

BIOVAIL CORP INTERNATIONAL  
Form 20-F  
June 30, 2005

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UNITED STATES  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 20-F**

o Registration Statement Pursuant to Section 12(b) or 12(g) of The Securities Exchange Act of 1934

OR

ý Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the fiscal year ended December 31, 2004

OR

o Transition Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934 for the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission file number 001-11145**

**BIOVAIL CORPORATION**

(Exact Name of Registrant as Specified in its Charter)

**Not Applicable**

(Translation of Registrant's Name into English)

**Province of Ontario, Canada**

(Jurisdiction of incorporation or organization)

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

(Address of principal executive offices)

Securities registered or to be 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 or to be registered pursuant to Section 12(g) of the Act: NONE

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: NONE

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Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 159,383,402 common shares, no par value, as of December 31, 2004

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17  Item 18

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## TABLE OF CONTENTS

## GENERAL INFORMATION

## PART 1

	<u>Page</u>	
Item 1.	Identity of Directors, Senior Management and Advisors	1
	A. Directors and Senior Management	1
	B. Advisers	1
	C. Auditors	1
Item 2.	Offer Statistics and Expected Timetable	1
	A. Offer Statistics	1
	B. Method and Expected Timetable	1
Item 3.	Key Information	1
	A. Selected Consolidated Financial Data	1
	B. Capitalization and Indebtedness	3
	C. Reasons for the Offer and Use of Proceeds	3
	D. Risk Factors	4
Item 4.	Information on the Company	15
	A. History and Development of the Company	15
	B. Business Overview	15
	C. Organizational Structure	53
	D. Property, Plant and Equipment	53
Item 5.	Operating and Financial Review and Prospects	56
	A. Operating Results	56
	B. Liquidity and Capital Resources	56
	C. Research and Development, Patents and Licenses	56
	D. Trend Information	56
	E. Off-Balance Sheet Arrangements	56
	F. Tabular Disclosure of Contractual Obligations	56
	G. Safe Harbor	56
Item 6.	Directors, Senior Management and Employees	110
	A. Directors and Senior Management	110
	B. Compensation	114
	C. Board Practices	126
	D. Employees	131
	E. Share Ownership	131
Item 7.	Major Shareholders and Related Party Transactions	132
	A. Major Shareholders	132
	B. Related Party Transactions	133
	C. Interests of Experts and Counsel	133

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Item 8.	Financial Information	134
	A. Consolidated Statements and Other Financial Information	134
	B. Significant Changes	134
Item 9.	The Offer and Listing	138
	A. Nature of Trading Market	138
	B. Plan of Distribution	139
	C. Markets	139
	D. Selling Shareholders	139
	E. Dilution	139
	F. Expenses of the Issue	140
Item 10.	Additional Information	140
	A. Share Capital	140
	B. Memorandum and Articles of Association	140
	C. Material Contracts	142
	D. Exchange Controls	142
	E. Taxation	143
	F. Dividends and Paying Agents	146
	G. Statements by Experts	146
	H. Documents on Display	146
	I. Subsidiary Information	147
Item 11.	Quantitative and Qualitative Disclosures About Market Risk	147
Item 12.	Description of Securities Other Than Equity Securities	147
	A. Debt Securities	147
	B. Warrants and Rights	147
	C. Other Securities	147
	D. American Depository Shares	147
<b>PART II</b>		
Item 13.	Defaults, Dividend Arrearages and Delinquencies	148
Item 14.	Material Modification to the Rights of Security Holders and Use of Proceeds	148
Item 15.	Controls and Procedures	148
Item 16.	<b>[Reserved]</b>	148
Item 16A	Audit Committee Financial Expert	148
Item 16B	Code of Ethics	148
Item 16C	Principal Accountant Fees and Services	149
Item 16D	Exemptions from the Listing Standards for Audit Committee	149
Item 16E	Purchases of Equity Securities by the Issuer and Affiliated Purchases	149
<b>PART III</b>		
Item 17.	Financial Statements	150
Item 18.	Financial Statements	150
Item 19.	Exhibits	151
	Signatures	153
	Certifications	

## Basis of Presentation

### General

Except where the context otherwise requires, all references in this Annual Report on Form 20-F ("Form 20-F") to the "Company", "Biovail", "we", "us", "our" or similar are to Biovail Corporation and its subsidiaries, taken together. In this Form 20-F, references to "\$" and "US\$" are to United States dollars, references to "C\$" are Canadian dollars and Canadian dollars, respectively, and unless otherwise indicated, the statistical and financial data contained in this Form 20-F are presented as at December 31, 2004.

Unless otherwise noted, prescription and market data are derived from IMS Health Inc. ("IMS"). IMS is a provider of information solutions to the pharmaceutical and health-care industries, including market intelligence and performance statistics.

### Trademarks

The following words are trademarks of the Company and are the subject of either registration, or application for registration, in one or more of Canada, the US or certain other jurisdictions: Ativan®, Biovail®, Cardisense®, Cardizem®, Cardizem® LA, CEFORM , DrinkUp , FlashDose®, Glumetza , Instatab , Isordil®, Ralivia , Shearform , Smartcoat , SportSafe®, Tiazac® XC, Tiazac®, Vasotec® and Vaseretic®.

Wellbutrin®, Wellbutrin SR®, Wellbutrin XL®, Zovirax®, and Zyban® are trademarks of The GlaxoSmithKline Group of Companies ("GSK") and are used by the Company under license.

### **Forward-Looking Statements**

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

*To the extent any statements made in this Form 20-F contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe", "anticipate", "expect", "intend", "plan", "will", "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, risks and uncertainties, including the difficulty of predicting U.S. Food and Drug Administration ("FDA") and Canadian Therapeutic Products Directorate ("TPD") approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials and finished products, the regulatory environment, the outcome of legal proceedings, consolidated tax rate assumptions, and other securities regulatory authorities, fluctuations in operating results and other risks detailed from time to time in the Company's filings with the U.S. Securities and Exchange Commission ("SEC"), the Ontario Securities Commission ("OSC"), and other securities regulatory authorities in Canada, including the risks set forth in Item 3 of this Form 20-F. We undertake no obligation to update or revise any forward-looking statement.*

**PART I**

**Item 1 Identity of Directors, Senior Management and Advisors**

**A. Director and Senior Management**

Not applicable

**B. Advisers**

Not applicable

**C. Auditors**

Not applicable

**Item 2 Offer Statistics and Expected Timetable**

**A. Offer Statistics**

Not applicable

**B. Method and Expected Timetable**

Not applicable

**Item 3 Key Information**

**A. Selected Consolidated Financial Data**

The following tables of selected consolidated financial data of the Company have been derived from financial statements prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and Canadian generally accepted accounting principals ("Canadian GAAP"), as indicated. The data is qualified by reference to, and should be read in conjunction with, the consolidated financial statements and related notes thereto prepared in accordance with U.S. GAAP and Canadian GAAP as applicable (See Item 18 "Financial Statements").

**Description of Significant Differences**

The consolidated financial statements prepared by the Company in accordance with U.S. GAAP differ in certain respects from those statements prepared in accordance with Canadian GAAP. The material differences as they apply to the Company's consolidated financial statements are noted below:

**Acquired research and development**

Under U.S. GAAP, acquired research and development having no alternative future use must be written off at the time of acquisition while under Canadian GAAP, acquired research and development is capitalized at the time of acquisition, and amortized over estimated useful lives that range from five to 15 years.

**Stock-based compensation**

Under U.S. GAAP, the Company recognizes employee stock-based compensation costs under the intrinsic value-based method. Accordingly, no compensation expense for stock options granted to employees at fair market value was included in the determination of net income in 2004.

Under Canadian GAAP, the Company began recognizing employee stock-based compensation costs under the fair value-based method in January 2004.



**In accordance with U.S. GAAP**  
**(All dollar amounts are expressed in thousands of U.S. dollars,**  
**except number of shares and per share data)**

Years ended December 31

	2004	2003	2002	2001	2000
<b>Consolidated operating data:</b>					
Revenue	\$ 886,543	\$ 823,722	\$ 788,025	\$ 583,263	\$ 309,170
Operating income (loss)	216,064 <sup>(1)</sup>	16,936 <sup>(3)</sup>	133,584 <sup>(5)</sup>	172,228 <sup>(6)</sup>	(77,796) <sup>(8)</sup>
Net income (loss)	160,994 <sup>(2)</sup>	(27,265) <sup>(4)</sup>	87,795 <sup>(5)</sup>	87,448 <sup>(7)</sup>	(147,976) <sup>(9)</sup>
Basic earnings (loss) per share	\$ 1.01 <sup>(2)</sup>	\$ (0.17) <sup>(4)</sup>	\$ 0.58 <sup>(5)</sup>	\$ 0.64 <sup>(7)</sup>	\$ (1.16) <sup>(9)</sup>
Diluted earnings (loss) per share	\$ 1.01 <sup>(2)</sup>	\$ (0.17) <sup>(4)</sup>	\$ 0.55 <sup>(5)</sup>	\$ 0.58 <sup>(7)</sup>	\$ (1.16) <sup>(9)</sup>

At December 31

	2004	2003	2002	2001	2000
<b>Consolidated balance sheet:</b>					
Cash and cash equivalents	\$ 34,324	\$ 133,261	\$ 56,080	\$ 434,891	\$ 125,144
Working capital	124,414	149,884	(23,527)	427,856	(25,295)
Total assets	1,711,060	1,922,774	1,833,804	1,331,483	1,107,267
Long-term obligations	478,936	822,927	747,350	46,161	438,744
Convertible Subordinated Preferred Equivalent Debentures					299,985
Shareholders' equity	\$ 1,053,913	\$ 881,595	\$ 845,686	\$ 1,126,074	\$ 237,458
Number of common shares issued and outstanding [000s]	159,383	158,797	158,120	157,496	131,461

- (1) Includes charges of \$40,685 relating to the write-down of certain assets (net of gain on disposal of \$1,471), and \$8,640 for acquired research and development.
- (2) Includes charges of \$40,685 relating to the write-down of certain assets (net of gain on disposal of \$1,471), \$8,640 for acquired research and development, and an equity loss of \$4,179.
- (3) Includes charges of \$7,539 for relocation costs, \$45,081 relating to the write-down of certain assets, \$124,720 for acquired research and development, and \$61,348 for the extinguishment of a royalty obligation.
- (4) Includes charges of \$7,539 for relocation costs, \$45,081 relating to the write-down of certain assets, \$124,720 for acquired research and development, \$61,348 for the extinguishment of a royalty obligation, \$13,061 for a foreign exchange loss on a long-term obligation, an equity loss of \$1,010, and a reduction in the provision for tax contingencies of \$12,000.
- (5) Includes charges of \$31,944 relating to the write-down of certain assets and \$167,745 for acquired research and development.
- (6) Includes a charge of \$80,482 relating to the write-down of certain assets.
- (7) Includes charges of \$80,482 relating to the write-down of certain assets and \$34,923 for the debt conversion premiums relating to the conversion of our 6.75% Convertible Subordinated Preferred Equivalent Debentures due 2025 ("Debentures").
- (8)



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Includes a charge of \$208,424 for acquired research and development.

(9)

Includes charges of \$208,424 for acquired research and development, \$20,039 for a premium paid on the early extinguishment of the 10<sup>7</sup>/<sub>8</sub>% U.S. Dollar Senior Notes due 2005 ("Senior Notes"), and \$43,500 (\$0.34 basic and diluted loss per share) for the cumulative effect of a change in accounting principles relating to the recognition of revenue.

**In accordance with Canadian GAAP**  
**(All dollar amounts are expressed in thousands of U.S. dollars,**  
**except number of shares and per share data)**

**Years ended December 31**

	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Consolidated operating data:</b>					
Revenue	\$ 886,543	\$ 823,722	\$ 788,025	\$ 583,263	\$ 311,457
Operating income (loss)	106,189 <sup>(1)</sup>	4,793 <sup>(3)</sup>	246,979 <sup>(5)</sup>	117,382 <sup>(6)</sup>	116,459
Net income (loss) attributable to common shareholders	52,747 <sup>(2)</sup>	(40,345) <sup>(4)</sup>	207,553 <sup>(5)</sup>	85,553 <sup>(7)</sup>	81,163 <sup>(8)</sup>
Basic earnings (loss) per share	\$ 0.33 <sup>(2)</sup>	\$ (0.25) <sup>(4)</sup>	\$ 1.37 <sup>(5)</sup>	\$ 0.62 <sup>(7)</sup>	\$ 0.63 <sup>(8)</sup>
Diluted earnings (loss) per share	\$ 0.33 <sup>(2)</sup>	\$ (0.25) <sup>(4)</sup>	\$ 1.29 <sup>(5)</sup>	\$ 0.57 <sup>(7)</sup>	\$ 0.57 <sup>(8)</sup>

**At December 31**

	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Consolidated balance sheet:</b>					
Cash and cash equivalents	\$ 34,324	\$ 133,261	\$ 56,080	\$ 434,891	\$ 125,144
Working capital	124,418	149,884	(23,527)	427,856	(25,295)
Total assets	2,012,180	2,297,604	2,237,666	1,643,026	1,460,967
Long-term obligations	475,651	812,526	732,111	46,161	438,744
Shareholders' equity	\$ 1,358,318	\$ 1,266,826	\$ 1,264,787	\$ 1,425,417	\$ 839,110
Number of common shares issued and outstanding [000s]	159,383	158,797	158,120	157,496	131,461

- (1) Includes a charge of \$40,685 relating to the write-down of certain assets (net of gain on disposal of \$1,471).
- (2) Includes a charge of \$40,685 relating to the write-down of certain assets (net of gain on disposal of \$1,471) and an equity loss of \$4,179.
- (3) Includes charges of \$7,539 for relocation costs, \$82,189 relating to the write-down of certain assets, and \$61,348 for the extinguishment of a royalty obligation.
- (4) Includes charges of \$7,539 for relocation costs, \$82,189 relating to the write-down of certain assets, \$61,348 for the extinguishment of a royalty obligation, \$13,061 for a foreign exchange loss on a long-term obligation, an equity loss of \$1,010, and a reduction in the provision for tax contingencies of \$12,000.
- (5) Includes a charge of \$31,944 relating to the write-down of certain assets.
- (6) Includes a charge of \$80,482 relating to the write-down of certain assets.
- (7) Includes charges of \$48,246, net of tax of \$32,236, relating to the write-down of certain assets and \$10,001 for the debt conversion premiums relating to the conversion of the Debentures.
- (8) Includes a charge \$20,039 for a premium paid on the early extinguishment of the Senior Notes.

**B. Capitalization and Indebtedness**

Not applicable.

**C. Reasons for the Offer and Use of Proceeds**

Not applicable.

**D. Risk Factors**

As a business in a highly regulated and competitive industry, we face many risks and challenges. Documented as follows are some of the key risk factors generally associated with the business. Investment in our common stock involves a degree of risk. These risks should be carefully considered before any investment is made. 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.

**A decrease in the sales of Wellbutrin XL® could significantly reduce revenues and earnings.**

Our revenue from the supply of Wellbutrin XL® is based on GSK's net selling price on the U.S. sales of Wellbutrin XL®. Biovail's product sales revenue for Wellbutrin XL® sales was \$317 million, which represents approximately 35% of Biovail's total revenue. This revenue item generates a larger proportion of net income relative to Biovail's own product sales as this product has a relatively high gross margin. Any factors that decrease sales of Wellbutrin XL® could significantly reduce revenues and earnings, and have a material adverse effect on Biovail's financial condition and results of operations. These include:

Issues relating to the production of Wellbutrin XL®;

Development and commercialization of competitive pharmaceuticals, including generic versions;

Loss of patent protection by competitors that are successful in challenging, circumventing or infringing Biovail's patents;

Changes in reimbursement policies of third-party payers;

Government action/intervention;

Marketing or pricing actions by our partners or competitors;

Public opinion toward anti-depressant treatments;

Changes in the product's label or other such regulatory intervention;

Product liability claims;

Changes in prescription-writing practices; and

Changes in GSK's purchasing patterns or inventory levels.

In mid-November 2004, we became aware of two separate Abbreviated New Drug Application ("ANDA") filings with the U.S. Food and Drug Administration ("FDA") for generic versions of Wellbutrin XL® by two pharmaceutical companies in the United States. The first was filed by Anchen Pharmaceuticals of Taiwan; the second was filed by Abrika Pharmaceuticals LLLP ("Abrika") of Florida. On December 22, 2004, Biovail initiated patent-infringement litigation against each company. In January 2005, we became aware of a third filing, and patent-infringement litigation was initiated against Impax Laboratories ("Impax") of California. The entry of generic competitive products could have a material adverse effect on sales of our branded patented products.

While we believe that we have a sound basis for concluding that these companies are infringing our patents, nevertheless, there is no certainty we will succeed in these actions, and thereby preclude the entry of these generic products from competing against the Wellbutrin XL® brand prior to patent expiry.

**We are subject to claims under U.S. securities laws.**

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The Company and several of our officers are defendants in a consolidated securities class action (see Item 8A "Legal Proceedings - Securities Class Actions"). We and the other defendants believe that there are meritorious defenses to the claims asserted in this Action, and we intend to defend ourselves vigorously. However, it is possible that this action could result in the award of substantial monetary

damages. The conduct of this action could negatively impact the market price of our securities. In addition, we expect to continue to incur expenses associated with the defense of this action, regardless of the outcome, and this pending action may divert the efforts and attention of our management team from normal business operations.

**We could be subject to fines, penalties, or other sanctions as a result of ongoing investigations and inquiries by the OSC and the SEC.**

On November 20, 2003, we received a letter from the SEC indicating that the Commission would be conducting an informal inquiry relating to our financial performance and certain accounting matters for the fiscal year 2003. In March 2005, the SEC advised Biovail that it had issued a formal order of investigation related to the previously disclosed informal inquiry initiated in November 2003 which sought historical financial and related information, including, but not limited to the Company's accounting and financial disclosure practices. The formal investigation continues to focus primarily on accounting practices; however, the scope of the investigation is broader and includes certain transactions associated with a corporate entity since acquired by the Company. The period under review is January 2001 through May 2004. Biovail has been fully co-operating with the SEC, and will continue to do so in an effort to bring the investigation to a conclusion as expeditiously as possible.

Since 2003, the OSC has been conducting an ongoing review of our disclosure and review of certain trading activities related to our common shares. The OSC has now clarified that it is investigating, among other things, certain accounting and disclosure matters in 2003, as well as several issues relating to trading activity in our shares. More specifically, staff of the OSC has advised us that it is investigating, among other things, two issues relating to our accounting and disclosure in 2003. The first is whether we improperly recognized revenue for accounting purposes in relation to our interim financial statements for each of the four quarters in 2003. The second is whether we provided misleading disclosure in our press release, dated October 3, 2003, concerning the reasons for our forecast of a revenue shortfall in respect of the three-month period ending September 30, 2003. OSC staff has also advised that it is investigating four issues relating to trading in our common shares. These issues include whether certain of our insiders complied with insider reporting requirements, and whether persons in a special relationship with us may have traded in our shares with knowledge of undisclosed material information. OSC staff is also investigating whether certain transactions may have resulted in, or contributed to, a misleading appearance of trading activity in our securities during 2003 and 2004, and whether certain registrants (who are our past, or present, directors) may have been in a conflict of interest in relation to trading of our shares. We are co-operating fully with the OSC's investigation.

**Our business could suffer as a result of manufacturing and other issues.**

The continued increase in the number of our products in the market, and the New Drug Applications ("NDAs") and New Drug Submissions ("NDSs") we have pending at the FDA and TPD respectively requires us to continue to expand our manufacturing capabilities, including making changes to our manufacturing facilities in Steinbach, Manitoba, and Dorado, Puerto Rico. The timely completion of these efforts is necessary for us to have sufficient manufacturing capacity for the anticipated quantities of our existing products and the products we expect to manufacture for marketing by us or for supply to partners in the future, and will require significant levels of capital investment. Our inability to complete our expansion and conversion projects, or adequately equip the facilities in a timely manner, or delays in receiving FDA and TPD approvals, could adversely affect our results of operations, financial condition and cash flows.

Our manufacturing and other processes utilize sophisticated equipment, which sometimes requires a significant amount of time to obtain and install. Although we endeavour to properly maintain our equipment and have key spare parts on hand, our business could suffer if certain manufacturing or other equipment, or a portion of our facilities, were to become inoperable for period of time. This could occur

for various reasons, including catastrophic events, such as a hurricane or other natural disaster, an explosion, an environmental accident, equipment failures and/or delays in obtaining components or replacements thereof, construction delays or defects and other events, both within and outside of our control.

We have, at times, 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. Operating on that basis and meeting the anticipated market demand requires minimal equipment failures and product rejections. However, because we manufacture products that employ a variety of technology platforms, some of our manufacturing capabilities may at times be over-utilized, while others may be under-utilized, resulting in inefficiencies, equipment failures and rejection of lots. Until our manufacturing processes are fully optimized, and/or our manufacturing facilities are expanded, we may have difficulty at times fulfilling all of the market demand for our existing and future products, which could adversely affect our results of operations, financial condition and cash flows.

A portion of our pharmaceutical manufacturing capacity, as well as other critical business functions, are located in areas subject to hurricane and earthquake casualty risks. Although we have certain limited protection afforded by insurance, our business and our earnings could be materially adversely affected in the event of a major weather-related or catastrophic event.

As manufacturing facilities are located outside the continental U.S., while most of our sales are within the U.S., any change in policy or policy implementation relating to U.S. border controls may have an impact on our ease of access to the U.S. marketplace.

Although we endeavour to manufacture our pharmaceutical products to meet good manufacturing practices ("GMP") requirements, it is possible that product we manufacture may need to be recalled and removed from the market. This could occur for various reasons, including failure of the product to meet and/or maintain specifications; stability issues; and/or our becoming aware of a product causing an adverse drug reaction(s) in patient(s). In turn, the removal of product from the market for either of these reasons, or any combination thereof, could have a significant adverse material impact on the Company's financial results.

The supply of our product to our customers is subject to and dependent upon the use of transportation services. Disruption of transportation services could have a material adverse impact on the Company's financial results.

A number of products sold by us are manufactured and supplied to us by third parties. Disruption in the supply of these products could have a material adverse impact on the Company's financial results.

**The restructuring of our U.S. commercial operations may not be successful**

We recently completed a major restructuring of our U.S. commercial operations through the divestiture of certain promoted products and a reduction in our workforce (see Item 4.B "Business Overview"). Our planning surrounding the restructuring was based on certain assumptions regarding the cost structure of our U.S. commercial operations, market conditions in the U.S. pharmaceutical industry and costs relating to the restructuring. Though we believe our assumptions were reasonable, we can provide no assurance that our cost structure, U.S. pharmaceutical industry market conditions or costs relating to the restructuring will be as anticipated. As a result, our restructuring may not lead to cost savings or improved results. In addition, because of the workforce reductions associated with the restructuring, we may find it more difficult to attract or retain qualified employees. If our remaining workforce is not the appropriate size or if we are not successful in attracting or retaining qualified employees, our ability to carry out our business plan effectively may be adversely affected. We can provide no assurance that any of the goals of our restructuring will be achieved or that any associated benefits of

the restructuring will be realized. Any failure to fully realize these benefits may have an adverse effect on our business and financial results.

**Our business could suffer as a result of adverse drug reactions ("ADRs").**

Unexpected ADRs by patients to any of our products could negatively impact utilization or market availability of our product.

**Our business could suffer as a result of actions by third parties who have marketing rights to our products.**

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

**Patent protection is unpredictable and uncertainty can arise regarding the applicability of our patents and proprietary technology.**

Our competitors may have filed patent applications, or hold issued patents, relating to products or processes competitive with those we are developing. Alternatively, our patent applications for a product or process may not be approved or may not be approved as desired. The patents of our competitors may impair our ability to do business in a particular area. Others may independently develop similar products or duplicate any of our unpatented products. Our success will depend, in part, on our ability in the future to obtain patents, protect trade secrets and other proprietary information and operate without infringing on the proprietary rights of others.

We rely on trade secrets, know-how and other proprietary information, as well as requiring our employees and other vendors and suppliers to sign confidentiality agreements. However, these confidentiality agreements may be breached, and we may not have adequate remedies for such breaches. Also, other persons may independently develop substantially equivalent proprietary information without infringing upon any proprietary technology. Third parties may otherwise gain access to our proprietary information and adopt it in a competitive manner.

With respect to the segment of our business where we manufacture and supply generic versions of existing drugs, there has been substantial litigation concerning the manufacture, use and sale of new products that are the subject of conflicting patent rights. When we file an ANDA for a bioequivalent version of a drug, we are required to certify to the FDA that any patent which has been listed with the FDA as covering the branded product has expired, or the date any such patent will expire, or that any such patent is invalid or will not be infringed by the manufacture, sale or use of the new drug for which the application is submitted. Approval of an ANDA is not effective until each listed patent expires, unless the applicant certifies that the patents at issue are not infringed or are invalid and so notifies the patent holder and the holder of the branded product NDA. A patent holder may challenge a notice of non-infringement or invalidity by suing for patent infringement within 45 days of receiving notice. Such a challenge would prevent FDA approval for a period that ends 30 months after the receipt of notice, or sooner, if an appropriate court rules that the patent is invalid or not infringed. From time to time, in the ordinary course of business, we face such challenges.

The expense of litigation, whether or not we are successful, could have a material adverse effect on our business, results of operations, financial condition and cash flows. Regardless of FDA approval, should anyone commence a lawsuit with respect to any alleged patent infringement by us, whether because of the filing of an ANDA or otherwise, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. Such lawsuits may be brought and the ultimate outcome of such litigation, if commenced, could have a material adverse effect on our business, results of operations, financial condition and cash flows.



**Our effective tax rate may increase.**

We have operations in various countries that have differing tax laws and rates. Our income tax reporting is subject to audit by both domestic and foreign tax authorities. The effective tax rate may change from year to year based on the mix of income 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; and changes in the estimated values of deferred tax assets and liabilities.

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

We have recorded a valuation allowance on deferred tax assets primarily relating to operating losses, future tax depreciation and tax credit carry forwards. We have assumed that these deferred tax assets are more likely than not to remain unrealized. 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 the provision for income taxes in a period.

Our future effective tax rate will depend on the relative profitability of our domestic and foreign operations, the statutory tax rates of the related tax jurisdictions, and the timing of the release, if any, of the valuation allowance.

**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.**

Our products face competition from conventional forms of drug delivery and from controlled-release, drug-delivery systems developed, or under development, by other pharmaceutical companies. We compete with companies in North America and internationally, including major pharmaceutical and chemical companies, specialized contract research organizations, research-and-development firms, universities and other research institutions. We have, or may in the future have, manufacturing and supply agreements with some of our competitors. Many of our competitors have greater financial resources and selling and marketing capabilities; have greater experience in clinical testing and human clinical trials of pharmaceutical products; and have greater experience in obtaining FDA, TPD and other regulatory approvals. Our competitors may succeed in developing technologies and products that are more effective or less expensive to use than any that we may develop or license. These developments could render our technologies and products obsolete or uncompetitive, which would have a material adverse effect on our business and financial results.

**The publication of negative results of studies or clinical trials may adversely impact our products.**

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. In the event of the publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our

products compete, our business, financial condition, results of operation and cash flows could be materially adversely affected.

**Future inability to obtain components and raw materials or products could affect our operations.**

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. In the event an existing supplier becomes unavailable or loses its regulatory status as an approved source, 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. To the extent such difficulties cannot be resolved within a reasonable time, and at a reasonable cost, or we are required to qualify a new supplier, our business, financial condition, results of operation and cash flows could be materially adversely affected.

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.

**Our operations could be disrupted if our information systems fail or if we are unsuccessful in implementing necessary upgrades.**

Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. If our systems were to fail or we are unable to successfully expand the capacity of these systems, or we are unable to integrate new technologies into our existing systems, our operations and financial results could suffer.

**There is no assurance that we will continue to be successful in our licensing and marketing operations.**

Certain of our products are marketed by third parties. Such third-party arrangements may not be successfully negotiated in the future. Any such arrangements may not be available on commercially reasonable terms. Even if acceptable and timely marketing arrangements are available, the products we develop may not be accepted in the marketplace, and even if such products are initially accepted, sales may thereafter decline. Additionally, our clients or marketing partners may make important marketing and other commercialization decisions with respect to products we develop that are not within our control. As a result, many of the variables that may affect our revenues, cash flows and net income are not exclusively within our control.

**The success of the strategic investments we make depends upon the performance of the companies in which we invest.**

Economic, governmental, industry and internal company factors outside our control affect each of the companies in which we may invest. Some of the material risks relating to the companies in which we may invest 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;

The ability of competitors of these companies to develop similar or more effective products, making the drugs developed by the companies in which we invest difficult or impossible to market;

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The ability of these companies to adequately secure patents for their products and protect their proprietary information;

The ability of these companies to enter the marketplace without infringing upon competitors' patents;

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 company in which we invest may devote to developing the products for which we collaborate with them. Any company in which we invest 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. If any of these events occurs, it could have a material adverse effect on our business and our financial results.

### **We must successfully integrate any businesses or products that we have acquired or will acquire in the future.**

We are actively pursuing product or business acquisitions that could complement or expand our business. However, there can be no assurance that we will be able to identify appropriate acquisition candidates in the future. If an acquisition candidate is identified, there can be no assurance that we will be able to successfully negotiate the terms of any such acquisition, finance such acquisition or integrate such acquired product or business into our existing products and business. Furthermore, the negotiation of potential acquisitions and integration of acquired companies and product lines could divert management's time and resources, and require significant resources to consummate. If we consummate one or more significant acquisitions through the issuance of common shares, holders of our common shares could suffer significant dilution of their ownership interests.

### **We depend on key scientific and managerial personnel for our continued success.**

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. In particular, our success to date in developing new products has resulted from the activities of a core group of research scientists. The continued availability of such a group is important to our ongoing success.

### **A relatively small group of products and customers may represent a significant portion of our net revenues or net earnings from time to time. If the volume or pricing of any of these products declines, or we lose customers, it could have a material adverse effect on our business, financial condition, cash flows and results of operations.**

Sales of a limited number of our products represent a significant portion of our net revenues or net earnings. If the volume or pricing of our largest selling products declines in the future, our business, financial condition, cash flows and results of operations could be materially adversely affected.

A significant portion of our net revenues is derived from sales to a limited number of customers. Any significant reduction or loss of business with one or several of these customers could have a material adverse effect on our business, financial condition, cash flows and results of operations.

**Our ability to obtain third-party reimbursement for the cost of products and related treatment may not be adequate.**

Our ability to successfully commercialize our products and product candidates even if FDA or TPD approval is obtained depends, in part, on whether appropriate reimbursement levels for the cost of the products and related treatments are obtained from government authorities and private health insurers and other organizations, such as Health Maintenance Organizations ("HMOs"), Managed-Care Organizations ("MCOs") and provincial formularies.

Third-party payors increasingly challenge the pricing of pharmaceutical products. In addition, the trend toward managed health-care in the U.S., the growth of organizations such as HMOs and MCOs, and legislative proposals to reform health-care and government insurance programs, could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. Such cost-containment measures and health-care reform could affect our ability to sell our products and may have a material adverse effect on our business, financial condition, cash flows and results of operations.

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. These issues could have a material adverse effect on our business, financial condition, cash flows and results of operations. We are unable to predict if additional legislation or regulation impacting the health-care industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

**Our business is subject to limitations imposed by government regulations.**

Government agencies in the U.S., Canada and other countries in which we conduct business regulate pharmaceutical products intended for human use. Regulations require extensive clinical trials and other testing, and government review and final approval, before we can market these products. The cost of complying with government regulation can be substantial. Governmental authorities in the U.S. and Canada and comparable authorities in foreign countries regulate the research and development, manufacture, testing and safety of pharmaceutical products. The regulations applicable to our existing and future products may change. There can be long delays in obtaining required clearances from regulatory authorities in any country after applications are filed.

Requirements for approval vary widely from country to country outside of the U.S. and Canada. Whether or not approved in the U.S. or Canada, regulatory authorities in other countries must approve a product prior to the commencement of marketing the product in those countries. The time required to obtain any such approval may be longer or shorter than in the U.S. or Canada.

Any failure or delay in obtaining regulatory approvals could adversely affect the marketing of any products we develop and therefore our business, financial condition, cash flows and results of operations.

**New legislation or regulatory proposals may adversely affect our revenues and profitability.**

A number of legislative and regulatory proposals aimed at changing the health-care system, including the cost of prescription products, importation and reimportation of prescription products from countries outside the U.S. and changes in the levels at which pharmaceutical companies are reimbursed for sales of their products, have been proposed. 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, results of operations and cash flows.

Changes to Medicare, Medicaid or similar governmental programs or the amounts paid by those programs for our services may adversely affect our earnings. 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. In the U.S., *The Medicare Prescription Drug, Improvement and Modernization Act of 2003* ("MMA"), creates a new, voluntary prescription drug benefit under the *Social Security Act*. For the first time, this will provide a substantial drug benefit to Medicare participants beginning in January 2006. This program enhancement will utilize commercial market entities to market Medicare Advantage and stand-alone, prescription drug-plan options to the approximately 40 million people eligible for Medicare. We are currently engaged, via our Managed Markets group, with key commercial entities as they develop their MMA drug-benefit formularies. It is our intention to create broad access within relevant therapeutic classes for Biovail agents, within these new commercial plans to serve this important segment of the population.

Recently enacted and proposed changes to the laws and regulations affecting public companies, including the provisions of the *Sarbanes-Oxley Act of 2002* in the U.S. and *Bill 198* in Ontario (now Part XXXIII.I of the *Securities Act* (Ontario) not yet in force) and related rules, will cause us to incur increased costs as we evaluate the implications of new rules and respond to new requirements. Delays, or a failure to comply with the new rules and regulations could result in enforcement actions or the assessment of other penalties. The new laws and regulations, 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 our Board of Directors, or as executive 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 presently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

**Rising insurance costs could negatively impact our profitability.**

The cost of insurance including insurance for directors and officers, worker's compensation, property, product-liability and general liability insurance rose significantly in the past year and is expected to continue to increase in 2005. In response, we may increase deductibles and/or decrease certain coverages to mitigate these costs. These increases, and our increased risk due to increased deductibles and reduced coverages, could have a negative impact on our results of operations, financial condition and cash flows.

**If we fail to comply with the "safe harbors" provided under various federal, provincial and state laws, our business could be adversely affected.**

We are subject to various federal and provincial and state laws pertaining to health-care fraud and abuse, including anti-kickback laws and false-claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to include, the referral of business, including the purchase or prescription of a particular drug. The U.S. federal government has published regulations that identify "safe harbors", or exemptions, for certain payment arrangements that do not violate the anti-kickback statutes. We seek to comply with the "safe harbors". Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions, it is possible that some of our practices might be challenged under anti-kickback or similar laws. Our activities relating to the sale and marketing of Cardizem® LA in the U.S. is subject to an ongoing investigation by the Office of the Inspector General ("OIG") of Health and Human Services (see "Item 8A Legal Proceedings Governmental and Regulatory Inquiries").

Violations of fraud and abuse of securities laws may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from U.S. federal health-care programs (including Medicaid and Medicare). Any such violations could have a material adverse effect on our business, financial condition, results of operations and cash flows.

**Our securities are subject to market price volatility.**

Market prices for the securities of pharmaceutical and biotechnology companies, including our own, 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, concern as to the safety of drugs, and general market conditions, can have an adverse effect on the market price of our securities. Any inability to bring our pipeline products to market profitably may have an adverse effect on our business, financial conditions, results or operations and our cash flows.

**We are not assured of successful development of our product pipeline.**

We have over 25 products at various stages of development or which are not yet marketed. We have filed or intend to file several products for approval with U.S. and Canadian regulators. Approval may not be granted for all or any of these products, nor may we be successful in submitting additional applications for the remaining pipeline products with the regulatory authorities.

**We may not have sufficient cash and may be limited in our ability to access financing for future capital requirements, which may prevent us from expanding our business and our portfolio of products.**

We may in the future need to incur additional debt or issue equity in order to satisfy working-capital and capital-expenditure requirements, as well as to make acquisitions and other investments. To the extent we are unable to raise new capital, we may be unable to expand our business. If we raise funds through the issuance of debt or equity, any debt securities or preferred shares issued will have rights and preferences and privileges senior to those of holders of our common shares. The terms of the debt securities may impose restrictions on our operations that have an adverse impact on our financial condition. If we raise funds through the issuance of equity, the proportional ownership interests of our shareholders could be diluted.

**We are subject to exposure relating to product-liability claims.**

We face an inherent business risk of exposure to product-liability and other claims in the event that the use of our products results, or is alleged to have resulted, in adverse effects. While we have taken, and will continue to take, what we believe are appropriate precautions, there can be no assurance that we will avoid significant product-liability claims. Although we currently carry product-liability insurance that we believe is appropriate for the risks that we face, there can be no assurance that we have sufficient coverage, or can in the future obtain sufficient coverage at a reasonable cost. 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. Our obligation to pay indemnities, to withdraw a product following complaints, or a product-liability claim could have a material adverse effect on our business, results of operations, cash flows and financial condition.

**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 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.

**We may incur liability if our continuing medical or health education programs and/or product promotions are determined, or are perceived to be inconsistent with regulatory guidelines.**

The FDA and the TPD provide guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavour to follow these guidelines, the FDA, TPD, or other 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 and our reputation could be damaged.

**We are exposed to risks relating to foreign currencies.**

We operate internationally, but a majority of our revenue and expense activities and capital expenditures are denominated in U.S. dollars. Our only other significant transactions are in Canadian dollars. In 2003, we incurred a foreign-exchange loss of \$13.1 million related to our Canadian dollar-denominated obligation to GSK for the acquisition of the Canadian rights to Wellbutrin® and Zyban®. We paid the final installment related to this obligation in March 2004 and, consequently, we do not have any material remaining non-U.S. dollar denominated obligations. We also face foreign-currency exposure on the translation of our operations in Canada and Ireland from their local currencies to the U.S. dollar. Currently, we do not utilize forward contracts to hedge against foreign-currency risk. We believe that a 10% change in foreign currency exchange rates would not have a material effect on our consolidated results of operations, financial position or cash flows.

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

We are exposed to interest-rate risk on borrowings under our revolving term credit facility. This credit facility bears interest based on London Interbank Offering Rates ("LIBOR"), U.S. dollar base rate, Canadian dollar prime rate or Canadian dollar bankers' acceptance rates. At our option, we may lock in a rate of interest for a period of up to one year. The imputed rates of interest used to discount our long-term obligations related to the acquisition of intangible assets are fixed and, consequently, the fair value of these obligations are affected by changes in interest rates. The fair value of our fixed-rate 7<sup>7</sup>/<sub>8</sub>% Senior Subordinated Notes ("Notes") is affected by changes in interest rates. We manage this exposure to interest-rate changes through the use of interest-rate swaps, which modify our exposure to interest-rate fluctuations by converting one-half of our fixed-rate Notes to floating rate. Based on our overall interest-rate exposure, a 10% change in interest rates would not have a material effect on our consolidated results of operations, financial position or cash flows.

**We are exposed to risks related to our investments in other companies.**

We are exposed to risks in the value of our investments in other companies. The fair values of our investments are subject to significant fluctuations due to stock-market volatility and changes in general market conditions. We regularly review the carrying values of our investments and record losses when events and circumstances indicate that there have been other-than-temporary declines in their fair values. A further decline in Ethypharm S.A.'s ("Ethypharm") financial condition and earnings prospects may necessitate an additional write down in our investment. A 10% change in the aggregate fair values of our investments would have a material effect on our consolidated results of operations; however, it would not have a material effect on our consolidated financial position or cash flows.

**Item 4. Information on the Company**

**A. History and Development of the Company**

Biovail is incorporated under the *Business Corporations Act* (Ontario) R.S.O. 1990, as amended. Biovail was established on February 18, 2000 as a result of the amalgamation of TXM Corporation ("TXM") and Biovail Corporation International ("BCI").

At the Company's Annual and Special Meeting of Shareholders on June 28, 2005 (the "Meeting") the Company's shareholders will consider a special resolution to authorize continuance of the Company (the "Continuance") under the *Canada Business Corporations Act* (the "CBCA"). Management of the Company has proposed the Continuance in order to take advantage of, among other things, more flexible requirements in respect of director residency and financial statement preparation that are available under the CBCA. For further information about the proposed continuance, please see the Company's Notice of Annual and Special Meeting of Shareholders & Management Proxy Circular (the "Management Information Circular") filed on Form 6-K on May 19, 2005.

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 U.S. is CT Corporation System, located at 111 Eighth Avenue, New York, New York, 10219, telephone number (212) 590-9200.

A description of our principal capital expenditures and divestitures and a description of acquisitions of material assets is found in our Management's Discussion and Analysis ("MD&A") and consolidated financial statements included elsewhere in this annual report.

**B. Business Overview**

*In May of 2005 we announced a new Strategic Plan (the "Plan"), whereby we decided to restructure our approach to selling and marketing products in the primary-care market of the U.S. The following sections describe our business in light of the announcement of the Plan.*

We are a specialty pharmaceutical company that applies advanced drug-delivery technologies to improve the clinical effectiveness of medicines. We drive business growth by commercializing these products both directly and through partners. Our main therapeutic areas of focus are cardiovascular disease (including Type II diabetes), central nervous system disorders ("CNS") and pain management. We aspire to be the world's premier specialty pharmaceutical company.

Our core competency lies in our expertise in the development and large-scale manufacturing of pharmaceutical products, incorporating oral drug-delivery technologies. We have a broad portfolio of these proprietary technologies that represent the foundation upon which the Company's strategy is based. These drug-delivery technologies are used to develop enhanced formulations of late-stage, pre-market and existing in-market drugs that confer meaningful benefits to patients. Enhancement of existing in-market products (or brands), also described as a product line-extension strategy, is currently being pursued by



many of the world's largest pharmaceutical companies as they look for ways to expand upon the significant clinical and marketing investments they have made in establishing high-value brands.

Our broad portfolio of oral drug-delivery technologies includes controlled release, graded release, enhanced absorption, rapid absorption, taste masking, and oral disintegration, among others. Importantly, these technologies can be combined to develop, for example, a controlled-release, orally disintegrating, taste-masked tablet. Our drug-delivery technologies are applicable to a wide range of molecules, and can, in many areas, address the pharmaceutical industry's more complex drug-delivery challenges. We strive to be at the forefront of the industry through internal research-and-development efforts ("R&D"), as well as through licensing agreements with third-party, drug-delivery companies, whereby we seek to gain access to promising new and/or complementary technologies. Upon receipt of regulatory approval, products emerging from our drug-development pipeline are either commercialized through our own marketing and sales divisions, through strategic partners, or both (in the case of a co-promotion arrangement).

We recently implemented the first phase of the Plan. A critical priority of the Plan was to enhance the return on investment of our U.S. marketing and sales operations, as the revenue potential of our portfolio of promoted products did not support the then-current level of commercial investment. The primary-care market has become increasingly more competitive in recent years; the average size of many primary-care sales organizations has increased considerably. Concurrently, primary-care physicians are giving pharmaceutical representatives less time to describe the benefits of various medications. As a result of this new dynamic, pharmaceutical companies spent over \$4.1 billion on direct-to-consumer advertising in 2004 as an alternative means to create awareness for their medications.

To better position us for long-term growth in the U.S., we realigned our U.S. marketing and sales operations in May 2005, changing the manner in which we commercialize products to the primary-care segment of the U.S. market. As a result of the realignment, we no longer promote our products directly to a broad audience of primary-care physicians in the U.S. To effect this strategy we entered into a multi-faceted agreement with Kos Pharmaceuticals, Inc. ("Kos") (see Item 4B "Three-Year History Material Developments"). In the U.S. we have adopted a business unit commercialization / specialist sales model (the "Business-Unit Model") whereby we focus our promotional efforts solely on high-prescribing specialists and primary-care physicians. To this end, we currently have an 85-member sales force in the U.S. that details our Zovirax® Ointment and Zovirax® Cream products to dermatologists and obstetricians / gynaecologists ("OB-GYNs"). We intend to rely on strategic partners with established franchises in primary care to promote our pipeline products to the broad U.S. primary-care physicians.

Our Business Unit Model is characterized by significantly reduced infrastructure costs and increased operational flexibility. We have established relationships with a number of important stakeholders, including pharmaceutical wholesalers, managed care organizations and specialist physicians (key opinion leaders in their respective fields). This facilitates the expansion and scale-up into other specialty markets. We anticipate establishing new specialty sales forces in other therapeutic markets as pipeline and business-development opportunities warrant.

In Canada, we have successfully targeted both specialist and primary-care physicians; as a result, Biovail Pharmaceuticals Canada ("BPC") has established itself as a leading pharmaceutical marketing and sales operation in the Canadian market. The division currently employs a 78-member sales force, which promotes a well-respected portfolio of products to approximately 9,000 physicians across the country. Products include Tiazac®, Tiazac® XC (launched in January 2005), Wellbutrin SR®, Zyban® and Retavase®.

In May 2005, we divested the Teveten® line of products, and entered into a strategic alliance with Kos for Cardizem® LA. We manufacture and supply Cardizem® LA to Kos at contractually determined supply prices that are in excess of 30% of Kos' net selling price. In October 2001, GSK acquired the global marketing rights (excluding Canada) to our once-daily formulation of bupropion. We currently manufacture and supply the product to GSK pursuant to a tiered-pricing supply agreement. GSK

successfully launched the product in the U.S. in September 2003 under the brand name Wellbutrin XL®, with plans to launch in other markets as regulatory approvals are received. In December 1997, we entered into a manufacturing and distribution agreement with a subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva") for a portfolio of bioequivalent (generic) products developed by us. We manufacture and sell these products to Teva for distribution in the U.S. Our selling prices to Teva increased as a result of a September 2004 amendment to the original agreement. In September 1995, Forest Laboratories, Inc. ("Forest") acquired the U.S. marketing rights to a once-daily formulation of diltiazem developed by us. The product was launched in February 1996 under the brand name Tiazac®. In April 2003, upon the product's genericization, Forest ceased promotional support for Tiazac® and now distributes a Tiazac® generic on our behalf.

In addition to the products directly promoted by us or through strategic partners, we also distribute a number of off-patent products. These products known as legacy products are not actively promoted. We are currently evaluating a number of options to better realize the potential value of our portfolio of legacy products. These products generate significant cash flow; however, prescriptions filled by our legacy products continue to decline. The decline in these products negatively affects our revenue and earnings-per-share ("EPS") growth. As such, these products are not strategic to our business, which is focused on long-term, sustainable growth opportunities. The options we are considering include a sale of these products to strategic or financial buyers, the transfer of the assets to a new entity and the sale of shares of the entity, pursuant to an initial public offering or a distribution to our shareholders as a return of capital.

We are actively exploring acquisition opportunities in the marketplace, including those that can add to our product portfolio or pipeline, enhance or complement our drug-delivery technology base, or strategically contribute to our sales and marketing capability in targeted therapeutic areas.

### **Competitive Strength**

The pharmaceutical industry is highly competitive and subject to rapid and significant technological change. Our products face competition from both conventional forms of drug delivery and controlled-release drug-delivery systems developed, or under development, by other pharmaceutical companies. Many of these competitors have greater financial resources and marketing capabilities than us. Our competitors in the U.S. and abroad are numerous and include, among others, major pharmaceutical and chemical companies, relationships, specialized contract research and research-and-development firms, universities, and other research institutions. We have, or may in the future have, manufacturing-and-supply agreements or other relationships with some of our competitors.

We believe that our controlled-release technology, combined with our strategy of funding and controlling most aspects of our controlled-release pharmaceutical product development business, will provide the cost savings, efficiencies in product development and acceleration of regulatory filings necessary for us to compete effectively with such firms and institutions.

Since our development efforts are focused on enhancing formulations of in-market drugs by providing clinically meaningful benefits and advantages to patients over existing formulations where safety and efficacy profiles are well known and established the development risk we face is typically reduced relative to companies pursuing new chemical entities ("NCEs").

For the same reasons, the development costs we incur to bring products to market are also lower. Upon receiving approval from the FDA, the enhanced medication typically receives three years of market exclusivity, compared with new chemical entities ("NCEs"), which typically receive five years of market exclusivity. Patents can often extend the lifecycles of these products beyond the expiry of exclusivity periods. (See section "Government Regulations").

One of our competitive advantages is our demonstrated ability to transfer technologies from the concept stage to full-scale commercial manufacturing of products incorporating our drug-delivery technologies. Our record of success in this regard includes products such as our generic pharmaceuticals portfolio, and branded products, such as Cardizem® LA, Tiazac® (anti-hypertensive) and Wellbutrin XL® (anti-depressant). Going forward, we anticipate manufacturing and commercializing once-daily or orally disintegrating tablet ("ODT") formulations of tramadol, (pain management), Glumetza (Type II diabetes), venlafaxine EA, Zolpidem ODT (sleep disorders) and other products currently under development. Biovail strives to be at the forefront of the industry through internal R&D, as well as through licensing agreements with third-party, drug-delivery companies, whereby we seek to gain access to promising new and/or complementary technologies.

Our direct commercialization process is based upon our Business-Unit Model. Using this focused approach, we primarily market directly to specialist physicians in the U.S., and to specialist and high-prescribing primary-care physicians in Canada. In the U.S., we utilize strategic alliances to commercialize Biovail-developed products that target primary-care markets where large investments in marketing and sales infrastructure have been made by the strategic partner. GSK's success in marketing Wellbutrin XL® demonstrates the potential of this approach, in addition to the value-add offered by our controlled-release technologies and expertise. In Canada, we believe Biovail has successfully established itself as a leader in the commercialization of both primary-care and specialty products in cardiology and CNS therapeutic areas.

### **Company Strategy**

Biovail is a specialty pharmaceutical company with a record of growth and innovation in developing products for the North American market. The application of proprietary drug-delivery technologies to in-market orally administered medications has provided us, and together with our partners, with the opportunity to extend product life cycles through the development of enhanced formulations. Given the highly competitive industry in which we operate, we are pursuing a number of strategic options to drive sustainable growth, including increasing product life cycles and patent protection of our pipeline products. Other parts of our strategy include the development of compound (or drug molecule) families, the effective utilization of both internal and external technical resources, focused business development efforts, and commercial flexibility, among others.

Our business strategy revolves around the following inter-related components:

1. We develop and manufacture products using multiple drug-delivery technology platforms that alter the release characteristics of drugs. Targeting drugs with high market potential (NCEs, established products and/or combinations), we introduce modifications whose clinical effects can be positively influenced by application of our delivery technologies.
2. We commercialize our pipeline either directly or through partners. This flexibility provides Biovail with an opportunity to maximize the market potential of its products.
3. Our direct commercialization process is based upon the Business-Unit Model and is focused on marketing to specialists and high-prescribing primary-care physicians in the United States and Canada.
4. We utilize strategic alliances to commercialize products we develop that target primary-care markets in the U.S. where large investments in sales-and-marketing infrastructure have been made by the strategic partner. Outside of North America, we partner all products.
5. We also generate revenues by promoting and/or co-promoting products on behalf of third parties, and through developmental research services to third parties using our in-place infrastructure more efficiently.

We applied this strategy successfully in the U.S. in the launch of Cardizem® LA (now promoted by Kos), as well as through our agreement with GSK for Wellbutrin XL® (a once-daily formulation of bupropion developed by Biovail) and in Canada through the launches of Tiazac® and Celexa. We intend to continue to exploit our drug-delivery technology assets and rich pipeline through our own commercialization efforts and in conjunction with leading global pharmaceutical companies.

### Industry Overview

Over the past several years, the pharmaceutical industry has experienced change. This change is in response to factors such as increased enrolment in HMO 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.

IMS reports that the total U.S. prescription drug market was approximately \$235 billion in 2004, an increase of 8% over \$216 billion for 2003. IMS estimates that during the years 2004-2008, branded products with 2003 sales in excess of approximately \$52 billion will lose patent protection. In 2004, the figure was \$13 billion.

To replace these revenues and reduce their dependence on internal development programs, the large pharmaceutical companies are increasingly entering into strategic licensing arrangements with specialty pharmaceutical companies and augmenting their product pipelines by acquiring smaller specialty companies with valuable research-and-development programs and technologies. Large pharmaceutical companies are also developing strategies to extend brand life-cycles and exclusivity periods and establish product differentiation. The pharmaceutical industry is also undergoing a period of consolidation.

According to IMS, prescription growth for 2004 in the U.S. pharmaceutical market for all forms of controlled-release drugs was approximately 3.3%. The oral-dosage, controlled-release segment of the market generated approximately \$21.8 billion of revenues in 2004, an increase of 11% over the prior year. The growth in this segment come from applications related to the proliferation of branded drugs at or near patent expiration and new product launches.

Controlled-release products are formulated to release the drug's active ingredient gradually and predictably over a 12-hour to 24-hour period. These formulations provide for: (1) greater effectiveness in the treatment of chronic conditions through more consistent delivery of the medication; (2) reduced side effects; (3) greater convenience; and (4) higher levels of patient compliance due to a simplified dosage schedule as compared to that of immediate-release drugs.

There are significant technical barriers to entry into the development of controlled-release drugs, with only a limited number of companies possessing the requisite expertise and technology. Despite the therapeutic advantages of controlled-release drugs versus their immediate-release counterparts, many pharmaceutical companies have not made the additional investment to develop a controlled-release version of a product while their immediate-release version is under patent protection.

The pharmaceutical industry is subject to ongoing political pressure to contain the growth in spending on drugs and to expedite and facilitate bioequivalent competition to branded products. In the U.S., changes to Medicare prescription drug coverage may be implemented in the near-term. Companies oriented toward improved drug-delivery and bioequivalent medications may benefit from the focus on cost-containment and therapeutic value.

For most of the 1990s, the FDA evidenced an accommodative stance to NDAs. Relatively fast drug approvals, in part, reflected the political imperative of bringing bioequivalent competition to the marketplace. In conjunction with several high-profile drug withdrawals over the past several years, there is now evidence of a more cautious stance from the FDA. This stance may operate to the benefit of drug-delivery and bioequivalent drug companies whose products are viewed as rapid and lower cost methods of bringing products to the market.

