology across Canada and in more than 50 other countries. She directed a staff of over 3,000 and managed a broad range of critical information-technology functions. Earlier in her career at Scotiabank, Mrs. Mulligan served as Senior Vice-President, Audit & Chief Inspector. Before joining Scotiabank, Mrs. Mulligan was an Audit Partner with PricewaterhouseCoopers in Toronto. Mrs. Mulligan currently serves on the board of Ontario Power Generation Inc. and recently served on the board of Resolve Business Outsourcing Income Fund. Her extensive community involvement has included serving as a Trustee of the Ontario Science Centre, a Governor of Appleby College and a Governor of the University of Waterloo. Mrs. Mulligan holds a B. Math (Honours) from the University of Waterloo and was named a Fellow of the Institute of Chartered Accountants of Ontario in 2003.

Mr. Godin was appointed Executive Vice-President and Chief Operating Officer of Biovail Corporation in June 2007. Mr. Godin is responsible for our commercial, scientific and product-development capabilities, as well as our manufacturing, contract-development and business development services. Mr. Godin joined us in May 2006 from MDS Pharma Services, a contract research organization that provides drug-discovery and development services to pharmaceutical and biotechnology companies and a business unit of MDS Inc. ("MDS"). During his eight years' tenure at MDS, he held a series of progressively responsible executive positions in Canada and the U.S., including that of President of MDS Pharma Services, a business unit of MDS, from October 2004 to April 2006. Before joining MDS Pharma Services in 1999, Mr. Godin spent eight years with Schering-Plough Corporation, a publicly traded company listed on the NYSE, where he held the technical leadership position in Canada and a business-unit management role in France. He has also held several positions with business and operational accountabilities during his seven-year tenure at L'Oreal Canada Inc. Mr. Godin has an M.B.A. from the John Molson School of Business at Concordia University in Montreal. He also holds an engineering degree from Sherbrooke University in Quebec.

Mr. Durham is Senior Vice President, Human Resources and Shared Services of Biovail Corporation, and joined us as Vice-President, Corporate Human Resources in February 2003. Mr. Durham came to us from Pharmacia Corporation, where he served as Vice-President for Human Resources for Global Marketing and North American country operations from 2000 to 2003. Prior to that time he spent 15 years with Pharmacia & Upjohn Inc. and held senior human resource positions in the U.S., Asia and Canada. In addition to human resources, Mr. Durham has held positions in manufacturing and sales operations. Mr. Durham is a graduate of Carleton University in Ottawa, where he received his B.A. Hons. in political science and economics.

Mr. Gubitz was appointed Senior Vice-President, Corporate Development of Biovail Corporation, in June 2007, and General Counsel of Biovail Corporation effective September 1, 2009. As Senior Vice-President, Corporate Development, Mr. Gubitz is responsible for Biovail's corporate development programs, including mergers and acquisitions. He also assists our Company in our strategic planning process. As general counsel, Mr. Gubitz is responsible for our overall legal operations. Mr. Gubitz joined us in March 2006 from MDS Capital Corp. ("MDS Capital"), a North American venture-capital company focused exclusively on life sciences, where he was Chief Operating Officer. He spent 10 years with MDS Capital in various senior roles, with accountability for all operational matters, institutional fundraising, investor relations, finance and legal affairs. Mr. Gubitz also became Chairman of MDS Capital's Investment Committee in 2004. Before joining MDS Capital in 1996, Mr. Gubitz was a partner practicing corporate and securities law at a leading Canadian law firm.

Table of Contents

He was called to the Bar in the Province of Ontario in 1984. Mr. Gubitz holds an LL.B. and a B.A. from McGill University in Montreal.

Mr. Chouinard is Chief Operating Officer of BLS in Barbados, and a member of its Board of Managers. He is responsible for the day to day management, of all aspects of BLS's business. Mr. Chouinard came to us in March 2000 from BioChem Pharma Inc., where he was Vice President of Global Commercialisation for vaccines for approximately three years. Prior to that he spent 18 years with American Cyanamid Company (Lederle), GlaxoSmithKline Inc. and Abbott, and held senior commercial and operations positions in the U.S. and Canada. Since joining our Company, Mr. Chouinard has held the positions of Vice President and General Manager of BPC and Vice President, Manufacturing Planning and Strategy of Biovail Corporation, before joining BLS in February 2006. Mr. Chouinard holds a B.A. (with a major in economics) from McGill University in Montreal.

Dr. Fibiger was appointed Senior Vice-President, Chief Scientific Officer of BLS effective November 24, 2008. Dr. Fibiger is actively involved in implementing BLS' drug development strategy, which includes the review of potential product developments and acquisitions and he is ultimately responsible for the strategic aspects of BLS' product development pipeline. Dr. Fibiger also serves as an advisor to BLS' President regarding the field of neuroscience from scientific, development and commercial perspectives. Dr. Fibiger, a Fellow of the American College of Neuropsychopharmacology, was most recently Chief Scientific Officer of MedGenesis Therapeutix Inc., a privately held biopharmaceutical company based in Victoria, British Columbia. From 2003 to 2007, Dr. Fibiger served as Vice-President and Global Therapeutic Area Head of Neuroscience for Amgen Inc. Prior to that, he served for five years at Eli Lilly & Co. as Vice-President of Neuroscience Discovery Research and Clinical Investigation. From 1972-1998, Dr. Fibiger was Professor and Head of the Division of Neurological Sciences and Chair of the University Graduate Program in Neuroscience at the University of British Columbia. Dr. Fibiger has received many honours for his research contributions. Dr. Fibiger received his Ph.D in Psychopharmacology from Princeton University.

Ms. Mayer is Senior Vice-President, Business Development Services at BTA. Ms. Mayer is responsible for leading the Business Development Services Team, which provides services in respect of identifying and analyzing new business and product licensing opportunities for us. Ms. Mayer joined us in May 2005 and was promoted to her current position effective January 1, 2007. Ms. Mayer has over 20 years of broad business experience in the pharmaceutical industry across many disciplines and therapeutic areas. Before joining us, she was Vice President of Global Business Development at sanofi-aventis (formerly Aventis), a publicly traded company listed on the NYSE, where she spent six years. Prior to that, she worked for 13 years at Johnson & Johnson, a publicly traded company listed on the NYSE, in the pharmaceutical sector, holding positions in various disciplines, including business development, marketing, sales and finance. Ms. Mayer also has four years of previous experience in large public accounting firms. Ms. Mayer holds an M.B.A. from Rutgers University in New Jersey and a B.A. from Glassboro College (now Rowan University) in New Jersey.

Table of Contents**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.****A. Market Information**

Our common shares are traded on the NYSE and on the Toronto Stock Exchange ("TSX") under the symbol "BVF". The following table sets forth the high and low per share sales prices for our common shares on the NYSE and TSX for the periods indicated.

	Common Shares			
	NYSE		TSX	
	High \$	Low \$	High C\$	Low C\$
2008				
Quarter 1	14.90	10.00	14.53	10.30
Quarter 2	12.96	9.53	12.91	9.64
Quarter 3	11.27	9.27	11.71	9.70
Quarter 4	9.88	6.65	11.69	7.84
2009				
Quarter 1	12.15	9.41	14.53	10.30
Quarter 2	13.75	9.26	15.90	10.90
Quarter 3	15.50	12.14	16.59	13.45
Quarter 4	15.49	12.91	16.55	13.78
2010				
January	16.14	14.02	16.57	14.60
February 1 to 24	15.10	13.64	15.95	14.62

Source: NYSEnet, TSX Historical Data Access

Market Price Volatility of Common Shares

Market prices for the securities of pharmaceutical and biotechnology companies, including our securities, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in our operating results, the aftermath of public announcements by us, concern as to safety of drugs and general market conditions can have an adverse effect on the market price of our common shares and other securities.

B. Holders

The approximate number of holders of record of our common shares as of February 24, 2010 is 1,245.

C. Dividends

In May 2009, the Board of Directors approved a modification to our dividend policy, which now contemplates a quarterly dividend of \$0.09 per common share. Each dividend declaration 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. The policy is reviewed by the Board of Directors from time to time with regard to our capital requirements, strategic and business development considerations, operations and results and any changes thereto.

We continue to believe that current operations and our existing pipeline products should generate sufficient cash flows to sustain our current quarterly dividend. However, business development activities designed to

Table of Contents

accelerate our specialty CNS strategy will have first priority over our cash flows and resources. Accordingly, the Board of Directors and management will continue to review the dividend policy on an ongoing basis to determine if a revision to the dividend policy, including the potential cancellation of the dividend, may be necessary.

Except for the contemplation of a quarterly dividend in accordance with our dividend policy, we have no specific procedure for the setting of the date of dividend entitlement but, in accordance with applicable laws, regulations and rules, will set a record date for share ownership to determine entitlement to any dividends declared. We have no specific procedures for holders not resident in Canada to claim dividends and will mail dividends to non-residents of Canada in the same manner as to holders resident in Canada. We have appointed CIBC Mellon to be the paying agent for dividends in the U.S. and elsewhere.

During 2008 and 2009, we declared dividends per common share as follows:

Date Declared	Dividend per Share	Payment Date
March 12, 2008	\$ 0.375	April 3, 2008
May 7, 2008	\$ 0.375	May 30, 2008
August 12, 2008	\$ 0.375	September 3, 2008
November 5, 2008	\$ 0.375	January 5, 2009
February 26, 2009	\$ 0.375	April 6, 2009
May 6, 2009	\$ 0.09	July 6, 2009
August 6, 2009	\$ 0.09	October 5, 2009
November 5, 2009	\$ 0.09	January 4, 2010
Total	\$ 2.145	

On February 24, 2010, we declared a cash dividend of \$0.09 per common share, payable on April 5, 2010.

See Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operation Selected Annual Information Cash Dividends", for additional details about our dividend payments.

D. Restrictions on Share Ownership by Non-Canadians

There are no limitations under the laws of Canada or in our organizational documents on the right of foreigners to hold or vote securities of our Company, except that the *Investment Canada Act (Canada)* (the "Investment Canada Act") may require review and approval by the Minister of Industry (Canada) of certain acquisitions of "control" of our Company by a "non-Canadian".

Investment Canada Act

The Investment Canada Act applies to every acquisition of control of a Canadian business by a non-Canadian. The acquisition of a majority of the voting interests of an entity or of a majority of the undivided ownership interests in the voting shares of an entity that is a corporation is deemed to be an acquisition of control of that entity. In the case of a corporation, the acquisition of less than a majority but one-third or more of the voting shares of a corporation or of an equivalent undivided ownership interest in the voting shares of the corporation is presumed to be an acquisition of control of that corporation unless it can be established that, on the acquisition, the corporation is not controlled in fact by the acquirer through the ownership of voting shares. The acquisition of all or substantially all of the assets used in carrying on a Canadian business also constitutes an acquisition of control. An acquisition of control of a Canadian business by a non-Canadian is either reviewable (a "Reviewable Transaction"), in which case it is subject to both a reporting obligation and an approval process, or notifiable (a "Notifiable Transaction"), in which case it is subject to only a post-closing reporting obligation. A transaction is a Reviewable Transaction or a Notifiable Transaction based on whether a prescribed monetary threshold is exceeded.

Table of Contents

A direct acquisition of control of a Canadian business by a non-Canadian through the acquisition of the voting interests of a Canadian entity or all or substantially all of the assets used in carrying on a Canadian business is a Reviewable Transaction if, in the case of an acquisition of voting interests, the aggregate value of the assets acquired (including assets situated outside of Canada), or, in the case of an acquisition of assets, the aggregate value of the assets in Canada acquired, is equal to or greater than C\$5 million. A substantially higher threshold applies, however, where the purchaser qualifies as a "WTO investor" or the Canadian business being acquired is controlled by a non-Canadian that qualifies as a WTO investor. For these transactions, the WTO threshold, for transactions completed in 2010, is expected to be C\$299 million (this threshold will become official once published in the *Canada Gazette*). The WTO threshold will change to C\$600 million upon the enactment of new regulations under the Investment Canada Act. The determination of the threshold will be based on a new test of "enterprise value" rather than asset value (although asset value may continue to be the relevant threshold for asset transactions). The manner for determining "enterprise value" will be set out by regulation. An indirect acquisition of a Canadian business by a non-Canadian is a Reviewable Transaction if either the value of the Canadian business' assets exceed C\$50 million and more than 50% of the value of the assets acquired are located outside of Canada, or exceeds C\$5 million and more than 50% of the value of the assets acquired are located in Canada. However, where the purchaser qualifies as a WTO investor or the Canadian business being acquired is controlled by a non-Canadian that qualifies as a WTO investor, the transaction qualifies as a Notifiable Transaction and not a Reviewable Transaction.

In the case of a Reviewable Transaction, the non-Canadian acquirer must submit an application for review with the prescribed information. The responsible Minister is then required to determine whether the Reviewable Transaction is likely to be of net benefit to Canada, taking into account the assessment factors specified in the Investment Canada Act and any written undertakings that may have been given by the non-Canadian acquirer. The Investment Canada Act contemplates an initial review period of up to 45 days after filing; however, if the responsible Minister has not completed the review by that date, the Minister may unilaterally extend the review period by up to 30 days (or such longer period as may be agreed to by the applicant and the Minister) to permit completion of the review. Subject to a few limited exceptions, a direct acquisition of a Canadian business that constitutes a Reviewable Transaction cannot be completed until the Minister responsible for administering the Investment Canada Act is satisfied, or is deemed to be satisfied, that the transaction "is likely to be of net benefit to Canada".

In the case of a Notifiable Transaction, a non-Canadian acquirer must submit a notice with the prescribed information at any time before or within 30 days following completion of the transaction.

In March 2009, the Investment Canada Act was amended to provide that any investment by a non-Canadian in a Canadian business, even where control has not been acquired, can be reviewed on grounds of whether it may be injurious to national security. Where an investment is determined to be injurious to national security, Cabinet can prohibit closing or, if closed, can order the investor to divest control. Short of a prohibition or divestment order, Cabinet can impose terms or conditions on the investment or can require the investor to provide binding undertakings to remove the national security concern.

Competition Act

Part IX of the *Competition Act* (Canada) (the "Competition Act") requires that a pre-merger notification filing be submitted to the Commissioner of Competition (the "Commissioner") in respect of certain classes of merger transactions that exceed certain prescribed thresholds. The thresholds applicable to the acquisition of the shares of a public corporation, or the acquisition of the assets of a corporation, are as follows:

Size of Parties: the parties to the transaction, together with their affiliates (as defined under the Act), must have assets in Canada that exceed C\$400 million in aggregate value, or have gross annual revenues from sales in, from or into Canada, that exceed C\$400 million in aggregate value;

Size of Transaction: generally, the aggregate value of the assets in Canada that are acquired through the transaction, or the gross revenues generated from sales in or from Canada from those assets, exceed C\$70 million (this threshold may increase annually by the Minister of Industry in accordance with an index formula set out in the Competition Act); and

Table of Contents

Size of Equity (in the case of a share transaction): the acquisition of more than 20% of the voting shares of a public corporation or, where this threshold has been exceeded but the acquirer owns less than a majority of the voting shares of a public corporation, the acquisition of more than 50% of the voting shares of a public corporation.

Note that in the case of an amalgamation, the Size of Transaction threshold is met only if the threshold set out above is exceeded by both the continuing corporation and at least two of the amalgamating corporations (except that in the case of the amalgamating corporations, the relevant revenues are sales in, from or into Canada). The Competition Act and the Notifiable Transactions Regulations thereto set out the basis upon which asset values and gross revenues are to be determined. Generally speaking, the relevant period for determining whether the thresholds are met is the period covered by the last audited financial statements, although complex rules apply under the Notifiable Transactions Regulations.

If a proposed transaction exceeds the above-described thresholds, subject to certain exceptions, a notification filing must be submitted to the Commissioner and the statutory waiting period must expire or be terminated early or waived by the Commissioner before the transaction can be completed. The waiting period is 30 calendar days after the day on which the parties to the proposed transaction submit the prescribed information, provided that, before the expiry of this period, the Commissioner has not notified the parties that she requires additional information that is relevant to the Commissioner's assessment of the proposed transaction (a "Supplementary Information Request"). In the event that the Commissioner provides the parties with a Supplementary Information Request, the parties cannot complete their proposed transaction until 30 calendar days after the day in which the parties complied with the Supplementary Information Request. At the end of the statutory waiting period, the parties can legally complete their transaction, unless the Commissioner has applied to the Competition Tribunal (a special purpose tribunal) for an interim order prohibiting closing. The Commissioner can apply to the Competition Tribunal for two such orders, each with a maximum period of 30 days (60 days in the aggregate). A transaction may be completed before the end of the applicable waiting period if the Commissioner notifies the parties that she does not, at such time, intend to challenge the transaction by making an application under Section 92 of the Competition Act. The Commissioner retains the right to challenge a transaction before the Competition Tribunal on substantive grounds (as described below) under Section 92 of the Competition Act at any time before, or within one year after, closing.

The parties to a transaction that is subject to pre-merger notification have an obligation to submit a pre-merger notification filing, and the waiting period will not begin until the parties have submitted a complete notification filing. The Competition Act prescribes special rules for hostile bids involving corporations whereby the bidder may unilaterally initiate the statutory waiting period by submitting its pre-merger notification filing.

The Commissioner may, upon request, issue an advance ruling certificate ("ARC") in respect of a proposed transaction where she is satisfied that she would not have sufficient grounds on which to apply to the Competition Tribunal for an order under Section 92 of the Competition Act. If the Commissioner issues an ARC, the parties are exempted from having to file a notification and the Commissioner is prohibited from challenging the transaction solely on the basis of information that is the same or substantially the same as the information on the basis of which the ARC was issued.

If the Commissioner is not prepared to issue an ARC, she may nevertheless issue a "no action" letter confirming that she is of the view that grounds do not then exist to initiate proceedings before the Competition Tribunal under the merger provisions of the Competition Act with respect to the proposed transaction, while preserving, for one year following the completion of the proposed transaction, her authority to initiate proceedings should circumstances change.

All mergers, regardless of whether they are subject to Part IX of the Competition Act, are subject to the substantive mergers provisions under Section 92 of the Competition Act. In particular, the Commissioner may challenge a transaction before the Competition Tribunal where the transaction prevents or lessens, or is likely to prevent or lessen, competition substantially in a market. The Competition Tribunal may issue an order that the parties not proceed with the transaction or part of it or, in the event that the transaction has already been completed, order its dissolution or the disposition of some or all of the assets or shares involved. In addition, the Competition Tribunal may, with the consent of the person against whom the order is directed and the

Table of Contents

Commissioner, order that person to take any other action as is deemed necessary to remedy any substantial lessening or prevention of competition that the Competition Tribunal determines would or would likely result from the transaction. The Commissioner may not make an application to the Competition Tribunal under Section 92 of the Competition Act more than one year after the merger has been substantially completed.

E. Exchange Controls

Canada has no system of exchange controls. There are no Canadian restrictions on the repatriation of capital or earnings of a Canadian public company to non-resident investors. There are no laws in Canada or exchange restrictions affecting the remittance of dividends, profits, interest, royalties and other payments to non-resident holders of our securities, except as discussed in Item 5.F. " Taxation".

F. Taxation

Canadian Federal Income Taxation

The following discussion is a summary of the principal Canadian federal income tax considerations generally applicable to a holder of our common shares who, at all relevant times, for purposes of the *Income Tax Act* (Canada) and the *Income Tax Regulations* (collectively, the "Canadian Tax Act") deals at arm's-length with, and is not affiliated with, us, holds its common shares as capital property and does not use or hold and is not deemed to use or hold such common shares in carrying on a business in Canada and who, at all relevant times, for purposes of the application of the Canadian Tax Act and the Canada-U.S. Income Tax Convention (1980, as amended) (the "U.S. Treaty"), is resident in the U.S., is not, and is not deemed to be, resident in Canada and is eligible for benefits under the U.S. Treaty (a "U.S. Holder"). Special rules, which are not discussed in the summary, may apply to a non-resident holder that is an insurer that carries on an insurance business in Canada and elsewhere or that is an "authorized foreign bank" as defined in the Canadian Tax Act.

Limited liability companies ("LLCs") that are not taxed as corporations pursuant to the provisions of the U.S. Internal Revenue Code of 1986, as amended (the "Code") do not qualify as resident in the U.S. for purposes of the U.S. Treaty. Under the U.S. Treaty, a resident of the U.S. who is a member of such an LLC and is otherwise eligible for benefits under the U.S. Treaty may generally be entitled to claim benefits under the U.S. Treaty in respect of income, profits or gains derived through the LLC. Generally, such entitlement commenced on February 1, 2009 for withholding taxes, and is in effect for other (non-withholding) taxes for taxable years beginning on or after January 1, 2009.

The U.S. Treaty includes limitation on benefits rules that restrict the ability of certain persons who are resident in the U.S. to claim any or all benefits under the U.S. Treaty. Residents of the U.S. should consult their own tax advisors with respect to their eligibility for benefits under the U.S. Treaty, having regard to these rules.

This summary is based upon the current provisions of the U.S. Treaty and the Canadian Tax Act and our understanding of the current administrative policies and assessing practices of the Canada Revenue Agency published in writing prior to the date hereof. This summary takes into account all specific proposals to amend the U.S. Treaty and the Canadian Tax Act publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof. This summary does not otherwise take into account or anticipate changes in law or administrative policies and assessing practices, whether by judicial, regulatory, administrative or legislative decision or action, nor does it take into account provincial, territorial or foreign tax legislation or considerations, which may differ from those discussed herein.

This summary is of a general nature only and is not intended to be, nor should it be construed to be, legal or tax advice generally or to any particular holder. U.S. Holders should consult their own tax advisors with respect to their own particular circumstances.

Table of Contents

Gains on Disposition of Common Shares

In general, a U.S. Holder will not be subject to tax under the Canadian Tax Act on capital gains arising on the disposition of such holder's common shares unless the common shares are "taxable Canadian property" to the U.S. Holder and are not "treaty-protected property".

Generally, a common share will not be taxable Canadian property to a U.S. Holder at a particular time; provided that, (a) such common share is listed on a designated stock exchange (which includes the NYSE and the TSX), (b) the U.S. Holder, persons with whom the U.S. holder does not deal at arm's-length, or the U.S. Holder together with all such persons, have not owned 25% or more of the issued shares of any class or series of the capital stock of our Company at any time during the 60-month period that ends at that time, and (c) common share is not otherwise deemed to be taxable Canadian property for purposes of the Canadian Tax Act.

Common shares will be treaty-protected property where the U.S. Holder is exempt from income tax under the Canadian Tax Act on the disposition of common shares because of the U.S. Treaty. Common shares owned by a U.S. Holder will generally be treaty-protected property where the value of the common shares is not derived principally from real property situated in Canada.

Dividends on Common Shares

Dividends paid or credited on the common shares or deemed to be paid or credited on the common shares to a U.S. Holder that is the beneficial owner of such dividends will generally be subject to non-resident withholding tax under the Canadian Tax Act and the U.S. Treaty at the rate of (a) 5% of the amounts paid or credited if the U.S. Holder is a company that owns (or is deemed to own) at least 10% of our voting stock, or (b) 15% of the amounts paid or credited in all other cases. The rate of withholding under the Canadian Tax Act in respect of dividends paid to non-residents of Canada is 25% where no tax treaty applies.

G. Sale of Unregistered Securities

5.375% Senior Convertible Notes due 2014

On June 10, 2009, the Company issued \$350.0 million aggregate principal amount of Notes in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act for net proceeds of approximately \$334.0 million, after deducting estimated fees and expenses of the offering. J.P. Morgan Securities Inc. acted as representative of the initial purchasers. The Notes were issued under an indenture dated June 10, 2009 entered into among us, as issuer, The Bank of New York Mellon, as trustee, and BNY Trust Company of Canada, as co-trustee. The Notes bear interest at a rate of 5.375% per year. Interest on the Notes accrues from June 10, 2009. Interest is payable semiannually in arrears on February 1 and August 1 of each year, beginning February 1, 2010. Holders may convert their Notes into common shares at the applicable conversion rate, prior to the close of business on the business day immediately preceding the maturity date, in multiples of \$1,000 principal amount, under the following circumstances:

during any fiscal quarter (and only during that quarter) commencing after June 30, 2009, if the closing sale price of our common shares is greater than or equal to 130% of the applicable conversion price then in effect for at least 20 trading days in the period of 30 consecutive trading days ending on, and including, the last trading day of the preceding fiscal quarter; during the five business day period after any five consecutive trading day period, or the measurement period, in which the trading price per \$1,000 principal amount of notes for each day of such measurement period was less than 98% of the product of the closing price of our common shares and the applicable conversion rate for the Notes;

if such Notes have been called for redemption;

upon the occurrence of specified corporate transactions; or

during the period beginning 25 trading days prior to maturity.

Table of Contents

The initial conversion rate for the Notes is 67.0880 common shares per \$1,000 principal amount of Notes (equal to a conversion price of approximately \$14.91 per common share), subject to adjustment. Upon conversion of a Note, we will have the right to elect to deliver cash or a combination of cash and common shares for the notes surrendered instead of delivering only common shares (plus cash in lieu of fractional shares). In addition, following certain corporate transactions that occur prior to maturity, we will increase the conversion rate for a holder who elects to convert its Notes in connection with such corporate transactions by a number of additional common shares. Holders will not receive any additional cash payment or additional common shares representing accrued and unpaid interest upon conversion of a Note, except in limited circumstances. Instead, interest will be deemed paid by the common shares and cash, if any, issued to the holder upon conversion. Our current intent and policy is to settle the Notes using a net share settlement approach, such that the principal amount of any Notes tendered for conversion would be settled in cash, and any excess conversion value settled in common shares.

We may redeem for cash all or a portion of the Notes at any time on or after August 2, 2012, at a purchase price equal to 100% of the principal amount being redeemed, plus any accrued and unpaid interest if the closing price of our common shares reaches a specified threshold. We may not otherwise redeem any of the Notes at our option prior to maturity, except upon the occurrence of certain changes to the laws governing Canadian withholding taxes.

H. Purchases of Equity Securities by the Company and Affiliated Purchases

On August 6, 2009 we announced that the Board of Directors had renewed our share repurchase program providing for the purchase of up to 15,800,000 common shares, representing approximately 10% of our public float (as defined by applicable rules). The Company may initially make purchases under the share repurchase program of up to 7.9 million common shares through the facilities of the NYSE, in accordance with applicable rules and guidelines. This represents approximately 5% of the Company's public float as of August 6, 2009. Following additional filings and related approvals, we may also purchase common shares over the TSX. The program does not require Biovail to repurchase a minimum number of common shares, and the program may be modified, suspended or terminated at any time without prior notice. The share repurchase program will terminate on August 11, 2010 or at such earlier time as the Company completes its purchases. Under the terms of our credit facility, we are not permitted to repurchase common shares in excess of \$75.0 million in the aggregate in any given calendar year without obtaining the lenders' prior consent. Given that we do not intend to exceed this threshold, we have not requested nor obtained such consent. No repurchases of common shares were made during the Company's fourth quarter in 2009.

Item 6. Selected Financial Data.

A. Selected Financial Data

The following table of selected consolidated financial data of our Company has been derived from financial statements prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The data is qualified by reference to, and should be read in conjunction with, the consolidated financial statements and

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Table of Contents

related notes thereto prepared in accordance with U.S. GAAP (see Item 15. "Exhibits, Financial Statement Schedules"). All dollar amounts are expressed in thousands of U.S. dollars, except per share data.

	Years Ended December 31				
	2009	2008	2007	2006	2005
Consolidated operating data:					
Revenue	820,430	\$ 757,178	\$ 842,818	\$ 1,067,722	\$ 938,343
Operating income	181,154 ⁽¹⁾	124,109 ⁽³⁾	188,014 ⁽⁵⁾	238,867 ⁽⁷⁾	313,279 ⁽¹⁰⁾
Income from continuing operations	176,455 ⁽²⁾	199,904 ⁽⁴⁾	195,539 ⁽⁶⁾	215,474 ⁽⁸⁾	257,015 ⁽¹¹⁾
Net income	176,455 ⁽²⁾	199,904 ⁽⁴⁾	195,539 ⁽⁶⁾	211,626 ⁽⁹⁾	246,440 ⁽¹²⁾
Basic and diluted earnings per share:					
Income from continuing operations	\$ 1.11 ⁽²⁾	\$ 1.25 ⁽⁴⁾	\$ 1.22 ⁽⁶⁾	\$ 1.35 ⁽⁸⁾	\$ 1.61 ⁽¹¹⁾
Net income	\$ 1.11 ⁽²⁾	\$ 1.25 ⁽⁴⁾	\$ 1.22 ⁽⁶⁾	\$ 1.32 ⁽⁹⁾	\$ 1.54 ⁽¹²⁾
Cash dividends declared per share	\$ 0.65	\$ 1.50	\$ 1.50	\$ 1.00	\$ 0.50

	At December 31				
	2009	2008	2007	2006	2005
Consolidated balance sheet:					
Cash and cash equivalents	114,463	\$ 317,547	\$ 433,641	\$ 834,540	\$ 445,289
Working capital	93,734	223,198	339,439	647,337	414,033
Total assets	2,067,044	1,623,565	1,782,115	2,192,442	2,036,820
Long-term obligations	326,085			410,525	436,058
Common shares	1,465,004	1,463,873	1,489,807	1,476,930	1,461,077
Shareholders' equity (net assets)	1,354,372	1,201,599	1,297,819	1,302,257	1,228,364
Number of Common Shares issued and outstanding (000s)	158,311	158,216	161,023	160,444	159,588

- (1) Includes charges of \$59,354 for acquired in-process research and development ("IPR&D"); \$19,065 for restructuring costs; \$10,968 for loss on sale and leaseback of assets; \$6,191 for legal settlements; \$5,596 for acquisition-related costs; \$2,887 for SEC/OSC independent consultant costs; and \$1,028 for proxy contest costs.
- (2) Includes charges of \$59,354 for IPR&D; \$19,065 for restructuring costs; \$10,968 for loss on sale and leaseback of assets; \$6,191 for legal settlements; \$5,596 for acquisition-related costs; \$2,887 for SEC/OSC independent consultant costs; \$1,028 for proxy contest costs; \$5,210 for impairment losses on debt and equity securities; and \$537 for write-down of deferred financing costs. Those charges were partially offset by a \$26,000 deferred income tax benefit; a \$22,000 gain on auction rate security settlement; and a gain of \$804 on disposal of investment.
- (3) Includes charges of \$70,202 for restructuring costs; \$32,565 for legal settlements; and \$13,606 for management succession and proxy contest costs.
- (4) Includes charges of \$70,202 for restructuring costs; \$32,565 for legal settlements; \$13,606 for management succession and proxy contest costs; \$9,869 for impairment losses on debt and equity securities; and an equity loss of \$1,195. Those charges were partially offset by a \$90,000 deferred income tax benefit; and a gain of \$6,534 on disposal of investments.
- (5) Includes charges of \$95,114 for legal settlements (net of insurance recoveries); \$9,910 for intangible asset impairments; and \$668 for restructuring costs. Those charges were partially offset by a \$1,735 contract recovery.
- (6) Includes charges of \$95,114 for legal settlements (net of insurance recoveries); \$9,910 for intangible asset impairments; \$668 for restructuring costs; \$12,463 for loss on early extinguishment of debt; \$8,949 for impairment losses on debt and equity securities; and an equity loss of \$2,528. Those charges were partially offset by a \$1,735 contract recovery; and a gain of \$24,356 on disposal of investments.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

- (7) Includes charges of \$143,000 for intangible asset impairments (net of gain on disposal of \$4,000); \$54,800 for contract losses; \$15,126 for restructuring costs; and \$14,400 for legal settlements.
- (8) Includes charges of \$143,000 for intangible asset impairments (net of gain on disposal of \$4,000); \$54,800 for contract losses; \$15,126 for restructuring costs; \$14,400 for legal settlements; and an equity loss of \$529.
- (9) Includes charges of \$143,000 for intangible asset impairments (net of gain on disposal of \$4,000); \$54,800 for contract losses; \$15,126 for restructuring costs; \$14,400 for legal settlements; an equity loss of \$529; and \$1,084 for asset impairments of discontinued operation.

Table of Contents

- (10) Includes charges of \$25,833 for intangible asset impairments; \$19,810 for restructuring costs; and \$4,862 for write-off of inventory.
- (11) Includes charges of \$25,833 for intangible asset impairments; \$19,810 for restructuring costs; \$4,862 for write-off of inventory; \$3,397 for loss on impairment of investments; and an equity loss of \$1,160.
- (12) Includes charges of \$25,833 for intangible asset impairments; \$19,810 for restructuring costs; \$4,862 for write-off of inventory; \$3,397 for loss on impairment of investments; an equity loss of \$1,160; and \$5,570 for asset impairments of discontinued operation.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

MANAGEMENT'S DISCUSSION AND ANALYSIS

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") should be read in conjunction with our audited consolidated financial statements and related notes thereto prepared in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP") for the fiscal year ended December 31, 2009 (our "2009 Financial Statements").

Additional information relating to Biovail Corporation, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (our "2009 Form 10-K"), is available on SEDAR at www.sedar.com and on the U.S. Securities and Exchange Commission ("SEC") website at www.sec.gov.

The discussion and analysis contained in this MD&A is as of February 26, 2010.

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:

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 and ability to invest approximately \$600 million in research and development between 2008 and 2012;

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;

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 efforts, including, but not limited to, the estimated costs and expected timing to complete the development of BVF-018 (tetrabenazine), and efforts related to the development of AZ-004 (Staccato® loxapine), BVF-014 (glial cell line-derived

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

neurotrophic factor ("GDNF"); BVF-025 (fipamezole), BVF-036, BVF-040 and BVF-048 (pimavanserin), and BVF-324 (tramadol), including the expected potential milestone and royalty payments in connection with pimavanserin, fipamezole, GDNF, Staccato® loxapine, and other research and development arrangements;

our intent to deploy a specialty U.S. sales force to support our specialty CNS strategy, and the timing and amount of costs associated with establishing such sales force;

our ability to secure other development partners for, and to share development costs associated with, certain product development programs;

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 credit facility, to support future spending and business development requirements;

the expected future taxable income in determining any required deferred tax asset valuation allowance;

the impact of market conditions on our ability to access additional funding at reasonable rates, and 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 2014 ("Convertible Notes");

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

expected timing and 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;

timing regarding the Zovirax® price allowance;

investment recovery, liquidity, valuation, impairment and other conclusions associated with our investment in auction rate securities;

expected timing and amount of principal and interest payments related to long-term obligations;

the impact of short-term fluctuations in our share price on the fair value of our reporting unit for purposes of testing goodwill for impairment;

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

availability of benefits under tax treaties and the continued availability of low effective tax rates for our operations;

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,

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

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 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 preclinical 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;

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 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 Canadian Securities Administrators ("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

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

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.

Strategic Initiatives

Prior to May 2008, our base business model was focused on the development and large-scale manufacture of pharmaceutical products incorporating oral drug-delivery technologies. Our main therapeutic areas of focus were non-specialty CNS disorders, pain management and cardiovascular disease. In May 2008, as a result of significant changes in the environment for oral controlled-release products over the previous several years, we adopted a new business model that concentrates our research and development and business development efforts on unmet medical needs in specialty CNS disorders.

Since adopting our specialty CNS strategy in May 2008, we have completed a number of in-license agreements and acquisitions that have enhanced our drug-development pipeline. Our business development activities have targeted a number of growth opportunities, including Huntington's disease, Parkinson's disease, and schizophrenia. Our specialty CNS pipeline currently includes seven projects in development, and we are seeking to leverage our growing credibility in the specialty CNS market to further expand our pipeline by entering into agreements with other companies to develop, license, or acquire promising compounds, technologies, or capabilities. Our target is to invest approximately \$600 million on research and development in the 2008 to 2012 timeframe, including upfront and milestone payments related to in-licensing activities.

The growth and development of our specialty CNS business is financially supported by our former base business model, which continues to provide revenues and significant operating cash flows that can be used to support and fund licensing and acquisition opportunities in specialty CNS. In addition, we are pursuing other complementary acquisitions or business opportunities (such as our May 2009 acquisition of the full U.S. commercialization rights to Wellbutrin XL®) that may be accretive to revenues and cash flows in the near-term. At December 31, 2009, we had available capital resources including cash on hand and available credit under our credit facility in excess of \$500 million with which to further pursue our specialty CNS strategy.

We also continue to promote efficiency in our operations, significantly reduce our cost structure to better align expenses with current projected revenues, and ensure capital is available to be deployed in support of our specialty CNS business model. Key initiatives in this regard include efforts to: (i) rationalize our manufacturing operations, pharmaceutical sciences operations, and general and administrative expenses; (ii) divest and monetize certain non-core assets; and (iii) resolve legacy litigation and regulatory matters.

We believe that our continued ability to successfully implement our specialty CNS strategy will be driven by a number of factors, including: (i) our strong balance sheet; (ii) ongoing cash flows generated by our former base business model; (iii) the in-licensing and acquisition opportunities currently available in the specialty CNS market; and (iv) our proven expertise in formulation, clinical development, regulatory affairs, manufacturing and marketing of prescription pharmaceutical products.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Business Development

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. 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 submission, 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 between \$10 million and \$20 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 will be accounted for as a purchase of acquired in-process research and development ("IPR&D") intangible assets with no alternative future use. Accordingly, the \$40.0 million upfront payment, together with any acquisition costs, will be charged to research and development expenses in the first quarter of 2010.

GDNF

On December 21, 2009, we entered into a license agreement with Amgen Inc. ("Amgen") and MedGenesis Therapeutix Inc. ("MedGenesis"), pursuant to which we were granted a license to exploit GDNF in certain CNS indications in certain countries (including the U.S., Canada, Japan, and a number of European countries). At the same time, we entered into a collaboration agreement with MedGenesis to develop and commercialize GDNF, initially for the treatment of Parkinson's disease in the U.S., Japan and certain European countries and, potentially, in other countries and other CNS indications. Pursuant to the collaboration agreement, we were granted a license to MedGenesis's Convection Enhanced Delivery platform for use with GDNF in CNS indications. GDNF for the treatment of Parkinson's disease is directly aligned with our specialty CNS strategy.

In connection with the collaboration agreement, we made an upfront payment to MedGenesis of \$6.0 million, and we could pay up to an additional \$20.0 million in potential developmental milestones to MedGenesis. We also have certain funding obligations towards the development of GDNF in Parkinson's disease in the U.S., totaling up to \$14.0 million for the Pre-Investigational New Drug ("IND") development phase and Phase 2 clinical trials. We intend to share with MedGenesis the development costs associated with Phase 3 clinical studies in the U.S. (as well as any development costs associated with Phase 2 clinical trials that exceed our initial funding obligation), and with the development programs in other countries. Together with MedGenesis, we could, in the aggregate, pay Amgen up to \$25.0 million in regulatory milestones and up to \$75.0 million in sales-based milestones, and will pay royalties to Amgen based on net sales of GDNF products.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

We will be responsible for commercializing GDNF products in the countries in which we have the GDNF license rights, and will pay MedGenesis a royalty in respect of net sales of GDNF products in those countries.

This acquisition was accounted for as a purchase of IPR&D intangible assets with no alternative future use. Accordingly, the \$6.0 million upfront payment, together with acquisition costs of \$2.9 million, was charged to research and development expenses at the acquisition date.

Fipamezole

On August 24, 2009, we entered into a collaboration and license agreement with Santhera Pharmaceuticals (Switzerland) Ltd. ("Santhera"), a subsidiary of Santhera Pharmaceuticals Holding AG, to acquire the U.S. and Canadian rights to develop, manufacture and commercialize fipamezole for the treatment of a number of neurological and psychiatric conditions, including levodopa-induced dyskinesia (BVF-025), also known as Parkinson's disease dyskinesia ("PDD"). Fipamezole for PDD is directly aligned with our specialty CNS strategy.

Pursuant to the terms of the collaboration and license agreement, we made an upfront payment of \$8.0 million to Santhera at the acquisition date, and made a further payment of \$4.0 million to Santhera on October 5, 2009, upon the closing of Santhera's acquisition of Oy Juvantia Pharma Ltd. We could pay up to \$35.0 million in potential developmental and regulatory milestones associated with the initiation of a Phase 3 study, regulatory submissions and approvals of fipamezole in PDD. Should we pursue a second indication, we could pay an additional \$20.0 million milestone upon regulatory approval. We will also make royalty payments of 8% to 15% on net commercial sales of fipamezole, as well as additional milestone payments of up to \$145.0 million as certain sales thresholds are met.

This acquisition was accounted for as a purchase of IPR&D intangible assets with no alternative future use. Accordingly, the \$8.0 million upfront payment, together with acquisition costs of \$0.1 million, was charged to research and development expenses at the acquisition date. The additional payment of \$4.0 million made to Santhera on October 5, 2009 was charged to research and development expenses in the fourth quarter of 2009.

We will be responsible for the development programs and associated costs in the U.S. and Canada for fipamezole for both PDD and the second indication if pursued.

Tetrabenazine

On June 19, 2009, we acquired the worldwide development and commercialization rights to the entire portfolio of tetrabenazine products, including Xenazine® and Nitoman®, held by Cambridge Laboratories (Ireland) Limited and its affiliates ("Cambridge"). As described below under "Prestwick", we had previously obtained certain licensing rights to tetrabenazine in the U.S. and Canada through the acquisition of Prestwick Pharmaceuticals, Inc. ("Prestwick") in September 2008. By means of this acquisition, we obtained Cambridge's economic interest in the supply of tetrabenazine for the U.S. and Canadian markets, as well as for a number of other countries in Europe and around the world through existing distribution arrangements. In addition, we assumed Cambridge's royalty obligations to third parties on the worldwide sales of tetrabenazine. The acquisition of tetrabenazine is directly aligned with our specialty CNS strategy.

This acquisition was accounted for as a business combination under the acquisition method of accounting. The total purchase price of \$226.8 million comprised cash consideration of \$200.0 million paid on closing, and additional payments of \$12.5 million and \$17.5 million due to Cambridge on the first and second anniversaries of the closing date, respectively. These additional payments were fair valued at \$26.8 million, using an imputed interest rate comparable to our available borrowing rate at the date of acquisition. We incurred \$5.6 million of costs related to this acquisition, which were expensed in the second quarter of 2009.

The purchase price was allocated to a product rights intangible asset (\$189.7 million), IPR&D intangible assets (\$36.0 million), and inventory (\$1.1 million). The product rights intangible asset represents the value of

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

the currently marketed immediate-release tetrabenazine products, with an estimated useful life of approximately nine years. The IPR&D intangible asset relates to a modified-release ("MR") formulation of tetrabenazine under development initially for the treatment of Tourette's Syndrome (BVF-018) and an isomer of tetrabenazine (RUS-350), both of which were in pre-clinical stages of development at the acquisition date. The values assigned to BVF-018 and RUS-350 were \$28.0 million and \$8.0 million, respectively.

BVF-018 has been granted orphan drug designation by the FDA for the treatment of Tourette's Syndrome in school-age children (aged 5-16 years), which provides the product with seven years of market exclusivity in the U.S. if successfully developed. We had a pre-IND application meeting with the FDA for this program in early July 2009, and contingent on successful safety assessments, our current plans are to initiate a Phase 2 clinical study in the third quarter of 2010. We expect to complete the development of BVF-018 in 2014. The total estimated costs to complete this project for its primary indication are approximately \$70 million to \$75 million, which will be shared with at least one development partner and possibly others. Through December 31, 2009, we incurred total direct expenditures related to this project of \$2.2 million (net of reimbursements from our development partner, which are reflected as a reduction of research and development expenses).

The efforts required to develop BVF-018 into a commercially viable product include completion of the pre-clinical development, clinical-trial testing, regulatory approval, and commercialization. The principal risks relating to this project include the outcomes of the formulation development, clinical studies, and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, we will not receive any benefits unless regulatory approval is obtained. As a result, there is no certainty that any of our development efforts related to this project will result in a commercially viable product.

In respect of RUS-350, we have decided to terminate this development program, as we determined, based on the results of development efforts completed subsequent to the acquisition date, that the isomer was unlikely to provide meaningful benefits to patients beyond that provided by tetrabenazine. As a result, in the fourth quarter of 2009, we recorded a charge of \$8.0 million to write off the related IPR&D intangible asset, which is recorded in research and development expenses.

The amount of incremental revenue and earnings (excluding amortization of the acquired product rights intangible asset) recognized from the worldwide sales of tetrabenazine from the acquisition date to December 31, 2009, amounted to approximately \$3.8 million and \$4.5 million, respectively, in our consolidated statement of income.

Wellbutrin XL®

On May 14, 2009, we acquired the full U.S. commercialization rights to Wellbutrin XL® from The GlaxoSmithKline Group of Companies ("GSK"). We had supplied Wellbutrin XL® to GSK for marketing or distribution in the U.S. since September 2003. The Wellbutrin XL® product formulation was developed, and is manufactured, by us under our own patents and proprietary technology. This acquisition does not materially impact our existing agreement with GSK as that agreement relates to countries outside the U.S. We will continue to manufacture and supply Wellbutrin XL® to GSK for distribution in these countries. In Canada, Wellbutrin® XL will continue to be marketed by our internal sales organization, Biovail Pharmaceuticals Canada ("BPC").

Pursuant to the terms of the asset purchase agreement, we paid \$510.0 million to GSK to acquire the U.S. NDA for Wellbutrin XL®. Pursuant to the terms of a trademark and license agreement with GSK, we also obtained an exclusive, royalty-free license to the Wellbutrin XL® trademark for use in the U.S. This acquisition was accounted for as a purchase of identifiable intangible assets. Accordingly, the total purchase price (including costs of acquisition of \$0.5 million) was allocated to the trademark intangible asset with an estimated useful life of 10 years. In addition, we acquired the Wellbutrin XL® finished goods inventory owned by GSK valued at \$10.5 million.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

This acquisition proved accretive to revenue by an amount in excess of \$100 million in 2009. The significant cash flows that were generated have been used to further expand our pipeline of specialty CNS products.

Pimavanserin

On May 1, 2009, we entered into a collaboration and license agreement with ACADIA Pharmaceuticals Inc. ("ACADIA") to acquire the U.S. and Canadian rights to develop, manufacture and commercialize pimavanserin in a number of neurological and psychiatric conditions, including Parkinson's disease psychosis ("PDP") (BVF-036), Alzheimer's disease psychosis ("ADP") (BVF-040), and, as an adjunctive therapy, to treat schizophrenia (BVF-048). Pimavanserin for PDP, ADP, and schizophrenia is directly aligned with our specialty CNS strategy.

Pursuant to the terms of the collaboration and license agreement, we paid an upfront fee of \$30.0 million to ACADIA, and could pay up to \$160.0 million in potential developmental milestones associated with the successful completion of clinical trials, regulatory submissions and approvals for pimavanserin in the PDP and ADP indications. In addition, we could pay up to \$45.0 million in success milestones for pimavanserin in a third indication. At this time, we intend to pursue pimavanserin as an adjunct therapy for schizophrenia as the third indication. We will also make tiered royalty payments of 15% to 20% on net sales of products containing pimavanserin, as well as additional milestone payments of up to \$160.0 million as certain net sales thresholds are met.

This acquisition was accounted for as a purchase of IPR&D intangible assets with no alternative future use. Accordingly, the \$30.0 million upfront payment, together with acquisition costs of \$0.4 million, was charged to research and development expenses at the acquisition date.

We will be responsible for funding all of the PDP, ADP and schizophrenia development expenses for pimavanserin, other than the cost of two Phase 3 clinical trials for PDP that ACADIA had in progress at the time of the agreement. The first of these Phase 3 PDP studies did not meet its primary endpoint of antipsychotic efficacy, but did meet the secondary endpoint of motoric tolerability. On October 5, 2009, we amended the collaboration and license agreement with ACADIA to provide that we will fund a third Phase 3 clinical trial for PDP; provided, however, that if the trial does not meet the primary endpoint, then ACADIA will reimburse us for 50% of the cost of the trial. If the third PDP trial or a subsequent pivotal trial in PDP meets its primary endpoint, we may credit 50% of the costs of the applicable trial against the potential milestone payment triggered by such trial. The amendment also provides that ACADIA may elect to pursue an initial clinical trial in ADP at its own expense. However, if the ADP trial meets its primary endpoint, then we would reimburse ACADIA 100% of the cost of the trial.

Prestwick

On September 16, 2008, we acquired 100% of Prestwick for a total net purchase price of \$101.9 million. The acquisition of Prestwick was accounted for as a business combination under the former purchase method of accounting. The purchase price paid was primarily allocated to identifiable intangible assets of \$157.9 million and deferred revenue of \$50.0 million. The identifiable intangible assets relate to the acquired Xenazine® and Nitoman® product rights as described below, which are being amortized over an estimated useful life of 10 years. Prestwick had acquired the licensing rights to Xenazine® in the U.S. and Nitoman® in Canada from Cambridge, which, at the time, held the worldwide license for tetrabenazine.

In August 2008, an NDA for Xenazine® received FDA approval for the treatment of chorea associated with Huntington's disease. Xenazine® was granted orphan drug designation by the FDA, which provides this product with seven years of market exclusivity in the U.S. from the date of FDA approval. Nitoman® has been available in Canada since 1996, where it is approved for the treatment of hyperkinetic movement disorders, including Huntington's chorea.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Xenazine® is being commercialized in the U.S. by Lundbeck Inc. (a subsidiary of H. Lundbeck A/S) ("Lundbeck"), formerly Ovation Pharmaceuticals, Inc. ("Ovation"), under an exclusive supply and distribution agreement entered into between Prestwick and Ovation prior to our acquisition of Prestwick. Ovation paid Prestwick \$50.0 million for the exclusive rights to market and distribute Xenazine® for an initial term of 15 years. We will supply Xenazine® product to Lundbeck for a variable percentage of Lundbeck's annual net sales of the product. For annual net sales up to \$125 million, our supply price will be 72% of net sales. Beyond \$125 million, our supply price will be 65% of net sales. Prior to the acquisition of the worldwide development and commercialization rights to tetrabenazine in June 2009, we acquired Xenazine® product from Cambridge at a supply price of 50% of Lundbeck's net sales.

Product Development Pipeline

The following table displays selected information regarding our specialty CNS drug-development programs (as more fully described above under " Business Development"):

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	PDP	Phase 3
BVF-048	Pimavanserin	Schizophrenia co-therapy	Phase 2
BVF-025	Fipamezole	PDD	Phase 2
BVF-040	Pimavanserin	ADP	Phase 1
BVF-018	Tetrabenazine MR	Tourette's Syndrome	Pre-clinical
BVF-014	GDNF	Parkinson's disease	Pre-IND

In addition to the programs outlined above, we continue to work on the development of a number of legacy programs that originated from our former base business model. In particular, Phase 3 clinical trials are underway in Europe for BVF-324 (the use of non-commercially available doses of tramadol for the treatment of premature ejaculation). In addition, during 2008, we filed three Abbreviated New Drug Applications ("ANDA") with the FDA for generic formulations of Effexor XR, Tricor and Seroquel XR. The following table displays selected information regarding these legacy programs:

PROGRAM	COMPOUND	INDICATION(S)	DEVELOPMENT STATUS
BVF-324	Tramadol	Sexual dysfunction	Phase 3
BVF-065	Venlafaxine (generic Effexor XR)	Depression	ANDA filed April 16, 2008 ⁽¹⁾
BVF-203		High cholesterol	

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

	Fenofibrate (generic Tricor)		ANDA filed July 1, 2008 ⁽²⁾
BVF-058	Quetiapine (generic Seroquel XR)	Schizophrenia and bipolar disorder	ANDA filed September 24, 2008 ⁽²⁾

(1)

We have settled an infringement claim related to this ANDA filing and have received a license to manufacture and sell the product 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.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

(2)

We are subject to infringement claims by the innovator companies related to both of these ANDA filings, thereby triggering a 30-month stay of the FDA's approval pursuant to the provisions of the *Hatch-Waxman Act*.

During 2009, we suspended further development of the legacy program BVF-045 (combination product consisting of Aplenzin and an undisclosed selective serotonin reuptake inhibitor), as a result of being unable to secure a development partner.

Any success in our product-development programs would be reflective of the investments in research and development we make over a number of years. On an ongoing basis, we review and optimize the projects in our development portfolio to reflect changes in the competitive environment and emerging opportunities. Our future level of research and development expenditures will depend on, among other things, the outcome of clinical testing of our products under development, delays or changes in government required testing and approval procedures, technological developments, and strategic marketing decisions.

Financing Arrangements

Convertible Notes

On June 10, 2009, we issued \$350.0 million principal amount of Convertible Notes in a private placement. The Convertible Notes were issued at par and interest is payable semi-annually on February 1 and August 1 of each year, beginning February 1, 2010. The Convertible Notes will mature on August 1, 2014. Noteholders may convert their holdings based on a conversion rate of 67.0880 common shares per \$1,000 principal amount of Convertible Notes, equivalent to a conversion price of approximately \$14.91 per share, subject to adjustment, at their option at any time prior to the maturity date under the following circumstances: (i) if the closing price of our common shares reaches, or the trading price of the Convertible Notes falls below, specified thresholds; (ii) if the Convertible Notes have been called for redemption; (iii) upon the occurrence of specified corporate transactions; and (iv) during the 25 trading days prior to the maturity date. Upon conversion, we will have the option to deliver cash, common shares or a combination of cash and common shares. In addition, following certain corporate transactions, we will in certain circumstances increase the conversion rate for noteholders who elect to convert their holdings in connection with such corporate transactions. Our 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.

We may redeem for cash all or a portion of the Convertible Notes at any time on or after August 2, 2012, at a purchase price equal to 100% of the principal amount being redeemed, plus any accrued and unpaid interest, if the closing price of our common shares reaches a specified threshold. We may not otherwise redeem any of the Convertible Notes at our option prior to maturity, except upon the occurrence of certain changes to the laws governing Canadian withholding taxes.

If we experience specified types of fundamental changes, noteholders may require us to repurchase for cash all or a portion of their holdings at a price equal to 100% of the principal amount of the Convertible Notes to be purchased plus any accrued and unpaid interest to, but excluding, the date of repurchase.

The liability (debt) and equity (conversion option) components of the Convertible Notes were separately accounted for in a manner that reflects our estimated borrowing rate for non-convertible debt with otherwise similar terms. The liability component was fair valued at \$293.3 million and the equity component was valued on a residual basis at \$56.7 million. The value assigned to the liability component was estimated based on a 9.5% market rate of interest for similar debt with no conversion rights. The value allocated to the liability component will be accreted to the face value of the Convertible Notes over the five-year period prior to maturity, using the effective interest method. The accretion of the liability component will be recognized as additional non-cash interest expense. The value assigned to the equity component was recorded in additional paid-in capital in shareholders' equity.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

We recognized a deferred tax liability of \$14.6 million for the original basis difference between the principal amount of the Convertible Notes and the value allocated to the liability component, which resulted in a corresponding reduction to the valuation allowance recorded against our deferred tax assets. The recognition of the deferred tax liability and the corresponding reduction in the valuation allowance were recorded as offsetting adjustments to additional paid-in capital. In subsequent periods, the deferred tax benefit resulting from the reversal of the deferred tax liability, will be offset by the deferred tax expense related to the corresponding realization of the deferred tax assets.

Credit Facility

On June 9, 2009, we established a \$410.0 million senior secured revolving credit facility with a syndicate of banks. This facility matures on June 9, 2012 and replaces our former \$250.0 million credit facility. This facility contains an accordion feature that, subject to certain conditions, allows the facility to be increased to up to \$550.0 million. The facility is guaranteed by our material subsidiaries and is secured by charges over substantially all of our assets and the assets of our material subsidiaries, and is subject to certain financial and non-financial covenants. At December 31, 2009, we had no outstanding borrowings under this facility, and were in compliance with all covenants.

Restructuring

In support of our specialty CNS strategy, we initiated restructuring measures in May 2008 that were intended to rationalize our manufacturing operations, pharmaceutical sciences operations, and general and administrative expenses. These measures included the closure of our research and development facility in Dublin, Ireland in August 2008, the sale of our Dorado, Puerto Rico manufacturing facility in January 2010, and the ultimate planned closure of our manufacturing facility in Carolina, Puerto Rico. In addition, in May 2009, we announced the closure of our research and development facility in Mississauga, Ontario and the consolidation of our research and development operations in Chantilly, Virginia. We have also reviewed our procurement levels and practices and the structure of our support functions to ensure they are appropriately aligned with our size and revenue base.

The following table summarizes the major components of the related restructuring costs recognized through December 31, 2009:

(\$ in 000s)	Asset Impairments		Employee Termination Benefits		Contract Termination and Other Costs	Total
	Manufacturing	Pharmaceutical Sciences	Manufacturing	Pharmaceutical Sciences		
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	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

Manufacturing Operations

The closure of our manufacturing facilities located in Dorado and Carolina, Puerto Rico, and the related transfer of certain manufacturing and packaging processes to our Steinbach, Manitoba manufacturing facility, is expected to reduce our cost infrastructure and improve the capacity utilization of our manufacturing operations.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

We expect to incur employee termination costs of approximately \$9.4 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 our 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 required future service period, including \$4.9 million and \$3.3 million recognized in 2009 and 2008, respectively.

In 2009 and 2008, we recorded impairment charges of \$7.6 million and \$42.6 million, respectively, to write-down the carrying value of the property, plant and equipment located in Puerto Rico to its estimated fair value. As at December 31, 2009, we had entered into an agreement in principle to sell the Dorado facility for net cash proceeds of \$8.5 million. The sale closed on January 15, 2010. We will continue to occupy the Dorado facility until March 31, 2010, pursuant to a short-term lease, during which time any remaining manufacturing and packaging processes will be transferred to the Steinbach facility. While we are continuing to actively market the Carolina facility, this site is expected to now 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.

Pharmaceutical Sciences Operations

The closures of our Dublin, Ireland and Mississauga, Ontario research and development facilities has reduced the overhead and ongoing infrastructure costs of our pharmaceutical sciences operations, and improved the efficiency of our internal research and development program management at our remaining site in Chantilly, Virginia.

In 2009, we incurred employee termination costs of \$1.4 million for severance and related benefits payable to the approximately 50 employees who have been, or will be, terminated as a result of the closure of the Mississauga facility, and the consolidation of the Chantilly operations. In addition, we recorded an impairment charge of \$0.5 million related to the write-down of the carrying value of the equipment and leasehold improvements located at the Mississauga facility to their estimated fair value. We also recognized \$1.6 million of accelerated depreciation arising from a reduced useful life of the leasehold improvements located at the Chantilly facility, and incurred lease termination costs of \$1.4 million as a result of vacating one of our premises in Chantilly in 2009.

In July 2009, we completed the sale of the Dublin facility for net cash proceeds of \$5.2 million, which resulted in an additional write-down of \$0.7 million to the carrying value of this facility in the second quarter of 2009. We had closed this facility in August 2008 and recorded an impairment charge of \$9.2 million to write down the carrying value of the building and equipment to their estimated fair value at that time. In addition, we recognized employee termination costs of \$2.7 million in 2008 for the approximately 50 employees affected by this closure.

Also in 2008, we recorded an impairment charge of \$7.5 million to write off the carrying value of certain technology intangible assets, which were related to proprietary drug-delivery technologies that were not expected to be utilized in the development of specialty CNS products.

Results of Efficiency Initiatives

In 2009, our efficiency initiatives, including the rationalization of our manufacturing operations, pharmaceutical sciences operations, and general and administrative expenses, resulted in savings of approximately \$30 million. We expect that these initiatives, once fully implemented, may result in annual savings of \$40 million to \$60 million. Our ongoing and planned efficiency initiatives have resulted in cumulative charges to earnings of \$97.2 million recorded through December 31, 2009. These charges are expected to be in the range of \$100 million to \$120 million, of which the cash component is expected to be up to \$40 million, including \$20.1 million incurred through December 31, 2009.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Sale of Non-Core Assets

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, through the following transactions:

In January 2010, we completed the sale of our Dorado, Puerto Rico manufacturing facility for net cash proceeds of \$8.5 million.

In November 2009, we completed the sale and leaseback of our corporate headquarters in Mississauga, Ontario for net cash proceeds of \$17.8 million. We recognized a loss on disposal of \$11.0 million in the fourth quarter of 2009, which is recorded in selling, general and administrative expenses. We will continue to occupy this facility under a 20-year operating lease at market rental rates.

In July 2009, we completed the sale of our Dublin, Ireland research and development facility for net cash proceeds of \$5.2 million.

In April 2009, we completed the sale of our corporate aircraft for cash proceeds of \$5.3 million and entered into a four-year operating lease for this aircraft. This transaction resulted in a gain on disposal of \$0.9 million, which was deferred and will reduce future lease rental expense over the lease term.

During 2009 and 2008, we disposed of our investments in Depomed, Inc. ("Depomed"), Financière Verdi ("Verdi"), formerly Etypharm S.A. ("Etypharm"), and Hemispherx Biopharma, Inc. ("Hemispherx") for total cash proceeds of \$26.3 million, resulting in a disposal gain of \$7.3 million in the aggregate.

Resolution of Legacy Litigation and Regulatory Matters

Since December 2007, we have resolved the following six legacy litigation and regulatory proceedings relating to matters which arose during the period from 2001 to March 2004:

an investigation by the U.S. Attorney's Office ("USAO") for the District of Massachusetts regarding promotional and marketing activities surrounding the 2003 commercial launch of Cardizem® LA;

an investigation and subsequent proceeding commenced by the Ontario Securities Commission ("OSC") related to specific accounting and financial disclosure practices that occurred between 2001 and March 2004;

an SEC complaint in connection with similar accounting and financial disclosure practices as described in the OSC proceeding for the period of 2001 to March 2004;

a securities class action lawsuit in the U.S. relating to statements made by our Company and certain former officers and directors between February 7, 2003 and March 2, 2004;

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

a Canadian securities class action lawsuit in respect of similar issues alleged in the U.S. class action; and

litigation involving former Banc of America Securities LLC analyst Jerry Treppel.

In connection with the settlement agreements entered into with the OSC and SEC, we agreed to the appointment of independent consultants to review and report on our accounting and related functions.

As described in note 24 to our 2009 Financial Statements, on February 27, 2010, S.A.C. Capital Advisors, LLC commenced an action against us alleging malicious prosecution related to our legacy complaint against it. A factually similar complaint was filed the same day by Gradient Analytics, Inc., and two individuals.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

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.
Nitoman®	Hyperkinetic movement disorders, including Huntington's chorea	Canada	Marketed and distributed by 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 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.
Pain Management			
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.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

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 ("Abbott")).
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.
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.

(1) 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.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**(All dollar amounts expressed in U.S. dollars)**

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
Authorized Generics			
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

The following table provides selected financial information for each of the last three years:

Years Ended December 31**Change**

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

(\$ in 000s, except per share data)	2009	2008	2007	2008 to 2009		2007 to 2008	
	\$	\$	\$	\$	%	\$	%
Revenue	820,430	757,178	842,818	63,252	8	(85,640)	(10)
Operating expenses	639,276	633,069	654,804	6,207	1	(21,735)	(3)
Net income	176,455	199,904	195,539	(23,449)	(12)	4,365	2
Basic and diluted earnings per share	1.11	1.25	1.22	(0.14)	(11)	0.03	2
Cash dividends declared per share	0.65	1.50	1.50	(0.85)	(57)		
Total assets	2,067,044	1,623,565	1,782,115	443,479	27	(158,550)	(9)
Long-term obligations, including current portion	326,085			326,085	NM		

NM Not meaningful

General Economic Conditions

While pharmaceutical consumption has traditionally been relatively unaffected by economic downturns, the global recession has nevertheless had a negative impact on our business, largely in the U.S. market. In particular, we have observed a decline in prescription demand for a number of our brand name products that we consider related to the growth of the uninsured and underinsured patient population in the U.S., which we believe is increasingly switching from branded to generic drugs where available. In addition, we have noted an increase in

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Medicaid utilization, as the recession has also increased the number of patients in these governmental programs, under which sales of pharmaceutical products are subject to substantial rebates and, in many U.S. states, to formulary restrictions limiting access to brand name drugs.

Although the challenging financial markets did not have any impact on our liquidity or our ability to raise capital, we were, however, subject to a higher cost of borrowing, as reflected in the pricing of the Convertible Notes and our credit facility in June 2009 at the then prevailing market rates. We have taken, and will continue to take, a conservative approach to the investment of our cash resources to ensure we maintain strong liquidity that provides us with the financial flexibility to achieve our strategic initiatives.

Beginning in late 2008 and continuing throughout 2009, foreign currency exchange rates between the U.S. dollar and the Canadian dollar have been experiencing significant volatility. Changes in foreign currency exchange rates decreased total revenue by approximately \$6.1 million, or 0.7%, in 2009, compared with 2008, due to a weakening of the Canadian dollar relative to the U.S. dollar on a year-over-year basis; however, changes in foreign currency exchange rates had a negligible overall effect on total revenue in 2008 relative to 2007. A weaker Canadian dollar, while unfavourable on revenue, has a positive 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 negative impact of a weaker 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 depreciation of the Canadian dollar in 2009 had the overall effect of marginally increasing our net income as reported in U.S. dollars.

Financial Performance

Changes in Revenue

Total revenue increased \$63.3 million, or 8%, to \$820.4 million in 2009, compared with \$757.2 million in 2008, primarily due to:

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

a full year's contribution from sales of Xenazine®/Nitoman® products in the U.S. and Canada, and the addition of rest-of-world sales of these products following the acquisition of the worldwide development and commercialization rights to tetrabenazine in June 2009;

the addition of Aplenzin to our product portfolio in April 2009; and

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

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;

a decline in Cardizem® LA product sales, due to lower inventory levels in the distribution channels and less product promotion by Abbott in anticipation of a potential loss of market exclusivity;

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

a decline in revenue from our bioequivalent ("Generic") products, other than generic Cardizem® CD, due to overall reductions in the prices and volume for these products;

a decline in the volume of third-party studies conducted by our contract research division;

the impact of lower prescription volumes and increased Medicaid utilization due to existing economic conditions in the U.S.; and

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

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

Total revenue declined \$85.6 million, or 10%, to \$757.2 million in 2008, compared with \$842.8 million in 2007, primarily due to:

lower revenue from Wellbutrin XL® product sales as a result of the launch of a generic version of the 150mg product in May 2008, which followed the earlier genericization of the 300mg dosage strength in December 2006; and

a reduction in Cardizem® LA product sales, due to lower prescription volumes in 2008, and higher shipments of 120mg and 180mg dosage strengths in the first quarter of 2007 to address a backorder that existed at the end of 2006.

Those factors were partially offset by:

the positive impact of higher pricing of our off-patent branded pharmaceutical ("Legacy") products, which more than offset declining prescription volumes for these products.

Changes in Net Income

Net income declined \$23.4 million, or 12%, to \$176.5 million (basic and diluted earnings per share ("EPS") of \$1.11) in 2009, compared with \$199.9 million (basic and diluted EPS of \$1.25) in 2008, primarily due to:

a decline of \$64.0 million in recognized net deferred income tax benefits, related to reductions in the valuation allowance recorded against U.S. operating loss carryforwards of \$26.0 million and \$90.0 million in the fourth quarters of 2009 and 2008, respectively (as described below under "Results of Operations – Income Taxes");

a \$59.4 million IPR&D charge in 2009 in connection with the acquisitions of the various rights to pimavanserin, fipamezole and GDNF, as well as the write-off of the \$8.0 million IPR&D intangible asset related to RUS-350;

a \$53.4 million increase in amortization expense in 2009, primarily related to the acquired Wellbutrin XL® and tetrabenazine intangible assets; and

a \$24.4 million increase in interest expense in 2009, which included incremental cash interest of \$10.5 million, and non-cash amortization of debt discount of \$5.0 million, on the Convertible Notes.

Those factors were partially offset by:

an increased contribution from product sales of \$67.3 million in 2009, 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;

a decline of \$51.1 million in restructuring costs in 2009, mainly due to lower asset impairment charges;

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

a decline of \$26.4 million in legal settlement charges in 2009, primarily related to the resolution of the USAO and OSC investigations in 2008, partially offset by \$6.2 million accrued in 2009 in connection with the settlement of certain other litigation matters;

a decline of \$22.3 million in internal research and development program expenses in 2009, reflecting reduced direct project spending as we transitioned from reformulation opportunities to the in-licensing, acquisition and development of specialty CNS products, and cost savings resulting from the closure of our Dublin, Ireland research and development facility; and

a settlement gain of \$22.0 million in 2009, in respect of our investment in auction rate securities (as described below under "Results of Operations Non-Operating Income (Expense) Gain on Auction Rate Security Settlement").

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Net income increased \$4.4 million, or 2%, to \$199.9 million (basic and diluted EPS of \$1.25) in 2008, compared with \$195.5 million (basic and diluted EPS of \$1.22) in 2007, primarily due to:

the \$90.0 million reduction in the valuation allowance recorded against U.S. operating loss carryforwards in 2008;

a decline of \$62.5 million in legal settlement charges in 2008, primarily related to the resolution of the U.S. and Canadian securities class action lawsuits and the SEC investigation in 2007; and

a decline of \$30.8 million in internal research and development program expenses in 2008, reflecting the closure of the Dublin facility and reduced direct project spending, as we sought to optimize the projects in our research and development portfolio.

Those factors were partially offset by:

a lower contribution from product sales of \$60.0 million in 2008, mainly due to the genericization of Wellbutrin XL®;

an increase in restructuring costs of \$69.5 million in 2008, mainly related to the impairment of the property, plant and equipment located in Puerto Rico and Ireland;

a decline of \$17.8 million in gains on the disposal of investments in 2008, mainly related to the disposal of our equity interests in Reliant Pharmaceuticals, Inc. ("Reliant") and Etypharm in 2007;

a decline in interest income of \$15.2 million in 2008, reflecting lower cash resources and interest rates; and

the inclusion of management succession costs of \$7.4 million and proxy contest costs of \$6.2 million in 2008.

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.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

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.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

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

(\$ in 000s, except per share data; Income (Expense))	2009		2008		2007	
	Amount	EPS Impact	Amount	EPS Impact	Amount	EPS Impact
IPR&D ⁽¹⁾	\$ (59,354)	\$ (0.37)	\$	\$	\$	\$
Reduction in valuation allowance on deferred tax assets ⁽²⁾	26,000	\$ 0.16	90,000	\$ 0.56		\$
Gain on auction rate security settlement	22,000	\$ 0.14		\$		\$
Restructuring costs	(19,065)	\$ (0.12)	(70,202)	\$ (0.44)	(668)	\$
Loss on sale and leaseback of assets ⁽³⁾	(10,968)	\$ (0.07)		\$		\$
Legal settlements, net of insurance recoveries	(6,191)	\$ (0.04)	(32,565)	\$ (0.20)	(95,114)	\$ (0.59)
Acquisition-related costs	(5,596)	\$ (0.04)		\$		\$
Impairment losses on debt and equity securities	(5,210)	\$ (0.03)	(9,869)	\$ (0.06)	(8,949)	\$ (0.06)
SEC/OSC independent consultant costs ⁽³⁾	(2,887)	\$ (0.02)		\$		\$
Proxy contest costs ⁽³⁾	(1,028)	\$ (0.01)	(6,192)	\$ (0.04)		\$
Gain on disposal of investments	804	\$ 0.01	6,534	\$ 0.04	24,356	\$ 0.15
Write-down of deferred financing costs ⁽⁴⁾	(537)	\$		\$		\$
Management succession costs ⁽³⁾		\$	(7,414)	\$ (0.05)		\$
Equity loss		\$	(1,195)	\$ (0.01)	(2,528)	\$ (0.02)
Loss on early extinguishment of debt		\$		\$	(12,463)	\$ (0.08)
Intangible asset impairments		\$		\$	(9,910)	\$ (0.06)
Contract recovery ⁽³⁾		\$		\$	1,735	\$ 0.01
Total	\$ (62,032)	\$ (0.39)	\$ (30,903)	\$ (0.19)	\$ (103,541)	\$ (0.64)

- (1) Included in research and development expenses.
- (2) Included in provision for (recovery of) income taxes.
- (3) Included in selling, general and administrative expenses.
- (4) Included in interest expenses.

With the exception of the reduction in the valuation allowance on deferred tax assets, 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 \$0.645 in 2009, compared with \$1.50 per share in each of 2008 and 2007. In May 2009, our Board of Directors approved a modification of our dividend policy, which now contemplates the payment of a quarterly dividend of \$0.09 per share, compared with \$0.375 per share under the former policy. 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. On February 24, 2010, our Board of Directors declared a quarterly cash dividend of \$0.09 per share, payable on April 5, 2010.

Changes in Financial Condition

At December 31, 2009, we had cash and cash equivalents of \$114.5 million (compared with \$317.5 million at December 31, 2008) and we had no borrowings outstanding under our \$410.0 million credit facility. At December 31, 2009, we had a long-term obligation to Cambridge of \$27.8 million in connection with the tetrabenazine acquisition in June 2009, and we had dividends payable of \$14.2 million in respect of our

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

third quarter 2009 results, which dividend was paid on January 4, 2010.

In 2009, we obtained financing of \$350.0 million from the issuance of the Convertible Notes and received total proceeds of \$23.1 million from the sale and leaseback of certain corporate assets. In addition, operating

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)**(All dollar amounts expressed in U.S. dollars)**

cash flows of \$360.9 million in 2009 were a significant source of liquidity. We paid total cash dividends of \$147.1 million in 2009, and incurred \$26.3 million of financing costs in connection with the issuance of the Convertible Notes and the establishment of our credit facility. We also utilized a substantial portion of our available cash resources to fund the following acquisition activities (exclusive of acquisition costs):

\$510.0 million for the full U.S. commercialization rights to Wellbutrin XL®;

\$200.0 million for the worldwide development and commercialization rights to tetrabenazine;

\$30.0 million for the U.S. and Canadian rights to develop, manufacture and commercialize pimavanserin;

\$12.0 million for the U.S. and Canadian rights to develop, manufacture and commercialize fipamezole; and

\$6.0 million to collaborate on the development and commercialization of GDNF in CNS indications.

In February 2010, we paid \$40.0 million in connection with the acquisition of the U.S. and Canadian development and commercialization rights to Staccato® loxapine.

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

Our revenue is derived primarily from the following sources:

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

pharmaceutical clinical research and laboratory testing services; and

royalties from the sale of products we developed or acquired.

The following table displays the dollar amount of each source of revenue for each of the last three years; the percentage of each source of revenue, compared with total revenue in the respective year; and the percentage changes in the dollar amount of each source of revenue. Percentages may not add due to rounding.

(\$ in 000s)	Years Ended December 31						Change			
	2009		2008		2007		2008 to 2009		2007 to 2008	
	\$	%	\$	%	\$	%	\$	%	\$	%
Product sales	789,026	96	714,548	94	801,046	95	74,478	10	(86,498)	(11)
Research and development	14,148	2	24,356	3	23,828	3	(10,208)	(42)	528	2
Royalty and other	17,256	2	18,274	2	17,944	2	(1,018)	(6)	330	2

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Total revenue	820,430	100	757,178	100	842,818	100	63,252	8	(85,640)	(10)
---------------	---------	-----	---------	-----	---------	-----	--------	---	----------	------

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Product Sales

The following table displays product sales by internal reporting category for each of the last three years; the percentage of each category compared with total product sales in the respective year; and the percentage changes in the dollar amount of each category. Percentages may not add due to rounding.