## Competition

The pharmaceutical industry is highly competitive, and subject to rapid and significant technological change. Our products face competition from both conventional forms of drug delivery and controlled-release drug-delivery systems developed, or under development, by other pharmaceutical companies. Many of these competitors have greater financial resources and marketing capabilities than us. Our competitors in the U.S. and abroad are numerous and include, among others, major pharmaceutical and chemical companies, including some of the licensees (or potential licensees) of our products; specialized contract research and research-and-development firms; universities; and other research institutions. We believe that our controlled-release technology, combined with our strategy of funding and controlling all or most aspects of our controlled-release pharmaceutical business, will provide the cost savings, efficiencies in product development and acceleration of regulatory filings necessary for us to compete effectively with such firms and institutions. Our competitors, however, may succeed in developing technologies and products that are as, or more, clinically or cost-effective than any that are being developed or licensed by us, or that would render our technologies and products obsolete or uncompetitive. In addition, certain of our competitors have greater experience than us in clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA and other regulatory approvals.

## Priority Markets

The primary markets for our products are the United States and Canada. The U.S. is the world's largest pharmaceutical market with total prescription spending of \$235 billion in 2004. U.S. prescription spending in 2004 increased 8% relative to 2003. Within the U.S., and Canadian markets, our therapeutic focus areas are cardiovascular disease (including Type II diabetes), CNS disorders and pain management. We also maintain the flexibility to exploit niche markets, as we have with our Zovirax® products for the treatment of herpes.

Our current portfolio of commercial products is heavily weighted to cardiovascular products, including those for the treatment of hypertension, angina, congestive heart failure and acute myocardial infarction. According to IMS, the U.S. market for cardiovascular products was valued at \$34.4 billion in 2004, of which \$16.2 billion was represented by anti-hypertensives. In 2004, our commercial portfolio of cardiovascular therapeutic products in the U.S. included Cardizem® LA (now promoted by Kos), Cardizem® CD, Tiazac®, Vasotec®, Vasoretic®, Teveten® (sold to Kos in May 2005), Teveten® HCT (sold to Kos in May 2005), Isordil®, and a number of generic pharmaceutical products.

In terms of direct selling in the U.S., we have a commercial presence in the herpes market—a market that was valued at \$1.3 billion in 2004—through our Zovirax® Ointment and Zovirax® Cream (launched in 2004) products. The Zovirax® line was recently designated the most widely recognized anti-viral brand in the U.S. by pharmaceutical industry publication *MedAd News*. Within the topical herpes market, Zovirax® held 64.8% share at the end of 2004. However, oral therapeutic products for herpes represent the vast majority of the overall herpes market, with 2004 sales of \$1.1 billion.

CNS disorders represent another of our therapeutic focus areas. According to IMS, the U.S. market for the treatment of CNS was valued at \$16.6 billion in 2004, with the majority—\$13.6 billion—represented by anti-depressants. Our commercial portfolio in these markets includes a once-daily formulation of bupropion sold by GSK as Wellbutrin XL® and Ativan®. Our development pipeline includes a focus on products for the treatment of CNS disorders.

We also market products directly in Canada through BPC, our Canadian marketing and sales division. The Canadian pharmaceutical market was valued by IMS at C\$17.3 billion in 2004. Similar to our U.S. strategy, BPC's therapeutic focus lies in cardiovascular disease (including Type II diabetes), CNS disorders, markets valued at C\$2.4 billion, C\$100 million, respectively. BPC's sales force consists of 78 representatives, which currently target approximately 9,000 physicians across the country. During 2004,

the anti-hypertensive/anti-angina medication Tiazac® was BPC's leading product, representing approximately 47% of our total Canadian product revenues.

We also have a significant presence in generic pharmaceuticals, an industry valued by IMS at \$41.3 billion in 2004, an 11% increase relative to 2003. Our focus in this segment has been on the development of generic formulations of branded controlled-release products, where the competitiveness and price discounting is significantly less than in the immediate-release generic market. Our generic pharmaceuticals, with the exception of Tiazac®, which is supplied to Forest in the U.S. are distributed by a subsidiary of Teva, originally signed in 1997, and extended and expanded in 2004. Although generic products are no longer strategic to our business going forward, we do have the ability to selectively pursue attractive opportunities within this market.

We own the U.S. rights to a number of pharmaceutical branded products that are not actively promoted. For the most part, these are products that have been genericized and generate revenue streams that are declining at reasonably predictable rates. These "legacy" products include Cardizem® CD, Ativan®, Isordil®, Tiazac®, Vasotec® and Vaseretic®. We are currently evaluating a number of options to better realize the value of our portfolio of legacy products.

We currently have several pipeline products either being reviewed (or recently reviewed) by the FDA or TPD targeting pain management and Type II diabetes. In addition, we have a number of pipeline products in these therapeutic areas currently in various stages of development. According to IMS, the U.S. markets for these indications were valued at \$14.3 billion and \$6.0 billion, respectively, for the 12 months ended March 31, 2005.

While our business focus is to develop products for the U.S. and Canadian markets, several of our products have been commercialized globally through licensing agreements with strategic marketing partners with expertise in their local markets. As in the past, we anticipate the commercialization of select pipeline products in global markets through strategic partners.

**Revenue Sources Products**

The following table summarizes our 2004 commercial product line:

<b>Product</b>	<b>Therapeutic Area</b>	<b>Indications</b>	<b>Therapeutic Market Size*</b>
<b>U.S. Promoted Products</b>			
Cardizem® LA <sup>(1)</sup>	Cardiovascular	Hypertension/angina	\$16.2 billion
Teveten® <sup>(2)</sup>	Cardiovascular	Hypertension	\$16.2 billion
Teveten® HCT <sup>(2)</sup>	Cardiovascular	Hypertension	\$16.2 billion
Zovirax® Cream	Antiviral	Herpes labialis (cold sores)	\$1.3 billion
Zovirax® Ointment	Antiviral	Genital herpes	\$1.3 billion
<b>Promoted/Distributed by Biovail Pharmaceuticals</b>			
<b>Canada</b>			
Tiazac®	Cardiovascular	Hypertension/angina	\$2.0 billion
Tiazac® XC	Cardiovascular	Hypertension	\$2.0 billion
Wellbutrin® SR	CNS	Depression	\$781 million
Monacor	Cardiovascular	Hypertension	\$2.0 billion
Retavase®	Cardiovascular	Acute myocardial infarction	\$43 million
Zyban®	CNS	Smoking cessation	\$96 million
Cardizem® CD	Cardiovascular	Hypertension/angina	\$2.0 billion
<b>Distributed by Partners</b>			
Tiazac® <sup>(3)</sup>	Cardiovascular	Hypertension/angina	\$16.2 billion
Wellbutrin® XL <sup>(4)</sup>	CNS	Depression	\$13.6 billion
<b>Legacy Products</b>			
Cardizem® CD	Cardiovascular	Hypertension/angina	\$16.2 billion
Ativan®	CNS	Anxiety	\$0.9 billion
Tiazac®	Cardiovascular	Hypertension	\$16.2 billion
Vasotec®	Cardiovascular	Hypertension/congestive heart failure	\$16.2 billion
Vaseretic®	Cardiovascular	Hypertension/congestive heart failure	\$16.2 billion
Isordil®	Cardiovascular	Angina	\$0.3 billion
<b>Bioequivalent (generic) Products</b>			
Adalat CC (nifedipine extended release) <sup>(5)</sup>	Cardiovascular	Hypertension/angina	\$16.2 billion
Cardizem® CD (diltiazem controlled release) <sup>(5)</sup>	Cardiovascular	Hypertension/angina	\$16.2 billion
Procardia XL (nifedipine extended release) <sup>(5)</sup>	Cardiovascular	Hypertension/angina	\$16.2 billion
Tiazac® (diltiazem) <sup>(6)</sup>	Cardiovascular	Hypertension/angina	\$16.2 billion
Trental (pentoxifylline) <sup>(5)</sup>	Cardiovascular	Peripheral vascular disease	\$0.2 billion
Voltaren XR (diclofenac controlled release) <sup>(5)</sup>	Inflammation	Arthritis	\$8.5 billion

\*

Market size according to IMS

(1)

As of May 2005, Cardizem® LA is promoted by Kos Pharmaceuticals Inc.

(2)

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In May 2005, we sold Teveten® and Teveten® HCT to Kos Pharmaceuticals Inc.

- (3) Tiazac® is distributed by Forest Laboratories, Inc. in the United States.
- (4) Wellbutrin XL® is a once-daily formulation of bupropion developed by us and marketed by GSK in the U.S.
- (5) Distributed by Teva.
- (6) Distributed by Forest.

We have capabilities in all aspects of the drug-development process from formulation and development to clinical testing, regulatory filing, manufacturing, marketing and distribution. This



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integrated approach results in operational synergies, increased flexibility and enhanced cost efficiencies. In 2004, we reported our product revenue based on the following five categories:

1. U.S. Promoted products;
2. Wellbutrin XL®;
3. Biovail Pharmaceuticals Canada
4. Legacy products; and
5. Generics.

Within the U.S. Promoted products category, we provided detail pertaining to product revenues for Cardizem® LA, the Teveten® line and the Zovirax® line. We also report a subtotal of core products which includes Promoted products, Wellbutrin XL® and BPC, as this represents the part of our business that we either actively promote and/or have organically developed, and manufactured for and supplied to, third parties who actively promote them.

The following table summarizes our product revenues for the fiscal years of 2004 and 2003:

Product / Product Line	Revenues (\$000)		Change %	% of Product Revenues	
	2004	2003		2004	2003
Cardizem® LA	53,625	47,743	12	6	8
Teveten®	17,600	22,241	(21)	2	4
Zovirax®	75,451	102,434	(26)	9	16
<b>U.S. Promoted Products Subtotal</b>	146,676	172,418	(15)	17	27
Wellbutrin XL®	317,298	64,932	389	38	10
Biovail Pharmaceuticals Canada	101,865	85,197	20	12	13
<b>Core Products Subtotal<sup>(1)</sup></b>	565,839	322,547	75	67	51
Legacy products	125,932	208,860	(40)	15	33
Generic products	149,675	101,491	47	18	16
<b>Total Product Revenues</b>	841,446	632,898	33	100	100

Represents U.S. Promoted products, Wellbutrin XL® and products of BPC.

### U.S. Promoted Products

This category refers to the group of products that we, through Biovail Pharmaceuticals, Inc. ("BPI") our wholly owned U.S. subsidiary, actively promoted in the U.S. in 2004. These products were Cardizem® LA, a novel, graded, extended-release formulation of diltiazem that provides 24-hour blood-pressure control with a single daily dose; Teveten®, an angiotensin-II receptor blocker ("ARB") that blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT<sub>1</sub> receptor found in many tissues; Teveten® HCT, a combination of Teveten® and the diuretic hydrochlorothiazide; Zovirax® Ointment, a topical formulation of a synthetic nucleoside analogue active against herpes viruses; and Zovirax® Cream, a topical antiviral medication used for the treatment of herpes labialis (cold sores).

In May 2005, we sold Teveten® and Teveten HCT® to Kos, and no longer have any financial interest in these products. We also entered into a manufacturing and supply agreement with Kos for Cardizem® LA, whereby we maintain a significant ongoing interest in the product's success (see "Three-Year History Material Developments"). Following the May 2005 realignment of our U.S. commercial operations and



our strategic alliance with Kos, our U.S. field force consists of 85 professionals that detail Zovirax Ointment and Zovirax® Cream to dermatologists and OB-GYNs in the U.S. These specialist physician populations represent an important target audience for BPI, as the prescribing patterns of specialists can influence those of primary-care physicians. The Zovirax® brand was recently identified as the most-recognized antiviral brand in North America by *MedAd News* (January 2005). It is our intention to expand into additional specialty markets as pipeline opportunities and business-development activities warrant.

***Cardizem® LA (diltiazem)***

Cardizem® branded products have been leading medications in the calcium channel blocker ("CCB") category of cardiovascular drugs for more than 20 years. In 2004, the CCB market was valued at \$4.4 billion, of which once-daily diltiazem products represented \$745 million. These once-daily products generated 18.8 million prescriptions in the U.S. in 2004, of which 11.8 million were written for Cardizem®, representing a market of \$494 million, including generics.

In April 2003, BPI launched Cardizem® LA. Cardizem® LA is a novel, graded, extended-release formulation of diltiazem HCl that provides 24-hour blood-pressure control with a single daily dose and offers physicians a flexible dosing range from 120mg to 540mg. 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 improved 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. Kos. now promotes Cardizem® LA pursuant to the May 2005 manufacturing and supply agreement between the two companies.

***Teveten® (eprosartan) and Teveten® HCT (eprosartan-hydrochlorothiazide)***

Teveten® is indicated for the treatment of hypertension (high blood pressure). Teveten® belongs to a class of antihypertensive drugs known as ARBs. Total U.S. sales for all ARBs in 2004 were \$4.4 billion. Teveten® blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT<sub>1</sub> receptor found in many tissues (e.g., vascular smooth muscle, adrenal gland). Solvay Pharmaceuticals Marketing and Licensing AG ("Solvay") first launched Teveten® in November 1999. We acquired the U.S. marketing rights to Teveten® and Teveten® HCT in March 2002. BPI re-launched Teveten® in the U.S. market in June 2002. In March 2003, BPI launched Teveten® HCT, a combination of Teveten® and the diuretic hydrochlorothiazide. In May 2005, we divested the Teveten® and Teveten® HCT products to Kos.

***Zovirax® Ointment/Zovirax® Cream (acyclovir)***

Zovirax® Ointment 5% is a topical formulation of a synthetic nucleoside analogue active against herpes viruses. Each gram of Zovirax® Ointment contains 50mg of acyclovir in a polyethylene glycol base. This product is indicated in 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 was not promoted by Glaxo Wellcome, and subsequently GSK, since 1997, Zovirax® Ointment remains the market leader with approximately a 50% share of total prescriptions for topical anti-herpes products in 2004.

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). The Zovirax® product line had a 64.8% share of the total prescriptions for topical anti-herpes products at the end of 2004.

**Wellbutrin XL® (bupropion hydrochloride)**

Launched in September 2003 by GSK, Wellbutrin XL®, an extended-release bupropion indicated as first-line therapy for the treatment of depression in adults, has been well received by U.S. physicians, and at the end of 2004, had captured 54.8% of all bupropion prescriptions. Pursuant to our manufacturing-and-supply agreement with GSK, we receive a three-tiered supply price that is based on GSK's net sales of Wellbutrin XL® in any given year. The tier thresholds increase and are reset at the beginning of each calendar year. In the lowest tier, we receive a supply price of less than 25% of GSK's net sales price. In the second tier, the supply price escalates to a value between 25% and 30% of GSK's net sales price. In the highest tier, the supply price is greater than 30% of GSK's net sales price. In 2004, Wellbutrin XL® was a key revenue driver for us as the product supply price entered the second tier of the pricing agreement in the second quarter and entered the third tier in the third quarter. In 2005, we anticipate reaching the higher thresholds at approximately the same times as in 2004.

**Biovail Pharmaceuticals Canada**

BPC's head office is located at our corporate headquarters in Mississauga, Ontario, Canada. BPC, our Canadian marketing and sales division, is dedicated to providing high-quality, cost-effective branded pharmaceuticals to Canadian health-care professionals and their patients. BPC's 78-member sales force currently detail select products to approximately 9,000 physicians across Canada. In addition to marketing products that we have developed, BPC has adopted a business strategy of selling in-licensed branded drug products. We believe that this strategy, combined with our portfolio of existing and new branded products utilizing our advanced drug-delivery technologies, well positions BPC in the Canadian pharmaceutical market.

BPC's strategy is to focus on drugs and therapies for the primary-care market, including drugs for the treatment of cardiovascular and CNS diseases. Both therapeutic areas represent rapidly growing market segments. Products within the BPC portfolio include Tiazac®, Tiazac® XC (launched January 2005), Wellbutrin SR®, Zyban®, Cardizem® CD, Retavase® and Monacor®. In 2004, BPC's sales force actively promoted Tiazac®, Wellbutrin SR® and Retavase®. Zyban®, a prescription product indicated for use in smoking cessation, was detailed through direct marketing activities. We anticipate leveraging the name recognition of the Wellbutrin® brand with the future launch of Wellbutrin XL® in Canada.] In January 2005, BPC formally launched Tiazac® XC to physicians in Canada; pre-launch activities, including pre-stocking of wholesalers, began in late 2004. BPC anticipates commercializing Glumetza®, a metformin-based treatment for Type II diabetes which received a Notice of Compliance ("NOC") from the TPD in June 2005, in the fourth quarter of 2005.

***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. According to IMS, the Canadian market for CCBs for 2004 was valued at approximately C\$632 million, an increase of 9.6% versus the previous year. At the end of 2004, Tiazac® held a 49.5% share of the once-daily diltiazem market. In August 2004, we received TPD approval for Tiazac® XC for the treatment of hypertension. Tiazac® XC is a novel, graded-release formulation of diltiazem taken at bedtime 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. As of the date of this document, we have received notification of formulary coverage in Quebec, Ontario, Manitoba, Saskatchewan and Alberta, with other provinces expected over the coming weeks. In addition, we have received formulary coverage on Health Canada's largest drug plan, the Non-Insured Health Benefit ("NIHB") program.

In August 2004, we filed a sNDS with the TPD for Tiazac® XC for the angina indication. The TPD accepted the file for review in late October 2004. In March 2005, we received a Notice of Non-Compliance from the TPD, citing deficiencies in the submission. In June 2005, we submitted a Complete Response to the Notice of Non-Compliance, within the 90-day time line set by the TPD.

***Wellbutrin SR® (bupropion)/Zyban® (bupropion)***

Biovail acquired the Canadian rights to Wellbutrin SR® and Zyban® from GSK in December 2002. Wellbutrin SR® (sustained-release bupropion) is indicated as first-line therapy for the treatment of depression. Wellbutrin®'s anti-depressant activity appears to be mediated by noradrenergic and dopaminergic mechanisms making it different than selective serotonin reuptake inhibitors ("SSRIs") and other known anti-depressant agents. In addition to anti-depressant efficacy, Wellbutrin® provides patients with the additional benefits of increased cognition and motivation and 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.

In 2003, GSK Canada marketed Wellbutrin SR® and Zyban® in Canada under contract for BPC, as our detailing efforts were focused on Celexa pursuant to a co-promotion agreement with H. Lundbeck A/S. With the termination of the Celexa agreement at the end of 2003, BPC assumed full responsibility for Wellbutrin SR®, and has been detailing the product since January 1, 2004. According to IMS, Canadian market for anti-depressants was valued at C\$781 million in 2004, a decrease of 2.2% over the previous year. In January 2005, we became aware that a formulation of generic Wellbutrin SR® had received an NOC, clearing the path for the product's introduction. To date, we understand that the distribution of this product has been limited to pharmacies in Ontario and British Columbia.

In February 2005, we submitted an sNDS to the TPD for Wellbutrin XL®. The file, which contained the results of two adequate and well-controlled trials in major depressive disorder, as well as other supporting clinical data, was accepted for review in late March 2005. Subject to final TPD approval, we expect to commercialize Wellbutrin XL® in Canada in 2007.

Zyban® is marketed through non-sales force-mediated, direct-marketing activities. According to IMS, the 2004 Canadian ethical drug market for smoking-cessation aids is estimated at C\$96 million.

***Monacor® (bisoprolol fumarate)***

Monacor® is a cardio-selective beta-blocker indicated for the treatment of mild to moderate hypertension and congestive heart failure. Monacor® first faced generic competition in July 2003. The beta-blocker market in Canada was valued at approximately C\$207 million in 2004.

***Retavase® (reteplase recombinant)***

Retavase®, licensed from Centocor Inc., is a tissue plasminogen activator used in thrombolytic therapy. The medication is administered to patients immediately after the incidence of acute myocardial infarction ("AMI" or heart attack) and acts to clear arterial blockage. The fibroanalytic market in Canada for 2004 was estimated to be approximately C\$43 million, which reflects a market shift away from fibrinolytics.

**Legacy Products**

This category includes the U.S. products that are not actively promoted. For the most part, these are products that have been genericized and generate revenue streams that are declining at reasonably predictable rates. The products in this reporting category are Cardizem® CD, Ativan®, Tiazac® Vasotec®, Vaseretic® and Isordil®. We are currently evaluating a number of options to better realize the value of our portfolio of legacy products. These products generate significant cash flow; however, prescriptions filled by

our legacy products continue to decline. These products negatively affect our revenue and EPS growth and are not strategic to our business, which is focused on long-term, sustainable growth. The options we are considering include a sale of these products to strategic or financial buyers, the transfer of the assets to a new entity and the sale of shares of that entity pursuant to an initial public offering or a distribution to our shareholders. We continue to evaluate options in this regard.

***Cardizem® CD (diltiazem)***

Cardizem® products have been leading medications in the CCB category of cardiovascular drugs for more than 20 years. In 2004, the CCB market was valued at \$4.4 billion, of which once-daily diltiazem products represented \$745 million. These once-daily products generated 18.8 million prescriptions in the U.S. in 2004, of which 11.8 million were written for Cardizem®, representing a market of \$494 million, including generics.

***Ativan® (lorazepam)***

Ativan® is a 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 in June 2003. Under the terms of the agreement, Wyeth will manufacture and supply the product for three years from the date of acquisition. The market for anxiety treatments was in excess of \$923 million for 2004, with Ativan® (lorazepam) generating 23.1 million prescriptions. Sales of benzodiazepine products were in excess of \$689 million for 2004. We are currently developing an ODT formulation of Ativan®.

***Tiazac® (diltiazem)***

Tiazac® belongs to a class of drugs called CCBs, used in the treatment of hypertension and angina, which generated sales in the U.S. of \$4.4 billion for the 12 months ended December 31, 2004. Within the CCB market, once-daily diltiazem products accounted for approximately \$745 million of this total. After being introduced in the U.S. in February 1996, Tiazac® reached a peak market share of 21.1% (measured as a percentage of total prescriptions for once-daily diltiazem products) in 2002. At December 31, 2004, this figure was 4% as the product competed against its first generic competitors in April 2003.

In 1995, 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 contractually determined supply price and Forest pays us a royalty payment on net sales of Tiazac®. Upon the onset of generic competition for Tiazac® in the United States, we launched a competing generic version through Forest under a variable supply price arrangement.

***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. Vasotec® is the maleate salt of enalapril, the ethyl ester of a long-acting angiotension converting enzyme ("ACE") inhibitor, enalaprilat. Enalapril is a pro-drug; following oral administration, it is bio-activated by hydrolysis of the ethyl ester to enalaprilat, which is the active ACE inhibitor. Vaseretic® combines Vasotec® and a diuretic, hydrochlorothiazide. The product is also indicated for the treatment of hypertension.

In 2004, the ACE inhibitor market had total sales of approximately \$3.9 billion with 144 million total prescriptions dispensed, a 5% increase over the previous year. Vasotec® (branded and generic) is one of the most widely prescribed ACE inhibitors and is one of the top five most recognized cardiovascular brands. Vasotec® lost its market exclusivity in August 2000 and its revenues have since been eroded by generic competition. Nevertheless, in 2004, there were 16.9 million prescriptions written for enalapril.

**Isordil® (isosorbide dinitrate)**

Isordil® (isosorbide dinitrate), a coronary vasodilator, is indicated for the prophylaxis of ischemic heart pain associated with coronary insufficiency (angina pectoris). We acquired U.S. marketing rights to Isordil® from Wyeth in June 2003. Under the terms of the agreement, Wyeth will manufacture and supply the product for three years from the date of acquisition. 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.

Sales of nitrate products were approximately \$264 million for 2004. Total prescriptions for orally administered nitrates were in excess of \$24 million in 2004.

**Generic Products**

This category is comprised of those products that are distributed in the U.S. for Biovail by Teva. In 2004, these included bioequivalent formulations of Cardizem® CD, Adalat CC®, Procardia XL®, Voltaren XR® and Trental®. In September 2004, we resolved arbitration proceedings initiated by us in 2004 against Teva and renegotiated certain aspects of the agreement. Amendments include an extension of the agreement by a period of four years (on a product by-product basis) and the sale of two development-stage ANDA programs to Teva. Furthermore, we renegotiated financial terms such that we now receive higher selling prices on all products within the portfolio.

The primary products in our controlled-release generics portfolio Cardizem® CD, Adalat CC and Procardia XL represent technically challenging products to formulate. These technological barriers may inhibit others from developing generic version of the products. This competitive landscape allows for pricing flexibility, mitigating the price discounting that can often reach 90% in the generic pharmaceuticals industry.

**Other Revenue**

Beyond the development, manufacture and distribution of pharmaceutical products, we also provide research, development and clinical contract research services to third parties. In 2004, the provision of these services generated revenues of \$20.5 million, compared with \$14.2 million in 2003. We also generate revenues related to the sale of a number of our controlled-release products by third parties. We have also, in the past, generated revenue by promoting and/or co-promoting products on behalf of third parties. In 2004, these efforts resulted in revenues of \$24.6 million, compared with \$176.6 million in 2003.

**Significant Customers**

The following table identifies external customers that accounted in 2004 for 10% or more of the Company's total revenue:

	Percentage of Total Revenue		
	2004 %	2003 %	2002 %
Customer A	36	9	7
Customer B	17	13	23
Customer C	13	17	11

**Product-Development Pipeline**

We are developing clinically enhanced, branded versions of a number of pharmaceutical compounds.

In 2004, our development efforts resulted in the filing of four NDAs. These included Tramadol ER (once-daily tramadol), Tramadol ODT, Citalopram ODT and Glumetza . In October 2004, we received an Approvable Letter from the FDA, a letter indicating that provided certain conditions are satisfied, the formulation may be approved, for Tramadol ER, and in March 2005, submitted a Complete Response, a document that responds to the FDA's comments/requests for information in an Approvable Letter. We received notification from the FDA on March 29, 2005 that our Complete Response will be treated as a Class II review, therefore subject to a six-month review, and that they are of the opinion that additional clinical data will be required. We are proceeding with a clinical program in response to the FDA's comments.

In November 2004, we submitted a Complete Response to the FDA Approvable Letter for Zolpidem ODT, and in May 2005 received tentative FDA approval. Final approval for zolpidem ODT cannot be made effective until the expiration of patent protection for Ambien in October 2006, which is held by Sanofi-Aventis.

In January 2005, Biovail received an Approvable Letter for Tramadol ODT, which involved the resolution of routine matters. A Complete Response was filed in March 2005, and final FDA approval was received in May 2005. At this time, we is in late-stage discussions with potential strategic partners to commercialize these pain products.

In February 2005, the FDA issued an Approvable Letter for Citalopram ODT, which involved the clarification of a number of chemistry and manufacturing issues. On June 23, we submitted a Complete Response to the FDA to address these issues.

In late-February 2005, Biovail and our partner Depomed Inc. of Menlo Park, California, received an Approvable Letter from the FDA for Glumetza . In April 2005, we submitted a Complete Response to the FDA, and in June 2005, received FDA approval. We are currently in discussions with potential partners to commercialize this product in the U.S. In Canada, Glumetza received TPD approval in June 2005, 14 months after submission of the application. BPC expects to launch the product in the fourth quarter of 2005.

Other pipeline products are in various stages of development. Despite the reduced risk profile of our pipeline programs (relative to NCEs), they do carry some residual development risk, and as such, we do not anticipate the commercialization of all of these products. In addition, we routinely review and prioritize our pipeline as new products are added, which can result in the discontinuation or delay of lower-priority development programs. This is a normal course of business in the pharmaceutical industry. As a result of this review, we discontinued our development efforts related to Vasotec® XL in 2004, and in 2005, for an oral formulation of acyclovir a product that we had licensed from Flamel Technologies SA.

Given that the successful development of any pipeline program is dependent on a number of variables, it is difficult to accurately predict timelines for regulatory approval, and accordingly, clinical development expenses. However, we have historically incurred research-and-development expenses in the range of approximately 7% to 12% of total revenues.



**Selected Development Pipeline Products**

Our new product-development efforts are subject to the process and regulatory requirements of the TPD (in Canada) and the FDA (in the U.S). Since we focus on enhanced formulations of existing drugs (with well-established safety and efficacy profiles), the development path we face is generally less onerous than that facing companies pursuing NCEs. The flow-chart below summarizes the steps required to bring our pipeline products to market.

<b>Product</b>	<b>Indication</b>	<b>Current Status</b>
<b>Pain Management</b>		
Tramadol ODT	Pain	FDA Approved
Tramadol ER	Pain	FDA Approvable Letter
Tramadol / Acetaminophen ODT	Pain	Under Development
Tramadol / NSAID combination	Pain/Inflammation	Under Development
Sumatriptan ODT	Migraine	Under Development
<b>Cardiovascular</b>		
Glumetza (Metformin)	Type II Diabetes	FDA/TPD Approval
Vasotec® / Cardizem® LA combination	Hypertension	Under Development
Teveten® SB (eprosartan)	Hypertension	Under Development
Metoprolol ER / ACE Inhibitor combination	Hypertension / AMI	Under Development
Carvedilol CR	CHF / Hypertension	Under Development
<b>Central Nervous System</b>		
Zolpidem ODT	Sleep Disorders	Tentative FDA Approval <sup>(1)</sup>
Citalopram ODT	Depression	FDA Approvable Letter
Fluoxetine ODT	Depression	FDA Approvable Letter
Venlafaxine EA	Depression	Under Development
Wellbutrin XL®	Depression	TPD Review
Bupropion/Venlafaxine Combination	Depression	Under Development
Wellbutrin XL® 450 mg (bupropion)	Depression	Under Development
Bupropion XL Line Extension (bupropion)	Depression	Under Development
Ativan® ODT (lorazepam)	Anxiety	Under Development

\*

Biovail is currently developing a number of undisclosed and other pipeline products.

(1)

Final approval for Zolpidem ODT cannot be made effective until the expiration of patent protection for Ambien in October 2006.

**Pain Management*****Tramadol ODT and Tramadol ER***

A four-to-six-times-daily, immediate-release formulation of tramadol, introduced in March 1995 by Johnson & Johnson ("J&J"), is sold in the U.S. under the brand name Ultram. In June 2002, generic competitors were introduced in the U.S. and now dominate the molecule's total prescription volume. In 2004, the U.S. tramadol market (including Ultram, its generics and Ultracet – a combination product consisting of tramadol and acetaminophen) was valued at approximately \$439 million, representing a total of 18.9 million prescriptions. Of this, according to IMS, Ultracet generated revenues of \$318 million and total prescriptions of 5.9 million.

*Indication:* Tramadol is indicated for the treatment of moderate to moderately severe pain a common symptom of many diseases, and generally seen in everyday clinical practice.

*Clinical Efficacy:* Tramadol is one of a number of analgesics, which are among the most effective and valuable medications for the treatment of chronic pain. Tramadol's minimal propensity to induce adverse effects is an advantage over other morphine-like agents. For example, relative to morphine, tramadol causes less dependence and less respiratory depression. Tramadol also appears to be a promising drug for post-operative pain relief.

Two long-term safety studies conducted on patients with chronic, non-malignant pain demonstrated the efficacy of the tramadol compound in a variety of pain conditions.

*Potential Enhancement:* Beyond the therapeutic and compliance benefits of once-daily dosing (relative to the current formulations that are dosed up to six times daily) that our products may offer, our Tramadol ER product could potentially feature an improved titration regimen. With respect to Tramadol ODT, the orally disintegrating tablets offer enhanced patient compliance, convenience and potentially other benefits, particularly for those patients who have difficulty swallowing, including the elderly, who are more likely to suffer from chronic pain.

*Status of Development:* In October 2004, Biovail received an Approvable Letter from the FDA for tramadol ER, and in March 2005, submitted a Complete Response. We received notification from the FDA on March 29, 2005 that our Complete Response will be treated as a Class II review, therefore subject to a six-month review, and that they recommended that additional clinical data be generated. We are proceeding with a clinical program to respond to the FDA's comments. We have indicated our desire to out-license Tramadol ER, and we are in late-stage negotiations with potential partners. In January 2005, Biovail received an Approvable Letter for Tramadol ODT, which involved the resolution of routine matters. A Complete Response was filed in March 2005, and final FDA approval was received in May 2005. At this time, we are in late-stage discussions with potential strategic partners to commercialize this product.

*Market Size:* The combined market for narcotic and non-narcotic analgesics generated U.S. sales of \$14.7 billion for 2004. This broader market includes the Cox-2 inhibitors such as Celebrex and Vioxx, in addition to narcotic products such as Oxycontin, Duragesic and Percocet.

#### ***Tramadol / Acetaminophen ODT Combination***

A four-to-six-times-daily, immediate-release combination product of tramadol and acetaminophen was introduced in the U.S. in September 2001 by Johnson & Johnson ("J&J") under the brand name Ultracet. In 2004, the U.S. tramadol market (including Ultram, its generics and Ultracet) was valued at approximately \$439 million, representing a total of 18.9 million prescriptions. Of this, according to IMS, Ultracet generated revenues of \$318 million and total prescriptions of 5.9 million.

*Indication:* The combination of tramadol and acetaminophen is indicated for the short-term (five days or less) management of acute pain a common symptom of many diseases, and generally seen in everyday clinical practice.

*Clinical Efficacy:* In pivotal single-dose studies conducted by the innovator in acute pain, two tablets of Ultracet administered to patients with pain following oral surgical procedures provided greater relief than placebo or either of the individual components given at the same dose. The onset of pain relief after Ultracet was faster than tramadol alone. Onset of analgesia occurred in less than one hour. The duration of pain relief after Ultracet was longer than acetaminophen alone. Analgesia was generally comparable to that of the comparator, ibuprofen.

*Potential Enhancement:* Our orally disintegrating tablets may offer compliance, convenience and potentially other benefits, particularly for those patients who have difficulty swallowing, including the elderly, who are more likely to suffer from chronic pain.

*Status of Development:* This product is currently in the formulation development stage.

*Market Size:* The combined market for narcotic and non-narcotic analgesics generated U.S. sales of \$14.7 billion for the 12 months ended December 31, 2004. This broader market includes the Cox-2 inhibitors such as Celebrex and Vioxx, in addition to narcotic products such as Oxycontin, Duragesic and Percocet.

#### ***Tramadol / NSAID Combination***

A four to six-times daily immediate release formulation of tramadol, introduced in March 1995 by J&J, is sold in the U.S. under the brand name Ultram. In June 2002, generic competitors were introduced in the U.S. and now dominate the molecule's total prescription volume. In 2004, the U.S. tramadol market (including Ultram, its generics and Ultracet – a combination product consisting of tramadol and acetaminophen) was valued at approximately \$439 million, representing a total of 18.9 million prescriptions. Non-steroidal anti-inflammatory drugs, or ("NSAIDs"), are used to relieve symptoms associated with arthritis, such as inflammation, swelling, stiffness, and joint pain. In 2004 the U.S. NSAID market was valued at \$2.1 billion, representing a total of 88.2 million prescriptions.

*Indication:* Tramadol is indicated for the treatment of a moderate to moderately severe pain – a common symptom of many diseases, and generally seen in everyday clinical practice. NSAIDs are used primarily to treat inflammation, mild to moderate pain, and fever. Specific uses include the treatment of headaches, arthritis, sports injuries, and menstrual cramps. Aspirin, an NSAID, is used to inhibit the clotting of blood and prevent strokes and heart attacks in individuals at high risk. NSAIDs also are included in many cold and allergy preparations.

*Clinical Efficacy:* Tramadol is one of a number of analgesics, which are among the most effective and valuable medications for the treatment of chronic pain. Tramadol's minimal propensity to induce adverse effects is an advantage over other morphine-like agents. For example, relative to morphine, tramadol causes less dependence and less respiratory depression. Tramadol also appears to be a promising drug for post-operative pain relief. NSAIDs block the activity of cyclooxygenase ("Cox") enzymes and reduce prostaglandins throughout the body, resulting in a decrease in inflammation, pain, and fever.

*Potential Enhancement:* The combination of Tramadol and an NSAID would provide physicians with a single-tablet option incorporating two separate classes of drugs – a centrally acting analgesic (tramadol) with an anti-inflammatory agent – providing a double-pronged approach to the management of pain and inflammation.

*Status of Development:* Our development program for a Tramadol / NSAID combination is currently in the formulation development stage.

*Market Size:* The combined market for narcotic and non-narcotic analgesics generated U.S. sales of \$14.7 billion for the 12 months ended December 31, 2004. This broader market includes the Cox-2 inhibitors such as Celebrex and Vioxx, in addition to narcotic products such as Oxycontin, Duragesic and Percocet.

#### ***Sumatriptan ODT***

Sumatriptan is a 5-HT<sub>1</sub>-receptor agonist (commonly referred to as "triptans") marketed in the U.S. by GSK under the brand name Imitrex. In 2004, the product generated U.S. revenues of \$1.1 billion, with over 5.9 million prescriptions dispensed.

*Indication:* Sumatriptan is indicated for the acute treatment of migraine attacks with or without aura in adults.

*Clinical Efficacy:* The efficacy of Imitrex tablets in the acute treatment of migraine headaches was demonstrated in three randomized, double-blind, placebo-controlled studies conducted by the innovator. In all three trials, the percentage of patients achieving headache response two and four hours after treatment was significantly greater among patients taking Imitrex at all doses, compared with those who received a placebo.

*Potential Enhancement:* The FlashDose® technology may provide the convenience of enabling administration of sumatriptan with or without water. In addition, unlike other Triptans in ODT form, our formulation does not show a significant prolongation of time to maximum concentration ("Tmax") compared to the immediate-release tablet.

*Status of Development:* We are in the process of conducting scale-up activities for this product.

*Market size:* In 2004, the U.S. anti-migraine market was valued at \$2.1 billion, representing a 4% increase over the prior year. More than 13.1 million prescriptions for these therapeutics were dispensed in 2004. Other products in this class include Amerge, Axert, Frova, Maxalt and Zomig.

### **Cardiovascular (Including Type II Diabetes)**

#### ***Glumetza (metformin)***

A two-to-three-times-daily, immediate-release formulation of metformin, introduced in April 1995 by Bristol-Myers Squibb Company ("BMS"), is sold in the U.S. under the brand name Glucophage. In October 2000, BMS introduced a controlled-release metformin formulation marketed as Glucophage XR. U.S. sales of Glucophage and Glucophage XR were approximately \$1.6 billion for 2004.

*Indication:* Metformin is indicated for the treatment of diabetes mellitus which cannot be controlled by proper dietary management, exercise and weight reduction or when insulin therapy is not appropriate. Diabetes is a common disorder in which there are inappropriately elevated blood glucose levels and a variety of end-organ complications leading to impaired kidney function and accelerated atherosclerosis.

*Clinical Efficacy:* Clinical advantages of metformin include achieving control of elevated blood-sugar levels without exacerbating weight gain, which is a common side effect of other anti-diabetic treatments. Metformin differs from the sulfonylureas in that it does not elevate insulin secretion and does not produce abnormally low blood-sugar levels.

In controlled trials conducted by the innovator, metformin has shown efficacy in lowering elevated blood-sugar levels in the treatment of diabetes mellitus. In one such study of 289 obese patients with non-insulin dependent diabetes, poorly controlled with diet, the patients were given metformin or a placebo. Blood-sugar levels were on average 29% lower in patients receiving metformin than in patients receiving a placebo. Furthermore, total cholesterol, low-density lipoprotein ("LDL") and triglyceride concentrations decreased in patients receiving metformin, but did not change in patients receiving a placebo.

*Potential Enhancement:* Our clinical program was conducted with a faster titration regimen, potentially allowing patients to get to their optimal dose more quickly.

*Status of Development:* In conjunction with our partner Depomed, we have successfully completed two large Phase III trials. In April 2004, we submitted an NDA to the FDA, and a NDS to the TPD for both a 500mg tablet (developed by Depomed) and a 1,000mg tablet (developed by Biovail). In February 2005, we received an Approvable Letter from the FDA that raised only a minor issue. We filed a Complete Response in April 2005, and in June 2005, received final FDA approval. We are currently in

discussion with several potential partners to market Glumetza in the U.S. In Canada, Glumetza received TPD approval in June 2005. BPC expects to launch the product in the fourth quarter of 2005.

*Market Size:* The Type II diabetes market represented approximately \$6.0 billion in U.S. sales for 2004, a 5% increase relative to the prior year. Other than Glucophage and its generics, Type II diabetes therapeutics include Glucotrol XL, Avandia and Actos. In Canada, Glumetza will be the first once-daily metformin formulation and will compete in the C\$300 million oral diabetes market.

***Vasotec® (enalapril) / Cardizem® LA (diltiazem) combination***

Enalapril is an ACE inhibitor originally launched in the U.S. in 1986 by Merck & Co., Inc. ("Merck") under the brand name Vasotec®. According to IMS, U.S. sales of Vasotec® and its generic equivalents were \$124 million for 2004. Cardizem® LA is a CCB that was developed by Biovail and launched in April 2003. Biovail reported Cardizem® LA revenues of \$53.6 million in 2004.

*Indication:* Vasotec® is indicated for the treatment of hypertension, symptomatic congestive heart failure, and asymptomatic left ventricular dysfunction. Cardizem® LA is indicated for the treatment of hypertension and angina.

*Clinical Efficacy:* Vasotec®, an ACE inhibitor, acts on the renin-angiotensin-aldosterone system ("RAAS"), inhibiting the conversion of Angiotensin I to Angiotensin II. This results in dilated blood vessels and lower blood pressure. Even in people with normal blood pressure, blocking the activation of angiotensin and dilating blood vessels is effective for treatment of the other conditions listed above.

Cardizem® LA, as a CCB, works by relaxing the coronary arteries and increasing the volume of blood that can circulate through them, thus reducing hypertension. With evening administration, clinical trials have shown Cardizem® LA improved 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 and stroke.

*Potential Enhancement:* The combination of Vasotec® and Cardizem® LA may provide physicians with a single-tablet option incorporating two separate classes of anti-hypertensive drugs, which target separate pathways important in the regulation of blood pressure.

*Status of Development:* Our development program for a Vasotec® / Cardizem® LA combination is currently in the formulation optimization stage. As part of our May 2005 agreement with Kos, the two companies will collaborate on the development of this program. An NDA filing is anticipated in the first half of 2007. Upon approval, Biovail will manufacture and supply the product to Kos for commercialization.

*Market Size:* The broader U.S. hypertension treatment market was valued at \$16.2 billion in 2004, a 9% increase relative to 2003. The ACE inhibitor market, which includes products such as Altace, Accupril, Lotensin, Vasotec® and Zestril, was valued at \$2.7 billion in 2004, a decrease of 13% relative to 2003, reflecting increased generic competition within the class. The CCB market, which includes products such as Norvasc, Cardizem® and Tiazac® was valued at \$4.4 billion in 2004, representing growth of 1% over 2003.

***Teveten® SB (eprosartan)***

Teveten®, an ARB, was approved by the FDA in December 1997 and launched by Solvay in 1999. In March 2002, Biovail acquired U.S. marketing rights to Teveten® and Teveten® HCT (a combination product of eprosartan and the diuretic hydrochlorothiazide from Solvay). Teveten® was not promoted by Solvay at the time of acquisition, and we re-launched Teveten® through our U.S. sales force in May 2002. Following FDA approval in February 2003, Teveten® HCT was launched in March 2003.

*Indication:* Teveten® is indicated for the treatment of hypertension.

*Clinical Efficacy:* The safety and efficacy of Teveten® have been evaluated in controlled clinical trials worldwide. The antihypertensive effects of Teveten® were demonstrated in five randomized studies involving 1,111 patients. At study endpoint, patients treated with Teveten® at doses of 600mg to 1,200mg given once daily experienced significant decreases in sitting systolic and diastolic blood pressure, with differences from placebo of approximately 5-10/3-6 mmHg. In August 2004, Solvay Pharmaceuticals AG released the results of the MOSES study a 1,400-patient trial comparing the efficacy of Teveten and nitrendipine (a leading CCB in Europe) in secondary stroke prevention and reducing cardiovascular and cerebrovascular morbidity and mortality. Despite producing equally effective reductions in blood pressure, there was a 20% greater reduction in the primary endpoint (total mortality and total cardiovascular and cerebrovascular events), a 25% greater reduction in the recurrence of stroke and associated disease, and a 30% greater reduction in first-time cardiovascular events in the Teveten® group vs. the nitrendipine group. All of these differences were statistically significant.

*Potential Enhancement:* An enhanced bioavailability formulation of Teveten® could allow a lower administered dose of the product, potentially reducing the size of the dosage form and improving our cost of goods for this product. This would also facilitate the development of additional combination products involving Teveten®.

*Status of Development:* Our development program for Teveten® SB is currently in bioavailability studies. Composition of matter patents protect the eprosartan compound until February 2010.

*Market Size:* The broader U.S. hypertension treatment market was valued at \$16.2 billion in 2004, a 9% increase relative to 2003. Within that market, ARBs represented the fastest-growing segment with revenues increasing 24% to \$4.4 billion. Other products competing in the ARB market include Diovan, Cozaar, Avapro and Benicar.

#### ***Metoprolol ER / ACE Inhibitor (undisclosed) combination***

Metoprolol is a beta 1-selective (cardio-selective) adrenoceptor blocking agent, or beta-blocker, originally launched in the United States in 1978. In February 1992, AstraZeneca launched a once-daily extended-release formulation of metoprolol under the brand name Toprol XL. In 2004, Toprol XL generated revenues of \$1.1 billion, with approximately 34 million prescriptions written, representing 58% of all metoprolol prescriptions (including generics).

*Indication:* Metoprolol is indicated for the treatment of hypertension, angina and heart failure. ACE inhibitors are indicated for the treatment of hypertension, symptomatic congestive heart failure, and asymptomatic left ventricular dysfunction.

*Clinical Efficacy:* Beta-blockers are a class of prescription drugs that counteract the stimulatory effects of adrenaline (epinephrine) on beta-receptors, which are found in many tissues of the body including the nervous system and heart. When beta-receptors are stimulated, the heart beats faster and harder and the blood vessels constrict, resulting in an elevation of blood pressure. If the coronary arteries are narrowed by atherosclerosis, the increased burden on the heart can cause inadequate oxygen delivery to the heart muscle (myocardium) itself, leading to the chest pain and other symptoms of angina pectoris. Metoprolol acts by suppressing these stimulatory impulses, resulting in the slowing of the heart rate and a reduction in blood pressure.

All ACE inhibitors act on the renin angiotensin aldosterone system ("RAAS"), inhibiting the conversion of Angiotensin I to Angiotensin II. This results in dilated blood vessels and lower blood pressure. Even in people with normal blood pressure, blocking the activation of angiotensin and dilating blood vessels is effective for treatment of the other conditions listed above.

*Potential Enhancement:* The combination of an extended-release metoprolol and an ACE inhibitor would provide physicians with a single-tablet option incorporating two separate classes of anti-hypertensive drugs, which target separate pathways important in the regulation of blood pressure.

*Status of Development:* Our development program for a metoprolol ER / ACE Inhibitor combination is currently in the formulation optimization stage.

*Market Size:* The broader U.S. hypertension treatment market was valued at \$16.2 billion in 2004, a 9% increase relative to 2003. The beta-blocker market, which includes products such as Coreg, Toprol XL, Tenormin and Inderal LA, was valued at \$1.9 billion in 2004, a 20% increase relative to 2003. The ACE inhibitor market, which includes products such as Altace, Accupril, Lotensin, Vasotec® and Zestril, was valued at \$2.7 billion in 2004, a decrease of 13% relative to 2003, reflecting increased generic competition within the class.

### ***Carvedilol CR***

Launched in 1997, Carvedilol is now marketed in the U.S. by GSK under the brand name Coreg. In 2004, the product generated U.S. revenues of \$850 million, representing growth of 37%, compared with the prior year period.

*Indication:* Carvedilol is indicated for the treatment of mild or moderate heart failure of ischemic or cardiomyopathic origin. Carvedilol is also indicated for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents.

*Clinical Efficacy:* Carvedilol belongs to a group of medicines called beta-adrenergic blocking agents, or more commonly, beta-blockers. These drugs work by decreasing the heart's need for blood and oxygen by reducing its workload. They also help the heart beat more regularly. When beta-receptors are stimulated, the heart beats faster and harder and the blood vessels constrict, resulting in an elevation of blood pressure.

The efficacy of Carvedilol as a treatment for heart failure was established in a total of 3,946 patients with mild to severe heart failure in placebo-controlled studies of Carvedilol conducted by the innovator. In the largest study, the COPERNICUS study, 2,289 patients with heart failure at rest or with minimal exertion and left ventricular ejection fraction <25% (mean 20%), despite digitalis (66%), diuretics (99%), and ACE inhibitors (89%) were randomized to placebo or Carvedilol. Carvedilol had a consistent and beneficial effect on all-cause mortality as well as the combined end points of all-cause mortality plus hospitalization in the overall study population and in all subgroups examined, including men and women, elderly and non-elderly, blacks and non-blacks, and diabetics and non-diabetics.

The efficacy of Carvedilol as a treatment for hypertension was established in two placebo-controlled trials that utilized twice-daily dosing.

*Potential Enhancement:* We are in the process of developing a formulation of Carvedilol with an improved 24-hour kinetic profile. Currently, Carvedilol is available in a twice-a-day formulation. Beyond convenience and compliance benefits, we believe an enhanced formulation of Carvedilol could potentially offer improved clinical benefit relative to the current in-market formulation.

*Status of Development:* Our development program for a Carvedilol CR is currently in the formulation optimization stage.

*Market Size:* The broader U.S. hypertension treatment market was valued at \$16.2 billion in 2004, a 9% increase relative to 2003. Within that market, alpha-beta blockers represented \$899 million in 2004, a 34% increase relative to 2003.

## Central Nervous System Disorders

### *Zolpidem ODT*

Zolpidem was launched in 1993 and is now marketed in the U.S. by Sanofi-Aventis under the brand name Ambien. In 2004, the product generated U.S. revenues of \$1.9 billion, representing growth of 20% relative to the prior year period.

*Indication:* Zolpidem is indicated for the short-term treatment of insomnia.

*Clinical Efficacy:* The safety and clinical efficacy of zolpidem has been evaluated in controlled clinical trials in transient insomnia and in chronic insomnia. Thirty-five normal elderly adults experiencing transient insomnia were evaluated in a double-blind, crossover, two-night trial comparing four doses of zolpidem (5mg, 10mg, 15mg and 20mg) and placebo. All zolpidem doses were superior to placebo on the two primary parameters (sleep latency and efficiency) and all four subjective outcome measures (sleep duration, sleep latency, number of awakenings, and sleep quality). Zolpidem was also shown to be effective in two controlled studies for the treatment of patients with chronic insomnia: a 75-patient double-blind, parallel group, five-week trial comparing zolpidem (10mg and 15mg) and placebo; and a 141-patient, double-blind, parallel group, four-week trial comparing zolpidem (10mg and 15mg) and placebo.

*Potential Enhancement:* The FlashDose® technology may provide the convenience of enabling administration of zolpidem with or without water, in addition to other potential advantages and benefits.

*Status of Development:* We filed an NDA with the FDA in December 2001 and received an Approvable Letter for this product in November 2002. In November of 2004, we filed a Complete Response to the FDA's Approvable Letter, and in May 2005, received tentative FDA approval. Final approval for Zolpidem ODT cannot be made effective until the expiration of patent protection for Ambien in October 2006, which is held by Sanofi-Aventis.

*Market Size:* The sleep disorder market in the U.S. was valued at \$2.1 billion for 2004. Ambien was the market leader with sales of \$1.9 billion during the same period. Other competitors include Lunesta (eszopiclone), Sonata, Restoril (brand and generics) and Halcion (brand and generics).

### *Citalopram ODT*

Citalopram is an SSRI introduced in the U.S. by Forest Labs in April 2000 under the brand name Celexa. According to IMS, Celexa (brand and generics) generated U.S. sales of \$1.0 billion for 2004 a 27% decrease relative to 2003, reflecting the introduction of generic formulations in 2004.

*Indication:* Citalopram is indicated for the treatment of depression. Incidences of major depression are frequently encountered by primary-care physicians. Depression may occur in neurosis as well as in mood disorders and is a manifestation of major psychiatric illness.

*Clinical Efficacy:* The efficacy of Celexa as a treatment for depression was established in two placebo-controlled studies (of four to six weeks in duration) in adult outpatients meeting diagnostic criteria for major depression.

*Potential Enhancement:* Our orally disintegrating formulation of citalopram could provide convenience and compliance benefits, particularly for geriatric patients that may have trouble swallowing tablets. The new dosage format may increase prescribing flexibility for physicians.

*Status of Development:* In February 2005, we received an Approvable Letter from the FDA that involves the clarification of a number of chemistry and manufacturing issues including issues related to a drug master file from one of our active pharmaceutical ingredients suppliers. On June 23, 2005 we submitted a Complete Response to the FDA to address these issues.



*Market Size:* Sales of anti-depressant products in the United States totaled \$13.6 billion for 2004. The anti-depressant market consists of four major drug categories: new-generation anti-depressants; SSRIs/SNRIs (selective serotonin reuptake inhibitors/selective norepinephrine reuptake inhibitors); tricyclic anti-depressants; and monoamine oxidase inhibitors. Major brands include Lexapro (escitalopram), Paxil (paroxetine), Zoloft (sertraline), Effexor XR (venlafaxine) and Wellbutrin®.

#### ***Fluoxetine ODT***

Fluoxetine is a SSRI introduced in the United States by Eli Lilly and Company ("Lilly") under the brand names Prozac, Prozac Weekly and Serafem, which is marketed by a subsidiary of Galen Holdings PLC. Fluoxetine was originally launched in January 1988 under the brand name Prozac. According to IMS, Prozac and its generic equivalents, generated U.S. sales of \$644.8 million for 2004, with 25.7 million prescriptions.

*Indication:* Fluoxetine is indicated for the treatment of depression, obsessive-compulsive disorder, panic disorder and bulimia.

*Clinical Efficacy:* The prevalence of depressive disorders in the general population is approximately 6%. Fluoxetine was the first SSRI anti-depressant to be introduced (January 1988). SSRIs are considered first-line treatment for major depressive disorders, panic disorders, social anxiety disorder and GAD. SSRIs have mainly replaced tricyclic anti-depressants and monoamine oxidase inhibitors in the treatment of depression because of their established efficacy, more favorable side-effect profile and wider therapeutic index, for instance lower potential for fatal overdose and drug interactions.

Our FlashDose® fluoxetine formulation is designed to provide patient flexibility, a reduction in adverse side effects and to provide greater patient compliance.

*Potential Enhancement:* Our orally disintegrating formulation of fluoxetine could provide convenience and compliance benefits, particularly for geriatric patients that may have trouble swallowing tablets. The new dosage format may increase prescribing flexibility for physicians.

*Status of Development:* Development of this product was completed and an NDA was filed with the FDA in September 2001. We received an Approvable Letter for this product from the FDA in July 2002.

*Market Size:* Sales of anti-depressant products in the United States totaled \$13.6 billion for 2004. The anti-depressant market consists of four major drug categories: new generation anti-depressants (bupropion); SSRIs/SNRIs; tricyclic anti-depressants, and monoamine oxidase inhibitors. Major marketed brands include Lexapro (escitalopram), Paxil (paroxetine), Zoloft (sertraline), Effexor XR (venlafaxine) and Wellbutrin®.

#### ***Venlafaxine EA***

A two-times-daily, immediate-release formulation of venlafaxine, introduced by Wyeth in March of 1994, is marketed in the U.S. under the brand name Effexor. In 1997, Wyeth introduced a controlled-release formulation marketed as Effexor XR. U.S. sales of Effexor and Effexor XR were approximately \$2.7 billion for 2004.

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*Indication:* Venlafaxine is indicated for the treatment of depression and general anxiety disorder ("GAD").

*Clinical Efficacy:* The efficacy of Effexor XR in the treatment of depression was established by the innovator in eight-week and 12-week controlled trials of outpatients whose diagnoses corresponded most closely to the diagnostic criteria for major depressive disorder.

The efficacy of Effexor XR as a treatment for GAD was established conducted by the innovator in two eight-week, placebo-controlled, fixed-dose studies; one six-month, placebo-controlled, fixed-dose study; and one six-month, placebo-controlled, flexible-dose study in outpatients meeting DSM-IV criteria for GAD.

In two head-to-head comparison studies, people with major depression treated with Effexor (venlafaxine) were more likely to recover completely than those treated with either Prozac (fluoxetine) or Zoloft (sertraline).

*Potential Enhancement:* We believe a super-bioavailable version of venlafaxine could allow us to reduce the administered dose, while achieving comparable blood levels and efficacy; or allow the attainment of higher blood levels without a substantial change in capsule size.

*Status of Development:* Formulation development and pilot bioavailability studies were successfully completed. We are currently in scale-up / pivotal biostudies. An NDS submission is anticipated in the second half of 2005.

*Market Size:* Sales of anti-depressant products in the United States totaled \$13.6 billion for 2004. The anti-depressant market consists of four major drug categories: new-generation anti-depressants (bupropion); selective serotonin reuptake inhibitors/selective norepinephrine reuptake inhibitors ("SSRIs/SNRIs"); tricyclic anti-depressants; and monoamine oxidase inhibitors. Major marketed brands include Prozac (fluoxetine), Lexapro (escitalopram), Paxil (paroxetine), Zoloft (sertraline), Effexor XR (venlafaxine) and Wellbutrin®.

### ***Bupropion / Venlafaxine combination***

A four-times-daily, immediate-release formulation of bupropion was introduced in July 1989 by GSK under the brand name Wellbutrin®. In 1996, GSK launched a twice-daily controlled-release formulation of bupropion, Wellbutrin SR®. In September 2003, GSK launched Wellbutrin XL®, a once-daily formulation of bupropion developed by us. The Wellbutrin® franchise generated U.S. sales of \$2.2 billion for 2004.

A two-times-daily, immediate-release formulation of venlafaxine, introduced by Wyeth in March of 1994, is marketed in the U.S. under the brand name Effexor. In 1997, Wyeth introduced a controlled-release formulation marketed as Effexor XR. U.S. sales of Effexor and Effexor XR were approximately \$2.7 billion for 2004.

*Indication:* Bupropion is indicated for the symptomatic relief of depressive illness. Venlafaxine is indicated for the treatment of depression and GAD.

*Clinical Efficacy:* Bupropion has proven to be effective in the treatment of depression in adults 18 years of age and older. An open, uncontrolled study of 3,167 patients at 105 sites showed that functional status improved in patients treated with Wellbutrin SR for up to 56 days. This improvement was highly correlated with improvement in clinical symptoms.

In two head-to-head comparison studies, people with major depression treated with Effexor (venlafaxine) were more likely to recover completely than those treated with either Prozac (fluoxetine) or Zoloft (sertraline).

*Potential Enhancement:* The combination of bupropion and venlafaxine would provide physicians with a single-tablet option incorporating two separate classes of anti-depressant drugs, which target separate pathways important in the treatment of depression.

*Status of Development:* Our development program for a bupropion / venlafaxine combination is currently in the formulation optimization stage.

*Market Size:* Sales of anti-depressant products totalled \$13.6 billion for the 12 months ended December 31, 2004. The anti-depressant market consists of four major drug categories: new generation antidepressants, SSRIs/SNRIs, tricyclic antidepressants, and monoamine oxidase inhibitors. Major marketed brands include Prozac (fluoxetine), Paxil (paroxetine), Zoloft (sertraline), Effexor XR (venlafaxine) and Wellbutrin (bupropion).

#### **Wellbutrin XL® 450mg and Bupropion Line Extensions**

A four-times-daily, immediate-release formulation of bupropion was introduced in July 1989 by GSK under the brand name Wellbutrin®. In 1996, GSK launched a twice-daily controlled-release formulation of bupropion, Wellbutrin SR®. In September 2003, GSK launched Wellbutrin XL®, a once-daily formulation of bupropion developed by us. The Wellbutrin® franchise generated U.S. sales of \$2.2 billion for 2004.

*Indication:* Bupropion is indicated for the treatment of depressive disorder. Incidences of major depression are frequently encountered by primary care physicians. Depression may occur in neurosis as well as in mood disorders and is a manifestation of major psychiatric illness.

*Clinical Efficacy:* Bupropion has proven to be effective in the treatment of depression in adults 18 years of age and older. An open, uncontrolled study of 3,167 patients at 105 sites showed that functional status improved in patients treated with Wellbutrin SR® for up to 56 days. This improvement was highly correlated with improvement in clinical symptoms.

*Potential Enhancement:* A 450mg formulation would complement the existing in-market doses of 150mg and 300mg, providing physicians with greater flexibility in their treatment regimens. We have not disclosed the enhancement opportunities we are pursuing with our bupropion line extension product.

*Status of Development:* The 450mg formulation of bupropion extended-release is under development. While we have not disclosed the development status of our bupropion line-extension programs, we expect to be in a position to file an NDA in the first half of 2006.

*Market Size:* Sales of anti-depressant products in the U.S. totaled \$13.6 billion for 2004. Bupropion is classified as a new generation anti-depressant. The anti-depressant market consists of four major drug categories: new-generation anti-depressants (bupropion); SSRIs/SNRIs; tricyclic anti-depressants; and monoamine oxidase inhibitors. Major brands include Prozac (fluoxetine), Lexapro (escitalopram), Paxil (paroxetine), Zoloft (sertraline) and Effexor XR (venlafaxine) and Wellbutrin®.

#### **Ativan® ODT**

Lorazepam is a benzodiazepine distributed in the U.S. by Biovail under the brand name Ativan®. In 2004, the brand and generic equivalents generated U.S. revenues of \$181.5 million, with over 23.1 million prescriptions dispensed.

*Indication:* Lorazepam is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms.

*Clinical Efficacy:* Studies in healthy volunteers show that in single high doses lorazepam has a tranquilizing action on the central nervous system with no appreciable effect on the respiratory or

cardiovascular systems. Lorazepam is readily absorbed with an absolute bioavailability of 90%. Peak concentrations in plasma occur approximately two hours following administration.

*Potential Enhancement:* The FlashDose® technology may provide the convenience of enabling administration of Ativan® with or without water, among other potential benefits.

*Status of Development:* Formulation development and pilot bioavailability studies were successfully completed. We are currently in scale-up / pivotal biostudies.

*Market Size:* In 2004, the U.S. anti-anxiety market was valued at \$923.1 million. Over 90.2 million prescriptions for these therapeutics were dispensed in 2004. Other products in this class include Xanax, Xanax XR, Buspar, Diazepam and Atarax.

## **Research and Development**

Biovail's global R&D organization leverages state-of-the-art drug-delivery technologies to develop high value enhancements and modifications to new and existing molecules.

Biovail R&D is positioned as a leader in the lifecycle management of commercially valuable primary-care and specialty pharmaceuticals. We believe we are unique among specialty pharmaceutical companies in our approach to combining advanced drug-delivery applications with innovative patent, regulatory and clinical approaches to extending product exclusivity. We seek to enhance and extend exclusivity through the staged introduction of product enhancements. These may include improvements in the frequency of administration of drug products, improvements in the convenience of administration, reduction in dose, reduction in side effects (improved tolerability), or improved therapeutic effect/benefit.

We leverage our formulation expertise to develop novel, fixed-dose combination products that address unmet medical needs by providing synergistic efficacy and safety advantages. We also consider the development of late-stage (Phase II) novel molecules that provide an acceptable risk/return ratio.

Important to our success is the ability to couple these new dosage forms and clinical outcomes with novel intellectual property (patents) and regulatory approaches which provide exclusivity beyond that afforded by formulation patents alone.

Our staff of scientists has expertise in all aspects of the drug-development process from pre-formulation studies and formulation development, to scale-up and manufacturing. We have appropriate delivery systems for pharmaceutical compounds exhibiting a wide range of solubility and hydrophobicity characteristics.

As part of our business strategy, we enter into R&D contracts with third-party formulators and developers to expand our development-pipeline opportunities. These third-party developers are typically paid with a combination of development milestone payments and royalty payments. In some cases, we have an ownership interest or an option to acquire an ownership position in the developer. In no case are we responsible for any of the developers' third-party liabilities, nor have we guaranteed any obligations of the developers, nor are we required under any circumstances to exercise any of our options.

## **Technology**

We have numerous proprietary drug-delivery technologies that are used to develop sustained-release, controlled-release, enhanced/modified-absorption and orally disintegrating products. We also have access to the technologies of our development partners through licensing agreements.

Oral, sustained-release and controlled-release technologies permit the development of specialized oral delivery systems that improve the absorption and utilization of drugs. Release patterns are characterized as "zero order", which indicates constant drug release over time, or "first order", which indicates decreasing release over time. These systems offer a number of advantages, in particular, to allow

the patient to take only one or two doses of the drug per day. This, combined with enhanced therapeutic effectiveness, reduced side effects, improved compliance and potential cost effectiveness, makes sustained-release and controlled-release drug products ideally suited for the treatment of chronic conditions.

Our sustained-release and controlled-release technologies can provide a broad range of release profiles, taking into account the physical and chemical characteristics of a drug product, the therapeutic use of the particular drug and the optimal site for release of the basic drug in the gastrointestinal tract (the "GI" tract). The objective is to provide a delivery system allowing for a single dose per 12-hour to 24-hour period, while assuring gradual and controlled-release of the subject drug at a suitable location(s) in the GI tract.

Our orally disintegrating (FlashDose®) formulations contain the same basic chemical compound found in the original branded products. The dry chemical compounds are encapsulated in microspheres utilizing our proprietary CEFORM technology. Our Shearform and other ODT technologies are used to produce matrices or excipient blends that are subsequently combined with the CEFORM microspheres. This final blend can be compressed into rapid-dissolve tablet formulations. The benefits of such rapid-dissolve formulations include the ease of administration for the elderly, young children, or people with disease states who may have difficulty swallowing tablets or capsules.

We believe our enhanced/modified-absorption technology platforms are unique in the sense that various formulation and physico-chemical tools can be applied alone or in combination to improve the absorption profile of a drug. As examples, it may be possible to increase the solubility, increase the amount absorbed, control the pre-systemic metabolism, and/or increase the rate of absorption, with or without modification of the total amount of drug into the bloodstream.

We use our proprietary drug-delivery platforms, as described in the paragraphs that follow, involving multi-particulate beads in capsules and other solid dosage forms. These platforms are capable of delivering a wide variety of drug compounds in sustained-release, controlled-release, enhanced/modified-absorption and orally disintegrating and rapid-dissolve, oral-dosage formulations.

#### ***Dimatrix***

Dimatrix is a diffusion-controlled matrix technology for water-soluble drugs in the form of tablets. The drug compound is uniformly dispersed in a polymer matrix. The mechanism of release involves the swelling of polymers within the matrix, thus enabling the drug to be dissolved and released by diffusion through an unstirred boundary layer. The release pattern is characterized as first order as the rate of drug diffusion out of the swollen matrix is dependent upon the concentration gradient.

#### ***Macrocap***

Macrocap consists of immediate-release beads made by extrusion/ spheronization/ pelletization techniques, or by layering powders or solutions onto nonpareil seeds. Release-modulating polymers are applied on the beads using a variety of specialized coating techniques. The coated beads are filled into hard gelatine capsules. Drug release occurs by diffusion associated with bio-erosion or by osmosis via the surface membrane. The release mechanism can be pH activated or pH independent. The beads can be formulated to produce first order or zero-order release.

#### ***Consurf***

Consurf is a zero-order drug-delivery system for hydrophilic and hydrophobic drugs in the form of matrix tablets. The drug compound is uniformly dispersed in a matrix consisting of a unique blend of polymers. The mechanism of release involves the concurrent swelling and erosion of the matrix such that a constant surface matrix area is maintained during transit through the GI tract. This can result in a zero-order release of the drug of interest.

### ***Multipart***

Multipart consists of a tablet carrier for the delivery of controlled-release beads that preserves the integrity and release properties of the beads. The distribution of the beads is triggered by disintegration of the tablet carrier in the stomach. Drug release from the beads can be pH activated or pH-independent, and can occur by disintegration or osmosis. The beads can be formulated to produce first or zero-order release.

### ***CEFORM***

CEFORM is a series of microsphere technology platforms used to produce uniformly sized and shaped microspheres of a wide range of pharmaceutical compounds. The microspheres are nearly perfectly spherical in shape and typically have a target diameter between 50-600 microns, depending on the application. For example, 150-180 micron microspheres may be used for FlashDose®, with high drug content and with high drug content, a taste-isolation coating applied for oral-cavity dispersion. CEFORM microspheres can also be incorporated into more conventional dosage forms, such as capsules, tablets, sprinkles and redispersible suspensions, providing advanced drug-delivery options in many different formats. The microspheres are produced using a continuous, single-step and solvent-free manufacturing process. Depending on the formulation and processing technologies applied, CEFORM can meet a wide range of drug-delivery goals. These include CEFORM TI (taste isolation), CEFORM EA (enhanced absorption), CEFORM RA (rapid absorption), CEFORM SR (sustained release), and CEFORM CR (controlled release).

### ***Shearform***

Shearform is used to produce matrices of saccharides, polysaccharides or other carrier materials that are subsequently processed into amorphous fibers or flakes and re-crystallized to a predetermined level. This process is used to produce rapid-dissolve formulations, including FlashDose®. Shearform can also be applied to food-product ingredients to provide enhanced flavoring. Newer directly compressible ODT technologies have been developed and applied internally by us, allowing for simpler manufacturing of ODTs as well. We also have access to the ODT technologies of a development partner.

### ***Smartcoat***

Smartcoat is a technology we developed with a third party development company, Pharma Pass, which developer we subsequently acquired (see section, "Three-Year History Material Developments"). This technology allows the manufacturing of very high potency sustained-release and controlled-release tablets, allowing for smaller-sized tablets while controlling the release over a 24-hour period. A thin, very strong molecular diffusion membrane controls the release and this rate can be adapted to a zero-order or Weibull function.

### ***Chronotabs***

Chronotabs are made of Multipart or Smartcoat tablets particularly adapted to chronotherapy (the science of treating diseases that follow the body's circadian rhythms), using a second layer of smart polymers made of dry- or film coating to optimize the active drug absorption profile for bedtime administration.

### ***Zero-Order Release System ("ZORS")***

ZORS is a technology that allows us to develop zero-order kinetic systems, based on a proprietary controlled-release matrix coating. ZORS allows us to develop controlled release tablets that alleviate food effect in drugs known to have their pharmacokinetic profile influenced by meals. This technology was developed and patented by Pharma Pass.

### ***Oral Colonic Delivery System***

The Oral Colonic Delivery System is a novel technology acquired from Pharma Pass. The technology uses a dosage form characterized by a dual triggering of drug release (known as DUALex). A review of the literature shows that products designed for oral delivery but that release their active ingredient in the intestine are based on: (1) a pH sensitive polymer coating; (2) enzymatic degradation; or (3) osmotic pressure. However, the variability of the intestinal medium creates a challenge with respect to predictability and reproducibility of the drug's release characteristics. Biovail's Oral Colonic Delivery System combines any two of the three mechanisms, thereby increasing the precision of the drug release triggering.

### **Other Business Operations and Services**

#### **Contract Research Division**

The Contract Research Division ("CRD") is a division of Biovail that provides us and other pharmaceutical companies with a broad range of Phase I, and Phase II clinical research services. These involve principally conducting pharmacokinetic studies and bioanalytical laboratory testing to establish a drug's bioavailability or its bioequivalence to another drug moiety. The CRD has an independent Institutional Review Board that assures that all studies are conducted in an ethical and safe manner, without compromising the health of the human subjects participating in these studies.

Operating as an independent business unit in Toronto, Ontario, the CRD is located in a 41,000-square-foot stand-alone facility owned by us, and a 10,500-square-foot leased facility. These facilities include a 230-bed capacity Clinic (five Study Clinics and a 12-bed Phase I first-in-man Unit), a Medical Recruiting and Subject Screening Unit, a fully equipped Bioanalytical Laboratory, and a Department of Biopharmaceutics.

To date, the CRD has designed and conducted in excess of 3,000 bioavailability, bioequivalence and/or drug interaction studies. The therapeutic areas in which studies have been completed include cardiovascular disease, cardiopulmonary, bone and joint disease, pain management, infectious diseases, CNS, gastroenterology and endocrinology. In addition, the CRD has performed Phase I first-in-man studies to establish the safety of new molecular entities.

The CRD has a database in excess of 62,000 healthy male and female volunteers for potential study enrolment as well as a large inventory of disease related patient groups, including post-menopausal women, renal-impaired and diabetic patients. The Bioanalytical Laboratory continues to add to its inventory of over 130 developed and validated assays. The CRD has its own independent Quality Assurance Department to assure that the operations of the CRD are subject to full compliance with the rules and regulations of the FDA, TPD and other comparable foreign regulatory bodies.

#### **Nutravail Technologies**

We develop and manufacture nutraceutical and food-ingredient products, incorporating our proprietary technologies, through our Nutravail Technologies division. Large-scale manufacture of nutraceutical products is currently handled through third-party contractors but a variety of higher value flavor encapsulations, gums and gum bases are developed and manufactured at our Chantilly, Virginia facility.

#### **Patents and Proprietary Rights**

Intellectual property, in particular, patents, trademarks, and trade secrets, are essential to our business. Patents exclude others from making, using, offering for sale, or selling an invention throughout the 20-year term of a patent, running from the date the patent application was first filed. We recognize the importance of this exclusivity and we seek to secure as broad a protection as allowable for our products by

filing patent applications as early as possible in the R&D phase with the intent of listing its issued patents, in the FDA Orange Book (in the U.S.) or the Patent Register (in Canada), as the case may be. Accordingly, novel products arising from our development efforts are typically patented, thereby providing intellectual property rights and associated market protection. To further strengthen our competitive edge, we may also seek, from third parties, an assignment or an exclusive or non-exclusive license or acquire the rights to a patent, patent application or other intellectual property such as trademarks, trade secrets, and/or know-how for the product(s) being developed or that are already being commercialized. We recognize the value of securing our own patent protection and/or obtaining exclusive rights to third party patents and/or patent applications, which are listable in the FDA Orange Book, or the Patent Register, as this allows us to assert the provisions of current legislation, being the Hatch-Waxman Amendments to the U.S. Federal Food, Drug, and Cosmetic Act (the "FDC Act") (in the U.S.) and the Patented Medicines Regulations (Notice of Compliance), promulgated under the Patent Act (in Canada). Such filing allows us to commence patent-infringement litigation against an applicant for a generic version of our branded products, if warranted, and thereby potentially delay generic drug entry into the market for a considerable period of time, or permanently. This strategy may include the exclusive use of a partner's patent portfolio to leverage our competitive edge.

We do not, however, depend exclusively on intellectual property filings and litigation to protect our products. The implementation of product-lifecycle management strategies is equally important and includes the reformulation of existing well-known products and thereby the creation of a new and improved version of such product(s), which may, in turn, lead to new intellectual property, often in the form of patents, to expand our scope of protection for a particular product.

Our strategy is not to seek to have patents issued on our controlled-release technologies platforms because this may provide potential competitors with information relating to our proprietary technology, and thus potentially enable such competitors to exploit our confidential technology that is not otherwise within the confines of such patent protection. We also rely on trade secrets, know-how and other proprietary information to maintain our competitive position. Efforts are taken to conduct as thoroughly as possible freedom-to-operate or non-infringement reviews of our trademark and patent applications prior to their filing as well as any intellectual property being in-licensed or acquired. However, there can be no assurance that any trademarks or patents will issue, or that, if issued, the use of the trademark or manufacture, use, sale, importation or offer for sale of such patented matter will not infringe upon other patents or technology. Our ability to compete effectively in the marketplace will depend, in part, upon our ability to maintain and safeguard the proprietary nature of our technology and to avoid infringing patents of others. Accordingly, we require all licensors, licensees and employees to enter into confidentiality agreements which are monitored and, if need be, enforced. There can be no assurance, however, that these agreements will 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. In addition, we monitor the activities of our competitors to ensure that our intellectual property rights are not infringed or eroded to the detriment of our marketed products or of our products in development.

## **Taxation**

A significant portion of our revenue and income are earned in a foreign 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 the mix of income among the different jurisdictions in which we operate, changes in tax laws in the jurisdictions in which we operate, changes in tax treaties between the various countries in which we operate, and changes in the estimated value of deferred taxes and liabilities. We conduct transfer pricing



studies to support the pricing of transactions between the various entities in the our structure. Our income tax reporting is subject to audit by domestic and foreign tax authorities.

### **Government Regulations and Quality Assurance**

Our Corporate Regulatory Affairs department is involved in the development and registration of each product and has prepared product submissions for regulatory agencies in the U.S. and Canada. This department also co-ordinates all data and document management, including amendments, supplements and adverse events reporting. Our Quality Assurance department seeks to ensure that all stages of product development and production fully comply with good clinical, laboratory and manufacturing practices.

### **Government Regulation**

The research and development, manufacture and marketing of pharmaceuticals are subject to regulation by U.S., Canadian and foreign governmental authorities and agencies. Such national agencies and other federal, state, provincial and local entities regulate the testing, manufacturing, safety and promotion of our products. The regulations applicable to our products may change as the currently limited number of approved controlled-release products increases and regulators acquire additional experience in this area.

### **U.S. Regulation**

#### *New Drug Application*

We are required by the FDA to comply with NDA procedures for our branded products prior to commencement of marketing by our partners or us. New drug compounds and new formulations for existing drug compounds which cannot be filed as ANDAs are subject to NDA procedures. These procedures include: (1) preclinical laboratory and animal toxicology tests; (2) scaling and testing of production batches; (3) an Investigational New Drug Application ("IND"), submission and acceptance of which is required before any human clinical trials can commence; (4) adequate and well-controlled replicate human clinical trials to establish the safety and efficacy of a drug for its intended indication; (5) the submission of the NDA to the FDA; and (6) FDA approval of the NDA prior to any commercial sale or shipment of the product, including pre-approval and post-approval inspections of its manufacturing and testing facilities. If all of the data in the product application are owned by the applicant, the FDA will issue its approval without regard to patent rights that might be infringed or exclusivity periods that would affect the FDA's ability to grant an approval if the application relied upon data which the applicant did not own.

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. Once the IND goes into effect, clinical trials may be initiated, unless a hold on clinical trials is subsequently issued by the FDA.

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 Institutional Review Board prior to the commencement of each clinical trial. Clinical studies are typically conducted in three sequential phases, which may overlap. In Phase I, the initial introduction of the product into healthy human subjects, the compound is tested for absorption, safety, dosage, tolerability, metabolic interaction, distribution, and excretion. Phase II involves studies in a limited patient population with the disease to be treated to (1) determine the effectiveness of the product for specific targeted indications, (2) determine optimal dosage and (3) identify possible

adverse effects and safety risks. In the event Phase II evaluations demonstrate that a pharmaceutical product is effective, has acceptable data to show an appropriate clinical dose, and has an acceptable safety profile, Phase III 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 on the clinical investigations are required. We, or the FDA, may suspend clinical trials at any time if either party believes the clinical subjects are being exposed to unacceptable health risks. The results of the product development, analytical laboratory studies and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing and commercialization of a pharmaceutical product.

The above-described NDA procedures are premised 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. These NDAs are governed by 21 U.S.C. § 355(b)(1), also known as Section 505(b)(1) of the FDC Act.

#### ***Abbreviated New Drug Application***

In certain cases, where the objective is to develop a bio-equivalent or generic version of an approved product already on the market, an ANDA may be filed in lieu of filing an NDA. 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, that is, demonstration that the generic drug produces comparable blood levels of drug in the body to its brand-name counterpart. It is mandatory that the generic version of a drug have the same pharmacokinetic profile, or change in blood concentration over time. The ANDA procedure would be available to us for a generic version of a drug product already approved by the FDA. 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: (1) route of administration, (2) dosage form, (3) strength and (4) 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 other kinds of changes from Listed Drugs. The information in a suitability petition must demonstrate that the change from the Listed Drug requested for the proposed drug product may be adequately evaluated for approval without data from investigations to show the proposed drug product's safety or effectiveness. The advantages of an ANDA over an NDA include lower R&D costs associated with bringing a product to market, and generally a shorter review and approval time at the FDA.

#### ***505(b)(2) Application Process***

Pharmaceutical companies may submit a 505(b)(2) application for a change in a drug when approval of the application relies on the FDA's previous finding of safety and/or effectiveness for a drug, and for which suitability for an ANDA is not appropriate or permitted. 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 drug that is not supported by a suitability petition. Regulation permits a 505(b)(2) applicant to rely on the FDA's finding of safety and effectiveness for an approved drug to the extent such reliance would be 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.

#### ***Patent Certification and Exclusivity Issues***

ANDAs and 505(b)(2) NDAs are required to 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 this information has been submitted to the FDA, the FDA must delay

approval of the ANDA or 505(b)(2) until the patents expire. If the applicant believes it will not infringe the patents, it can make a patent certification to the holder of patents on the drug for which a generic drug approval is being sought, which may result in patent infringement litigation which could delay the FDA approval of the ANDA or 505(b)(2) for up to 30 months. If the drug product covered by an ANDA or 505(b)(2) were to be found by a court to infringe another company's patents, approval of the ANDA could be delayed until the patents expire. Under the FDC Act, the first filer of an ANDA with a "non-infringement" certification is entitled to receive 180 days of market exclusivity. Subsequent filers of generic products would be entitled to market their approved product six months after the earlier of the first commercial marketing of the first filer's generic product or a successful defense of a patent infringement suit.

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 compound.

The FDC 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. Exclusivity refers to the fact that the effective date of approval of a potential competitor's ANDA to copy the pioneer drug may be delayed or, in certain cases, an ANDA may not be submitted until the exclusivity period expires. Five years of exclusivity are granted to the first approval of an NCE. Three years of exclusivity may apply to products which are not NCEs, but for which new clinical investigations are essential to the approval. For example, a new indication for use, or new dosage strength of a previously approved product, may be entitled to exclusivity, but only with respect to that indication or dosage strength. Exclusivity only offers protection against a competitor entering the market via the ANDA and 505(b)(2) routes, and does not operate against a competitor that generates all of its own data and submits a full NDA under Section 505(b)(1) of the FDC Act.

If applicable regulatory criteria are not satisfied, the FDA may deny approval of an 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.

### **Canadian Regulation**

The requirements for obtaining regulatory approval for pharmaceutical drugs in Canada are substantially similar to those of the U.S. described above, with the exception of the 505(b)(2) application, and marketing exclusivity under the FDC Act.

### ***Clinical Trial Application***

Before conducting clinical trials of a new drug in Canada, we must submit a Clinical Trial Application to the TPD. This application includes information about the proposed trial, the methods of manufacture of the drug and controls, preclinical laboratory and animal toxicology tests on the safety and potential efficacy of the drug, and information on any previously executed clinical trials with the new drug. If, within 30 days of receiving the application, the TPD does not provide notice that the application is unsatisfactory, clinical trials of the drug may proceed. The phases of clinical trials are the same as those described earlier in the document in this section, (see "U.S. Regulation - New Drug Application").

***New Drug Submission***

Before selling a new drug in Canada, we 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, the methods of manufacturing, processing, and packaging the new drug, the controls applicable to these operations, the tests conducted to establish the safety of the new drug, the tests to be applied to control the potency, purity, stability, and safety of the new drug, the results of biopharmaceutics and clinical trials as appropriate, the intended indications for which the new drug may be prescribed and the effectiveness of the new drug when used as intended. The TPD reviews the NDS or sNDS. If the submission meets the requirements of Canada's *Food and Drug Act* and regulations thereunder, the TPD will issue a NOC for the new drug.

Where the TPD has already approved a drug for sale in controlled-release dosages, companies may seek approval from the TPD to sell an equivalent generic drug through an Abbreviated New Drug Submission ("ANDS"). In certain cases, the TPD does not require the manufacturer to conduct clinical trials for 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 TPD may deny approval or may require additional testing of a proposed new drug if applicable regulatory criteria are not met. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Contravention of *Canada's Food and Drug Act*, or the regulations thereunder, can result in fines and other sanctions, including product seizures and criminal prosecutions.

Proposals have recently been made that, if implemented, would significantly change Canada's drug approval system. In general, the recommendations emphasize the need for efficiency in Canadian drug review. Proposals include establishment of a separate agency for drug regulation and modeling the approval system on those found in European Union countries. There is no assurance, however, that such changes will be implemented or, if implemented, will expedite the approval of new drugs.

Regulations prohibit the issuance of a NOC for a patented medicine to a generic competitor, provided that the patentee or an exclusive licensee has filed a list of its Canadian patents covering that medicine with the Ministry of Health and Welfare (the "Ministry"). After submitting the list, the patentee or an exclusive licensee can commence a proceeding to obtain an order of prohibition directed to the Ministry prohibiting him or her from issuing a NOC. The Ministry may be prohibited from issuing a NOC permitting the importation or sale of a patented medicine to a generic competitor until patents on the medicine expire or the waiver of infringement and/or validity of the patent(s) in question is resolved by litigation in the manner set out in such regulations. There may be additional patents relating to a company's proposed manufacture, use or sale of a product that could potentially prohibit such company's proposed commercialization of a drug compound.

Certain provincial regulatory authorities in Canada have the ability to determine whether the consumers of a drug sold within such province will be reimbursed by a provincial government health plan for that drug by listing drugs on formularies. The listing or non-listing of a drug on provincial formularies may affect the prices of drugs sold within provinces and the volume of drugs sold within provinces.

***Additional Regulatory Considerations***

Sales of our products by our licensees outside the U.S. and Canada are subject to regulatory requirements governing the testing, registration and marketing of pharmaceuticals, which vary widely from country to country.

Our manufacturing facilities located at Steinbach, Manitoba, Chantilly, Virginia, and in Dorado, Puerto Rico and Carolina, Puerto Rico, operate according to FDA-mandated and TPD-mandated GMPs. These manufacturing facilities are inspected on a regular basis by the FDA, the TPD, and other regulatory authorities. Our internal quality assurance auditing team monitors compliance on an ongoing basis with these GMPs. 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 law, including requirements regarding occupational safety, 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 of the pharmaceutical industry. We believe that we are in compliance in all material respects with such regulations as are currently in effect.

### **Three-Year History Material Developments**

#### **Strategic Alliance with Kos Pharmaceuticals, Inc.**

On May 2, 2005, we sold our interest in Teveten®, and entered into a manufacturing-and-supply agreement for Cardizem® LA in the U.S. with Kos. We will be the exclusive manufacturer and supplier of Cardizem® LA to Kos over an initial seven-year term, at contractually determined prices that are in excess of 30% of Kos's net selling prices. In accordance with the agreement, Kos has to date hired 163 former employees from Biovail's U.S. sales and marketing operations. Kos will collaborate with us on the development of up to three products, including a combination product comprising Cardizem® LA and enalapril (Vasotec®). Subject to FDA approval, we will be the exclusive manufacturer and supplier of this combination product to Kos. In consideration for these transactions, Kos paid us approximately \$104 million in cash, and Kos will make payments to us related to the development of the combination product.

#### **Acquisitions of intangible assets**

##### ***Tramadol products***

In September 2003 and February 2004, we acquired from Ethypharm the rights (including all relevant patents) to Ethypharm's ODT formulations of tramadol ("Tramadol ODT") and combination of tramadol and acetaminophen ("Tramadol/Acetaminophen ODT") for \$16.0 million.

##### ***Ativan® and Isordil®***

In May 2003, we acquired from Wyeth the rights to Ativan® and Isordil® in the United States for \$163.8 million. Ativan® is indicated for the management of anxiety disorders; Isordil® is indicated for the prevention of angina pectoris due to coronary-artery disease. Wyeth will manufacture and supply Ativan® and Isordil® to us for three years from the date of acquisition. We also acquired a license to use certain technologies relating to Wyeth's Canadian sublingual version of Ativan® to develop new Ativan® products to be sold in the United States. According to IMS, sales of these products from the time they were acquired through the three months ended March 31, 2005 were approximately \$78 million.

##### ***Athpharma products***

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

treatment of high cholesterol. We are currently in discussions with Athpharma to substitute certain new products in place of the original products acquired or to terminate the development and license agreement.

***Wellbutrin SR® and Zyban®***

In December 2002, we acquired from GSK the rights to Wellbutrin SR® and Zyban® in Canada for \$72.0 million. Wellbutrin SR® is prescribed for the treatment of depression; Zyban® is indicated as a treatment for smoking cessation in conjunction with behavior modification. GSK will manufacture and supply Wellbutrin® SR and Zyban® to us for four years from the date of acquisition. In addition, we acquired the rights to market our bupropion hydrochloride ("HCl") extended-release tablets (Wellbutrin XL®) in Canada, subject to regulatory approval. According to the IMS, sales of these products from the time they were acquired through the three months ended March 31, 2005 were approximately \$115 million.

***Vasotec® and Vaseretic®***

In May 2002, we acquired from Merck the rights to Vasotec® and Vaseretic® in the United States for \$245.3 million. Vasotec® and Vaseretic® are indicated for the treatments of hypertension and congestive heart failure. Merck will manufacture and supply Vasotec® and Vaseretic® to us for five years from the date of acquisition. We also entered into a separate agreement with Merck to develop a new dosage format (using our CEFORM technology) of a Merck product under development.

***Teveten® and Teveten® HCT***

In March 2002, we acquired from Solvay the rights to Teveten® and Teveten® HCT in the United States for \$94.3 million. Teveten® and Teveten HCT® are indicated for the treatment of hypertension either alone or in conjunction with other antihypertensive medications. Solvay will manufacture and supply Teveten® and Teveten HCT® to us for up to 12 years from the date of acquisition. In May 2005, we sold Teveten® and Teveten HCT® to Kos.

***Zovirax®***

Effective January 1, 2002, we acquired from GSK the exclusive distribution rights to Zovirax® Ointment and Zovirax® Cream in the United States for \$133.4 million. Zovirax® is a topical anti-viral product. Zovirax® Ointment is indicated for the treatment of herpes and Zovirax® Cream is indicated for the treatment of cold sores. In December 2002, we agreed to pay GSK \$40.0 million to extend the term of the Zovirax® distribution and supply agreement from 10 to 20 years. We also agreed to pay GSK an aggregate amount of \$45.0 million, over four years beginning in 2004, to amend several terms of the original Zovirax® distribution-and-supply agreement, including a reduction in the supply price for this product. GSK will manufacture and supply Zovirax® Ointment and Zovirax® Cream to us over the term of the amended Zovirax® distribution-and-supply agreement. According to IMS, sales of these products from the time they were acquired through the three months ended March 31, 2005 were approximately \$345 million.

**Disposition of assets**

***Cedax® (ceftibuten)***

Cedax® is a third-generation, broad-spectrum oral cephalosporin antibiotic indicated for the treatment of chronic bronchitis, otitis media and pharyngitis/tonsillitis. In July 2004, we disposed of the Cedax® product rights.

***Teveten® and Teveten® HCT***

In May 2005, we sold Teveten® and Teveten HCT® to Kos.

**Acquisitions of Businesses**

***BNC-PHARMAPASS***

In July 2003, we formed BNC-PHARMAPASS, LLC ("BNC-PHARMAPASS") with Pharma Pass II, LLC ("PPII") to advance the development of carvedilol, eprosartan and tamsulosin. On the formation of BNC-PHARMAPASS, PPII contributed all of its intellectual property relating to these products, and we contributed cash in the amount of \$30.1 million. Subsequent to the date of formation, PPII reduced its interest in BNC-PHARMAPASS through a series of withdrawals of cash from BNC-PHARMAPASS. In February 2004, we acquired PPII's remaining interest in BNC-PHARMAPASS for \$5.0 million, for a total purchase price of \$35.1 million. We also agreed with PPII to terminate our development of tamsulosin, and the intellectual property related to this product was returned to PPII.

***Pharma Pass***

In December 2002, we acquired Pharma Pass LLC and Pharma Pass S.A. (collectively, "Pharma Pass") for \$178.7 million. Pharma Pass was a developer of advanced oral controlled-release technologies and formulations for pharmaceutical companies, including us, in the United States and Europe.

At the time of acquisition, Pharma Pass was involved in the development of approximately 20 branded and generic products. Subsequent to the date of acquisition, one of these products (Wellbutrin XL®) received FDA approval, another has received an Approvable Letter (Tramadol ER), and we divested two additional products. We are continuing the development programs for the remaining products. Through this acquisition, we extinguished any future milestone or royalty obligations that we may have had to Pharma Pass resulting from the approval and successful commercialization of any of the products under development pursuant to the R&D agreements we previously entered into with Pharma Pass.

Through this acquisition, we also obtained Pharma Pass's interests in certain licensed products, including Tricor (fenofibrate), and a participating interest in the gross profit on sales by a third party of generic omeprazole. In addition, we obtained Pharma Pass's Zero-Order Release System, a drug-delivery technology that controls the rate of release of a drug and/or significantly enhances the systemic absorption of a drug molecule; and its oral colonic delivery system, a drug-delivery technology designed for the targeted release of medication into the lower intestine and upper colon.

***Pharma Tech***

In December 2002, we acquired Pharmaceutical Technologies Corporation ("Pharma Tech") for \$65.7 million. Pharma Tech was a development-stage company engaged in the application of drug-delivery technologies to the formulation and development of a portfolio of products. Pharma Tech contracted directly with third parties, including us, to conduct contract research-and-development services.

At the time of acquisition, Pharma Tech was involved in a number of product-development projects that were in various stages of completion and had not been submitted for approval by the FDA. Subsequent to the date of acquisition, we received an Approvable Letter for one of these products and discontinued the development of another product. At the date of acquisition, two additional products had received Approvable Letters from the FDA. We are continuing to work to resolve the issues raised in these letters. Through this acquisition, we extinguished any future milestone or royalty obligations that we may have had to Pharma Tech resulting from the approval and successful commercialization of any of the products under development pursuant to the R&D agreements we previously entered into with Pharma Tech.

**C. Organizational Structure**

At December 31, 2004, each of the subsidiaries listed below either represents at least 10% of Biovail's total assets, or sales and operating revenues on a consolidated basis, or are entities through which Biovail conducts its business.

<b>Company</b>	<b>Jurisdiction of Incorporation</b>	<b>Nature of Business</b>	<b>Group Share %</b>	<b>Registered Office</b>
Biovail Americas Corp	Delaware	Holding company	100	700 Route 202/206 North Bridgewater, New Jersey
Biovail Insurance Incorporated.	Barbados	Captive insurance company	100	Chelston Park, Bldg 2, Collymore Rock, St. Michael, Barbados
Biovail Distribution Corporation	Delaware	Distribution of pharmaceutical products	100	700 Route 202/206 North Bridgewater, New Jersey
Biovail Laboratories Incorporated	Barbados	Manufacture, sale, development, licensing of pharmaceutical products, strategic planning and management of intellectual property	100	Chelston Park, Bldg 2 Collymore Rock, St. Michael, Barbados
Biovail Pharmaceuticals, Inc.	Delaware	Sales and distribution of pharmaceutical products	100	700 Route 202/206 North Bridgewater, New Jersey
Biovail Laboratories International SRL	Barbados	Manufacture, sale, development, licensing of pharmaceutical products, strategic planning and management of intellectual property	100	Chelston Park, Bldg 2 Collymore Rock, St. Michael, Barbados
Biovail Technologies (Ireland) Limited	Ireland	Development of pharmaceutical products	100	3200 Lake Drive Citywest Business Campus Dublin 24
Biovail Technologies Ltd.	Delaware	Manufacture and development of pharmaceutical products	100	3701 Concorde Parkway, Chantilly, Virginia 20151

**D. Property, Plant and Equipment****Manufacturing and Properties**

We own and lease space for manufacturing, warehousing, research, development, sales, marketing, and administrative purposes. We currently operate four modern, fully integrated pharmaceutical manufacturing facilities located in Steinbach, Manitoba; Chantilly, Virginia; Dorado, Puerto Rico; and Carolina, Puerto Rico. All of 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.

We have owned our Steinbach, Manitoba facility since 1992. This facility totals 145,000 square feet, most recently expanded in 2003. Among the products currently made here include Wellbutrin XL®, Cardizem® LA and Tiazac XC®. The facility doubled production output in 2004, compared with 2003, as a result of supplying Wellbutrin XL® to our partner GSK. In February 2005, we announced a \$27.6 million expansion project to further enhance the manufacturing capability of this facility. Construction on the Steinbach expansion project, which began in April 2005, will include the addition of approximately 75,000 square feet, bringing the total to 220,000 square feet. Most areas of the site will be enlarged, including manufacturing, packaging, warehousing, laboratory operations and office space. Biovail expects the work to be completed in 2006.



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The Dorado, Puerto Rico facility totals 140,000 square feet. This facility has been built for the manufacture of controlled-release and FlashDose® products, several of which have been filed and are in the approval process. Among the products currently made here include Tiazac®, Diltiazem ER, Diltiazem CD and diltiazem beads. This facility also houses the packaging operations for Tiazac® for the U.S. market, and will provide additional capacity for manufacturing of Cardizem® LA. The Dorado manufacturing facility has been owned by us since January 2001, and was upgraded to accommodate Biovail process requirements. Packaging operations at this facility commenced in January 2003.

The Carolina, Puerto Rico facility totals 34,000 square feet, including a 23,000-square-foot owned manufacturing facility and an 11,000-square-foot, leased warehouse space. This plant is specially constructed for the high-volume production of controlled-release beads. Soil samples from the Carolina site have identified certain contaminants, which we believe have migrated from an adjacent site. This does not impact the operations of the facility, however, it could impact the saleability of the facility, or could require remedial action, which we believe would be the responsibility of the owners of the adjacent site.

The Chantilly, Virginia facility continues to be primarily an R&D and technology transfer site, but remains an FDA-approved manufacturing facility. It is available as an alternate or back-up site for the production of FlashDose® products.

In September 2002, we completed the construction of our corporate headquarters facility in Mississauga, Ontario and relocated all corporate and administrative staff to the new facility. A corporate administrative office was opened in Toronto in February 2005.

The Dublin, Ireland, facility (purchased in 2002) is used for research-and-development activities.

The St. Michael, Barbados facility (leased in 1992) is used for product sales, development, licensing, intellectual property management and administration.

Land in Christ Church, Barbados (purchased in 2002) is planned for the construction of a 14,000-square-foot office facility for the operations located in Barbados. No commitment has yet been made on this construction.

The Bridgewater, New Jersey facility (leased in 2003) continues to be used for our U.S. sales and marketing operations, and certain clinical and research-and-development operations.

We believe our facilities are in satisfactory condition and are suitable for their intended use. We plan further investments to improve and expand our manufacturing and other related facilities over the next 24-month period. A portion of our pharmaceutical manufacturing capacity, as well as other critical business functions, are located in areas subject to hurricane and earthquake casualty risks. Although we have certain limited protection afforded by insurance, our business and our earnings could be materially adversely affected in the event of a major windstorm, earthquake or other natural disaster.

We believe that we have sufficient facilities to conduct our operations during 2005. However, we continue to evaluate the purchase or lease of additional properties, as our business requires.

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	55,000 square feet	Owned
Mississauga, Ontario, Canada	Research and development	24,300 square feet	Leased
Toronto, Ontario, Canada	Corporate administrative office	2,000 square feet	Leased
Toronto, Ontario, Canada	Contract research and development	40,000 square feet	Owned
		11,000 square feet	Leased

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Steinbach, Manitoba, Canada	Manufacturing	145,000 square feet	Owned
Chantilly, Virginia, U.S.A.	Research, development	80,000 square feet	Leased
Chantilly, Virginia, U.S.A.	Manufacturing, research, development and warehousing	60,000 square feet	Leased
Bridgewater, New Jersey, U.S.A.	Sales, marketing and administration	110,000 square feet	Leased
Morrisville, North Carolina, U.S.A. <sup>(1)</sup>	Sales, marketing and administration	42,000 square feet	Leased
Dorado, Puerto Rico	Manufacturing	140,000 square feet	Owned
Carolina, Puerto Rico	Manufacturing	34,000 square feet	Owned
Carolina, Puerto Rico	Warehousing	11,200 square feet	Leased
St. Michael, Barbados	Product Sales, development, licensing, intellectual property management and administration	5,000 square feet	Leased
Christ Church, Barbados	Vacant land (held for future expansion)	1.8 acres	Owned
Dublin, Ireland	Research and development	27,000 square feet	Owned

(1) Leased facility has been vacated and sub-leased.

**Item 5. Operating and Financial Review and Prospects**

- A. **Operating Results**
- B. **Liquidity and Capital Resources**
- C. **Research and Development, Patents and Licenses**
- D. **Trend Information**
- E. **Off-Balance Sheet Arrangements**
- F. **Tabular Disclosure of Contractual Obligations**
- G. **Safe Harbor**

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

The following MD&A prepared in accordance with U.S. GAAP should be read in conjunction with the audited consolidated financial statements and related notes thereto prepared in accordance with U.S. GAAP included under Item 18 "Financial Statements". Likewise, the following MD&A prepared in accordance with Canadian GAAP should be read in conjunction with the audited consolidated financial statements and related notes thereto prepared in accordance with Canadian GAAP also included under Item 18.

	<b>Page</b>
MD&A in accordance with U.S. GAAP	57
MD&A in accordance with Canadian GAAP	84

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56

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

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

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

The following Management's Discussion and Analysis of Results of Operations and Financial Condition ("MD&A") prepared in accordance with U.S. generally accepted accounting principles ("GAAP") should be read in conjunction with our audited consolidated financial statements and related notes thereto prepared in accordance with U.S. GAAP.

The discussion and analysis contained in this MD&A are as of March 30, 2005.

**PROFILE**

We are primarily engaged in the formulation, clinical testing, registration, manufacture and commercialization of pharmaceutical products utilizing advanced oral drug-delivery technologies. Our main therapeutic areas of focus are cardiovascular (including Type II diabetes), central nervous system and pain management. We have various research and development, clinical testing, manufacturing and commercial operations located in the United States, Canada, Barbados, Puerto Rico and Ireland.

**OVERVIEW**

Our financial performance in 2004 reflected our focus on growing our existing business (after several years of acquisition-related activity) and strengthening our financial position through the reduction of debt. We realized record revenue driven by the exceptionally strong performance of our bupropion hydrochloride ("HCl") extended-release tablets ("Wellbutrin XL"), which we manufacture and sell to GlaxoSmithKline plc ("GSK") for marketing and distribution in the United States. GSK's gross sales of Wellbutrin XL were in excess of \$1.0 billion in this product's first full calendar year on the market. We used cash generated from operations to repay nearly \$350 million of long-term obligations. As a result, we had no outstanding borrowings under our \$400 million revolving term credit facility at the end of 2004.

During 2004 and into 2005, we achieved a number of milestones from our late-stage product-development pipeline. We received FDA approval for an angina indication for Cardizem® LA and we received TPD approval for a hypertension indication for Tiazac® XC, designed for bedtime dosing. We received Approvable Letters from the FDA for our extended-release ("ER") and orally disintegrating tablet ("ODT") formulations of the analgesic tramadol HCl, as well as for the anti-depressant citalopram ODT and Glumetza (metformin HCl) for the treatment of Type II diabetes. We filed New Drug Applications ("NDA") with the FDA for tramadol ER, tramadol ODT, citalopram ODT and Glumetza . We filed a New Drug Submission ("NDS") with the TPD for Glumetza , and we submitted supplemental NDSs for Wellbutrin XL and an angina indication for Tiazac® XC.

In November 2004, we effected the separation of the roles of Chairman of the Board and Chief Executive Officer ("CEO"), with the hiring of Douglas Squires as our new CEO. Dr. Squires has over 29 years of global pharmaceutical industry management experience. Since joining us, Dr. Squires has led the development of the strategic plan that is discussed below.

Eugene Melnyk continues his duties as Chairman of the Board. In conjunction with the Board of Directors, Mr. Melnyk has initiated a comprehensive review of our corporate governance practices. This review is consistent with our commitment to enhance investor confidence.

## STRATEGIC PLAN

We are currently in the process of developing a long-term strategic plan aimed at revitalizing our operations, aligning our development pipeline and increasing shareholder value. Our most critical priority is to enhance the return on investment of our U.S. commercial operations, as we recognize that the extent of our existing portfolio of promoted products does not support the current level of investment in our primary care sales force. The primary care market has become increasingly more competitive in recent years and the average size of many primary care sales organizations has increased considerably. In addition, primary care physicians are giving pharmaceutical representatives less time to describe the benefits of various medications, so pharmaceutical companies spent over \$3 billion on direct-to-consumer advertising in 2004 as an alternative means to create awareness for their medications. For these, and other reasons, we are re-evaluating our strategic approach to commercializing our products in the U.S. primary care market.

We are also currently evaluating a number of options to increase the value of our portfolio of legacy products. These products are in decline due to generic competition and are not strategic to our business, which is focused on long-term, sustainable growth. The options we are considering include: a sale of these products to strategic or financial buyers; the transfer of the assets to a new entity and the sale of shares of that entity pursuant to an initial public offering; or a distribution to our shareholders as a return of capital.

At this time, we cannot assess the impact that the outcome of the strategic-planning process will have on our results of operations, financial position and cash flows going forward. We expect to complete this process during the first half of 2005.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Critical accounting policies and estimates are those policies and estimates that are most important and material to the preparation of our consolidated financial statements, and which require management's most subjective and complex judgment due to the need to select policies from among alternatives available, and 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 agreements, we rely on estimates made by our third-party licensees. 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 position could be materially impacted.

Our critical accounting policies and estimates relate to the following:

Revenue recognition.

Valuation of acquired research and development.

Evaluation of long-term investments for impairment.

Useful lives of intangible assets and the evaluation of those assets for impairment.

Hedge effectiveness of derivative financial instruments.

Determination of the provision for income taxes.

Outcome of legal proceedings.

Assessment of insurance reserves.

### **Revenue recognition**

We recognize product sales revenue when title has transferred to the customer, provided that we have not retained any significant risks of ownership or future obligations with respect to the product sold. Revenue from product sales is recognized net of provisions for estimated returns, rebates and chargebacks. We establish these provisions concurrently with the recognition of product sales revenue. In connection with these provisions related to sales of products manufactured by us for distribution by our third-party licensees, we rely on estimates made by these licensees.

We allow customers to return product within a specified period of time before and after its expiration date. Provisions for these returns are estimated based on historical return and exchange levels, and third-party data with respect to inventory levels in our distribution channels. A significant change in these estimates could have a material impact on our results of operations. In late 2004 and early 2005, we entered into fee-based distribution agreements with our three major U.S. wholesalers. These agreements generally establish limits on inventory levels owned by these wholesalers, which is expected to moderate investment buying by these wholesalers that can result in sales fluctuations unrelated to end-customer demand. As a result, we expect lower levels of product returns in the future from these wholesalers due to product expiration and overstocking. In addition, these wholesalers are required to provide us with more extensive data with respect to the sales and inventory levels of our products, which will enable us to more reliably estimate our provision for returns, as well as our provisions for rebates and chargebacks.

We are subject to rebates and chargebacks on sales made under governmental and managed care pricing programs. Provisions for these rebates and chargebacks are estimated based on historical experience, contractual sales terms with wholesalers and indirect customers, and relevant statutes with respect to governmental pricing programs. The largest of these rebates and chargebacks are associated with sales covered by Medicaid. Medicaid rebates are typically billed up to six months after the product is shipped. As a result, a 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 our distribution channels is sold through to end-customers. 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 may incorporate revisions of this rebate provision for several periods.

### **Acquired research and development**

The costs of assets that are purchased through asset acquisitions or business combinations for a particular research and development project are expensed as acquired research and development at the time of acquisition. The amount allocated to acquired research and development is determined by identifying those specific in-process research and development projects that we intend to continue, and for which: technological feasibility had not been established at the date of acquisition; and there was no alternative future use. We classify the cost of acquired research and development as a cash outflow from investing activities because we expect to generate future income and cash flows from these assets if they can be developed into commercially successful products.

We generally engage independent valuation specialists to perform valuations of acquired research and development assets. There are several methods that can be used to determine the fair value of acquired assets. For acquired research and development, an income approach is generally used. This approach starts with a forecast of all of the estimated future cash flows. 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 expected costs to develop the acquired research and development into commercially viable products; the projected future cash flows from the projects when completed; the timing of the 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.

#### **Long-term investments**

We are required to estimate the fair value of our long-term investments in order to evaluate these investments for impairment. In the event that the cost of an investment exceeds its fair value, we determine whether the decline in fair value is other-than-temporary. In doing so, we consider general market conditions, the duration and extent to which the cost basis exceeds the fair value, and our ability and intent to hold the investment. We also consider the financial condition and earnings prospects of the investee.

Certain of our investments are not publicly traded securities and, as a result, the estimation of the fair values of these investments involves a greater degree of uncertainty. For these types of investments, we determine fair value based on the estimated discounted future cash flows of the investee. Some of the more significant estimates and assumptions inherent in this methodology for determining fair value include: the amount and timing of the future cash flows of the investee; 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.