(\$ in 000s)	Years Ended December 31						Change			
	2009		2008		2007		2008 to 2009		2007 to 2008	
	\$	%	\$	%	\$	%	\$	%	\$	%
Wellbutrin XL®	173,288	22	120,745	17	212,325	27	52,543	44	(91,580)	(43)
Aplenzin	11,150	1					11,150	NM		
Ultram® ER	53,986	7	81,875	11	86,714	11	(27,889)	(34)	(4,839)	(6)
Xenazine® ^{(1),(2)}	48,433	6	3,736	1			44,697	NM	3,736	NM
Zovirax®	146,267	19	150,613	21	147,120	18	(4,346)	(3)	3,493	2
BPC ⁽³⁾	79,936	10	70,580	10	61,889	8	9,356	13	8,691	14
Cardizem® LA	42,002	5	48,002	7	69,300	9	(6,000)	(12)	(21,298)	(31)
Legacy	165,679	21	154,206	22	136,855	17	11,473	7	17,351	13
Generic	67,035	8	83,246	12	86,843	11	(16,211)	(19)	(3,597)	(4)
Glumetza® (U.S.)	1,250		1,545				(295)	(19)	1,545	NM
Total product sales	789,026	100	714,548	100	801,046	100	74,478	10	(86,498)	(11)

NM Not meaningful

- (1) Includes Nitoman® sales in Canada made prior to December 1, 2008.
- (2) Includes sales of Xenazine®/Xenazina®/Nitoman® outside the U.S. and Canada from June 19, 2009.
- (3) Effective December 1, 2008, BPC assumed the marketing and distribution of Nitoman®.

Wholesaler Inventory Levels

Three drug wholesale customers account for the majority of our Zovirax®, Legacy, and, since May 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 1/2 and 1 1/2 months of supply of our products. As indicated in the following table, at December 31, 2009 and 2008, these wholesalers owned overall 1.0 and 1.1 months of supply of our products, respectively, of which only \$0.2 million of inventory had less than 12 months remaining shelf life as at both December 31, 2009 and 2008.

(\$ in 000s)	At December 31, 2009				At December 31, 2008			
	Original Shelf Life In Months	Total Inventory \$	Months On Hand In Months	Inventory With Less Than 12 Months Remaining Shelf Life	Total Inventory \$	Months On Hand In Months	Inventory With Less Than 12 Months Remaining Shelf Life	
				\$			\$	
Wellbutrin XL®	18	15,389	1.0	34	NA	NA	NA	
Zovirax®	36-48	14,689	1.1	93	17,769	1.3	91	
Cardizem®	36-48	8,380	1.1	21	7,146	0.8	15	
Ativan®	24	2,300	1.1	77	2,523	1.0	80	
Vasotec® and Vaseretic®	24	1,468	1.1	9	2,034	1.1	10	
Isordil®	36-60	265	1.2	1	273	1.1	1	

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Total	18-60	41,491	1.0	235	29,745	1.1	197
-------	-------	--------	-----	-----	--------	-----	-----

NA Not applicable

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Wellbutrin XL®

Wellbutrin XL® product sales increased \$52.5 million, or 44%, to \$173.3 million in 2009, compared with \$120.7 million in 2008, reflecting incremental revenue of approximately \$109.0 million earned following 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 volumes due to generic competition to the 150mg dosage strength product since May 2008, as well as the continuing sales erosion of the 300mg dosage strength following its genericization in December 2006.

Wellbutrin XL® product sales declined \$91.6 million, or 43%, to \$120.7 million in 2008, compared with \$212.3 million in 2007, reflecting the impact on volumes resulting from the introduction of generic competition, which more than offset the positive effect on our supply prices of price increases implemented by GSK during 2008. In addition, our supply price for Wellbutrin XL® was based on an increasing tiered percentage of GSK's net selling price, which was reset to the lowest tier at the start of each calendar year. As a result of the introduction of generic competition to the 150mg product, GSK's sales of Wellbutrin XL® did not meet the sales-dollar threshold to increase our supply price above the first tier in 2008, which accounted for a portion of the year-over-year decline.

Aplenzin

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 2009, we supplied sanofi-aventis with \$11.2 million of Aplenzin, including sample supplies.

Ultram® ER

On November 13, 2009, Par Pharmaceuticals Companies, Inc. ("Par") introduced its 100mg and 200mg generic versions of Ultram® ER, following a Court ruling in its favour on patent non-infringement. On the same date, PriCara's affiliate Patriot launched 100mg and 200mg authorized generic versions of Ultram® ER, which we manufacture and supply to Patriot. Upon generic entry, our contractual supply price to PriCara for branded Ultram® ER 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 Ultram® ER 300mg product, our supply price to PriCara for that dosage strength remains unchanged. Par is, however, seeking FDA approval for a 300mg generic version of Ultram® ER.

Ultram® ER product sales declined \$27.9 million, or 34%, to \$54.0 million in 2009, compared with \$81.9 million in 2008, as a result of lower prescription demand and supply pricing for the 100mg and 200mg dosage strengths, which was partially offset by revenue generated through our supply of the authorized generics. In addition, inventory levels in the distribution channels were reduced during 2009 in anticipation of the loss of market exclusivity, and PriCara increased its provision for expected returns of the branded product, which had a negative impact on our supply price. Also contributing to the decline in prescription volumes was the launch in early May 2009 of a competing once-daily formulation of tramadol in 100mg, 200mg and 300mg dosage strengths. All of those factors were partially offset by higher shipments of 100mg tablets in the first quarter of 2009 to replace certain lots that had been recalled in the fourth quarter of 2008, and a \$1.1 million reduction to the related recall provision in the first quarter of 2009, as a result of lower than expected returns from wholesalers and pharmacies in connection with this recall, as well as the positive effect on our supply price of a price increase implemented by PriCara in 2009.

Ultram® ER product sales declined \$4.8 million, or 6%, to \$81.9 million in 2008, compared with \$86.7 million in 2007, reflecting a provision of \$6.5 million (exclusive of \$0.6 million of inventory write-offs and \$1.0 million of administrative expenses) related to the voluntary recall of certain lots of 100mg tablets, which included affected product still at PriCara. Ultram® ER product sales were also impacted in 2008 by lower sales of sample supplies to PriCara. Those factors were partially offset by the positive effect on our supply price of

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

price increases implemented by PriCara during 2008 and a change in prescription mix from the 100mg product to the higher 200mg and 300mg dosage strengths.

Xenazine®

Our revenue from sales of Xenazine® amounted to \$48.4 million in 2009 and \$3.7 million in 2008. Xenazine® revenue comprises sales of the product to Lundbeck for marketing and distribution in the U.S. since November 2008, and sales of the product to third-party distributors for distribution in other countries in Europe and around the world following the acquisition of the worldwide development and commercialization rights to tetrabenazine in June 2009. In addition, Xenazine® revenue included sales of Nitoman® in Canada made prior to December 1, 2008; Canadian sales after December 1, 2008 are included in BPC product sales described below.

Zovirax®

Zovirax® product sales declined \$4.3 million, or 3%, to \$146.3 million in 2009, compared with \$150.6 million in 2008, due to lower prescription volumes and a reduction of inventory levels by our major wholesale customers, partially offset by price increases implemented for these products during 2009. The decline in prescription volumes was partially due to increasing competition from available oral therapies. In addition, Publicis is limiting its detailing efforts to certain specialist physicians.

Zovirax® product sales increased \$3.5 million, or 2%, to \$150.6 million in 2008, compared with \$147.1 million in 2007, reflecting price increases we implemented in 2008, which more than offset a modest decline in prescription volumes.

BPC

Sales of BPC products increased \$9.4 million, or 13%, to \$79.9 million in 2009, compared with \$70.6 million in 2008, and increased \$8.7 million, or 14%, in 2008, compared with \$61.9 million in 2007. Excluding the negative effect on BPC Canadian dollar-denominated revenue of the weakening of the Canadian dollar relative to the U.S. dollar, BPC product sales increased 20% in 2009, compared with 2008; however, changes in exchange rates between the Canadian dollar and the U.S. dollar had a negligible overall effect on BPC revenue in 2008, compared with 2007.

The year-over-year increases in BPC revenue in each of 2009 and 2008 reflected higher sales of our promoted Wellbutrin® XL, Tiazac® XC, Ralivia® and Glumetza® products, which more than offset lower sales of our genericized Tiazac® and Wellbutrin® SR products. Also contributing to the increase in 2009, compared with 2008, was the inclusion of \$5.0 million of Nitoman® product sales in 2009, compared with \$0.4 million recognized in December 2008.

In January 2010, a Canadian Court ruled in favour of Apotex Inc. on patent infringement proceedings relating to our Glumetza® 500mg product. The introduction of generic competition to the 500mg dosage strength could result in a substantial reduction in our Glumetza® branded product sales in Canada. Glumetza® generated revenues of \$6.6 million in 2009.

Cardizem® LA

A subsidiary of Watson Pharmaceuticals, Inc. ("Watson") is seeking FDA approval for a generic version of Cardizem® LA in all dosage strengths; however, to our knowledge, Watson has not yet received FDA approval. Although we will be entitled to a royalty from Watson based on any sales of its generic Cardizem® LA product, the introduction of generic competition could have a material adverse impact on our revenues and earnings.

Revenue from sales of Cardizem® LA declined \$6.0 million, or 12%, to \$42.0 million in 2009, compared with \$48.0 million in 2008, which reflected lower prescription volumes and a reduction in inventory levels in the

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

distribution channels, as promotional activities by Abbott have been curtailed in anticipation of the potential loss of market exclusivity.

Cardizem® LA product sales declined \$21.3 million, or 31%, to \$48.0 million in 2008, compared with \$69.3 million in 2007, reflecting lower prescription volumes in 2008, and higher shipments of 120mg and 180mg Cardizem® LA products to Abbott in the first quarter of 2007 made to address the backorder for those strengths that existed at the end of 2006. Those factors were partially offset by the positive effect on our supply price of price increases implemented by Abbott during 2008.

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 being amortized over seven years on a straight-line basis. This amortization amounted to \$15.1 million in each of the last three years.

Legacy

Our Legacy products include Ativan®, Cardizem® CD, Vasotec®, Vaseretic®, Tiazac® and Isordil®, which are sold primarily in the U.S. Although we do not actively promote these products as they have been genericized, our Legacy products continue to benefit from high brand awareness and physician and patient loyalty.

Sun Pharmaceutical Industries, Ltd., India ("Sun India") is seeking FDA approval for generic versions of Cardizem® CD, including the 360mg dosage strength which currently is not subject to generic competition. There are currently no unexpired patents listed against our 360mg Cardizem® CD product in the FDA's Orange Book database. FDA approval of Sun India's 360mg product could have a material adverse impact on the overall sales of our Cardizem® CD branded product and on the carrying value of the intangible asset associated with the Cardizem® trademark.

Sales of our Legacy products increased \$11.5 million, or 7%, to \$165.7 million in 2009, compared with \$154.2 million in 2008, which reflected higher sales of generic Tiazac®, attributable to competitors' manufacturing issues. In addition, declining prescription volumes for our other Legacy brands were largely offset by price increases implemented during 2009.

Sales of Legacy products increased \$17.4 million, or 13%, to \$154.2 million in 2008, compared with \$136.9 million in 2007, reflecting the price increases implemented for these products in 2008, which more than offset a decline in prescription volumes.

Generic

Our Generic products consist of bioequivalent versions of Adalat CC, Cardizem® CD, Procardia XL, Trental, and Voltaren XR, which are sold to Teva for distribution in the U.S.

Sales of Generic products declined \$16.2 million, or 19%, to \$67.0 million in 2009, compared with \$83.2 million in 2008, reflecting the effects of lower pricing and prescription volumes for most products. Also contributing to the year-over-year decline was the recognition in 2008 of a \$4.5 million adjustment made in our favour by Teva to reduce its chargeback provision related to past sales of our products. Those factors were partially offset by higher sales of generic Cardizem® CD in the fourth quarter of 2009, attributable to competitors' manufacturing issues.

Sales of Generic products declined \$3.6 million, or 4%, to \$83.2 million in 2008, compared with \$86.8 million in 2007, primarily due to lower prescription volumes and pricing for these products, as well as shelf-stock adjustments granted by Teva to its customers. Those factors were partially offset by the favourable impact of the \$4.5 million chargeback adjustment made by Teva in 2008.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Research and Development Revenue

Research and development revenue declined \$10.2 million, or 42%, to \$14.1 million in 2009, compared with \$24.4 million in 2008, as a result of a lower level of clinical research and laboratory testing services provided to external customers by our contract research division, together with the negative impact of the weakening of the Canadian dollar relative to the U.S. dollar.

Research and development revenue increased \$0.5 million, or 2%, to \$24.4 million in 2008, compared with \$23.8 million in 2007, primarily reflecting the relative volume of clinical research and laboratory testing services conducted on behalf of external customers.

Royalty and Other Revenue

Royalties from third parties on sales of products we developed or acquired and other revenue declined \$1.0 million, or 6%, to \$17.3 million in 2009, compared with \$18.3 million in 2008, mainly due to lower revenue based on sales of fenofibrate in the U.S., and increased \$0.3 million, or 2%, in 2008, compared with \$17.9 million in 2007.

Operating Expenses

The following table displays the dollar amount of each operating expense category for each of the last three years; the percentage of each category compared with total revenue in the respective year; and the percentage changes in the dollar amount of each category. Percentages may not add due to rounding.

(\$ in 000s)	Years Ended December 31						Change			
	2009		2008		2007		2008 to 2009		2007 to 2008	
	\$	%	\$	%	\$	%	\$	%	\$	%
Cost of goods sold (exclusive of amortization of intangible assets shown separately below)	204,309	25	197,167	26	223,680	27	7,142	4	(26,513)	(12)
Research and development	120,784	15	92,844	12	118,117	14	27,940	30	(25,273)	(21)
Selling, general and administrative	178,601	22	188,922	25	159,266	19	(10,321)	(5)	29,656	19
Amortization of intangible assets	104,730	13	51,369	7	48,049	6	53,361	104	3,320	7
Restructuring costs	19,065	2	70,202	9	668		(51,137)	(73)	69,534	NM
Legal settlements, net of insurance recoveries	6,191	1	32,565	4	95,114	11	(26,374)	(81)	(62,549)	(66)
Acquisition-related costs	5,596	1					5,596	NM		
Intangible asset impairments					9,910	1			(9,910)	(100)
Total operating expenses	639,276	78	633,069	84	654,804	78	6,207	1	(21,735)	(3)

NM Not meaningful

Cost of Goods Sold

Cost of goods sold includes: manufacturing, packaging, shipping and handling costs for products we produce; the cost of products we purchase from third parties; royalty payments we make to third parties; depreciation of manufacturing facilities and equipment; and lower of cost or market adjustments to inventories. Cost of goods sold excludes the amortization of intangible assets described separately below under "Amortization of Intangible Assets".

Since October 1, 2002, we have been entitled to purchase a pre-determined quantity of Zovirax® inventory from GSK at reduced prices under a price allowance. We expect that any remaining inventory acquired at the reduced supply prices will be sold in the first quarter of 2010, after which time the cost of inventory purchased from GSK at full price will have a material impact on the contribution from Zovirax® product sales.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Cost of goods sold increased \$7.1 million, or 4%, to \$204.3 million in 2009, compared with \$197.2 million in 2008. The percentage increase in cost of goods sold was less than the corresponding 10% increase in total product sales in 2009, primarily due to:

lower labour and overhead costs at our Puerto Rico manufacturing facilities, and higher absorption at our Steinbach, Manitoba manufacturing facility, as 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;

the positive impact of price increases we implemented for Wellbutrin XL®, Zovirax® and certain Legacy products during 2009, and the positive effect on our supply prices for Wellbutrin XL® (prior to the acquisition of the full U.S. commercialization rights), Ultram® ER and Cardizem® LA of the price increases implemented in 2009 by GSK, PriCara and Abbott, respectively; and

the positive impact on labour and overhead costs at the Steinbach facility as a result of the weakening of the Canadian dollar relative to the U.S. dollar.

Those factors were partially offset by:

the inclusion of lower margin Xenazine® and Nitoman® product sales;

a higher cost basis related to the \$10.5 million of Wellbutrin XL® inventory reacquired from GSK, in connection with the acquisition of the full U.S. commercialization rights, which was subsequently sold to our wholesale customers during 2009;

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 reduction in our contractual supply price for Ultram® ER, and the increase in PriCara's provision for expected returns of the product as a result of generic entry; and

an increase of \$3.9 million in costs associated with the transfer of certain manufacturing and packaging processes from the Puerto Rico facilities to the Steinbach facility, partially offset by lower depreciation expense as a result of the write-down of the property, plant and equipment located in Puerto Rico.

Cost of goods sold declined \$26.5 million, or 12%, to \$197.2 million in 2008, compared with \$223.7 million in 2007. The percentage decline in cost of goods sold was greater than the corresponding 11% decline in total product sales in 2008, primarily due to:

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

the reduced contribution from higher margin 150mg Wellbutrin XL® product sales as a result of the introduction of generic competition, and the inclusion of lower margin Xenazine® and Nitoman® product sales;

the \$6.5 million provision for returns of recalled Ultram® ER 100mg tablets in 2008, and the write-off to cost of goods sold of \$0.6 million of affected Ultram® ER product remaining in our inventory;

an increase in amortization expense of \$6.4 million in 2008, compared with 2007, related to the \$40.7 million deferred charge for payments we made to GSK in consideration for the Zovirax® price allowance; and

the inclusion of \$2.4 million of costs associated with the transfer of certain manufacturing and packaging processes from the Puerto Rico facilities to the Steinbach facility, partially reduced by lower depreciation expense.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Those factors were partially offset by:

the positive impact of price increases we implemented for Zovirax® and certain Legacy products during 2008, and the positive effect on our supply prices for Wellbutrin XL®, Ultram® ER and Cardizem® LA of the price increases implemented in 2008 by GSK, PriCara and Abbott, respectively;

the inclusion of the \$4.5 million chargeback adjustment from Teva in 2008; and

lower charges for obsolescence related to inventories of certain of our products that were in excess of anticipated demand, and a recovery from PriCara in 2008 of \$1.0 million related to the cost of Ultram® oral disintegrating tablet ("ODT") inventory that had been previously written-off.

Research and Development Expenses

Expenses related to internal research and development programs include: employee compensation costs; overhead and occupancy costs; depreciation of research and development facilities and equipment; clinical trial costs; clinical manufacturing and scale-up costs; and other third-party development costs. Acquired IPR&D represents compounds, new indications, or line extensions under development that have not received regulatory approval for marketing at the time of acquisition. IPR&D acquired through an asset acquisition is written-off at the acquisition date if the assets have no alternative future use. IPR&D acquired in a business combination is capitalized as indefinite-lived intangible assets (irrespective of whether these assets have an alternative future use) until completion or abandonment of the related research and development activities. Costs associated with the development of IPR&D are expensed as incurred. The costs associated with providing contract research services to external customers are also included in research and development expenses.

The following table displays the dollar amount of research and development expenses by internal reporting category for each of the last three years; the percentage of each category compared with total revenue in the respective year; and the percentage changes in the dollar amount of each category. Percentages may not add due to rounding.

(\$ in 000s)	Years Ended December 31						Change			
	2009		2008		2007		2008 to 2009		2007 to 2008	
	\$	%	\$	%	\$	%	\$	%	\$	%
IPR&D	59,354	7					59,354	NM		
Internal research and development programs	47,581	6	69,811	9	100,610	12	(22,230)	(32)	(30,799)	(31)
Contract research services provided to external customers	13,849	2	23,033	3	17,507	2	(9,184)	(40)	5,526	32
Total research and development expenses	120,784	15	92,844	12	118,117	14	27,940	30	(25,273)	(21)

NM Not meaningful

As described above under "Overview Business Development", we recorded a total IPR&D charge of \$59.4 million in 2009, related to the acquisitions of the various rights to pimavanserin, fipamezole and GDNF, as well as the write-off of the \$8.0 million IPR&D intangible asset related to RUS-350 upon the termination of that project.

Internal research and development program expenses declined \$22.2 million, or 32%, to \$47.6 million in 2009, compared with \$69.8 million in 2008, reflecting reduced direct project spending as we transitioned from reformulation opportunities to the in-licensing, acquisition and development of specialty CNS products, and cost savings as a result of the closures of our Dublin, Ireland and Mississauga, Ontario research and development facilities. Also contributing to the year-over-year decline in 2009 was the recognition in the first quarter of 2008 of \$7.9 million in costs related to the termination of the BVF-146 program to develop a combination of tramadol and a non-steroidal

anti-inflammatory drug.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Internal research and development program expenses declined \$30.8 million, or 31%, to \$69.8 million in 2008, compared with \$100.6 million in 2007, reflecting the closure of our facility in Ireland and reduced direct project spending as we sought to optimize the projects in our development portfolio. These declines also reflected the cost of clinical trial and scale-up activities conducted in 2007 related to Aplenin and Phase 3 safety studies conducted in connection with the BVF-146 program.

Costs associated with providing contract research services to external customers declined \$9.2 million, or 40%, to \$13.8 million in 2009, compared with \$23.0 million in 2008, 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 and the fourth quarter of 2008, as well as a positive impact on labour and overhead costs as a result of the weakening of the Canadian dollar relative to the U.S. dollar.

Contract research services costs increased \$5.5 million, or 32%, to \$23.0 million in 2008, compared with \$17.5 million in 2007, reflecting higher unabsorbed overhead and employee termination costs at our contract research division due to a decline in activity related to internal product-development programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses include: employee compensation costs associated with sales and marketing, finance, legal, information technology, human resources, and other administrative functions; outside legal fees and consultancy costs; product promotion expenses; overhead and occupancy costs; depreciation of corporate facilities and equipment; and other general and administrative costs.

Selling, general and administrative expenses declined \$10.3 million, or 5%, to \$178.6 million in 2009, compared with \$188.9 million in 2008, and increased \$29.7 million, or 19%, in 2008, compared with \$159.3 million in 2007.

The decline in selling, general and administrative expenses in 2009, compared with 2008, was primarily due to:

a decrease of \$14.5 million in payments due to Sciele Pharma, Inc. ("Sciele"), as a result of the termination of our Zovirax® promotional services agreement with Sciele in October 2008;

a decrease of \$10.1 million related to a reversal in the fourth quarter of 2009 of a potential voluntary compliance undertaking ("VCU") liability, as a result of the closure of an investigation into the introductory pricing of Glumetza® in Canada, which determined that our prices for the 500mg and 1000mg dosage strengths were appropriate;

a decrease of \$7.4 million related to management succession costs, associated primarily with a change in our Chief Executive Officer in May 2008;

a decrease in proxy contest costs of \$5.2 million, primarily reflecting expenses incurred in 2008 in connection with the contested election of our nominees to the Board of Directors at our 2008 annual meeting of shareholders;

a decrease of \$4.1 million related to consulting costs incurred in 2008 related to the development and implementation of our specialty CNS strategy; and

the positive effects of the weakening of the Canadian dollar relative to the U.S. dollar and overall cost containment initiatives.

Those factors were partially offset by:

the inclusion of the \$11.0 million loss on the sale and leaseback of our Mississauga, Ontario corporate headquarters;

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

the inclusion of \$8.8 million in fees owed to Publicis and an increase of \$6.4 million in other costs related to the promotion of Zovirax®;

an increase in legal fees of \$3.8 million, primarily related to indemnification obligations to certain former officers and directors, primarily in connection with enforcement proceedings against these former officers and directors by the SEC and OSC;

the inclusion of \$2.9 million in costs related to an examination of our accounting and related functions by independent consultants retained by us pursuant to the settlement agreements we entered into with the OSC and SEC; and

an increase in compensation expense of \$1.4 million related to deferred share units ("DSUs") granted to directors, primarily due to the impact of a year-over-year increase in the underlying trading price of our common shares.

The increase in selling, general and administrative expenses in 2008, compared with 2007, was primarily due to:

a decrease in insurance recoveries related to legal costs of \$20.5 million in 2008, as we had exhausted our director and officer liability insurance for claims related to the legacy litigation and regulatory matters in respect of our 2002 to 2004 policy period;

the inclusion of management succession costs of \$7.4 million and proxy contest costs of \$6.2 million;

the inclusion of consulting costs of \$4.1 million in connection with the development of our specialty CNS strategy;

an increase in promotional spending related to the launch of Ralivia® in Canada of \$3.6 million;

an increase in DSU-related compensation expense of \$1.5 million, as the cost of the annual grant of DSUs in 2007 was more than offset by a decline in the fair value of outstanding DSUs, due to a decline in the underlying trading price of our common shares during 2007; and

the inclusion of \$1.0 million of third-party administrative costs associated with the recall of Ultram® ER 100mg tablets in 2008.

Those factors were partially offset by:

a decrease in legal fees of \$18.9 million in 2008, as a result of the settlement of certain legacy litigation and regulatory matters, partially offset by higher indemnification payments to former officers and directors.

Legal costs amounted to \$45.1 million, \$41.3 million and \$39.6 million in 2009, 2008 and 2007, respectively. Legal costs in 2007 were reported net of insurance recoveries of \$20.5 million. Legal costs included indemnification obligations to certain former officers and directors of \$19.6 million, \$16.4 million and \$10.1 million in 2009, 2008 and 2007, respectively. A portion of these costs may continue for an indefinite period, as we cannot predict the outcome or timing of when the outstanding enforcement proceedings by the SEC and OSC may be resolved.

Amortization of Intangible Assets

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Amortization expense increased \$53.4 million, or 104%, to \$104.7 million in 2009, compared with \$51.4 million in 2008, due to the inclusion of amortization of the Wellbutrin XL® trademark intangible asset acquired in May 2009, and the tetrabenazine product rights intangible assets arising from the acquisition of the worldwide development and commercialization rights in June 2009 and in connection with the Prestwick acquisition in September 2008.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Amortization expense increased \$3.3 million, or 7%, to \$51.4 million in 2008, compared with \$48.0 million in 2007, due to the inclusion of amortization of the Prestwick identifiable intangible assets.

Restructuring Costs

We recorded restructuring charges of \$19.1 million and \$70.2 million in 2009 and 2008, respectively, as described above under "Overview Restructuring".

Legal Settlements, Net

In 2009, we recorded a charge of \$6.2 million in connection with the settlement of certain litigation matters.

In 2008, we recorded a charge of \$32.6 million, of which \$24.6 million related to the USAO settlement in respect of the Cardizem® LA matter and \$5.3 million related to the settlement of the OSC investigation.

In 2007, we recorded a net charge of \$95.1 million, of which \$83.1 million (net of expected insurance recoveries) related to the settlement of the securities class actions in the U.S. and Canada, and \$10.0 million related to the settlement of the SEC investigation.

Acquisition-Related Costs

In the second quarter of 2009, we incurred direct costs of \$5.6 million in connection with the acquisition of the worldwide development and commercialization rights to tetrabenazine.

Intangible Asset Impairments, Net

We perform an evaluation of amortizable intangible assets for impairment at least annually, or whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. Impairment exists when the carrying amount of an asset is not recoverable based on related undiscounted future cash flows, and its carrying amount exceeds its estimated fair value based on related discounted future cash flows.

In 2007, we recorded an impairment charge of \$9.9 million to write down the carrying value of Zolpidem ODT and Ultram® ODT product rights, due to a lack of commercial potential for these products, as well as to write down certain other identified product rights and technology intangible assets.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Non-Operating Income (Expense)

The following table displays the dollar amount of each non-operating income or expense category for each of the last three years; and the percentage changes in the dollar amount of each category.

(\$ in 000s; Income (Expense))	Years Ended December 31			Change			
	2009	2008	2007	2008 to 2009		2007 to 2008	
	\$	\$	\$	\$	%	\$	%
Interest income	1,118	9,400	24,563	(8,282)	(88)	(15,163)	(62)
Interest expense	(25,418)	(1,018)	(9,745)	(24,400)	NM	8,727	(90)
Foreign exchange gain (loss)	507	(1,057)	5,491	1,564	(148)	(6,548)	(119)
Gain on auction rate security settlement	22,000			22,000	NM		
Gain on disposal of investments	804	6,534	24,356	(5,730)	(88)	(17,822)	(73)
Impairment loss on debt securities	(5,210)	(8,613)	(6,000)	3,403	(40)	(2,613)	44
Impairment loss on equity securities		(1,256)	(2,949)	1,256	(100)	1,693	(57)
Equity loss		(1,195)	(2,528)	1,195	(100)	1,333	(53)
Loss on early extinguishment of debt			(12,463)			12,463	(100)
Total non-operating income (expense)	(6,199)	2,795	20,725	(8,994)	(322)	(17,930)	(87)

NM Not meaningful

Interest Income

Interest income declined \$8.3 million, or 88%, to \$1.1 million in 2009, compared with \$9.4 million in 2008, and declined \$15.2 million, or 62%, in 2008, compared with \$24.6 million in 2007, reflecting year-over-year declines in our cash resources as a result of business development activities and legal settlement payments, as well as the redemption of our 7^{7/8}% Senior Subordinated Notes ("Subordinated Notes") effective April 1, 2007, together with lower prevailing interest rates.

Interest Expense

Interest expense increased \$24.4 million to \$25.4 million in 2009, compared with \$1.0 million in 2008, and declined \$8.7 million, or 90%, in 2008, compared with \$9.7 million in 2007. Interest expense incurred in 2009 included non-cash amortization of debt discounts on the Convertible Notes and the Cambridge obligation of \$6.0 million and the non-cash amortization of deferred financing costs associated with the Convertible Notes and our current and former credit facilities of \$3.1 million. In addition, in the second quarter of 2009, we wrote off the remaining unamortized deferred financing costs of \$0.5 million related to our former credit facility.

Prior to 2009, interest expense comprised standby fees and the amortization of deferred financing costs related to our former credit facility, as well as interest on the Subordinated Notes prior to their redemption in April 2007.

Gain on Auction Rate Security Settlement

In May 2008, we commenced an arbitration against the investment bank that invested our assets in auction rate securities. In May 2009, we resolved this matter with the investment bank for a payment to us in the amount of \$22.0 million, which represented a recovery of 82% of the original \$26.8 million principal invested in these securities. We retained ownership of these securities under the terms of this settlement. This settlement does not change our conclusion that we do not intend to sell these securities and it is not more likely than not that we will be required to sell these securities before a recovery of their amortized cost bases (as described below under "Financial Condition, Liquidity and Capital Resources - Net Financial Assets (Liabilities) - Auction Rate Securities").

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Gain on Disposal of Investments

In 2009, we recognized a gain of \$0.8 million on the sale of our equity interests in Depomed and Hemispherx for total cash proceeds of \$0.9 million.

In 2008, we recognized a gain of \$3.1 million on the sale of a portion of our investment in common shares of Depomed for cash proceeds of \$13.2 million, and we recognized a gain of \$3.5 million on the disposal of our investment in common shares and convertible debt of Verdi for cash proceeds of \$12.2 million.

In 2007, we received cash consideration of \$14.9 million on the liquidation of our investment in convertible preferred stock of Reliant, following its acquisition by GSK, resulting in a gain on disposal of \$8.6 million. We also recorded a gain of \$15.7 million on the sale to Verdi of a portion of our investment in common shares of Ethypharm. We received proceeds on disposal of \$39.4 million in cash and \$5.6 million in convertible debt of Verdi. We exchanged the remaining portion of our Ethypharm investment for common shares of Verdi.

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 \$5.2 million, \$8.6 million and \$6.0 million in 2009, 2008 and 2007, respectively (as described below under "Financial Condition, Liquidity and Capital Resources – Net Financial Assets (Liabilities) – Auction Rate Securities").

Loss on Early Extinguishment of Debt

In 2007, we recorded a charge of \$12.5 million on the early redemption of the Subordinated Notes, which comprised the premium paid to the noteholders of \$7.9 million, as well as the net write-off of unamortized deferred financing costs, discount, and fair value adjustment associated with these notes, which totaled \$4.6 million.

Income Taxes

The following table displays the dollar amount of the current and deferred provisions for income taxes for each of the last three years; and the percentage changes in the dollar amount of each provision. Percentages may not add due to rounding.

	Years Ended December 31			Change			
	2009	2008	2007	2008 to 2009		2007 to 2008	
(\$ in 000s; Income (Expense))	\$	\$	\$	\$	%	\$	%
Current income tax expense	(14,500)	(17,000)	(13,200)	2,500	(15)	(3,800)	29
Deferred income tax benefit	16,000	90,000		(74,000)	(82)	90,000	NM
Total recovery of (provision for) income taxes	1,500	73,000	(13,200)	(71,500)	(98)	86,200	(653)

NM Not meaningful

Our effective tax rate was approximately 14% in 2009, compared with approximately 13% and 6% in 2008 and 2007, respectively. The effective tax rate reflects the impact of certain items that are not deductible, including IPR&D charges, restructuring costs, and legal settlements, or do not effect the income tax provision because of unrecognized tax losses in the local jurisdictions. In addition, the low effective tax rate reflects the fact that most of our revenue and income was earned in Barbados, which has lower statutory tax rates than those that apply in Canada. Dividends from such after-tax business income are received tax-free in Canada.

In each of the fourth quarters of 2009 and 2008, we assessed the realizability of a portion of our deferred tax assets related to operating loss carryforwards in the U.S. Our U.S. operations have generated positive earnings

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

in each fiscal year commencing with 2006, reflecting a reduction in the overall cost structure, including the elimination of our U.S. sales force, through restructuring measures implemented in 2006 and 2005. As a result, we reduced the valuation allowance recorded against available U.S. operating loss carryforwards by \$26.0 million and \$90.0 million in the fourth quarters of 2009 and 2008, respectively, with corresponding increases to net income. In determining the amount of the valuation allowance that is necessary, we consider the amount of operating loss carryforwards that we will more likely than not be able to utilize based on the taxable income expected to be generated in the U.S. in future years. In 2009, we recorded a provision for deferred income taxes of \$10.0 million related to the utilization of a portion of these loss carryforwards to reduce taxable income in the U.S.

SUMMARY OF QUARTERLY RESULTS (UNAUDITED)

The following table presents a summary of our unaudited quarterly results of operations and cash flows in 2009 and 2008:

(\$ in 000s, except per share data)	2009				2008			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenue	\$ 173,319	\$ 193,535	\$ 212,523	\$ 241,053	\$ 208,498	\$ 186,095	\$ 181,089	\$ 181,496
Expenses	119,704	182,988	154,179	182,405	145,358	210,368	132,726	144,617
Operating income (loss)	53,615	10,547	58,344	58,648	63,140	(24,273)	48,363	36,879
Net income (loss)	39,003	24,090	40,362	73,000	56,376	(25,289)	48,437	120,380
Basic and diluted earnings (loss) per share	\$ 0.25	\$ 0.15	\$ 0.25	\$ 0.46	\$ 0.35	\$ (0.16)	\$ 0.31	\$ 0.76
Net cash provided by (used in) operating activities	\$ 46,972	\$ 97,081	\$ 89,197	\$ 127,647	\$ 92,676	\$ 67,056	\$ (62,370)	\$ 106,963

The following table displays the specific items identified by management (as described above under "Overview Selected Financial Information Specific Items Impacting Net Income") that impacted net income or loss in each of the quarters in 2009 and 2008, and the impact of these items in the aggregate on basic and diluted EPS.

(\$ in 000s, except per share data; Income (Expense))	2009				2008			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
IPR&D ⁽¹⁾	\$	\$ (30,414)	\$ (8,126)	\$ (20,814)	\$	\$	\$	\$
Reduction in valuation allowance on deferred tax assets ⁽²⁾				26,000				90,000
Gain on auction rate security settlement		22,000						
Restructuring costs	(1,348)	(11,367)	(2,413)	(3,937)		(51,760)	(7,587)	(10,855)
Loss on sale and leaseback of assets ⁽³⁾				(10,968)				
Legal settlements, net of insurance recoveries	(241)			(5,950)		(24,648)	(2,000)	(5,917)
Acquisition-related costs		(5,596)						
Impairment losses on debt and equity securities	(2,707)	(1,617)	(385)	(501)	(3,616)	(489)	(1,223)	(4,541)
SEC/OSC independent consultant costs ⁽³⁾	(1,427)	(1,546)	169	(83)				
Proxy contest costs ⁽³⁾		(629)	(399)			(5,414)	(728)	(50)
Gain (loss) on disposal of investments	(6)	344	466			3,461	4,156	(1,083)
Write-down of deferred financing costs ⁽⁴⁾		(537)						
Management succession costs ⁽³⁾						(6,052)		(1,362)
Equity loss					(1,195)			
Total	\$ (5,729)	\$ (29,362)	\$ (10,688)	\$ (16,253)	\$ (4,811)	\$ (84,902)	\$ (7,382)	\$ 66,192
EPS impact	\$ (0.04)	\$ (0.19)	\$ (0.07)	\$ (0.10)	\$ (0.03)	\$ (0.53)	\$ (0.05)	\$ 0.42

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

- (1) Included in research and development expenses.
- (2) Included in provision for (recovery of) income taxes.
- (3) Included in selling, general and administrative expenses.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

(4) Included in interest expense.

Fourth Quarter of 2009 Compared to Fourth Quarter of 2008

Results of Operations

Revenue

Total revenue increased \$59.6 million, or 33%, to \$241.1 million in the fourth quarter of 2009, compared with \$181.5 million in the fourth quarter of 2008, primarily due to:

incremental revenue of approximately \$42.0 million from Wellbutrin XL® product sales, as a result of the acquisition of the full U.S. commercialization rights in May 2009;

an increase of \$13.7 million in Xenazine® product sales, reflecting a growth in prescription volumes in the U.S. since the product's launch in November 2008, and incremental revenue from the inclusion of worldwide sales of the product;

the recognition in the fourth quarter of 2009 of \$4.4 million of product intended for sale to Teva in the third quarter of 2009 but delayed due to customs clearance issues; and

a strengthening of the Canadian dollar relative to the U.S. dollar in the fourth quarter of 2009, compared with the fourth quarter of 2008, which positively impacted BPC product sales by approximately \$3.3 million.

Those factors were partially offset by:

a \$13.1 million decline in Ultram® ER product sales, mainly due to the introduction of generic competition in November 2009, which resulted in lower prescription volumes and the reduction in our contractual supply price for the 100mg and 200mg dosage strengths, as well as the increase in PriCara's provision for expected product returns.