#### **Intangible assets**

Intangible assets are stated at cost, less accumulated amortization generally computed using the straight-line method based on their estimated useful lives ranging from eight to 20 years. We amortize intangible assets on a systematic basis to reflect the pattern in which the economic benefits of the asset are consumed, if that basis can be reliably determined. 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 limitations, known technological advances, anticipated demand and the existence or absence of competition. A significant change in these factors may warrant a revision of the expected remaining useful life of an intangible asset, which could have a material impact on our results of operations.

Intangible assets acquired through asset acquisitions or business combinations are initially recorded at fair value based on an allocation of the purchase price. We often engage independent valuation specialists to perform valuations of the assets acquired. We subsequently evaluate intangible assets annually for impairment, or 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 obsolescence, plans to discontinue use or restructure, and poor financial performance compared with original plans. Impairment exists when the carrying amount of an asset is not recoverable

and its carrying amount exceeds its estimated fair value. There are several methods that can be used to determine fair value. For intangible assets, an income approach is generally used. This approach starts with a forecast of all of the estimated future cash flows. 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 the 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.

As previously discussed, we are currently reviewing our strategic approach to commercializing our products in the United States. The outcome of this review is not presently determinable, but it could result in a write-down in the carrying values of certain of our intangible assets.

#### **Derivative financial instruments**

We manage our exposure to interest rate risks through the use of derivative financial instruments. Our objective is to maintain a balance of fixed to floating interest rate exposure. We do not utilize derivative financial instruments for trading or speculative purposes. On the dates we enter into the derivative contracts, we designate the derivative financial instruments as a hedge of the fair value of an identified portion of a recognized long-term obligation. For a derivative financial instrument that is designated and qualifies as a fair value hedge, the derivative financial instrument is marked-to-market at each balance sheet date, with the gain or loss on the derivative financial instrument, and the respective offsetting loss or gain on the underlying hedged item, recognized in net income or loss. A discontinuance of fair value hedge accounting could have a material impact on our results of operations. Such a discontinuance did occur in 2003, and could occur in the future if changes in the fair value of the derivative financial instrument are not sufficiently correlated with changes in the fair value of the long-term obligation, based on the methods for testing effectiveness as outlined in our hedge documentation.

#### **Provision for income taxes**

Our provision for income taxes is subject to a number of different estimates made by management. A change in these estimates could have a material effect on the effective tax rate.

We have operations in various countries that have differing tax laws and rates. Our income tax reporting is subject to audit by both domestic and foreign tax authorities. The effective tax rate may change from year to year based on the mix of income 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, and changes in the estimated values of deferred tax assets and liabilities.

We have recorded a valuation allowance on deferred tax assets primarily relating to operating losses, future tax depreciation and tax credit carryforwards. We have assumed that these deferred tax assets are more likely than not to remain unrealized. 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 the provision for income taxes in a period.



**Legal proceedings**

We are required to accrue for a loss contingency with respect to legal proceedings against us if it is probable that the outcome will be unfavourable, and if the amount of the loss can be reasonably estimated. Management evaluates our exposure to loss based on the progress of each legal proceeding, experience in similar proceedings and consultation with legal counsel. We re-evaluate all legal proceedings as additional information becomes available. The ultimate outcome of any legal proceeding may be materially different from the amounts estimated, given the uncertainties inherent in complex litigation. For a discussion of our current legal proceedings, see note 24 to our audited consolidated financial statements.

**Insurance reserves**

We are self-insured for a portion of our automobile physical damage and product liability coverages. Reserves are established for all reported but unpaid claims and for estimates of incurred but not reported ("IBNR") claims. We engage an independent actuary to conduct an actuarial assessment of our IBNR liability. Significant judgment is applied to estimate IBNR liabilities. 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.

**SELECTED ANNUAL INFORMATION**

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

	Years Ended December 31		
	2004	2003	2002
	(\$ in 000s, except per share data)		
Revenue	\$ 886,543	\$ 823,722	\$ 788,025
Net income (loss)	160,994	(27,265)	87,795
Basic earnings (loss) per share	\$ 1.01	\$ (0.17)	\$ 0.58
Diluted earnings (loss) per share	\$ 1.01	\$ (0.17)	\$ 0.55
Total assets	\$ 1,711,060	\$ 1,922,774	\$ 1,833,804
Long-term obligations	478,936	822,927	747,350

Revenue increased 8% in 2004 compared with 2003, due mainly to higher Wellbutrin XL, Cardizem® LA and generic product sales in the United States, and higher Tiazac® and Wellbutrin® SR product sales in Canada. These factors more than offset declines in revenue from our participating interest in the gross profit on sales by a third- party of generic omeprazole and from our co-promotion of H. Lundbeck A/S's Celexa in Canada and GSK's Wellbutrin SR in the United States. In 2004, product sales revenue in the United States was negatively impacted by a work-down of wholesaler inventory levels. Revenue increased 5% in 2003 compared with 2002, due mainly to higher revenue from our interest in generic omeprazole that more than offset a decline in revenue from our co-promotion of GSK's Wellbutrin SR in the United States. A strengthening of the Canadian dollar relative to the U.S. dollar increased revenue by 1% in 2004 compared with 2003 and by 2% in 2003 compared with 2002.

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Our results of operations were impacted by specific events that affected the comparability of these results between years. These events include, but are not limited to:

Asset write-downs.

Gains on asset dispositions.

Acquisitions involving non-capitalized expenses, such as acquired research and development.

Equity losses related to a non-strategic investment in a biotechnology fund that is not part of our ongoing research and development program.

Early extinguishments of obligations.

We believe that the identification of these events enhances an analysis of our results of operations when comparing these results with those of a previous or subsequent period. In addition, management excludes these events when analyzing our operating performance. However, it should be noted that the determination of these events involves judgment by us. The impacts of these events on our net income and basic and diluted earnings per share for the last three years are identified in the following table:

	Years ended December 31		
	2004	2003	2002
	(\$ in 000s, except per share data)		
Write-down of assets	\$ 42,156	\$ 45,081	\$ 31,944
Gain on disposal of assets	(1,471)		
Acquired research and development	8,640	124,720	167,745
Equity loss	4,179	1,010	
Extinguishment of royalty obligation		61,348	
Foreign exchange loss on long-term obligation		13,061	
Relocation costs		7,539	
Reduction in tax contingency provision		(12,000)	
	\$ 53,504	\$ 240,759	\$ 199,689
Total per share:			
Basic	\$ 0.34	\$ 1.52	\$ 1.31
Diluted	\$ 0.34	\$ 1.51	\$ 1.24

Total assets declined \$211.7 million from 2003 to 2004, due mainly to a lower cash and cash equivalents balance (following the repayment of long-term obligations), the amortization of intangible assets and an other-than-temporary decline in the value of our investment in Ethypharm S.A. ("Ethypharm"). Long-term obligations declined \$344.0 million from 2003 to 2004, due mainly to the repayment of all outstanding borrowings under our revolving term credit facility, as well as repayments of other long-term obligations related to the acquisitions of intangible assets.

### RESULTS OF OPERATIONS

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

**REVENUE**

Our revenue is derived from the following sources:

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

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

Co-promotion of pharmaceutical products owned by other companies.

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

License fees from the out-licensing of our technologies or product rights.

The following table displays the dollar amount of each source of revenue for 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.

	Years Ended December 31						Percentage Change	
	2004		2003		2002		2003 to 2004	2002 to 2003
	\$	%	\$	%	\$	%		
	(\$ in 000s)							
Product sales	841,446	95	632,898	77	645,986	82	33%	(2)%
Research and development	20,452	2	14,239	2	28,425	4	44%	(50)%
Co-promotion, royalty and licensing	24,645	3	176,585	21	113,614	14	(86)%	55%
	886,543	100	823,722	100	788,025	100	8%	5%

**Product sales**

Product sales revenue comprises the following reporting categories:

*Promoted products*

Our promoted products are Cardizem® LA, Zovirax Ointment and Zovirax Cream, and Teveten® and Teveten® HCT. We promote these products directly to physicians in the United States. These products are sold primarily in the United States to drug wholesalers that serve retail pharmacies, hospitals, government agencies and managed care providers.

*Wellbutrin XL*

We are the exclusive manufacturer and supplier of Wellbutrin XL to GSK for marketing and distribution in the United States.

*Biovail Pharmaceuticals Canada ("BPC") products*

Our BPC products are Tiazac® XC, Tiazac®, Wellbutrin® SR, Zyban®, Monocor and Retavase. We currently promote Tiazac® XC and Wellbutrin® SR directly to physicians in Canada. BPC products are sold in Canada to drug wholesalers, retail pharmacies and hospitals.

*Core products*

Core products consist of our promoted products, Wellbutrin XL and BPC products, and include sales of all products that we actively promote and/or developed and licensed to third parties who promote them.

*Legacy products*

Our legacy products are Tiazac® (brand and generic), Cardizem® CD, Vasotec®, Vaseretic®, Ativan® and Isordil®. We do not actively promote these products as they have been genericized. We manufacture and sell Tiazac® to Forest Laboratories, Inc. ("Forest") for distribution in the United States. The remaining legacy products are sold primarily in the United States to drug wholesalers.

*Generic products*

Our generic products are bioequivalent versions of Adalat CC, Cardizem® CD, Procardia XL, Trental and Voltaren XR. We manufacture and sell these products to Teva Pharmaceutical Industries Ltd. ("Teva") for distribution in the United States.

The following table displays product sales by category for 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.

	Years Ended December 31						Percentage Change	
	2004		2003		2002		2003 to 2004	2002 to 2003
	\$	%	\$	%	\$	%		
	(\$ in 000s)							
Promoted products	146,676	17	172,418	27	108,261	17	(15)%	59%
Wellbutrin XL	317,298	38	64,932	10			389%	N/A
BPC products	101,865	12	85,197	13	32,565	5	20%	162%
Core products	565,839	67	322,547	51	140,826	22	75%	129%
Legacy products	125,932	15	208,860	33	323,626	50	(40)%	(35)%
Generic products	149,675	18	101,491	16	181,534	28	47%	(44)%
	841,446	100	632,898	100	645,986	100	33%	(2)%

*Promoted products*

Promoted product sales declined 15% in 2004 compared with 2003 and increased 59% in 2003 compared with 2002. The decline in promoted product sales in 2004 reflected reductions in inventories of these products at the wholesale level that were generally not related to the market share performance of these products. A significant portion of our promoted product sales is made to three major U.S. wholesalers. These wholesalers took steps together with us to work down inventory levels in

anticipation of the transition to the aforementioned fee-based distribution agreements. However, sales of Cardizem® LA (which was launched in April 2003) increased 12% in 2004 compared with 2003, reflecting increased prescription demand that more than offset the reduction in wholesaler inventory levels of this product.

The increase in promoted product sales in 2003 reflected the launches of Cardizem® LA, Teveten® HCT and Zovirax Cream during that year.

#### *Wellbutrin XL*

Wellbutrin XL sales have increased dramatically since its launch by GSK in September 2003. Under the terms of our supply agreement with GSK, we ship Wellbutrin XL according to purchase orders received from GSK. In 2004, GSK ordered additional quantities of Wellbutrin XL to build an optimal safety-stock level. The supply price for Wellbutrin XL trade product is based on an increasing tiered percentage of revenue generated on GSK's net sales (after taking into consideration GSK's provisions for estimated discounts, returns, rebates and chargebacks). In the second quarter of 2004, GSK net sales of Wellbutrin XL exceeded the threshold to increase the supply price from the first to the second tier and, in the third quarter of 2004, the threshold was exceeded to increase the supply price from the second to the third tier. As a result, all Wellbutrin XL sales were recorded at the highest tier supply price in the fourth quarter of 2004, except for any safety-stock held by GSK at the end of 2004, which was recorded at the lowest tier supply price. The supply price is reset to the lowest tier at the start of each calendar year and the sales thresholds to achieve the second and third tier supply prices generally increase each year. As a result, we anticipate a decline in Wellbutrin XL revenue in the first half of 2005 compared with the latter half of 2004.

Three companies have filed Abbreviated New Drug Applications seeking FDA approval for generic versions of Wellbutrin XL. We have filed patent infringement suits against these companies, which effectively precludes the FDA from granting approval for the earlier of 30 months or upon a court decision of non-infringement. As a result, we anticipate the introduction of generic competition for Wellbutrin XL in mid-2007.

#### *BPC products*

BPC product sales increased 20% in 2004 compared with 2003 and by 162% in 2003 compared with 2002. The increases in BPC product sales were due in part to the continuing growth in Tiazac® sales, which included pre-launch shipments of Tiazac® XC in the fourth quarter of 2004. In January 2005, we began to actively promote Tiazac® XC to Canadian physicians. Also contributing to the increases in BPC product sales were the additions of Wellbutrin® SR and Zyban, which we acquired from GSK in December 2002. We began to actively promote Wellbutrin® SR in January 2004. In early 2005, a generic version of Wellbutrin® SR was introduced in Canada, which may result in a significant decline in our sales of this product.

#### *Core products*

Core product sales increased 75% in 2004 compared with 2003 and by 129% in 2003 compared with 2002. The increases in core product sales reflected primarily the positive market share performance of Wellbutrin XL and Cardizem® LA in 2004 and 2003, as well as the added contributions from Zovirax Cream and Teveten® HCT in 2003.

*Legacy products*

Legacy product sales declined 40% in 2004 compared with 2003 and by 35% in 2003 compared with 2002. The declines in legacy product sales were due in part to the introduction in the United States of a generic version of Tiazac® in April 2003. Consequently, Forest ceased all promotional efforts for Tiazac® as of September 2003. The decline in sales of Tiazac® brand was partially offset by sales of our own generic version of Tiazac® by Forest. Sales of our other legacy products were impacted by generic competition, as well as reductions in wholesaler inventory levels for the reasons discussed above for our promoted products. Sales of Cardizem® CD were also affected by the promotion of, and conversion to, Cardizem® LA.

*Generic products*

Generic product sales increased 47% in 2004 compared with 2003 following a decline of 44% in 2003 compared with 2002. The increase in generic product sales in 2004 reflected the stabilization of inventory levels by Teva following a reduction of these levels during 2003. In September 2004, we resolved our pending arbitration with Teva related to a dispute over our existing distribution agreement. Under the terms of the settlement agreements, we granted Teva a four-year extension to the 10-year supply term for each of our generic products currently marketed by them. In consideration for this extension, beginning in the fourth quarter of 2004, our selling price to Teva for each generic product is increased for the remainder of the extended supply term.

**Research and development**

Research and development revenue increased 44% in 2004 compared with 2003 and declined 50% in 2003 compared with 2002. The increase in research and development revenue in 2004 reflected a higher level of clinical research and laboratory testing services provided to external customers by our contract research operation. The decline in research and development revenue in 2003 reflected that we earned \$11.5 million in 2002 associated with the final development of Wellbutrin XL in collaboration with GSK.

**Co-promotion, royalty and licensing**

Co-promotion, royalty and licensing revenue declined 86% in 2004 compared with 2003 and increased 55% in 2003 compared with 2002. The changes in the level of co-promotion, royalty and licensing revenue between those years reflected mainly the relative contribution from our interest in generic omeprazole, which amounted to \$1.7 million, \$103.0 million and \$20.3 million in 2004, 2003 and 2002, respectively. In 2004, we received the final revenue from this interest. In addition, we did not derive any revenue from co-promotion activities in 2004 compared with \$43.1 million and \$61.0 million in 2003 and 2002, respectively, related to the co-promotion of Celexa in Canada and GSK's Wellbutrin SR in the United States. We discontinued the co-promotion of Celexa effective December 31, 2003, in order to focus our marketing efforts on our Wellbutrin® SR in Canada, and we concluded our co-promotion of Wellbutrin SR in the United States in the first quarter of 2003.

**OPERATING EXPENSES**

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

	Years Ended December 31						Percentage Change	
	2004		2003		2002		2003 to 2004	2002 to 2003
	\$	%	\$	%	\$	%		
	(\$ in 000s)							
Cost of goods sold	228,278	26	139,456	17	164,706	21	64%	(15)%
Research and development	70,493	8	86,570	11	52,150	7	(19)%	66%
Selling, general and administrative	257,407	29	242,771	29	166,397	21	6%	46%
Amortization	64,976	7	140,895	17	71,499	9	(54)%	97%
Write-down of assets, net of gain on disposal	40,685	5	45,081	5	31,944	4	(10)%	41%
Acquired research and development	8,640	1	124,720	15	167,745	21	(93)%	(26)%
Extinguishment of royalty obligation			61,348	7			(100)%	N/A
Settlements			(34,055)	(4)			(100)%	N/A
	670,479	76	806,786	98	654,441	83	(17)%	23%

**Cost of goods sold and gross margins**

Cost of goods sold increased 64% in 2004 compared with 2003 and declined 15% in 2003 compared with 2002. Gross margins based on product sales were 73%, 78% and 75% in 2004, 2003 and 2002, respectively. The decline in the gross margin in 2004 reflected a significantly higher proportion of Wellbutrin XL in the product sales mix. The cost of producing Wellbutrin XL was higher relative to our other products in 2004, due to start-up manufacturing inefficiencies and a more costly active ingredient. We also produced a higher initial proportion of lower margin Wellbutrin XL sample product versus trade product.

The increase in the gross margin in 2003 reflected the recognition of a \$25.5 million cumulative reduction in the Zovirax supply price, in accordance with amendments to our distribution agreement with GSK. This cumulative reduction was subject to repayment if the FDA did not approve Wellbutrin XL. Accordingly, prior to the second quarter of 2003, we had been deferring the value of the reduction in the supply price pending the outcome of the Wellbutrin XL approval.

**Research and development**

Research and development expenses declined 19% in 2004 compared with 2003 and increased 66% in 2003 compared with 2002. We invested 8% of total revenue in research and development activities in 2004 compared with 11% and 7% in 2003 and 2002, respectively. The changes in the level of research and development spending in those years reflected mainly the costs of the tramadol ER Phase III clinical trial program conducted during 2003. In addition, research and development expenses in 2003 included the costs associated with a clinical program designed to evaluate the use of Cardizem® LA in a clinical practice setting.



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Our long-term success depends, to a great extent, on our ability to continue to develop innovative new products. We have achieved a number of recent successes from our late-stage product-development pipeline, including the following milestones:

Filings of NDAs for tramadol ER and tramadol ODT in February and May 2004, respectively.

Filing of an NDA for Glumetza in June 2004. This filing was made in collaboration with Depomed, Inc. ("Depomed").

Filing of an NDA for citalopram ODT in June 2004.

Approval by the FDA of Cardizem® LA for an angina indication in June 2004.

Filing of an NDS in collaboration with Depomed for Glumetza in August 2004.

Approval by the TPD of Tiazac® XC, for the treatment of hypertension, in August 2004.

Submission of a supplemental NDS for an angina indication for Tiazac® XC in October 2004. In March 2005, we received a Notice of Non-Compliance from the TPD related to this submission. We have 90 days in which to prepare a response to the TPD to address the issues raised in this notice.

Receipt of an Approvable Letter from the FDA for tramadol ER in October 2004. In March 2005, we submitted a Complete Response to this letter. We received notification from the FDA on March 29, 2005 that this response will be subject to a six-month review, and that they are of the opinion that additional clinical data will be required. We are proceeding with a clinical program to address the FDA's comments.

Filing of a Complete Response in November 2004 to an Approvable Letter received from the FDA in October 2002 for zolpidem ODT, for the treatment of insomnia. This response bridges zolpidem ODT from a floss to a non-floss formulation for 5 mg and 10 mg dosage strengths, and is subject to a six-month review by the FDA.

Receipt of an Approvable Letter from the FDA for tramadol ODT in January 2005. This letter involves the resolution of labeling issues only. In March 2005, we submitted a Complete Response to this letter. We anticipate receiving final FDA approval for this product in May 2005.

Receipt of an Approvable Letter from the FDA for citalopram ODT in February 2005. This letter involves the clarification of a number of chemistry and manufacturing issues, primarily involving the level of detail provided to the file for review. We are working with the FDA to resolve these issues.

Submission of a supplemental NDS for Wellbutrin XL in February 2005. We retained the rights from GSK to market and sell this product in Canada, subject to TPD approval.

Receipt of an Approvable Letter from the FDA for Glumetza in March 2005. This letter involves the completion of discussions with regard to a manufacturing issue and we anticipate resolving this issue with the FDA in the near term. We will be required to pay \$25.0 million to Depomed on receipt of FDA approval for Glumetza .

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 and competitive developments, and strategic marketing decisions.



### **Selling, general and administrative**

Selling, general and administrative expenses increased 6% in 2004 compared with 2003 and by 46% in 2003 compared with 2002. As a percentage of total revenue, selling, general and administrative expenses were 29% in both 2004 and 2003 compared with 21% in 2002. The increase in selling, general and administrative expenses in 2004 reflected a higher level of spending on sales and marketing activities to support our promoted products, as well as an increase in headcount and higher legal expenses. In addition, we incurred incremental costs associated with the expansion and realignment of our primary care sales force in the United States, and the recruitment and deployment of two specialty sales forces that will detail our promoted products to medical specialists. The increased costs associated with our expanded sales forces were offset partially by the elimination of co-promotion fees paid to Reliant Pharmaceuticals, LLC ("Reliant") in 2003 and 2002. Effective December 31, 2003, we mutually agreed with Reliant to terminate their co-promotion of certain of our products.

The increase in selling, general and administrative expenses in 2003 reflected an increase in costs associated with the expansion of our U.S. commercial operations, as well as relocation costs of \$7.5 million associated with the transition of our commercial operations head office from Raleigh, North Carolina, and certain research and development personnel from Chantilly, Virginia, to our facility in Bridgewater, New Jersey. Also contributing to the increase in 2003 was advertising and promotional expenses related to the launches of Cardizem® LA, Teveten® HCT and Zovirax Cream.

### **Amortization**

Amortization expense declined 54% in 2004 compared with 2003 and increased 97% in 2003 compared with 2002. As a percentage of total revenue, amortization expense was 7%, 17% and 9% in 2004, 2003 and 2002, respectively. The changes in the level of amortization expense between those years reflected mainly the relative amortization of our interest in generic omeprazole, which amounted to \$1.1 million, \$70.7 million and \$13.5 million in 2004, 2003 and 2002, respectively. Amortization was recorded on a proportionate basis relative to the revenue earned from this interest. In 2004, we recorded the final amortization as we had received all of the revenue from this interest.

### **Write-down of assets, net of gain on disposal**

In December 2004, we recorded a \$37.8 million write-down to the carrying value of our equity investment in Ethypharm to reflect an other-than-temporary decline in the estimated fair value of this investment. We have price protection on our investment in the event of any private or public financing undertaken by Ethypharm; however, we currently consider it unlikely that we will realize the value of this investment through such a refinancing, as this price protection expires in June 2005. Consequently, we evaluated our investment in Ethypharm and determined that the carrying value of this investment may not be fully realized in the foreseeable future. Nevertheless, Ethypharm has been executing on a restructuring plan to improve its profitability and financial condition, and it continues to invest a significant portion of its revenue into research and development activities. For these reasons, we may ultimately be able to recover the full value of our investment in Ethypharm.

In November 2004, we wrote off the remaining \$4.4 million net book value of the Rondec product rights, following a decision not to reformulate this product line and to discontinue all remaining related marketing and sales efforts. Without continued reformulation and support, Rondec will be subject to

higher levels of generic substitution. Consequently, we evaluated the fair value of the Rondec product rights and determined that these rights had been permanently impaired.

In July 2004, we disposed of the Cedax product rights, as well as our remaining Cedax inventories and promotional materials, for proceeds of \$3.0 million, which resulted in a gain on disposal of \$1.5 million.

In 2003, we recorded a charge of \$45.1 million primarily related to the write-down of the net book values of the Cedax and Rondec product rights to their estimated fair values at that time. In December 2003, as part of the transition of our U.S. commercial operations, we evaluated our future interest in our Cedax and Rondec products. We intended to focus our therapeutically aligned sales efforts on Cardizem® LA, Teveten® and Zovirax. Without continued promotion, the economic viability of Cedax and Rondec was substantially lower, as these products required significant marketing and sales efforts in order to maintain market share. We evaluated the current and forecasted market shares at the time for Cedax and Rondec and determined that the undiscounted future cash flows from these products were below the carrying values of the related product rights. Accordingly, we wrote down the carrying values of these product rights to their estimated fair values at that time.

In 2002, we recorded a charge of \$31.9 million primarily related to the write-down of the net book value of the generic Adalat CC product rights acquired from Elan Corporation, plc ("Elan"), net of our corresponding obligation to them. In June 2002, we entered into a settlement with Elan and the U.S. Federal Trade Commission with respect to the introduction of generic versions of Adalat CC. As a result of this settlement, our agreements with Elan related to our in-licensing of Elan's generic versions of Adalat CC were terminated.

#### **Acquired research and development**

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

In 2003, we recorded a charge of \$124.7 million to acquired research and development expense related to the following transactions:

Acquisition of ODT formulations of tramadol and tramadol/acetaminophen ("APAP") from Ethypharm for \$16.0 million. Since the date of acquisition, we have received an aforementioned Approvable Letter from the FDA for tramadol ODT. Tramadol/APAP is in a pre-clinical phase of development.

Acquisition of our initial interest in BNC-PHARMAPASS's products for \$26.4 million.

Acquisition of certain cardiovascular products from Athpharma Limited ("Athpharma") for \$44.2 million. We are currently in discussions with Athpharma to either substitute certain new products in place of the original products acquired or to terminate the development and license agreement.

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Acquisition of certain Ativan® products under development from Wyeth Pharmaceuticals Inc. ("Wyeth"), which were valued at \$38.1 million. An ODT product for the treatment of anxiety is in an early clinical phase of development.

In 2002, we recorded a charge of \$167.7 million to acquired research and development expense related to the following transactions:

Acquisition of Pharma Pass LLC and Pharma Pass S.A. (collectively, "Pharma Pass"). At the date of acquisition, Pharma Pass was involved in the development of a number of products for us, as well as other pharmaceutical companies, which were valued at \$107.2 million. Since the date of acquisition, one of the products (Wellbutrin XL) received FDA approval, another has received an aforementioned Approvable Letter (tramadol ER) and two others were sold to Teva under the terms of the aforementioned September 2004 settlement agreements. We are continuing the development programs for the remaining products, which are in various stages of completion.

Acquisition of Pharmaceuticals Technologies Corporation ("Pharma Tech"). At the date of acquisition, Pharma Tech was involved with a number of product-development projects, which were valued at \$60.5 million. Since the date of acquisition, we discontinued the development of one of the product-development projects and we received an Approvable Letter from the FDA for one of the remaining products.

### **Extinguishment of royalty obligation**

In December 2003, we mutually agreed with Reliant to terminate their co-promotion of our products, and we incurred a charge of \$61.3 million related to a payment to extinguish our trailing royalty obligation to them.

### **Settlements**

In 2003, we negotiated an overall settlement with Pfizer Inc. and certain other companies through which all pending patent infringement and antitrust actions relating to generic versions of Procardia XL and Adalat CC were dismissed. We also reached settlements with Eli Lilly and Company ("Lilly") with respect to Lilly's inability to supply us with Keftab, and with Mylan Pharmaceuticals Inc. ("Mylan") with respect to Mylan's failure to supply us with generic Verelan, as well as with Elan with respect to the termination of our rights to Elan's generic versions of Adalat CC.

In relation to these matters, we received settlement payments of \$34.1 million in 2003, mainly related to our lost profits on sales of generic Procardia XL, Keftab and generic Verelan. We also received payments totaling \$16.2 million in 2003, mainly related to a recovery of certain charges related to Elan's supply to us of generic Adalat CC, which was recorded as a reduction to cost of goods sold, and compensation for legal and other expenses, which were recorded as a reduction to selling, general and administrative expenses, and interest income. We received an additional \$14.6 million in 2003, which was recorded as a reduction to assets related to the recoverable value of the Keftab product rights and the value of the destroyed Keftab inventory.

### **OPERATING INCOME**

We recorded operating income of \$216.1 million in 2004 compared with \$16.9 million in 2003 and \$133.6 million in 2002. Charges for acquired research and development, write-downs of assets (net of gain

of disposal), the extinguishment of the Reliant royalty obligation and relocation activities, reduced operating income by a total of \$49.3 million in 2004 compared with \$238.7 million in 2003 and \$199.7 million in 2002.

Operating income in 2004 compared with 2003 reflected higher product sales revenue and lower research and development spending. These factors were offset partially by the lower contribution from our interest in generic omeprazole and the decline in co-promotion revenue related to Celexa and Wellbutrin SR, as well as costs associated with the expansion of our U.S. commercial operations, and higher spending on sales and marketing activities.

Operating income in 2003 compared with 2002 reflected a modest increase in revenue that was more than offset by higher costs associated with the expansion of our U.S. commercial operations, and increased spending on research and development, and sales and marketing activities. These factors were partially offset by the recognition of settlement payments, which had the effect of increasing operating income by \$47.5 million in 2003, and the contribution from our interest in generic omeprazole.

## **NON-OPERATING ITEMS**

### **Interest income and expense**

Interest income was \$1.0 million in 2004 compared with \$7.2 million in 2003 and \$3.6 million in 2002. In 2003, interest income included interest on settlement payments.

Interest expense was \$40.1 million in 2004 compared with \$40.4 million in 2003 and \$32.0 million in 2002. Interest expense mainly comprised interest on our 7<sup>7</sup>/<sub>8</sub>% Senior Subordinated Notes due April 1, 2010 ("Notes"), which were issued in March 2002. In June 2002, we entered into three interest rate swaps in an aggregate notional amount of \$200.0 million. In June 2004, we terminated those swaps and we replaced them with a new interest rate swap in the same notional amount. The new and terminated swaps involve(d) the receipt of amounts based on a fixed rate of 7<sup>7</sup>/<sub>8</sub>% in exchange for floating rate interest payments based on six-month London Interbank Offering Rate ("LIBOR") plus a spread. Net receipts relating to these swaps, which amounted to \$6.4 million, \$7.3 million and \$3.3 million in 2004, 2003 and 2002, respectively, were recorded as a reduction to interest expense.

### **Foreign exchange gain or loss**

We recorded foreign exchange losses of \$0.6 million in 2004 and \$14.0 million in 2003 and a foreign exchange gain of \$0.7 million in 2002. These amounts reflected the impact of foreign exchange fluctuations on our non-U.S. dollar-denominated cash and cash equivalents, accounts receivable and accounts payable balances. The amount in 2003 also included a \$13.1 million foreign exchange loss on a Canadian dollar-denominated obligation to GSK related to our acquisition of the Canadian rights to Wellbutrin® and Zyban®, and was the result of a strengthening of the Canadian dollar relative to the U.S. dollar during 2003. We paid the final instalment related to this obligation in March 2004.

### **Equity loss**

In 2004 and 2003, we recorded equity losses of \$4.2 million and \$1.0 million, respectively, related to our investment in a venture fund that invests in early-stage biotechnology companies. Included in these equity losses was our share of goodwill impairment charges related to certain subsidiaries of this fund, as well as write-downs to the carrying values of other investments held by this fund. At December 31, 2004,

we had invested a total of \$5.8 million in this fund. The nature of this fund is no longer consistent with our business strategy, and we will not be making any additional capital contributions in it beyond our remaining commitment of \$2.0 million.

**Other income or expense**

The changes in the fair values of the terminated interest rate swaps, as well as the offsetting changes in the fair value of the portion of our Notes being hedged (during those periods that hedge accounting was applied), were recorded in other income or expense. In the first half of 2004, we recorded a loss of \$2.3 million related to these changes in fair values. In 2003 and 2002, we recorded net gains of \$0.1 million and \$3.4 million, respectively, related to these changes in fair values. The new interest rate swap has a call feature and other critical terms that are consistent with those of the Notes; therefore, we can assume that there is no ineffectiveness present in the new hedging relationship, which permits us to apply the shortcut method of accounting in accordance with the Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities". As a result, in the second half of 2004, the \$3.4 million gain in the fair value of this swap exactly offset the loss in the fair value of the Notes.

**Income taxes**

Our effective tax rate depends on the relative profitability of our domestic and foreign operations and the statutory tax rates of the related tax jurisdictions. Our low effective tax rate in the last three years reflected the fact that most of our income was derived from foreign subsidiaries with lower statutory tax rates than those that apply in Canada. We recorded a provision for income taxes of \$9.0 million in 2004 compared with a recovery of income taxes of \$4.0 million in 2003 (which included a reduction in our provision for tax contingencies of \$12.0 million, due to the resolution of certain tax uncertainties and incremental tax losses in the United States), and a provision for income taxes of \$21.5 million in 2002. Our effective tax rate was affected by the availability of unrecognized tax loss carryforwards that can be used to offset taxable income in Canada and the United States, as well as losses that were incurred in the United States due to the expansion of our commercial operations, and sales and marketing costs to support our promoted products.

**SUMMARY OF QUARTERLY RESULTS**

The following table presents a summary of our quarterly results of operations in 2004 and 2003:

	2004				
	Q1	Q2	Q3	Q4	Full Year
	(\$ in 000s, except per share data)				
Revenue	\$ 186,626	\$ 206,313	\$ 215,725	\$ 277,879	\$ 886,543
Net income	21,106	44,208	49,635	46,045	160,994
Basic and diluted earnings per share	\$ 0.13	\$ 0.28	\$ 0.31	\$ 0.29	\$ 1.01
	2003				
	Q1	Q2	Q3	Q4	Full Year
	(\$ in 000s, except per share data)				
Revenue	\$ 191,390	\$ 217,283	\$ 215,314	\$ 199,735	\$ 823,722
Net income (loss)	57,599	(4,940)	16,114	(96,038)	(27,265)
Basic and diluted earnings (loss) per share	\$ 0.36	\$ (0.03)	\$ 0.10	\$ (0.60)	\$ (0.17)

**RESULTS FOR THE FOURTH QUARTER**

Revenue increased 39% from \$199.7 million in the fourth quarter of 2003 to \$277.9 million in the fourth quarter of 2004, due mainly to higher Zovirax, Wellbutrin XL and generic product sales. Zovirax product sales in the fourth quarter of 2004 reflected end-customer demand, as our major U.S. wholesalers had reduced their inventories of this product to an optimal safety-stock level by the end of the third quarter of 2004. Wellbutrin XL product sales increased 126% in the fourth quarter of 2004 compared with the corresponding period of 2003, reflecting a higher-tier supply price, an increase in prescription demand, and a build-up of safety-stock levels by GSK. Generic product sales increased 66% in the fourth quarter of 2004 compared with the corresponding period of 2003, reflecting the stabilization of inventory levels of these products by Teva and the aforementioned increase in our selling price to Teva for each generic product. The increase in product sales revenue more than offset the declines in revenue from our interest in generic omeprazole and from our co-promotion of Celexa in Canada, which amounted to \$11.3 million and \$9.7 million, respectively, in the fourth quarter of 2003. Net income for the fourth quarter of 2004 was \$46.0 million (basic and diluted earnings per share of \$0.29) compared with a net loss of \$96.0 million (basic and diluted loss per share of \$0.60) in the fourth quarter of 2003. Our results of operations for the fourth quarters of 2004 and 2003 were impacted by specific events that affected the comparability of these



results between those periods. The impacts of these events on net income and basic and diluted earnings per share for the fourth quarters of 2004 and 2003 are identified in the following table:

	Q4	
	2004	2003
	(\$ in 000s, except per share data)	
Write-down of assets	\$ 42,156	\$ 45,081
Equity loss	4,052	786
Extinguishment of royalty obligation		61,348
Acquired research and development		22,111
Relocation costs		4,383
Foreign exchange loss on long-term obligation		1,723
Reduction in tax contingency provision		(12,000)
<b>Total</b>	<b>\$ 46,208</b>	<b>\$ 123,432</b>
<b>Total per share:</b>		
Basic	\$ 0.29	\$ 0.78
Diluted	\$ 0.29	\$ 0.77

Net income and earnings per share in the fourth quarter of 2004 compared with the corresponding period of 2003 reflected higher product sales revenue and an improved gross margin on Wellbutrin XL, due to a higher-tier supply price and less shipments of lower value sample product. These factors were offset partially by the lower contribution from our interest in generic omeprazole and the decline in revenue from our co-promotion of Celexa.

Net cash provided by operating activities increased \$73.8 million from \$37.9 million in the fourth quarter of 2003 to \$111.7 million in the fourth quarter of 2004, primarily due to the aforementioned payment to Reliant of \$61.3 million in December 2003 to extinguish our trailing royalty obligation to them.

## FINANCIAL CONDITION

The following table presents a summary of our financial condition in 2004 and 2003:

	At December 31	
	2004	2003
	(\$ in 000s)	
Working capital	\$ 124,414	\$ 149,884
Long-lived assets	1,328,363	1,396,776
Long-term obligations	478,936	822,927
Shareholders' equity	1,053,913	881,595

### Working capital

The \$25.5 million decrease in working capital from 2003 to 2004 was primarily due to:

Repayments of long-term obligations of \$346.3 million;



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A decrease in accounts receivable of \$30.6 million mainly related to the timing of collections;

Additions to property, plant and equipment of \$28.0 million; and

Acquisitions of BNC-PHARMAPASS and other long-term investments for \$12.2 million.

Partially offset by:

Cash generated from operations of \$317.3 million before changes in operating assets and liabilities;

An increase in inventories of \$26.1 million mainly related to higher Wellbutrin XL production volumes;

A decrease in accounts payable of \$26.8 million mainly related to the timing of payments and inventory purchases; and

A decrease in provisions for product returns, rebates and chargebacks of \$22.1 million, as a result of the reduction in inventories at the wholesale level.

### Long-lived assets

Long-lived assets comprise property, plant and equipment, goodwill, intangible and other assets, net of accumulated depreciation and amortization. The \$68.4 million decrease in long-lived assets from 2003 to 2004 reflected primarily the depreciation of plant and equipment of \$22.3 million and the amortization of intangible assets of \$66.0 million, offset partially by capital expenditures on property, plant and equipment of \$28.0 million. These expenditures consisted mainly of additions to our manufacturing capacity in Steinbach, Manitoba and Dorado, Puerto Rico, to meet demand for Wellbutrin XL and Cardizem® LA, as well as leasehold improvements to our Bridgewater facility.

### Long-term obligations

The \$344.0 million decrease in long-term obligations, including the current portion thereof, from 2003 to 2004 reflected the repayment of \$280.0 million under our revolving term credit facility. In addition, we repaid \$66.3 million of other long-term obligations, including the following instalments:

Final payment of \$21.8 million related to the acquisition of the Canadian rights to Wellbutrin® and Zyban®.

Payments of \$19.7 million related to the acquisition of Vasotec® and Vaseretic®;

Payment of \$11.3 million related to the aforementioned amendments to the Zovirax distribution agreement.

Payment of \$9.2 million related to the acquisition of Ativan® and Isordil®.

### Shareholders' equity

The \$172.3 million increase in shareholders' equity from 2003 to 2004 reflected net income of \$161.0 million and proceeds of \$8.0 million received from the issuance of common shares on the exercise of stock options and through our Employee Stock Purchase Plan. We recorded a \$7.0 million unrealized holding loss on our available-for-sale investments, primarily related to our equity investment in Depomed,



and a foreign currency translation gain of \$10.5 million due mainly to a strengthening of the Canadian dollar relative to the U.S. dollar.

## CASH FLOWS

At December 31, 2004, we had cash and cash equivalents of \$34.3 million compared with \$133.3 million at December 31, 2003. The following table displays cash flow information for the last three years:

	Years ended December 31		
	2004	2003	2002
	(\$ in 000s)		
Net cash provided by operating activities	\$ 277,090	\$ 281,979	\$ 334,104
Net cash used in investing activities	(42,263)	(278,446)	(792,467)
Net cash provided by (used in) financing activities	(334,526)	72,523	79,533
Effect of exchange rate changes on cash and cash equivalents	762	1,125	19
Net increase (decrease) in cash and cash equivalents	\$ (98,937)	\$ 77,181	\$ (378,811)

### Operating activities

Net cash provided by operating activities in 2004 was comparable to 2003 reflecting relatively level income from operations (net of non-cash items), and the fact that the receipt of the settlement payments in 2003 largely offset the payment we made to Reliant to extinguish our trailing royalty obligation to them. Net cash provided by operating activities declined \$52.1 million from 2002 to 2003 primarily due to lower income from operations (net of non-cash items), primarily due to the higher costs associated with the expansion of our U.S. commercial operations. Net cash provided by operating activities was primarily used to repay long-term obligations in 2004 and to fund acquisition related activities in 2003 and 2002.

### Investing activities

Net cash used in investing activities declined \$236.2 million from 2003 to 2004 primarily due to:

A decrease of \$242.3 million in acquisitions of intangible assets. In 2003, we made initial cash payments of \$146.3 million to Wyeth for Ativan® and Isordil®, and we acquired the Athpharma products for \$44.2 million, Ethypharm's tramadol products for \$16.0 million and an interest in generic omeprazole for \$35.5 million; and

A decrease of \$16.4 million in acquisitions of businesses. In 2004, we acquired PPII's remaining interest in BNC-PHARMAPASS for \$9.3 million. In 2003, we acquired our initial interest in BNC-PHARMAPASS for \$25.7 million.

Net cash used in investing activities declined \$514.0 million from 2002 to 2003 primarily due to:

A decrease of \$214.8 million in acquisitions of businesses. In 2002, we acquired Pharma Pass for \$178.7 million and Pharma Tech for \$61.9 million;

A decrease of \$133.1 in acquisitions of intangible assets. In 2002, we made initial cash payments of \$145.7 million to Merck & Co., Inc. ("Merck") for Vasotec® and Vaseretic®, we purchased the

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distribution rights to Zovirax from GSK for \$133.4 million, and we acquired Teveten® from Solvay Pharmaceuticals Marketing & Licensing AG for \$94.3 million;

A decrease of \$80.6 million in acquisitions of long-term investments. In 2002, we made equity investments in Ethypharm and Depomed of \$67.8 million and \$13.7 million, respectively; and

A decrease of \$24.5 million in additions to property, plant and equipment. In 2002, we undertook a major expansion of our Steinbach manufacturing facility in order to increase capacity for the production of Wellbutrin XL.

### Financing activities

Net cash used in financing activities increased \$407.0 million from 2003 to 2004 primarily due to:

An increase of \$280.0 million in repayments under our revolving term credit facility; and

A decrease of \$170.0 million in borrowings under our revolving term credit facility.

Partially offset by:

A decrease of \$53.1 million in repayments of other long-term obligations. In 2004, we made the final payment related to the acquisition of the Canadian rights to Wellbutrin® and Zyban®. In 2003, we made three payments related to that acquisition and we paid \$40.0 million to GSK related to the extension of the Zovirax distribution agreement from 10 to 20 years.

Net cash provided by financing activities decreased \$7.0 million from 2002 to 2003 primarily due to:

A decrease in net proceeds of \$384.3 million related to the issuance of our Notes in 2002;

A decrease in net proceeds of \$112.8 million related to the exercise of warrants in 2002. The warrants to acquire our common shares expired on September 30, 2002; and

An increase of \$77.4 million in repayments of other long-term obligations related to the acquisition of the Canadian rights to Wellbutrin® and Zyban® and the extension of the Zovirax distribution agreement.

Partially offset by:

A decrease of \$503.1 million in repurchases of our common shares under our 2002 stock repurchase program; and

An increase of \$60.0 million in borrowings under our revolving term credit facility.

### LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2004, we had total long-term obligations of \$478.9 million, including the current portion thereof, which included the carrying value of our Notes of \$405.5 million and obligations related to the acquisitions of intangible assets of \$69.0 million. In March 2004, we renewed our revolving term credit facility at \$400.0 million. The revolving period of this facility extends to May 25, 2005, following the lenders' consent to extend the renewal date of this facility from March 25, 2005. This facility is renewable for one-year revolving terms at the lenders' option, with a one-year term out at our option if the lenders do not renew. We are currently in the process of renewing the revolving term of this facility. This facility may be used for general corporate purposes, including acquisitions. At December 31, 2004, we were in



compliance with all financial and non-financial covenants associated with this facility. At December 31, 2004, we had no outstanding borrowings under this facility; however, we had a letter of credit with a balance of \$36.7 million issued under this facility. This letter of credit secures the remaining semi-annual payments we are required to make to Merck related to the acquisition of Vasotec® and Vaseretic®. At December 31, 2004, we had a remaining balance of \$363.3 million available to borrow under this facility. Our current corporate credit ratings from Standard & Poor's ("S&P") and Moody's Investors Service ("Moody's") are BB+ and B1, respectively, and the current ratings on our Notes from S&P and Moody's are BB- and B2, respectively.

Commencing in 2005, we plan to invest approximately \$27.6 million to further expand and optimize the capacity at our Steinbach manufacturing facility. This expansion will enable us to meet the anticipated demand for our existing products, as well as products in our development pipeline, such as tramadol ER. We expect this expansion will be completed in late 2006.

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

### CONTRACTUAL OBLIGATIONS

The following table summarizes our fixed contractual obligations at December 31, 2004:

	Payments Due by Period				
	Total	2005	2006 and 2007	2008 and 2009	Thereafter
	(\$ in 000s)				
Long-term obligations	\$ 472,167	\$ 35,656	\$ 36,511	\$ 11,300	\$ 400,000
Operating lease obligations	58,600	9,900	17,300	11,300	20,100
Purchase obligation	7,399	3,810	3,589		
Total contractual obligations	\$ 538,166	\$ 49,366	\$ 57,400	\$ 11,300	\$ 420,100

The above purchase obligation is in connection with the manufacture and supply of Vasotec® and Vaseretic®. We are obligated to make semi-annual payments to Merck for minimum product quantities (regardless of the actual product supplied).

The above table does not reflect any milestone payments in connection with research and development collaborations with third parties. These payments are contingent on the achievement of specific developmental, regulatory and/or commercial milestones. In the event that all research and development projects are successful, we would have to make aggregate milestone payments of \$133.7 million, which includes the aforementioned \$25.0 million payable to Depomed on FDA approval of Glumetza. In addition, under certain arrangements, we may have to make royalty payments based on a percentage of future sales of the products in the event regulatory approval for marketing is obtained. From a business perspective, we view these payments favourably as they signify that the products are moving successfully through the development phase toward commercialization.



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

#### **OFF-BALANCE SHEET ARRANGEMENTS**

We did not have any off-balance sheet arrangements at December 31, 2004, other than operating leases, purchase obligations and contingent milestone payments, which are disclosed above under contractual obligations.

#### **QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

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

#### **Foreign currency risk**

We operate internationally but a majority of our revenue and expense activities and capital expenditures are denominated in U.S. dollars. Our only other significant transactions are in Canadian dollars. In 2003, we incurred a foreign exchange loss of \$13.1 million related to our Canadian dollar-denominated obligation to GSK for the acquisition of the Canadian rights to Wellbutrin® and Zyban®. We paid the final instalment related to this obligation in March 2004 and, consequently, we do not have any material remaining non-U.S. dollar-denominated obligations. We also face foreign currency exposure on the translation of our operations in Canada and Ireland from their local currencies to the U.S. dollar. Currently, we do not utilize forward contracts to hedge against foreign currency risk; however, a 10% change in foreign currency exchange rates would not have a material impact on our consolidated results of operations, financial position or cash flows.

#### **Interest rate risk**

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

We are exposed to interest rate risk on borrowings under our revolving term credit facility. This credit facility bears interest based on LIBOR, U.S. dollar base rate, Canadian dollar prime rate or Canadian dollar bankers' acceptance. At our option we may lock in a rate of interest for a period of up to one year. The imputed rates of interest used to discount our long-term obligations related to the acquisitions of intangible assets are fixed and, consequently, the fair values of these obligations are affected by changes in interest rates. The fair value of our fixed rate Notes is affected by changes in interest rates. We manage this exposure to interest rate changes through the use of interest rate swaps, which modify our exposure to

interest rate fluctuations by converting one-half of our fixed rate Notes to floating rate. Based on our overall interest rate exposure, a 10% change in interest rates would not have a material impact on our consolidated results of operations, financial position or cash flows.

#### **Investment risk**

We are exposed to investment risks on our investments in other companies. The fair values of our investments are subject to significant fluctuations due to stock market volatility and changes in general market conditions. We regularly review the carrying values of our investments and record losses whenever events and circumstances indicate that there have been other-than-temporary declines in their fair values. A further decline in Ethypharm's financial condition and earnings prospects may necessitate an additional write down of our investment. A 10% change in the aggregate fair values of our investments would have a material impact on our consolidated results of operations; however, it would not have a material impact on our consolidated financial position or cash flows.

#### **RECENT ACCOUNTING PRONOUNCEMENTS**

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

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"), which revises SFAS No. 123, "Accounting for Stock-Based Compensation", and supercedes Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees". SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS No. 123 will no longer be an alternative to financial statement recognition. Under SFAS No. 123R, we must determine the appropriate option-pricing model to be used for valuing share-based payments and the transition method to be used at date of adoption. The transition alternatives are the modified-prospective and modified-retrospective methods. Both of these methods require that compensation expense be recorded for all share-based payments granted, modified or settled after the date of adoption and for all unvested stock options at the date of adoption; however, under the modified-retrospective method, prior periods are restated by recognizing compensation cost in amounts previously reported in the pro forma note disclosures under SFAS No. 123. Prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. SFAS No. 123R is effective at the beginning of the first interim or annual period after June 15, 2005. Accordingly, we are required to adopt SFAS No. 123R beginning July 1, 2005. We are currently evaluating the requirements of SFAS No. 123R and expect that the adoption of this statement will have a material negative impact on our consolidated results of operations. We have not yet determined the method of adoption or the effect of adopting SFAS No. 123R, and we have not determined whether the adoption will result in amounts that are similar to our current pro forma disclosures under SFAS No. 123.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets — An Amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions" ("SFAS No. 153"). SFAS No. 153 eliminates the exception from fair value measurement for nonmonetary exchanges of similar productive assets and replaces it with an exception for exchanges that do not have commercial substance. SFAS No. 153 specifies that a nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for non-monetary transactions occurring in fiscal periods beginning after June 15, 2005. Accordingly, we are required to adopt SFAS No. 153 beginning January 1, 2006. We are currently evaluating the effect that the adoption of SFAS No. 153 will have on our consolidated results of operations and financial position but we do not expect it to have a material impact.

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

**In accordance with Canadian generally accepted accounting principles**

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

The following Management's Discussion and Analysis of Results of Operations and Financial Condition ("MD&A") prepared in accordance with Canadian generally accepted accounting principles ("GAAP") should be read in conjunction with our audited consolidated financial statements and related notes thereto prepared in accordance with Canadian GAAP.

The discussion and analysis contained in this MD&A are as of March 30, 2005.

**FORWARD-LOOKING STATEMENTS**

To the extent any statements made in this MD&A contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe", "anticipate", "expect", "intend", "plan", "will", "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to various risks and uncertainties including, but not necessarily limited to, the difficulty of predicting U.S. Food and Drug Administration ("FDA") and Canadian Therapeutic Products Directorate ("TPD") approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials and finished products, the regulatory environment, the outcome of legal proceedings, fluctuations in operating results and other risks detailed from time to time in our filings with the U.S. Securities and Exchange Commission, the Ontario Securities Commission, and other securities regulatory authorities in Canada. We undertake no obligation to update or revise any forward-looking statement.

**PROFILE**

We are primarily engaged in the formulation, clinical testing, registration, manufacture and commercialization of pharmaceutical products utilizing advanced oral drug-delivery technologies. Our main therapeutic areas of focus are cardiovascular (including Type II diabetes), central nervous system and pain management. We have various research and development, clinical testing, manufacturing and commercial operations located in the United States, Canada, Barbados, Puerto Rico and Ireland.

**OVERVIEW**

Our financial performance in 2004 reflected our focus on growing our existing business (after several years of acquisition-related activity) and strengthening our financial position through the reduction of debt. We realized record revenue driven by the exceptionally strong performance of our bupropion hydrochloride ("HCl") extended-release tablets ("Wellbutrin XL"), which we manufacture and sell to GlaxoSmithKline plc ("GSK") for marketing and distribution in the United States. GSK's gross sales of Wellbutrin XL were in excess of \$1.0 billion in this product's first full calendar year on the market. We used cash generated from operations to repay nearly \$350 million of long-term obligations. As a result, we had no outstanding borrowings under our \$400 million revolving term credit facility at the end of 2004.

During 2004 and into 2005, we achieved a number of milestones from our late-stage product-development pipeline. We received FDA approval for an angina indication for Cardizem® LA and we received TPD approval for a hypertension indication for Tiazac® XC, designed for bedtime dosing. We received Approvable Letters from the FDA for our extended-release ("ER") and orally disintegrating tablet ("ODT") formulations of the analgesic tramadol HCl, as well as for the anti-depressant citalopram ODT and Glumetza (metformin HCl) for the treatment of Type II diabetes. We filed New Drug Applications ("NDA") with the FDA for tramadol ER, tramadol ODT, citalopram ODT and Glumetza . We filed a New Drug Submission ("NDS") with the TPD for Glumetza , and we submitted supplemental NDSs for Wellbutrin XL and an angina indication for Tiazac® XC.

In November 2004, we effected the separation of the roles of Chairman of the Board and Chief Executive Officer ("CEO"), with the hiring of Douglas Squires as our new CEO. Dr. Squires has over 29 years of global pharmaceutical industry management experience. Since joining us, Dr. Squires has led the development of the strategic plan that is discussed below.

Eugene Melnyk continues his duties as Chairman of the Board. In conjunction with the Board of Directors, Mr. Melnyk has initiated a comprehensive review of our corporate governance practices. This review is consistent with our commitment to enhance investor confidence.

## **STRATEGIC PLAN**

We are currently in the process of developing a long-term strategic plan aimed at revitalizing our operations, aligning our development pipeline and increasing shareholder value. Our most critical priority is to enhance the return on investment of our U.S. commercial operations, as we recognize that the extent of our existing portfolio of promoted products does not support the current level of investment in our primary care sales force. The primary care market has become increasingly more competitive in recent years and the average size of many primary care sales organizations has increased considerably. In addition, primary care physicians are giving pharmaceutical representatives less time to describe the benefits of various medications, so pharmaceutical companies spent over \$3 billion on direct-to-consumer advertising in 2004 as an alternative means to create awareness for their medications. For these, and other reasons, we are re-evaluating our strategic approach to commercializing our products in the U.S. primary care market.

We are also currently evaluating a number of options to increase the value of our portfolio of legacy products. These products are in decline due to generic competition and are not strategic to our business, which is focused on long-term, sustainable growth. The options we are considering include: a sale of these products to strategic or financial buyers; the transfer of the assets to a new entity and the sale of shares of that entity pursuant to an initial public offering; or a distribution to our shareholders as a return of capital.

At this time, we cannot assess the impact that the outcome of the strategic-planning process will have on our results of operations, financial position and cash flows going forward. We expect to complete this process during the first half of 2005.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

Critical accounting policies and estimates are those policies and estimates that are most important and material to the preparation of our consolidated financial statements, and which require management's most subjective and complex judgment due to the need to select policies from among alternatives available,

and 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 agreements, we rely on estimates made by our third-party licensees. 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 position could be materially impacted.

Our critical accounting policies and estimates relate to the following:

Revenue recognition.

Calculation of stock-based compensation.

Valuation of acquired research and development.

Evaluation of long-term investments for impairment.

Useful lives of intangible assets and the evaluation of those assets for impairment.

Hedge effectiveness of derivative financial instruments.

Determination of the provision for income taxes.

Outcome of legal proceedings.

Assessment of insurance reserves.

#### **Revenue recognition**

We recognize product sales revenue when title has transferred to the customer, provided that we have not retained any significant risks of ownership or future obligations with respect to the product sold. Revenue from product sales is recognized net of provisions for estimated returns, rebates and chargebacks. We establish these provisions concurrently with the recognition of product sales revenue. In connection with these provisions related to sales of products manufactured by us for distribution by our third-party licensees, we rely on estimates made by these licensees.

We allow customers to return product within a specified period of time before and after its expiration date. Provisions for these returns are estimated based on historical return and exchange levels, and third-party data with respect to inventory levels in our distribution channels. A significant change in these estimates could have a material impact on our results of operations. In late 2004 and early 2005, we entered into fee-based distribution agreements with our three major U.S. wholesalers. These agreements generally establish limits on inventory levels owned by these wholesalers, which is expected to moderate investment buying by these wholesalers that can result in sales fluctuations unrelated to end-customer demand. As a result, we expect lower levels of product returns in the future from these wholesalers due to product expiration and overstocking. In addition, these wholesalers are required to provide us with more extensive data with respect to the sales and inventory levels of our products, which will enable us to more reliably estimate our provision for returns, as well as our provisions for rebates and chargebacks.

We are subject to rebates and chargebacks on sales made under governmental and managed care pricing programs. Provisions for these rebates and chargebacks are estimated based on historical experience, contractual sales terms with wholesalers and indirect customers, and relevant statutes with

respect to governmental pricing programs. The largest of these rebates and chargebacks are associated with sales covered by Medicaid. Medicaid rebates are typically billed up to six months after the product is shipped. As a result, a 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 our distribution channels is sold through to end-customers. 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 may incorporate revisions of this rebate provision for several periods.

### **Stock-based compensation**

Effective January 1, 2004, we adopted the fair value-based method for recognizing employee stock-based compensation in accordance with The Canadian Institute of Chartered Accountants' ("CICA") Handbook Section 3870, "Stock-Based Compensation and Other Stock-Based Payments". Prior to 2004, we did not recognize stock-based compensation. At January 1, 2004, the cumulative effect of this change in accounting policy on prior periods resulted in a charge to deficit of \$88.3 million relating to the fair value of stock options vested since January 1, 1996; an increase to common shares of \$40.9 million related to the fair value of stock options exercised since January 1, 1996; and an increase of \$47.4 million to contributed surplus related to the fair value of options vested but unexercised since January 1, 1996. We recorded total stock-based compensation expense of \$20.4 million in 2004.

We use the Black-Scholes option-pricing model to calculate stock option values, which requires certain assumptions including the future stock price volatility and expected time to exercise. Changes to any of these assumptions, or the use of a different option-pricing model (such as the binomial model) could produce a different fair value for stock-based compensation, which could have a material impact on our results of operations.

### **Acquired research and development**

The costs of assets that are purchased through asset acquisitions or business combinations for a particular research and development project are capitalized as acquired research and development at the time of acquisition, and amortized over their estimated useful lives, which range from five to 15 years. The amount allocated to acquired research and development is determined by identifying those specific in-process research and development projects that we intend to continue, and for which: technological feasibility had not been established at the date of acquisition; and there was no alternative future use. We classify the cost of acquired research and development as a cash outflow from investing activities because we expect to generate future income and cash flows from these assets if they can be developed into commercially successful products.

We generally engage independent valuation specialists to perform valuations of acquired research and development assets. There are several methods that can be used to determine the fair value of acquired assets. For acquired research and development, an income approach is generally used. This approach starts with a forecast of all of the estimated future cash flows. 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 expected costs to develop the acquired research and development into commercially viable products; the

projected future cash flows from the projects when completed; the timing of the 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.

### **Long-term investments**

We are required to estimate the fair value of our long-term investments in order to evaluate these investments for impairment. In the event that the cost of an investment exceeds its fair value, we determine whether the decline in fair value is other-than-temporary. In doing so, we consider general market conditions, the duration and extent to which the cost basis exceeds the fair value, and our ability and intent to hold the investment. We also consider the financial condition and earnings prospects of the investee.

Certain of our investments are not publicly traded securities and, as a result, the estimation of the fair values of these investments involves a greater degree of uncertainty. For these types of investments, we determine fair value based on the estimated discounted future cash flows of the investee. Some of the more significant estimates and assumptions inherent in this methodology for determining fair value include: the amount and timing of the future cash flows of the investee; 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.

### **Intangible assets**

Intangible assets are stated at cost, less accumulated amortization generally computed using the straight-line method based on their estimated useful lives ranging from eight to 20 years. We amortize intangible assets on a systematic basis to reflect the pattern in which the economic benefits of the asset are consumed, if that basis can be reliably determined. 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 limitations, known technological advances, anticipated demand and the existence or absence of competition. A significant change in these factors may warrant a revision of the expected remaining useful life of an intangible asset, which could have a material impact on our results of operations.

Intangible assets acquired through asset acquisitions or business combinations are initially recorded at fair value based on an allocation of the purchase price. We often engage independent valuation specialists to perform valuations of the assets acquired. We subsequently evaluate intangible assets annually for impairment, or 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 obsolescence, plans to discontinue use or restructure, and poor financial performance compared with original plans. Impairment exists when the carrying amount of an asset is not recoverable and its carrying amount exceeds its estimated fair value. There are several methods that can be used to determine fair value. For intangible assets, an income approach is generally used. This approach starts with a forecast of all of the estimated future cash flows. 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 the 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.

As previously discussed, we are currently reviewing our strategic approach to commercializing our products in the United States. The outcome of this review is not presently determinable, but it could result in a write-down in the carrying values of certain of our intangible assets.

#### **Derivative financial instruments**

Effective January 1, 2004, we adopted CICA Accounting Guideline ("AcG") 13, "Hedging Relationships", which establishes the criteria for identification, designation, documentation and effectiveness of hedging relationships, for the purpose of applying hedge accounting. AcG-13 does not specify hedge-accounting methods. The CICA's Emerging Issues Committee Abstract EIC 128, "Accounting for Trading, Speculative or Non-Hedging Derivative Financial Instruments" establishes that a derivative financial instrument that is entered into for trading or speculative purposes, or that does not qualify for hedge accounting under AcG-13, should be recognized in the balance sheet and measured at fair value, with changes in fair value recognized in net income. The adoptions of AcG No. 13 and EIC 128 had no effect on our results of operations or financial position.

We manage our exposure to interest rate risks through the use of derivative financial instruments. Our objective is to maintain a balance of fixed to floating interest rate exposure. We do not utilize derivative financial instruments for trading or speculative purposes. On the dates we enter into the derivative contracts, we designate the derivative financial instruments as a hedge of the fair value of an identified portion of a recognized long-term obligation. For a derivative financial instrument that is designated and qualifies as a fair value hedge, we do not recognize unrealized gains or losses resulting from changes in the marked-to-market value of the derivative financial instrument, or from changes in the fair value of the underlying hedged item. A discontinuance of fair value hedge accounting would result in the derivative financial instrument being recognized in the balance sheet at fair value, with changes in fair value recognized in net income, which could have a material impact on our results of operations. Such a discontinuance did occur in 2003, and could occur in the future if changes in the fair value of the derivative financial instrument are not sufficiently correlated with changes in the fair value of the long-term obligation, based on the methods for testing effectiveness as outlined in our hedge documentation.

#### **Provision for income taxes**

Our provision for income taxes is subject to a number of different estimates made by management. A change in these estimates could have a material effect on the effective tax rate.

We have operations in various countries that have differing tax laws and rates. Our income tax reporting is subject to audit by both domestic and foreign tax authorities. The effective tax rate may change from year to year based on the mix of income 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, and changes in the estimated values of future tax assets and liabilities.

We have recorded a valuation allowance on future tax assets primarily relating to operating losses, future tax depreciation and tax credit carryforwards. We have assumed that these future tax assets are more likely than not to remain unrealized. 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 the provision for income taxes in a period.

### Legal proceedings

We are required to accrue for a loss contingency with respect to legal proceedings against us if it is probable that the outcome will be unfavourable, and if the amount of the loss can be reasonably estimated. Management evaluates our exposure to loss based on the progress of each legal proceeding, experience in similar proceedings and consultation with legal counsel. We re-evaluate all legal proceedings as additional information becomes available. The ultimate outcome of any legal proceeding may be materially different from the amounts estimated, given the uncertainties inherent in complex litigation. For a discussion of our current legal proceedings, see note 24 to our audited consolidated financial statements.

### Insurance reserves

We are self-insured for a portion of our automobile physical damage and product liability coverages. Reserves are established for all reported but unpaid claims and for estimates of incurred but not reported ("IBNR") claims. We engage an independent actuary to conduct an actuarial assessment of our IBNR liability. Significant judgment is applied to estimate IBNR liabilities. 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.

### SELECTED ANNUAL INFORMATION

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

	Years Ended December 31		
	2004	2003	2002
	(\$ in 000s, except per share data)		
Revenue	\$ 886,543	\$ 823,722	\$ 788,025
Net income (loss)	52,747	(40,345)	207,553
Basic earnings (loss) per share	\$ 0.33	\$ (0.25)	\$ 1.37
Diluted earnings (loss) per share	\$ 0.33	\$ (0.25)	\$ 1.29
Total assets	\$ 2,012,180	\$ 2,297,604	\$ 2,237,666
Long-term obligations	475,651	812,526	732,111

Revenue increased 8% in 2004 compared with 2003, due mainly to higher Wellbutrin XL, Cardizem® LA and generic product sales in the United States, and higher Tiazac® and Wellbutrin® SR product sales in Canada. These factors more than offset declines in revenue from our participating interest in the gross profit on sales by a third-party of generic omeprazole and from our co-promotion of H. Lundbeck A/S's Celexa in Canada and GSK's Wellbutrin SR in the United States. In 2004, product sales revenue in the United States was negatively impacted by a work-down of wholesaler inventory levels. Revenue increased 5% in 2003 compared with 2002, due mainly to higher revenue from our interest in generic omeprazole that more than offset a decline in revenue from our co-promotion of GSK's Wellbutrin SR in the United States. A strengthening of the Canadian dollar relative to the U.S. dollar increased revenue by 1% in 2004 compared with 2003 and by 2% in 2003 compared with 2002.

Our results of operations were impacted by specific events that affected the comparability of these results between years. These events include, but are not limited to:

Asset write-downs.

Gains on asset dispositions.

Equity losses related to a non-strategic investment in a biotechnology fund that is not part of our ongoing research and development program.

Early extinguishments of obligations.

We believe that the identification of these events enhances an analysis of our results of operations when comparing these results with those of a previous or subsequent period. In addition, management excludes these events when analyzing our operating performance. However, it should be noted that the determination of these events involves judgment by us. The impacts of these events on our net income and basic and diluted earnings per share for the last three years are identified in the following table:

	Years ended December 31		
	2004	2003	2002
	(\$ in 000s, except per share data)		
Write-down of assets	\$ 42,156	\$ 82,189	\$ 31,944
Gain on disposal of assets	(1,471)		
Equity loss	4,179	1,010	
Extinguishment of royalty obligation		61,348	
Foreign exchange loss on long-term obligation		13,061	
Relocation costs		7,539	
Reduction in tax contingency provision		(12,000)	
<b>Total</b>	<b>\$ 44,864</b>	<b>\$ 153,147</b>	<b>\$ 31,944</b>
<b>Total per share:</b>			
Basic	\$ 0.28	\$ 0.97	\$ 0.21
Diluted	\$ 0.28	\$ 0.96	\$ 0.20

Total assets declined \$285.4 million from 2003 to 2004, due mainly to a lower cash and cash equivalents balance (following the repayment of long-term obligations), the amortization of intangible assets and an other-than-temporary decline in the value of our investment in Ethypharm S.A. ("Ethypharm"). Long-term obligations declined \$336.9 million from 2003 to 2004, due mainly to the repayment of all outstanding borrowings under our revolving term credit facility, as well as repayments of other long-term obligations related to the acquisitions of intangible assets.

## RESULTS OF OPERATIONS

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

**REVENUE**

Our revenue is derived from the following sources:

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

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

Co-promotion of pharmaceutical products owned by other companies.

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

License fees from the out-licensing of our technologies or product rights.

The following table displays the dollar amount of each source of revenue for 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.

	Years Ended December 31						Percentage Change	
	2004		2003		2002		2003 to 2004	2002 to 2003
	\$	%	\$	%	\$	%		
	(\$ in 000s)							
Product sales	841,446	95	632,898	77	645,986	82	33%	(2)%
Research and development	20,452	2	14,239	2	28,425	4	44%	(50)%
Co-promotion, royalty and licensing	24,645	3	176,585	21	113,614	14	(86)%	55%
	886,543	100	823,722	100	788,025	100	8%	5%

**Product sales**

Product sales revenue comprises the following reporting categories:

*Promoted products*

Our promoted products are Cardizem® LA, Zovirax Ointment and Zovirax Cream, and Teveten® and Teveten® HCT. We promote these products directly to physicians in the United States. These products are sold primarily in the United States to drug wholesalers that serve retail pharmacies, hospitals, government agencies and managed care providers.

*Wellbutrin XL*

We are the exclusive manufacturer and supplier of Wellbutrin XL to GSK for marketing and distribution in the United States.

*Biovail Pharmaceuticals Canada ("BPC") products*

Our BPC products are Tiazac® XC, Tiazac®, Wellbutrin® SR, Zyban®, Monocor and Retavase. We currently promote Tiazac® XC and Wellbutrin® SR directly to physicians in Canada. BPC products are sold in Canada to drug wholesalers, retail pharmacies and hospitals.

*Core products*

Core products consist of our promoted products, Wellbutrin XL and BPC products, and include sales of all products that we actively promote and/or developed and licensed to third parties who promote them.

*Legacy products*

Our legacy products are Tiazac® (brand and generic), Cardizem® CD, Vasotec®, Vaseretic®, Ativan® and Isordil®. We do not actively promote these products as they have been genericized. We manufacture and sell Tiazac® to Forest Laboratories, Inc. ("Forest") for distribution in the United States. The remaining legacy products are sold primarily in the United States to drug wholesalers.

*Generic products*

Our generic products are bioequivalent versions of Adalat CC, Cardizem® CD, Procardia XL, Trental and Voltaren XR. We manufacture and sell these products to Teva Pharmaceutical Industries Ltd. ("Teva") for distribution in the United States.

The following table displays product sales by category for 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.

	Years Ended December 31						Percentage Change	
	2004		2003		2002		2003 to 2004	2002 to 2003
	\$	%	\$	%	\$	%		
	(\$ in 000s)							
Promoted products	146,676	17	172,418	27	108,261	17	(15)%	59%
Wellbutrin XL	317,298	38	64,932	10			389%	N/A
BPC products	101,865	12	85,197	13	32,565	5	20%	162%
Core products	565,839	67	322,547	51	140,826	22	75%	129%
Legacy products	125,932	15	208,860	33	323,626	50	(40)%	(35)%
Generic products	149,675	18	101,491	16	181,534	28	47%	(44)%
	841,446	100	632,898	100	645,986	100	33%	(2)%

*Promoted products*

Promoted product sales declined 15% in 2004 compared with 2003 and increased 59% in 2003 compared with 2002. The decline in promoted product sales in 2004 reflected reductions in inventories of these products at the wholesale level that were generally not related to the market share performance of these products. A significant portion of our promoted product sales is made to three major U.S. wholesalers. These wholesalers took steps together with us to work down inventory levels in

anticipation of the transition to the aforementioned fee-based distribution agreements. However, sales of Cardizem® LA (which was launched in April 2003) increased 12% in 2004 compared with 2003, reflecting increased prescription demand that more than offset the reduction in wholesaler inventory levels of this product.

The increase in promoted product sales in 2003 reflected the launches of Cardizem® LA, Teveten® HCT and Zovirax Cream during that year.

#### *Wellbutrin XL*

Wellbutrin XL sales have increased dramatically since its launch by GSK in September 2003. Under the terms of our supply agreement with GSK, we ship Wellbutrin XL according to purchase orders received from GSK. In 2004, GSK ordered additional quantities of Wellbutrin XL to build an optimal safety-stock level. The supply price for Wellbutrin XL trade product is based on an increasing tiered percentage of revenue generated on GSK's net sales (after taking into consideration GSK's provisions for estimated discounts, returns, rebates and chargebacks). In the second quarter of 2004, GSK net sales of Wellbutrin XL exceeded the threshold to increase the supply price from the first to the second tier and, in the third quarter of 2004, the threshold was exceeded to increase the supply price from the second to the third tier. As a result, all Wellbutrin XL sales were recorded at the highest tier supply price in the fourth quarter of 2004, except for any safety-stock held by GSK at the end of 2004, which was recorded at the lowest tier supply price. The supply price is reset to the lowest tier at the start of each calendar year and the sales thresholds to achieve the second and third tier supply prices generally increase each year. As a result, we anticipate a decline in Wellbutrin XL revenue in the first half of 2005 compared with the latter half of 2004.

Three companies have filed Abbreviated New Drug Applications seeking FDA approval for generic versions of Wellbutrin XL. We have filed patent infringement suits against these companies, which effectively precludes the FDA from granting approval for the earlier of 30 months or upon a court decision of non-infringement. As a result, we anticipate the introduction of generic competition for Wellbutrin XL in mid-2007.

#### *BPC products*

BPC product sales increased 20% in 2004 compared with 2003 and by 162% in 2003 compared with 2002. The increases in BPC product sales were due in part to the continuing growth in Tiazac® sales, which included pre-launch shipments of Tiazac® XC in the fourth quarter of 2004. In January 2005, we began to actively promote Tiazac® XC to Canadian physicians. Also contributing to the increases in BPC product sales were the additions of Wellbutrin® SR and Zyban, which we acquired from GSK in December 2002. We began to actively promote Wellbutrin® SR in January 2004. In early 2005, a generic version of Wellbutrin® SR was introduced in Canada, which may result in a significant decline in our sales of this product.

#### *Core products*

Core product sales increased 75% in 2004 compared with 2003 and by 129% in 2003 compared with 2002. The increases in core product sales reflected primarily the positive market share performance of Wellbutrin XL and Cardizem® LA in 2004 and 2003, as well as the added contributions from Zovirax Cream and Teveten® HCT in 2003.

*Legacy products*

Legacy product sales declined 40% in 2004 compared with 2003 and by 35% in 2003 compared with 2002. The declines in legacy product sales were due in part to the introduction in the United States of a generic version of Tiazac® in April 2003. Consequently, Forest ceased all promotional efforts for Tiazac® as of September 2003. The decline in sales of Tiazac® brand was partially offset by sales of our own generic version of Tiazac® by Forest. Sales of our other legacy products were impacted by generic competition, as well as reductions in wholesaler inventory levels for the reasons discussed above for our promoted products. Sales of Cardizem® CD were also affected by the promotion of, and conversion to, Cardizem® LA.

*Generic products*

Generic product sales increased 47% in 2004 compared with 2003 following a decline of 44% in 2003 compared with 2002. The increase in generic product sales in 2004 reflected the stabilization of inventory levels by Teva following a reduction of these levels during 2003. In September 2004, we resolved our pending arbitration with Teva related to a dispute over our existing distribution agreement. Under the terms of the settlement agreements, we granted Teva a four-year extension to the 10-year supply term for each of our generic products currently marketed by them. In consideration for this extension, beginning in the fourth quarter of 2004, our selling price to Teva for each generic product is increased for the remainder of the extended supply term.

**Research and development**

Research and development revenue increased 44% in 2004 compared with 2003 and declined 50% in 2003 compared with 2002. The increase in research and development revenue in 2004 reflected a higher level of clinical research and laboratory testing services provided to external customers by our contract research operation. The decline in research and development revenue in 2003 reflected that we earned \$11.5 million in 2002 associated with the final development of Wellbutrin XL in collaboration with GSK.

**Co-promotion, royalty and licensing**

Co-promotion, royalty and licensing revenue declined 86% in 2004 compared with 2003 and increased 55% in 2003 compared with 2002. The changes in the level of co-promotion, royalty and licensing revenue between those years reflected mainly the relative contribution from our interest in generic omeprazole, which amounted to \$1.7 million, \$103.0 million and \$20.3 million in 2004, 2003 and 2002, respectively. In 2004, we received the final revenue from this interest. In addition, we did not derive any revenue from co-promotion activities in 2004 compared with \$43.1 million and \$61.0 million in 2003 and 2002, respectively, related to the co-promotion of Celexa in Canada and GSK's Wellbutrin SR in the United States. We discontinued the co-promotion of Celexa effective December 31, 2003, in order to focus our marketing efforts on our Wellbutrin® SR in Canada, and we concluded our co-promotion of Wellbutrin SR in the United States in the first quarter of 2003.

**OPERATING EXPENSES**

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

	Years Ended December 31						Percentage Change	
	2004		2003		2002		2003 to 2004	2002 to 2003
	\$	%	\$	%	\$	%		
	(\$ in 000s)							
Cost of goods sold	229,528	26	139,456	17	164,706	21	65%	(15)%
Research and development	72,500	8	86,570	11	52,150	7	(16)%	66%
Selling, general and administrative	274,553	31	242,771	29	166,397	21	13%	46%
Amortization	163,088	18	240,650	29	125,849	16	(32)%	91%
Write-down of assets, net of gain on disposal	40,685	5	82,189	10	31,944	4	(50)%	157%
Extinguishment of royalty obligation			61,348	7			(100)%	N/A
Settlements			(34,055)	(4)			(100)%	N/A
	780,354	88	818,929	99	541,046	69	(5)%	51%

**Cost of goods sold and gross margins**

Cost of goods sold increased 65% in 2004 compared with 2003 and declined 15% in 2003 compared with 2002. In 2004, cost of goods sold included \$1.3 million of stock-based compensation. Gross margins based on product sales were 73%, 78% and 75% in 2004, 2003 and 2002, respectively. The decline in the gross margin in 2004 reflected a significantly higher proportion of Wellbutrin XL in the product sales mix. The cost of producing Wellbutrin XL was higher relative to our other products in 2004, due to start-up manufacturing inefficiencies and a more costly active ingredient. We also produced a higher initial proportion of lower margin Wellbutrin XL sample product versus trade product.

The increase in the gross margin in 2003 reflected the recognition of a \$25.5 million cumulative reduction in the Zovirax supply price, in accordance with amendments to our distribution agreement with GSK. This cumulative reduction was subject to repayment if the FDA did not approve Wellbutrin XL. Accordingly, prior to the second quarter of 2003, we had been deferring the value of the reduction in the supply price pending the outcome of the Wellbutrin XL approval.

**Research and development**

Research and development expenses declined 16% in 2004 compared with 2003 and increased 66% in 2003 compared with 2002. In 2004, research and development expenses included \$2.0 million of stock-based compensation. We invested 8% of total revenue in research and development activities in 2004 compared with 11% and 7% in 2003 and 2002, respectively. The changes in the level of research and development spending in those years reflected mainly the costs of the tramadol ER Phase III clinical trial program conducted during 2003. In addition, research and development expenses in 2003 included the costs associated with a clinical program designed to evaluate the use of Cardizem® LA in a clinical practice setting.



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Our long-term success depends, to a great extent, on our ability to continue to develop innovative new products. We have achieved a number of recent successes from our late-stage product-development pipeline, including the following milestones:

Filings of NDAs for tramadol ER and tramadol ODT in February and May 2004, respectively.

Filing of an NDA for Glumetza in June 2004. This filing was made in collaboration with Depomed, Inc. ("Depomed").

Filing of an NDA for citalopram ODT in June 2004.

Approval by the FDA of Cardizem® LA for an angina indication in June 2004.

Filing of an NDS in collaboration with Depomed for Glumetza in August 2004.

Approval by the TPD of Tiazac® XC, for the treatment of hypertension, in August 2004.

Submission of a supplemental NDS for an angina indication for Tiazac® XC in October 2004. In March 2005, we received a Notice of Non-Compliance from the TPD related to this submission. We have 90 days in which to prepare a response to the TPD to address the issues raised in this notice.

Receipt of an Approvable Letter from the FDA for tramadol ER in October 2004. In March 2005, we submitted a Complete Response to this letter. We received notification from the FDA on March 29, 2005 that this response will be subject to a six-month review, and that they are of the opinion that additional clinical data will be required. We are proceeding with a clinical program to address the FDA's comments.

Filing of a Complete Response in November 2004 to an Approvable Letter received from the FDA in October 2002 for zolpidem ODT, for the treatment of insomnia. This response bridges zolpidem ODT from a floss to a non-floss formulation for 5 mg and 10 mg dosage strengths, and is subject to a six-month review by the FDA.

Receipt of an Approvable Letter from the FDA for tramadol ODT in January 2005. This letter involves the resolution of labeling issues only. In March 2005, we submitted a Complete Response to this letter. We anticipate receiving final FDA approval for this product in May 2005.

Receipt of an Approvable Letter from the FDA for citalopram ODT in February 2005. This letter involves the clarification of a number of chemistry and manufacturing issues, primarily involving the level of detail provided to the file for review. We are working with the FDA to resolve these issues.

Submission of a supplemental NDS for Wellbutrin XL in February 2005. We retained the rights from GSK to market and sell this product in Canada, subject to TPD approval.

Receipt of an Approvable Letter from the FDA for Glumetza in March 2005. This letter involves the completion of discussions with regard to a manufacturing issue and we anticipate resolving this issue with the FDA in the near term. We will be required to pay \$25.0 million to Depomed on receipt of FDA approval for Glumetza .

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 and competitive developments, and strategic marketing decisions.



### **Selling, general and administrative**

Selling, general and administrative expenses increased 13% in 2004 compared with 2003 and by 46% in 2003 compared with 2002. In 2004, selling, general and administrative expenses included \$17.1 million of stock-based compensation. As a percentage of total revenue, selling, general and administrative expenses were 31%, 29% and 21% in 2004, 2003 and 2002, respectively. The increase in selling, general and administrative expenses in 2004 reflected a higher level of spending on sales and marketing activities to support our promoted products, as well as an increase in headcount and higher legal expenses. In addition, we incurred incremental costs associated with the expansion and realignment of our primary care sales force in the United States, and the recruitment and deployment of two specialty sales forces that will detail our promoted products to medical specialists. The increased costs associated with our expanded sales forces were offset partially by the elimination of co-promotion fees paid to Reliant Pharmaceuticals, LLC ("Reliant") in 2003 and 2002. Effective December 31, 2003, we mutually agreed with Reliant to terminate their co-promotion of certain of our products.

The increase in selling, general and administrative expenses in 2003 reflected an increase in costs associated with the expansion of our U.S. commercial operations, as well as relocation costs of \$7.5 million associated with the transition of our commercial operations head office from Raleigh, North Carolina, and certain research and development personnel from Chantilly, Virginia, to our facility in Bridgewater, New Jersey. Also contributing to the increase in 2003 was advertising and promotional expenses related to the launches of Cardizem® LA, Teveten® HCT and Zovirax Cream.

### **Amortization**

Amortization expense declined 32% in 2004 compared with 2003 and increased 91% in 2003 compared with 2002. As a percentage of total revenue, amortization expense was 18%, 29% and 16% in 2004, 2003 and 2002, respectively. The changes in the level of amortization expense between those years reflected mainly the relative amortization of our interest in generic omeprazole, which amounted to \$1.1 million, \$70.7 million and \$13.5 million in 2004, 2003 and 2002, respectively. Amortization was recorded on a proportionate basis relative to the revenue earned from this interest. In 2004, we recorded the final amortization as we had received all of the revenue from this interest.

### **Write-down of assets, net of gain on disposal**

In December 2004, we recorded a \$37.8 million write-down to the carrying value of our equity investment in Ethypharm to reflect an other-than-temporary decline in the estimated fair value of this investment. We have price protection on our investment in the event of any private or public financing undertaken by Ethypharm; however, we currently consider it unlikely that we will realize the value of this investment through such a refinancing, as this price protection expires in June 2005. Consequently, we evaluated our investment in Ethypharm and determined that the carrying value of this investment may not be fully realized in the foreseeable future. Nevertheless, Ethypharm has been executing on a restructuring plan to improve its profitability and financial condition, and it continues to invest a significant portion of its revenue into research and development activities. For these reasons, we may ultimately be able to recover the full value of our investment in Ethypharm.

In November 2004, we wrote off the remaining \$4.4 million net book value of the Rondec product rights, following a decision not to reformulate this product line and to discontinue all remaining related marketing and sales efforts. Without continued reformulation and support, Rondec will be subject to

higher levels of generic substitution. Consequently, we evaluated the fair value of the Rondec product rights and determined that these rights had been permanently impaired.

In July 2004, we disposed of the Cedax product rights, as well as our remaining Cedax inventories and promotional materials, for proceeds of \$3.0 million, which resulted in a gain on disposal of \$1.5 million.

In 2003, we recorded a charge of \$45.1 million primarily related to the write-down of the net book values of the Cedax and Rondec product rights to their estimated fair values at that time. In December 2003, as part of the transition of our U.S. commercial operations, we evaluated our future interest in our Cedax and Rondec products. We intended to focus our therapeutically aligned sales efforts on Cardizem® LA, Teveten® and Zovirax. Without continued promotion, the economic viability of Cedax and Rondec was substantially lower, as these products required significant marketing and sales efforts in order to maintain market share. We evaluated the current and forecasted market shares at the time for Cedax and Rondec and determined that the undiscounted future cash flows from these products were below the carrying values of the related product rights. Accordingly, we wrote down the carrying values of these product rights to their estimated fair values at that time. In addition, we recorded a charge of \$37.1 million related to the write-down of acquired research and development associated with product-development projects that we had discontinued.

In 2002, we recorded a charge of \$31.9 million primarily related to the write-down of the net book value of the generic Adalat CC product rights acquired from Elan Corporation, plc ("Elan"), net of our corresponding obligation to them. In June 2002, we entered into a settlement with Elan and the U.S. Federal Trade Commission with respect to the introduction of generic versions of Adalat CC. As a result of this settlement, our agreements with Elan related to our in-licensing of Elan's generic versions of Adalat CC were terminated.

#### **Extinguishment of royalty obligation**

In December 2003, we mutually agreed with Reliant to terminate their co-promotion of our products, and we incurred a charge of \$61.3 million related to a payment to extinguish our trailing royalty obligation to them.

#### **Settlements**

In 2003, we negotiated an overall settlement with Pfizer Inc. and certain other companies through which all pending patent infringement and antitrust actions relating to generic versions of Procardia XL and Adalat CC were dismissed. We also reached settlements with Eli Lilly and Company ("Lilly") with respect to Lilly's inability to supply us with Keftab, and with Mylan Pharmaceuticals Inc. ("Mylan") with respect to Mylan's failure to supply us with generic Verelan, as well as with Elan with respect to the termination of our rights to Elan's generic versions of Adalat CC.

In relation to these matters, we received settlement payments of \$34.1 million in 2003, mainly related to our lost profits on sales of generic Procardia XL, Keftab and generic Verelan. We also received payments totaling \$16.2 million in 2003, mainly related to a recovery of certain charges related to Elan's supply to us of generic Adalat CC, which was recorded as a reduction to cost of goods sold, and compensation for legal and other expenses, which were recorded as a reduction to selling, general and administrative expenses, and interest income. We received an additional \$14.6 million in 2003, which was

recorded as a reduction to assets related to the recoverable value of the Keftab product rights and the value of the destroyed Keftab inventory.

## **OPERATING INCOME**

We recorded operating income of \$106.2 million in 2004 compared with \$4.8 million in 2003 and \$247.0 million in 2002. Charges for write-downs of assets (net of gain of disposal), the extinguishment of the Reliant royalty obligation and relocation activities, reduced operating income by a total of \$40.7 million in 2004 compared with \$151.1 million in 2003 and \$31.9 million in 2002.

Operating income in 2004 compared with 2003 reflected higher product sales revenue and lower research and development spending. These factors were offset partially by the lower contribution from our interest in generic omeprazole and the decline in co-promotion revenue related to Celexa and Wellbutrin SR, as well as costs associated with the expansion of our U.S. commercial operations, higher spending on sales and marketing activities, and the cost of stock-based compensation.

Operating income in 2003 compared with 2002 reflected a modest increase in revenue that was more than offset by higher costs associated with the expansion of our U.S. commercial operations, and increased spending on research and development, and sales and marketing activities. These factors were partially offset by the recognition of settlement payments, which had the effect of increasing operating income by \$47.5 million in 2003, and the contribution from our interest in generic omeprazole.

## **NON-OPERATING ITEMS**

### **Interest income and expense**

Interest income was \$1.0 million in 2004 compared with \$7.2 million in 2003 and \$3.6 million in 2002. In 2003, interest income included interest on settlement payments.

Interest expense was \$40.8 million in 2004 compared with \$41.3 million in 2003 and \$32.0 million in 2002. Interest expense mainly comprised interest on our 7<sup>7</sup>/<sub>8</sub>% Senior Subordinated Notes due April 1, 2010 ("Notes"), which were issued in March 2002. In June 2002, we entered into three interest rate swaps in an aggregate notional amount of \$200.0 million. In June 2004, we terminated those swaps and we replaced them with a new interest rate swap in the same notional amount. The new and terminated swaps involve(d) the receipt of amounts based on a fixed rate of 7<sup>7</sup>/<sub>8</sub>% in exchange for floating rate interest payments based on six-month London Interbank Offering Rate ("LIBOR") plus a spread. Net receipts relating to these swaps, which amounted to \$6.4 million, \$7.3 million and \$3.3 million in 2004, 2003 and 2002, respectively, were recorded as a reduction to interest expense.

### **Foreign exchange gain or loss**

We recorded foreign exchange losses of \$0.6 million in 2004 and \$14.0 million in 2003 and a foreign exchange gain of \$0.7 million in 2002. These amounts reflected the impact of foreign exchange fluctuations on our non-U.S. dollar-denominated cash and cash equivalents, accounts receivable and accounts payable balances. The amount in 2003 also included a \$13.1 million foreign exchange loss on a Canadian dollar-denominated obligation to GSK related to our acquisition of the Canadian rights to Wellbutrin® and Zyban®, and was the result of a strengthening of the Canadian dollar relative to the U.S. dollar during 2003. We paid the final instalment related to this obligation in March 2004.

**Equity loss**

In 2004 and 2003, we recorded equity losses of \$4.2 million and \$1.0 million, respectively, related to our investment in a venture fund that invests in early-stage biotechnology companies. Included in these equity losses was our share of goodwill impairment charges related to certain subsidiaries of this fund, as well as write-downs to the carrying values of other investments held by this fund. At December 31, 2004, we had invested a total of \$5.8 million in this fund. The nature of this fund is no longer consistent with our business strategy, and we will not be making any additional capital contributions in it beyond our remaining commitment of \$2.0 million.

**Income taxes**

Our effective tax rate depends on the relative profitability of our domestic and foreign operations and the statutory tax rates of the related tax jurisdictions. Our low effective tax rate in the last three years reflected the fact that most of our income was derived from foreign subsidiaries with lower statutory tax rates than those that apply in Canada. We recorded a provision for income taxes of \$9.0 million in 2004 compared with a recovery of income taxes of \$4.0 million in 2003 (which included a reduction in our provision for tax contingencies of \$12.0 million, due to the resolution of certain tax uncertainties and incremental tax losses in the United States), and a provision for income taxes of \$11.7 million in 2002 (which included a \$9.8 million recovery of future income taxes related to the reversal of temporary differences in the United States). Our effective tax rate was affected by the availability of unrecognized tax loss carryforwards that can be used to offset taxable income in Canada and the United States, as well as losses that were incurred in the United States due to the expansion of our commercial operations, and sales and marketing costs to support our promoted products.

**SUMMARY OF QUARTERLY RESULTS**

The following table presents a summary of our quarterly results of operations in 2004 and 2003:

	<b>2004</b>				
	<b>Q1</b>	<b>Q2</b>	<b>Q3</b>	<b>Q4</b>	<b>Full Year</b>
	(\$ in 000s, except per share data)				
Revenue	\$ 186,626	\$ 206,313	\$ 215,725	\$ 277,879	\$ 886,543
Net income (loss)	(1,914)	16,873	20,186	17,602	52,747
Basic and diluted earnings (loss) per share	\$ (0.01)	\$ 0.11	\$ 0.13	\$ 0.11	\$ 0.33
	<b>2003</b>				
	<b>Q1</b>	<b>Q2</b>	<b>Q3</b>	<b>Q4</b>	<b>Full Year</b>
	(\$ in 000s, except per share data)				
Revenue	\$ 191,390	\$ 217,283	\$ 215,314	\$ 199,735	\$ 823,722
Net income (loss)	35,368	49,238	13,351	(138,302)	(40,345)
Basic and diluted earnings (loss) per share	\$ 0.22	\$ 0.31	\$ 0.08	\$ (0.87)	\$ (0.25)

**RESULTS FOR THE FOURTH QUARTER**

Revenue increased 39% from \$199.7 million in the fourth quarter of 2003 to \$277.9 million in the fourth quarter of 2004, due mainly to higher Zovirax, Wellbutrin XL and generic product sales. Zovirax product sales in the fourth quarter of 2004 reflected end-customer demand, as our major U.S. wholesalers had reduced their inventories of this product to an optimal safety-stock level by the end of the third quarter of 2004. Wellbutrin XL product sales increased 126% in the fourth quarter of 2004 compared with the corresponding period of 2003, reflecting a higher-tier supply price, an increase in prescription demand, and a build-up of safety-stock levels by GSK. Generic product sales increased 66% in the fourth quarter of 2004 compared with the corresponding period of 2003, reflecting the stabilization of inventory levels of these products by Teva, and the aforementioned increase in our selling price to Teva for each generic product. The increase in product sales revenue more than offset the declines in revenue from our interest in generic omeprazole and from our co-promotion of Celexa in Canada, which amounted to \$11.3 million and \$9.7 million, respectively, in the fourth quarter of 2003.

Net income for the fourth quarter of 2004 was \$17.6 million (basic and diluted earnings per share of \$0.11) compared with a net loss of \$138.3 million (basic and diluted loss per share of \$0.87) in the fourth quarter of 2003. Our results of operations for the fourth quarters of 2004 and 2003 were impacted by specific events that affected the comparability of these results between those periods. The impacts of these events on net income and basic and diluted earnings per share for the fourth quarters of 2004 and 2003 are identified in the following table:

	Q4	
	2004	2003
	(\$ in 000s, except per share data)	
Write-down of assets	\$ 42,156	\$ 82,189
Equity loss	4,052	786
Extinguishment of royalty obligation		61,348
Relocation costs		4,383
Foreign exchange loss on long-term obligation		1,723
Reduction in tax contingency provision		(12,000)
<b>Total</b>	<b>\$ 46,208</b>	<b>\$ 138,429</b>
Total per share:		
Basic and diluted	\$ 0.29	\$ 0.87

Net income and earnings per share in the fourth quarter of 2004 compared with the corresponding period of 2003 reflected higher product sales revenue and an improved gross margin on Wellbutrin XL, due to a higher-tier supply price and less shipments of lower value sample product. These factors were offset partially by the lower contribution from our interest in generic omeprazole and the decline in revenue from our co-promotion of Celexa.

Net cash provided by operating activities increased \$73.8 million from \$37.9 million in the fourth quarter of 2003 to \$111.7 million in the fourth quarter of 2004, primarily due to the aforementioned payment to Reliant of \$61.3 million in December 2003 to extinguish our trailing royalty obligation to them.

**FINANCIAL CONDITION**

The following table presents a summary of our financial condition in 2004 and 2003:

	At December 31	
	2004	2003
	(\$ in 000s)	
Working capital	\$ 124,418	\$ 149,884
Long-lived assets	1,643,255	1,792,396
Long-term obligations	475,651	812,526
Shareholders' equity	1,358,318	1,266,826

**Working capital**

The \$25.5 million decrease in working capital from 2003 to 2004 was primarily due to:

Repayments of long-term obligations of \$346.3 million;

A decrease in accounts receivable of \$30.6 million mainly related to the timing of collections;

Additions to property, plant and equipment of \$28.0 million; and

Acquisitions of BNC-PHARMAPASS and other long-term investments for \$12.2 million.

Partially offset by:

Cash generated from operations of \$317.3 million before changes in operating assets and liabilities;

An increase in inventories of \$26.1 million mainly related to higher Wellbutrin XL production volumes;

A decrease in accounts payable of \$26.8 million mainly related to the timing of payments and inventory purchases; and

A decrease in provisions for product returns, rebates and chargebacks of \$22.1 million, as a result of the reduction in inventories at the wholesale level.

**Long-lived assets**

Long-lived assets comprise property, plant and equipment, goodwill, intangible and other assets, net of accumulated depreciation and amortization. The \$149.1 million decrease in long-lived assets from 2003 to 2004 reflected primarily the depreciation of plant and equipment of \$22.3 million and the amortization of intangible assets of \$164.2 million, offset partially by capital expenditures on property, plant and equipment of \$28.0 million. These expenditures consisted mainly of additions to our manufacturing capacity in Steinbach, Manitoba and Dorado, Puerto Rico, to meet demand for Wellbutrin XL and Cardizem® LA, as well as leasehold improvements to our Bridgewater facility. In addition, we capitalized \$8.6 million to acquired research and development related to our acquisition of Pharma Pass II, LLC's ("PPII") remaining interest in BNC-PHARMAPASS, LLC ("BNC-PHARMAPASS"). In 2003, we formed BNC-PHARMAPASS with PPII to advance the development of three products (carvedilol, eprosartan and tamsulosin). We subsequently agreed with PPII to terminate the development of tamsulosin, and the intellectual property related to this product was returned to PPII.





**Long-term obligations**

The \$336.9 million decrease in long-term obligations, including the current portion thereof, from 2003 to 2004 reflected the repayment of \$280.0 million under our revolving term credit facility. In addition, we repaid \$66.3 million of other long-term obligations, including the following instalments:

Final payment of \$21.8 million related to the acquisition of the Canadian rights to Wellbutrin® and Zyban®.

Payments of \$19.7 million related to the acquisition of Vasotec® and Vaseretic®;

Payment of \$11.3 million related to the aforementioned amendments to the Zovirax distribution agreement.

Payment of \$9.2 million related to the acquisition of Ativan® and Isordil®.

**Shareholders' equity**

The \$91.4 million increase in shareholders' equity from 2003 to 2004 reflected net income of \$52.7 million (which included \$20.4 million of stock-based compensation added to contributed surplus) and proceeds of \$8.0 million received from the issuance of common shares on the exercise of stock options and through our Employee Stock Purchase Plan. We recorded a foreign currency translation gain of \$10.5 million due mainly to a strengthening of the Canadian dollar relative to the U.S. dollar.

**CASH FLOWS**

At December 31, 2004, we had cash and cash equivalents of \$34.3 million compared with \$133.3 million at December 31, 2003. The following table displays cash flow information for the last three years:

	Years ended December 31		
	2004	2003	2002
	(\$ in 000s)		
Net cash provided by operating activities	\$ 277,090	\$ 281,979	\$ 334,104
Net cash used in investing activities	(42,263)	(278,446)	(792,467)
Net cash provided by (used in) financing activities	(334,526)	72,523	79,533
Effect of exchange rate changes on cash and cash equivalents	762	1,125	19
Net increase (decrease) in cash and cash equivalents	\$ (98,937)	\$ 77,181	\$ (378,811)

**Operating activities**

Net cash provided by operating activities in 2004 was comparable to 2003 reflecting relatively level income from operations (net of non-cash items), and the fact that the receipt of the settlement payments in 2003 largely offset the payment we made to Reliant to extinguish our trailing royalty obligation to them. Net cash provided by operating activities declined \$52.1 million from 2002 to 2003 primarily due to lower income from operations (net of non-cash items), primarily due to the higher costs associated with the expansion of our U.S. commercial operations. Net cash provided by operating activities was primarily used to repay long-term obligations in 2004 and to fund acquisition related activities in 2003 and 2002.

### Investing activities

Net cash used in investing activities declined \$236.2 million from 2003 to 2004 primarily due to:

A decrease of \$242.3 million in acquisitions of intangible assets. In 2003, we made initial cash payments of \$146.3 million to Wyeth Pharmaceuticals Inc. ("Wyeth") for Ativan® and Isordil®, and we acquired certain cardiovascular products from Athpharma Limited for \$44.2 million, ODT formulations of tramadol and tramadol and acetaminophen from Ethypharm for \$16.0 million, and an interest in generic omeprazole for \$35.5 million; and

A decrease of \$16.4 million in acquisitions of businesses. In 2004, we acquired PPII's remaining interest in BNC-PHARMAPASS for \$9.3 million. In 2003, we acquired our initial interest in BNC-PHARMAPASS for \$25.7 million.

Net cash used in investing activities declined \$514.0 million from 2002 to 2003 primarily due to:

A decrease of \$214.8 million in acquisitions of businesses. In 2002, we acquired Pharma Pass LLC and Pharma Pass S.A. for \$178.7 million and Pharmaceutical Technologies Corporation for \$61.9 million;

A decrease of \$133.1 million in acquisitions of intangible assets. In 2002, we made initial cash payments of \$145.7 million to Merck & Co., Inc. ("Merck") for Vasotec® and Vaseretic®, we purchased the distribution rights to Zovirax from GSK for \$133.4 million and we acquired Teveten® from Solvay Pharmaceuticals Marketing & Licensing AG for \$94.3 million;

A decrease of \$80.6 million in acquisitions of long-term investments. In 2002, we made equity investments in Ethypharm and Depomed of \$67.8 million and \$13.7 million, respectively; and

A decrease of \$24.5 million in additions to property, plant and equipment. In 2002, we undertook a major expansion of our Steinbach manufacturing facility in order to increase capacity for the production of Wellbutrin XL.

### Financing activities

Net cash used in financing activities increased \$407.0 million from 2003 to 2004 primarily due to:

An increase of \$280.0 million in repayments under our revolving term credit facility; and

A decrease of \$170.0 million in borrowings under our revolving term credit facility.

Partially offset by:

A decrease of \$53.1 million in repayments of other long-term obligations. In 2004, we made the final payment related to the acquisition of the Canadian rights to Wellbutrin® and Zyban®. In 2003, we made three payments related to that acquisition and we paid \$40.0 million to GSK related to the extension of the Zovirax distribution agreement from 10 to 20 years.

Net cash provided by financing activities decreased \$7.0 million from 2002 to 2003 primarily due to:

A decrease in net proceeds of \$384.3 million related to the issuance of our Notes in 2002;

A decrease in net proceeds of \$112.8 million related to the exercise of warrants in 2002. The warrants to acquire our common shares expired on September 30, 2002; and

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An increase of \$77.4 million in repayments of other long-term obligations related to the acquisition of the Canadian rights to Wellbutrin® and Zyban® and the extension of the Zovirax distribution agreement.

Partially offset by:

A decrease of \$503.1 million in repurchases of our common shares under our 2002 stock repurchase program; and

An increase of \$60.0 million in borrowings under our revolving term credit facility.

### LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2004, we had total long-term obligations of \$475.7 million, including the current portion thereof, which included the carrying value of our Notes of \$402.2 million and obligations related to the acquisitions of intangible assets of \$69.0 million. In March 2004, we renewed our revolving term credit facility at \$400.0 million. The revolving period of this facility extends to May 25, 2005, following the lenders' consent to extend the renewal date of this facility from March 25, 2005. This facility is renewable for one-year revolving terms at the lenders' option, with a one-year term out at our option if the lenders do not renew. We are currently in the process of renewing the revolving term of this facility. This facility may be used for general corporate purposes, including acquisitions. At December 31, 2004, we were in compliance with all financial and non-financial covenants associated with this facility. At December 31, 2004, we had no outstanding borrowings under this facility; however, we had a letter of credit with a balance of \$36.7 million issued under this facility. This letter of credit secures the remaining semi-annual payments we are required to make to Merck related to the acquisition of Vasotec® and Vaseretic®. At December 31, 2004, we had a remaining balance of \$363.3 million available to borrow under this facility. Our current corporate credit ratings from Standard & Poor's ("S&P") and Moody's Investors Service ("Moody's") are BB+ and B1, respectively, and the current ratings on our Notes from S&P and Moody's are BB- and B2, respectively.

Commencing in 2005, we plan to invest approximately \$27.6 million to further expand and optimize the capacity at our Steinbach manufacturing facility. This expansion will enable us to meet the anticipated demand for our existing products, as well as products in our development pipeline, such as tramadol ER. We expect this expansion will be completed in late 2006.

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

**CONTRACTUAL OBLIGATIONS**

The following table summarizes our fixed contractual obligations at December 31, 2004:

	Payments Due by Period				
	Total	2005	2006 and 2007	2008 and 2009	Thereafter
	(\$ in 000s)				
Long-term obligations	\$ 472,167	\$ 35,656	\$ 36,511	\$	\$ 400,000
Operating lease obligations	58,600	9,900	17,300	11,300	20,100
Purchase obligation	7,399	3,810	3,589		
Total contractual obligations	\$ 538,166	\$ 49,366	\$ 57,400	\$ 11,300	\$ 420,100

The above purchase obligation is in connection with the manufacture and supply of Vasotec® and Vaseretic®. We are obligated to make semi-annual payments to Merck for minimum product quantities (regardless of the actual product supplied).

The above table does not reflect any milestone payments in connection with research and development collaborations with third parties. These payments are contingent on the achievement of specific developmental, regulatory and/or commercial milestones. In the event that all research and development projects are successful, we would have to make aggregate milestone payments of \$133.7 million, which includes the aforementioned \$25.0 million payable to Depomed on FDA approval of Glumetza. In addition, under certain arrangements, we may have to make royalty payments based on a percentage of future sales of the products in the event regulatory approval for marketing is obtained. From a business perspective, we view these payments favourably as they signify that the products are moving successfully through the development phase toward commercialization.

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

**OFF-BALANCE SHEET ARRANGEMENTS**

We did not have any off-balance sheet arrangements at December 31, 2004, other than operating leases, purchase obligations and contingent milestone payments, which are disclosed above under contractual obligations.

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

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

### **Foreign currency risk**

We operate internationally but a majority of our revenue and expense activities and capital expenditures are denominated in U.S. dollars. Our only other significant transactions are in Canadian dollars. In 2003, we incurred a foreign exchange loss of \$13.1 million related to our Canadian dollar-denominated obligation to GSK for the acquisition of the Canadian rights to Wellbutrin® and Zyban®. We paid the final instalment related to this obligation in March 2004 and, consequently, we do not have any material remaining non-U.S. dollar-denominated obligations. We also face foreign currency exposure on the translation of our operations in Canada and Ireland from their local currencies to the U.S. dollar. Currently, we do not utilize forward contracts to hedge against foreign currency risk; however, a 10% change in foreign currency exchange rates would not have a material impact on our consolidated results of operations, financial position or cash flows.

### **Interest rate risk**

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

We are exposed to interest rate risk on borrowings under our revolving term credit facility. This credit facility bears interest based on LIBOR, U.S. dollar base rate, Canadian dollar prime rate or Canadian dollar bankers' acceptance. At our option we may lock in a rate of interest for a period of up to one year. The imputed rates of interest used to discount our long-term obligations related to the acquisitions of intangible assets are fixed and, consequently, the fair values of these obligations are affected by changes in interest rates. The fair value of our fixed rate Notes is affected by changes in interest rates. We manage this exposure to interest rate changes through the use of interest rate swaps, which modify our exposure to interest rate fluctuations by converting one-half of our fixed rate Notes to floating rate. Based on our overall interest rate exposure, a 10% change in interest rates would not have a material impact on our consolidated results of operations, financial position or cash flows.

### **Investment risk**

We are exposed to investment risks on our investments in other companies. The fair values of our investments are subject to significant fluctuations due to stock market volatility and changes in general market conditions. We regularly review the carrying values of our investments and record losses whenever events and circumstances indicate that there have been other-than-temporary declines in their fair values. A further decline in Ethypharm's financial condition and earnings prospects may necessitate an additional write down of our investment. A 10% change in the aggregate fair values of our investments would have a material impact on our consolidated results of operations; however, it would not have a material impact on our consolidated financial position or cash flows.

### **RECENT ACCOUNTING PRONOUNCEMENTS**

In June 2003, the CICA issued AcG-15, "Consolidation of Variable Interest Entities". AcG-15 provides guidance for applying the principles in CICA Handbook Section 1590, "Subsidiaries", to a variable interest entity ("VIE"). AcG-15 requires consolidation of a VIE by the primary beneficiary of

the entity's expected results of operations. AcG-15 is effective for annual and interim periods beginning after November 1, 2004. Accordingly, we adopted AcG-15 beginning January 1, 2005. The adoption of this guideline did not have any impact on our results of operations or financial position.

In January 2005, the CICA issued Handbook Sections 1530, Comprehensive Income; 3855, "Financial Instruments - Recognition and Measurement"; and 3865, "Hedges". Handbook Section 1530 sets the standards for reporting and display of comprehensive income. Comprehensive income includes, among other components, gains and losses arising on the translation of self-sustaining foreign operations. Under Handbook Section 3855, financial assets and liabilities would, with certain exceptions, be initially measured at fair value. After initial recognition, gains and losses on financial assets and liabilities measured at fair value would be recognized in net income with the exception of gains or losses arising from financial assets classified as available-for-sale, for which unrealized gains and loss would be recognized in comprehensive income. Handbook Section 3865 builds on existing AcG-13, by specifying how hedge accounting is applied for different types of hedging relationships. Unrealized gains and losses on certain financial instruments that qualify for hedge accounting would be included in comprehensive income. These standards are effective for annual and interim periods beginning on or after October 1, 2006; however, early adoption is permitted. We are currently evaluating the effect that the adoption of these standards will have on our results of operations and financial position.