Net Income

Net income declined \$47.4 million, or 39%, to \$73.0 million in the fourth quarter of 2009, compared with \$120.4 million in the fourth quarter of 2008, primarily due to:

a decrease of \$64.0 million in deferred income tax benefits, related to the reductions in the valuation allowance recorded against U.S. operating loss carryforwards of \$26.0 million and \$90.0 million in the fourth quarters of 2009 and 2008, respectively;

a decrease of \$20.8 million related to IPR&D charges in the fourth quarter of 2009, comprising \$4.0 million for the additional payment related to fipamezole and \$8.8 million for GDNF, as well as the write-off of the \$8.0 million IPR&D intangible asset related to RUS-350;

incremental amortization expense of \$18.7 million related to the acquisition of the various rights to Wellbutrin XL® and tetrabenazine;

the inclusion in selling, general and administrative expenses of the \$11.0 million loss on the sale and leaseback of our corporate headquarters; and

an increase of \$9.7 million in interest expense, primarily related to the Convertible Notes.

Those factors were partially offset by:

an increased contribution from product sales of \$53.5 million, primarily related to the incremental revenue from Wellbutrin XL® and Xenazine® (partially offset by lower Ultram® ER product sales), and reduced costs and improved capacity utilization of our manufacturing operations;

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

an increase of \$10.1 million in selling, general and administrative expenses related to the release of the Glumetza® VCU liability; and

a decrease of \$6.9 million in restructuring costs, mainly due to lower asset impairment charges.

Cash Flows from Operating Activities

Net cash provided by operating activities increased \$20.7 million, or 19%, to \$127.6 million in the fourth quarter of 2009, compared with \$107.0 million in the fourth quarter of 2008, primarily due to:

the increased contribution from product sales of \$53.5 million; and

an increase of \$23.8 million related to the change in accounts payable, mainly due to an increased supply price for Zovirax® inventory purchased from GSK after the conclusion of the price allowance, the addition of clinical trial costs associated with BVF-324, and the inclusion of an amount of \$10.7 million owing to Teva in respect of Generic product sales provisions.

Those factors were partially offset by:

a decrease of \$28.7 million related to the change in accounts receivable, mainly due to higher sales of Wellbutrin XL® in the fourth quarter of 2009, following the May 2009 acquisition of the full U.S. commercialization rights, and lower Wellbutrin XL® product sales in the fourth quarter of 2008, as a result of the genericization of the 150mg dosage strength; and

a decrease of \$25.7 million related to the change in inventories, reflecting the higher cost base of Zovirax® inventory, and increased production of generic Tiazac® and generic Cardizem® CD to meet higher expected demand for these products in 2010, attributable to competitors' manufacturing issues.

FINANCIAL CONDITION, LIQUIDITY AND CAPITAL RESOURCES**Selected Measures of Financial Condition**

The following table presents a summary of our financial condition at December 31, 2009 and 2008:

(\$ in 000s; Asset (Liability))	At December 31		Change	
	2009 \$	2008 \$	\$	%
Working capital ⁽¹⁾	93,734	223,198	(129,464)	(58)
Long-lived assets ⁽²⁾	1,539,364	968,935	570,429	59
Long-term obligations, including current portion	(326,085)		(326,085)	NM
Shareholders' equity	(1,354,372)	(1,201,599)	(152,773)	13

(1) Total current assets less total current liabilities.

(2)

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Property, plant and equipment, intangible assets, and goodwill.

Working Capital

Working capital declined \$129.5 million, or 58%, to \$93.7 million at December 31, 2009, compared with \$223.2 million at December 31, 2008, primarily due to:

a net decline in cash and cash equivalents of \$203.1 million, which primarily reflected: \$761.8 million paid in the aggregate to acquire the various rights to Wellbutrin XL®, tetrabenazine, pimavanserin, fipamezole and GDNF, and \$147.1 million paid in dividends; partially offset by \$373.1 million received in the aggregate through the issuance of the Convertible Notes and the sale and leaseback of certain corporate assets, and \$360.9 million in operating cash flows;

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

an increase in accrued liabilities of \$36.7 million, mainly due to the inclusion of interest payable on the Convertible Notes, the addition of product return, rebate and chargeback provisions related to Wellbutrin XL® sales occurring after the May 2009 acquisition of the full U.S. commercialization rights (including a balance owed to GSK for governmental rebate claims administered and paid by GSK on our behalf), and the assumption of the royalty obligations on worldwide sales of tetrabenazine, partially offset by the release of the Glumetza® VCU liability;

an increase in accounts payable of \$31.0 million, mainly due to the increased supply price for Zovirax® inventory and purchases of tetrabenazine inventory, the addition of clinical trial costs associated with BVF-324, and the inclusion of the amount owing to Teva in respect of Generic product sales provisions (offset by a corresponding decrease in deferred revenue); and

the inclusion of \$12.1 million in current portion of long-term obligations, related to the payment due to Cambridge in June 2010 in connection with the acquisition of the worldwide development and commercialization rights to tetrabenazine.

Those factors were partially offset by:

a decrease in dividends payable of \$45.1 million, reflecting the reduction in our quarterly cash dividend policy to \$0.09 per share commencing in May 2009, compared with \$0.375 per share in 2008;

a decrease in accrued legal settlements of \$24.6 million, related to payments of \$30.8 million made in 2009 primarily to settle the USAO and OSC investigations, partially offset by the \$6.2 million accrued in 2009 in connection with the settlement of certain other litigation matters;

an increase in accounts receivable of \$29.9 million, corresponding to higher Wellbutrin XL® product sales following the May 2009 acquisition of the full U.S. commercialization rights; and

an increase in inventories of \$23.2 million, reflecting the higher cost base of Zovirax® inventory and the build-up of generic Tiazac® and generic Cardizem® CD inventories to meet the higher expected demand for these products in 2010, attributable to competitors' manufacturing issues.

Long-Lived Assets

Long-lived assets increased \$570.4 million, or 59%, to \$1,539.4 million at December 31, 2009, compared with \$968.9 million at December 31, 2008, primarily due to:

the addition of the Wellbutrin XL® trademark intangible asset of \$510.5 million;

the addition of the tetrabenazine identifiable intangible assets of \$225.7 million;

an increase of \$15.7 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 December 31, 2009, compared with December 31, 2008; and

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

additions to property, plant and equipment of \$7.4 million.

Those factors were partially offset by:

the depreciation of plant and equipment of \$18.8 million and the amortization of intangible assets of \$113.9 million;

the sale and leaseback of certain corporate assets with a total carrying value of \$33.2 million;

an impairment charge of \$7.6 million related to the write-down of the property, plant and equipment located in Puerto Rico, and the reclassification of the remaining \$8.5 million carrying value of the Dorado facility to assets held for sale; and

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

the \$8.0 million impairment charge in respect of the write-off of the IPR&D intangible asset related to RUS-350.

Long-term Obligations

Long-term obligations (including the current portion thereof) of \$326.1 million at December 31, 2009, comprised the following:

the \$298.3 million liability component of the Convertible Notes (net of debt discount of \$51.7 million); and

the Cambridge obligation of \$27.8 million (net of debt discount of \$2.2 million).

Shareholders' Equity

Shareholders' equity increased \$152.8 million, or 13%, to \$1,354.4 million at December 31, 2009, compared with \$1,201.6 million at December 31, 2008, primarily due to:

net income of \$176.5 million (including \$5.6 million of stock-based compensation recorded in additional paid-in capital);

the value assigned to the equity component of the Convertible Notes of \$56.7 million, which was recorded in additional paid-in capital; and

a positive foreign currency translation adjustment of \$17.2 million to other comprehensive income, mainly due to the impact of the strengthening of Canadian dollar relative to the U.S. dollar at December 31, 2009, compared with December 31, 2008, which increased the reported value of our Canadian dollar-denominated net assets.

Those factors were partially offset by:

cash dividends declared and dividend equivalents on restricted share units ("RSUs") of \$102.5 million in the aggregate.

Cash Flows

Our primary sources of cash include: the collection of accounts receivable related to product sales; borrowings under our credit facility and the issuance of debt; and proceeds from the sale of non-core assets. Our primary uses of cash include: business development transactions; dividend payments; legal costs and litigation and regulatory settlements; salaries and benefits; inventory purchases; research and development spending; sales and marketing activities; capital expenditures; and interest and principal payments. The following table displays cash flow information for each of the last three years:

	Years Ended December 31			Change			
	2009	2008	2007	2008 to 2009		2007 to 2008	
(\$ in 000s)	\$	\$	\$	\$	%	\$	%
Net cash provided by operating activities	360,897	204,325	340,853	156,572	77	(136,528)	(40)
Net cash used in investing activities	(742,772)	(107,831)	(15,045)	(634,941)	589	(92,786)	617
Net cash provided by (used in) financing activities	177,047	(210,311)	(728,650)	387,358	(184)	518,339	(71)
Effect of exchange rate changes on cash and cash equivalents	1,744	(2,277)	1,943	4,021	(177)	(4,220)	(217)

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Net decrease in cash and cash equivalents	(203,084)	(116,094)	(400,899)	(86,990)	75	284,805	(71)
Cash and cash equivalents, beginning of year	317,547	433,641	834,540	(116,094)	(27)	(400,899)	(48)
Cash and cash equivalents, end of year	114,463	317,547	433,641	(203,084)	(64)	(116,094)	(27)

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Operating Activities

Net cash provided by operating activities increased \$156.6 million, or 77%, to \$360.9 million in 2009, compared with \$204.3 million in 2008, attributable to the net effect of the following factors:

an increase in income from operations before changes in operating assets and liabilities of \$201.7 million, or 125%, to \$362.4 million in 2009, compared with \$160.8 million in 2008, primarily due to:

an increase of \$93.0 million related to payments made in 2008 to fund the settlement of the U.S. and Canadian securities class actions (\$83.0 million) and to settle the SEC investigation (\$10.0 million);

an increased contribution from product sales of \$67.3 million, mainly related to the incremental revenue from Wellbutrin XL® and Xenazine® (partially offset by lower Ultram® ER product sales), together with the reduced costs and improved capacity utilization of our manufacturing operations;

an increase of \$45.1 million related to a contractual payment made to GSK in 2008 in connection with the introduction of generic competition to Wellbutrin XL®; and

an increase related to the \$22.0 million gain realized on the auction rate security settlement in the second quarter of 2009.

Those factors were partially offset by:

a decrease of \$30.8 million primarily related to the payments made in 2009 to settle the USAO and OSC investigations.

a decrease related to the change in operating assets and liabilities of \$45.1 million, or 104%, to cash used of \$1.5 million in 2009, compared with cash provided of \$43.6 million in 2008, primarily due to:

a decrease of \$50.6 million related to the change in accounts receivable, mainly due to higher revenue from Wellbutrin XL® product sales in 2009, following the May 2009 acquisition of the full U.S. commercialization rights, and lower sales of Wellbutrin XL® in 2008, as a result of the genericization of the 150mg dosage strength; and

a decrease of \$46.8 million related to the change in inventories, reflecting the higher cost base of Zovirax® inventory and increased inventories of generic Tiazac® and generic Cardizem® CD in 2009, and lower expected production requirements for Wellbutrin XL®, Cardizem® LA and Generic products in 2008.

Those factors were partially offset by:

an increase of \$36.9 million related to the change in accounts payable, mainly due to the increased supply price for Zovirax® inventory, the addition of clinical trial costs associated with BVF-324, and the inclusion of the amount owed to Teva in respect of Generic product sales provisions; and

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

an increase of \$32.8 million related to the change in accrued liabilities, which reflected the additions of the interest payable on the Convertible Notes, the additions of Wellbutrin XL® product sales provisions and the tetrabenazine royalty obligations, partially offset by the release of the Glumetza® VCU liability.

Net cash provided by operating activities declined \$136.5 million, or 40%, to \$204.3 million in 2008, compared with \$340.9 million in 2007, attributable to the net effect of the following factors:

a decrease in income from operations before changes in operating assets and liabilities of \$209.0 million, or 57%, to \$160.8 million in 2008, compared with \$370.0 million in 2007, mainly due to:

a decrease of \$93.0 million related to the payments made in 2008 to settle the U.S. and Canadian securities class actions and the SEC investigation;

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

a decrease of \$45.1 million related to the Wellbutrin XL® contract payment made to GSK in 2008; and

a decrease in the contribution from product sales of \$60.0 million, reflecting lower sales of Wellbutrin XL® and Cardizem® LA, partially offset by higher Legacy product sales.

an increase related to the change in operating assets and liabilities of \$72.5 million, or 251%, to cash provided of \$43.6 million in 2008, compared with cash used of \$28.9 million in 2008, primarily due to:

an increase of \$30.1 million related to the change in accrued liabilities, mainly due to the settlement of restructuring costs and the elimination of interest payable following the redemption of the Subordinated Notes in 2007;

an increase of \$17.6 million related to the change in inventories, mainly due to lower production requirements for Wellbutrin XL®, Cardizem® LA and Generic products;

an increase of \$16.2 million related to the change in income taxes payable, mainly due to the timing of payments; and

an increase of \$15.2 million related to the change in insurance recoveries receivable, reflecting the timing of reimbursement of certain legal costs by our insurance carriers.

Investing Activities

Net cash used in investing activities increased \$634.9 million, or 589%, to \$742.8 million in 2009, compared with \$107.8 million in 2008, primarily due to:

an increase related to the acquisition in 2009 of the various rights to Wellbutrin XL®, pimavanserin, fipamezole and GDNF for \$561.8 million in the aggregate;

an increase related to the \$200.0 million paid in 2009 to acquire the worldwide development and commercialization rights to tetrabenazine; and

lower proceeds on the sale of long-term investments, primarily related to the disposal of our investments in Depomed and Verdi in 2008 for cash proceeds of \$25.2 million.

Those factors were partially offset by:

a decrease related to the \$101.9 million paid in 2008 to acquire Prestwick, net of cash acquired;

a decrease related to the proceeds of \$23.1 million received on the sale and leaseback of certain corporate assets in 2009; and

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

a decrease in capital expenditures of \$14.6 million, mainly due to the wind-down of operations at our Puerto Rico manufacturing facilities.

Net cash used in investing activities increased \$92.8 million, or 617%, to \$107.8 million in 2008, compared with \$15.0 million in 2007, primarily due to:

an increase related to the \$101.9 million paid to acquire Prestwick in 2008; and

lower proceeds on the sale of long-term investments, related to the disposal of our investments in Depomed and Verdi in 2008 for cash proceeds of \$25.2 million, compared with the disposal of our investments in Ethypharm and Reliant in 2007 for net proceeds of \$52.7 million.

Those factors were partially offset by:

a decrease in additions to marketable securities, primarily related to \$27.0 million of auction rate securities purchased in 2007; and

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

a decrease in capital expenditures of \$13.1 million, mainly as a result of the decision to close the Puerto Rico facilities.

Financing Activities

Net cash provided by financing activities increased \$387.4 million, or 184%, to \$177.0 million in 2009, compared with cash used of \$210.3 million in 2008, primarily due to:

an increase of \$350.0 million related to proceeds from the issuance of the Convertible Notes in 2009;

an increase of \$33.1 million related to dividends paid, reflecting the reduction in our quarterly cash dividend policy to \$0.09 per share commencing in May 2009, compared with \$0.375 per share in 2008; and

an increase of \$29.8 million related to the repurchase of common shares in 2008 (as described below under " Share Repurchase Programs").

Those factors were partially offset by:

a decrease of \$26.3 million related to deferred financing costs incurred in 2009, in connection with the issuance of the Convertible Notes and the establishment of our credit facility.

Net cash used in financing activities declined \$518.3 million, or 71%, to \$210.3 million in 2008, compared with \$728.7 million in 2007, primarily due to:

a decrease of \$406.8 million related to principal and premium payments to redeem the Subordinated Notes in 2007;

a decrease of \$141.2 million in dividends paid related to an increase in declared but unpaid dividends in 2008, and the payment of a special dividend of \$0.50 per share in 2007; and

a decrease of \$11.2 million related to the final payment made to GSK in 2007 related to the Zovirax® price allowance.

Those factors were partially offset by:

an increase of \$29.8 million related to the repurchase of common shares in 2008; and

an increase of \$11.2 million related to proceeds from the issuance of common shares on the exercise of stock options in 2007.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Net Financial Assets (Liabilities)

The following table displays our net financial asset (liability) position at December 31, 2009 and 2008:

(\$ in 000s)	At December 31			
	2009	2008	Change	
	\$	\$	\$	%
Financial Assets				
Cash and cash equivalents	114,463	317,547	(203,084)	(64)
Marketable securities	21,082	22,635	(1,553)	(7)
Total financial assets	135,545	340,182	(204,637)	(60)
Financial Liabilities				
Convertible Notes	(298,285)		(298,285)	NM
Cambridge obligation	(27,800)		(27,800)	NM
Total financial liabilities	(326,085)		(326,085)	NM
Net financial assets (liabilities)	(190,540)	340,182	(530,722)	(156)

 NM Not meaningful

We believe that cash expected to be generated by operations and from the potential sale of 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 24 to our 2009 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.

Cash and Cash Equivalents

Our cash and cash equivalents are 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. As described above under "Results of Operations Non-Operating Income (Expense) Gain on Auction Rate Security Settlement", 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 and retained ownership of the securities. The estimated fair values of these securities at December 31, 2009 and 2008 were \$6.0 million and \$10.3 million, respectively, which reflected write-downs of \$20.8 million and \$16.4 million, respectively, to the cost bases at those dates. We recorded an impairment charge of \$5.2 million in 2009 (including \$0.7 million reclassified from other comprehensive income), compared with

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

\$8.6 million in 2008 (including \$4.4 million reclassified from other comprehensive income) and \$6.0 million in 2007, reflecting the portion of the auction rate securities that we concluded has an other-than-temporary decline in estimated fair value due to a shortfall in the underlying collateral value for these securities. These charges did not have a material impact on our liquidity.

Effective April 1, 2009, we adopted the recently issued guidance on the recognition and presentation of other-than-temporary impairments (as described below under "Recent Accounting Guidance - Adoption of New Accounting Guidance"). This guidance requires an other-than-temporary impairment of a debt security to be separated into (i) the amount representing the decrease in cash flows expected to be collected, or the credit loss portion, which is recognized in earnings, and (ii) the amount related to all other factors, or the non-credit portion, which is recognized in other comprehensive income in circumstances in which management asserts that it does not have the intent to sell the security, and it is more likely than not that it will not be required to sell the security before recovery of its amortized cost basis. Prior to the adoption of this guidance, the entire other-than-temporary impairment loss was recognized in earnings. Upon the adoption of this guidance, the cumulative effect adjustment to reclassify the non-credit losses previously recognized through earnings from accumulated other comprehensive income to opening accumulated deficit was not material to our 2009 Financial Statements. In addition, the non-credit portion of the \$5.2 million other-than-temporary impairment charges recognized in 2009 was not material to our 2009 Financial Statements.

We recorded an unrealized gain in other comprehensive income of \$0.2 million in 2009, compared with unrealized losses of \$3.4 million in 2008 and \$2.8 million in 2007, reflecting adjustments to the portion of the auction rate securities that we have concluded have a temporary decline in estimated fair value. We do not consider the overall decline in the estimated fair value of these securities to be other-than-temporary based on the adequacy of the underlying collateral value for the securities. In addition, we concluded that we do not intend to sell these securities and it is not more likely than not that we will be required to sell these securities before a recovery of their amortized cost bases.

If uncertainties in the credit and capital markets continue through 2010 and beyond, or these markets deteriorate further, or we experience any additional declines in underlying collateral values on the auction rate securities, we may incur additional write-downs to these securities; however, any additional write-downs would not have a material impact on our results of operations and cash flows.

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 December 31, 2009, we were in compliance with all covenants associated with this facility.

Share Repurchase Programs

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.

During 2008, we repurchased 2.8 million common shares for total consideration of \$29.8 million under a prior share repurchase 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,

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

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.

The following table summarizes our contractual obligations at December 31, 2009:

(\$ in 000s)	Total	Payments Due by Period			Thereafter
		2010	2011 and 2012	2013 and 2014	
Long-term obligations ⁽¹⁾	\$487,125	\$38,127	\$61,374	\$387,624	\$
Operating lease obligations	59,975	7,839	13,988	10,922	27,226
Purchase obligations ⁽²⁾	61,159	49,583	11,337	239	
Total contractual obligations	\$608,259	\$95,549	\$86,699	\$398,785	\$27,226

(1) Expected interest payments assume repayment of the principal amount of the debt obligations at maturity.

(2) Purchase obligations consist of agreements to purchase goods and services that are enforceable and legally binding and include obligations for minimum inventory and capital expenditures, and outsourced information technology, product promotion and clinical research services.

The above table does not reflect any contingent milestone or royalty payments in connection with research and development arrangements with third parties. These arrangements generally permit us to unilaterally terminate development of the products, which would allow us to avoid making the contingent payments. From a business perspective, however, we view these payments favourably as they signify that the products are moving successfully through the development phase toward commercialization. As described above under "Overview Business Development", we may be required to make milestone payments of up to \$775.0 million in the aggregate pursuant to the terms of the collaboration and license agreements for pimavanserin, fipamezole, GDNF, and Staccato® loxapine. 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 pimavanserin, fipamezole, GDNF, or Staccato® loxapine products in the event regulatory approval is obtained and such products are commercialized.

Also excluded from the above table is a liability for uncertain tax positions totaling \$66.2 million. This liability has been excluded because we cannot currently make a reliable estimate of the period in which the liability will be payable, if ever.

OUTSTANDING SHARE DATA

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

At February 24, 2010, we had 158,372,110 issued and outstanding common shares, as well as 3,925,605 stock options, 367,122 RSUs without performance goals and 679,405 RSUs with performance goals outstanding. Each stock option entitles the holder to purchase one of our common shares at the end of the vesting period at a pre-determined option price. Each RSU without performance goals represents the right of the holder to receive one of our common shares at the end of the vesting period. Each vested RSU with performance goals represents the right of a holder to receive a number of our common shares, up to 200% of the RSUs granted, depending on our performance relative to an industry comparator group. If our performance is below a specified performance level, no common shares will be paid. A maximum of 1,358,810 common shares could be issued upon vesting of the RSUs with performance goals outstanding at February 24, 2010.

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

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Convertible Notes, subject to adjustment); however, our intent and policy is to settle the Convertible Notes using a net share settlement approach.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Inflation; Seasonality

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

Foreign Currency Risk

We operate internationally, but a majority of our revenue and expense activities and capital expenditures are denominated in U.S. dollars. Our only other significant transactions are denominated in Canadian dollars. We also face foreign currency exposure on the translation of our operations in Canada from Canadian dollars to U.S. dollars. Where possible, we manage foreign currency risk by managing same currency assets in relation to same currency liabilities, and same currency revenue in relation to same currency expenses. As a result, both favourable and unfavourable foreign currency impacts to our Canadian dollar-denominated operating expenses are mitigated to a certain extent by the natural, opposite impact on our Canadian dollar-denominated revenue. At December 31, 2009, the effect of a hypothetical 10% immediate and adverse change in the Canadian dollar exchange rate (relative to the U.S. dollar) on our Canadian dollar-denominated cash, cash equivalent, accounts receivable, accounts payable, and intercompany balances would not have a material impact on our net income. In the first quarter of 2009, we entered into limited short-dated forward contracts to seek to mitigate foreign exchange risk. These contracts were settled prior to March 31, 2009, and did not have a material effect on our results of operations or cash flows.

The eventual payment of our U.S. dollar-denominated Convertible Notes will likely result in a foreign exchange gain or loss for Canadian income tax purposes. The amount of this gain or loss will depend on the exchange rate between the U.S. and Canadian dollar at the time the Convertible Notes are paid. At December 31, 2009, the unrealized foreign exchange gain on the translation of the face value of the Convertible Notes to Canadian dollars for Canadian income tax purposes was approximately \$20.0 million. If all of our outstanding Convertible Notes had been paid at December 31, 2009, one-half of this foreign exchange gain would be included in our Canadian taxable income, which would result in a corresponding reduction in our available Canadian operating losses and tax credit carryforward balances (with an offsetting reduction to the valuation allowance provided against those balances). However, the payment of our Convertible Notes will not result in a foreign exchange gain or loss being recognized in our consolidated financial statements, as those statements are prepared in U.S. dollars.

Interest Rate Risk

The primary objective of our policy for the investment of temporary cash surpluses is the protection of principal, and, accordingly, we generally invest in investment-grade debt securities with varying maturities, but typically less than three months. As it is our intent and policy to hold these investments until maturity, we do not have a material exposure to interest rate risk, and, as a result, a hypothetical 100 basis point immediate and adverse change in interest rates would not have a material impact on the realized value of these investments.

We are also exposed to interest rate risk on our investment in auction rate securities. Interest rates on these securities are typically reset every month; however, following the failure to complete successful auctions and the reset of interest rates due to market liquidity issues, interest on these securities is being calculated based on prescribed spreads to LIBOR. As we are entitled to a fixed spread to market interest rates, our interest rate risk

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

exposure is minimal, and, as a result, a hypothetical 100 basis point immediate and adverse change in interest rates would not have a material impact on the fair value of these securities.

We are exposed to interest rate risk on borrowings under our credit facility. This variable-rate facility bears interest based on U.S. dollar LIBOR, U.S. dollar base rate, Canadian dollar prime rate, and/or Canadian dollar bankers' acceptance. As we currently have no outstanding borrowings under this facility, a hypothetical 100 basis point change in interest rates would not have any impact on our interest expense or cash flows.

The fair value of our fixed-rate Convertible Notes is affected by changes in interest rates. In addition, the imputed rate of interest used to discount the Cambridge obligation is fixed and, consequently, the fair value of this obligation is also affected by changes in interest rates. A hypothetical 100 basis point change in interest rates would increase or decrease the fair value of our outstanding fixed-rate obligations by approximately \$7.0 million.

Market Price Risk

The fair value of our Convertible Notes is also affected by changes in the market price of our common shares. A hypothetical 10% change in our share price would increase or decrease the fair value of the Convertible Notes by approximately \$22.0 million.

Investment Risk

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

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 judgments due to the need to select policies from among alternatives available, and to make estimates about matters that are inherently uncertain. We base our estimates on historical experience and other factors that we believe to be reasonable under the circumstances. Under certain product manufacturing and supply agreements, we rely on estimates for future returns, rebates, and chargebacks made by our commercialization counterparties. On an ongoing basis, we review our estimates to ensure that these estimates appropriately reflect changes in our business and new information as it becomes available. If historical experience and other factors we use to make these estimates do not reasonably reflect future activity, our results of operations and financial condition could be materially impacted.

Our critical accounting policies and estimates relate to the following:

revenue recognition;

acquisitions;

intangible assets;

goodwill;

contingencies;

income taxes; and

stock-based compensation.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Revenue Recognition

We recognize product sales revenue when title has transferred to the customer and the customer has assumed the risks and rewards of ownership. Revenue from product sales is recognized net of provisions for estimated cash discounts, allowances, returns, rebates, and chargebacks, as well as distribution fees paid to certain of our wholesale customers. We establish these provisions concurrently with the recognition of product sales revenue.

Our supply prices in the U.S. for Wellbutrin XL® (prior to the acquisition of the full U.S. commercialization rights in May 2009), Aplenzin®, Ultram® ER, Xenazine®, Cardizem® LA, Tiazac®, and Generic products are determined after taking into consideration estimates for future returns, rebates, and chargebacks provided to us by each of our commercialization counterparties. We make adjustments as needed to state these estimates on a basis consistent with our revenue recognition policy and our methodology for estimating returns, rebates, and chargebacks related to our own direct product sales. Revenue from sales of these products accounted for approximately 30% of our total gross product sales in 2009, compared with 45% and 55% in 2008 and 2007, respectively. The year-over-year declines in the percentage of gross product sales comprised of these products was primarily due to the acquisition of the Wellbutrin XL® commercialization rights in 2009, and the impact of the genericization of 150mg and 300mg dosage strengths of Wellbutrin XL® in May 2008 and December 2006, respectively.

We continually monitor our product sales provisions and evaluate the estimates used as additional information becomes available. We make adjustments to these provisions periodically to reflect new facts and circumstances that may indicate that historical experience may not be indicative of current and/or future results. We are required to make subjective judgments based primarily on our evaluation of current market conditions and trade inventory levels related to our products. This evaluation may result in an increase or decrease in the experience rate that is applied to current and future sales, or an adjustment related to past sales, or both.

Continuity of Product Sales Provisions

The following table presents the activity and ending balances for our product sales provisions for each of the last three years.

(\$ in 000s)	Cash		Returns	Rebates and	Distribution	Total
	Discounts	Allowances		Chargebacks	Fees	
Balance, January 1, 2007	\$ 309	\$ 341	\$ 25,121	\$ 6,742	\$ 2,350	\$ 34,863
Current year provision	6,304	1,110	13,868	18,969	12,583	52,834
Prior year provision			(563)	(1,500)		(2,063)
Payments or credits	(5,871)	(1,152)	(19,064)	(16,248)	(10,607)	(52,942)
Balance, December 31, 2007	742	299	19,362	7,963	4,326	32,692
Current year provision	6,766	1,632	19,919	24,448	10,670	63,435
Prior year provision			(4,599)	(1,297)		(5,896)
Payments or credits	(6,898)	(1,702)	(9,590)	(24,841)	(11,278)	(54,309)
Balance, December 31, 2008	610	229	25,092	6,273	3,718	35,922
Current year provision	11,711	1,679	16,498	48,350	16,894	95,132
Prior year provision			3,767	6,852		10,619
Payments or credits	(11,050)	(1,497)	(20,773)	(38,245)	(15,154)	(86,719)
Balance, December 31, 2009	\$ 1,271	\$ 411	\$ 24,584	\$ 23,230	\$ 5,458	\$ 54,954

The increase in the provision for product rebates and chargebacks as at December 31, 2009, compared with December 31, 2008, reflects the acquisition of the full U.S. commercialization rights to Wellbutrin XL® in May 2009. In particular, we assumed the financial responsibility for governmental rebate programs for product sold after the acquisition date. The provision for rebates and chargebacks at December 31, 2009 includes a balance owing to GSK for rebate claims administered and paid by GSK on our behalf.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Use of Information from External Sources

We use information from external sources to estimate our product sales provisions. We obtain prescription data for our products from IMS Health Inc., an independent provider of information solutions to the pharmaceutical and healthcare industries. We use this data to identify sales trends based on prescription demand and to estimate inventory requirements. We obtain inventory data directly from our three major U.S. wholesalers, McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal") and AmerisourceBergen Corporation ("ABC"), which together accounted for approximately 90% of our direct product sales in the U.S. over the past three years. The inventory data received from these wholesalers excludes inventory held by customers to whom they sell. Third-party data with respect to prescription demand and inventory levels are subject to the inherent limitations of estimates that rely on information from external sources, as this information may itself rely on certain estimates and reflect other limitations.

Our inventory levels in the wholesale distribution channel do not vary substantially, as our distribution agreements with McKesson, Cardinal and ABC limit the amount of inventory they can own to between $1/2$ and $1\ 1/2$ months of supply of our products. The inventory data from these wholesalers is provided to us in the aggregate rather than by specific lot number, which is the level of detail that would be required to determine the original sale date and remaining shelf life of the inventory. However, the inventory reports we receive from these wholesalers include data with respect to inventories on hand with less than 12 months remaining shelf life (as described above under "Results of Operations Revenue Product Sales Wholesaler Inventory Levels").

Cash Discounts and Allowances

We offer cash discounts for prompt payment and allowances for volume purchases to customers. Provisions for cash discounts are estimated at the time of sale and recorded as direct reductions to accounts receivable and revenue. Provisions for allowances are recorded in accrued liabilities. We estimate provisions for cash discounts and allowances based on contractual sales terms with customers, an analysis of unpaid invoices, and historical payment experience. Estimated cash discounts and allowances have historically been predictable and less subjective, due to the limited number of assumptions involved, the consistency of historical experience, and the fact that we generally settle these amounts within one month of incurring the liability.

Returns

Consistent with industry practice, we generally allow customers to return product within a specified period before and after its expiration date. Our product returns provision is estimated based on historical sales and return rates over the period during which customers have a right of return. We utilize the following information to estimate our provision for returns:

historical return and exchange levels;

external data with respect to inventory levels in the wholesale distribution channel;

external data with respect to prescription demand for our products;

remaining shelf lives of our products at the date of sale; and

estimated returns liability to be processed by year of sale based on an analysis of lot information related to actual historical returns.

In determining our estimates for returns, we are required to make certain assumptions regarding the timing of the introduction of new products and the potential of these products to capture market share. In addition, we make certain assumptions with respect to the extent and pattern of decline associated with generic competition. To make these assessments we utilize market data for similar products as analogs for our estimates. We use our best judgment to formulate these assumptions based on past experience and information available to us at the

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

time. We continually reassess and make the appropriate changes to our estimates and assumptions as new information becomes available to us.

Our provision for returns was 2.7% of direct product sales in 2009, compared with 4.8% and 3.6% in 2008 and 2007, respectively. The decline in the returns provision as a percentage of direct product sales in 2009, compared with 2008, was mainly due to the inclusion of the \$6.5 million provision for the recall of Ultram® ER 100mg product in the fourth quarter of 2008, and the \$1.1 reduction to that provision in the first quarter of 2009. Excluding the impact of the Ultram® ER recall, our provision for returns would have been 2.8% and 3.2% of direct product sales in 2009 and 2008, respectively.

Our estimate for returns may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. When we are aware of an increase in the level of inventory of our products in the distribution channel, we consider the reasons for the increase to determine if the increase may be temporary or other-than-temporary. Increases in inventory levels assessed as temporary will not result in an adjustment to our provision for returns. Other-than-temporary increases in inventory levels, however, may be an indication that future product returns could be higher than originally anticipated, and, as a result, we may need to adjust our estimate for returns. Some of the factors that may suggest that an increase in inventory levels will be temporary include:

recently implemented or announced price increases for our products;

new product launches or expanded indications for our existing products; and

timing of purchases by our wholesale customers.

Conversely, factors that may suggest that an increase in inventory levels will be other-than-temporary include:

declining sales trends based on prescription demand;

introduction of new products or generic competition;

increasing price competition from generic competitors;

recent regulatory approvals to extend the shelf life of our products, which could result in a period of higher returns related to older products with the shorter shelf life; and

recent changes to the U.S. National Drug Codes ("NDC") of our products, which could result in a period of higher returns related to products with the old NDC, as our customers generally permit only one NDC per product for identification and tracking within their inventory systems.

We made an adjustment of \$3.8 million to increase the provision for returns in 2009, compared with adjustments to reduce the provision for returns by \$4.6 million and \$0.6 million in 2008 and 2007, respectively. These adjustments generally related to sales made in preceding years, as the shelf lives of our products are in excess of one year, and our customers are not permitted to return product with more than six months of shelf life remaining. The adjustment in 2009 was primarily related to higher than anticipated returns of Tiazac® that had been sold in Canada prior to the genericization of the product in January 2006 (Tiazac® has 48-month dating). The adjustment in 2008 reflected lower actual returns experience in the period since our entry into distribution agreements with our major U.S. wholesale customers in late 2004 and early 2005.

Rebates and Chargebacks

We are subject to rebates on sales made under governmental and managed-care pricing programs in the U.S. The largest of these rebates is associated with sales covered by Medicaid. We participate in state government-managed Medicaid programs, as well as certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating government entities. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be as much as 270 days after the quarter in

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

which the product is dispensed to the Medicaid participant. As a result, our Medicaid rebate provision includes an estimate of outstanding claims for end-customer sales that occurred but for which the related claim has not been billed, and an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants. Our calculation also requires other estimates, such as estimates of sales mix, to determine which sales are subject to rebates and the amount of such rebates. Periodically, we adjust the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual claims paid may incorporate revisions of that provision for several periods.

Chargebacks relate to our contractual agreements to sell products to group purchasing organizations and other indirect customers at contractual prices that are lower than the list prices we charge wholesalers. When these group purchasing organizations or other indirect customers purchase our products through wholesalers at these reduced prices, the wholesaler charges us for the difference between the prices they paid us and the prices at which they sold the products to the indirect customers.

In estimating our provisions for rebates and chargebacks, we consider relevant statutes with respect to governmental pricing programs and contractual sales terms with managed-care providers and group purchasing organizations. We estimate the amount of our product sales subject to these programs based on historical utilization levels. Changes in the level of utilization of our products through private or public benefit plans and group purchasing organizations will affect the amount of rebates and chargebacks that we are obligated to pay. We continually update these factors based on new contractual or statutory requirements, and any significant changes in sales trends that may impact the percentage of our products subject to rebates or chargebacks.

Our provisions for rebates and chargebacks were 7.8%, 5.9% and 5.0% of direct product sales in 2009, 2008 and 2007, respectively. The amount of rebates and chargebacks has become more significant as a result of a combination of deeper discounts due to the price increases we implemented in each of the last three years and increased Medicaid utilization due to existing economic conditions in the U.S. Our estimate for rebates and chargebacks may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. If the level of inventory of our products in the distribution channel increased or decreased by a one-month supply, the provision for rebates and chargebacks would increase or decrease, as applicable, by approximately \$3.6 million.

We do not process or track actual rebate payments or credits by period in which the original sale was made, as the necessary lot information is not required to be provided to us by the private or public benefit providers. Accordingly, we generally assume that adjustments made to rebate provisions relate to sales made in the prior years due to the delay in billing. However, we assume that adjustments made to chargebacks are generally related to sales made in the current year, as we settle these amounts within a few months of original sale. We recorded an adjustment of \$6.9 million in 2009 to increase the provision for rebates as a result of higher than anticipated Medicaid utilization, due to the economic condition in the U.S. and the related increase in the number of patients in these governmental programs.

Acquisitions

We account for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Amounts allocated to acquired IPR&D are recognized at fair value and initially characterized as indefinite-lived intangible assets, irrespective of whether the acquired IPR&D has an alternative future use. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense at the acquisition date.

The judgments made in determining the estimated fair value assigned to each class of asset acquired and liability assumed can materially impact our results of operations. As a result, we typically engage independent valuation specialists to perform valuations of the net assets acquired. There are several methods that can be used to determine fair value. For intangible assets, including IPR&D, we typically use an income approach. This

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

approach starts with a forecast of the net cash flows expected to be generated by the asset over its estimated useful life. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include:

the amount and timing of projected future cash flows, adjusted for the probability of technical and marketing success;

the amount and timing of projected costs to develop IPR&D into commercially viable products;

the discount rate selected to measure the risks inherent in the future cash flows; and

an assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry.