**Item 6. Directors, Senior Management and Employees****A. Directors and Senior Management**

The name, municipality of residence, their ages as of June 14, 2005, and position with the Company of each of the directors and executive officers are set forth below:

**Directors**

<b>Name</b>	<b>Age</b>	<b>Position</b>
Eugene N. Melnyk <sup>(1)</sup> St. Michael, Barbados, WI	46	Executive Chairman of the Board; Director
Wilfred G. Bristow <sup>(1)(2)(3)</sup> Campbellville, Ontario, Canada	73	Director
Michael R. Van Every <sup>(1)(1)(4)</sup> Nobleton, Ontario, Canada	64	Director
Laurence E. Paul, MD <sup>(1)(2)(4)</sup> Los Angeles, California, USA	40	Director
Sheldon Plener <sup>(1)(2)</sup> Toronto, Ontario, Canada	53	Director
Roger R. Rowan <sup>(1)(3)(4)(5)</sup> Toronto, Ontario, Canada	52	Director
Rolf K. Reininghaus <sup>(2)(6)</sup> Mississauga, Ontario, Canada	59	Senior Vice-President, Corporate and Strategic Development and Director

**Senior Management**

<b>Name</b>	<b>Age</b>	<b>Position</b>
Dr. Douglas J.P. Squires <sup>(7)</sup> Villanova, Pennsylvania, USA	57	Chief Executive Officer and Director nominee
Kenneth C. Cancellara, Q.C. Toronto, Ontario, Canada	58	Senior Vice-President, Chief Legal Officer and Corporate Secretary
Charles A. Rowland Jr. Flemington, New Jersey, USA	46	Senior Vice-President and Chief Financial Officer
Brian H. Crombie Mississauga, Ontario, Canada	46	Senior Vice-President, Strategic Development
Dr. Gregory Szpunar Chester, New Jersey, USA	47	Senior Vice-President, Research & Development and Chief Scientific Officer
David R. Keefer New Hope, Pennsylvania, USA	52	Senior Vice-President, Commercial Operations
John R. Miszuk Mississauga, Ontario, Canada	52	Vice-President, Controller and Assistant Secretary
Kenneth G. Howling Toronto, Ontario, Canada	47	Vice-President, Finance and Corporate Affairs

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John Sebben Oakville, Ontario, Canada	52	Vice-President, Global Manufacturing
Suzanne Villeneuve Brampton, Ontario, Canada	44	Vice-President, General Manager, Biovail Pharmaceuticals Canada

- (1) Directors hold office until the next annual and special meeting of shareholders or until their successors are elected or appointed.
- (2) Member of the Compensation Committee.
- (3) Member of the Nominating and Governance Committee.
- (4) Member of Audit Committee.
- (5) Mr. Rowan will not be standing for re-election as a Director at the Meeting.
- (6) Mr. Reininghaus will not be standing for re-election as a Director at the Meeting. Mr. Reininghaus is expected to retire from the Company during the course of 2005.
- (7) Dr. Squires is not currently a Director, however due to director residency requirements under the Corporation's governing statute, the *Business Corporations Act* (Ontario) (the "OBCA"), if Dr. Squires were elected as a director of the Corporation at the Meeting, the Board of Directors would not be properly constituted. Instead, if the resolution approving continuance of the Corporation under the *Canada Business Corporations Act* is passed at the Meeting, Dr. Squires will be appointed as a director on the continuance of the Corporation. If the resolution approving continuance of the Corporation is not passed at the Meeting, Dr. Squires will be appointed as a director upon the Board identifying a further Canadian resident that it also wishes to appoint a director.

### Directors

*Mr. Melnyk* is Executive Chairman of the Board, a position he has held since November 2004. From December 2001 to October 2004, Mr. Melnyk was Chairman and Chief Executive Officer of Biovail. He has been the Chairman and a Director since March 1994 when Biovail's predecessors, Trimel Corporation ("Trimel") and BCI, amalgamated. From October 1991 to March 1994, Mr. Melnyk served as Chairman of the Board of BCI and was instrumental in acquiring, financing and organizing the businesses of that company. Mr. Melnyk also founded Trimel, a leading Canadian medical publisher, and served as its President and Chief Executive Officer from 1983 through July 1991. Mr. Melnyk is also a member of the boards of the Ottawa Senators Foundation, the National Hockey League Board of Governors, the New York Racing Association, the Thoroughbred Owners and Breeders Association and the Grayson Jockey Club Research Foundation. He is an Honorary Director of Help Us Help the Children, Canada Benefactor of the Tourette Syndrome Association and an Honorary Director of the Belmont Child Care Association.

*Mr. Bristow* has been a Director of Biovail since the amalgamation of Biovail's predecessors, Trimel and BCI, in 1994. From January 1993 to February 1994, he was a Director of BCI. Mr. Bristow has been a Vice-President and senior investment advisor at BMO Nesbitt Burns Inc., a Canadian investment-banking firm since December 1991. From September 1975 to December 1991, he served as Vice-President and Director of Richardson Greenshields of Canada, an investment banking firm.

*Mr. Van Every* was elected to the Board of Directors in June 2004. He is also a member of the boards of Kelman Technologies Inc., which services oil-and-gas exploration companies, Woods Canada Limited, Erewhon Brands International Limited and The Jockey Club of Canada. Mr. Van Every is a chartered accountant and until 2004, was a partner in the professional services firm of PricewaterhouseCoopers LLP ("PWC"). He has practised public accounting since 1966. From 1969 to 1998, he was a partner of Coopers & Lybrand, one of the predecessor firms of PWC. During that period, he served for various periods as Partner-in-Charge of an office, a member of the Management Committee, a member of the Partnership Board, and Chair of the Partnership Audit and Governance Committees. Mr. Van Every has

been lead engagement partner responsible for audit and other services to a number of public and private companies.

*Dr. Paul* was elected to the Board of Directors in June 2002. Dr. Paul is a founding principal of Laurel Crown Capital, LLC, a leveraged buyout and principal investment company based in Santa Monica, CA. Prior to his work at Laurel Crown and its predecessor, Dr. Paul was a Managing Director at Donaldson, Lufkin, Jenrette, Inc. ("DLJ"), a New York based securities and brokerage firm and then Credit Suisse First Boston, after its purchase of DLJ. At DLJ, Dr. Paul was responsible for building and overseeing much of the firm's effort in the life-sciences sector. Dr. Paul received his B.A. and M.D. from Harvard University and subsequently received his M.B.A. from Stanford University. Dr. Paul also sits on the boards of Morton's Restaurant Group, Ampco-Pittsburgh Corp., Harvard Medical School, the Biomedical Services Division of the American Red Cross, and the Los Angeles Chapter of the American Red Cross.

*Mr. Plener* was elected to the Board of Directors in June 2002. He is also a member of the boards of SMC Hockey Corp. and Capital Sports & Entertainment Inc. and its affiliates. Mr. Plener is a senior partner in the Business Law practice group at the law firm of Cassels Brock & Blackwell LLP. He has been practising with the firm since 1978. During his tenure with the firm he has been a Managing Partner, a member of the firm's Executive and Operations Committee and a Chairman of its Finance Committee. Mr. Plener has been lead counsel to many public and private clients in a broad range of industries, including the pharmaceutical sector.

*Mr. Rowan* was elected to the Board of Directors in June 1997. Mr. Rowan has been President and Chief Operating Officer of Watt Carmichael Inc., a private investment firm, since May 1994. Prior thereto, Mr. Rowan was the Executive Vice-President and Chief Operating Officer of Watt Carmichael Inc. since 1991. Mr. Rowan will not be standing for re-election as a Director.

*Mr. Reininghaus* has been a Senior Vice-President, and a Director since March 1994 and has been the Senior Vice-President, Corporate and Strategic Development and the President of Biovail Ventures since December 1999. Previously he was President of BPC since November 1997, President, Chief Operating Officer and a Director of BCI since October 1991 and Executive Vice-President and a Director of Trimel Corp. or its affiliates since November 1987. Prior to his employment by Trimel, Mr. Reininghaus was the Marketing Manager of the Canadian operations of Miles Pharmaceuticals, a division of Bayer AG. Mr. Reininghaus is expected to retire from Biovail during the course of 2005 and will not be standing for re-election as a Director.

Our Board of Directors has approved the nominations of Jamie Sokalsky, Executive Vice-President and Chief Financial Officer of Barrick Gold Corporation, William (Bill) Wells, Chief Financial Officer of Bunge Limited and Dr. Douglas Squires, Biovail's CEO for election, or appointment, to our Board of Directors. The nominations will be considered by our Company's shareholders at the Annual and Special Meeting of Shareholders on June 28, 2005 in Toronto.

#### **Senior Management**

*Dr. Squires* is the Chief Executive Officer of Biovail. Before joining Biovail in November 2004, Dr. Squires spent six years at MDS Inc., the last three as President and Chief Executive Officer of MDS Pharma Services, which provides drug-discovery and development services to pharmaceutical and biotechnology companies in 24 countries. Before joining MDS, Dr. Squires spent more than 22 years with The Upjohn Company and Pharmacia Upjohn Inc., where he held multiple senior positions in Canada, the United States and the Pacific Rim.

*Mr. Cancellara, Q.C.*, has been Senior Vice-President and the Chief Legal Officer since August 2002. Previously he was the Senior Vice-President and General Counsel from March 1996, was appointed Secretary in April 1996, and was a director of the Company from May 1995 to June 2000. Prior to that time, Mr. Cancellara was a partner with the law firm of Cassels, Brock and Blackwell, LLP from 1980

where he held many positions including Chairman of the Executive Committee and managing partner. Mr. Cancellara holds a Juris Doctor degree from the University of Toronto Faculty of Law and a Masters of Law in Business from Osgoode Hall law school.

*Mr. Rowland* is the Senior Vice-President and Chief Financial Officer of the Company, a position he has held since August 2004. Prior to that he was the Chief Operating and Financial Officer of Breakaway Technologies, Inc. from September 2001 to August 2004 and Group Vice-President, Finance of Pharmacia Corporation from March 1998 to August 2001.

*Mr. Crombie* has been Senior Vice-President, Strategic Development since August 2004. Previously he was Chief Financial Officer of the Company from May 2000 to August 2004. Mr. Crombie came to Biovail from The Jim Pattison Group, one of Canada's largest private holding companies where he served as Managing Director Corporate Finance from 1998 to 2000 and was responsible for corporate development and treasury. Prior to that time, he spent seven years in finance and general management positions with The Molson Companies most recently as Senior Vice-President Corporate Finance and Treasurer responsible for planning, accounting and control, corporate development, treasury and investor relations. Mr. Crombie is a graduate of The Harvard Graduate School of Business where he received his M.B.A.

*Dr. Szpunar* joined Biovail as Senior Vice-President and Chief Scientific Officer in April 2003. Dr. Szpunar came to Biovail from Pharmacia Corporation, where he was Senior Vice-President of Product Development. Dr. Szpunar has held various executive and scientific positions with Pharmacia, Pharmacia and Upjohn and The Upjohn Company over the prior 19 years. These have included participation in and responsibility for directing global R&D operations ranging from early pre-clinical development through Phase IV product support. He has served in direct leadership positions in clinical and pre-clinical pharmacokinetics and drug metabolism, biopharmaceutics research, project management, portfolio analysis, and quality assurance. Dr. Szpunar holds a B.Pharm from Wayne State University, and a Ph.D. in Pharmaceutics from The University of Michigan.

*Mr. Keefer* is the Senior Vice-President, Commercial Operations, a position he has held since August 2004. Prior to that he was the Company's Group Vice-President Sales from May 2003 August 2004. From March 2001 to May 2003, Mr. Keefer was Vice-President, Sales at Pharmacia Corporation and from April 1995 to February 2001 he was Vice-President, Business-Unit Director at Wyeth-Ayerst Laboratories.

*Mr. Miszuk* is the Vice-President, Controller and Assistant Secretary of the Company, a position he has held since February 2000. Prior to that he was Vice-President, Controller for the period November 1998 to February 2000.

*Mr. Howling* is the Vice-President, Finance and Corporate Affairs, a position he has held since October 2004. Prior to that he was the Company's Vice-President, Finance from May 2000 to October 2004 and before that Vice-President and Chief Financial Officer of the Company from November 1997 to May 2000.

*Mr. Sebben* is the Company's Vice-President, Global Manufacturing, a position he has held since August 2004. Prior to that Mr. Sebben was Vice-President, Operations at the Torpharm Division of Apotex Inc. from January 2002 to May 2004 and Director, Operations at GlaxoSmithKline Canada from June 1995 to December 2001.

*Ms. Villeneuve* is the Vice-President, General Manager, BPC, a position that she has held since April 2004. Prior to that she was Vice-President, Marketing, BPC from March 2001 to April 2004. From December 2000 to March 2001 she was Director, Consumerization at GlaxoSmithKline Canada and from December 1999 to November 2000 she was Regional Sales Manager, Quebec for GlaxoSmithKline Canada.

**B. Compensation*****Compensation of Directors***

There are currently seven directors on the Biovail Board. As members of management, neither Mr. Melnyk nor Mr. Reininghaus receive any of the director's fees outlined below. For more on Mr. Melnyk's compensation, please see the table under the subheading, "Compensation of Named Executive Officers". In 2004, Biovail's directors were compensated through a combination of an annual retainer, committee chair retainers, committee member retainers and meeting fees. Biovail also pays travel fees in connection with meetings and reimburses the directors for out-of-pocket expenses incurred in attending such meetings. For the fiscal year ended December 31, 2004, the total remuneration paid to Directors was \$398,500.

Annual retainer: \$30,000 per year;

Meeting fee: \$1,500 for each Board or Committee meeting; \$750 for each Committee meeting held on the same day as a Board meeting;

Committee Chair retainers: Audit Committee \$20,000; Nominating and Corporate Governance Committee \$5,000; and Compensation Committee \$5,000;

Audit Committee member retainer: \$10,000; other Committee member retainers: \$5,000;

Special assignments: \$1,500 per day for a total of \$11,250; and

Reimbursement for related travel and out-of-pocket expenses

In addition, in June 2004, each Director received a grant of 10,000 options having an exercise price of \$18.75 and an expiry date of June 25, 2009. The \$18.75 exercise price for the options was calculated June 24, 2004.

Special assignments involve additional time that individual directors spend on Board-related matters outside of regular meetings, including matters such as the recruitment of the Chief Executive Officer and litigation.

In 2004, options to purchase Common Shares were granted to Directors (other than Directors that are Named Executive Officers) as follows:

<b>Name</b>	<b>Options Granted</b>	<b>Exercise Price</b>	<b>Market Value of Securities Underlying Options on the Date of Grant</b>	<b>Expiration Date</b>
Wilfred Bristow	10,000	\$ 18.75	\$ 18.64	June 25, 2009
Michael Van Every	10,000	\$ 18.75	\$ 18.64	June 25, 2009
Laurence Paul	10,000	\$ 18.75	\$ 18.64	June 25, 2009
Sheldon Plener	10,000	\$ 18.75	\$ 18.64	June 25, 2009
Roger Rowan	10,000	\$ 18.75	\$ 18.64	June 25, 2009

***Compensation of Named Executive Officers***

The following table sets forth the compensation of Biovail's Executive Chairman, Chief Executive Officer, Chief Financial Officer and the five other most highly compensated executive officers of Biovail

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and its subsidiaries (the "Named Executive Officers") for the three most recently completed financial years of the Company.

Name and Principal Position	Year	Annual Compensation		Long-Term Compensation Awards <sup>(1)</sup>		
		Salary <sup>(2)</sup> (US\$) <sup>(3)</sup>	Bonus <sup>(2)</sup> (US\$)	Securities Under Options Granted (#)	Restricted Share Units (#)	All Other Compensation (US\$)
Eugene N. Melnyk Executive Chairman of the Board and Chief Executive Officer <sup>(4)</sup>	2004	714,765		100		
	2003	668,699		300,100		
	2002	607,908		501,100		
Dr. Douglas J.P. Squires Chief Executive Officer <sup>(5)</sup>	2004	96,923 <sup>(6)</sup>	72,692	150,000 <sup>(7)</sup>		
Charles A. Rowland, Jr. Senior Vice-President and Chief Financial Officer <sup>(8)</sup>	2004	153,846 <sup>(9)</sup>	73,077	50,000 <sup>(10)</sup>		7,569 <sup>(11)</sup>
David R. Keefer <sup>(12)</sup> Senior Vice-President, Commercial Operations	2004	325,308	89,460	8,750		12,300 <sup>(11)</sup>
	2003	190,385	71,394	52,500 <sup>(13)</sup>		
Dr. Gregory J. Szpunar Senior Vice-President, Research and Development <sup>(14)</sup>	2004	340,393	170,197	100,000		9,693 <sup>(11)</sup>
	2003	201,923	100,962	100,000 <sup>(15)</sup>		
Brian H. Crombie Senior Vice-President and Chief Financial Officer/Senior Vice-President, Strategic Development <sup>(16)</sup>	2004	435,799	217,899	37,600		17,301 <sup>(11)</sup>
	2003	424,096	75,269	135,100		17,242 <sup>(11)(17)</sup>
	2002	228,339	195,190	115,100		14,530 <sup>(11)(17)</sup>
Kenneth C. Cancellara Senior Vice-President, Chief Legal Officer and Corporate Secretary	2004	435,799	217,900	37,600		
	2003	401,759	75,269	135,100		
	2002	277,398	195,190	115,600		2,855
						8,241
Rolf K. Reininghaus Senior Vice-President, Corporate and Strategic Development	2004	154,276	77,138	39,100		
	2003	386,602	75,269	135,100		
	2002	189,135	195,190	85,100		2,553
						7,368

(1) In previous years, this table included a column for long-term incentive-plan ("LTIP") payouts. The amounts disclosed in this column would have more properly been disclosed in the separate table titled "Aggregate Options Exercised in Last Fiscal Year and Option Values". Biovail is amending this disclosure for the first time this year. The amounts disclosed last year were as follows: (i) Eugene N. Melnyk: 2002 \$41,310,000, 2001 \$78,570,000; (ii) Kenneth C. Cancellara: 2002 \$1,499,694, 2001 \$1,034,331; and (iii) Rolf K. Reininghaus: 2003 \$7,981,136. In 2004, there were no LTIP payouts under long-term compensation awards.

(2) The figures in these columns differ with respect to 2003 and 2002 from figures disclosed in respect of years ending prior to December 31, 2004. Prior disclosure reflected salary and bonus paid, rather than earned, in respect of each of these years. This disclosure has been amended this year to reflect salary and bonus earned in respect of these years. The disclosure in the previous years was as follows: (i) Brian H. Crombie: 2003 \$219,793 (Bonus); 2002 \$53,882 (Bonus); and (ii) Kenneth C. Cancellara: 2003 \$219,793 (Bonus); 2002 \$29,332 (Bonus).

(3) Historical exchange rates C\$ to US\$: 2004 0.7684; 2003 0.7138; 2002 0.6339.

(4) Mr. Melnyk was Chief Executive Officer until November 2004.

(5) Dr. Squires was appointed Chief Executive Officer in November 2004.

(6)

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Dr. Squires only served as Chief Executive Officer for a portion of 2004. His annualized salary for 2004 was US\$700,000.

(7)

Dr. Squires was awarded 150,000 sign-on options.

(8)

Mr. Rowland was appointed Senior Vice-President and Chief Financial Officer in August 2004.

(9)

Mr. Rowland served as Senior Vice-President and Chief Financial Officer only for a portion of 2004. His annualized salary for 2004 was US\$400,000.

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- (10) Mr. Rowland was awarded 50,000 sign-on options.
- (11) Represents Biovail contribution to 401K (U.S.) and Deferred Profit Sharing Plan (Canada).
- (12) Mr. Keefer was appointed Senior Vice-President, Commercial Operations in August 2004. Mr. Keefer joined Biovail in May 2003, as Group Vice-President, U.S. Field Operations.
- (13) Mr. Keefer was awarded 35,000 sign-on options and 17,500 options in respect of contributions made in 2003.
- (14) Dr. Szpunar was appointed Senior Vice-President, Research and Development in April 2003.
- (15) Dr. Szpunar was awarded 50,000 sign-on options and 50,000 options in respect of contributions made in 2003.
- (16) Mr. Crombie served as Senior Vice-President and Chief Financial Officer until August 2004, at which point he assumed the role of Senior Vice-President, Strategic Development.
- (17) Car allowance.

### Stock-Option Grants

The following table sets out options to purchase Common Shares granted by the Company to the Named Executive Officers in the year ended December 31, 2004. For more information on the Stock-Option Plans, please see "Stock-Option Plans" below.

Name	Securities Under Options Granted <sup>(1)</sup> (#)	% of Total Options Granted to Employees in 2004	Exercise or Base Price (\$/Security)	Market Value of Securities Underlying Options on the Date of Grant (\$/Security)	Expiration Date
Eugene N. Melnyk <sup>(2)</sup>	100	0.01	18.75	17.67	June 11, 2009
Dr. Douglas J.P. Squires <sup>(3)</sup>	150,000	12.08	18.75	18.59	October 7, 2009
Charles A. Rowland, Jr. <sup>(4)</sup>	50,000	4.03	18.75	15.86	August 9, 2009
David R. Keefer <sup>(5)</sup>	8,750	0.70	18.75	18.60	March 3, 2009
Dr. Gregory J. Szpunar <sup>(5)(6)</sup>	50,000	4.03	18.75	17.67	June 11, 2009
	50,000	4.03	18.75	17.67	June 11, 2009
Brian H. Crombie <sup>(5)(2)</sup>	37,500	3.02	18.75	17.67	June 11, 2009
	100	0.01	18.75	17.67	June 11, 2009
Kenneth C. Cancellara <sup>(1)(2)(1)(5)</sup>	37,500	3.02	18.75	17.67	June 11, 2009
	100	0.01	18.75	17.67	June 11, 2009
Rolf K. Reininghaus <sup>(7)</sup>	39,100	3.15	18.75	17.67	June 11, 2009

- (1) All options were granted under the Company's Stock-Option Plans. All options are for the purchase of Common Shares of the Company and are for a term of five years.
- (2) The options become exercisable as at December 31, 2005.
- (3) The options become exercisable as to a maximum of 25% on November 15, 2005, 2006, 2007 and 2008.
- (4) The options become exercisable as to a maximum of 25% on August 9, 2005, 2006, 2007 and 2008.
- (5)



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The options become exercisable as to a maximum of 25% upon grant and thereafter an additional 25% of the grant becomes exercisable on March 1 of 2005, 2006 and 2007.

- (6) The options become exercisable as to a maximum of 25% upon grant and thereafter an additional 25% of the grant becomes exercisable on April 21, 2005, 2006 and 2007.
- (7) Mr. Reininghaus' options are scheduled to expire on June 28, 2006. However, under the terms of the Stock-Option Plans, when an option holder's age plus the option holder's number of years of service with the Company equal 70, all unvested options held by such person vest immediately and such vested options expire on the earlier of (i) the expiry date of the option, and (ii) one year following the termination of the option holder's employment or term of office with the Company. Accordingly, all of Mr. Reininghaus' options vested on June 16, 2002 and are subject to the above-described extended expiry period.

**AGGREGATED OPTIONS EXERCISED DURING MOST RECENTLY COMPLETED FINANCIAL YEAR AND VALUE OF OPTIONS AT DECEMBER 31, 2004**

The following table sets out certain information with respect to options to purchase Common Shares that were exercised by Named Executive Officers during the year ended December 31, 2004 and Common Shares under option to the Named Executive Officers as at December 31, 2004.

Name	Securities Acquired on Exercise	Aggregate Value Realized	Unexercised Options at December 31, 2004		Value of Unexercised in-the-Money Options at December 31, 2004 <sup>(2)</sup>
			Exercisable	Unexercisable	Exercisable
Eugene N. Melnyk <sup>(1)</sup>	120,000	\$ 1,599,600	1,477,700	350,100	
Dr. Douglas J.P. Squires				150,000	
Charles A. Rowland, Jr.				50,000	
David R. Keefer			15,312	45,938	
Dr. Gregory J. Szpunar			50,000	150,000	
Brian H. Crombie			282,075	140,725	
Kenneth C. Cancellara			314,075	140,725	
Rolf K. Reininghaus			291,400		

(1) Mr. Melnyk exercised 120,000 options on January 14, 2004 at a strike price of US\$10.00. The options were scheduled to expire on January 19, 2004.

(2) The value of unexercised in-the-money options is calculated using the closing price of the Common Shares of the Company, on the NYSE on December 31, 2004 (\$16.53), less the exercise price of such options. As at December 31, 2004, there were no in-the-money options held by the Named Executive Officers. Securities Authorized for Issuance under Equity Compensation Plans The following table shows, as of December 31, 2004, compensation plans under which equity securities of Biovail are authorized for issuance from the treasury. The information has been aggregated either by equity compensation plans requiring the issuance of Biovail Common Shares previously approved by shareholders, or by equity compensation plans requiring the issuance of Biovail Common Shares not previously approved by shareholders, of which there are none to report. The numbers shown under "Equity Compensation Plans Approved by Security Holders" relate to Biovail's Stock Option Plans. Please refer to the description of the Stock Option Plans under "Report on Executive Compensation" on page 17 of this Circular.

**Components of Compensation Package**

The compensation package for executive officers has three components:

Competitive base salaries;

Cash bonuses under the annual incentive program; and

Stock options under the annual incentive program.

The overall compensation of the Named Executive Officers is set out under "Compensation of Named Executive Officers" on page 115 of this Form 20-F and is based on corporate performance and an evaluation of the results of each officer's individual contribution.

The chart below sets out the relative weighting of each component of the total compensation target for each category of Named Executive Officers.

Title	Percentage of Target Total Direct Compensation		
	Base Salary	Short-Term Incentive	Long-Term Incentive (Options)
Executive Chairman	24%	0%	76%
Chief Executive Officer	32%	16%	52%
Senior Vice-Presidents	31%	16%	53%

**Base Salary**

Each year, the Compensation Committee reviews the individual salaries of the executive officers, including the Named Executive Officers. As described above, we compare our salary structure not only to the Company's comparator group, but also to other large U.S. pharmaceuticals and certain Canadian companies. The Compensation Committee targets that each officer's compensation package is in the 50<sup>th</sup> percentile of each component (base salary, annual incentives, long-term incentives and benefits) as well as total compensation, with reference to similar positions at the comparator group of companies. This allows us to respond better to changing business conditions, manage salaries, and minimize the automatic ratcheting up of salaries due to narrow competitive targets. If needed, adjustments are made to reflect market trends, individual performance, the executive's role in the organization, and level of experience. This approach allows us to differentiate salaries that reflect a range of experience and performance levels among executives. This orientation applies uniformly throughout the Company for all employees and determines how the Compensation Committee sets the salaries of the CEO and other senior executives.

**Annual Incentive Program**

We believe incentive pay rewards employees for their contribution to our overall performance. All our executives participate in the Management Incentive Compensation Program (the "MICP"). The MICP has two elements:

Cash bonuses; and

Stock options.

The Chief Executive Officer may receive up to 75% of his base salary in the form of a cash bonus. The other Named Executive Officers may receive up to 50% of base salary in the form of a cash bonus. Because we place a major emphasis on the achievement of financial goals and our operating results each year, it is expected that cash bonus payments may vary significantly year over year. The objective is to give executives a strong incentive to maintain focus on continuous improvement of results and meeting corporate objectives. In addition, this element of the compensation program provides emphasis on short-term milestones against which we measure progress toward strategic goals. These milestones include annually set financial, commercial and research and development and other objectives targeted to the executive's area of responsibility. In addition, milestones in respect of the Company's key strategic initiatives applicable to an executive's area of responsibility are also included to ensure that the executive's short-term incentives are aligned with our longer-term thresholds. Each year, the Board approves Biovail's strategic plan for the year. Our strategic plan forms the basis for the three benchmarks used to award incentives under our annual incentive program:

25% of the target bonus is based on achievement of certain predetermined corporate goals which include strategic, operational and financial goals during the fiscal year;

50% based on achievement of divisional objectives; and

25% based on achievement of personal objectives.

For the Chief Executive Officer, the annual incentive program uses two benchmarks: 75% is based on achievement of corporate goals and the remaining 25% is based on the achievement of personal objectives.

For 2004, the bonus payments awarded to the Named Executive Officers reflect the Compensation Committee's evaluation of the above measures and the corporate goals accomplished through the achievement of target diluted EPS. By using this earnings per share target as the basis for determining the amount of each executive officer's corporate performance-based bonus, we are giving recognition to the fact that our management is shared by the Chief Executive Officer and the other Named Executive Officers as a team and therefore, the performance of Biovail, as measured by the achievement of EPS, reflects the joint efforts of the group. The Compensation Committee believes that management has a more direct impact on earnings, by being able to increase productivity and control expenses, than it does on shareholder return, which is subject to changes in market conditions that are beyond management's control.

In 2004, Biovail achieved its target EPS of \$1.35, before special charges.

The Compensation Committee also evaluated each Executive Officer's divisional objectives and personal objectives. For those Executive Officers who have specific responsibility for a particular business group, achievement percentages were based on that business group's achievement of their goals over the performance period. For those Executive Officers who have responsibility for a variety of business groups, the percentage were based on a combination of the achievement of the various areas of responsibility. As described above, we set the goals annually and they may vary from year to year.

For the year ended December 31, 2004, the Compensation Committee evaluated each Executive Officer against their corporate and individual goals. As a result of this evaluation, one executive received a bonus less than target as a result of that executive's business group not achieving its goal for the year. One Executive Officer received a bonus less than target as a result of that officer not achieving personal goals. All other Executive Officers achieved their target bonuses.

The employment agreements of three of the Named Executive Officers provide that half of their bonus payments are guaranteed. The remaining 50% of their incentive bonus is based on corporate and individual performance. Final awards were made based on the Compensation Committee's assessment of the achievement of their key strategic initiatives.

### **Stock Option Plans**

In 1993, we established a stock-option plan (the "1993 Option Plan") which was subsequently approved by shareholders on March 28, 1994. On June 25, 2004, our shareholders approved a further stock-option plan (the "2004 Option Plan", and together with the 1993 Option Plan, the "Stock Option Plans"). The 2004 Option Plan was adopted so that we could continue to grant stock options to Directors, selected employees, and consultants to provide them with an incentive to encourage and facilitate personal stock ownership, thus strengthening their personal commitment to us to provide a longer-term alignment with our goals. Based on the attainment of corporate and personal goals, participants are eligible to receive a form of compensation that is tied to increases in the market value of Common Shares.

The 1993 Option Plan was replaced by the 2004 Option Plan and no further options are issuable under the 1993 Option Plan. However, all options granted under the 1993 Option Plan are exercisable in accordance with the terms of that plan. The following provides a brief summary of the terms of the 1993 Option Plan and the 2004 Option Plan.

The 1993 Option Plan provides that the exercise price per Common Share of an option is the closing market price at which the shares are traded on the TSX on the day prior to the date the option is granted,

or if not so traded, the average between the closing bid and ask prices thereof as reported for that day. As at June 14, 2005, a maximum of 6,372,146 Common Shares were issuable in respect of options outstanding under the 1993 Option Plan, representing 4.0% of our issued and outstanding Common Shares. As at June 14, 2005, 19,907,960 Common Shares had been issued on the exercise of options issued under the 1993 Option Plan, representing 12.5% of our issued and outstanding Common Shares.

Options granted under the 1993 Option Plan have a term of up to 10 years and cannot be assigned or transferred, except in limited circumstances. Under the 1993 Option Plan, the Board may determine the periods of time during which an option holder may exercise an option following termination of employment or other relationship with the Company or the death or permanent and total disability of the option holder.

Under the 2004 Option Plan, options may be granted to such eligible individuals as the Board of Directors may determine. The terms of the 2004 Option Plan provide that the Board may in its discretion vary the manner and terms pursuant to which options granted under the Plan are exercised. A maximum of 5,000,000 Common Shares, representing 3.14% of our issued and outstanding capital as at May 10, 2005, may be issued pursuant to the exercise of options under the 2004 Option Plan. Subject to applicable law and the obtaining of shareholder approval, the Board, may in its discretion, amend the 2004 Option Plan to increase the number of Common Shares that may be issued. As at May 10, 2005, a maximum of 2,262,764 Common Shares were issuable in respect of options outstanding under the 2004 Option Plan, representing 1.4% of our issued and outstanding Common Shares. As at May 10, 2005, no Common Shares had been issued on the exercise of options issued under the 2004 Option Plan.

The Compensation Committee of the Board has determined options granted to the Board under the 2004 Option Plan not vest immediately but vest in equal proportions on the first, second and third anniversaries of the option grant.

Under the terms of the 2004 Option Plan, the maximum number of Common Shares reserved for issuance under options to any one participant cannot exceed 5% of our issued and outstanding Common Shares. Participants under the 2004 Option Plan that have already been granted options cannot be granted Common Shares exceeding 5% of our issued and outstanding Common Shares. In addition, the maximum number of Common Shares reserved for issuance at any time cannot exceed 10% of Biovail's issued and outstanding Common Shares. The 2004 Option Plan also contains certain restrictions with respect to the awarding of options to insiders of the Company:

The maximum number of Common Shares that can be issued to an insider within any one-year period, together with Common Shares issuable to insiders during that one year period under Biovail's other share compensation arrangements, cannot exceed 10% of our Common Shares that are issued and outstanding; and

The maximum number of Common Shares that can be issued to any one insider (and the insider's associates) within a one-year period, together with Common Shares issuable to such persons within that one-year period under our other share compensation arrangements, cannot exceed 5% of our Common Shares that are issued and outstanding.

Options granted under the 2004 Option Plan have a term of up to 10 years and cannot be assigned or transferred, except in limited circumstances. The exercise price of each option is determined by the Board and, under the 2004 Option Plan, cannot be less than the weighted average trading price of the Common Shares on the TSX or the New York Stock Exchange ("NYSE"), if the trading volume of Common Shares on that day is greater on the NYSE, on the trading day prior to the grant date. If the Common Shares are not traded on that day, the weighted average trading price on the next day, or while there was trading, shall be used for this purpose. However, effective January 1, 2005, under the rules of the TSX, generally the exercise price of an option may not be less than the volume weighted average trading price on the TSX or the stock exchange on which the majority of the trading volume and value of the listed

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securities occurs, for the five trading days immediately preceding the relevant date. Accordingly, options issued under the 2004 Option Plan will be issued at the greater of the exercise prices calculated under the terms of the 2004 Option Plan and the new TSX rules.

Options granted under the 2004 Option Plan can only be exercised while an option holder is employed with the Company, subject to the following conditions:

If an option holder becomes entitled to the payment of disability benefits, all options that have vested may continue to be exercised by the option holder up to a maximum of 180 days from the date of disability;

If an option holder dies while employed by us, all options that have vested may continue to be exercised by legal representatives of the option holder up to a maximum of 180 days following the date of death;

If an option holder retires, all options that have vested may continue to be exercised by the option holder up to a maximum of 180 days from the date of retirement; and

If an option holder is terminated without cause or voluntarily resigns, all options that have vested may continue to be exercised by the option holder up to a maximum period of 30 days after the date of termination.

In addition to the foregoing limitation, the 2004 Option Plan contains certain other restrictions:

If an option holder engages in a business that competes with that of the Company, or any activity that would be considered detrimental to us, prior to any exercise of an option or during the one-year period following the date an option is exercised or becomes vested, the option holder will be required to pay to us an amount that equals any gain realized as a result of the exercise of the option; and

If an option holder has been employed by us or one of its affiliates for at least 10 consecutive years, the 2004 Option Plan provides that on the date that the sum of the option holder's age and the years of service with us, or an affiliate, equals 70, (a) all of the unvested options held by such option holder will immediately vest and (b) all such vested options shall expire on the earlier of (i) the expiration of the term of such options, and (ii) one year following the termination of employment or term of office with us.

If there is a change-in-control of the Company, the 2004 Option Plan provides that the Board may accelerate the vesting of any or all outstanding options. In the alternative, the Board is entitled to make adequate provision to ensure that, following the completion of the proposed transaction that will result in a change-in-control, the number and kind of shares subject to outstanding options and/or the exercise price of such options shall be appropriately adjusted to prevent substantial dilution or enlargement of the rights granted to option holders.

### **Employment Agreements**

Following is an outline of the key material terms of the employment agreements for the Named Executive Officers.

*Eugene N. Melnyk*, as Executive Chairman of the Board, pursuant to an employment agreement effective February 1, 1992, receives annual compensation of \$706,147, subject to 10% annual increases during the term of the employment agreement, and is reimbursed for business-related expenses. The employment agreement also grants Mr. Melnyk up to 300,000 options per year. The employment agreement continues automatically for renewal periods of one year unless terminated by either Biovail or Mr. Melnyk. Mr. Melnyk is not entitled to any payments upon termination of his employment agreement

upon a change of control. Biovail is in the process of replacing this agreement with a new agreement reflecting his role as Executive Chairman.

Mr. Melnyk will receive no compensation for his role as Executive Chairman although he will continue to be compensated for his role with one or more Biovail subsidiaries. Such compensation will be paid in a combination of DSU's and cash.

*Dr. Douglas J.P. Squires*, as Chief Executive Officer, according to an employment agreement effective October 7, 2004, receives a base salary of \$700,000, with a cost-of-living annual increase, reimbursement of business expenses, plus the right to receive up to 75% of eligible earnings as a cash-based performance bonus, together with up to 150,000 options per year, subject to the attainment of certain corporate and personal objectives. As part of his agreement, Dr. Squires was awarded 150,000 options as a one-time signing incentive which will vest in four equal annual instalments of 37,500 options on the anniversary date of the commencement of his employment. The employment agreement has an indefinite term. Dr. Squires must provide the Company with 90 days prior written notice upon his intention to terminate the agreement. Where Dr. Squires' employment agreement is terminated other than for cause, he is entitled to 24 months severance in lieu of notice including the vesting during the severance period of any unvested options he holds that would, but for the termination, otherwise vest. Where the Company enters into a transaction, the result of which is that there is a "Change of Control", Dr. Squires is entitled to 24 months base and bonus and any unvested options held by Dr. Squires shall have their vesting accelerated in full so as to become 100% vested and immediately exercisable in full as of the date of closing of such Change of Control transaction. In addition, Dr. Squires shall be entitled to full vesting of all options due to be granted to him during the 12 months following the public announcement of the Change of Control transaction (which options) shall be deemed to have been priced at the same price as those in the immediately preceding year (and such options shall vest immediately upon the closing of the Change of Control transaction but shall be exercisable as to 33% on that date; 33% on the first anniversary of such closing; and the remainder on the second anniversary of such closing). If Dr. Squires' employment with the Company ceases prior to the second anniversary of the closing of the Change of Control transaction, all unexercised options become immediately exercisable by Dr. Squires. The surviving Company may decide in its sole discretion whether to continue Dr. Squires employment. However, Dr. Squires' resignation or termination effected within 6 months from the closing of the Change of Control transaction shall be deemed to have been made as a result of the Change of Control. For the purposes of Dr. Squires' employment agreement, a "Change of Control" means (a) the lease, exchange, license or similar disposition of all or substantially all of the assets of the Company in one transaction or a series of transactions; or (b) with the approval of shareholders of the Company, a merger, amalgamation, reorganization, plan of arrangement, consolidation or other similar transaction (a "Merger") in a single transaction or a series of transactions, the result of which is that the individuals or entities acquiring voting securities of the Company hold pursuant to such Merger directly or indirectly more than 50% of the outstanding shares of the resultant Company; or (c) the acquisition of more than 50% of the voting securities of the Company by any persons or entity (other than Mr. Melnyk or any of his affiliates) pursuant to a tender offer or similar transaction and Mr. Melnyk is no longer Chairman of the Company.

*Charles A. Rowland Jr.*, as Senior Vice-President and Chief Financial Officer, pursuant to an employment agreement made as of July 15, 2004, receives a base salary of \$400,000, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year, subject to the attainment of certain corporate and personal objectives. As part of his employment agreement, Mr. Rowland was awarded 50,000 sign-on options. The employment agreement has an indefinite term. Mr. Rowland must provide the Company with 90 days prior written notice upon his intention to terminate his contract. Where Mr. Rowland's contract is terminated other than for cause, he is entitled to 12 months severance in lieu of notice, including the vesting of any unvested options during the severance period held by Mr. Rowland that would, but for the termination, otherwise vest. Where the Company enters into a transaction the result of which is that there is a Change

of Control of the Company, Mr. Rowland is entitled to 24 months base and bonus in lieu of notice and any unvested options held by Mr. Rowland shall have their vesting accelerated in full so as to become immediately exercisable in full as of the date of closing of such Change in Control transaction. In addition, Mr. Rowland shall be entitled to full vesting of all options granted to him during the 12 months following the announcement of the Change of Control transaction (which options) shall be deemed to have been priced at the same price as those in the immediately preceding year (and such options shall vest immediately upon the closing of the Change of Control transaction but shall be exercisable as to 33% on the date of closing of the Change of Control transaction, 33% on the first anniversary of such closing; and the remainder on the second anniversary of such closing. If Mr. Rowland's employment with the Company ceases prior to the second anniversary of the closing of the Change of Control transaction, all unexercised options become immediately exercisable by Mr. Rowland. For the purposes of Mr. Rowland's employment agreement, a "Change of Control" means (a) the lease, exchange, license or similar disposition of all or substantially all of the assets of the Company in one transaction or a series of transactions; or (b) with the approval of shareholders of the Company; a merger, amalgamation, reorganization, plan of arrangement, consolidation or other similar transaction (a "Merger"), the result of which is that the individuals or entities acquiring voting securities of the Company hold directly or indirectly more than 50% of the outstanding shares of the resulting entity; or (c) the acquisition of more than 50% of the voting securities of the Company by any persons or entity (other than Mr. Melnyk or any of his affiliates) pursuant to a tender offer or similar transaction and Mr. Melnyk is no longer Chairman of the Company.

*David R. Keefer*, as Senior Vice-President, Commercial Operations, receives a base salary of \$350,000 as of August 4, 2004, subject to a cost-of-living adjustment, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 35,000 options per year, subject to the attainment of certain corporate and personal objectives. Mr. Keefer's employment agreement made as of February 18, 2003, has an indefinite term. Mr. Keefer must provide the Company with 90 days prior written notice upon his intention to terminate his contract. Where Mr. Keefer's contract is terminated other than for cause, he is entitled to 12 months severance in lieu of notice. If Mr. Keefer's termination is effected as result of a "Change of Control", the Company shall provide to the Executive a severance payment of 24 months base and bonus and any unvested held by Mr. Keefer shall have their vesting accelerated in full so as to become 100% vested and immediately exercisable in full as of the date of closing of such Change of Control transaction. In addition, Mr. Keefer shall be entitled to a full vesting of all options due to be granted to the Executive during the twelve months following the public announcement of the Change of Control transactions (which options) shall be deemed to have been priced at the same price as those in the immediately preceding year (and such options shall vest immediately upon the closing of the Change of Control transaction, but shall be exercisable as to 33% on that date, 33% on the first anniversary of the closing of the Change of Control transaction and the remainder on the second anniversary of the closing of the closing of the Change of Control transaction). Notwithstanding such staggered schedule for the exercise of the options, if Mr. Keefer's employment ceases prior to the second anniversary of the closing of the Change of Control transaction, all unexercised options shall be immediately exercisable by Mr. Keefer upon his cessation of employment. The surviving Company may decide in its sole discretion whether to continue Mr. Keefer's employment with the Company.

For purposes of Mr. Keefer's employment "Change of Control" means an acquisition by approval by the stockholders of the Company of a merger, reorganization, consolidation or other transaction (a "Merger") in a single transaction or a series of related transactions, as a result of which the individuals and entities who were respective beneficial owner of common shares and voting securities of the Company immediately before such Merger are not expected to beneficially own, immediately after such Merger, directly or indirectly, more than 50% of, respectively, the common stock and combined voting power of the voting securities of the Company resulting from such Merger in substantially the same proportions as immediately before the Merger.



*Dr. Gregory J. Szpunar*, as Senior Vice-President, Chief Scientific Officer, pursuant to an employment agreement made as of March 1, 2003, receives a base salary of \$350,010, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year of which 50,000 are to be unconditionally granted and 50,000 are awarded subject to the attainment of certain corporate and personal objectives. The employment agreement has an indefinite term. Dr. Szpunar must provide the Company with 60 days prior written notice upon his intention to terminate his contract. Where Dr. Szpunar's contract is terminated other than for cause, he is entitled to 12 months severance in lieu of notice, including the vesting during the severance period of any unvested options held by Dr. Szpunar that would, but for the termination, otherwise vest. If Dr. Szpunar's termination is effected as result of a "Change of Control", the Company shall provide to the Executive a severance payment of 24 months base and bonus and any unvested options held by Dr. Szpunar shall have their vesting accelerated in full so as to become 100% vested and immediately exercisable in full as of the date of closing of such Change of Control transaction. In addition, Dr. Szpunar shall be entitled to a full vesting of all options due to be granted to him during the twelve months following the public announcement of the Change of Control transactions (which options) shall be deemed to have been priced at the same price as those in the immediately preceding year (and such options shall vest immediately upon the closing of the Change of Control transaction, but shall be exercisable as to 33% on that date, 33% on the first anniversary of the closing of the Change of Control transaction and the remainder on the second anniversary of the closing of the closing of the Change of Control transaction. Notwithstanding such staggered schedule for the exercise of the options, if Dr. Szpunar's employment ceases prior to the second anniversary of the closing of the Change of Control transaction, all unexercised options shall be immediately exercisable by Dr. Szpunar upon his cessation of employment. The surviving Company may decide in its sole discretion whether to continue Dr. Szpunar's employment with the Company. If Dr. Szpunar's termination is effected within six months from the closing of the Change of Control transaction, it shall be deemed to have been made as a result of the Change of Control.

For purposes of Dr. Szpunar's employment "Change of Control" means an acquisition with (i) approval by the stockholders of the Company of a merger, reorganization, consolidation or other transaction ("Merger"), in a single transaction or series of related transactions, as a result of which the individuals and entities who were respective beneficial owners of common shares and voting securities of the Company immediately before the Merger are not expected to beneficially own, immediately after the merger, directly or indirectly more than 50% of, respectively, the common stock and the combined voting power of the voting securities of the Company resulting from such Merger in substantially the same proportions as immediately before such Merger, or (ii) the sale of substantially all of the assets of the Company, or (iii) the acquisition of more than 50% of the stock of the Company by any person or persons, pursuant to a tender offer or otherwise, who do not currently own a controlling interest in the stock of the Company.

*Brian H. Crombie*, as Senior Vice-President, Chief Financial Officer and Senior Vice-President, Strategic Development thereafter until August 2004, receives an annual salary of \$412,000, according to the terms of an employment agreement effective March 1, 2003. It is subject to a cost-of-living adjustment, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year of which 50,000 are to be unconditionally granted and 50,000 are subject to the attainment of corporate and personal objectives. The employment agreement has an indefinite term. Mr. Crombie must provide the Company with 60 days written notice of his intention to terminate the contract. Where Mr. Crombie's contract is terminated other than for cause, he is entitled to 12 months severance in lieu of notice. Where the Company enters into a transaction that results in a "Change of Control", Mr. Crombie is entitled to 24 months base and bonus in lieu of notice, and any unvested options held by Mr. Crombie shall have their vesting accelerated in full so as to become 100% vested and immediately exercisable in full as of the date of the closing of the Change in Control transaction. Mr. Crombie shall have 12 months from the closing of the Change of Control transaction (which options) shall be deemed to have been priced at the same price as those in the immediately preceding

year (and such options shall vest immediately upon the closing of the Change of Control transaction but shall be exercisable as to 33% on the date of closing of the Change of Control transaction, 33% on the first anniversary of such closing and the remainder on the second anniversary of such closing). If Mr. Crombie's employment with the Company ceases prior to the second anniversary of the closing of the Change of Control transaction, all unexercised options become immediately exercisable by Mr. Crombie. For the purposes of Mr. Crombie's employment agreement, a "Change of Control" means (a) the lease, exchange, license or similar disposition of all or substantially all of the assets of the Company in one transaction or a series of related transactions and Mr. Melnyk is no longer Chairman of the Company, or (b) with the approval of shareholders of the Company, a merger, amalgamation, reorganization, plan of arrangement, consolidation or other similar transaction (a "Merger") in one transaction or a series of related transactions; or, the result of which is that the individuals or entities acquiring voting securities of the Company pursuant to such Merger hold directly or indirectly more than 50% of the outstanding shares of the resultant Corporation and Mr. Melnyk is no longer Chairman of the Company, or (c) the acquisition of more than 50% of the voting securities of the Company by any persons or entity (other than Mr. Melnyk or any of his affiliates) pursuant to a tender offer or similar transaction and Mr. Melnyk is no longer Chairman of the Company.

*Kenneth C. Cancellara*, as Senior Vice-President, Chief Legal Officer and Corporate Secretary, receives an annual salary of \$412,000 according to an employment agreement made as of March 1, 2003 and amended on January 25, 2005. It is subject to a cost-of-living adjustment, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year of which 50,000 are to be unconditionally granted and 50,000 of which are subject to the attainment of certain corporate and personal objectives. All options granted (but not yet vested) to the Executive shall fully and unconditionally vest upon: a Change of Control (as defined below); or when Mr. Cancellara has completed at least 10 years of employment with the Company and his years of employment plus his age shall equal 70 and the Executive is no longer employed with the Company (provided that no vesting shall occur with respect to these options granted to Mr. Cancellara in the year when Mr. Cancellara ceases to be employed with the Company); or upon Mr. Cancellara's death. Mr. Cancellara may exercise his options for one year following the cessation of his employment or following the termination of an agreed affiliation with the Company. If Mr. Cancellara is terminated for just cause, all vested options must be exercised by Mr. Cancellara within 30 days from the date of termination. Upon his death, Mr. Cancellara's estate may exercise any of Mr. Cancellara's unexercised options for a period of one year thereafter.

The employment agreement will terminate on December 31, 2006. On June 30, 2005 Mr. Cancellara will become Senior Counsel and will no longer have the titles of General Counsel or Corporate Secretary. From that time until the termination of his contract, he will be responsible for certain litigation and other legal matters. If Mr. Cancellara's contract is terminated other than for cause, he is entitled to severance based on the lesser of 12 months and the balance of the term of his employment. If the Company enters into a transaction that results in a Change of Control of the Company, he will be entitled to be paid the balance of the remuneration that would have been payable to him under the terms of the agreement. For the purposes of Mr. Cancellara's employment agreement, "Change of Control" means (i) the lease, exchange, license, sale or other similar disposition of all or substantially all of the assets of the Company in one transaction or a series of related transactions and Eugene Melnyk is no longer Chairman of the Company; or (ii) with the approval of the stockholders of the Company, a merger, amalgamation, reorganization, plan of arrangement, consolidation or other similar transaction (collectively a "Merger"), in a single transaction or a series of related transactions, the result of which Merger is that the individuals or entities acquiring voting securities of the Company pursuant to such Merger hold, directly or indirectly, more than 50% of the outstanding shares of the resultant Company and Mr. Melnyk is no longer Chairman of the Company; or (iii) the acquisition of more than 50% of the voting securities of the Company by any person(s) or entity (other than Mr. Melnyk or any of his affiliates), pursuant to a tender offer or similar transaction and Mr. Melnyk is no longer Chairman of the Company.

*Rolf K. Reininghaus*, as Senior Vice-President, Corporate and Strategic Development and Director, pursuant to an employment agreement made as of March 1, 2003, is entitled to receive an annual salary of \$400,000, subject to a cost-of-living adjustment, reimbursement of business expenses, plus the right to receive up to 50% of annual salary as a performance cash-based bonus, together with up to 100,000 options per year, of which 50,000 are to be unconditionally granted and 50,000 are to be awarded subject to the attainment of certain corporate and personal objectives. Mr. Reininghaus must provide the Company with 60 days prior written notice upon his intention to terminate the contract. Where Mr. Reininghaus' contract is terminated other than for cause, he is entitled to 12 months severance in lieu of notice. Where the Company enters into a transaction the result of which is that there is a Change of Control, Mr. Reininghaus is entitled to 24 months base and bonus, and any unvested options held by Mr. Reininghaus shall have their vesting accelerated in full so as to become 100% vested and immediately exercisable in full as of the date of closing of such Change of Control transaction. In addition, Mr. Reininghaus shall be entitled to full vesting of all options due to be granted to him during the 12 months following the public announcement of the Change of Control transaction (which options) shall be deemed to have been priced at the same price as those in the immediately preceding year (and such options shall vest immediately upon closing of the Change of Control transaction but shall be exercisable as to 33% on that date, 33% on the first anniversary of such closing and the remainder on the second anniversary of such closing). If Mr. Reininghaus' employment with the Company ceases prior to the second anniversary of the closing of the change-in-control transaction, all unexercised options become immediately exercisable by Mr. Reininghaus. For the purposes of Mr. Reininghaus' employment agreement, a "Change of Control" means (a) the lease, exchange, license or similar disposition of all or substantially all of the assets of the Company in one transaction or a series of related transactions and Mr. Melnyk is no longer Chairman of the Company; (b) with the approval of shareholders of the Company, a merger, amalgamation, reorganization, plan of arrangement, consolidation or other similar transaction (a "Merger") in a single transaction or a series of related transactions, the result of which is that the individuals or entities acquiring voting securities of the Company pursuant to such Merger hold directly or indirectly more than 50% of the outstanding shares of the resultant Company and Mr. Melnyk is no longer Chairman of the Company; or (c) the acquisition of more than 50% of the voting securities of the Company by any persons or entity (other than Mr. Melnyk or any of his affiliates) pursuant to a tender offer or similar transaction and Mr. Melnyk is no longer Chairman of the Company. Effective January 1, 2004, Mr. Reininghaus has been working 25 business days per quarter and his compensation and has been correspondingly reduced.

#### **Directors' and Officers' Liability Insurance**

We maintained insurance during 2004 for certain liabilities incurred by directors and officers in their capacity with the Company or its subsidiaries. The policy was subject to a limit of \$75 million for the period January 1, 2004 to November 15, 2004, and is subject to a limit of \$100 million for the period November 15, 2004 to November 15, 2005. The policy governing such insurance is subject to standard exclusions and limitations and a deductible of \$5 million, in respect of class-action securities claims, and \$1 million, in respect of other claims. In addition, where we are a party to a class-action proceeding regarding a securities matter, after the deductible limit is reached, we must pay 30% of all defense costs and other losses above the \$5 million deductible threshold. During the 2004 fiscal year, the amount of premiums paid in respect of such insurance was \$5.9 million. No part of the premium was paid by any individual officer or director.

It is anticipated that the amount of premiums to be paid in respect of such insurance for the 2005 fiscal year will be approximately \$5.1 million.

### **Employee Stock Purchase Plan**

Our Employee Stock Purchase Plan ("ESPP") was approved by the shareholders at the Special Shareholders' Meeting held on January 1, 1996 and was established in 1996. The purpose of the ESPP is to provide a convenient method for our full-time employees to participate in the share ownership of the Company or to increase their share ownership in the Company via payroll or contractual deduction. Directors, senior officers or insiders of the Company are not eligible to participate in the ESPP. The aggregate number of shares reserved for issuance under the ESPP, taking into consideration stock splits, shall not exceed 1.2 million common shares. At the discretion of a committee of the Board of Directors that administers the ESPP, we may issue directly from treasury or purchase shares in the market from time to time to satisfy the obligations under the ESPP. A participant may authorize a payroll or contractual deduction up to a maximum of 10% of the base salary or remuneration to be received during any purchase period. The purchase price shall be 90% of the fair market value per share of stock on the date on which the eligible period ends. At December 31, 2004, a total of 88,698 shares have been issued under the ESPP.

### **C. Board Practices**

In 2004, we instituted a governance-enhancement process. This process began with the announcement by Chairman Eugene Melnyk in June 2004 of Biovail's commitment to increase investor confidence in the Company. As the first step in achieving that objective, Mr. Melnyk proposed that the Board of Directors undertake a comprehensive review of Biovail's governance policies and practices and act upon findings of that review. The proposal was approved unanimously by the Board of Directors and embraced by management.

#### **Overview of the Company's Corporate-Governance Practices**

The Board of Directors identified several goals at the outset of the governance-enhancement initiative: first, to build the skills, experience and resources of the Board of Directors to allow its governance oversight function to operate most effectively; second, to support an effective management decision-making process; third, to enhance investor and regulator confidence in Biovail; and fourth, to contribute to our ongoing objective of generating value for its shareholders.

We have taken a number of steps in the area of its governance practices to date. These actions have resulted in a number of changes in the composition of our Board of Directors, the way in which it interacts with management and the processes by which it discharges its responsibilities. The actions taken by the our Board of Directors in the governance area over the past year can be summarized under the following broad headings:

Defining the Responsibilities of the Board of Directors and Management;

Enhancing the Effectiveness of the Board of Directors; and

Improving Communication with Shareholders.

For more information on the governance enhancement measures already implemented, those that are in the process of being implemented and those that have been approved for implementation and are being proposed to the Company's shareholders, please see the Management Information Circular.

## **Role of the Board of Directors**

The Board of Directors is required by law to manage or supervise the management of our business and affairs. The Board of Directors has adopted a written charter that sets out certain of its functions (while not detracting from its overall responsibility for supervising the management of our business and affairs).

The amount of time spent on each function in any year will vary, depending on the issues facing us. During 2004, the Board of Directors has spent significant time on strategic initiatives, including the a new strategic plan developed by the Chief Executive Officer, on monitoring certain risks facing the Company (including litigation), and on the governance enhancement process.

### *Composition of the Board of Directors*

We believe that a smaller Board of Directors is more cohesive and works more effectively than a larger Board of Directors. The Board of Directors is currently comprised of the following individuals: Mr. Melnyk (Executive Chairman); Wilfred G. Bristow, Michael R. Van Every, Dr. Laurence E. Paul, Sheldon Plener, Roger D. Rowan and Rolf K. Reininghaus. In keeping with recommended practices, four of the seven directors currently in office are independent and five of the eight directors proposed for election at this year's Annual and Special Meeting of shareholders, which is to be held on June 28, 2005 (the "Meeting") (or for appointment immediately thereafter) are independent. Independence has been determined in the case of each director on the basis of whether that director has any relationship (other than as a director of Biovail) with us or any of our subsidiaries. Any relationship between a director and Biovail, or one of our subsidiaries will cause a director not to be considered independent if it is a direct relationship or is a relationship with an organization in respect of which the director is a partner, shareholder or officer. We include commercial, industrial, banking, consulting, legal, accounting, charitable and familial relationships among the relationships that would cause a director not to be independent.

As Executive Chairman, Mr. Melnyk confers with the Chief Executive Officer on matters of strategic importance to us and, accordingly, is not considered by the Board of Directors to be independent of management. Mr. Reininghaus has been a member of management for a number of years and is therefore also not considered independent. Mr. Plener is a partner in a major law firm that acts for Biovail and its subsidiaries from time to time on matters of a minor nature. Also, his firm has acted for Mr. Melnyk in certain of his business activities that are unrelated to Biovail (and may continue to act on such matters in the future). For this reason, Mr. Plener did not participate in any decisions of the Compensation Committee or the Board of Directors with respect to Mr. Melnyk's position as Executive Chairman or his remuneration in respect of that position. The Board of Directors is confident that Mr. Plener exercises independent judgement and has concluded that Mr. Plener otherwise satisfies all of the tests of independence applicable to our Board of Directors. However, in order to reinforce investor confidence in the independence of our Board of Directors and its processes, the Board of Directors has determined not to categorize Mr. Plener as being independent for the time being.

The current term of office of the members of our Board of Directors expires at our Annual and Special Meeting. Please refer to the disclosure under Item 6A "Directors and Senior Management" above for information regarding the length of time each of the directors standing for re-election at this year's Meeting has served as a Director of the Company. There are no provisions in the service contracts of Biovail's directors which provide for benefits upon the termination of employment us.

### *Responsibilities*

Pursuant to the written charter of the Board of Directors, the Board of Director's has assumed responsibility for:

Nominating individuals for election by the shareholders to the Board of Directors;

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Developing our approach to corporate-governance;

Establishing of a culture of integrity among management and throughout Biovail;

Succession planning and executive compensation;

Overseeing our business and affairs; and

Reviewing and assessing the effectiveness of the Board of Directors and its committees.

The charter of the Board of Directors is posted on Biovail's Web site at [www.biovail.com](http://www.biovail.com) (see Investor Relations/Corporate Governance).

### **Role of the Committees of the Board of Directors**

As part of its governance enhancement initiative, the Board of Directors has reviewed its committee structure as well as the charters and membership of each committee.

#### *Committee Structure*

The Board of Directors currently has three committees – the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee has reviewed and recommended to the Board of Directors revised charters for each of these committees in recent months. This process is designed to provide a greater level of detail and to reflect changes in regulatory and stock exchange requirements. The amendments to these charters were reviewed by the Nominating and Corporate Governance Committee and recommended to the Board of Directors. The amended charters, as approved by the Board of Directors, are posted on Biovail's Web site at [www.biovail.com](http://www.biovail.com) (see Investor Relations/Corporate Governance).

The Board of Directors has resolved to establish a Risk and Compliance Committee in 2005. This committee will assist the Board of Directors in discharging its responsibility for overseeing the identification and appropriate management of risks facing Biovail. The committee will also oversee and monitor compliance programs established as part of our risk management strategy.

### **Nominating and Corporate Governance Committee**

#### *Composition*

Our Nominating and Corporate Governance Committee is comprised of Mr. Bristow (Chair), Mr. Rowan and Mr. Van Every. Each of the members of the Nominating and Corporate Governance Committee is an independent director.

#### *Responsibilities*

The Nominating and Corporate Governance Committee, which operates pursuant to a written charter, is appointed by the Board of Directors and its responsibilities include:

Assisting the Board of Directors by identifying individuals qualified to become members of the Board of Directors, consistent with criteria established by the Board of Directors;

Recommending that the Board of Directors select the director nominees for the next annual meeting of shareholders;

Developing and recommending to the Board of Directors a set of corporate-governance principles applicable to Biovail;

Overseeing the evaluation of the Board of Directors and senior management; and



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Such other matters as are set out in its charter or as may otherwise be assigned to the Nominating and Corporate Governance Committee by the Board of Directors.

The Nominating and Corporate Governance Committee and its Chairman are appointed annually by the Board of Directors. As part of each meeting, Committee members meet without any member of management present. The Committee has the authority to retain and compensate any consultants and advisors it considers necessary to fulfill its mandate.

### **Audit Committee**

#### *Composition*

Our Audit Committee is comprised of Mr. Van Every (Chair), Dr. Paul and Mr. Rowan. Each of the members of the Audit Committee is an independent director as that term is defined in connection with audit committee membership under all applicable legislation, regulation and stock exchange rules. The Board of Directors has concluded that both Mr. Van Every and Dr. Paul are "financial experts" as defined in the *Sarbanes-Oxley Act of 2002*.

#### *Responsibilities*

The Audit Committee operates pursuant to a written charter that includes (among other things) all these responsibilities assigned to it by law. These responsibilities include providing assistance to the Board of Directors in fulfilling its oversight function with respect to:

The integrity of our financial statements;

Our compliance with legal and regulatory requirements;

The external auditor's qualifications and independence; and

The performance of our internal audit function.

As contemplated in its charter, the Audit Committee meets regularly with our external auditors without management being present.

### **Compensation Committee**

#### *Composition*

Our Compensation Committee is comprised of Dr. Paul (Chair), Mr. Bristow and Mr. Plener. Each of Dr. Paul and Mr. Bristow is an independent director. As discussed above, the Board of Directors has chosen not to categorize Mr. Plener as independent director. For this reason, Mr. Plener did not participate in any decisions of the Compensation Committee with respect to Mr. Melnyk's position as Executive Chairman or his remuneration in respect of that position. After the Meeting, Mr. Plener will be replaced as a member of the Compensation Committee by Mr. Van Every.

#### *Responsibilities*

The Compensation Committee, which operates pursuant to a written charter, is appointed by the Board of Directors to assist oversight by the Board of Directors of executive and director compensation, including with respect to:

Reviewing and approving compensation of our CEO;

Recommending to the Board of Directors non-CEO compensation, incentive-based plans and equity-based compensation plans, including, without limitation, stock option and restricted stock plans, in which officers or employees may participate;





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Arrangements with executive officers relating to their employment relationships with us, including, without limitation, employment agreements, severance agreements, supplemental pension or savings arrangements, change in control agreements and restrictive covenants;

Approving and monitoring insider trading and share ownership policies; and

Reviewing compensation disclosure in public documents, including the Compensation Committee's annual report on executive compensation for inclusion in our Management Information (proxy) Circular, in accordance with applicable rules and regulations.

The Compensation Committee considers matters within its mandate and makes recommendations to the full Board of Directors. The Committee and its Chair are appointed annually by the Board of Directors. As part of each meeting, Committee members meet without any member of management present. The Committee has the authority to retain and compensate any consultants and advisors it considers necessary. In this regard, the Committee has retained an independent compensation consultant to assist in the discharge of its mandate.

### *Pension Plan*

We do not maintain a pension plan for our employees, officers or directors.

### **D. Employees**

The following table sets out the Company's number of employees at the end of each of the last three calendar years. None of these employees are represented by a collective bargaining agreement.

<b>Function</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>
Manufacturing	866	668	527
Sales and marketing	849	788	863
Research and development	423	403	392
Administration	153	99	75
<b>Total</b>	<b>2,291</b>	<b>1,958</b>	<b>1,857</b>

Following the transaction with Kos and the realignment of our U.S. Commercial operations and once the Workers' Adjourment and Retraining Notification ("WARN") period expires in July 2005, Biovail will have approximately 1,730 employees.

### **E. Share Ownership**

The following table shows the number and percent of Common Shares beneficially owned by Eugene Melnyk and the directors and Named Executive Officers as a group (12 persons) as of June 14, 2005. Other than Mr. Melnyk, no director or Named Executive Officer of the Company beneficially owns 1% or more of our Common Shares. As used in the table below, "beneficial ownership" means sole or shared power to vote or direct the voting of the security, or the sole or shared investment power with respect to a security (i.e., the power to dispose, or direct a disposition, of a security). A person is deemed at any date to have

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"beneficial ownership" of any security that the person has a right to acquire within 60 days. More than one person may be deemed to have beneficial ownership of the same securities.

Name of Beneficial Owner	Common Shares Owned	Percent <sup>(1)</sup>
Eugene N. Melnyk	22,688,246 <sup>(2)</sup>	14.0%
Directors and Named Executive Officers as a group (13 persons)	25,231,930 <sup>(3)</sup>	15.4%

(1) Based on 159,401,451 common shares outstanding at June 14, 2005 and common shares issuable upon the exercise of exercisable stock options held by the Beneficial Owner as of June 14, 2005.

(2) Includes exercisable stock options to purchase 2,560,300 common shares.

(3) Includes exercisable stock options to purchase 4,102,435 common shares.

**Item 7 Major Shareholders and Related Party Transactions**

**A. Major Shareholders**

We are not directly or indirectly owned or controlled by another corporation(s) or by any foreign government.

To the knowledge of the directors and senior officers of the Company, at June 14, 2005, set out below are the only persons/entities who beneficially owned, directly or indirectly, or exercised control or direction over our common shares carrying more than 10% of the voting rights attached to all our common shares. As used in the table below, "beneficial ownership" means sole or shared power to vote or direct the voting of the security, or the sole or shared investment power with respect to a security (i.e., the power to dispose, or direct a disposition, of a security). A person is deemed at any date to have "beneficial ownership" of any security that the person has a right to acquire within 60 days. More than one person may be deemed to have beneficial ownership of the same securities.

Name of Shareholder	Approximate Number of Common Shares Beneficially Owned, Directly or Indirectly, or over which Control or Direction is Exercised	Percentage of Outstanding Common Shares Represented
Eugene N. Melnyk	22,688,246	14.0%
McLean Budden Ltd.	13,360,956	8.4%
Phillips, Hager & North Investment Management Ltd.	12,717,383	8.0%

None of the shareholders set out above have different voting rights from the other shareholders.

The following table indicates as of June 14, 2005, the approximate total number of holders of record of Common Shares, the total number of Common Shares outstanding, the number of holders of record of Common Shares with U.S. addresses, the portion of the outstanding Common Shares held in the U.S., and the percentage of Common Shares held in the U.S.:

Total Number of Holders of Record <sup>(1)</sup>	Total Number of Common Shares Outstanding	Number of U.S. Holders of Record <sup>(2)</sup>	Number of Common Shares Held by U.S. Holders of Record	Percentage of Common Shares Held by U.S. Holders of Record
1,473	159,401,451	637	141,706,781	88.9%

(1)

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A substantial number of the Common Shares are held by depositories, brokerage firms and financial institutions in "street name". Based upon the number of annual reports and proxy statements requested by such nominees, the Company estimates that the total number of beneficial holders of Common Shares exceeds 70,000 holders.

(2)

The computation of the number of Common Shares held in the U.S. is based upon the number of holders of record with U.S. addresses. U.S. residents may beneficially own Common Shares owned of record by non-U.S. residents.

**B. Related Party Transactions**

*Indebtedness of Executive Officers*

Our policy not to provide financial assistance to shareholders, directors, officers or employees in connection with the purchase of Biovail, or any of its affiliates, Common Shares. In addition, Biovail does not grant personal loans to our directors and officers.

During fiscal year 2004, no loans were made by us to any of our senior executives and no securities were purchased by any Director or officer during 2004 with our financial assistance. Furthermore, no director, officer or executive was indebted to Biovail in connection with securities purchase programs during the fiscal year ended December 31, 2004. During fiscal year 2004, there was no indebtedness owing by any officer or director to the Company. In March 2001, we loaned \$600,000 to Mr. William Poole, former President, North American Pharmaceuticals. Mr. Poole ceased to be President, North American Pharmaceuticals on May 6, 2003. This loan is secured by the former Executive Officer's personal residence and bears interest commencing on March 1, 2004 at a rate equal to our rate of borrowing. The loan is due on March 31, 2008.

*Executive Stock Purchase Plan Loans ("ExSPP")*

In September 2001, we made ExSPP loans in an aggregate amount of \$9,988,000 to certain Executive Officers in order to finance the acquisition of our common shares on the open market. These loans were full recourse and were secured by the common shares purchased pursuant to these loans and bore interest at a rate equal to the Company's rate for borrowing. Interest was payable quarterly in arrears. These loans were due and payable on September 30, 2003.

At December 31, 2003, four Executive Officers were indebted to us in an aggregate amount of \$7,990,000 in connection with the ExSPP loans. To facilitate repayment of these loans, on December 31, 2003, Mr. Melnyk, Executive Chairman of the Board, in his individual capacity, made loans to these executives in an amount equal to the amount of their indebtedness to us and the ExSPP loans from us were repaid. These executives pledged to Mr. Melnyk, as collateral for their loans, an aggregate of 176,080 of our shares, and their interest in the proceeds from 200,000 options to acquire our shares having a strike price of \$31 per share. The loan arrangements provide that there will be no recourse to these executives in addition to the collateral pledged by them, except in certain instances.

**C. Interests of Experts and Counsel**

Not applicable.

**Item 8. Financial Information**

**A. Consolidated Statements and Other Financial Information**

The financial statements filed as part of this annual report are filed under Item 18.

**B. Significant Changes**

*Subsequent Events*

On May 2, 2005, we sold all of our rights to Teveten® and Teveten® HCT, and the distribution rights to Cardizem® LA in the United States, to Kos. We will be the exclusive manufacturer and supplier of Cardizem® LA to Kos over an initial seven-year supply term, at contractually determined prices that are in excess of 30% of Kos's net selling prices. To date, Kos has offered employment to 163 employees of the Company's U.S. workforce. Kos will also collaborate with us on the development of up to three products, including a combination product comprising Cardizem® LA and enalapril (Vasotec®). Subject to FDA approval, we will be the exclusive manufacturer and supplier of the combination product to Kos. In consideration for these transactions, Kos paid us approximately \$104 million in cash, and Kos will pay us milestones related to the development of the combination product. We are currently finalizing the accounting for these transactions; however, we expect that the revenue and costs associated with these transactions will be recognized in earnings over the term of the Cardizem® LA supply agreement. In addition, the disposal of Teveten® and Teveten® HCT will likely result in a write-down of the carrying value of these product rights to reflect their fair value at the date of disposition.

Concurrent with the above transactions, we reduced our remaining U.S. workforce by an additional 340 employees. Following this reduction, we have approximately 85 remaining U.S. primary care and specialty sales representatives who will initially focus exclusively on the promotion of Zovirax® Ointment and Zovirax® Cream to specialist physicians. We expect to incur a related restructuring charge of approximately \$20 million to \$25 million, primarily associated with employee termination benefits and contract termination costs.

*Legal Proceedings*

From time to time, we become 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 we routinely become involved but which individually and collectively are not material.

We cannot currently predict or foresee the outcome of the legal proceedings it is involved in, or reasonably estimate the amount of any losses that may result from these proceedings. Accordingly, we have not accrued for any loss contingencies related to these proceedings at June 14, 2005. An adverse outcome in certain of these proceedings could have a material adverse effect on our results of operations, financial position and cash flows.

*Intellectual Property*

RhoxalPharma Inc. ("RhoxalPharma") has filed an Abbreviated New Drug Submission ("ANDS") in Canada, seeking approval of a generic version of Tiazac® (120mg, 180mg, 240mg, 300mg and 360mg). We have two patents listed in the Patent Registry and on April 1, 2004, instituted legal proceedings in the Federal Court of Canada that will prohibit the issuance of a NOC to RhoxalPharma until these proceedings are concluded, or until the expiry of 24 months from the date of the Notice of Allegation, whichever is earlier. A court date is expected to occur in, or about September 2005.

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

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

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

Torpharm, Inc. ("Torpharm") has filed an ANDA in the United States, seeking approval for a generic version of Cardizem® CD (120mg, 180mg, 240mg and 300mg). On November 21, 2001, we instituted legal proceedings in the United States District Court for the Northern District of Illinois Eastern Division pursuant to the Hatch-Waxman Act which had the effect of precluding the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a court decision of non-infringement or patent invalidity or a court decision to abbreviate the 30-month stay. This litigation was settled by agreement of the parties on April 29, 2005. The settlement encompassed a general dismissal of all claims, counterclaims and defenses by all parties without any admission of liability by any party and without further consideration being exchanged.

Torpharm has filed an ANDA in the United States, seeking approval for a generic version of Tiazac® (120mg, 180mg, 240mg, 300mg and 360mg). On September 3, 2002, we instituted legal proceedings in the United States District Court for the Eastern District of Pennsylvania pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay. This litigation was settled by agreement of the parties on April 29, 2005. The settlement encompassed a general dismissal of all claims, counterclaims and defenses by all parties without any admission of liability by any party and without further consideration being given.

Anchen Pharmaceuticals Inc. ("Anchen") has filed an ANDA in the United States, seeking approval for a generic version of Wellbutrin XL® (150mg and 300mg). On December 21, 2004, we instituted legal proceedings pursuant in the United States District Court for the Central District of California to the Hatch-Waxman Act that preclude the FDA from granting approval to Anchen until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

Abrika Pharmaceuticals LLLP ("Abrika") has filed an ANDA in the United States, seeking approval for a generic version of Wellbutrin XL® (150mg and 300mg). On December 21, 2004, we instituted legal proceedings in the United States District Court for the Southern District of Florida pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Abrika until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

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Impax Laboratories Inc. ("Impax") has filed an ANDA in the United States, seeking approval for a generic version of Wellbutrin XL® (150mg). On March 7, 2005, we instituted legal proceedings in the United States District Court for the Eastern District of Pennsylvania pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Impax until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

### *Product Liability*

BPI has been named in two complaints Superior Court of the State of California for the County of Los Angeles (January 4, 2002) and United States District Court or the Western District of Washington at Seattle (October 23, 2003) alleging personal injuries arising from Plaintiffs' use of Dura-Vent, a product containing phenylpropanolamine and formerly marketed by BPI. The California case has been dismissed without prejudice. We have never been served with a summons in the second case. The Plaintiff in the second case has agreed to stay the action pending the outcome of the multi-district litigation involving other parties. Damages have not been quantified.

### *Antitrust*

Several class-action complaints in multiple jurisdictions have been filed against us in which the Plaintiffs have alleged that we have improperly impeded the approval of a generic form of Tiazac®. Those actions filed in federal courts have been transferred to, and in some cases consolidated in, the United States District Court for the District of Columbia. We believe that the complaints are without merit and that the Company's actions were in accordance with its rights as contained in the Hatch-Waxman Amendments and the law. Moreover, our position is that it is not responsible for Andrx Corporation's ("Andrx") inability to receive timely final marketing approval from the FDA for its generic Tiazac® considering that the Andrx product did not receive FDA approval for a lengthy period following the removal of all legal or regulatory impediments by the Company. The Court has granted our Motion for Summary Judgment seeking to dismiss several of those actions. We intend to attempt to use this successful result in order to seek to have several State Court actions currently pending in the Superior Court of the State of California for Los Angeles County, Superior Court of California for the County of San Diego and Superior Court of the State of California for the County of Alameda, which had been stayed, similarly dismissed. Damages have not been quantified.

Several class-action complaints in multiple jurisdictions have been commenced jointly against us, Elan Corporation, plc ("Elan") and Teva relating to an agreement between us and Elan for the licensing of Adalat CC products from Elan. These complaints were transferred to the United States District Court for the District of Columbia. The agreement in question has since been dissolved as a result of a consent decree with the U.S. Federal Trade Commission ("FTC"). We believe these suits are without merit because, among other reasons, it is the Company's position that any delay in the marketing or out-licensing of our Adalat CC product was due to manufacturing difficulties we encountered and not because of any improper activity on its part. We filed a motion for the summary dismissal of these actions. The Court has denied our motion to dismiss the damage claims brought on behalf of a purported class of so-called "direct purchasers", generally consisting of distributors and large chain drug stores, but dismissed the claims of a class of consumers and "end-payors". The consumer and "end-payor" claims were re-filed in Superior Court of the State of California. The actions are proceeding on their merits through normal legal process. Damages have not been quantified.

### *Securities Class Actions*

In the fourth quarter of 2003, a number of securities class-action complaints were filed in the United States District Court for the Southern District of New York naming Biovail and certain officers as



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Defendants. On or about June 18, 2004, the Plaintiffs filed a Consolidated Amended Complaint (the "Complaint"). The Complaint alleges, among other matters, that the Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. More specifically, the Complaint alleges that the Defendants made materially false and misleading statements that inflated the price of our stock between February 7, 2003 and March 2, 2004. The Plaintiffs seek to represent a class consisting of all persons other than the Defendants and their affiliates who purchased our stock during that period.

The Defendants responded to the Complaint by filing a motion to dismiss. The Court denied the motion to dismiss. The action is now proceeding on its merits through normal legal process. The Plaintiffs have not quantified the amount of the damages they are seeking.

### *Defamation and Tort*

On April 29, 2003, Jerry I. Treppel, a former analyst at Banc of America Securities, commenced an action in the United States District Court for the Southern District of New York naming as Defendants the Company and certain officers thereof, and against Michael Sitrick and Sitrick & Company, Inc. (in their capacities as our consultants), in which the Plaintiff has alleged that he was defamed by the Defendants and that our actions resulted in damages to him by way of lost employment and employment opportunities.

We filed a motion for summary dismissal of this action. The Court has dismissed a number of claims and named defendants, with the remaining defendants and claims to proceed through the litigation process on the merits. In an attempt to reinstate the dismissed defendants and claims, the Plaintiff filed a Second Amended Complaint on March 24, 2005. We responded by filing a second motion to dismiss relying on the same legal arguments successfully used in the first motion. Our second motion to dismiss is currently pending. Treppel has claimed \$100 million in damages but has provided no basis for the calculation of his claim.

### *General Civil Actions*

Complaints have been filed by the City of New York, the State of Alabama and a number of counties within the State of New York, and elsewhere in the United States, claiming that we, and numerous other pharmaceutical companies, made fraudulent misstatements concerning the "average wholesale price" of their prescription drugs, resulting in alleged overpayments by the plaintiffs for pharmaceutical products sold by the companies. The United States Judicial Panel on Multi-District Litigation has ordered that all the New York cases be consolidated and coordinated with similar class-action pending in the United States District Court for the District of Massachusetts. Activity in each case has been stayed pending the resolution of certain procedural matters. We have filed a pre-answer motion to dismiss the Amended Complaint brought by the State of Alabama. Based on the information currently available, and given the small number of Biovail products at issue and the limited time frame in respect of such sales, we anticipate that even if these actions were successful, any recovery against Biovail would likely not be material.

### *Governmental and Regulatory Inquiries*

In July 2003, we received notification from the U.S. Attorney, District of Massachusetts, on behalf of the OIG that a preliminary administrative inquiry has been initiated into our clinical experience program related to the commercialization of Cardizem® LA. In November 2004, our executives met with the OIG representatives to discuss the OIG's review of the program in question, which was utilized by us from April 2003 to August 2003, and to advise them that it had taken precautionary steps to ensure that the program in question met the applicable rules and regulations. Recently, the OIG has indicated, through the issuance of subpoenas, its desire to interview certain persons (employees and non-employees) in order

to confirm our position as presented to the OIG. We are working diligently to resolve this matter, although we cannot predict the outcome or the timing of when this matter may be resolved.

In March 2005, the SEC advised us that it had issued a subpoena to us pursuant to a formal order of investigation. The subpoena continues to seek the same historical financial and related information, including, but not limited to our accounting and financial disclosure practices, as had been requested in the previously disclosed informal inquiry initiated in November 2003. However, the scope of the subpoena is broader, includes certain transactions associated with a corporate entity since acquired by us, and covers time periods from January 2001 through May 31, 2004. We have been fully co-operating, and continues to co-operate fully, with the SEC's investigation. We cannot predict either the outcome or the timing when this matter may be resolved.

The OSC has advised us that it is investigating, among other things, two issues relating to Biovail's accounting and disclosure in 2003. The first is whether we improperly recognized revenue for accounting purposes in relation to its interim financial statements for each of the four quarters in 2003. The second is whether we provided misleading disclosure in our press release dated October 3, 2003 concerning the reasons for Biovail's forecast of a revenue shortfall in respect of the three-month period ending September 30, 2003. The OSC has also advised that it is investigating four issues relating to trading in our common shares. These issues include whether insiders of the Company complied with insider reporting requirements, and whether persons in a special relationship with us may have traded in our shares with knowledge of undisclosed material information. The OSC is also investigating whether certain transactions may have resulted in, or contributed to, a misleading appearance of trading activity in our securities during 2003 and 2004, and whether certain registrants (who are past, or present, directors of Biovail) may have been in a conflict of interest in relation to trading of our shares. We have been co-operating and continues to co-operate fully with the OSC in these matters. We cannot predict the outcome or the timing of when this matter may be resolved.

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

## **Item 9. The Offer and Listing Details**

### **A. Nature of Trading Market**

Our common shares are traded on the NYSE and on the TSX under the symbol "BVF". The last reported sales price of our common shares on June 14, 2005 on the NYSE was \$15.86 and on the TSX was C\$19.85. 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\$
<b>2000</b>	45.38	19.13	69.50	27.50
<b>2001</b>	57.18	29.03	91.00	45.80
<b>2002</b>	56.40	19.90	09.41	31.52
<b>2003</b>				
Quarter 1	41.00	26.72	60.62	42.40
Quarter 2	51.30	35.10	69.58	49.80
Quarter 3	48.09	36.00	65.15	49.36
Quarter 4	37.77	16.51	50.69	21.50
<b>2004</b>				
Quarter 1	26.01	15.50	33.98	20.40
Quarter 2	19.89	15.56	27.35	20.45
Quarter 3	19.03	14.80	25.20	19.50
Quarter 4	20.38	14.30	24.80	16.90
December	16.70	15.09	21.95	18.10
<b>2005</b>				
Quarter 1	18.02	14.90	20.27	17.82
January	16.75	15.13	20.36	18.25
February	17.35	16.02	21.84	19.55
March	18.02	14.90	21.95	18.10
April	15.65	13.74	19.05	17.25
May	16.32	13.76	20.61	17.25
June (through June 14, 2005)	16.16	15.62	20.12	19.51

#### 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. Plan of Distribution

Not applicable.

#### C. Markets

Our Common Shares, no par value are traded on the NYSE and the TSX under the symbol "BVF".

#### D. Selling Shareholders

Not applicable.

#### E. Dilution

Not applicable.

**F. Expenses of the Issue**

Not applicable.

**Item 10. Additional Information**

**A. Share Capital**

Not applicable.

**B. Memorandum and Articles of Association**

**Articles of Amalgamation**

We are governed by our articles of amalgamation (the "Articles") under the OBCA and by our by-laws (the "By-laws"). Our Ontario corporation number is 1402077. Our articles provide that there are no restrictions on the business we may carry on or on the powers we may exercise. Companies incorporated under the OBCA are not required to include specific objects or purposes in their articles or by-laws.

On June 28, 2005, at the Meeting our shareholders will consider a special resolution authorizing the continuance of Biovail from the OBCA to the CBCA. If this special resolution is approved by two-thirds of the votes cast at the Meeting, on filing of the new articles of continuance, Biovail will be subject to the CBCA rather than the OBCA. Under the CBCA, shareholders are provided with materially the same rights as are available to shareholders under the OBCA. For a brief summary of the differences between the OBCA and the CBCA that we believe may be material to shareholders (see Management Information Circular under the heading Section 2: Business of Meeting Information about the Continuance of Biovail).

**Directors**

Subject to certain exceptions, including in respect of their own compensation, directors may not vote on matters in which they have a material interest. The directors are entitled to remuneration as shall from time to time be determined by the Board with no requirement for a quorum of independent directors. The directors may exercise all of the Company's power to borrow money. These powers may be amended by resolution of the shareholders. Directors are not required to retire at a particular age. There is no requirement for the directors to hold shares.

**Rights, Preferences and Dividends Attaching to Shares**

The holders of Common Shares have the right to receive dividends if and when declared. Any dividend unclaimed after a period of two years from the date on which such dividend is declared to be payable shall be forfeited and shall revert to us. Each of the holders of Common Shares, as of the record date prior to a meeting, is entitled to attend and to cast one vote for each common share held at such annual and/or special meeting, including with respect to the re-election of directors. Subject to the provisions of our by-laws, all directors may, if still qualified to serve as directors, stand for re-election. Our Board of Directors is not replaced at staggered intervals.

On a distribution of assets on a winding-up, dissolution or other return of capital (subject to certain exceptions) the holders of Common Shares shall have a right to receive their pro rata share of such distribution. There are no sinking fund or redemption provisions in respect of Common Shares. Our shareholders have no liability to further capital calls as all shares issued and outstanding are fully paid and non-assessable.

We are permitted under our Articles to issue Class A Special Shares on such terms and in such manner as the directors may determine. As of the date hereof, no Class A Special shares are issued and outstanding.

### **Action Necessary to Change the Rights of Shareholders**

The rights attaching to the different classes of shares may be varied by special resolution passed at a meeting of that class's shareholders.

### **Annual and Special Meetings of Shareholders**

We are required to mail a notice of meeting and Management Information Circular to registered shareholders not less than 21 days not more than 50 days prior to the date of the meeting (this was done on May 20, 2005). Such materials must be filed concurrently with the applicable securities regulatory authorities in Canada and the United States. Subject to certain provisions of the By-laws, a quorum of two shareholders in person or represented by proxy holding or representing by proxy not less than 25 percent of the total number of issued and outstanding shares is required to properly constitute a meeting of shareholders. Shareholders and their duly appointed proxies and corporate representatives are entitled to be admitted to our annual and/or special meetings.

### **Limitations on the Rights to Own Shares**

The Articles do not contain any limitations on the rights to own shares. There are currently no limitations imposed by Canadian federal or provincial laws on the rights of non-resident or foreign owners of Canadian securities to hold or vote the securities held. There are also no such limitations imposed by the Articles and Bylaws with respect to our Common Shares.

### **Disclosure of Share Ownership**

The *Securities Act* (Ontario) provides that a person or company who beneficially owns, directly or indirectly, voting securities of an issuer or who exercises control or direction over voting securities of an issuer or a combination of both, carrying more than 10% of the voting rights attached to all the issuer's outstanding voting securities (an "insider") must, within 10 days of becoming an insider, file a report in the required form effective the date on which the person became an insider, disclosing any direct or indirect beneficial ownership of, or control or direction over, securities of the reporting issuer. The *Securities Act* (Ontario) also provides for the filing of a report by an insider of a reporting issuer who acquires or transfers securities of the issuer. This report must be filed within 10 days after the end of the month in which the acquisition or transfer takes place.

The rules in the United States governing the ownership threshold above which shareholder ownership must be disclosed are more stringent than those discussed above. Section 13 of the *Securities Exchange Act of 1934* (the "Exchange Act") imposes reporting requirements on persons who acquire beneficial ownership (as such term is defined in the Rule 13d-3 under the Exchange Act) of more than 5% of a class of an equity security registered under Section 12 of the Exchange Act. In general, such persons must file, within 10 days after such acquisition, a report of beneficial ownership with the SEC containing the information prescribed by the regulations under Section 13 of the Exchange Act. This information is also required to be sent to the issuer of the securities and to each exchange where the securities are traded.

### **Other Provisions of Articles and By-laws**

There are no provisions in the Articles or By-laws:

Delaying or prohibiting a change-in-control of the Company that operate only with respect to a merger, acquisition or corporate restructuring;

Discriminating against any existing or prospective holder of shares as a result of such shareholder owning a substantial number of shares;

Requiring disclosure of share ownership; or

Governing changes in capital, where such provisions are more stringent than those required by law.

**C. Material Contracts**

In the prior two years, we have not entered into any contract other than in the ordinary course of business.

**D. 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 the Company's securities, except as discussed in Section E, Taxation.

**Restrictions on Share Ownership by Non-Canadians**

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

**Investment Canada Act**

Under the Investment Canada Act, the acquisition of control of a Canadian business satisfying prescribed financial thresholds by a "non-Canadian" investor will be subject to review by the Minister of Industry (Canada) and/or if the business is engaged in cultural activities by the Minister of Canadian Heritage. A reviewable acquisition will not be allowed unless the responsible Minister finds that the investment is likely to be of "net benefit" to Canada.

Where either the investor is a member of the World Trade Organization ("WTO"), or a WTO member-controlled company or the Canadian business that is subject of the acquisition, is prior to the acquisition, controlled by a WTO investor and the Canadian business is not engaged in any defined sensitive sector business, the acquisition of control is reviewable only if it involves the direct acquisition of a Canadian business with assets of C\$250 million or more for the year 2005 (this figure is adjusted annually to reflect inflation). Significantly lower review thresholds apply where neither the investor nor the Canadian business are controlled by a WTO investor. Significantly lower review thresholds and sector-specific policies and procedures apply to the acquisition of control of a Canadian business that is engaged in certain sensitive sectors such as uranium production, financial services, transportation or culture.

Even if the transaction is not reviewable because it does not meet or exceed the applicable threshold, the non-Canadian investor must still give notice to Industry Canada of its acquisition of control of a Canadian business within 30 days of its implementation.

**Competition Act**

Under the *Competition Act* (Canada) (the "Competition Act"), certain transactions are subject to pre-merger notification to the Commissioner of Competition (the "Commissioner") and may be subject to challenge by the Commission (not a private party) where the Commissioner believes they are likely to prevent or lessen competition substantially. Such transactions may not be completed until (i) the applicable statutory waiting periods (namely 14 days or 42 days for a short-form or long-form filing, respectively) have expired or been earlier terminated by the Commissioner without the Commissioner having taken any action to prohibit the implementation of the transaction; or (ii) the Commissioner has issued an advance ruling certificate or has waived the obligation to notify. Where the parties elect to file a short-form notification, the Commissioner may require a long-form filing, in which case the waiting period is 42 days from the time the parties submit their long form-filing.

A proposed transaction is subject to pre-merger notification only if the party size threshold is satisfied and the applicable transaction size is satisfied. The party size threshold requires that the parties to the

transaction together with their affiliates have total assets in Canada or total revenues from sales in, from or into Canada that exceed C\$400 million in aggregate value. There are specific transaction size thresholds for asset acquisitions, share acquisitions as well as for amalgamation, combination and joint venture arrangements. There are exemptions from the notification provisions for transactions involving only affiliates and other prescribed transactions.

Regardless of whether a pre-merger notification filing is required, the Commissioner may apply to the Competition Tribunal, a specialized tribunal empowered to deal with certain matters under the Competition Act, with respect to any "merger" (as defined in the Competition Act). If the Competition Tribunal finds that any merger is likely to prevent or lessen competition substantially it may order that the merger not proceed or, if the merger has been completed, order its dissolution or the disposition of some of the assets or shares involved.

## **E. 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 the purposes of the Canadian Tax Act (as defined below), and any applicable income tax convention, is not, and is not deemed to be resident in Canada, deals at arm's length with the Company and is not affiliated with the Company, holds such Common Shares as capital property, and does not use or hold and is not deemed or otherwise considered to use or hold such Common Shares in carrying on a business in Canada (a "Non-Resident Shareholder"). 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.

This summary is based upon the current provisions of the *Income Tax Act* (Canada) (the "Canadian Tax Act"), the regulations thereunder, and the Company's understanding of the current administrative and assessing policies and 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 Canadian Tax Act and the regulations thereunder 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 or assessing practice, 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 be different 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. Holders should consult their own tax advisors with respect to their own particular circumstances.

#### *Gains on Disposition of Common Shares*

No tax will generally be payable under the Canadian Tax Act on any capital gain realized by a Non-Resident Shareholder on the disposition of such Non-Resident Shareholder's Common Shares unless the Common Shares are "taxable Canadian property" to the Non-Resident Shareholder and the Non-Resident Shareholder is not entitled to relief under an applicable income tax convention.

Generally, the Common Shares will not be taxable Canadian property to a Non-Resident Shareholder at a particular time provided that (1) the Common Shares are listed on a prescribed stock exchange (which includes the TSX) at that time, and (2) the Non-Resident Shareholder, persons with whom the Non-Resident Shareholder does not deal with at arm's length, or the Non-Resident Shareholder 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 the Company at any time during the 60-month period that ends at that time. Notwithstanding the foregoing, in certain circumstances set out in the Canadian Tax Act, Common Shares could be deemed to be taxable Canadian property.

#### *Dividends on Common Shares*

Subject to the provisions of an applicable income tax convention between Canada and the country in which the Non-Resident Shareholder is resident, dividends paid or credited on the Common Shares or deemed to be paid or credited on the Common Shares to a Non-Resident Shareholder will generally be subject to non-resident withholding tax under the Canadian Tax Act at the rate of 25% of the amounts paid or credited. Under the provisions of the Canada-U.S. Income Tax Convention, (1980) (the "Convention"), the rate of withholding tax on dividends paid by the Company to a Non-Resident Shareholder that is a resident of the U.S. entitled to benefits under the Convention and is the beneficial owner of such dividends is generally reduced to (a) 5% if the Non-Resident Shareholder is a company which owns at least 10% of the Company's voting stock or (b) 15% in all other cases.

#### **U.S. Federal Income Taxation**

The following discussion is a summary of certain material U.S. federal income tax consequences of the ownership and disposition of common shares to U.S. Holders (as defined below) who hold common shares as capital assets. This discussion is based upon laws, regulations, rulings and decisions currently in effect, all of which are subject to change, retroactively or prospectively.

The discussion is for general information only and may not apply to certain categories of shareholders subject to special treatment under the *Internal Revenue Code of 1986*, as amended (the "Code"), such as Non-U.S. Holders (as defined below), holders that are passthrough entities or investors in passthrough entities, dealers or traders in securities or currencies, banks, insurance companies, traders who elect to mark-to-market their securities, persons whose "functional currency" is not the U.S. dollar, tax-exempt entities, and persons that hold common shares as a position in a straddle or as part of a "hedging," "integrated," "constructive sale" or "conversion" transaction. Moreover, the discussion summarizes only federal income tax consequences and does not address any other U.S. federal tax consequences or any state, local or other tax consequences. Accordingly, prospective investors are urged to consult their own tax advisors to determine the specific tax consequences of the ownership and disposition of common shares to them, including any U.S. Federal, State, Local or other tax consequences (including any tax return filing or other tax reporting requirements) of the ownership and disposition of Common Shares.

For purposes of the following discussion, the term "U.S. Holder" means a beneficial owner of common shares that is, for U.S. federal income tax purposes, a U.S. citizen or resident, a corporation created or organized in or under the laws of the United States or any political subdivision thereof, an estate the income of which is includable in gross income for U.S. income tax purposes regardless of its source, or a trust if (a) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more United States fiduciaries have the authority to control all substantial decisions of the trust, or (b) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person. A "Non-U.S. Holder" means a beneficial owner of common shares that is, for U.S. federal income tax purposes, a non-resident alien or a corporation, estate or trust that is not a U.S. Holder.



### ***Taxation of Dividends***

Subject to the following discussion of special rules applicable to Passive Foreign Investment Companies ("PFICs"), the gross amount of any dividends, if any, paid by the Company to U.S. holders, without reduction for Canadian withholding taxes, will be taxed for U.S. federal income tax purposes at recently enacted lower rates applicable to certain qualified dividends. The maximum federal income tax rate imposed on dividends received from U.S. and certain foreign corporations for years 2003 through 2008 is 15%. Recipients of dividends from foreign corporations will be taxed at this rate, provided that certain holding period requirements are satisfied, if the dividends are received from certain "qualified foreign corporations," which generally includes corporations located in a jurisdiction with which the United States has an income tax treaty that the Secretary of the Treasury determines is satisfactory and includes an information exchange program. Dividends paid with respect to stock of a foreign corporation which is readily tradable on an established securities market in the United States will also be treated as having been received from a "qualified foreign corporation." The United States Department of the Treasury and the Internal Revenue Service have determined that the Canada-U.S. Income tax Treaty is satisfactory for this purpose. In addition, the United States Department of the Treasury and the Internal Revenue Service have determined that common shares are considered readily tradable on an established securities market if they are listed on an established securities market in the United States such as the NYSE. Accordingly, dividends received by U.S. Holders should be entitled to favorable treatment as dividends received with respect to stock of a "qualified foreign corporation."

In certain circumstances, U.S. Holders may be eligible to receive a foreign tax credit for the Canadian withholding taxes and, in the case of a corporate U.S. Holder owning 10% or more of the voting shares of the Company, for a portion of the Canadian taxes paid by the Company itself. Dividends paid by the Company, if any, generally will not qualify for the dividends received deduction otherwise available to corporate U.S. Holders.

The amount of any dividend paid in Canadian dollars will equal the U.S. dollar value of the Canadian dollars received calculated by reference to the exchange rate in effect on the date the dividend is distributed regardless of whether the Canadian dollars are converted into U.S. dollars. If the Canadian dollars received as a dividend are not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a basis in the Canadian dollars equal to its U.S. dollar value on the date of receipt. Any gain or loss realized on a subsequent conversion or other disposition of the Canadian dollars will be treated as ordinary income or loss.

It is possible that the Company is, or at some future time will be, at least 50% owned by United States persons. Dividends paid by a foreign corporation that is at least 50% owned by United States persons may be treated as United States source income (rather than foreign source income) for foreign tax credit purposes to the extent the foreign corporation has more than an insignificant amount of United States source income. The effect of this rule may be to treat a portion of any dividends paid by the Company as United States source income. The Code permits a U.S. Holder entitled to benefits under the Canada-U.S. Income Tax Treaty to elect to treat any Company dividends as foreign source income for foreign tax credit limitation purposes if the dividend income is separated from other income items for purposes of calculating the U.S. Holder's foreign tax credit. U.S. Holders should consult their own tax advisors about the desirability of making, and the method of making, such an election.

### **Sale, Exchange or Other Disposition**

Subject to the following discussion of special rules applicable to "PFICs," U.S. Holders will generally recognize capital gain or loss on the sale, exchange or other disposition of common shares. Such gain or loss will be long-term capital gain or loss if the common shares have been held for more than one year. Any gain or loss recognized by a U.S. Holder will generally be treated as United States source gain or loss. The deduction of capital losses is subject to limitations.

***Passive Foreign Investment Company Considerations***

A PFIC is any foreign corporation if, after the application of certain "look-through" rules, (i) at least 75% of its gross income is "passive income"; or (ii) at least 50% of the average value of its assets is attributable to assets that produce passive income or are held for the production of passive income. The determination as to PFIC status is made annually. If a U.S. Holder is treated as owning PFIC stock, the U.S. Holder will be subject to special rules generally intended to eliminate the benefit of the deferral of U.S. federal income tax that results from investing in a foreign corporation that does not distribute all its earnings currently. These rules may adversely affect the tax treatment to a U.S. Holder of dividends paid by us and of sales, exchanges and other dispositions of our common shares, and may result in other adverse U.S. federal income tax consequences.

We believe that we are not currently a PFIC, and we do not expect to become a PFIC in the future. However, there can be no assurance that the Internal Revenue Service will not successfully challenge the Company's position or that the Company will not become a PFIC at some future time as a result of changes in its assets, income or business operations.

***Information Reporting and Backup Withholding***

In general, information reporting requirements will apply to dividends in respect of the common shares and the proceeds received on the disposition of common shares paid within the United States (and, in certain cases, outside the U.S.) to U.S. Holders other than certain exempt recipients (such as corporations), and backup withholding may apply to such amounts if the U.S. Holder fails to provide an accurate taxpayer identification number or is otherwise subject to backup withholding. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability.

**F. Dividends and Paying Agents**

We have not declared or paid any cash dividends on our common shares to date. Any future determination to pay dividends will be at the discretion of our Board of Directors and will depend upon our results of operations, capital requirements and other relevant factors.

We have certain covenants in our Notes which would govern the amount of dividends that may be paid. The payment of dividends is a restricted payment for the purposes of indenture governing the Notes. Dividends and other payments and transactions that come within the definition of "restricted payments" may be paid or implemented provided they do not, in the aggregate, exceed the threshold calculated in accordance with the indenture. That threshold is calculated with reference to Biovail's cumulative consolidated net income and transactions that affect shareholders' equity.

**G. Statements by Experts**

Not applicable.

**H. Documents on Display**

We are subject to the informational requirements of the Exchange Act and file reports and other information with the SEC. You may read and copy any of our reports and other information at, and obtain copies upon payment of prescribed fees from, the Public Reference Room maintained by the SEC at 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549. In addition, the SEC maintains a Web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC at <http://www.sec.gov>. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

We are required to file reports and other information with the securities commissions in all provinces of Canada. You are invited to read and copy any reports, statements or other information, other than confidential filings, that we file with the provincial securities commissions. These filings are also electronically available from the Canadian System for Electronic Document Analysis and Retrieval (SEDAR) (<http://www.sedar.com>), the Canadian equivalent of the SEC's electronic document gathering and retrieval system.

We "incorporate by reference" information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this Annual Report on Form 20-F and more recent information automatically updates and supersedes more dated information contained or incorporated by reference in this Annual Report on Form 20-F.

As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of proxy statements to shareholder. We have included in this report certain information disclosed in our Proxy Statement prepared under Canadian securities rules.

We will provide without charge to each person, including any beneficial owner, to whom a copy of this Annual Report has been delivered, on the written or oral request of such person, a copy of any or all documents referred to above which have been or may be incorporated by reference in this Annual Report (not including exhibits to such incorporated information that are not specifically incorporated by reference into such information). 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. Telephone (905) 286-3000. Facsimile (905) 286-3500 EMAIL: [ir@biovail.com](mailto:ir@biovail.com)

#### **I. Subsidiary Information**

The subsidiaries of the Company are detailed under Item "4C Organizational Structure"

#### **Item 11 Quantitative and Qualitative Disclosures About Market Risk**

Information relating to quantitative and qualitative disclosures about market risk is detailed in Item 5.

#### **Item 12 Description of Securities Other Than Equity Securities**

##### **A. Debt Securities**

Not applicable.

##### **B. Warrants and Rights**

Not applicable.

##### **C. Other Securities**

Not applicable.

##### **D. American Depositary Shares**

Not applicable.

**PART II**

**Item 13 Defaults, Dividend Arrearages and Delinquencies**

None.

**Item 14 Material Modification to the Rights of Security Holders and Use of Proceeds**

On December 31, 1999, we filed Articles of Amendment to effect a subdivision of our Common Shares on the basis of two Common Shares for every one Common Share held and an increase in our authorized capital from 120,000,000 common shares to an unlimited number of Common Shares. An amendment was also made to our current by-law to change the quorum requirements for shareholders meetings from two shareholders holding 51% of the outstanding shares to two shareholders holding 25% of the outstanding shares.

On October 10, 2000, we filed Articles of Amendment to effect a subdivision of our Common Shares on the basis of two common shares for every one common share.

**Item 15 Controls and Procedures**

(a)

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 Form 20-F and filed with the SEC is recorded, processed, summarized and reported timely. 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. Notwithstanding the foregoing, there can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within Biovail to disclose material information otherwise required to be set forth in our reports.

**Item 16**

**A. Audit Committee Financial Expert**

Our Board of Directors has determined that each of Mr. Michael Van Every and Dr. Laurence Paul is an "audit committee financial expert" and is independent under the applicable rules promulgated by the SEC and the NYSE.

**B. Code of Ethics**

Our Board of Directors has adopted a Code of Ethics for the Chief Executive Officer and Senior Finance Executives that applies to our Chief Executive Officer, Chief Financial Officer, Corporate Controller and Corporate Treasurer.

**C. Principal Accounting Fees and Services.***Fees and Services*

The table below summarizes the audit fees (expressed in thousands of US dollars) paid by us and our consolidated subsidiaries during each of 2003 and 2004.

	2003		2004	
	Amount	%	Amount	%
Audit Services	\$ 1,301	71.7	\$ 1,158	70.4
Audit-Related Services <sup>(1)</sup>	382	21.1	333	20.3
Tax Services <sup>(2)</sup>	132	7.2	153	9.3
Total	\$ 1,815	100.00	\$ 1,644	100.0

(1) Audit-related services are generally related to due-diligence investigations, audits of combined financial statements prepared for purposes of the contemplated disposal of certain of our activities or of combined financial statements of companies that we acquired, review of prospectuses issued by us, and to other assignments relating to internal accounting functions and procedures.

(2) Tax services are professional services rendered by our auditors for tax compliance, tax advice on actual or contemplated transactions, tax consulting associated with international transfer prices and employee tax services.

*Audit Committee's pre-approval policies and procedures*

The Audit Committee of our Board of Directors chooses and engages our independent auditors to audit our financial statements. In 2003, our Audit Committee also adopted a policy requiring management to obtain the audit committee's approval before engaging our independent auditors to provide any other audit or permitted non-audit services to us or our subsidiaries. This policy, which is designed to assure that such engagements do not impair the independence of our auditors, requires the audit committee to pre-approve audit and non-audit services that may be performed by our auditors.

On a quarterly basis, we inform the audit committee of the pre-approved services actually provided by our auditors. Services of a type that are not pre-approved by the audit committee require pre-approval by the audit committee's chairman on a case-by-case basis. The Chairman of our Audit Committee is not permitted to approve any engagement of our auditors if the services to be performed either fall into a category of services that are not permitted by applicable law or the services would be inconsistent with maintaining the auditors' independence.

**Item 16D. Exemptions from the Listing Standards for Audit Committee**

Not applicable.

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchases**

Not applicable.

**PART III**

**Item 17 Financial Statements**

We have elected to provide financial statements pursuant to Item 18.

**Item 18 Financial Statements**

The financial statements appear on pages F-1 through F-93.