Determining the useful life of an intangible asset also requires judgment, as different types of intangible assets will have different useful lives and certain assets may even be considered to have indefinite useful lives. Useful life is the period over which the intangible asset is expected to contribute directly or indirectly to our future cash flows. We determine the useful lives of intangible assets based on a number of factors, such as legal, regulatory, or contractual provisions that may limit the useful life, and the effects of obsolescence, anticipated demand, existence or absence of competition, and other economic factors on useful life.

Intangible Assets

We evaluate amortizable intangible assets acquired through asset acquisitions or business combinations for impairment annually, and more frequently if events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable. Our evaluation is based on an assessment of potential indicators of impairment, such as:

an adverse change in legal factors or in the business climate that could affect the value of an asset. For example, a successful challenge of our patent rights resulting in earlier than expected generic competition;

an adverse change in the extent or manner in which an asset is used or is expected to be used. For example, a decision not to pursue a product line-extension strategy to enhance an existing product due to changes in market conditions and/or technological advances; or

current or forecasted operating or cash flow losses that demonstrate continuing losses associated with the use of an asset. For example, the introduction of a competing product that results in a significant loss of market share.

Impairment exists when the carrying amount of an amortizable intangible asset is not recoverable and its carrying amount exceeds its estimated fair value. A discounted cash flow analysis is typically used to determine fair value using estimates and assumptions that market participants would apply. Some of the estimates and assumptions inherent in a discounted cash flow model include the amount and timing of the projected future cash flows, and the discount rate used to reflect the risks inherent in the future cash flows. A change in any of these estimates and assumptions could produce a different fair value, which could have a material impact on our results of operations. In addition, an intangible asset's expected useful life can increase estimation risk, as longer-lived assets necessarily require longer-term cash flow forecasts, which for some of our intangible assets can be up to 20 years. In connection with an impairment evaluation, we also reassess the remaining useful life of the intangible asset and modify it, as appropriate.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Indefinite-lived intangible assets, including IPR&D, are tested for impairment annually, or more frequently if events or changes in circumstances between annual tests indicate that the asset may be impaired. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of their fair value to carrying value, without consideration of any recoverability test.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Goodwill

Goodwill represents the excess of the purchase price of acquired businesses over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least annually at the reporting unit level. A reporting unit is the same as, or one level below, an operating segment. We currently have one operating segment and one reporting unit, which is our Company. The fair value of a reporting unit refers to the price that would be received to sell the unit as a whole in an orderly transaction between market participants. We believe our market capitalization based on the quoted market price of our underlying common shares is the best evidence of the estimated fair value of the reporting unit. Accordingly, we test goodwill for impairment by comparing our market capitalization to the carrying value of our consolidated net assets.

We monitor changes in our share price between annual impairment tests to ensure that our market capitalization continues to exceed the carrying value of the reporting unit. We consider a decline in our share price that corresponds to an overall deterioration in stock market conditions to be less of an indicator of goodwill impairment than a unilateral decline in our share price reflecting adverse changes in our underlying operating performance, cash flows, financial condition, and/or liquidity. In the event that our market capitalization does decline below its book value, we would consider the length and severity of the decline and the reason for the decline when assessing whether potential goodwill impairment exists. We believe that short-term fluctuations in share prices may not necessarily reflect underlying values. For example, a decline in share price due to the following reasons may not be indicative of an actual decline in the fair value of the reporting unit:

the decline is linked to external events or conditions, such as broad market reaction to circumstances associated with one (or a few) pharmaceutical companies, which could cause temporary market declines for other companies in the same sector; or

the decline is associated with unusual market activity, such as a spike in short selling activity, which may have a temporary impact on a company's market capitalization but not reflect its underlying fair value.

However, if a decline in our market capitalization below book value persists for an extended period of time, we would likely consider the decline to be indicative of a decline in the fair value of the reporting unit.

Contingencies

In the normal course of business, we are subject to loss contingencies, such as claims and assessments arising from litigation and other legal proceedings; contractual indemnities; product and environmental liabilities; and tax matters. We are required to accrue for such loss contingencies if it is probable that the outcome will be unfavourable and if the amount of the loss can be reasonably estimated. We are often unable to develop a best estimate of loss, in which case the minimum amount of loss, which could be zero, is recorded. We evaluate our exposure to loss based on the progress of each contingency, experience in similar contingencies, and consultation with internal and external legal counsel. We re-evaluate all contingencies as additional information becomes available. Given the uncertainties inherent in complex litigation and other contingencies, these evaluations can involve significant judgment about future events. The ultimate outcome of any litigation or other contingency may be material to our results of operations, financial condition, and cash flows. For a discussion of our current legal proceedings, see note 24 to our 2009 Financial Statements.

Prior to July 1, 2009, we were self-insured for a portion of our product liability coverage. Reserves have been established for estimates of incurred but not reported claims. Significant judgment is applied to estimate these reserves, and we engage an independent actuary to conduct an actuarial assessment of our liability. If actual claims are in excess of these estimates, additional reserves may be required, which could have a material impact on our results of operations, financial condition and cash flows. Effective July 1, 2009, our entire product liability coverage is provided by third-party insurers.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Income Taxes

We have operations in various countries that have differing tax laws and rates. A significant portion of our revenue and income is earned in Barbados, which has low domestic tax rates. Our tax structure is supported by current domestic tax laws in the countries in which we operate and the application of tax treaties between the various countries in which we operate. Our income tax reporting is subject to audit by domestic and foreign tax authorities. Our effective tax rate may change from year to year based on changes in the mix of activities and income allocated or earned among the different jurisdictions in which we operate, changes in tax laws in these jurisdictions, changes in tax treaties between various countries in which we operate, changes in our eligibility for benefits under those tax treaties, and changes in the estimated values of deferred tax assets and liabilities. Such changes could result in an increase in the effective tax rate on all or a portion of our income and/or any of our subsidiaries to a rate possibly exceeding the applicable statutory tax rate in Canada or the U.S.

Our provision for income taxes is based on a number of estimates and assumptions made by management. Our consolidated income tax rate is affected by the amount of income earned in our various operating jurisdictions, the availability of benefits under tax treaties, and the rates of taxes payable in respect of that income. We enter into many transactions and arrangements in the ordinary course of business in which the tax treatment is not entirely certain. We must therefore make estimates and judgments based on our knowledge and understanding of applicable tax laws and tax treaties, and the application of those tax laws and tax treaties to our business, in determining our consolidated tax provision. For example, certain countries could seek to tax a greater share of income than has been provided for by us. The final outcome of any audits by taxation authorities may differ from the estimates and assumptions we have used in determining our consolidated income tax provisions and accruals. This could result in a material effect on our consolidated income tax provision, results of operations, and financial condition for the period in which such determinations are made.

We have recorded a valuation allowance on the net deferred tax assets primarily relating to our Canadian operating losses, Scientific Research and Experimental Development ("SR&ED") pool, investment tax credit ("ITC") carryforward balances, and future tax depreciation. We have assumed that the deferred tax assets in respect of our Canadian operating losses, SR&ED pool and ITCs are more likely than not to remain unrealized. Our deferred tax assets and related valuation allowances are affected by events and transactions arising in the ordinary course of business, acquisitions of assets and businesses, and non-recurring items. The assessment of the appropriate amount of the valuation allowance against the net deferred tax asset is dependent upon several factors, including estimates of the realization of deferred income tax assets, which realization is primarily based on forecasts of future taxable income. Significant judgment is applied to determine the appropriate amount of valuation allowance to record. Changes in the amount of the valuation allowance required could materially increase or decrease our provision for income taxes in a given period.

Stock-Based Compensation

We recognize employee stock-based compensation, including grants of stock options and RSUs, at estimated fair value. As there is no market for trading our employee stock options, we use the Black-Scholes option-pricing model to calculate stock option fair values, which requires certain assumptions related to the expected life of the stock option, future stock price volatility, risk-free interest rate, and dividend yield. The expected life of the stock option is based on historical exercise and forfeiture patterns. Future stock price volatility is based on historical volatility of our common shares over the expected life of the stock option. The risk-free interest rate is based on the rate at the time of grant for Canadian government bonds with a remaining term equal to the expected life of the stock option. Dividend yield is based on the stock option's exercise price and expected annual dividend rate at the time of grant. Changes to any of these assumptions, or the use of a different option-pricing model, such as the lattice model, could produce a different fair value for stock-based compensation expense, which could have a material impact on our results of operations.

Commencing in 2008, we began to award RSUs, rather than stock options, to most employees under our equity compensation plan. We determine the fair value of each RSU granted based on the trading price of our

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

common shares on the date of grant, unless the vesting of the RSU is conditional on the attainment of any applicable performance goals, in which case we use a Monte Carlo simulation model. The Monte Carlo simulation model utilizes multiple input variables to estimate the probability that the performance condition will be achieved. Changes to any of these inputs could materially affect the measurement of the fair value of the RSUs with performance goals.

RECENT ACCOUNTING GUIDANCE

Adoption of New Accounting Guidance

Effective October 1, 2009, we adopted the following accounting guidance:

Authoritative guidance clarifying the measurement of liabilities at fair value. When a quoted price in an active market for the identical liability is not available, this guidance requires that the fair value of a liability be measured using one or more of the prescribed valuation techniques. In addition, the guidance clarifies how the quoted price of a debt security when traded as an asset should be considered in estimating the fair value of the issuer's liability. The adoption of this guidance did not have a material impact on our 2009 Financial Statements.

Effective July 1, 2009, we adopted the following accounting guidance:

In June 2009, the Financial Accounting Standards Board ("FASB") established the FASB Accounting Standards Codification (the "Codification") as the source of authoritative accounting principles recognized by the FASB to be applied in the preparation of financial statements in conformity with U.S. GAAP. As the issuance of the Codification does not change U.S. GAAP, its adoption did not have any impact on our 2009 Financial Statements.

Effective April 1, 2009, we adopted the following accounting guidance:

Authoritative guidance on subsequent events, which identifies the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements and the disclosures that should be made about events or transactions that occurred after the balance sheet date. As this guidance is largely consistent with previous auditing literature, its adoption did not have a material impact on our 2009 Financial Statements.

Authoritative guidance on the recognition and presentation of other-than-temporary impairments, which requires entities to separate an other-than-temporary impairment of a debt security into (i) the amount representing the decrease in cash flows expected to be collected, or the credit loss portion, which is recognized in earnings, and (ii) the amount related to all other factors, or the non-credit portion, which is recognized in other comprehensive income in circumstances in which management asserts that it does not have the intent to sell the security, and it is more likely than not that it will not be required to sell the security before recovery of its amortized cost basis. Upon the adoption of this guidance, the cumulative effect adjustment to reclassify the non-credit losses previously recognized through earnings from accumulated other comprehensive income to opening accumulated deficit was not material to our 2009 Financial Statements.

Authoritative guidance on determining fair value when the volume and level of activity for the asset or liability have significantly decreased and on identifying transactions that are not orderly, which provides additional guidance on estimating fair value when there has been a significant decrease in the volume and level of activity for the asset or liability in relation to the normal market activity for the asset or liability. The guidance also provides circumstances that may indicate that a transaction for the asset or liability is not orderly. The adoption of this guidance did not have a material impact on our 2009 Financial Statements.

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

Effective January 1, 2009, we adopted the following accounting guidance:

Authoritative guidance on convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement), which requires that the liability (debt) and equity (conversion option) components of convertible debt instruments that may be settled in cash upon conversion be separately accounted for in a manner that reflects an issuer's non-convertible debt borrowing rate. This new method of accounting results in recognizing interest expense at rates reflective of what the issuer would have incurred had it issued non-convertible debt with otherwise similar terms. The adoption of this guidance impacted our accounting for the Convertible Notes (as described above under "Overview Financing Arrangements Convertible Notes"). This guidance will also have a material impact on interest expense recognized during the period that the Convertible Notes remain outstanding, but will have no impact on our future cash flows.

Authoritative guidance on business combinations and non-controlling interests, which significantly changes the accounting for, and reporting of, business combination transactions and non-controlling (minority) interests in consolidated financial statements, including requirements to: recognize non-controlling interests at fair value; capitalize IPR&D assets acquired; and expense acquisition-related costs as incurred. The guidance also requires post-acquisition adjustments related to business combination deferred tax asset valuation allowances and liabilities for uncertain tax positions to be recorded in current period income tax expense. The adoption of this guidance impacted our accounting for the acquisition of the worldwide development and commercialization rights to tetrabenazine (as described above under "Overview Business Development Tetrabenazine").

Authoritative guidance on fair value measurements, which establishes a framework for measuring fair value in U.S. GAAP, clarifies the definition of fair value within that framework, and expands disclosures about the use of fair value measurements. The guidance applies to all other authoritative guidance that requires (or permits) fair value measurements, but does not require any new fair value measurements in U.S. GAAP. The guidance was effective January 1, 2009 for non-financial assets and non-financial liabilities not recognized or disclosed at fair value on a recurring basis. We previously adopted this guidance for financial assets and financial liabilities effective January 1, 2008. The adoption of this guidance for non-financial assets and non-financial liabilities did not have a material impact on our 2009 Financial Statements.

Authoritative guidance on the accounting for collaborative arrangements, which provides guidance for determining if a collaborative arrangement exists and establishes reporting requirements for revenues and costs generated from transactions between parties within a collaborative arrangement, as well as between the parties in a collaborative arrangement and third parties, and provides guidance for financial statement disclosures of collaborative arrangements. The adoption of this guidance did not have a material impact on our 2009 Financial Statements.

Recently Issued Accounting Guidance, Not Adopted as of December 31, 2009

In October 2009, the FASB issued authoritative guidance on multiple-element revenue arrangements, which requires an entity to allocate arrangement consideration at the inception of the arrangement to all of its deliverables based on relative selling prices. This guidance eliminates the use of the residual method of allocation and expands the ongoing disclosure requirements. The guidance is effective for the first fiscal year beginning after June 15, 2010, and may be adopted through prospective or retrospective application. Accordingly, we are required to adopt this guidance beginning January 1, 2011. We are currently evaluating the effect that the adoption of this guidance will have on our consolidated financial statements.

In June 2009, the FASB issued authoritative guidance for determining whether an entity is a variable interest entity ("VIE") and requires an enterprise to perform an analysis to determine whether the enterprise's variable interest or interests give it a controlling financial interest in a VIE. Under this guidance, an enterprise has a controlling financial interest when it has (i) the power to direct the activities of a VIE that most

MANAGEMENT'S DISCUSSION AND ANALYSIS (Continued)

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

significantly impact the entity's economic performance, and (ii) 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. We are required to adopt this guidance beginning January 1, 2010. We are currently evaluating the effect that the adoption of this guidance will have on our consolidated financial statements.

International Financial Reporting Standards

International Financial Reporting Standards ("IFRS") will replace Canadian standards and interpretations as Canadian GAAP effective January 1, 2011. On June 27, 2008, the CSA issued Staff Notice 52-321, "Early Adoption of International Financial Reporting Standards, Use of U.S. GAAP and References to IFRS-IASB", which indicates that the CSA staff propose retaining the existing option for Canadian public companies that are also SEC issuers to use U.S. GAAP. Accordingly, we currently intend to continue our practice of following U.S. GAAP in financial statements filed with the CSA and the SEC. We believe that U.S. GAAP financial statements afford better comparability with our U.S.-based industry peers.

MANAGEMENT'S REPORT ON DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROL OVER FINANCIAL REPORTING

Disclosure Controls and Procedures

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed on reports and filed or submitted with the SEC is recorded, processed, summarized, and reported in a timely manner. Based on our evaluation, our management, including the CEO and Chief Financial Officer ("CFO"), has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of December 31, 2009 are effective. Notwithstanding the foregoing, there can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within our Company to disclose material information otherwise required to be set forth in our reports.

Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal accounting controls systems are designed to provide reasonable assurance that assets are safeguarded, that transactions are executed in accordance with management's authorization and are properly recorded, and that accounting records are adequate for preparation of financial statements in accordance with U.S. GAAP and other financial information.

Under the supervision and with the participation of management, including the CEO and CFO, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation under this framework, management concluded that our internal controls over financial reporting were effective as of December 31, 2009.

The effectiveness of our Company's internal controls over financial reporting as of December 31, 2009 has been audited by Ernst & Young LLP, as stated in their report on page F-4 of our 2009 Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting identified in connection with the evaluation thereof by our management, including the CEO and CFO, during the quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Table of Contents

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Information relating to quantitative and qualitative disclosures about market risk is detailed in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and is incorporated herein by reference.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item is contained in the financial statements set forth in Item 15. "Exhibits, Financial Statement Schedules" under the caption "*Consolidated Financial Statements and Supplementary Data*" as part of this Annual Report on Form 10-K and is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

There have been no changes in or disagreements with accountants on accounting or financial disclosure matters.

Item 9A. Controls and Procedures.

(a)

Disclosure Controls and Procedures. We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed on reports and filed or submitted with the SEC is recorded, processed, summarized and reported in a timely manner. Based on our evaluation, our management, including the CEO and CFO, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this report are effective.

(b)

Management's Annual Report on Changes in Internal Controls Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal accounting controls systems are designed to provide reasonable assurance that assets are safeguarded, that transactions are executed in accordance with management's authorization and are properly recorded, and that accounting records are adequate for preparation of financial statements in accordance with U.S. GAAP and other financial information.

Under the supervision and with the participation of management, including the CEO and CFO, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation under this framework, management concluded that our internal controls over financial reporting were effective as of December 31, 2009.

The effectiveness of our Company's internal control over financial reporting as of December 31, 2009 has been audited by Ernst & Young LLP, as stated in its report on page F-4 herein and is incorporated herein by reference.

(c)

Changes in Internal Control Over Financial Reporting. There were no changes in our internal controls over financial reporting identified in connection with the evaluation thereof by our management, including the CEO and CFO, during the quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. Other Information.

Not applicable.

Table of Contents

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required under this Item relating to our directors is incorporated herein by reference from information included in our definitive proxy statement for the 2010 Annual and Special meeting of Shareholders expected to be filed with the SEC no later than 120 days after the end of the fiscal year covered by this Form 10-K (the "2010 Proxy Statement").

Information relating to our executive officers is furnished in Part I hereof under a separate unnumbered item captioned "Executive Officers of the Registrant."

Information required under this Item relating to certain filing obligations of our directors and executive officers under the federal securities laws set forth in the 2010 Proxy Statement relating to compliance with section 16(a) of the Exchange Act is incorporated herein by reference.

The Board of Directors has adopted a Code of Professional Conduct that applies to our Chief Executive Officer, Chief Financial Officer and the principal accounting officer or controller, or persons performing similar functions. A copy of the Code of Professional Conduct can be found on our website at: www.biovail.com (under the tab "About Biovail" and subtab "Corporate Governance"). In addition, a copy of our Code of Professional Conduct can be provided, without charge, upon request to: Biovail Corporation, 7150 Mississauga Road, Mississauga, Ontario, Canada, L5N 8M5, Attention: Investor Relations; by telephone at (905) 263-3002; by facsimile at (905) 286-3050; or by email to ir@biovail.com.

Information required under this Item relating to our audit committee, including the members of the committee and designation of "audit committee financial experts" under applicable SEC and NYSE rules, is incorporated herein by reference from information included in the 2010 Proxy Statement.

Item 11. Executive Compensation.

Information required under this Item relating to executive compensation is incorporated herein by reference from information included in the 2010 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required under this Item relating to securities authorized for issuance under equity compensation plans and to security ownership of certain beneficial owners and management is incorporated herein by reference from information included in the 2010 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required under this Item relating to certain relationships and transactions with related parties and about director independence is incorporated herein by reference from information included in the 2010 Proxy Statement.

Item 14. Principal Accounting Fees and Services.

Information required under this Item relating to the fees for professional services rendered by our independent auditors in 2008 and 2009 is incorporated herein by reference from information included in the 2010 Proxy Statement.

Table of Contents**PART IV****Item 15. Exhibits, Financial Statement Schedules.**

Documents filed as a part of the report:

- (1) The consolidated financial statements required to be filed in the Annual Report on Form 10-K are listed on page F-1 hereof.
- (2) Schedule II Valuation and Qualifying Accounts.

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS
(All dollar amounts expressed in thousands of U.S. dollars)

Column A	Column B Balance at beginning of period	Column C Additions Charged to (recovered from) Costs and Expenses	Column D Deductions/ Write-Offs	Column E Balance at end of period
Allowance for doubtful accounts and cash discounts, deducted from accounts receivable				
Year ended December 31, 2009	1,179	1,304	(46)	2,437
Year ended December 31, 2008	1,217	(23)	(15)	1,179
Year ended December 31, 2007	3,194	736	(2,713)	1,217
(3) Exhibit Index				

Table of Contents

EXHIBIT INDEX

Exhibit Number	Exhibit Description
2.1	Agreement and Plan of Merger, dated as of September 16, 2008, by and among Biovail Americas Corp., Prestwick Holdings, Inc., Prestwick Pharmaceuticals, Inc. and Sofinnova Management V 2005, LLC and Edgar G. Engleman, M.D., as the Stockholder Representatives.**
2.2	Asset Purchase Agreement, dated as of May 5, 2009, by and between Biovail Laboratories International SRL and SmithKline Beecham Corporation.**
2.3	Asset Purchase Agreement, dated as of May 16, 2009, between Cambridge Laboratories (Ireland) Limited and Biovail Laboratories International (Barbados) SRL (the "Cambridge Asset Purchase Agreement").**
2.4	Amendment No. 1 to Cambridge Asset Purchase Agreement, dated as of June 19, 2009, between Cambridge Laboratories (Ireland) Limited and Biovail Laboratories International (Barbados) SRL.
3.1	Articles of Continuance of Biovail Corporation.
3.2	By-Law No. 1 of Biovail Corporation.
3.3	By-Law No. 2 of Biovail Corporation.
4.1	Indenture, dated as of June 10, 2009, among Biovail Corporation, The Bank of New York Mellon and BNY Trust Company of Canada.
4.2	Form of 5.375% Senior Convertible Notes due 2014.
10.1	Trademark License Agreement, dated as of May 14, 2009, by and between SmithKline Beecham Corporation and Biovail Laboratories International SRL.**
10.2	License Agreement, dated as of February 9, 2007, among GlaxoSmithKline, PLC, SmithKline Beecham Corporation and Andrx Pharmaceuticals LLC.**
10.3	Amended and Restated Distribution Rights Agreement, effective as of October 26, 2001, by and among SmithKline Beecham Corporation and Biovail Laboratories Incorporated (the "Zovirax Distribution Agreement").**
10.4	Amendment No. 1 to Zovirax Distribution Agreement, dated as of May 1, 2005, by and between Biovail Laboratories International SRL and SmithKline Beecham Corporation.
10.5	Amendment No. 2 to Zovirax Distribution Agreement, dated as of October 12, 2005, by and between Biovail Laboratories International SRL and SmithKline Beecham Corporation.**
10.6	Amendment No. 3 to Zovirax Distribution Agreement, dated as of December 18, 2006, by and between Biovail Laboratories International SRL and SmithKline Beecham Corporation.**
10.7	Amendment No. 4 to Zovirax Distribution Agreement, dated as of November 21, 2008, by and between Biovail Laboratories International SRL and SmithKline Beecham Corporation.
10.8	Amendment No. 5 to Zovirax Distribution Agreement, dated as of May 14, 2009, by and between Biovail Laboratories International SRL and SmithKline Beecham Corporation.
10.9	Amendment No. 6 to Zovirax Distribution Agreement, dated as of September 16, 2009, by and between Biovail Laboratories International SRL and SmithKline Beecham Corporation.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

- 10.10 Amendment No. 7 to Zovirax Distribution Agreement, dated as of November 24, 2009, by and between Biovail Laboratories International SRL and SmithKline Beecham Corporation.
- 10.11 Supply Agreement, dated as of October 1, 2004, between Plantex USA, Inc. and Biovail Laboratories Incorporated (the "Diltiazem Supply Agreement").**

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Table of Contents

Exhibit Number	Exhibit Description
10.12	Amendment No. 1 to Diltiazem Supply Agreement, dated as of December 30, 2005, between Plantex USA, Inc. and Biovail Laboratories International SRL.**
10.13	Amendment No. 2 to Diltiazem Supply Agreement, dated as of December 19, 2006, by and between Plantex USA, Inc. and Biovail Laboratories International SRL.**
10.14	Amendment No. 3 to Diltiazem Supply Agreement, dated as of June 25, 2007, by and between Plantex USA, Inc. and Biovail Laboratories International SRL.**
10.15	Product Development and License Agreement dated as of May 31, 2000, between Biovail Laboratories Incorporated and Universiteit Gent, (the "Product Development and License Agreement").**
10.16	Amendment to Product Development and License Agreement, dated as of July 21, 2009, between Ghent University and Biovail Laboratories International SRL.**
10.17	Non-Exclusive License Agreement, dated as of December 5, 1996, between Ethypharm S.A. and Hoechst Marion Roussel, Inc. (the "Ethypharm License").**
10.18	Amendment to Ethypharm License, dated as of July 21, 2000, between Aventis Pharmaceuticals Inc. and Ethypharm S.A.**
10.19	Amendment to Ethypharm License, dated as of December 29, 2000, between Biovail Laboratories Incorporated and Ethypharm S.A.**
10.20	Marketing, Distribution and Supply Agreement for Xenazine, dated as of September 16, 2008, by and between Prestwick Pharmaceuticals, Inc. and Ovation Pharmaceuticals, Inc.**
10.21	License Agreement, dated as of December 10, 1998, between LifeHealth Limited (now H. Lundbeck A/S) and Cambridge Selfcare Diagnostics Limited (the "LifeHealth License Agreement").**
10.22	Side Letter to the LifeHealth License Agreement, dated as of October 29, 2002, between LifeHealth Limited (now H. Lundbeck A/S) and Cambridge Laboratories Limited.**
10.23	Side Letter to the LifeHealth License Agreement, dated as of March 31, 2004, between LifeHealth Limited (now H. Lundbeck A/S) and Cambridge Laboratories Limited.**
10.24	Side Letter to the LifeHealth License Agreement, dated as of August 12, 2004, between LifeHealth Limited (now H. Lundbeck A/S) and Cambridge Laboratories Limited.**
10.25	Side Letter to the LifeHealth License Agreement, dated as of June 19, 2009, between LifeHealth Limited (now H. Lundbeck A/S) and Cambridge Laboratories Limited.**
10.26	Deed of Novation and Amendment to the LifeHealth License Agreement, dated as of June 19, 2009, between Lifehealth Limited, Cambridge Laboratories (Ireland) Limited, Cambridge Laboratories Limited and Biovail Laboratories International (Barbados) SRL.**
10.27	Supply Agreement, dated as of July 31, 1998, between Cambridge Laboratories (Division of Cambridge Selfcare Diagnostics Limited and Plasto S.A. (Synkem Division) (the "Synkem Supply Agreement").**
10.28	Amendment to Synkem Supply Agreement, dated as of February 25, 2005, between Cambridge Laboratories (Division of Cambridge Selfcare Diagnostics Limited and Plasto S.A. (Synkem Division)).**
10.29	Contract Manufacture Agreement, dated as of May 9, 2005, between Laboratoires Fournier S.A. and Cambridge Laboratories Limited.**

10.30 Plea Agreement and Side Letter, dated as of May 16, 2008, between United States Attorney for the District of Massachusetts and Biovail Pharmaceuticals, Inc.

128

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Table of Contents

Exhibit Number	Exhibit Description
10.31	Corporate Integrity Agreement, dated as of September 11, 2009, between Biovail Corporation and the Office of Inspector General of the Department of Health and Human Services.
10.32	Settlement Agreement, dated as of September 11, 2009, among the United States of America, United States Department of Justice, Office of Inspector General of the Department of Health and Human Services and Biovail Corporation.
10.33	Securities Litigation, Stipulation and Agreement of Settlement, dated as of April 4, 2008, between the United States District Court, Southern District of New York and Biovail Corporation.
10.34	Settlement Agreement, dated January 7, 2009, between Staff of the Ontario Securities Commission and Biovail Corporation.
10.35	Settlement Agreement, dated March 2008, between the U.S. Securities and Exchange Commission and Biovail Corporation.
10.36	Credit Agreement, dated as of June 9, 2009, among Biovail Corporation, JPMorgan Chase Bank, N.A., Toronto Branch, J.P. Morgan Securities Inc. and Scotia Capital Inc., The Bank of Nova Scotia and National Bank of Canada and HSBC Bank Canada and The Toronto-Dominion Bank.**
10.37	Chairman Agreement of Douglas J.P. Squires, dated as of May 1, 2008.
10.38	Confidential Separation Agreement and General Release of Douglas J.P. Squires, dated as of May 6, 2008.
10.39	Employment Agreement of William M. Wells effective May 1, 2008.
10.40	Employment Agreement of Margaret Mulligan effective September 3, 2008.
10.41	Amended and Restated Employment Agreement of Gilbert Godin effective July 3, 2009.
10.42	Employment Agreement of Gregory Gubitz effective July 3, 2009.
10.43	Employment Agreement of Mark Durham effective July 3, 2009.
10.44	Employment Agreement of Dr. H. Christian Fibiger effective November 4, 2008.
10.45	Employment Agreement of Christine Mayer effective January 1, 2007.
10.46	Employment Agreement of Michel Chouinard effective February 24, 2010.
10.47	Employment Agreement of Michel Chouinard effective June 16, 2008.
10.48	Consulting Agreement by and between Biovail Laboratories SRL and Bord de Lac Ltd. dated as of February 27, 2006.
10.49	Biovail Corporation 2007 Equity Compensation Plan dated as of May 16, 2007.
10.50	Amendment No. 1 to the Biovail Corporation 2007 Equity Compensation Plan dated as of December 18, 2008.
10.51	Biovail Corporation Amended and Restated 2004 Stock Option Plan dated as of June 25, 2004 (the "2004 Stock Option Plan").
10.52	Amendment to the 2004 Stock Option Plan dated March 14, 2007.
10.53	Amendment to the 2004 Stock Option Plan dated May 16, 2007.
10.54	Biovail Corporation Amended and Restated 1993 Stock Option Plan (the "1993 Stock Option Plan").

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

10.55 Amendment to the 1993 Stock Option Plan dated March 14, 2007.

10.56 Amendment to the 1993 Stock Option Plan dated May 16, 2007.

129

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Table of Contents

Exhibit

Number Exhibit Description

- 10.57 Biovail Corporation Deferred Share Unit Plan for Canadian Directors, approved on May 3, 2005, as amended.
 - 10.58 Biovail Corporation Deferred Share Unit Plan for U.S. Directors, approved on May 3, 2005, as amended and restated.
 - 10.59 Biovail Laboratories International SRL Deferred Share Unit Plan effective May 3, 2005, as amended.
 - 10.60 Biovail Amercias Corp. Executive Deferred Compensation Plan, as amended and restated effective January 1, 2009.
 - 10.61 Biovail Corporation Short-Term Incentive Plan, as amended and restated effective January 1, 2009.
 - 14.1 Code of Professional Conduct for the Senior Finance Executives of Biovail Corporation.
 - 21.1 Subsidiaries of Biovail Corporation.
 - 23.1 Consent of Ernst & Young LLP.
 - 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 32.1 Certificate of the Chief Executive Officer of Biovail Corporation pursuant to 18 U.S.C. § 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - 32.2 Certificate of the Senior Vice President and Chief Financial Officer of Biovail Corporation pursuant to 18 U.S.C. § 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
-

**

An application for confidential treatment for selected portions of this agreement has been filed with the Securities and Exchange Commission.

Pursuant to item 601(b)(2) of Regulation S-K, Biovail Corporation hereby agrees to furnish supplementally to the Securities and Exchange Commission a copy of any omitted schedule or exhibit to this agreement.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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)

Date: February 26, 2010

By: /s/ WILLIAM M. WELLS

William M. Wells
Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ WILLIAM M. WELLS</u> William M. Wells	Chief Executive Officer and Director	February 26, 2010
<u>/s/ MARGARET MULLIGAN</u> Margaret Mulligan	Senior Vice-President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 26, 2010
<u>/s/ DAVID H. LAIDLEY</u> David H. Laidley	Director	February 26, 2010
<u>/s/ DR. DOUGLAS J.P. SQUIRES</u> Dr. Douglas J.P. Squires	Director	February 26, 2010
<u>/s/ FRANK POTTER</u> Frank Potter	Director	February 26, 2010
<u>/s/ J. SPENCER LANTHIER</u> J. Spencer Lanthier	Director	February 26, 2010
<u>/s/ DR. LAURENCE E. PAUL</u> Dr. Laurence E. Paul	Director	February 26, 2010
<u>/s/ LLOYD M. SEGAL</u> Lloyd M. Segal	Director	February 26, 2010

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Table of Contents

Signature	Title	Date
<u>/s/ MARK PARRISH</u> Mark Parrish	Director	February 26, 2010
<u>/s/ MICHAEL VAN EVERY</u> Michael Van Every	Director	February 26, 2010
<u>/s/ ROBERT N. POWER</u> Robert N. Power	Director	February 26, 2010
<u>/s/ SERGE GOUIN</u> Serge Gouin	Director	February 26, 2010
<u>/s/ SIR LOUIS TULL</u> Sir Louis Tull	Director	February 26, 2010

INDEX TO FINANCIAL STATEMENTS

	Page
Report of Management on Financial Statements and Internal Control over Financial Reporting	F-2
Report of Independent Registered Public Accounting Firm	F-3
Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting	F-4
Consolidated Balance Sheets as at December 31, 2009 and 2008	F-5
Consolidated Statements of Income for the years ended December 31, 2009, 2008 and 2007	F-6
Consolidated Statements of Shareholders' Equity for the years ended December 31, 2009, 2008 and 2007	F-7
Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007	F-8
Notes to the Consolidated Financial Statements	F-9

F-1

**REPORT OF MANAGEMENT ON FINANCIAL STATEMENTS
AND INTERNAL CONTROL OVER FINANCIAL REPORTING**

Financial Statements

The Company's management is responsible for preparing the accompanying consolidated financial statements in conformity with United States generally accepted accounting principles ("U.S. GAAP"). In preparing these consolidated financial statements, management selects appropriate accounting policies and uses its judgment and best estimates to report events and transactions as they occur. Management has determined such amounts on a reasonable basis in order to ensure that the consolidated financial statements are presented fairly, in all material respects. Financial information included throughout this Annual Report is prepared on a basis consistent with that of the accompanying consolidated financial statements.

Ernst & Young LLP has been engaged by the Company's shareholders to audit the consolidated financial statements.

The Board of Directors is responsible for ensuring that management fulfills its responsibility for financial reporting and is ultimately responsible for reviewing and approving the consolidated financial statements. The Board of Directors carries out this responsibility principally through its Audit Committee. The members of the Audit Committee are outside Directors. The Audit Committee considers, for review by the Board of Directors and approval by the shareholders, the engagement or reappointment of the external auditors. Ernst & Young LLP has full and free access to the Audit Committee.

Management acknowledges its responsibility to provide financial information that is representative of the Company's operations, is consistent and reliable, and is relevant for the informed evaluation of the Company's activities.

Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. The Company's internal accounting controls systems are designed to provide reasonable assurance that assets are safeguarded, that transactions are executed in accordance with management's authorization and are properly recorded, and that accounting records are adequate for preparation of financial statements in accordance with U.S. GAAP and other financial information.

Under the supervision and with the participation of management, including the Company's Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its evaluation under this framework, management concluded that the Company's internal controls over financial reporting were effective as of December 31, 2009.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2009 has been audited by Ernst & Young LLP, as stated in their report on page F-4 herein.

/s/ WILLIAM WELLS
William Wells
Chief Executive Officer

/s/ MARGARET MULLIGAN
Margaret Mulligan
Senior Vice-President and
Chief Financial Officer

February 26, 2010

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

Biovail Corporation

We have audited the accompanying consolidated balance sheets of Biovail Corporation as of December 31, 2009 and 2008, and the related consolidated statements of income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2009. Our audits also included the financial statement schedule II included in Item 15. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Biovail Corporation at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with United States generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in note 2 to the consolidated financial statements, effective January 1, 2009, Biovail Corporation changed its method of accounting for convertible debt instruments, business combinations, fair value measurements for non-financial assets and non-financial liabilities and collaborative arrangements, effective April 1, 2009 changed its method of accounting for other-than-temporary impairments and effective January 1, 2008 changed its method of accounting related to the optional use of fair value for certain financial assets and liabilities, in each case due to the issuance of new authoritative guidance.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Biovail Corporation's internal control over financial reporting as of December 31, 2009, based on criteria established in the Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2010 expressed an unqualified opinion thereon.

Toronto, Canada
February 26, 2010

/s/ ERNST & YOUNG LLP
Chartered Accountants
Licensed Public Accountants

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

To the Board of Directors and Shareholders of

Biovail Corporation

We have audited Biovail Corporation's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO" criteria). Biovail Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Biovail Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the accompanying consolidated balance sheets of Biovail Corporation as of December 31, 2009 and 2008, and the related consolidated statements of income, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2009, and our report dated February 26, 2010, expressed an unqualified opinion thereon.

Toronto, Canada,
February 26, 2010

/s/ ERNST & YOUNG LLP
Chartered Accountants
Licensed Public Accountants

BIOVAIL CORPORATION

CONSOLIDATED BALANCE SHEETS

In accordance with United States Generally Accepted Accounting Principles

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

	At December 31	
	2009	2008
ASSETS		
Current		
Cash and cash equivalents	\$ 114,463	\$ 317,547
Marketable securities	9,566	719
Accounts receivable	119,919	90,051
Insurance recoveries receivable		812
Inventories	82,773	59,561
Assets held for sale	8,542	6,814
Prepaid expenses and other current assets	15,377	14,860
	350,640	490,364
Marketable securities	11,516	21,916
Property, plant and equipment, net	103,848	148,269
Intangible assets, net	1,335,222	720,372
Goodwill	100,294	100,294
Deferred tax assets, net of valuation allowance	132,800	116,800
Other long-term assets, net	32,724	25,550
	\$2,067,044	\$1,623,565
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current		
Accounts payable	\$ 72,022	\$ 41,070
Dividends payable	14,246	59,331
Accrued liabilities	121,898	85,169
Accrued legal settlements	7,950	32,565
Income taxes payable	6,846	8,596
Deferred revenue	21,834	40,435
Current portion of long-term obligations	12,110	
	256,906	267,166
Deferred revenue	69,247	84,953
Income taxes payable	66,200	63,700
Long-term obligations	313,975	
Other long-term liabilities	6,344	6,147
	712,672	421,966
Shareholders' equity		
Common shares, no par value, unlimited shares authorized, 158,310,884 and 158,216,132 issued and outstanding at December 31, 2009 and 2008, respectively	1,465,004	1,463,873
Additional paid-in capital	91,768	31,966
Accumulated deficit	(245,974)	(319,909)
Accumulated other comprehensive income	43,574	25,669
	1,354,372	1,201,599

\$2,067,044 \$1,623,565

Commitments and contingencies (notes 24 and 25)

On behalf of the Board:

/s/ WILLIAM WELLS

/s/ MICHAEL VAN EVERY

William Wells
Director

Michael Van Every
Director

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

F-5

BIOVAIL CORPORATION

CONSOLIDATED STATEMENTS OF INCOME

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

	Years Ended December 31		
	2009	2008	2007
REVENUE			
Product sales	\$ 789,026	\$ 714,548	\$ 801,046
Research and development	14,148	24,356	23,828
Royalty and other	17,256	18,274	17,944
	820,430	757,178	842,818
EXPENSES			
Cost of goods sold (exclusive of amortization of intangible assets shown separately below)	204,309	197,167	223,680
Research and development	120,784	92,844	118,117
Selling, general and administrative	178,601	188,922	159,266
Amortization of intangible assets	104,730	51,369	48,049
Restructuring costs	19,065	70,202	668
Legal settlements, net of insurance recoveries	6,191	32,565	95,114
Acquisition-related costs	5,596		
Intangible asset impairments			9,910
	639,276	633,069	654,804
Operating income	181,154	124,109	188,014
Interest income	1,118	9,400	24,563
Interest expense	(25,418)	(1,018)	(9,745)
Foreign exchange gain (loss)	507	(1,057)	5,491
Gain on auction rate security settlement	22,000		
Gain on disposal of investments	804	6,534	24,356
Impairment loss on debt securities	(5,210)	(8,613)	(6,000)
Impairment loss on equity securities		(1,256)	(2,949)
Equity loss		(1,195)	(2,528)
Loss on early extinguishment of debt			(12,463)
Income before provision for (recovery of) income taxes	174,955	126,904	208,739
Provision for (recovery of) income taxes	(1,500)	(73,000)	13,200
Net income	\$ 176,455	\$ 199,904	\$ 195,539
Basic and diluted earnings per share	\$ 1.11	\$ 1.25	\$ 1.22
Weighted-average number of common shares outstanding (000s)			
Basic	158,236	159,730	160,839
Diluted	158,510	159,730	160,875
Cash dividends declared per share	\$ 0.65	\$ 1.50	\$ 1.50

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

BIOVAIL CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

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

	Common Shares		Additional	Accumulated	Accumulated	Total
	Shares (000s)	Amount	Paid-In Capital	Deficit	Other Comprehensive Income	
Balance, January 1, 2007	160,444	\$ 1,476,930	\$ 14,952	\$ (232,733)	\$ 43,108	\$ 1,302,257
Common shares issued under stock-based compensation plans	580	12,877	(1,660)			11,217
Stock-based compensation			10,633			10,633
Cash dividends declared (\$1.50 per share)				(241,301)		(241,301)
	161,024	1,489,807	23,925	(474,034)	43,108	1,082,806
Comprehensive income:						
Net income				195,539		195,539
Other comprehensive income					19,474	19,474
Total comprehensive income						215,013
Balance, December 31, 2007	161,024	1,489,807	23,925	(278,495)	62,582	1,297,819
Repurchase of common shares	(2,818)	(26,077)		(3,765)		(29,842)
Common shares issued under stock-based compensation plans	10	143	(143)			
Stock-based compensation			7,906			7,906
Cash dividends declared and dividend equivalents (\$1.50 per share)			278	(239,896)		(239,618)
Cumulative effect adjustment				2,343		2,343
	158,216	1,463,873	31,966	(519,813)	62,582	1,038,608
Comprehensive income:						
Net income				199,904		199,904
Other comprehensive loss					(36,913)	(36,913)
Total comprehensive income						162,991
Balance, December 31, 2008	158,216	1,463,873	31,966	(319,909)	25,669	1,201,599
Equity component of Convertible Notes, net of issuance costs			53,995			53,995
Common shares issued under stock-based compensation plans	95	1,131	(265)			866
Stock-based compensation			5,613			5,613
Cash dividends declared and dividend equivalents (\$0.65 per share)			459	(102,520)		(102,061)
	158,311	1,465,004	91,768	(422,429)	25,669	1,160,012
Comprehensive income:						
Net income				176,455		176,455
Other comprehensive income					17,905	17,905
Total comprehensive income						194,360

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Balance, December 31, 2009	158,311	\$ 1,465,004	\$ 91,768	\$ (245,974)	\$ 43,574	\$ 1,354,372
----------------------------	---------	--------------	-----------	--------------	-----------	--------------

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

F-7

BIOVAIL CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

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

	Years Ended December 31		
	2009	2008	2007
CASH FLOWS FROM OPERATING ACTIVITIES			
Net income	\$ 176,455	\$ 199,904	\$ 195,539
Adjustments to reconcile net income to net cash provided by operating activities			
Depreciation and amortization	149,260	102,905	94,985
Amortization of deferred revenue	(21,201)	(18,246)	(19,168)
Amortization and write-down of discounts on long-term obligations	5,986		962
Amortization and write-down of deferred financing costs	3,620	520	4,821
Deferred income taxes	(16,000)	(90,000)	
Acquired in-process research and development	59,354		
Impairment charges	13,969	69,056	21,468
Stock-based compensation	5,613	7,906	10,633
Loss on sale and leaseback of assets	10,968		
Gain on disposal of investments	(804)	(6,534)	(24,356)
Payment of accrued legal settlements, net of insurance recoveries	(30,806)	(93,048)	(16,462)
Additions to accrued legal settlements, net of insurance recoveries	6,191	32,565	95,114
Accrued contract costs		(45,065)	(8,000)
Equity loss		1,195	2,528
Premium paid on early extinguishment of debt			7,854
Other	(177)	(389)	3,843
Changes in operating assets and liabilities:			
Accounts receivable	(30,140)	20,441	18,052
Insurance recoveries receivable	812	7,178	(7,994)
Inventories	(26,212)	20,577	3,023
Prepaid expenses and other current assets	(796)	318	376
Accounts payable	30,771	(6,135)	3,273
Accrued liabilities	36,414	3,584	(26,496)
Income taxes payable	726	8,700	(7,514)
Deferred revenue	(13,106)	(11,107)	(11,628)
Net cash provided by operating activities	360,897	204,325	340,853
CASH FLOWS FROM INVESTING ACTIVITIES			
Acquisition of intangible assets	(561,829)		
Acquisition of businesses, net of cash acquired	(200,000)	(101,920)	
Proceeds from sale and leaseback of assets	23,113		
Additions to property, plant and equipment, net	(7,423)	(21,999)	(35,086)
Transfer to restricted cash	(5,250)	(83,048)	
Transfer from restricted cash	5,250	83,048	
Proceeds from sale of property, plant and equipment	5,189		
Additions to marketable securities	(3,823)	(6,290)	(34,534)
Proceeds from sale and maturity of marketable securities	1,078	4,450	3,282
Proceeds on disposal of long-term investments, net of costs	923	25,206	52,669
Proceeds from sale of short-term investments		79,735	
Additions to short-term investments		(79,725)	
Additions to restricted assets		(7,288)	
Additions to long-term investments			(1,376)
Net cash used in investing activities	(742,772)	(107,831)	(15,045)
CASH FLOWS FROM FINANCING ACTIVITIES			
Issuance of Convertible Notes	350,000		
Cash dividends paid	(147,146)	(180,287)	(321,523)
Advances under credit facility	130,000		
Repayments under credit facility	(130,000)		
Financing costs paid	(26,274)		
Issuance of common shares	866		11,217

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Repayment of deferred compensation obligation, net	(399)	(182)	(338)
Repurchase of common shares		(29,842)	
Redemption of Senior Subordinated Notes			(406,756)
Repayments of other long-term obligations			(11,250)
Net cash provided by (used in) financing activities	177,047	(210,311)	(728,650)
Effect of exchange rate changes on cash and cash equivalents	1,744	(2,277)	1,943
Net decrease in cash and cash equivalents	(203,084)	(116,094)	(400,899)
Cash and cash equivalents, beginning of year	317,547	433,641	834,540
Cash and cash equivalents, end of year	\$ 114,463	\$ 317,547	\$ 433,641

NON-CASH INVESTING AND FINANCING ACTIVITIES

Cash dividends declared but unpaid	(14,246)	(59,331)	
Long-term obligation related to acquisition of business	(26,768)		
Proceeds receivable from sale of long-term investment		169	

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

BIOVAIL CORPORATION

NOTES TO 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)**

1. DESCRIPTION OF BUSINESS

Biovail Corporation ("Biovail" or the "Company") was established on March 29, 1994, and was continued under the *Canada Business Corporations Act* on June 29, 2005. Biovail 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 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"), applied on a consistent basis.

Certain of the prior years' figures have been reclassified to conform to the presentation adopted in 2009.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and those of its subsidiaries. All intercompany transactions and balances have been eliminated.

The Company has entered into collaboration and license arrangements with other entities for various products under development. These arrangements typically include upfront and contingent milestone and royalty payments. All such arrangements were determined not to be variable interests in the entities. Accordingly, the Company does not consolidate the financial results of any of these entities.

Acquisitions

Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. Acquired in-process research and development ("IPR&D") is recognized at fair value and initially characterized as indefinite-lived intangible assets, irrespective of whether the acquired IPR&D has an alternative future use. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized. In an asset acquisition, the amount allocated to acquired IPR&D with no alternative future use is charged to expense at the acquisition date.

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 date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. Significant estimates made by management include: provisions for product returns, rebates and chargebacks; useful lives of amortizable intangible assets; expected future cash flows used in evaluating intangible assets for impairment; reporting unit fair value in testing goodwill for impairment; provisions for loss contingencies; provisions for income taxes and realizability of deferred tax assets; and the allocation of the purchase price of acquired assets and businesses. Under certain product manufacturing and supply agreements, management relies on estimates for future returns, rebates and chargebacks made by the Company's commercialization counterparties. 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 consolidated financial statements could be materially impacted.

Fair Value of Financial Instruments

The estimated fair values of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their carrying values due to their short maturity periods. The fair values of marketable securities, short-term and long-term investments, and long-term obligations are based on quoted market prices, if available, or estimated discounted future cash flows.

Cash and Cash Equivalents

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Cash and cash equivalents include certificates of deposit, treasury bills, and investment-grade commercial paper with maturities of three months or less when purchased.

F-9

BIOVAIL CORPORATION**NOTES TO 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)**

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

Marketable debt securities are classified as being available-for-sale. These securities are reported at fair value with all unrealized gains and temporary unrealized losses recognized in other comprehensive income. Other-than-temporary credit losses that represent a decrease in the cash flows expected to be collected on these securities are recognized in net income. Other-than-temporary non-credit losses related to all other factors are recognized in other comprehensive income, if the Company does not intend to sell the security and it is not more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. Realized gains and losses on the sale of these securities are recognized in net income. 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. The amortization of acquisition premiums or discounts is recorded as a deduction from or addition to interest income earned on these securities.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, and accounts receivable.

The Company invests its excess cash in high-quality, liquid money market instruments with varying maturities, but typically less than three months. The Company maintains its cash and cash equivalents with major financial institutions. The Company has not experienced any significant losses on its cash or cash equivalents.

The Company's marketable securities portfolio includes investment-grade corporate, government or government-sponsored enterprise fixed income debt securities with a maximum term to maturity of three years. No single issuer comprises more than 20% of the portfolio.

The Company's marketable securities portfolio also includes investments in nine individual auction rate securities. These securities represent interests in collateralized debt obligations supported by pools of residential and commercial mortgages or credit cards, insurance securitizations, and other structured credits, including corporate bonds. Some of the underlying collateral for these securities consists of sub-prime mortgages.

A significant portion of the Company's product sales is made to major drug wholesalers in the U.S. and Canada, as well as its commercialization counterparties. At December 31, 2009 and 2008, five individual customer balances accounted for 80% and 67% of trade receivables, respectively. The Company performs periodic credit evaluations of customers and generally does not require collateral. An allowance for doubtful accounts is maintained for potential credit losses based on the aging of accounts receivable, historical bad debts experience, and changes in customer payment patterns. Accounts receivable balances are written off against the allowance when it is probable that the receivable will not be collected. The Company has not experienced any significant losses from uncollectible accounts in the three-year period ended December 31, 2009.

Inventories

Inventories comprise raw materials, work in process, and finished goods, which are valued at the lower of cost or market, on a first-in, first-out basis. Cost for work in process and finished goods inventories includes materials, direct labour, and an allocation of overheads. Market for raw materials is replacement cost, and for work in process and finished goods is net realizable value. Allowances are maintained for slow-moving inventories based on the remaining shelf life of, and estimated time required to sell, such inventories. Obsolete inventory is written off against the allowance. Rejected product is written off directly to cost of goods sold.

Property, Plant and Equipment

Property, plant and equipment are reported at cost, less accumulated depreciation. Costs incurred on assets under construction are capitalized as construction in progress. Depreciation is calculated using the straight-line method, commencing when the assets become available for productive use, based on the following estimated useful lives:

Buildings	25 years
Machinery and equipment	5-10 years
Other equipment	3-10 years
Leasehold improvements	Lesser of term of lease or 10 years

BIOVAIL CORPORATION

NOTES TO 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)

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

Intangible Assets

Intangible assets are reported at cost, less accumulated amortization. Intangible assets with finite lives are amortized over their estimated useful lives. Amortization is calculated using the straight-line method based on the following estimated useful lives:

Trademarks	10-20 years
Product rights	7-20 years

IPR&D

The fair value of IPR&D acquired through a business combination is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized.

The fair value of an IPR&D intangible asset is determined using an income approach. This approach starts with a forecast of the net cash flows expected to be generated by the asset over its estimated useful life. The net cash flows reflect the asset's stage of completion, the probability of technical success, the projected costs to complete, expected market competition, and an assessment of the asset's life cycle. The net cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams.

Impairment of Long-Lived Assets

The Company tests long-lived assets with finite lives for impairment at least annually, or whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Indicators of potential impairment include: an adverse change in legal factors or in the business climate that could affect the value of the asset; an adverse change in the extent or manner in which the asset is used or is expected to be used, or in its physical condition; and current or forecasted operating or cash flow losses that demonstrate continuing losses associated with the use of the asset. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows.

Indefinite-lived intangible assets, including IPR&D, are tested for impairment annually, or more frequently if events or changes in circumstances between annual tests indicate that the asset may be impaired. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value, without consideration of any recoverability test.

Goodwill

Goodwill represents the excess of the purchase price of acquired businesses over the estimated fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment at least annually at the reporting unit level. A reporting unit is the same as, or one level below, an operating segment. The Company currently has one operating segment and one reporting unit, which is the consolidated company. The Company uses its market capitalization as the measurement basis for the estimated fair value of its reporting unit. Accordingly, the Company tests goodwill for impairment by comparing its market capitalization to the carrying value of its consolidated net assets. On that basis, there was no indication of goodwill impairment at December 31, 2009 or 2008.

Deferred Financing Costs

Deferred financing costs are reported at cost, less accumulated amortization, and are recorded in other long-term assets. Amortization expense is included in interest expense.

Derivative Financial Instruments

From time to time, the Company utilizes derivative financial instruments to manage its exposure to market risks. The Company does not utilize derivative financial instruments for trading or speculative purposes. The Company accounts for derivative financial instruments as either assets or liabilities at fair value. The Company did not hold any derivative financial instruments at December 31, 2009 or 2008.

BIOVAIL CORPORATION

NOTES TO 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)**

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

Foreign Currency Translation

The financial statements of the Company's operations having a functional currency other than the U.S. dollar are translated into U.S. dollars at the rate of exchange prevailing at the balance sheet date for asset and liability accounts, and at the average rate of exchange for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive income in shareholders' equity.

Foreign currency exchange gains and losses on transactions occurring in a currency other than an operation's functional currency are recognized in net income.

Revenue Recognition

Effective January 1, 2000, the Company adopted the provisions of the U.S. Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"), as amended by SAB No. 104, "Revenue Recognition". The amortization of revenue deferred upon the adoption of SAB 101 amounted to \$2,100,000, \$2,200,000 and \$3,400,000 in 2009, 2008 and 2007, respectively. The SAB 101 deferred revenue balance was fully amortized as of December 31, 2009.

Revenue is realized or realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price to the customer is fixed or determinable, and collectibility is reasonably assured.

Product Sales

Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership. Amounts received from customers as prepayments for products to be shipped in the future are recorded in deferred revenue.

Revenue from product sales is recognized net of provisions for estimated discounts, allowances, returns, rebates, and chargebacks. The Company offers discounts for prompt payment and other incentive allowances to customers. Provisions for discounts and allowances are estimated based on contractual sales terms with customers and historical payment experience. The Company allows customers to return product within a specified period of time before and after its expiration date. Provisions for returns are estimated based on historical return and exchange levels, and third-party data with respect to prescription demand for the Company's products and inventory levels of the Company's products in the wholesale distribution channel. The Company is subject to rebates on sales made under governmental and managed-care pricing programs, and chargebacks on sales made to group purchasing organizations. Provisions for rebates and chargebacks are estimated based on historical experience, relevant statutes with respect to governmental pricing programs, and contractual sales terms with managed-care providers and group purchasing organizations.

The Company is party to manufacturing and supply agreements with a number of commercialization counterparties in the U.S. Under the terms of these agreements, the Company's supply prices for its products are determined after taking into consideration estimates for future returns, rebates, and chargebacks provided to the Company by each counterparty. The Company makes adjustments as needed to state these estimates on a basis consistent with this policy, and the Company's methodology for estimating returns, rebates, and chargebacks related to its own direct product sales.

Research and Development

Research and development revenue attributable to the performance of contract research services is recognized as the services are performed, under the proportionate performance convention of revenue recognition. Performance is measured based on units-of-work performed relative to total units-of-work contracted. For clinical research services, units-of-work is generally measured in terms of bed night stays, and for laboratory-testing services, units-of-work is generally measured in terms of numbers of samples analyzed. Costs and profit margin related to these services that are in excess of amounts billed are recorded in accounts receivable, and amounts billed related to these services that are in excess of costs and profit margin are recorded in deferred revenue.

Non-refundable, up-front fees for access to the Company's proprietary technology in connection with certain research and development arrangements are deferred and recognized as revenue on a straight-line basis over the term of the related arrangement. Contingent revenue in connection with those arrangements attributable to the achievement of regulatory or developmental milestones is recognized only on the achievement of the applicable milestone.

BIOVAIL CORPORATION

NOTES TO 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)**

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

Royalty

Royalty revenue is recognized based on the terms of the specific licensing contracts, and when the Company has no future obligations with respect to the royalty fee. Royalty revenue is recognized net of amounts payable to sublicensees where the Company is simply acting as an agent for the sublicensee.

Other

Licensing revenue is deferred and recognized on a straight-line basis over the licensing period.

Shipping and Handling Costs

The Company generally does not charge customers for shipping and handling costs. These costs are included in cost of goods sold.

Research and Development Expenses

Research and development expenses include the amount allocated to acquired IPR&D with no alternative future use in an asset acquisition. Costs related to internal research and development programs, including costs associated with the development of IPR&D, are expensed as goods are delivered or services are performed. Under certain research and development arrangements with third parties, the Company may be required to make payments that are contingent on the achievement of specific developmental, regulatory and/or commercial milestones. Before a product receives regulatory approval, milestone payments made to third parties are expensed when the milestone is achieved. Milestone payments made to third parties after regulatory approval is received are capitalized and amortized over the estimated useful life of the approved product.

Amounts due from third parties as reimbursement of development activities conducted under certain research and development arrangements are recognized as a reduction of research and development expenses.

Costs associated with providing contract research services to third parties are included in research and development expenses. These costs amounted to \$13,849,000, \$23,033,000 and \$17,507,000 in 2009, 2008 and 2007, respectively.

Legal Costs

Legal fees and other costs related to litigation and other legal proceedings are expensed as incurred and included in selling, general and administrative expenses. Legal costs expensed are reported net of expected insurance recoveries. A claim for insurance recovery is recognized when the claim becomes probable of realization.

Advertising Costs

Advertising costs comprise product samples, print media, and promotional materials. Advertising costs related to new product launches are expensed on the first use of the advertisement. The Company did not have any deferred advertising costs at December 31, 2009 or 2008.

Advertising costs expensed in 2009, 2008 and 2007 were \$10,013,000, \$7,757,000 and \$3,773,000, respectively. These costs are included in selling, general and administrative expenses.

Stock-Based Compensation

The Company recognizes all share-based payments to employees, including grants of employee stock options and restricted share units ("RSUs"), at estimated fair value. The Company amortizes the fair value of stock option or RSU grants on a straight-line basis over the requisite service period of the individual stock option or RSU grant, which generally equals the vesting period. Stock option and RSU forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

The fair value of Deferred Share Units ("DSUs") granted to non-management directors is recognized as compensation expense at the grant date, and a DSU liability is recorded on the consolidated balance sheet. The fair value of the DSU liability is remeasured at each reporting date, with a corresponding adjustment to compensation expense in the reporting period.

Stock-based compensation is recorded in cost of goods sold, research and development expenses, and selling, general and administrative expenses, as appropriate.

F-13

BIOVAIL CORPORATION

NOTES TO 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)**

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

Interest Expense

Interest expense includes standby fees and the amortization of debt discounts and deferred financing costs. Interest costs are expensed as incurred, except to the extent such interest is related to construction in progress, in which case interest is capitalized. The Company did not capitalize any interest costs in 2009, 2008 or 2007. Interest paid in 2009, 2008 and 2007 amounted to \$4,182,000, \$459,000 and \$16,098,000, respectively.

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the differences between the financial statement and income tax bases of assets and liabilities, and for operating losses and tax credit carryforwards. A valuation allowance is provided for the portion of deferred tax assets that is more likely than not to remain unrealized. Deferred tax assets and liabilities are measured using enacted tax rates and laws.

The tax benefit from an uncertain tax position is recognized only if it is more likely than not that the tax position will be sustained upon examination by the appropriate taxing authority, based on the technical merits of the position. The tax benefits recognized from such a position are measured based on the amount that is greater than 50% likely of being realized upon settlement. Liabilities associated with uncertain tax positions are classified as long-term unless expected to be paid within one year. Interest and penalties related to uncertain tax positions, if any, are recorded in the provision for income taxes and classified with the related liability on the consolidated balance sheet.

Earnings Per Share

Basic earnings per share is calculated by dividing net income by the weighted-average number of common shares outstanding during the reporting period. Diluted earnings per share is calculated by dividing net income by the weighted-average number of common shares outstanding during the reporting period after giving effect to dilutive potential common shares for stock options, RSUs, and convertible debt, determined using the treasury stock method.

Comprehensive Income

Comprehensive income comprises net income and other comprehensive income. Other comprehensive income comprises foreign currency translation adjustments, unrealized temporary holding gains or losses on available-for-sale investments, and the non-credit component of other-than-temporary losses on marketable debt securities. Accumulated other comprehensive income is recorded as a component of shareholders' equity.

Contingencies

In the normal course of business, the Company is subject to loss contingencies, such as claims and assessments arising from litigation and other legal proceedings, contractual indemnities, product and environmental liabilities, and tax matters. Accruals for loss contingencies are recorded when the Company determines that it is both probable that a liability has been incurred and the amount of loss can be reasonably estimated. If the estimate of the amount of the loss is a range and some amount within the range appears to be a better estimate than any other amount within the range, that amount is accrued as a liability. If no amount within the range is a better estimate than any other amount, the minimum amount of the range is accrued as a liability.

Adoption of New Accounting Standards

Effective January 1, 2009, the Company adopted the following accounting guidance:

Authoritative guidance on convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement), which requires that the liability (debt) and equity (conversion option) components of convertible debt instruments that may be settled in cash upon conversion be separately accounted for in a manner that reflects an issuer's non-convertible debt borrowing rate. This new method of accounting results in recognizing interest expense at rates reflective of what the issuer would have incurred had it issued non-convertible debt with otherwise similar terms. The adoption of this guidance impacted the Company's accounting for the Convertible Notes (as described in note 17). This guidance will also have a material impact on interest expense recognized during the period that the Convertible Notes are outstanding, but will have no impact on the Company's future cash flows.

Authoritative guidance on business combinations and non-controlling interests, which significantly changes the accounting for, and reporting of, business combination transactions and non-controlling (minority) interests in consolidated financial statements,

F-14

BIOVAIL CORPORATION

NOTES TO 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)**

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

including requirements to: recognize non-controlling interests at fair value; capitalize IPR&D; and expense acquisition-related costs as incurred. The guidance also requires post-acquisition adjustments related to business combination deferred tax asset valuation allowances and liabilities for uncertain tax positions to be recorded in current period income tax expense. The guidance is effective for business combinations occurring on or after January 1, 2009. The adoption of this guidance impacted the Company's accounting for the acquisition of the worldwide development and commercialization rights to tetrabenazine (as described in note 3).

Authoritative guidance on fair value measurements, which establishes a framework for measuring fair value in U.S. GAAP, clarifies the definition of fair value within that framework, and expands disclosures about the use of fair value measurements. The guidance applies to all other authoritative guidance that requires (or permits) fair value measurements, but does not require any new fair value measurements in U.S. GAAP. The guidance was effective January 1, 2009 for non-financial assets and non-financial liabilities not recognized or disclosed at fair value on a recurring basis. The Company previously adopted this guidance for financial assets and financial liabilities effective January 1, 2008. The adoption of this guidance for non-financial assets and non-financial liabilities did not have a material impact on the Company's consolidated financial statements.

Authoritative guidance on the accounting for collaborative arrangements, which provides guidance for determining if a collaborative arrangement exists and establishes reporting requirements for revenues and costs generated from transactions between parties within a collaborative arrangement, as well as between the parties in a collaborative arrangement and third parties, and provides guidance for financial statement disclosures of collaborative arrangements. The guidance is effective for collaborative arrangements existing on or after January 1, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Effective April 1, 2009, the Company adopted the following accounting guidance:

Authoritative guidance on subsequent events, which identifies the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements and the disclosures that should be made about events or transactions that occurred after the balance sheet date. As this guidance is largely consistent with previous auditing literature, its adoption did not have a material impact on the Company's consolidated financial statements.

Authoritative guidance on the recognition and presentation of other-than-temporary impairments, which requires entities to separate an other-than-temporary impairment of a debt security into (i) the amount representing the decrease in cash flows expected to be collected, or the credit loss portion, which is recognized in earnings, and (ii) the amount related to all other factors, or the non-credit portion, which is recognized in other comprehensive income in circumstances in which management asserts that it does not have the intent to sell the security, and it is more likely than not that it will not be required to sell the security before recovery of its amortized cost basis. Upon the adoption of this guidance, the cumulative effect adjustment to reclassify the non-credit losses previously recognized through earnings from accumulated other comprehensive income to opening accumulated deficit was not material to the Company's consolidated financial statements.

Authoritative guidance on determining fair value when the volume and level of activity for the asset or liability have significantly decreased and on identifying transactions that are not orderly, which provides additional guidance on estimating fair value when there has been a significant decrease in the volume and level of activity for the asset or liability in relation to the normal market activity for the asset or liability. The guidance also provides circumstances that may indicate that a transaction for the asset or liability is not orderly. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Effective July 1, 2009, the Company adopted the following accounting guidance:

In June 2009, the Financial Accounting Standards Board ("FASB") established the FASB Accounting Standards Codification (the "Codification") as the source of authoritative accounting principles recognized by the FASB to be applied in the preparation of financial statements in conformity with U.S. GAAP. As the issuance of the Codification does not change U.S. GAAP, its adoption did not have any impact on the Company's consolidated financial statements.

Effective October 1, 2009, the Company adopted the following accounting guidance:

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Authoritative guidance clarifying the measurement of liabilities at fair value. When a quoted price in an active market for the identical liability is not available, this guidance requires that the fair value of a liability be measured using one or more of the prescribed valuation techniques. In addition, the guidance clarifies that when estimating the fair value of a liability, an entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of the liability. The guidance also clarifies how the quoted price of a debt security when traded as an asset should be considered in estimating the fair value of the issuer's liability. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

F-15

BIOVAIL CORPORATION

NOTES TO 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)**

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

Recently Issued Accounting Guidance, Not Adopted as of December 31, 2009

In June 2009, the FASB issued authoritative guidance for determining whether an entity is a variable interest entity ("VIE") and requires an enterprise to perform an analysis to determine whether the enterprise's variable interest or interests give it a controlling financial interest in a VIE. Under the guidance, an enterprise has a controlling financial interest when it has (i) the power to direct the activities of a VIE that most significantly impact the entity's economic performance, and (ii) 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. In addition, the guidance requires an enterprise to assess whether it has an implicit financial responsibility to ensure that a VIE operates as designed when determining whether it has power to direct the activities of the VIE that most significantly impact the entity's economic performance. The guidance also requires ongoing assessments of whether an enterprise is the primary beneficiary of a VIE, requires enhanced disclosures, and eliminates the scope exclusion for qualifying special purpose entities. The guidance is effective for interim and annual periods beginning after November 15, 2009. Accordingly, the Company is required to adopt this guidance beginning January 1, 2010. The Company is currently evaluating the effect that the adoption of this guidance will have on its consolidated financial statements.

In October 2009, the FASB issued authoritative guidance on multiple-element revenue arrangements, which requires an entity to allocate arrangement consideration at the inception of the arrangement to all of its deliverables based on relative selling prices. The guidance eliminates the use of the residual method of allocation and expands the ongoing disclosure requirements. The guidance is effective for the first fiscal year beginning after June 15, 2010, and may be adopted through prospective or retrospective application. Accordingly, the Company is required to adopt this guidance beginning January 1, 2011. The Company is currently evaluating the effect that the adoption of this guidance will have on its consolidated financial statements.

3. BUSINESS COMBINATIONS

Tetrabenazine

On June 19, 2009, the Company acquired the worldwide development and commercialization rights to the entire portfolio of tetrabenazine products, including Xenazine® and Nitoman®, held by Cambridge Laboratories (Ireland) Limited and its affiliates ("Cambridge"). As described below, the Company had previously obtained certain licensing rights to tetrabenazine in the U.S. and Canada through the acquisition of Prestwick Pharmaceuticals, Inc. ("Prestwick") in September 2008. By means of this acquisition, the Company has obtained Cambridge's economic interest in the supply of tetrabenazine for the U.S. and Canadian markets, as well as for a number of other countries in Europe and around the world through existing distribution arrangements. In addition, the Company assumed Cambridge's royalty obligations to third parties on the worldwide sales of tetrabenazine. The acquisition of tetrabenazine is aligned with the Company's specialty CNS strategy.

This acquisition was accounted for as a business combination under the acquisition method of accounting. The total purchase price comprised cash consideration of \$200,000,000 paid on closing, and additional payments of \$12,500,000 and \$17,500,000 due to Cambridge on the first and second anniversaries of the closing date, respectively. The second payment is subject to a right of set-off against amounts for which the Company has a claim against Cambridge. These additional payments were fair valued at \$26,768,000, using an imputed interest rate comparable to the Company's available borrowing rate at the date of acquisition, and are recorded in long-term obligations (as described in note 17). No gain or loss was recognized in conjunction with the effective settlement of the contractual relationship between Prestwick and Cambridge as a result of this acquisition, as the pre-existing contracts could have been terminated without financial penalty. The Company incurred \$5,596,000 of costs related to this acquisition, which were expensed as acquisition-related costs in the consolidated statement of income as of the acquisition date.

BIOVAIL CORPORATION

NOTES TO 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)

3. BUSINESS COMBINATIONS (Continued)

The following table summarizes the estimated fair values of the assets acquired at the acquisition date.

Inventory	\$ 1,068
Intangible assets:	
Product rights	189,700
IPR&D	36,000
Assets acquired	\$226,768

A multi-period excess earnings methodology (income approach) was used to determine the estimated fair values of the identifiable intangible assets acquired. These fair value measurements were primarily based on significant inputs that are not observable in the market, and, therefore, represent Level 3 inputs in the fair value hierarchy (as described in note 7). The income approach is used to determine fair value for an acquired asset based on the present value of the cash flows projected to be generated by the asset.

The value of the currently marketed immediate-release tetrabenazine products was allocated to the product rights intangible asset, with an estimated useful life of approximately nine years. The projected cash flows from the products were adjusted for the probabilities of genericization and competition from the IPR&D projects described below. A risk-adjusted discount rate of 17% was used to present value the projected cash flows.

The IPR&D intangible asset relates to a modified-release formulation of tetrabenazine under development initially for the treatment of Tourette's Syndrome (BVF-018) and an isomer of tetrabenazine (RUS-350). The values assigned to BVF-018 and RUS-350 were \$28,000,000 and \$8,000,000, respectively. The projected cash flows from the projects were adjusted for the probabilities of successful development and commercialization of each project. A risk-adjusted discount rate of 20% was used to present value the projected cash flows. Based on the results of development efforts completed subsequent to the acquisition date, the Company has decided to terminate the RUS-350 project, having determined that the isomer was unlikely to provide meaningful benefits to patients beyond that provided by tetrabenazine. As a result, in the three-month period ended December 31, 2009, the Company recorded a charge of \$8,000,000 to write off the related IPR&D intangible asset, which is recorded in research and development expenses.

The amount of incremental revenue and pre-tax earnings (excluding amortization of the acquired product rights intangible asset) recognized from the worldwide sales of tetrabenazine from the acquisition date to December 31, 2009, amounted to approximately \$3,800,000 and \$4,500,000, respectively, in the Company's consolidated statement of income.

The following table presents unaudited pro forma consolidated results of operations as if this acquisition had occurred as of January 1, 2008, and includes amortization of the acquired product rights intangible asset and excludes the acquisition-related costs. All transactions between the Company and Cambridge related to the supply of tetrabenazine for the U.S. and Canadian markets prior to the date of acquisition have been eliminated. This pro forma information is not necessarily indicative of the Company's consolidated results of operations had this acquisition occurred as of January 1, 2008, nor necessarily indicative of the future results of operations of the Company.

	2009	2008
Revenue	\$827,125	\$774,253
Net income	181,026	186,719
Basic and diluted earnings per share	\$ 1.14	\$ 1.17

Prestwick

On September 16, 2008, the Company acquired 100% of Prestwick, which was accounted for as a business combination under the former purchase method of accounting. Accordingly, the results of Prestwick's operations have been included in the Company's consolidated financial statements since September 16, 2008. Prestwick had acquired the licensing rights to Xenazine® in the U.S. and Nitoman® in Canada from Cambridge, which, at the time, held the worldwide license for tetrabenazine. On August 15, 2008, a New Drug Application ("NDA") for Xenazine® received U.S. Food and Drug Administration ("FDA") approval for the treatment of chorea associated with Huntington's disease and was granted orphan drug designation by the FDA, which provides the product with seven years of market exclusivity in the U.S. from the date of FDA approval. Nitoman® has been available in Canada since 1996, where it is approved for the treatment of hyperkinetic movement disorders including Huntington's chorea.

BIOVAIL CORPORATION

NOTES TO 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)

3. BUSINESS COMBINATIONS (Continued)

Prior to the Company's acquisition of Prestwick, Prestwick entered into an exclusive supply and distribution agreement with Lundbeck Inc. (a subsidiary of H. Lundbeck A/S) ("Lundbeck"), formerly known as Ovation Pharmaceuticals, Inc. ("Ovation"), for Xenazine® in the U.S. Ovation paid Prestwick \$50,000,000 for the exclusive rights to market and distribute Xenazine® for an initial term of 15 years. Following its acquisition of Prestwick, the Company supplies Xenazine® product to Lundbeck for a variable percentage of Lundbeck's annual net sales of the product. For annual net sales up to \$125,000,000, the Company's supply price will be 72% of net sales. Beyond \$125,000,000, the Company's supply price will be 65% of net sales. Prior to the acquisition of the worldwide development and commercialization rights to tetrabenazine (as described above), the Company acquired Xenazine® product from Cambridge at a supply price of 50% of Lundbeck's net sales.

The total purchase price, including acquisition costs of \$3,442,000, less cash acquired of \$1,067,000, was \$101,920,000. The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the date of acquisition.

Current assets (excluding cash acquired)	\$ 2,166
Intangible assets	157,862
Current liabilities (excluding deferred revenue)	(8,108)
Deferred revenue:	
Current	(3,000)
Long-term	(47,000)
Net assets acquired	\$ 101,920

The identifiable intangible assets are associated with the acquired Xenazine® and Nitoman® product rights, and have an estimated useful life of 10 years. The current liabilities assumed at the date of acquisition included \$3,477,000 related to severance benefits payable to 12 employees of Prestwick who were terminated as a result of the acquisition. The affected employees were notified and the related benefits paid out prior to the end of 2008. The deferred revenue liability recognized at the date of acquisition represents a performance obligation assumed by the Company to supply Xenazine® to Lundbeck over the 15-year term of the supply and distribution agreement.

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

4. ASSET ACQUISITIONS

GDNF

On December 21, 2009, the Company entered into a license agreement with Amgen Inc. ("Amgen") and MedGenesis Therapeutix Inc. ("MedGenesis"), pursuant to which the Company was granted a license to exploit GDNF in certain CNS indications in certain countries (including the U.S., Canada, Japan, and a number of European countries). At the same time, the Company entered into a collaboration agreement with MedGenesis to develop and commercialize GDNF, initially for the treatment of Parkinson's disease in the U.S., Japan and certain European countries and, potentially, in other countries and other CNS indications. Pursuant to the collaboration agreement, the Company was granted a license to MedGenesis's Convection Enhanced Delivery platform for use with GDNF in CNS indications.

In connection with the collaboration agreement, the Company made an upfront payment to MedGenesis of \$5,950,000, and could pay up to an additional \$20,000,000 in potential developmental milestones to MedGenesis. The Company also has certain funding obligations towards the development of GDNF in Parkinson's disease in the U.S., totaling up to \$14,000,000 for the Pre-Investigational New Drug development phase and Phase 2 clinical trials. The Company intends to share with MedGenesis the development costs associated with Phase 3 clinical studies in the U.S., (as well as any development costs associated with Phase 2 clinical trials that exceed the Company's initial funding obligation) and with the development programs in other countries. The Company and MedGenesis could, in the aggregate, pay Amgen up to \$25,000,000 in regulatory milestones and up to \$75,000,000 in sales-based milestones, and will pay royalties to Amgen based on net sales of GDNF products. The Company will be responsible for commercializing GDNF products in the

BIOVAIL CORPORATION

NOTES TO 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)**

4. ASSET ACQUISITIONS (Continued)

countries in which it has the GDNF license rights, and will pay MedGenesis a royalty in respect of net sales of GDNF products in those countries.

This acquisition was accounted for as a purchase of IPR&D intangible assets with no alternative future use. Accordingly, the \$5,950,000 upfront payment, together with acquisition costs of \$2,864,000, was charged to research and development expenses at the acquisition date.

Fipamezole

On August 24, 2009, the Company entered into a collaboration and license agreement with Santhera Pharmaceuticals (Switzerland) Ltd. ("Santhera"), a subsidiary of Santhera Pharmaceuticals Holding AG, to acquire the U.S. and Canadian rights to develop, manufacture and commercialize fipamezole for the treatment of a number of neurological and psychiatric conditions, including levodopa-induced dyskinesia, also known as Parkinson's disease dyskinesia ("PDD").

Pursuant to the terms of the collaboration and license agreement, the Company made an upfront payment of \$8,000,000 to Santhera at the acquisition date, and made a further payment of \$4,000,000 to Santhera on October 5, 2009, upon the closing of Santhera's acquisition of Oy Juvantia Pharma Ltd. The Company could pay up to \$35,000,000 in potential developmental and regulatory milestones associated with the initiation of a Phase 3 study, regulatory submissions and approvals of fipamezole in PDD. Should the Company pursue a second indication, it could pay an additional \$20,000,000 milestone upon regulatory approval. The Company will also make royalty payments of 8% to 15% on net commercial sales of fipamezole, as well as additional milestone payments of up to \$145,000,000 as certain sales thresholds are met.

This acquisition was accounted for as a purchase of IPR&D intangible assets with no alternative future use. Accordingly, the \$8,000,000 upfront payment, together with acquisition costs of \$126,000, was charged to research and development expenses at the acquisition date. The additional payment of \$4,000,000 made to Santhera on October 5, 2009 was charged to research and development expenses on the payment date.

The Company will be responsible for the development programs and associated costs in the U.S. and Canada for fipamezole for both PDD and the second indication if pursued.

Wellbutrin XL®

On May 14, 2009, the Company acquired the full U.S. commercialization rights to Wellbutrin XL® from The GlaxoSmithKline Group of Companies ("GSK"). The Company had supplied Wellbutrin XL® to GSK for marketing or distribution in the U.S. since September 2003. The Wellbutrin XL® product formulation was developed and is manufactured by the Company under its own patents and proprietary technology.

Pursuant to the terms of the asset purchase agreement, the Company paid \$510,000,000 to GSK to acquire the U.S. NDA for Wellbutrin XL®. Pursuant to the terms of a trademark and license agreement with GSK, the Company also obtained an exclusive, royalty-free license to the Wellbutrin XL® trademark for use in the U.S. This acquisition was accounted for as a purchase of identifiable intangible assets. Accordingly, the total purchase price (including costs of acquisition of \$475,000) was allocated to the trademark intangible asset, with an estimated useful life of 10 years. In addition, the Company acquired the Wellbutrin XL® finished goods inventory owned by GSK valued at \$10,490,000.

Pimavanserin

On May 1, 2009, the Company entered into a collaboration and license agreement with ACADIA Pharmaceuticals Inc. ("ACADIA") to acquire the U.S. and Canadian rights to develop, manufacture and commercialize pimavanserin in a number of neurological and psychiatric conditions, including Parkinson's disease psychosis ("PDP"), Alzheimer's disease psychosis ("ADP"), and, as an adjunctive therapy, to treat schizophrenia.

Pursuant to the terms of the collaboration and license agreement, the Company paid an upfront fee of \$30,000,000 to ACADIA, and could pay up to \$160,000,000 in potential developmental milestones associated with the successful completion of clinical trials, regulatory submissions and approvals for pimavanserin in the PDP and ADP indications. In addition, the Company could pay up to \$45,000,000 in success milestones for pimavanserin in a third indication. At this time, the Company intends to pursue pimavanserin as an adjunct therapy for schizophrenia as the third indication. The Company will also make tiered royalty payments of 15% to 20% on net sales of products containing pimavanserin, as well as additional milestone payments of up to \$160,000,000 as certain net sales thresholds are met.

BIOVAIL CORPORATION

NOTES TO 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)

4. ASSET ACQUISITIONS (Continued)

This acquisition was accounted for as a purchase of IPR&D intangible assets with no alternative future use. Accordingly, the \$30,000,000 upfront payment, together with acquisition costs of \$414,000, was charged to research and development expenses at the acquisition date.

The Company will be responsible for funding all of the PDP, ADP and schizophrenia development expenses for pimavanserin, other than the cost of two Phase 3 clinical trials for pimavanserin for PDP that ACADIA had in progress at the time of the agreement. The first of these Phase 3 PDP studies did not meet its primary endpoint of antipsychotic efficacy, but did meet the secondary endpoint of motoric tolerability. As a result, on October 5, 2009, the Company and ACADIA amended the collaboration and license agreement to provide that the Company will fund a third Phase 3 clinical trial for PDP; provided, however, that if the trial does not meet the primary endpoint, then ACADIA will reimburse the Company for 50% of the cost of the trial. If the third PDP trial or a subsequent pivotal trial in PDP meets its primary endpoint, the Company may credit 50% of the costs of the applicable trial against the potential milestone payment triggered by such trial. The amendment also provides that ACADIA may elect to pursue an initial clinical trial in ADP at its own expense. However, if the ADP trial meets its primary endpoint, then the Company would reimburse ACADIA 100% of the cost of the trial.

5. LICENSING AGREEMENT

Aplenzin

In December 2008, the Company entered into a distribution and supply agreement with sanofi-aventis U.S. LLC ("sanofi-aventis") for the commercialization of Aplenzin in the U.S. and Puerto Rico. Aplenzin is a once-daily formulation of bupropion hydrobromide and has been launched by sanofi-aventis in 174mg, 348mg, and 522mg dosage strengths. The Company manufactures and supplies Aplenzin to sanofi-aventis at contractually determined supply prices ranging from 25% to 35% of sanofi-aventis's net selling price, depending on the level of net sales of Aplenzin in each calendar year.

6. 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. These measures included the closure of the Company's research and development facility in Dublin, Ireland in August 2008, the sale of its Dorado, Puerto Rico manufacturing facility in January 2010, and the ultimate planned closure of its manufacturing facility in Carolina, Puerto Rico. In addition, in May 2009, the Company announced the closure of its research and development facility in Mississauga, Ontario and the consolidation of its research and development operations in Chantilly, Virginia.

The following table summarizes the major components of the restructuring costs recognized through December 31, 2009:

	Asset Impairments		Employee Termination Benefits		Contract Termination and Other Costs	Total
	Manufacturing	Pharmaceutical Sciences	Manufacturing	Pharmaceutical Sciences		
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	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)
	\$	\$	\$ 6,210	\$ 234	\$ 4,332	\$ 10,776

Balance, December 31,
2009

F-20

BIOVAIL CORPORATION

NOTES TO 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)**

6. RESTRUCTURING (Continued)

Manufacturing Operations

The Company expects to incur employee termination costs of approximately \$9,400,000 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 its Dorado and Carolina, Puerto Rico manufacturing 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 required future service period, including \$4,942,000 and \$3,309,000 recognized in 2009 and 2008, respectively.

In 2009 and 2008, the Company recorded impairment charges of \$7,591,000 and \$42,602,000, respectively, to write down the carrying value of the property, plant and equipment located in Puerto Rico to its estimated fair value. At December 31, 2009, the Company had entered into an agreement in principle to sell the Dorado facility for net cash proceeds of \$8,542,000. Accordingly, the related property, plant and equipment was reclassified as assets held for sale on the consolidated balance sheet at December 31, 2009. The sale closed on January 15, 2010. The Company will continue 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 the Carolina facility.

Pharmaceutical Sciences Operations

In 2009, the Company incurred employee termination costs of \$1,441,000 for severance and related benefits payable to the approximately 50 employees who have been, or will be, terminated as a result of the closure of the Company's Mississauga, Ontario research and development facility and the consolidation of its Chantilly, Virginia research and development operations. In addition, the Company recorded an impairment charge of \$463,000 related to the write-down of the carrying value of the equipment and leasehold improvements located at the Mississauga facility to their estimated fair value. The Company also recognized \$1,616,000 of accelerated depreciation arising from a reduced useful life of the leasehold improvements located at the Chantilly facility, and incurred lease termination costs of \$1,422,000 as a result of vacating one of its premises in Chantilly in 2009.

On July 21, 2009, the Company completed the sale of the Dublin, Ireland research and development facility for net cash proceeds of \$5,189,000, which resulted in an additional write-down of \$705,000 to the carrying value of this facility in 2009. The Company had closed this facility in August 2008 and recorded an impairment charge of \$9,242,000 to write down the carrying value of the property, plant and equipment to its estimated fair value of \$5,894,000 at that time, which was classified as assets held for sale on the consolidated balance sheet at December 31, 2008. In addition, the Company recognized employee termination costs of \$2,724,000 in 2008 for the approximately 50 employees affected by this closure.

In December 2008, the Company identified certain of its proprietary drug-delivery technologies that were not expected to be utilized in the development of specialty CNS products consistent with the Company's strategy. As a result, the Company recorded an impairment charge of \$7,460,000 in 2008 to write off the carrying value of the related technology intangible assets.

Contract Termination Costs

In connection with a restructuring of its U.S. commercial operations in May 2005, the Company vacated a portion of its Bridgewater, New Jersey facility. The Company recognized a restructuring charge at that time for a gross operating lease obligation related to the vacant space, offset by estimated sublease rentals that could be reasonably obtained. The Company's evaluation of general economic and commercial real estate market conditions indicated that an additional charge of \$4,215,000 was required in 2008 to reflect lower estimated future sublease rentals, based on the expected time required to locate and contract a suitable sublease and the expected market rates for such a sublease.

7. FAIR VALUE MEASUREMENTS

Fair Value Hierarchy

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants at the measurement date. The fair value hierarchy prioritizes the inputs to valuation techniques used in measuring fair value. There are three levels to the fair value hierarchy based on the reliability of inputs, as follows:

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

BIOVAIL CORPORATION

NOTES TO 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)

7. FAIR VALUE MEASUREMENTS (Continued)

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

Level 3 Unobservable inputs for the asset or liability.
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:

	Carrying Value	2009		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale debt securities	\$ 23,067	\$ 7,994	\$ 15,073	\$
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	\$	\$
Marketable securities	21,082		15,073	6,009
Total financial assets	\$ 29,076	\$ 7,994	\$ 15,073	\$ 6,009

	Carrying Value	2008		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale debt securities	\$ 203,688	\$ 112,834	\$ 90,854	\$
Available-for-sale equity securities	380	380		
Auction rate securities	10,333			10,333
Total financial assets	\$ 214,401	\$ 113,214	\$ 90,854	\$ 10,333
Cash and cash equivalents	\$ 191,386	\$ 112,834	\$ 78,552	\$
Marketable securities	22,635		12,302	10,333
Other	380	380		
Total financial assets	\$ 214,401	\$ 113,214	\$ 90,854	\$ 10,333

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

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

At December 31, 2009 and 2008, the Company did not have any financial liabilities that were subject to fair value measurements.

F-22

BIOVAIL CORPORATION

NOTES TO 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)

7. 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):

	2009	2008
Balance, beginning of year	\$ 10,333	\$ 18,000
Total unrealized gains (losses):		
Included in net income ⁽¹⁾ :		
Arising during the year	(4,479)	(4,261)
Reclassification from other comprehensive income	(731)	(4,352)
Included in other comprehensive income:		
Arising during the year	155	(3,356)
Reclassification to net income	731	4,352
Settlements		(50)
Balance, end of year	\$ 6,009	\$ 10,333

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

Assets Measured at Fair Value on a Non-Recurring Basis

The following table presents the Company's non-financial assets measured at fair value on a non-recurring basis:

	Carrying Value	2009 Quoted Prices in Active Markets for Identical Assets (Level 1)	Total Loss
Assets held for sale	\$ 8,542	\$ 8,542	\$ 7,591

As described in note 6, the property, plant and equipment located in Puerto Rico was written down to its fair value less costs to sell, resulting in an impairment charge of \$7,591,000 in 2009.

The Company did not have any non-financial liabilities that were measured at fair value on a recurring or non-recurring basis in 2009.

BIOVAIL CORPORATION

NOTES TO 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)

8. MARKETABLE SECURITIES

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

	2009			
	Cost Basis	Fair Value	Gross Unrealized	
			Gains	Losses
Corporate and government bonds	\$ 10,626	\$ 10,880	\$ 254	\$
Government-sponsored enterprise securities	4,100	4,193	93	
Auction rate securities	26,775	6,009		(20,766)
	\$ 41,501	\$ 21,082	\$ 347	\$ (20,766)

	2008			
	Cost Basis	Fair Value	Gross Unrealized	
			Gains	Losses
Corporate and government bonds	\$ 6,869	\$ 6,926	\$ 70	\$ (13)
Government-sponsored enterprise securities	5,159	5,376	217	
Auction rate securities	26,775	10,333		(16,442)
	\$ 38,803	\$ 22,635	\$ 287	\$ (16,455)

The contractual maturities of marketable securities held at December 31, 2009 were as follows:

	Cost Basis	Fair Value
Within one year	\$ 9,391	\$ 9,566
One to three years	5,335	5,507
After three years	26,775	6,009
	\$ 41,501	\$ 21,082

Gross gains and losses realized on the sale of marketable securities were not material in 2009, 2008 or 2007.

Auction Rate Securities

The Company's marketable securities portfolio currently includes \$26,775,000 of principal invested in nine individual auction rate securities; eight with an original principal amount of \$3,000,000 each, and one with an original principal amount of \$2,775,000. The total estimated fair values of these securities at December 31, 2009 and 2008 were \$6,009,000 and \$10,333,000, respectively, which reflected write-downs of \$20,766,000 and \$16,442,000, respectively, to the cost bases at those dates.

As described in note 24, on May 6, 2008, the Company commenced an arbitration against the investment bank that invested the Company's assets in auction rate securities. On May 28, 2009, the Company resolved this matter with the investment bank for a payment in the amount of \$22,000,000, and the Company retained ownership of these securities under the terms of this settlement.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Of the nine individual auction rate securities, three of the securities have no underlying collateral value, and have defaulted on their interest payments. The Company considers the likelihood of collecting any portion of the outstanding principal or interest on these three securities to be remote, and has written down the carrying value of these securities to zero through an impairment charge to earnings. Two other securities have no underlying collateral value, but are continuing to accrue interest at the prescribed rates. The Company has assessed the likelihood of collecting any portion of the outstanding principal or accrued and unpaid interest on these two securities as remote, and has written down the carrying value of these securities to zero through an impairment charge to earnings.

Of the remaining four individual auction rate securities, two securities are continuing to pay cash interest at the prescribed rates, but have significant shortfalls in their underlying collateral value. In particular, one of these securities has available collateral coverage of 69% and the other has collateral coverage of 23%. As a result, the Company does not consider it probable that it will be able to recover

F-24

BIOVAIL CORPORATION

NOTES TO 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)

8. MARKETABLE SECURITIES (Continued)

the entire cost bases of these two securities, and, therefore, the Company considers these securities to be other-than-temporarily impaired. In accordance with the adoption of the recently issued guidance on the recognition and presentation of other-than-temporary impairments (as described in note 2), the Company assessed whether the other-than-temporary impairment was related to credit factors, or the credit loss portion, or was not related to credit factors, or the non-credit loss portion. The credit loss portion of the other-than-temporary impairment is determined based on the difference between the amortized cost base of each individual security and the estimated present value of the principal and interest cash flows expected to be collected from the security. The non-credit loss portion is the residual amount of the other-than-temporary impairment. In calculating the present value of the expected cash flows to determine the credit loss portion of the other-than-temporary impairment, the Company estimated the amount and timing of projected cash flows for each security based on the underlying collateral coverage, and applied a discount rate equal to the current yield on the securities. Based on this calculation, the Company determined that the portion of the other-than-temporary impairment loss not related to credit factors was not material to the Company's consolidated financial statements. The Company recognized other-than-temporary impairment losses, to write down the carrying value of these securities to their estimated fair value, of \$5,210,000, \$8,613,000 and \$6,000,000 in 2009, 2008 and 2007, respectively.

The remaining two individual auction rate securities currently have adequate underlying collateral value with which to repay the entire principal amount (in particular, one of these securities has available collateral coverage of 222% and the other has collateral coverage of 137%), and cash interest payments on these securities are not in arrears. As a result, the Company does not consider the decline in the fair value of these remaining securities to be other-than-temporary, based on the adequacy of the underlying collateral value, and the Company's conclusion that it does not intend to sell these securities and it is not more likely than not that it will be required to sell these securities before a recovery of their amortized cost bases. Therefore, the Company has recognized the unrealized gains or losses on these securities through other comprehensive income. In 2009, the Company recorded an unrealized gain of \$155,000 in other comprehensive income, compared with unrealized losses of \$3,356,000 and \$2,825,000 in 2008 and 2007, respectively. These securities have been in a continuous overall loss position for at least 12 months.

9. ACCOUNTS RECEIVABLE

	2009	2008
Trade	\$ 109,607	\$ 81,072
Less allowance for doubtful accounts	2,437	1,179
	107,170	79,893
Royalties	6,313	6,877
Other	6,436	3,281
	\$ 119,919	\$ 90,051

10. INVENTORIES

	2009	2008
Raw materials	\$ 14,290	\$ 19,042
Work in process	25,012	13,563
Finished goods	43,471	26,956
	\$ 82,773	\$ 59,561

BIOVAIL CORPORATION

NOTES TO 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)

11. PROPERTY, PLANT AND EQUIPMENT

	2009		2008	
	Cost	Accumulated Depreciation	Cost	Accumulated Depreciation
Land	\$ 3,398	\$	\$ 9,528	\$
Buildings	80,560	23,713	103,355	22,266
Machinery and equipment	74,560	51,199	76,002	44,912
Other equipment and leasehold improvements	56,248	43,186	73,182	51,271
Construction in progress	7,180		4,651	
	221,946	\$ 118,098	266,718	\$ 118,449
Less accumulated depreciation	118,098		118,449	
	\$ 103,848		\$ 148,269	

Depreciation expense amounted to \$18,764,000, \$25,824,000 and \$27,644,000 in 2009, 2008 and 2007, respectively.

Sale and Leaseback Transactions

On November 4, 2009, the Company completed the sale and leaseback of its corporate headquarters in Mississauga, Ontario for net proceeds of \$17,813,000. Included in this transaction was a vacant parcel of land adjacent to this facility, which was sold but not leased back. The Company recognized a loss on disposal of \$10,968,000, which is recorded in selling, general and administrative expenses. The Company will continue to occupy the facility under a 20-year operating lease at market rental rates.

In April 2009, the Company completed the sale of its corporate aircraft for proceeds of \$5,300,000 and entered into a four-year operating lease for this aircraft. This transaction resulted in a gain on disposal of \$914,000, which was deferred and will reduce future lease rental expense over the lease term.

BIOVAIL CORPORATION

NOTES TO 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)

12. INTANGIBLE ASSETS

	2009		2008	
	Cost	Accumulated Amortization	Cost	Accumulated Amortization
Trademarks				
Wellbutrin XL®	\$ 510,475	\$ 31,905	\$	\$
Cardizem®	406,058	183,849	406,058	163,650
Ativan® and Isordil®	107,542	35,483	107,542	30,114
Vasotec® and Vaseretic®	35,908	7,447	35,908	5,156
Wellbutrin® and Zyban®	24,243	8,565	24,243	7,360
	1,084,226	267,249	573,751	206,280
Product rights				
Xenazine® and Nitoman®	348,197	31,699	157,862	4,598
Zovirax®	173,518	72,253	173,518	63,816
Cardizem® LA	56,719	37,814	56,719	29,710
Wellbutrin® and Zyban®	45,000	21,000	45,000	18,000
Vasotec® and Vaseretic®	17,984	5,479	17,984	3,792
Ativan® and Isordil®	16,041	7,029	16,041	5,958
Tiazac®	15,000	12,857	15,000	11,786
Glumetza®	6,667	2,500	6,667	1,730
Other	14,000	12,250	14,000	10,500
	693,126	202,881	502,791	149,890
IPR&D	28,000			
	1,805,352	\$ 470,130	1,076,542	\$ 356,170
Less accumulated amortization	470,130		356,170	
	\$ 1,335,222		\$ 720,372	

Additions to Intangible Assets

As described in notes 3 and 4, additions to identifiable intangible assets by component in 2009 were as follows:

	Trademarks	Product Rights	IPR&D	Total
Wellbutrin XL®	\$ 510,475	\$	\$	\$510,475
Tetrabenazine		189,700 ⁽¹⁾	36,000 ⁽²⁾	225,700
	\$ 510,475	\$ 189,700	\$36,000	\$736,175

(1) Included in Xenazine® and Nitoman® product rights.

(2) As described in note 3, subsequent to the acquisition date of the worldwide development and commercialization rights to tetrabenazine, the Company terminated the RUS-350 development program and recorded a charge of \$8,000,000 to write off the related IPR&D intangible asset.

Weighted-Average Useful Lives

Trademarks and product rights have estimated weighted-average useful lives of approximately 14 years and 11 years, respectively. Total amortizable intangible assets have an estimated weighted-average useful life of approximately 12 years.

Amortization Expense

Amortization expense related to intangible assets that contribute to multiple business activities, including research and development, manufacturing and supply, royalty and licensing, and/or sales, marketing and distribution, is included in amortization expense.

F-27

BIOVAIL CORPORATION

NOTES TO 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)

12. INTANGIBLE ASSETS (Continued)

Amortization expense related to intangible assets that are associated with a single business activity is included in cost of goods sold, or another income statement line item, as appropriate.

Amortization expense for the years ended December 31 was recorded as follows:

	2009	2008	2007
Royalty and other revenue	\$ 1,072	\$ 1,072	\$ 1,072
Cost of goods sold	8,103	8,103	8,103
Amortization expense	104,730	51,369	48,049
	\$ 113,905	\$ 60,544	\$ 57,224

Estimated amortization expense for each of the five succeeding years ending December 31 is as follows:

	2010	2011	2012	2013	2014
Amortization expense	\$ 142,437	\$ 140,687	\$ 134,213	\$ 131,512	\$ 131,512

13. OTHER LONG-TERM ASSETS

	2009	2008
Deferred financing costs, less accumulated amortization (2009 \$2,865; 2008 \$9,221) (as described in note 17)	\$ 20,735	\$ 754
Security in trust pursuant to reinsurance agreement	7,288	7,288
Zovirax® price allowance, less accumulated amortization (2009 \$40,656; 2008 \$28,971)	11,685	11,685
Other	4,701	5,823
	\$ 32,724	\$ 25,550

Zovirax® Price Allowance

Effective October 1, 2002, the Company amended several terms of the original Zovirax® distribution agreement with GSK, including reductions in the supply price for this product. The supply price reductions consisted of an initial price allowance and a supplemental price allowance. In consideration for the supplemental price allowance, the Company agreed to pay GSK \$11,250,000 per year in four annual instalments on March 31 of each year beginning in 2004. The present value of those payments was determined to be \$40,656,000, which was recorded as a deferred charge. The amortization of the deferred charge commenced once the initial price allowance had been used up in March 2007. Amortization is allocated to the cost of inventory on a proportionate basis relative to the total amount of Zovirax® that can be purchased at the reduced supply price under the supplemental price allowance. In 2009, the remaining supplemental price allowance was used up and the related deferred charge was fully amortized.

BIOVAIL CORPORATION

NOTES TO 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)

14. ACCRUED LIABILITIES

	2009	2008
Product returns	\$ 24,584	\$ 25,092
Product rebates and chargebacks ⁽¹⁾	23,230	6,273
Employee costs	17,536	14,892
Accrued interest	11,627	
Restructuring costs (as described in note 6)	10,776	6,655
Royalties	9,934	2,606
Professional fees	5,601	8,804
Distribution fees	5,458	3,718
DSUs	4,796	2,137
Other	8,356	14,992
	\$ 121,898	\$ 85,169

(1)

In connection with the acquisition of the full U.S. commercialization right to Wellbutrin® XL on May 14, 2009 (as described in note 4), the Company assumed financial responsibility for governmental rebate programs for product sold after the acquisition date. The provision at December 31, 2009 includes a balance owing to GSK for rebate claims administered and paid by GSK on behalf of the Company.

15. ACCRUED LEGAL SETTLEMENTS

	2009	2008
U.S. Attorney's Office (MA) investigation	\$	\$ 24,648
Ontario Securities Commission investigation		5,337
Other litigation matters	7,950	2,580
	\$ 7,950	\$ 32,565

U.S. Attorney's Office (MA) Investigation

On May 16, 2008, Biovail Pharmaceuticals, Inc. (now Biovail Pharmaceuticals LLC), a subsidiary of the Company, and the Company entered into agreements in principle to settle the U.S. Attorney's Office ("USAO") for the District of Massachusetts investigation into activities surrounding the 2003 commercial launch of Cardizem® LA (as described in note 24). On September 14, 2009, the agreements received Court approval, and Biovail Pharmaceuticals LLC and the Company paid \$22,244,000 and \$2,404,000, respectively, to fully settle this matter.

Ontario Securities Commission Investigation

On January 9, 2009, the Ontario Securities Commission ("OSC") approved a settlement agreement in respect of its investigation of the Company related to specific accounting and financial disclosure practices from 2001 to March 2004 (as described in note 24). Pursuant to the terms of the settlement agreement, the Company paid \$5,337,000, including costs, to fully settle this matter.

16. DEFERRED REVENUE

	2009	2008
Xenazine®, less accumulated amortization (2009 \$3,611; 2008 \$278) (as described in note 3)	\$ 46,389	\$ 49,722
Cardizem® LA, less accumulated amortization (2009 \$70,318; 2008 \$55,250)	35,159	50,227
Other	9,533	25,439

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

	91,081	125,388
Less current portion	21,834	40,435
	\$ 69,247	\$ 84,953

F-29

BIOVAIL CORPORATION

NOTES TO 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)

16. DEFERRED REVENUE (Continued)

Cardizem® LA

In May 2005, the Company received up-front cash consideration of \$105,477,000 from Kos Pharmaceuticals, Inc. (now known as Abbott Laboratories ("Abbott")) in connection with the disposition of the distribution rights to Cardizem® LA and product rights to Teveten. Commencing in 2005, this consideration is being amortized to product sales on a straight-line basis over seven years.

Other

Other deferred revenue includes up-front licensing fees, research and development fees, customer prepayments, and adjustments made by the Company to product sales provisions estimated by its commercialization counterparties. At December 31, 2009, the Company reclassified from deferred revenue to accounts payable an amount of \$10,701,000 owed to Teva Pharmaceuticals Industries Ltd. ("Teva") for the Company's share of returns, rebates and chargebacks in respect of third-party sales of its bioequivalent products by Teva.

17. LONG-TERM OBLIGATIONS

	2009	2008
Convertible Notes (net of unamortized debt discount of \$51,715)	\$298,285	\$
Cambridge obligation (net of unamortized debt discount of \$2,200)	27,800	
	326,085	
Less current portion	12,110	
	\$313,975	\$

Convertible Notes

On June 10, 2009, the Company issued \$350,000,000 principal amount of 5.375% Senior Convertible Notes due 2014 ("Convertible Notes") in a private placement. The Convertible Notes were issued at par and pay interest at a rate of 5.375%. Interest is payable semi-annually on February 1 and August 1 of each year, beginning February 1, 2010. The Convertible Notes will mature on August 1, 2014. 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). The conversion rate will be adjusted if the Company makes specified types of distributions or enters into certain other transactions in respect of its common shares. In addition, following certain corporate transactions that occur prior to maturity, the conversion rate will be increased for Noteholders who elect to convert their holdings in connection with such corporate transactions.

The Convertible Notes are convertible at any time prior to the maturity date under the following circumstances:

during any calendar quarter if the closing price of the Company's common shares exceeds 130% of the conversion price then in effect during a defined period at the end of the previous quarter;

during a defined period if the trading price of the Convertible Notes falls below specified thresholds for a defined trading period;

if the Convertible Notes have been called for redemption;

upon the occurrence of specified corporate transactions; or

25 trading days prior to the maturity date.

F-30

BIOVAIL CORPORATION

NOTES TO 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)**

17. 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.

The Company may redeem for cash all or a portion of the Convertible Notes at any time on or after August 2, 2012, at a price equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus any accrued and unpaid interest, if during a defined period the closing price of the Company's common shares exceeds 130% of the conversion price then in effect. The Company may not otherwise redeem any of the Convertible Notes at its option prior to maturity, except upon the occurrence of certain changes to the laws governing Canadian withholding taxes. Noteholders may require the Company to repurchase for cash all or a portion of their holdings at 100% of the principal amount of the Convertible Notes to be purchased, plus any accrued and unpaid interest, upon the occurrence of a specified fundamental change (such as a change of control).

Because the Convertible Notes' conversion option would be classified in shareholders' equity (as the Company has no requirement to cash settle the conversion option) and the conversion option is considered indexed to the Company's own common shares, the conversion option was not accounted for as an embedded derivative. Accordingly, the recently issued guidance on the accounting for convertible debt instruments (as described in note 2) applies to the Convertible Notes, such that the principal amount of the Convertible Notes was allocated into a liability component and an equity component. The liability component was fair valued at \$293,331,000, based on a 9.5% market rate of interest for similar debt with no conversion rights. The value allocated to the liability component will be accreted to the face value of the Convertible Notes over the five-year period prior to maturity, using the effective interest method. The accretion of the liability component will be recognized as additional non-cash interest expense. The difference between the principal amount of the Convertible Notes and the value allocated to the liability component of \$56,669,000 was recorded in additional paid-in capital in shareholders' equity, as the carrying amount of the equity component.

In connection with the issuance of the Convertible Notes, the Company incurred financing costs of \$16,515,000, which were allocated to the liability and equity components in proportion to the preceding allocation of the principal amount of the Convertible Notes. Accordingly, \$13,841,000 of the financing costs were accounted for as debt issuance costs to be amortized over five years using the effective interest method, and \$2,674,000 of the financing costs were accounted for as equity issuance costs and recorded as a reduction to additional paid-in capital.

As the Company's current intent and policy is to settle the Convertible Notes using a net share settlement approach, only the common shares potentially issuable with respect to the excess conversion value of the Convertible Notes over their principal amount, if any, will be considered as dilutive potential common shares for purposes of calculating diluted earnings per share. At December 31, 2009, the if-converted value of the Convertible Notes was less than the related principal amount.

Interest expense of \$15,458,000 was recognized on the Convertible Notes in the period ended December 31, 2009, which comprised accrued cash interest of \$10,504,000 and non-cash amortization of the discount on the liability component of \$4,954,000.

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

Credit Facility

On June 9, 2009, the Company established a \$410,000,000 senior secured revolving credit facility with a syndicate of banks. This facility matures on June 9, 2012 and replaces the Company's former \$250,000,000 credit facility. The new facility contains an accordion feature that, subject to certain conditions, allows it to be increased to up to \$550,000,000.

Borrowings under this 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. This facility includes certain financial and non-financial covenants. The financial covenants require the Company to maintain a minimum adjusted equity (defined as shareholders' equity excluding IPR&D charges) of no less than \$1,000,000,000; an EBITDA (defined as earnings before interest, taxes, depreciation, amortization, and certain non-cash and non-recurring charges, including IPR&D charges) to cash interest expense ratio of no less than 3.0 to 1.0; and a total debt to EBITDA ratio of no greater than 2.5 to 1.0. Non-financial covenants include, but are not limited to, restrictions on investments, dispositions, and capital and debt restructurings.

Borrowings under this facility may be by way of U.S. dollar LIBOR and U.S. base rate advances, Canadian dollar prime rate and bankers' acceptance advances, and letters of credit. Borrowing margins, determined by reference to the total debt to EBITDA ratio, range from 3.5% to 5.0% in the case of LIBOR advances, bankers' acceptance advances and letters of credit, and 2.5% to 4.0% in the case of U.S. base rate and prime rate advances.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

In connection with the establishment of this facility, the Company incurred financing costs of \$9,759,000, which will be amortized on a straight-line basis over the three-year term of the facility. In 2009, the Company wrote off \$537,000 of unamortized deferred financing costs related to its former credit facility.

F-31

BIOVAIL CORPORATION

NOTES TO 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)

17. LONG-TERM OBLIGATIONS (Continued)

At December 31, 2009, the Company had no outstanding borrowings under this credit facility.

Cambridge Obligation

In connection with the acquisition of the worldwide development and commercialization rights to tetrabenazine (as described in note 3), the Company will make payments of \$12,500,000 and \$17,500,000 to 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. At December 31, 2009, the fair value of these payments approximated their carrying value based on current borrowing rates available to the Company.

Maturities

Aggregate maturities of long-term obligations for the years ending December 31 are as follows:

	Convertible Notes	Cambridge Obligation	Total
2010	\$	\$ 12,500	\$ 12,500
2011		17,500	17,500
2014	350,000		350,000
Total gross maturities	350,000	30,000	380,000
Unamortized discounts	(51,715)	(2,200)	(53,915)
Total long-term obligations	\$ 298,285	\$ 27,800	\$ 326,085

18. SHAREHOLDERS' EQUITY

Share Repurchase Programs

In August 2009, the Company's Board of Directors approved the purchase of up to 15,800,000 common shares of the Company on the open market under a share repurchase program or normal course issuer bid, subject to a maximum of \$75,000,000 of common shares being repurchased during any fiscal year pursuant to a covenant in the Company's credit facility (unless such condition is waived or varied by the Company's lenders). The Company did not repurchase any of its common shares in 2009.

In May 2008, the Company's Board of Directors approved a share repurchase program of up to 14,000,000 common shares. During 2008, a total of 2,818,400 common shares were repurchased through open-market transactions on the New York Stock Exchange ("NYSE"), at a weighted-average price of \$10.46 per share, for total consideration of \$29,842,000. The excess of the cost of the common shares repurchased over their assigned value, totaling \$3,765,000, was charged to accumulated deficit. This share repurchase program terminated on June 1, 2009.

Stock-Based Compensation Plans

Under the Company's stock-based compensation plans, the Company may issue up to 12,000,000 common shares on the exercise of stock options and in connection with the vesting of RSUs. Stock options and/or RSUs may be granted to eligible employees, officers, and consultants. The Company's non-management directors are not eligible to receive stock options or RSUs. The Company will use reserved and unissued common shares to satisfy its obligations under its stock-based compensation plans.

BIOVAIL CORPORATION

NOTES TO 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)

18. SHAREHOLDERS' EQUITY (Continued)

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

	2009	2008	2007
Stock options	\$2,613	\$5,243	\$10,591
RSUs	3,000	2,663	42
Stock-based compensation expense	\$5,613	\$7,906	\$10,633
Cost of goods sold	\$ 525	\$ 581	\$ 882
Research and development expenses	726	871	1,608
Selling, general and administrative expenses	4,362	6,454	8,143
Stock-based compensation expense	\$5,613	\$7,906	\$10,633

The Company did not recognize any tax benefits for stock-based compensation expense in 2009, 2008 or 2007.

Stock Options

All stock options granted expire on the fifth anniversary of the grant date. The exercise price of any stock option granted, which may be denominated in Canadian or U.S. dollars, will be determined by the Board of Directors, but in any event will not be less than the volume-weighted average trading price of the Company's common shares on the Toronto Stock Exchange ("TSX"), the NYSE, or other stock exchange where the majority of the trading volume and value of the Company's common shares occurs, for the five trading days immediately preceding the date of grant (or, for participants subject to U.S. taxation, on the single trading day immediately preceding the date of grant, whichever is greater). In March 2007, the Board of Directors adopted a policy whereby stock options will vest in equal proportions on the first, second, and third anniversaries of the stock option grant. Prior to this, stock options vested as to 25% on the first, second, third and fourth anniversaries of the stock option grant, or as to 25% on the date of grant and the first, second and third anniversaries of the stock option grant.

The fair values of all stock options granted were estimated as of the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	2009	2008	2007
Expected stock option life (years) ⁽¹⁾	4.0	4.0	4.0
Expected volatility ⁽²⁾	45.2%	43.2%	48.9%
Risk-free interest rate ⁽³⁾	1.6%	3.0%	4.0%
Expected dividend yield ⁽⁴⁾	14.6%	14.1%	6.9%

-
- (1) Determined based on historical exercise and forfeiture patterns.
- (2) Determined based on historical volatility of the Company's common shares over the expected life of the stock option.
- (3) Determined based on the rate at the time of grant for zero-coupon Canadian government bonds with maturity dates equal to the expected life of the stock option.
- (4) Determined based on the stock option's exercise price and expected annual dividend rate at the time of grant.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

The Black-Scholes option-pricing model used by the Company to calculate stock option values was developed to estimate the fair value of freely tradeable, fully transferable stock options without vesting restrictions, which significantly differ from the Company's stock option awards. This model also requires highly subjective assumptions, including future stock price volatility and expected time until exercise, which greatly affect the calculated values.

F-33

BIOVAIL CORPORATION

NOTES TO 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)

18. SHAREHOLDERS' EQUITY (Continued)

The following table summarizes stock option activity during 2009:

	Stock Options (000s)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, January 1, 2009	4,201	\$ 19.06		
Granted	1,087	10.86		
Exercised	(80)	10.86		
Expired or forfeited	(1,220)	18.97		
Outstanding, December 31, 2009	3,988	\$ 17.02	2.5	\$ 5,630
Vested and exercisable, December 31, 2009	2,340	\$ 20.25	1.7	\$ 1,130

The weighted-average fair values of all stock options granted in 2009, 2008 and 2007 were \$0.92, \$1.07 and \$5.41, respectively. The total intrinsic value of stock options exercised in 2009 and 2007 was \$239,000 and \$2,474,000, respectively. Proceeds received on the exercise of stock options in 2009 and 2007 were \$866,000 and \$11,217,000, respectively. No stock options were exercised in 2008.

The following table summarizes non-vested stock option activity during 2009:

	Stock Options (000s)	Weighted- Average Grant-Date Fair Value
Non-vested, January 1, 2009	1,357	\$ 3.79
Granted	1,087	0.92
Vested	(667)	4.58
Forfeited	(129)	2.24
Non-vested, December 31, 2009	1,648	\$ 1.81

At December 31, 2009, the total remaining unrecognized compensation expense related to non-vested stock options amounted to \$1,405,000, which will be amortized over the weighted-average remaining requisite service period of approximately 16 months. The total fair value of stock options vested in 2009 was \$3,055,000 (2008 \$8,412,000; 2007 \$11,460,000).

The following table summarizes information about stock options outstanding and exercisable at December 31, 2009:

Range of Exercise Prices	Outstanding (000s)	Weighted- Average Remaining Contractual Life (Years)	Weighted- Average Exercise Price	Exercisable (000s)	Weighted- Average Exercise Price
\$9.95 \$14.84	1,810	3.8	\$ 10.87	388	\$ 11.14
16.15 24.15	1,394	1.5	20.70	1,219	20.51
24.50 25.78	784	1.2	24.69	733	24.66
	3,988	2.5	\$ 17.02	2,340	\$ 20.25

RSUs

RSUs vest on the third anniversary date from the date of grant, unless provided otherwise in the applicable unit agreement, subject to the attainment of any applicable performance goals specified by the Board of Directors. If the vesting of the RSUs is conditional upon

BIOVAIL CORPORATION

NOTES TO 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)**

18. SHAREHOLDERS' EQUITY (Continued)

the attainment of performance goals, any RSUs that do not vest as a result of a determination that a holder of RSUs has failed to attain the prescribed performance goals will be forfeited immediately upon such determination. RSUs are credited with dividend equivalents, in the form of additional RSUs, when dividends are paid on the Company's common shares. Such additional RSUs will have the same vesting dates and will vest under the same terms as the RSUs in respect of which such additional RSUs are credited.

Unless provided otherwise in the applicable RSU agreement, the Company may, in lieu of all or a portion of the common shares which would otherwise be provided to a holder, elect to pay a cash amount equivalent to the market price of the Company's common shares on the vesting date for each vested RSU. The amount of cash payment will be determined based on the average market price of the Company's common shares on the vesting date on the TSX, the NYSE, or other stock exchange where the majority of the trading volume and value of the Company's common shares occurs. The Company's current intent and policy is to settle vested RSUs through the issuance of common shares.

RSUs (Without Performance Goals)

Each vested RSU without performance goals represents the right of a holder to receive one of the Company's common shares. The fair value of each RSU granted is estimated based on the trading price of the Company's common shares on the date of grant.

The following table summarizes non-vested RSU activity during 2009:

	RSUs (Without Performance Goals) (000s)	Weighted- Average Grant-Date Fair Value
Non-vested, January 1, 2009	182	\$ 13.08
Granted	227	10.77
Reinvested dividend equivalents	25	11.05
Vested	(11)	12.62
Forfeited	(44)	11.95
Non-vested, December 31, 2009	379	\$ 11.71

At December 31, 2009, the total remaining unrecognized compensation expense related to non-vested RSUs amounted to \$2,165,000, which will be amortized over the weighted-average remaining requisite service period of approximately 21 months. The total fair value of RSUs vested in 2009 was \$133,000 (2008 \$198,000; 2007 nil).

RSUs (With Performance Goals)

Each vested RSU with performance goals 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 performance of the Company's shareholder return relative to an industry comparator group. If the Company's performance is below a specified performance level, no common shares will be paid.

The fair value of each RSU granted was estimated using a Monte Carlo simulation model, which utilizes multiple input variables to estimate the probability that the performance condition will be achieved, with the following weighted-average assumptions:

	2009	2008	2007
Contractual term (years)	5.0	4.6	5.0
Expected Company share price volatility ⁽¹⁾	44.0%	42.9%	45.3%
Average comparator group share price volatility ⁽¹⁾	35.9%	34.0%	34.2%
Risk-free interest rate ⁽²⁾	3.1%	3.0%	3.3%

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

- (1) Determined based on historical volatility over the contractual term of the RSU.
- (2) Determined based on the rate at the time of grant for zero-coupon U.S. government bonds with maturity dates equal to the contractual term of the RSUs.

F-35

BIOVAIL CORPORATION

NOTES TO 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)

18. SHAREHOLDERS' EQUITY (Continued)

The following table summarizes non-vested RSU activity during 2009:

	RSUs (With Performance Goals) (000s)	Weighted- Average Grant-Date Fair Value
Non-vested, January 1, 2009	174	\$ 17.61
Granted	487	19.63
Reinvested dividend equivalents	15	11.75
Non-vested, December 31, 2009	676	\$ 18.94

At December 31, 2009, the total remaining unrecognized compensation expense related to the non-vested RSUs amounted to \$10,880,000, which will be amortized over the weighted-average remaining requisite service period of approximately 50 months. A maximum of 1,352,000 common shares could be issued upon vesting of the RSUs outstanding at December 31, 2009.

DSUs

Non-management directors receive an annual grant of DSUs, and may elect to receive all or part of their annual board and committee retainers in the form of DSUs. A DSU is a notional unit, equivalent in value to a common share. DSUs are credited with dividend equivalents, in the form of additional DSUs, when dividends are paid on the Company's common shares. Directors may not receive any payment in respect of their DSUs until they cease to be a director of the Company.

The amount of compensation deferred is converted into DSUs based on the volume-weighted average trading price of the Company's common shares on the TSX or the NYSE, generally based on where the majority of the trading volume and value occurs, for the five trading days immediately preceding the date of grant (for directors subject to U.S. taxation, the calculation is based on the greater of the five-day or one-day volume-weighted average trading price). The Company recognizes compensation expense throughout the deferral period to the extent that the trading price of its common shares increases, and reduces compensation expense throughout the deferral period to the extent that the trading price of its common shares decreases.

The following table summarizes the Company's DSU activity during 2009:

	DSUs (000s)	Weighted- Average Grant-Date Fair Value
Outstanding, January 1, 2009	226	\$ 13.86
Granted	124	12.68
Reinvested dividend equivalents	20	11.13
Settled for cash	(27)	19.68
Outstanding, December 31, 2009	343	\$ 12.82

During 2009, a cash payment of \$371,000 was made to settle 26,836 DSUs previously granted to a former director of the Company.

The Company recorded compensation expense related to DSUs of \$2,454,000 and \$1,103,000 in 2009 and 2008, respectively, and recorded a recovery of compensation expense of \$425,000 in 2007. At December 31, 2009 and 2008, the Company had a liability related to its DSU plans of \$4,796,000 and \$2,137,000, respectively, based on the trading price of the Company's common shares at those dates.

BIOVAIL CORPORATION

NOTES TO 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)

18. SHAREHOLDERS' EQUITY (Continued)

Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income were as follows:

	Foreign Currency Translation Adjustment	Net Unrealized Holding Gain (Loss) on Available- for-Sale Investments	Unrealized Holding Loss on Auction Rate Securities	Total
Balance, January 1, 2007	\$ 37,264	\$ 5,844	\$	\$ 43,108
Foreign currency translation adjustment	21,352			21,352
Net unrealized holding loss on available-for-sale securities		(2,000)		(2,000)
Unrealized holding loss on auction rate securities			(2,825)	(2,825)
Reclassification adjustment to net income		2,947 ⁽²⁾		2,947
Balance, December 31, 2007	58,616	6,791	(2,825)	62,582
Foreign currency translation adjustment	(32,378)			(32,378)
Net unrealized holding loss on available-for-sale securities		(304)		(304)
Unrealized holding loss on auction rate securities			(3,356)	(3,356)
Reclassification adjustments to net income	828 ⁽¹⁾	(3,712) ⁽²⁾	4,352 ⁽³⁾	1,468
Cumulative effect adjustment		(2,343)		(2,343)
Balance, December 31, 2008	27,066	432	(1,829)	25,669
Foreign currency translation adjustment	17,220			17,220
Net unrealized holding gain on available-for-sale securities		802		802
Unrealized holding gain on auction rate securities			155	155
Reclassification adjustments to net income		(1,003) ⁽²⁾	731 ⁽³⁾	(272)
Balance, December 31, 2009	\$ 44,286	\$ 231	\$ (943)	\$ 43,574

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

(2) Included in gain on disposal of investments in the consolidated statements of income.

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

Income taxes are not provided for foreign currency translation adjustments arising on the translation of the Company's operations having a functional currency other than the U.S. dollar. Income taxes allocated to other components of other comprehensive income, including reclassification adjustments, were not material.

19. INTANGIBLE ASSET IMPAIRMENTS

In December 2007, the Company discontinued plans to market Zolpidem oral disintegrating tablets ("ODT") for the treatment of insomnia following a negative assessment of its commercial potential due to the genericization of the brand name drug (Ambien) in April 2007. Also in December 2007, the Company's commercialization counterparty decided to terminate a supply agreement for Ultram® ODT based on market considerations. As a result, the Company recorded an impairment charge of \$4,000,000 to write down the aggregate carrying value of these product rights to zero.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Also in December 2007, during its annual evaluation of intangible assets for impairment, the Company identified certain other product rights and technology intangible assets that had been adversely affected due to changes in market conditions and/or technological advances. As a result, the Company recorded an impairment charge of \$5,910,000 to write down the aggregate carrying value of these assets to zero.

F-37

BIOVAIL CORPORATION

NOTES TO 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)

20. GAIN ON DISPOSAL OF INVESTMENTS

In 2009, the Company sold its investment in common shares of Hemispherx Biopharma, Inc. for cash consideration of \$566,000, resulting in a gain of \$466,000, and the Company realized a gain of \$338,000 on the sale of 168,376 common shares of Depomed, Inc. ("Depomed") for cash proceeds of \$357,000.

In 2008, the Company realized a gain of \$3,073,000 on the sale of 4,234,132 common shares of Depomed for cash proceeds of \$13,188,000, and the Company sold its entire investment in common shares and convertible debt of Financière Verdi ("Verdi"), formerly Ethypharm S.A. ("Ethypharm"), for cash consideration of \$12,187,000, resulting in a gain on disposal of \$3,461,000.

In 2007, the Company received cash consideration of \$14,900,000 on the liquidation of its investment in convertible preferred stock of Reliant Pharmaceuticals, Inc. ("Reliant") upon Reliant's acquisition by GSK, resulting in a gain on disposal of \$8,640,000. In addition, the Company sold a portion of its investment in common shares of Ethypharm to Verdi for consideration of \$39,406,000 in cash and \$5,637,000 in convertible bonds of Verdi, resulting in a gain on disposal of \$15,716,000 (net of costs). The Company exchanged the remaining portion of its Ethypharm investment for common shares of Verdi.

21. LOSS ON EARLY EXTINGUISHMENT OF DEBT

Effective April 1, 2007, the Company redeemed all of its outstanding 7⁷/₈% Senior Subordinated Notes for \$406,756,000, which included an early redemption premium of \$7,854,000. The Company recorded a loss on early extinguishment of debt of \$12,463,000, which comprised the premium paid, as well as the net write-off of the unamortized deferred financing costs, discount, and fair value adjustment associated with these notes, which totaled \$4,609,000.

22. INCOME TAXES

The components of income before provision for (recovery of) income taxes were as follows:

	2009	2008	2007
Domestic	\$ (81,978)	\$ (86,734)	\$ (150,622)
Foreign	256,933	213,638	359,361
	\$ 174,955	\$ 126,904	\$ 208,739

The components of the provision for (recovery of) income taxes were as follows:

	2009	2008	2007
Current			
Domestic	\$	\$	\$
Foreign	14,500	17,000	13,200
	14,500	17,000	13,200
Deferred			
Domestic			
Foreign	(16,000)	(90,000)	
	(16,000)	(90,000)	
	\$ (1,500)	\$ (73,000)	\$ 13,200

BIOVAIL CORPORATION

NOTES TO 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)

22. INCOME TAXES (Continued)

The reported provision for (recovery of) income taxes differs from the expected amount calculated by applying the Company's Canadian statutory rate to income before provision for income taxes. The reasons for this difference and the related tax effects are as follows:

	2009	2008	2007
Income before provision for (recovery of) income taxes	\$ 174,955	\$ 126,904	\$ 208,739
Expected Canadian statutory rate	32.4%	33.3%	36.1%
Expected provision for income taxes	56,685	42,259	75,354
Non-deductible amounts:			
IPR&D	21,063		
Amortization	11,962	11,800	17,345
Equity loss		398	913
Intangible asset impairments		2,482	3,578
Non-taxable gain on disposal of investments	(3,838)	(2,174)	(6,276)
Write-down of investments	1,690	3,089	
Legal settlement costs	2,944	10,233	
Changes in enacted income tax rates	9,800		
Canadian dollar foreign exchange gain for Canadian tax purposes	2,500		28,887
Change in valuation allowance related to U.S. operating losses	(26,000)	(90,000)	
Change in valuation allowance from utilization of losses and tax rate changes	(11,000)	(13,993)	(52,006)
Foreign tax rate differences	(99,045)	(92,581)	(114,908)
Unrecognized income tax benefit of losses	25,496	44,380	54,406
Alternative minimum and other taxes	1,877		
Withholding taxes on foreign income	3,450	2,886	2,105
Other	916	8,221	3,802
	\$ (1,500)	\$ (73,000)	\$ 13,200

Income taxes paid amounted to \$12,139,000, \$6,738,000 and \$20,424,000 in 2009, 2008 and 2007, respectively. Stock option exercises did not impact taxes paid in 2009, 2008 or 2007.

The Company has provided for foreign withholding taxes on the portion of undistributed earnings of foreign subsidiaries expected to be remitted.

BIOVAIL CORPORATION

NOTES TO 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)

22. INCOME TAXES (Continued)

The tax effect of major items recorded as deferred tax assets and liabilities is as follows:

	2009	2008
Deferred tax assets		
Tax loss carryforwards	\$ 159,669	\$ 159,210
Scientific Research and Experimental Development pool	58,914	53,095
Investment tax credits	42,659	35,199
Provisions	24,990	20,565
Provisions for legal settlements (net of expected insurance recoveries)		211
Plant, equipment and technology	34,019	24,395
Deferred revenue	33,433	38,825
Deferred financing and share issue costs		361
Other	5,014	4,189
Total deferred tax assets	358,698	336,050
Less valuation allowance	(153,955)	(157,137)
Net deferred tax assets	204,743	178,913
Deferred tax liabilities		
Intangible assets	53,906	60,693
Convertible Notes ⁽¹⁾	15,622	
Prepaid expenses	1,434	1,314
Other	981	106
Total deferred tax liabilities	71,943	62,113
Net deferred income taxes	\$ 132,800	\$ 116,800

(1)

In connection with the issuance of the Convertible Notes (as described in note 17), the Company recognized a deferred tax liability of \$14,621,000 for the original basis difference between the principal amount of the Convertible Notes and the value allocated to the liability component, which resulted in a corresponding reduction to the valuation allowance recorded against deferred tax assets. The recognition of the deferred tax liability and the corresponding reduction in the valuation allowance were recorded as offsetting adjustments to additional paid-in capital. In the period ended December 31, 2009, the deferred tax benefit resulting from the reversal of a portion of the deferred tax liability was offset by the deferred tax expense related to the corresponding realization of the deferred tax assets.

The eventual payment of the U.S. dollar-denominated Convertible Notes will likely result in a foreign exchange gain or loss for Canadian income tax purposes. The amount of this gain or loss will depend on the exchange rate between the U.S. and Canadian dollar at the time the Convertible Notes are paid. At December 31, 2009, the Company recognized a \$2,500,000 deferred tax liability (and corresponding reduction to the valuation allowance) related to the unrealized foreign exchange gain on the translation of the face value of the Convertible Notes to Canadian dollars for Canadian income tax purposes of approximately \$20,000,000. If all of the outstanding Convertible Notes had been paid at December 31, 2009, one-half of this foreign exchange gain would be included in the Company's Canadian taxable income, which would result in a corresponding reduction in the Company's available Canadian operating losses and tax credit carryforward balances (with an offsetting reduction to the valuation allowance provided against those balances). However, the payment of the Convertible Notes will not result in a foreign exchange gain or loss being recognized in the Company's consolidated financial statements, as these statements are prepared in U.S. dollars.

The realization of deferred tax assets is dependent on the Company generating sufficient domestic and foreign taxable income in the years that the temporary differences become deductible. A valuation allowance has been provided for the portion of the deferred tax assets that the Company determined is more likely than not to remain unrealized based on estimated future taxable income and tax planning strategies. In 2009, the valuation

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

allowance decreased by \$3,182,000, due mainly to the recognition of additional future benefits of U.S. tax loss carryforwards and the impact of a decrease in enacted income tax rates on the reported value of net deferred income taxes, partially offset by the impact of foreign exchange rate changes on the reported value in U.S. dollars of Canadian tax loss carryforwards, investment tax credits ("ITCs"), and pooled Scientific Research and Experimental Development ("SR&ED") expenditures. In 2008, the valuation allowance decreased by \$161,146,000 due mainly to the recognition of the future benefit of U.S. tax

F-40

BIOVAIL CORPORATION

NOTES TO 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)**

22. INCOME TAXES (Continued)

loss carryforwards, the recording of a net deferred tax liability in respect of the Prestwick acquisition, and a reversal of temporary differences in respect of provisions for legal settlements.

At December 31, 2009, the Company had accumulated tax losses of approximately \$123,600,000 (2008 \$87,900,000) available for federal and provincial purposes in Canada. At December 31, 2009, the Company had approximately \$42,700,000 (2008 \$35,199,000) of unclaimed Canadian ITCs, which expire from 2020 to 2029. These losses and ITCs can be used to offset future years' taxable income and federal tax, respectively.

In addition, at December 31, 2009, the Company had pooled SR&ED expenditures amounting to approximately \$271,000,000 (2008 \$224,000,000) available to offset against future years' taxable income from its Canadian operations, which may be carried forward indefinitely.

At December 31, 2009, the Company has accumulated tax losses of approximately \$335,000,000 (2008 \$349,300,000) for federal purposes in the U.S., which expire from 2021 to 2028. These losses can be used to offset future years' taxable income. There may be limitations on the annual utilization of these losses as a result of certain changes in ownership that have occurred, or that may occur in the future.

At December 31, 2009, the total amount of unrecognized tax benefits (including interest and penalties) was \$66,200,000 (2008 \$63,700,000), of which \$45,200,000 (2008 \$36,900,000) would affect the effective tax rate. In the year ended December 31, 2009, the Company recognized a \$1,000,000 (2008 \$1,000,000) increase and a \$1,500,000 (2008 \$8,600,000) net increase in the amount of unrecognized tax benefits related to tax positions taken in the current and prior years, respectively, which have resulted in a corresponding decrease in the valuation allowance against the net deferred tax asset.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes. At December 31, 2009, approximately \$14,200,000 (2008 \$12,200,000) was accrued for the payment of interest and penalties. In the year ended December 31, 2009, the Company recognized approximately \$2,000,000 (2008 \$4,000,000) in interest and penalties.

The Company and one or more of its subsidiaries file federal income tax returns in Barbados, Canada, the U.S., and other foreign jurisdictions, as well as various provinces and states in Canada and the U.S. The Company and its subsidiaries have open tax years primarily from 1996 to 2008 with significant taxing jurisdictions including Barbados, Canada, and the U.S. These open years contain certain matters that could be subject to differing interpretations of applicable tax laws and regulations, and tax treaties, as they relate to the amount, timing, or inclusion of revenues and expenses, or the sustainability of income tax positions of the Company and its subsidiaries. Certain of these tax years are expected to remain open indefinitely.

In 2009, the Canada Revenue Agency ("CRA") continued its audit of the Company's 2003 and 2004 Canadian income tax returns and has recently made a revised proposal for audit adjustments to the Company. The Company is reviewing the revised proposal. While the matter has not been settled, the Company has recorded a \$1,200,000 decrease in the net deferred tax assets and a corresponding decrease in the valuation allowance against the net deferred tax assets. The CRA has commenced audits of the Company's 2005 and 2006 Canadian income tax returns, and claims for SR&ED expenditures and related ITCs for the 2006 and 2007 taxation years. During 2009, the Company settled certain tax audits. The settlement of these audits did not result in adjustments to the total amount of uncertain tax benefits. It is otherwise not possible for the Company to estimate a range of reasonably possible outcomes, or timing, of any adjustments to the total amount of uncertain tax benefits that may result from these audits.

The following table presents a reconciliation of the beginning and ending amounts of unrecognized tax benefits:

	2009	2008
Balance, beginning of year	\$63,700	\$54,100
Additions based on tax positions related to the current year	1,000	1,000
Additions for tax positions of prior years	3,400	13,300
Reductions for tax positions of prior years	(1,900)	(4,700)
Balance, end of year	\$66,200	\$63,700

The Company does not expect any significant change to the above unrecognized tax benefits during the next 12 months.

BIOVAIL CORPORATION

NOTES TO 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)

23. EARNINGS PER SHARE

Earnings per share were calculated as follows:

	2009	2008	2007
Net income	\$ 176,455	\$ 199,904	\$ 195,539
Basic weighted-average number of common shares outstanding (000s)	158,236	159,730	160,839
Dilutive effect of stock options and RSUs (000s)	274		36
Diluted weighted-average number of common shares outstanding (000s)	158,510	159,730	160,875
Basic and diluted earnings per share	\$ 1.11	\$ 1.25	\$ 1.22

In the period ended December 31, 2009, the average conversion value of the Convertible Notes was less than the related principal amount, and, accordingly, no common shares were assumed to be issued for purposes of calculating diluted earnings per share.

Stock options to purchase approximately 2,950,000, 4,540,000 and 4,555,000 common shares of the Company during 2009, 2008 and 2007, respectively, had exercise prices greater than the average trading price of the Company's common shares. These stock options were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive.

24. 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 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 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.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

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.

F-42

BIOVAIL CORPORATION

NOTES TO 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)**

24. LEGAL PROCEEDINGS (Continued)

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

On March 24, 2008, the SEC filed a civil complaint against the Company, Eugene Melnyk, the Company's former Chairman and Chief Executive Officer ("CEO"), Brian Crombie, the Company's former Chief Financial Officer ("CFO"), and two former officers, Kenneth Howling and John Miszuk, related to the matters investigated by the SEC. The Company has entered into a Consent Decree with the SEC in which it has not admitted to the civil charges contained in the complaint but has paid \$10.0 million to the SEC to fully settle the matter. As part of the settlement, the Company has also agreed to an examination of its accounting and related functions by an independent consultant. The settlement does not include the four individuals although the Company understands Mr. Howling has also reached a settlement with the SEC. The matter is proceeding as against former officers Mr. Melnyk, Mr. Crombie and Mr. Miszuk in the ordinary course and no hearing date has been set. The Company is indemnifying these individuals for their legal costs.

In the Spring of 2007, the Company was contacted by the USAO for the Eastern District of New York ("EDNY"), which informed the Company that the office is conducting an investigation into the same matters that the SEC is investigating. The USAO for the EDNY conducted interviews of several of the Company's current or former employees and requested documents related to fiscal years 2002 and 2003. The Company cooperated with this request and has not been contacted further. The Company cannot predict the outcome or timing of when this matter may be resolved.

Over the last few years, the Company received a number of communications from the OSC relating to its disclosure, and/or seeking information pertaining to certain financial periods. Similar to the SEC, the OSC advised the Company that it had investigated whether the Company improperly recognized revenue for accounting purposes in relation to the interim financial statements filed by the Company for each of the four quarters in 2001, 2002 and 2003, and the first quarter of 2004, and related disclosure issues. The OSC also investigated whether the Company provided misleading disclosure concerning the reasons for its forecast of a revenue shortfall in respect of the three-month period ending September 30, 2003, and certain transactions associated with a corporate entity that the Company acquired in 2002, as well as issues relating to trading in its common shares. These issues included whether the Company's insiders complied with insider reporting requirements, whether persons in a special relationship with the Company may have traded in its common shares with knowledge of undisclosed material information, whether certain transactions may have resulted in, or contributed to, a misleading appearance of trading activity in the Company's securities during 2003 and 2004 and whether certain registrants (who are the Company's former directors) may have had conflicts of interest in relation to the trading of the Company's common shares.

Pursuant to a Notice of Hearing dated July 28, 2006, the staff of the OSC gave notice that an administrative hearing pursuant to sections 127 and 127.1 of the Ontario Securities Act would be held related to the issues surrounding the trading in the Company's common shares. The respondents in the hearing included former Chairman and CEO Eugene Melnyk and a former director of the Company, among others. The Company was not a party to this proceeding. The proceeding as against Eugene Melnyk has been settled. In a decision released June 20, 2008, a panel of the OSC found that the former director acted contrary to the public interest and breached section 107 of the Ontario Securities Act when he (a) failed to provide the Company with accurate information concerning common shares over which he shared control and direction, (b) failed to file insider reports in respect of certain trades in the Company's securities and (c) engaged in a high volume of discretionary trading in its securities during blackout periods imposed by the Company.

Pursuant to a Notice of Hearing dated March 24, 2008, the staff of the OSC gave notice that an administrative hearing would be held related to the other matters investigated. The notice named the Company, former Chairman and CEO Eugene Melnyk, former CFO Brian Crombie, and Kenneth Howling and John Miszuk, two former officers. On January 9, 2009, the OSC approved a settlement reached with the Company. Pursuant to the terms of this settlement, the Company paid approximately \$5.3 million in costs and sanctions and agreed to the appointment of an independent consultant to examine and report on the Company's training of its personnel concerning compliance with financial and other reporting requirements under applicable securities laws in Ontario. On January 27, 2009, the OSC approved a settlement with Messrs. Howling and Miszuk and on February 10, 2009, the OSC approved a settlement with Mr. Crombie. The Company understands that the matter is proceeding against Mr. Melnyk. The hearing has now concluded and a decision is under reserve.

BIOVAIL CORPORATION

NOTES TO 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)**

24. LEGAL PROCEEDINGS (Continued)

Securities Class Action

On October 8, 2008, a proposed securities class action lawsuit was filed in the U.S. District Court Southern District of New York against the Company, its current Chairman, one current officer and two former officers. The complaint was filed on behalf of all persons and entities that purchased the Company's securities from December 14, 2006 through July 19, 2007. The complaint related to public statements alleged to have been made in respect of Aplenzin® (bupropion hydrobromide tablets) during the product's U.S. regulatory approval process. The Company believed the claim was without merit and filed a motion to dismiss this action in its entirety. The motion was granted and the action was dismissed with prejudice on May 8, 2009. Sanctions were thereafter sought by the Company. The decision granting the motion to dismiss was appealed by the plaintiffs. Pursuant to an agreement reached between the parties, the plaintiffs agreed to dismiss the appeal in exchange for the Company withdrawing its request for sanctions. On June 26, 2009, the appeal was dismissed. This matter has concluded.

Antitrust

Several class action and individual action complaints in multiple jurisdictions have been commenced jointly against the Company, Elan Corporation plc ("Elan") and 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 D.C. 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.

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.

The Company has now reached 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 and made no admission of wrong doing. The Opt-out actions will be dismissed.

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.

BIOVAIL CORPORATION

NOTES TO 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)**

24. LEGAL PROCEEDINGS (Continued)

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.

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

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

The defendants served the Company with a Statement of Defence and Counterclaim on May 15, 2006. The Company delivered its reply on May 30, 2006, and pleadings closed in June 2006. Pursuant to an agreement by the parties, the claim and counter claim have been dismissed.

In August 2006, 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 damages in another unrelated action. The Supreme Court of Canada has now denied leave. A trial will likely occur in the later half of 2010 or early 2011, depending on the court's schedule.

On November 7, 2008, Novopharm Limited (now Teva Canada) brought an action against the Company under section 8 of the PMNOC Regulations demanding damages for having been kept off the market with its generic version of Wellbutrin® SR due to prohibition proceedings taken against them by the Company under the PMNOC Regulations. The prohibition proceedings were subsequently dismissed in January 2005. The parties reached an agreement to resolve this matter. The action has now been dismissed.

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 to market in Canada its generic version of 500 mg Glumetza® by Health Canada on February 4, 2010. 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 filed a Claim for infringement against Apotex in Canadian Federal Court on February 8, 2010.

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

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Pharmaceutical Group Ltd. ("Napp") and Ortho-McNeil, Inc. ("OMI") filed a complaint in the U.S. District Court

F-45

BIOVAIL CORPORATION

NOTES TO 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)**

24. LEGAL PROCEEDINGS (Continued)

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, and was granted, a motion for dismissal of BLS from the cases. 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.

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 Court of Appeals for the Federal Circuit on September 3, 2009. OMI also appealed its dismissal at the same time, but the appeal has been withdrawn. 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, and was granted, a motion for dismissal from the case. OMI has also been dismissed from this case. 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"), who have 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.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

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.

F-46

BIOVAIL CORPORATION

NOTES TO 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)**

24. LEGAL PROCEEDINGS (Continued)

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 that 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 agreement in November, 2009 and, subsequently, BLS and Wyeth have 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.

On or about June 26, 2008, BLS received Notices of Paragraph IV Certification from Sun Pharmaceutical Industries, Ltd., India ("Sun India") for diltiazem hydrochloride extended release capsules, 120 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 India in the U.S. District Court of New Jersey alleging patent infringement of U.S. Patent Nos. 5,470,584, 5,286,497 and 5,439,689 pursuant to the provisions of the Hatch-Waxman Act. BLS has also sought declaratory judgment of infringement for all three patents. These suits are expected to result in a 30-month stay of the FDA approval of the 120 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 India delivered its Answer and Counterclaim, which include declarations of non-infringement, invalidity and unenforceability as well as certain antitrust allegations. This case is currently stayed, pending settlement discussions.

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 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 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. No Markman hearing to determine claim scope and meaning nor a trial date have yet been set.

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 hearing has been scheduled for late May 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 Bupropion 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 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®

BIOVAIL CORPORATION

NOTES TO 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)**

24. LEGAL PROCEEDINGS (Continued)

are invalid and/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 and/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.

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 Bupropion 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 bupropion hydrobromide are not infringed and/or invalid. The Company will be filing suit against Paddock no later than March 8, 2010.

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.

On January 26, 2007, the Company was found to have breached the terms of a protective order in a securities class action then proceeding against it and certain of its former officers in New York Federal Court (the "New York class action"). The New York class action was settled in December 2008. Specifically, the Company was found to have breached the terms of the protective order by using documents obtained from a non-party in the S.A.C. Complaint. The Court ordered that the Company and its counsel return copies of the documents and redact the S.A.C. Complaint accordingly. On February 22, 2007, the Company filed an Amended Complaint. On September 10, 2007, the Company resolved a motion for sanctions previously pending in the New York class action in connection with the breach of the protective order referred to above. As part of that resolution, the Company dismissed defendant Maris from this action and filed a First Amended Complaint on October 3, 2007.

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 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 defend once served.

General Civil Actions

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

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.

F-48

BIOVAIL CORPORATION

NOTES TO 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)**

24. LEGAL PROCEEDINGS (Continued)

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 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 product formerly owned by Biovail, was 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 on or before April 19, 2010.

On May 6, 2008, BLS commenced an arbitration under Financial Industry Regulatory Authority rules against an investment institution at which it held a cash management account seeking \$26.8 million in compensatory damages and \$53.6 million in punitive damages. The Statement of Claim alleged that the investment institution, as non-discretionary manager of BLS's cash management account, fraudulently or negligently, and in breach of the parties' customer agreement, invested BLS's assets in auction rate securities, which were not among BLS's approved investments. The investment institution subsequently delivered its Answer and Response. A hearing was scheduled to commence on July 8, 2009. The matter has now been settled as between the parties for payment to BLS in the amount of \$22.0 million. BLS continues to hold the auction rate securities.

25. COMMITMENTS AND CONTINGENCIES**Operating Lease Commitments**

The Company leases certain facilities, vehicles and equipment under operating leases. Rental expense amounted to \$4,832,000, \$4,928,000 and \$4,088,000 in 2009, 2008 and 2007, respectively.

Minimum future rental payments under non-cancelable operating leases (net of sublease rentals) for the years ending December 31 are as follows:

2010	\$ 7,839
2011	6,974
2012	7,014
2013	5,562
2014	5,360
Thereafter	27,226
Total minimum future rental payments	\$59,975

Other Commitments

Commitments related to capital expenditures totaled approximately \$2,300,000 at December 31, 2009.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

Net sales of certain products of the Company are subject to royalties payable to third parties. Royalty expense recorded in cost of goods sold amounted to \$24,230,000, \$11,829,000 and \$15,024,000 in 2009, 2008 and 2007, respectively.

F-49

BIOVAIL CORPORATION

NOTES TO 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)

25. COMMITMENTS AND CONTINGENCIES (Continued)

Under certain research and development agreements, the Company may be required to make payments contingent upon the achievement of specific developmental, regulatory, or commercial milestones. As described in notes 4 and 27, the Company may be required to make milestone payments of up to \$775,000,000 in the aggregate pursuant to the terms of the collaboration and license agreements for pimavanserin, fipamezole, GDNF, and Staccato® loxapine. Because it is uncertain if and when these milestones will be achieved, the Company did not accrue for any of these payments at December 31, 2009 or 2008.

Product Liability Insurance

Prior to July 1, 2009, the Company was self-insured for up to the first \$20,000,000 of costs incurred relating to product liability claims arising during an annual policy period. The Company provided for unsettled reported losses and losses incurred but not reported based on an independent review of all claims made against the Company. Accruals for estimated losses related to the period of self-insurance were not material at December 31, 2009 or 2008. Effective July 1, 2009, the Company's entire product liability coverage is provided by third-party insurers.

Indemnification Provisions

In the normal course of business, the Company enters into agreements that include indemnification provisions for product liability and other matters. These provisions are generally subject to maximum amounts, specified claim periods, and other conditions and limits. At December 31, 2009 or 2008, no material amounts were accrued for the Company's obligations under these indemnification provisions. In addition, the Company is obligated to indemnify its officers and directors in respect of any legal claims or actions initiated against them in their capacity as officers and directors of the Company in accordance with applicable law. Pursuant to such indemnities, the Company is indemnifying certain former officers and directors in respect of certain litigation and regulatory matters (as described in note 24).

26. 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.

Revenue by Therapeutic Area

The following table displays revenue by therapeutic area:

	2009	2008	2007
Product sales			
CNS ⁽¹⁾	\$ 299,430	\$ 186,007	\$ 269,828
Cardiovascular ⁽²⁾	284,668	292,371	296,907
Antiviral ⁽³⁾	146,267	150,613	147,120
Pain management ⁽⁴⁾	58,661	85,557	87,191
	789,026	714,548	801,046
Research and development	14,148	24,356	23,828
Royalty and other	17,256	18,274	17,944
	\$ 820,430	\$ 757,178	\$ 842,818

(1) CNS products consist of Wellbutrin®, Aplenzin®, Zyban®, Ativan®, Xenazine®, and Nitoman®.

(2) Cardiovascular products include Cardizem®, Tiazac®, Vasotec®, Vaseretic®, Isordil®, Glumetza®, and bioequivalent versions of Cardizem® CD, Procardia XL, and Adalat CC.

- (3) Antiviral products consist of Zovirax®.
- (4) Pain management products consist of Ultram® and Ralivia .

F-50

BIOVAIL CORPORATION

NOTES TO 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)

26. SEGMENT INFORMATION (Continued)

Geographic Information

The following table displays revenue and long-lived assets by geographic area:

	Revenue ⁽¹⁾			Long-Lived Assets ⁽²⁾		
	2009	2008	2007	2009	2008	2007
Canada	\$ 94,142	\$ 88,952	\$ 75,051	\$ 83,471	\$ 107,918	\$ 139,279
U.S. and Puerto Rico	710,214	656,490	755,484	11,067	31,377	77,379
Barbados				9,310	8,974	4,703
Other countries	16,074	11,736	12,283			17,096
	\$ 820,430	\$ 757,178	\$ 842,818	\$ 103,848	\$ 148,269	\$ 238,457

(1) Revenue is attributed to countries based on the location of the customer.

(2) Long-lived assets consist of property, plant and equipment, net of accumulated depreciation. Property, plant and equipment is attributed to countries based on physical location.

Major Customers

The following table identifies external customers that accounted for 10% or more of the Company's total revenue:

	2009	2008	2007
McKesson Corporation	25%	22%	20%
Cardinal Health, Inc.	21%	16%	10%
AmerisourceBergen Corporation	10%	7%	6%
Teva	7%	11%	11%
PriCara	5%	11%	10%
GSK	4%	16%	25%

27. SUBSEQUENT EVENT

The Company has evaluated subsequent events for disclosure in these consolidated financial statements through February 26, 2010, the date on which the financial statements were issued.

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 an 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 submission, 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.

Edgar Filing: BIOVAIL CORP INTERNATIONAL - Form 10-K

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

F-51