**Item 19 Exhibits**

- 1.1 Amendment to By-Laws of the Company to change quorum requirements for meetings of shareholders of the Corporation, dated December 30, 1999<sup>(1)</sup>
- 1.2 Conforming Copy of Amended By-Laws of the Company effective December 30, 1999<sup>(1)</sup>
- 1.3 Articles of Amendment dated December 31, 1999 effecting a stock split and an increase in the authorized share capital of the Company<sup>(2)</sup>
- 1.4 Articles of Amalgamation dated February 18, 2000 effecting a change in the name of the Company<sup>(2)</sup>
- 1.5 Articles of Amalgamation of Biovail Corporation International<sup>(2)</sup>
- 1.6 Articles of Amendment of Biovail Corporation International<sup>(2)</sup>
- 1.7 Articles of Amalgamation of Biovail Corporation<sup>(2)</sup>
- 1.8 By-law No. 1A of Biovail Corporation<sup>(2)</sup>
- 2.1 Indenture, dated as of March 28, 2002, between Biovail Corporation, Computershare Trust Company, Inc., as U.S. trustee and Computershare Trust Company of Canada, as Canadian trustee<sup>(3)</sup>
- 2.2 First Supplemental Indenture, dated as of March 28, 2002, between Biovail Corporation, Computershare Trust Company, Inc., as U.S. trustee and Computershare Trust Company of Canada, as Canadian trustee<sup>(4)</sup>
- 4 Executive Employment Agreement
  - 4.1 Kenneth Cancellara
  - 4.1(a) Amendment Agreement for Kenneth Cancellara
  - 4.2 Brian Crombie
  - 4.3 Gregory J. Szpunar
  - 4.4 Charles A. Rowland, Jr.
  - 4.5 Douglas John Paul Squires
  - 4.6 D. Rick Keefer
  - 4.7 Rolf K. Reininghaus
- 8.1 Subsidiaries of Biovail Corporation (see Item 10.I of this report)
- 10.a.1 Consent of Ernst & Young LLP
- 11.1 Code of Ethics
- 12.1 Certification of the Chief Executive Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002.
- 12.2 Certification of the Chief Financial Officer pursuant to §302 of the Sarbanes-Oxley Act of 2002.
- 13.1 Certificate of the Chief Executive Officer of Biovail Corporation to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 13.2 Certificate of the Senior Vice-President and Chief Financial Officer of Biovail Corporation pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) Incorporated by reference to Registrant's Annual Report on Form 20-F for the fiscal year ended December 31, 1999, File No. 001-11145.
- (2) Incorporated by reference to Registrant's Registration Statement on Form 8-A, filed with the SEC on March 17, 2000, File No. 001-14956.
- (3) Incorporated by reference to Exhibit 1.1 on registrants report on Form 6-K dated May 21, 2002 submitted to the SEC on May 21, 2002, file #00114956.
- (4) Incorporated by reference to Exhibit 1.1 on registrants report on Form 6-K dated May 21, 2002 submitted to the SEC on May 21, 2002, file #00114956.



**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

BIOVAIL CORPORATION

Date: June 30, 2005

By: /s/ CHARLES A. ROWLAND, JR.

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Charles A. Rowland, Jr.  
*Senior Vice-President,  
Chief Financial Officer*

153

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## INDEX TO FINANCIAL STATEMENTS

	<u>Page</u>
<b>BIOVAIL CORPORATION</b> Financial Statements completed in accordance with U.S. GAAP	
Management Report	F-2
Auditors' Report	F-3
Consolidated Balance Sheets as at December 31, 2003 and 2002	F-4
Consolidated Statements of Income (Loss) for the years ended December 31, 2003, 2002 and 2001	F-6
Consolidated Statements of Shareholders' Equity for the years ended December 31, 2003, 2002 and 2001	F-7
Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001	F-8
Notes to the Consolidated Financial Statements	F-9
<b>BIOVAIL CORPORATION</b> Financial Statements completed in accordance with Canadian GAAP	
Management Report	F-48
Auditors' Report	F-49
Consolidated Balance Sheets as at December 31, 2003 and 2002	F-50
Consolidated Statements of Income for the years ended December 31, 2003, 2002 and 2001	F-52
Consolidated Statements of Shareholders' Equity for the years ended December 31, 2003, 2002 and 2001	F-53
Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001	F-54
Notes to the Consolidated Financial Statements	F-55

## MANAGEMENT REPORT

The Company's management is responsible for preparing the accompanying consolidated financial statements in conformity with United States generally accepted accounting principles ("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.

The consolidated financial statements and information contained in the Management's Discussion and Analysis ("MD&A") necessarily includes amounts based on informed judgments and estimates of the expected effects of current events and transactions with appropriate considerations to materiality. In addition, in preparing the financial information management must interpret the requirements described above, make determinations as to the relevancy of information to be included, and make estimates and assumptions that affect reported information. The MD&A also includes information regarding the estimated impact of current transactions and events, sources of liquidity and capital resources, operating trends, risks and uncertainties. Actual results in the future may differ materially from our present assessment of this information because future events and circumstances may not occur as expected.

The Company maintains a system of internal accounting controls designed to provide reasonable assurance, at a reasonable cost, that assets are safeguarded and that transactions are executed and recorded in accordance with the Company's policies for doing business. This system is supported by written policies and procedures for key business activities; the hiring of qualified, competent staff; and by a continuous planning and monitoring program.

Ernst & Young LLP has been engaged by the Company's shareholders to audit the consolidated financial statements. During the course of their audit, Ernst & Young LLP reviewed the Company's system of internal controls to the extent necessary to render their opinion on the consolidated financial statements. However, Ernst & Young LLP was not engaged to audit the Company's internal controls over financial reporting.

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.

**DOUGLAS J. P. SQUIRES**  
Chief Executive Officer

**CHARLES A. ROWLAND, JR.**  
Senior Vice President and  
Chief Financial Officer  
F-2

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Shareholders of  
Biovail Corporation

We have audited the consolidated balance sheets of **Biovail Corporation** at December 31, 2004 and 2003 and the consolidated statements of income (loss), shareholders' equity and cash flows for each of the years in the three-year period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian generally accepted auditing standards and 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, these consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2004 and 2003 and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2004 in accordance with United States generally accepted accounting principles.

On March 8, 2005, we reported separately to the shareholders of **Biovail Corporation** on the consolidated financial statements for the same periods, prepared in accordance with Canadian generally accepted accounting principles.

Toronto, Canada,

March 8, 2005

F-3

Chartered Accountants

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## BIOVAIL CORPORATION

## CONSOLIDATED BALANCE SHEETS

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

	At December 31	
	2004	2003
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents	\$ 34,324	\$ 133,261
Marketable securities	5,016	
Accounts receivable	148,762	179,374
Inventories	110,154	84,058
Deposits and prepaid expenses	16,395	15,759
	<u>314,651</u>	<u>412,452</u>
Long-term investments	68,046	113,546
Property, plant and equipment, net	186,556	173,804
Goodwill	100,294	100,814
Intangible assets, net	978,073	1,049,475
Other assets, net	63,440	72,683
	<u>\$ 1,711,060</u>	<u>\$ 1,922,774</u>
<b>LIABILITIES</b>		
<b>Current</b>		
Accounts payable	\$ 41,120	\$ 67,932
Accrued liabilities	82,917	105,201
Minority interest		679
Income taxes payable	24,594	24,175
Deferred revenue	8,141	5,765
Current portion of long-term obligations	33,465	58,816
	<u>190,237</u>	<u>262,568</u>
Deferred revenue	16,525	14,500
Deferred leasehold inducements	4,914	
Long-term obligations	445,471	764,111
	<u>657,147</u>	<u>1,041,179</u>
<b>SHAREHOLDERS' EQUITY</b>		
Common shares, no par value, unlimited shares authorized, 159,383,402 and 158,796,978 issued and outstanding at December 31, 2004 and 2003, respectively	1,457,065	1,448,353
Stock options outstanding	1,450	2,290
Deficit	(446,684)	(607,678)
Accumulated other comprehensive income	42,082	38,630
	<u>1,053,913</u>	<u>881,595</u>
	<u>\$ 1,711,060</u>	<u>\$ 1,922,774</u>

At December 31

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Commitments and contingencies (notes 2, 3, 24 and 25)

F-4

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On behalf of the Board:

**EUGENE N. MELNYK**

Chairman of the Board

**MICHAEL VAN EVERY**

Director

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

F-5

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## BIOVAIL CORPORATION

## CONSOLIDATED STATEMENTS OF INCOME (LOSS)

In accordance with U.S. generally accepted accounting principles  
(All dollar amounts expressed in thousands of U.S. dollars, except per share data)

	Years ended December 31		
	2004	2003	2002
<b>REVENUE</b>			
Product sales	\$ 841,446	\$ 632,898	\$ 645,986
Research and development	20,452	14,239	28,425
Co-promotion, royalty and licensing	24,645	176,585	113,614
	<u>886,543</u>	<u>823,722</u>	<u>788,025</u>
<b>EXPENSES</b>			
Cost of goods sold	228,278	139,456	164,706
Research and development	70,493	86,570	52,150
Selling, general and administrative	257,407	242,771	166,397
Amortization	64,976	140,895	71,499
Write-down of assets, net of gain on disposal	40,685	45,081	31,944
Acquired research and development	8,640	124,720	167,745
Extinguishment of royalty obligation		61,348	
Settlements		(34,055)	
	<u>670,479</u>	<u>806,786</u>	<u>654,441</u>
Operating income	216,064	16,936	133,584
Interest income	1,034	7,165	3,608
Interest expense	(40,104)	(40,421)	(32,005)
Foreign exchange gain (loss)	(564)	(14,007)	700
Equity loss	(4,179)	(1,010)	
Other income (expense)	(2,307)	72	3,408
	<u>169,944</u>	<u>(31,265)</u>	<u>109,295</u>
Income (loss) before provision for (recovery of) income taxes	169,944	(31,265)	109,295
Provision for (recovery of) income taxes	8,950	(4,000)	21,500
	<u>160,994</u>	<u>(27,265)</u>	<u>87,795</u>
Net income (loss)	\$ 160,994	\$ (27,265)	\$ 87,795
<b>Earnings (loss) per share</b>			
Basic	\$ 1.01	\$ (0.17)	\$ 0.58
Diluted	\$ 1.01	\$ (0.17)	\$ 0.55
<b>Weighted average number of common shares outstanding (000s)</b>			
Basic	159,115	158,516	151,960
Diluted	159,258	158,516	160,463

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



## BIOVAIL CORPORATION

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

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

## Common shares

	Shares (000s)	Amount	Stock options outstanding	Executive Stock Purchase Plan loans	Warrants outstanding	Deficit	Accumulated other comprehensive income (loss)	Total
<b>Balance, January 1, 2002</b>	157,496	\$ 1,407,507	\$ 5,067	\$ (9,988)	\$ 6,221	\$ (280,004)	\$ (2,729)	\$ 1,126,074
Issued on the exercise of stock options	2,197	21,506	(2,210)					19,296
Issued under Employee Stock Purchase Plan	17	463						463
Cancelled under stock repurchase program	(12,872)	(114,896)				(388,204)		(503,100)
Issued on exercise of warrants	11,282	119,044			(6,221)			112,823
Stock-based compensation			1,999					1,999
	<b>158,120</b>	<b>1,433,624</b>	<b>4,856</b>	<b>(9,988)</b>		<b>(668,208)</b>	<b>(2,729)</b>	<b>757,555</b>
Net income						87,795		87,795
<b>Other comprehensive income</b>								
Foreign currency translation adjustment							336	336
Other comprehensive income							336	336
Comprehensive income								88,131
<b>Balance, December 31, 2002</b>	<b>158,120</b>	<b>1,433,624</b>	<b>4,856</b>	<b>(9,988)</b>		<b>(580,413)</b>	<b>(2,393)</b>	<b>845,686</b>
Issued on the exercise of stock options	663	14,247	(2,650)					11,597
Issued under Employee Stock Purchase Plan	14	482						482
Stock-based compensation			84					84
Repayment of Executive Stock Purchase Plan loans				9,988				9,988
	<b>158,797</b>	<b>1,448,353</b>	<b>2,290</b>			<b>(580,413)</b>	<b>(2,393)</b>	<b>867,837</b>
Net loss						(27,265)		(27,265)
<b>Other comprehensive income</b>								
Foreign currency translation adjustment							20,233	20,233
Unrealized holding gains on available-for-sale investments							20,790	20,790
Other comprehensive income							41,023	41,023
Comprehensive income								13,758

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Common shares

<b>Balance, December 31, 2003</b>	158,797	1,448,353	2,290		(607,678)	38,630	881,595	
Issued on the exercise of stock options	561	8,279	(700)				7,579	
Issued under Employee Stock Purchase Plan	25	433					433	
Cancellation of employee stock options			(140)				(140)	
	159,383	1,457,065	1,450		(607,678)	38,630	889,467	
Net income					160,994		160,994	
<b>Other comprehensive income</b>								
Foreign currency translation adjustment						10,470	10,470	
Unrealized holding losses on available-for-sale investments						(7,018)	(7,018)	
Other comprehensive income						3,452	3,452	
Comprehensive income							164,446	
<b>Balance, December 31, 2004</b>	159,383	\$ 1,457,065	\$ 1,450	\$	\$ (446,684)	\$ 42,082	\$ 1,053,913	

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

## BIOVAIL CORPORATION

## CONSOLIDATED STATEMENTS OF CASH FLOWS

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

	Years ended December 31		
	2004	2003	2002
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net income (loss)	\$ 160,994	\$ (27,265)	\$ 87,795
<b>Adjustments to reconcile net income (loss) to cash provided by operating activities</b>			
Depreciation and amortization	88,307	157,317	82,368
Amortization and write-down of deferred financing costs	4,322	2,975	2,267
Amortization of discounts on long-term obligations	3,218	6,562	5,329
Write-down of assets	42,156	45,081	31,944
Gain on disposal of intangible assets	(1,471)		
Acquired research and development	8,640	124,720	167,745
Equity loss	4,179	1,010	
Receipt of leasehold inducements	5,232		
Stock-based compensation		84	1,999
Other	1,688	4,799	(3,408)
Changes in operating assets and liabilities	(40,175)	(33,304)	(41,935)
<b>Net cash provided by operating activities</b>	<b>277,090</b>	<b>281,979</b>	<b>334,104</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Additions to property, plant and equipment	(28,029)	(36,923)	(61,382)
Acquisitions of businesses, net of cash acquired	(9,319)	(25,741)	(240,581)
Purchases of marketable securities	(5,038)		
Acquisitions of long-term investments	(2,877)	(4,555)	(85,119)
Proceeds on disposal of intangible assets	3,000	10,000	
Acquisitions of intangible assets		(242,298)	(375,385)
Advance of loan receivable		(40,000)	(30,000)
Repayment of loan receivable		61,071	
<b>Net cash used in investing activities</b>	<b>(42,263)</b>	<b>(278,446)</b>	<b>(792,467)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Advances (repayments) under revolving term credit facility, including financing costs	(282,550)	169,800	107,895
Repayments of other long-term obligations	(66,288)	(119,344)	(41,980)
Issuance of common shares, net of issue costs	8,012	12,079	19,615
Proceeds on termination of interest rate swaps	6,300		
Repayment of Executive Stock Purchase Plan loans		9,988	
Repurchase of common shares			(503,100)
Issuance of Senior Subordinated Notes, net of financing costs			384,280
Proceeds from exercise of warrants			112,823
<b>Net cash provided by (used in) financing activities</b>	<b>(334,526)</b>	<b>72,523</b>	<b>79,533</b>
Effect of exchange rate changes on cash and cash equivalents	762	1,125	19

	Years ended December 31		
<b>Net increase (decrease) in cash and cash equivalents</b>	(98,937)	77,181	(378,811)
Cash and cash equivalents, beginning of year	133,261	56,080	434,891
<b>Cash and cash equivalents, end of year</b>	<b>\$ 34,324</b>	<b>\$ 133,261</b>	<b>\$ 56,080</b>

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

**BIOVAIL CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In accordance with U.S. generally accepted accounting principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**December 31, 2004**

**1. GOVERNING STATUTE AND NATURE OF OPERATIONS**

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

**2. SIGNIFICANT ACCOUNTING POLICIES**

**Basis of presentation**

The consolidated financial statements have been prepared by the Company in U.S. dollars and in accordance with U.S. generally accepted accounting principles ("GAAP"), applied on a consistent basis. Consolidated financial statements prepared in U.S. dollars and in accordance with Canadian GAAP are separately made available to all shareholders and filed with necessary regulatory authorities.

**Principles of consolidation**

The consolidated financial statements include the accounts of the Company and those of all its wholly-owned and majority-owned subsidiaries. All significant intercompany transactions and balances have been eliminated.

**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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Under certain agreements, management relies on estimates and assumptions made by the Company's third-party licensees. Significant estimates made by management include allowances for accounts receivable and inventories, provisions for product returns, rebates and chargebacks, the useful lives of long-lived assets, the expected future cash flows used in evaluating long-lived assets and investments for impairment, the realizability of deferred tax assets, and the allocation of the purchase price of acquired assets and businesses. 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 financial position and results of operations could be materially impacted.

**Fair value of financial instruments**

Fair value of a financial instrument is defined as the amount at which the instrument could be exchanged in a current transaction between willing parties. The estimated fair values of cash equivalents, marketable securities, accounts receivable, accounts payable, accrued liabilities and income taxes payable approximate their carrying values due to their short maturity periods. The fair values of marketable securities, long-term investments, long-term obligations and derivative financial instruments are based on quoted market prices, if available, or estimated discounted future cash flows.

**Cash and cash equivalents**

Cash and cash equivalents include highly liquid investments with original maturities of 90 days or less when purchased.

**Marketable securities**

Marketable securities comprise investment-grade debt securities with original maturities greater than 90 days when purchased and are accounted for as being available-for-sale. These securities are reported at fair value with all unrealized gains and losses recognized in comprehensive income or loss. Realized gains and losses on the sale of these securities are recognized in net

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income or loss. The amortization of acquisition premiums or discounts is recorded as a deduction from or addition to interest income earned on these securities.

### Accounts receivable

The Company performs ongoing credit evaluations of customers and generally does not require collateral. Allowances are maintained for potential credit losses based on the aging of accounts receivable, historical bad debts experience and changes in customer payment patterns.

### 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 and rejected product are written off to cost of goods sold.

### Long-term investments

Long-term investments with readily determinable market values, where the Company does not have the ability to exercise significant influence, are accounted for as being available-for-sale. These investments are reported at fair value with all unrealized gains and temporary unrealized losses recognized in comprehensive income or loss. Unrealized losses on these investments that are considered to be other-than-temporary are recognized in net income or loss.

Long-term investments without readily determinable market values, where the Company does not have the ability to exercise significant influence, are accounted for using the cost method. Declines in the fair value of these investments below their cost basis that are considered to be other-than-temporary are recognized in net income or loss.

A long-term investment over which the Company has the ability to exercise significant influence is accounted for using the equity method. The Company's share of the losses of this investee is recognized in net income or loss.

On an ongoing basis, the Company evaluates its long-term investments to determine if a decline in fair value is other-than-temporary. Factors that the Company considers include general market conditions, the duration and extent to which the fair value of an investment is below its cost basis and the Company's ability and intent to hold the investment.

### Property, plant and equipment

Property, plant and equipment are reported at cost, less accumulated depreciation. Cost includes interest costs attributable to major capital projects prior to the related assets becoming available for productive use. 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

### Goodwill

Goodwill represents the excess of the purchase price of acquired businesses over the fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment by comparing the fair value of the reporting unit to which the goodwill relates to the carrying value of the reporting unit. The Company tests goodwill for impairment on an annual basis and

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between annual tests whenever events or changes in circumstances indicate that the fair value of the reporting unit may be below its carrying value.

### Intangible assets

Intangible assets acquired through asset acquisitions or business combinations are initially recognized at fair value based on an allocation of the purchase price. Intangible assets with finite lives are amortized over their estimated useful lives. The Company does not have any indefinite-lived intangible assets. Intangible assets are reported at cost, less accumulated amortization. Amortization is generally calculated using the straight-line method based on the following estimated useful lives:

Trademarks	20 years
Product rights	8-20 years
Technology	15 years

### Impairment of long-lived assets

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

The Company's evaluation of long-lived assets is based on management's assessment of potential indicators of impairment, such as damage or obsolescence, plans to discontinue use or restructure, and poor financial performance compared with original plans. While there were no significant indications of impairment at December 31, 2004, the Company is currently reviewing its strategic approach to commercializing its products in the United States. The outcome of this review is not presently determinable, but it could result in a write-down in the carrying values of certain of the Company's long-lived assets.

### Deferred financing costs

Deferred financing costs are reported at cost, less accumulated amortization. Amortization is calculated using the straight-line method over the term of the related long-term obligations. Amortization expense related to deferred financing costs is included in interest expense.

### Deferred compensation plan

The Company maintains a deferred compensation plan to provide certain employees with the opportunity to supplement their retirement income through the deferral of pre-tax income. The assets of this plan are placed in trust, and are recorded in other assets with a corresponding liability recorded in long-term obligations. The terms of the trust agreement state that the assets of the trust are available to satisfy the claims of general creditors of the Company in the event of bankruptcy, thereby qualifying this trust as a rabbi trust for U.S. income tax purposes. Changes in the value of the assets held by this trust, and a corresponding charge or credit to compensation expense (to reflect the fair value of the amount owed to the participants), are recognized in net income or loss.

### Derivative financial instruments

The Company manages its exposure to interest rate risks through the use of derivative financial instruments that are designated as a fair value hedge of an identified portion of a recognized long-term obligation. 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. For a derivative financial instrument that is designated and qualifies as a highly effective fair

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value hedge, the derivative financial instrument is marked-to-market with the gain or loss on the derivative financial instrument and the respective offsetting loss or gain on the underlying hedged item recognized in net income or loss. Net receipts or payments relating to the derivative financial instruments are recorded as an adjustment to interest expense.

### **Deferred leasehold inducements**

Leasehold inducements comprise free rent and leasehold improvement incentives. Leasehold inducements are deferred and amortized to reduce rental expense on a straight-line basis over the term of the related lease.

### **Foreign currency translation**

The financial statements of the Company's operations having a functional currency other than U.S. dollars 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 or loss in shareholders' equity. Foreign currency gains and losses related to the remeasurement of the Company's Irish operation into its U.S. dollar functional currency are recognized in net income or loss.

Foreign currency exchange gains and losses on transactions occurring in a currency other than an operation's functional currency are recognized in net income or loss.

### **Revenue recognition**

Revenue is deemed to be realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the Company's price to the customer is fixed or determinable, and collectibility is reasonably assured. Management evaluates revenue arrangements with multiple deliverables to determine whether the deliverables represent one or more units of accounting. A delivered item is considered a separate unit of accounting if the following separation criteria are met: (i) the delivered item has standalone value to the customer; (ii) the fair value of any undelivered items can be reliably determined; and (iii) the delivery of undelivered items is probable and substantially in the Company's control. The relevant revenue recognition accounting policy is applied to each separate unit of accounting.

### **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 reported as deferred revenue.

Revenue from product sales is recognized net of provisions for estimated discounts and allowances, returns, rebates and chargebacks. In connection with these provisions related to sales of products manufactured by the Company for distribution by third-party licensees, the Company relies on estimates and assumptions made by these licensees. The Company offers discounts for prompt payment and other incentive allowances to customers. Provisions for these 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 these returns are estimated based on historical return and exchange levels, and third-party data with respect to inventory levels in the Company's distribution channels. The Company is subject to rebates and chargebacks on sales made under governmental and managed care pricing programs. Provisions for these rebates and chargebacks are estimated based on historical experience, contractual sales terms with wholesalers and indirect customers, and relevant statutes with respect to governmental pricing programs.

### **Research and development**

Research and development revenue attributable to the performance of contract services is recognized as the services are performed, in accordance with the terms of the specific development contracts. On long-term research and development



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collaborations, revenue is recognized on a proportionate basis relative to the total level of effort necessary to meet all regulatory and developmental requirements. Costs and profit margin related to these collaborations that are in excess of amounts billed are recorded in accounts receivable, and amounts billed related to these collaborations that are in excess of costs and profit margin are recorded in deferred revenue. Contingent revenue attributable to the achievement of regulatory or developmental milestones is recognized only on the achievement of the applicable milestone. Non-refundable, up-front fees for access to the Company's proprietary technology in connection with certain research and development collaborations are deferred and recognized as revenue on a systematic basis over the term of the related collaboration.

### **Co-promotion**

Co-promotion revenue is recognized based on the terms of the specific co-promotion contracts, and is generally determined based on a percentage of the net sales of the co-promoted products. Sales and marketing costs related to co-promotion revenue are recorded in selling, general and administrative expenses. The Company did not earn any co-promotion revenue in 2004.

### **Royalty and licensing**

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. Licensing revenue is deferred and recognized on a systematic basis over the licensing period.

### **Shipping and handling costs**

Shipping and handling costs comprising freight-out are included in cost of goods sold. The Company does not charge customers for shipping and handling costs.

### **Research and development expenses**

Costs related to proprietary research and development programs are expensed as incurred. Milestone payments made to third parties in connection with research and development collaborations are expensed as incurred prior to the receipt of regulatory approval. Milestone payments made to third parties after regulatory approval is received are capitalized and amortized over the estimated useful lives of the related products.

Costs associated with revenue generated from research and development collaborations, and with providing contract research services are included in research and development expenses and were \$12,956,000, \$9,503,000 and \$11,570,000 in 2004, 2003 and 2002, respectively.

### **Acquired research and development expense**

The costs of assets that are purchased through asset acquisitions or business combinations for a particular research and development project are expensed as acquired research and development at the time of acquisition. The amount allocated to acquired research and development is determined by identifying those specific in-process research and development projects that the Company intends to continue, and for which: (i) technological feasibility had not been established at the date of acquisition; and (ii) there was no alternative future use.

The efforts required to develop the acquired research and development into commercially viable products include the completion of the development stages of these projects, clinical-trial testing, regulatory approval and commercialization. The principal risks relating to these projects include the outcomes of the formulation development, clinical studies and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, the Company will not receive any benefits unless regulatory approval is obtained. The completion of these projects may require significant amounts of future time and effort, as well as additional development costs, which may be incurred by the Company. Consequently, there is significant technological and regulatory approval risk associated with these projects at the date of acquisition.

The research being undertaken on these projects relates specifically to developing novel formulations of the associated molecules. Consequently, the Company does not foresee any alternative future benefit from the acquired research and development other than specifically related to these projects.

The fair value of acquired research and development is determined using an income approach on a project-by-project basis. The estimated future net cash flows related to these projects include the costs to develop these projects into commercially viable products, and the projected revenues to be earned on commercialization of these projects when complete. The discount rates used to present value the estimated future net cash flows related to each of these projects are determined based on the relative risk of achieving each of these project's net cash flows. The discount rates reflect the project's stage of completion and other risk factors, which include the nature and complexity of the product, the projected costs to complete, market competition and the estimated useful life of the product.

#### **Advertising costs**

Advertising costs comprise product samples, print media and promotional materials. Advertising costs related to new product launches are expensed on the first showing of the product. The Company did not have any deferred advertising costs at December 31, 2004 or 2003.

Advertising costs expensed in 2004, 2003 and 2002 were \$29,040,000, \$23,013,000 and \$18,795,000, respectively. These costs are included in selling, general and administrative expenses.

#### **Co-promotion fees**

Co-promotion fees payable by the Company are accrued based on a percentage of the net sales of the co-promoted products. Co-promotion fees are included in selling, general and administrative expenses. The Company did not incur any co-promotion fees in 2004.

#### **Stock-based compensation**

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

The Company recognizes employee stock-based compensation costs under the intrinsic value-based method of APB No. 25. Accordingly, no compensation expense for stock options granted to employees at fair market value was included in the determination of net income or loss in 2004, 2003 or 2002; however, the Company recorded compensation expense in 2003 and 2002 for stock options granted (at the date of acquisition) to the employees of DJ Pharma, Inc. ("DJ Pharma"). The following

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

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net income (loss) as reported	\$ 160,994	\$ (27,265)	\$ 87,795
Pro forma stock-based compensation expense determined under fair value-based method	(20,403)	(16,903)	(14,254)
<b>Pro forma net income (loss)</b>	<b>\$ 140,591</b>	<b>\$ (44,168)</b>	<b>\$ 73,541</b>
<b>Basic earnings (loss) per share</b>			
As reported	\$ 1.01	\$ (0.17)	\$ 0.58
Pro forma	\$ 0.88	\$ (0.28)	\$ 0.48
<b>Diluted earnings (loss) per share</b>			
As reported	\$ 1.01	\$ (0.17)	\$ 0.55
Pro forma	\$ 0.88	\$ (0.28)	\$ 0.46

The weighted average fair values of all stock options granted during 2004, 2003 and 2002 were \$8.09, \$11.48 and \$13.58, respectively, estimated as of the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Expected option life (years)	4.0	4.0	3.8
Volatility	55.8%	54.7%	46.8%
Risk-free interest rate	3.7%	3.9%	4.5%
Dividend yield	%	%	%

The Black-Scholes option-pricing model used by the Company to calculate option values was developed to estimate the fair value of freely tradeable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. This model also requires highly subjective assumptions, including future stock price volatility and expected time until exercise, which greatly affect the calculated values.

### 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.

### Earnings or loss per share

Basic earnings or loss per share are calculated by dividing net income or loss by the weighted average number of common shares outstanding during the reporting period. Diluted earnings or loss per share are calculated by dividing net income or loss by the weighted average number of common shares outstanding during the reporting period after giving effect to dilutive potential common shares. The dilutive effects of stock options and warrants are determined using the treasury stock method. The dilutive effects of convertible securities are determined using the if-converted method.

**Comprehensive income or loss**

Comprehensive income or loss comprises net income or loss and other comprehensive income or loss. Other comprehensive income or loss comprises foreign currency translation adjustments and unrealized holding gains or losses on available-for-sale investments. Accumulated other comprehensive income or loss is recorded as a component of shareholders' equity.

**Recent accounting pronouncements**

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

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS No. 123R"), which revises SFAS No. 123 and supercedes APB No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS No. 123 will no longer be an alternative to financial statement recognition. Under SFAS No. 123R, the Company must determine the appropriate option-pricing model to be used for valuing share-based payments and the transition method to be used at date of adoption. The transition alternatives are the modified-prospective and modified-retrospective methods. Both of these methods require that compensation expense be recorded for all share-based payments granted, modified or settled after the date of adoption and for all unvested stock options at the date of adoption; however, under the modified-retrospective method, prior periods are restated by recognizing compensation cost in amounts previously reported in the pro forma note disclosures under SFAS No. 123. Prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. SFAS No. 123R is effective at the beginning of the first interim or annual period after June 15, 2005. Accordingly, the Company is required to adopt SFAS No. 123R beginning July 1, 2005. The Company is currently evaluating the requirements of SFAS No. 123R and expects that the adoption of this standard will have a material negative impact on its consolidated results of operations. The Company has not yet determined the method of adoption or the effect of adopting SFAS No. 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets - An Amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions" ("SFAS No. 153"). SFAS No. 153 eliminates the exception from fair value measurement for nonmonetary exchanges of similar productive assets and replaces it with an exception for exchanges that do not have commercial substance. SFAS No. 153 specifies that a nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for non-monetary transactions occurring in fiscal periods beginning after June 15, 2005. Accordingly, the Company is required to adopt SFAS No. 153 beginning January 1, 2006. The Company is currently evaluating the effect that the adoption of SFAS No. 153 will have on its consolidated results of operations and financial position but does not expect it to have a material impact.

## 3. DISPOSITION AND ACQUISITIONS OF INTANGIBLE ASSETS

**Year ended December 31, 2004****Disposition of Cedax**

In July 2004, Biovail terminated its sub-license and manufacturing agreements with Schering-Plough Corporation ("Schering") to market and distribute Cedax in the United States. Biovail had obtained the co-exclusive rights to Cedax through its acquisition of DJ Pharma in October 2000. Shionogi & Co., Ltd. of Japan and its affiliates ("Shionogi") assumed the marketing and distribution of Cedax in the United States from Schering. Shionogi agreed to pay Biovail \$3,000,000 in consideration for the conveyance of Biovail's rights under the sub-license agreements, and Shionogi may pay Biovail up to an additional \$3,000,000 contingent on the achievement of certain target annual gross sales of Cedax. Biovail will only recognize this contingent consideration if Shionogi realizes the sales targets. Shionogi also acquired Biovail's remaining Cedax inventories and promotional materials. This transaction resulted in a gain on disposal of \$1,471,000, which is netted against write-down of assets.

**Year ended December 31, 2003****Acquisitions of intangible assets**

During 2003, the Company acquired the following intangible assets. Total consideration related to each of these acquisitions was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition:

	<b>Tramadol products</b>	<b>Ativan® and Isordil®</b>	<b>Athpharma products</b>	<b>Generic omeprazole</b>	<b>Other</b>	<b>Total</b>
<b>Acquired assets</b>						
Acquired research and development expense	\$ 16,000	\$ 38,100	\$ 44,200	\$	\$	\$ 98,300
Trademarks		107,542				107,542
Product rights		16,041		35,500	256	51,797
Technology		2,156				2,156
	<u>\$ 16,000</u>	<u>\$ 163,839</u>	<u>\$ 44,200</u>	<u>\$ 35,500</u>	<u>\$ 256</u>	<u>\$ 259,795</u>
<b>Consideration</b>						
Cash paid	\$ 16,000	\$ 146,342	\$ 44,200	\$ 35,500	\$ 256	\$ 242,298
Long-term obligation		17,497				17,497
	<u>\$ 16,000</u>	<u>\$ 163,839</u>	<u>\$ 44,200</u>	<u>\$ 35,500</u>	<u>\$ 256</u>	<u>\$ 259,795</u>

**Tramadol products**

In April 2002, Biovail obtained the rights to market six products under development by Ethypharm S.A. ("Ethypharm") (as described in note 23 Research and Development Collaborations). The products under development included Ethypharm's orally disintegrating tablet ("ODT") formulations of tramadol hydrochloride ("HCl") ("Tramadol ODT"), and combination of tramadol HCl and acetaminophen ("Tramadol/APAP"). Tramadol is indicated for the treatment of moderate to moderately severe pain.

In September 2003 (as amended in February 2004 to confirm conditions that existed at December 31, 2003), Biovail acquired Ethypharm's remaining interest in Tramadol ODT (including all relevant patents) for \$16,000,000. Through this acquisition, Biovail extinguished any future milestone or royalty obligations that it may have had to Ethypharm related to Tramadol ODT, except for a \$1,000,000 milestone payment if Tramadol ODT is approved by the U.S. Food and Drug Administration ("FDA"). In addition to Tramadol ODT, Biovail acquired Ethypharm's remaining interest in Tramadol/APAP (including all relevant patents). Biovail will pay Ethypharm a royalty on any future sales of Tramadol/APAP.

#### **Acquired research and development**

At the dates of acquisition, Tramadol ODT was in a late-stage clinical phase of development and Tramadol/APAP was in a pre-clinical phase of development, and neither of these products had been submitted for approval by the FDA. In May 2004, the FDA accepted Biovail's New Drug Application ("NDA") submission for Tramadol ODT for review. In January 2005, Biovail received an Approvable Letter from the FDA for Tramadol ODT, which indicated that approval is pending resolution of labeling issues.

#### **Ativan® and Isordil®**

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

The purchase price for Ativan® and Isordil® was \$163,839,000 comprising cash consideration, including costs of acquisition, of \$146,342,000, and the two remaining fixed annual payments. The remaining fixed annual payments were present valued using an imputed interest rate of 3.00%, which was comparable to Biovail's available borrowing rate at the date of acquisition. Accordingly, the present value of the remaining fixed annual payments was determined to be \$17,497,000.

The fair values of the acquired assets were determined using an income approach. The discount rates used to present value the estimated future cash flows related to each acquired asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were in the range of 10.5% to 35%.

The trademarks are being amortized over their estimated useful lives of 20 years. The product rights and technology are being amortized over their estimated useful lives of 15 years. The estimated weighted average useful life of the trademarks, product rights and technology is approximately 19 years.

#### **Acquired research and development**

At the date of acquisition, the Ativan® line extension products were in pre-clinical phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 30% to 35% and the costs to complete the development of these products were estimated to be up to \$23,500,000. An ODT formulation of Ativan®, for the treatment of anxiety, is in an early clinical phase of development.

#### **Athpharma products**

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

**Acquired research and development**

At the date of acquisition, Bisochron and Isochron were both entering Phase III clinical studies, and Hepacol I and Hepacol II were both in pre-clinical phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 45% to 70% and Biovail's share of the costs to complete the development of these products was estimated to be \$20,000,000. The following values were assigned to these products: Bisochron \$21,550,000, Isochron \$13,100,000, Hepacol I \$6,985,000 and Hepacol II \$2,565,000. Biovail and Athpharma are currently in discussions to either substitute certain new products in place of Bisochron, Isochron, Hepacol I and Hepacol II or to terminate the development and license agreement.

**Generic omeprazole**

In May 2003, Biovail paid \$35,500,000 to the previous owners of Pharma Pass LLC (a company acquired by Biovail in December 2002, as described in note 4 Acquisitions of Businesses) related to an additional participating interest in the gross profit on sales of generic omeprazole owned by those parties. The generic omeprazole product right was being amortized on a proportionate basis relative to the revenue received from this interest. Amortization expense of \$1,121,000 and \$34,379,000 was recorded in 2004 and 2003, respectively, as Biovail had received all of the value from this interest by March 31, 2004.

**Year ended December 31, 2002****Acquisitions of intangible assets**

During 2002, the Company acquired the following intangible assets. Total consideration related to each of these acquisitions was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition:

	<b>Wellbutrin® and Zyban®</b>	<b>Vasotec® and Vaseretic®</b>	<b>Teveten®</b>	<b>Zovirax</b>	<b>Total</b>
<b>Acquired assets</b>					
Prepaid expenses	\$ 2,609	\$	\$	\$	\$ 2,609
Trademarks	24,349	165,804			190,153
Product rights	45,000	79,500	94,340	173,364	392,204
	<b>\$ 71,958</b>	<b>\$ 245,304</b>	<b>\$ 94,340</b>	<b>\$ 173,364</b>	<b>\$ 584,966</b>
<b>Consideration</b>					
Cash paid, net of gross profit on acquired assets	\$ 1,997	\$ 145,684	\$ 94,340	\$ 133,364	\$ 375,385
Long-term obligations	69,961	99,620		40,000	209,581
	<b>\$ 71,958</b>	<b>\$ 245,304</b>	<b>\$ 94,340</b>	<b>\$ 173,364</b>	<b>\$ 584,966</b>

**Wellbutrin® and Zyban®**

In December 2002, Biovail acquired from GlaxoSmithKline plc ("GSK") the rights to Wellbutrin® SR and Zyban® (bupropion HCl) in Canada. Biovail also acquired the right to market its bupropion HCl extended-release tablets ("Wellbutrin XL") in Canada if regulatory approval is received. Wellbutrin® SR is indicated for the treatment of depression and Zyban® is administered for the treatment of nicotine addiction as an aid to smoking cessation. Biovail obtained the beneficial rights to Wellbutrin® SR and Zyban® effective December 1, 2002, and obtained full legal rights on March 2, 2004, following the completion of the payments described below.

GSK will continue to manufacture and supply Wellbutrin® SR and Zyban® to Biovail for four years from the date of acquisition. GSK continued to market Wellbutrin® SR and Zyban® in Canada during the period from December 1, 2002 to December 31,

2003 and, in consideration, Biovail paid GSK a tiered royalty on the net sales of these products during this period. Effective January 1, 2004, Biovail began to actively promote Wellbutrin® SR in Canada.

The purchase price for Wellbutrin® and Zyban® comprised cash consideration, including costs of acquisition, of \$3,320,000, less GSK's gross profit on the acquired assets from December 1, 2002 (the effective date of the transaction) to December 26, 2002 (the closing date of the transaction) of \$1,323,000, plus remaining payments of \$72,072,000 paid in four quarterly instalments from June 1, 2003 to March 1, 2004. These payments were present valued using an imputed interest rate of 3.74%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$69,961,000. Biovail will also pay GSK a royalty on any future sales of Wellbutrin XL in Canada for a period of 20 years from the date of commercial launch of this product.

The prepaid expenses were amortized over a one-year period from January 1, 2003. These expenses related to the minimum amount that GSK committed to spend on the marketing of Wellbutrin® SR and Zyban® in Canada during that period. The trademarks and product rights are being amortized over their estimated useful lives of 20 years and 15 years, respectively. The estimated weighted average useful life of the acquired assets is approximately 16 years.

#### **Vasotec® and Vaseretic®**

In May 2002, Biovail acquired from Merck & Co., Inc. ("Merck") the rights to Vasotec® (enalapril maleate) and Vaseretic® (enalapril maleate and hydrochlorothiazide) in the United States. Vasotec® and Vaseretic® are indicated for the treatments of hypertension and congestive heart failure. Biovail also acquired the fixed-dose combination NDA of enalapril and diltiazem maleate. Merck will continue to manufacture and supply Vasotec® and Vaseretic® to Biovail for five years from the date of acquisition. Biovail will make semi-annual payments to Merck over a five-year term for minimum product quantities and a minimum fixed royalty (regardless of the actual product supplied). Biovail will also pay Merck royalties on any future sales of any life cycle products developed and marketed in the United States.

Biovail also entered into a separate agreement with Merck to develop, license and supply a new dosage format of a Merck product under development. Utilizing CEFORM technology, Biovail and Merck will conduct the development program and, subject to approval by the FDA, Biovail will manufacture and supply this new dosage format to Merck for commercialization. Biovail is entitled to receive a milestone payment on regulatory approval of \$250,000, as well as royalties on any future sales of this new dosage format.

The purchase price for Vasotec® and Vaseretic® comprised cash consideration, including costs of acquisition, of \$155,634,000, less Merck's gross profit on the acquired assets from April 1, 2002 (the effective date of the transaction) to May 10, 2002 (the closing date of the transaction) of \$9,950,000, plus the minimum fixed royalty payments required to be made by Biovail to Merck of \$109,276,000. These payments were present valued using an imputed interest rate of 5.75%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$99,620,000.

The trademarks and product rights are being amortized over their estimated useful lives of 20 years and 15 years, respectively. The estimated weighted average useful life of the acquired assets is approximately 19 years.

#### **Teveten®**

In March 2002, Biovail acquired from Solvay Pharmaceuticals Marketing & Licensing AG ("Solvay") the rights to Teveten® (eprosartan mesylate) and Teveten® HCT (eprosartan mesylate and hydrochlorothiazide) in the United States. Teveten® is an angiotensin-II receptor blocker for the treatment of hypertension and is indicated for use either alone or in conjunction with other antihypertensive medications.

The purchase price for Teveten® comprised cash consideration of \$94,340,000, including costs of acquisition. The product rights are being amortized over their estimated useful life of 20 years.



Solvay will continue to manufacture and supply Teveten® and Teveten® HCT to Biovail for up to 12 years from the date of acquisition, and will assist in qualifying a Biovail facility to achieve the transition of the manufacturing process. Solvay will continue to manufacture and market Teveten® and Teveten® HCT in areas outside of the United States. Solvay paid Biovail a \$20,000,000 marketing allowance to reimburse Biovail for the agreed upon direct costs related to the re-launch and marketing of Teveten® and Teveten® HCT in the United States. Biovail recorded one-half of the marketing allowance each year in 2003 and 2002 as a reduction of selling, general and administrative expenses. Biovail formed a joint business development committee with Solvay to discuss future clinical and product-development options that could enhance the performance or expand the utilization of Teveten®. Solvay has the option to acquire, for worldwide markets excluding the United States, all potential future modifications and innovations developed by Biovail for Teveten®.

#### **Zovirax**

Effective January 1, 2002, Biovail acquired from GSK the exclusive distribution rights for Zovirax Ointment and Zovirax Cream in the United States. Zovirax (acyclovir) is a topical anti-viral product. Zovirax Ointment is indicated for the treatment of herpes, and Zovirax Cream is indicated for the treatment of cold sores. GSK will continue to manufacture and supply Zovirax Ointment and Zovirax Cream to Biovail over the term of the distribution agreement.

The purchase price for Zovirax comprised cash consideration of \$133,364,000, including costs of acquisition. The product rights were being amortized over their estimated useful life of 10 years, based on the original term of the distribution agreement.

In the event of the termination of the Wellbutrin XL agreement (as described in note 22 Marketing and Distribution Agreements) by either Biovail or GSK, Biovail would be required to pay GSK additional payments for the rights to Zovirax of \$22,000,000 per year in calendar years 2005 and 2006, and in calendar years 2007 through 2011, Biovail would be required to pay GSK additional payments based on a percentage of Biovail's gross sales of Zovirax during the immediately preceding calendar year.

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

In December 2002, Biovail and GSK agreed to extend the Zovirax distribution agreement from 10 to 20 years. In consideration for this extension, Biovail paid GSK \$40,000,000 in March 2003. This amount was added to the value of the unamortized Zovirax product rights and, subsequent to the date of amendment, these product rights are being amortized over their revised estimated remaining useful life of 19 years.

#### **4. ACQUISITIONS OF BUSINESSES**

**Years ended December 31, 2004 and 2003**

##### **BNC-PHARMAPASS**

##### **Description of acquisition**

In July 2003, Biovail and Pharma Pass II, LLC ("PPII") formed BNC-PHARMAPASS, LLC ("BNC-PHARMAPASS") to advance the development of three products. These products were carvedilol (Coreg), a beta-blocker indicated for the treatment of congestive heart failure, eprosartan (Teveten®), indicated for the treatment of hypertension, and tamsulosin (Flomax), indicated for the treatment of benign prostatic hyperplasia. On the formation of BNC-PHARMAPASS, PPII contributed all of

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its intellectual property relating to these products, which was fair valued at an amount of \$31,350,000, for a 51% interest in this company, and Biovail contributed cash in the amount of \$30,060,000, for a 49% interest in this company. PPII agreed to complete the formulation work in connection with these products. Biovail agreed to pay the cost of all clinical trials and certain other development costs related to these products. Biovail had an option to acquire PPII's interest in BNC-PHARMAPASS for cash consideration plus a royalty on any future sales of these products.

Subsequent to date of formation, PPII reduced its capital in BNC-PHARMAPASS through the withdrawal of \$25,741,000 of cash from BNC-PHARMAPASS. As a result, PPII's interest in BNC-PHARMAPASS was reduced to 16%, and Biovail's interest in BNC-PHARMAPASS increased to 84% at December 31, 2003.

At December 31, 2003, Biovail's investment in BNC-PHARMAPASS was recorded as follows:

Cash	\$ 4,319
Minority interest	(679)
Acquired research and development expense	26,420
	<hr style="width: 100%;"/>
Cash contributed	\$ 30,060
	<hr style="width: 100%;"/>

In January 2004, PPII further reduced its interest in BNC-PHARMAPASS through the withdrawal of the remaining \$4,319,000 of cash from BNC-PHARMAPASS. In February 2004, Biovail acquired PPII's remaining interest in BNC-PHARMAPASS for \$5,000,000. Biovail and PPII also agreed to terminate the development of tamsulosin, and the intellectual property related to this product was returned to PPII. The increase in Biovail's share of the fair values of the two remaining products (carvedilol and eprosartan) after the withdrawal of cash, together with the consideration paid to acquire PPII's remaining interest in BNC-PHARMAPASS, resulted in an additional \$8,640,000 charge to acquired research and development expense in 2004.

### Acquired research and development

At the dates of acquisition, the carvedilol, eprosartan and tamsulosin products were in pre-formulation and formulation phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 30% to 45% and the costs to complete the development of these products were estimated to be \$50,000,000. Biovail is continuing the development programs for carvedilol and eprosartan, which are in early clinical phases of development.

### Year ended December 31, 2002

During 2002, Biovail completed the acquisitions of Pharmaceutical Technologies Corporation ("Pharma Tech") and Pharma Pass LLC and Pharma Pass S.A. (collectively, "Pharma Pass"). These acquisitions were accounted for under the purchase method of accounting. Total consideration, including costs of acquisition, was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition as follows:

	Pharma Tech	Pharma Pass	Total
<b>Acquired assets</b>			
Acquired research and development expense	\$ 60,558	\$ 107,187	\$ 167,745
Product rights	5,000	63,800	68,800
Technology		7,700	7,700
Current liabilities	(3,664)		(3,664)
	<hr style="width: 100%;"/>	<hr style="width: 100%;"/>	<hr style="width: 100%;"/>
Consideration, net of cash acquired	\$ 61,894	\$ 178,687	\$ 240,581
	<hr style="width: 100%;"/>	<hr style="width: 100%;"/>	<hr style="width: 100%;"/>

## Pharma Tech

### Background

Pharma Tech was a development-stage company engaged in the application of drug delivery technologies to the formulation and development of a portfolio of products. Pharma Tech contracted directly with third parties, including Biovail, to conduct the contract research and development services. Biovail provided contract research and advisory services consistent with contractual relationships it had with other third parties. On the completion of the development of Biovail's products, Biovail had the right to manufacture and sell the products and Pharma Tech was entitled to royalties from the net sales of each product for a period of 10 years from the date of launch of each product. Biovail had options to acquire Pharma Tech's interest in the products or to acquire Pharma Tech.

Prior to the acquisition, Biovail earned revenue from providing advisory and contract research services to Pharma Tech of \$2,844,000 and \$2,189,000 in 2002 and 2001, respectively. The costs of providing these services to Pharma Tech were \$2,053,000 and \$1,679,000 in 2002 and 2001, respectively, and Biovail was reimbursed amounts at cost of \$2,509,000 and \$1,395,000 in 2002 and 2001, respectively. In 2002, Biovail also recorded \$6,689,000 of up-front fees in research and development revenue. These fees had been received from Pharma Tech in 2001, at which time they were deferred for subsequent amortization to revenue. The deferred revenue was fully amortized at December 31, 2002.

### Description of acquisition

On December 17, 2002, Biovail paid \$43,080,000 to Pharma Tech to terminate the development by Pharma Tech of one of the products under development and the associated royalties on future sales of this product if approved by the FDA. At the date of termination, this product had not been submitted for approval by the FDA. Accordingly, the termination payment was expensed as acquired research and development.

On December 31, 2002, Biovail acquired 100% of the outstanding shares of Pharma Tech for \$22,600,000, including costs of acquisition. Through the acquisition of Pharma Tech, Biovail extinguished any future milestone or royalty obligations that Biovail may have had to Pharma Tech resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements previously entered into between Biovail and Pharma Tech.

The acquired assets of Pharma Tech were fair valued using an income approach. The discount rates used to present value the estimated future cash flows related to each asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were in the range of 30% to 45%.

### Acquired research and development

At the date of acquisition, Pharma Tech was involved in a number of product-development projects that were in various stages of completion and had not been submitted for approval by the FDA. At the date of acquisition, an additional product had received an Approvable Letter from the FDA; however, significant technical issues required resolution before final approval would be granted. Therefore, the technological feasibility of this product had not been established at the date of acquisition. Biovail is continuing to work to resolve these issues. Subsequent to the date of acquisition, Biovail discontinued one of the product-development projects and it received an Approvable Letter from the FDA for one of the remaining products.

### Product rights

At the date of acquisition, Pharma Tech was involved with a product-development project that had been submitted for approval by the FDA. This product has received an approvable letter from the FDA, which raised only routine matters. Biovail believes that these matters can be successfully resolved and that final approval will be granted. However, since pharmaceutical products cannot be marketed without regulatory approvals, Biovail will not receive any benefits until regulatory approval is obtained. The product rights are being amortized over their estimated useful life of 15 years.

## Pharma Pass

### Background

Pharma Pass was a developer of advanced oral controlled-release technologies and formulations for pharmaceutical companies, including Biovail, in Europe and the United States. On the completion of the development of Biovail's products, Biovail had the right to manufacture and sell the products and Pharma Pass was entitled to royalties from the net sales of each product for a period of 15 years from the date of launch of each product.

### Description of acquisition

On December 6, 2002, Biovail acquired 100% of the outstanding interests of Pharma Pass LLC and 100% of the outstanding shares of Pharma Pass S.A. for \$178,687,000, including costs of acquisition. Through the acquisition of Pharma Pass, Biovail extinguished any future milestone or royalty obligations that Biovail may have had to Pharma Pass resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements previously entered into between Biovail and Pharma Pass.

The acquired assets of Pharma Pass were fair valued using an income approach. The discount rates used to present value the estimated future cash flows related to each asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were generally in the range of 9% to 45%. The estimated weighted average useful life of the acquired assets is approximately four years.

### Acquired research and development

At the date of acquisition, Pharma Pass was involved in approximately 20 product-development projects for a number of pharmaceutical companies including Biovail. At the date of acquisition, a number of these products had been submitted for approval by the FDA and the remaining products were in various stages of completion. Subsequent to the date of acquisition, one of these products (bupropion HCl) received FDA approval and another (tramadol HCl) received an Approvable Letter from the FDA. Two other products were sold to Teva Pharmaceuticals Industries Ltd. ("Teva") (as described in note 22 Marketing and Distribution Agreements). Biovail is continuing the development programs for the remaining products.

### Product rights

Biovail obtained interests in certain licensed products including Tricor (fenofibrate) and generic omeprazole. Biovail is entitled to receive royalties on sales of Tricor and was entitled to a participating interest in the gross profit on sales of generic omeprazole. The Tricor product right is being amortized over its estimated useful life of eight years. The generic omeprazole product right was being amortized on a proportionate basis relative to the revenue received from the participating interest. The generic omeprazole product right was fully amortized in 2003, as Biovail had received all of the value from this interest by December 31, 2003.

### Technology

Biovail obtained the patents related to Pharma Pass's Zero Order Release System, a drug delivery technology that controls the rate of release of a drug and/or significantly enhances the systemic absorption of a drug molecule. Biovail believes this technology has application to products currently in formulation and to the future development of controlled-release products. Biovail also obtained Pharma Pass's oral Colonic Delivery System, a drug delivery technology designed for the targeted release of medication into the lower intestine and upper colon. Biovail has the option to continue the development of four products utilizing this technology. Biovail will pay PPII up to \$10,000,000 in milestone fees subject to the successful completion of the development of these products. Biovail will obtain ownership of the related patents following the net payment of \$10,000,000 less the sum of the milestone fees paid. Biovail is currently in the process of selecting the four products to be developed. The technology is being amortized over its estimated useful life of 15 years.

**5. CASH AND CASH EQUIVALENTS**

	<b>2004</b>	<b>2003</b>
Cash and bank certificates of deposit	\$ 33,562	\$ 72,928
Money market funds	762	54,914
Canadian government securities		5,419
	<b>\$ 34,324</b>	<b>\$ 133,261</b>

**6. MARKETABLE SECURITIES**

The amortized cost and estimated fair value of marketable securities held at December 31, 2004 were as follows:

	<b>Amortized cost</b>	<b>Unrealized losses</b>	<b>Fair value</b>
Debt securities	\$ 5,020	(4)	\$ 5,016

All marketable securities held at December 31, 2004 mature within one year.

**7. ACCOUNTS RECEIVABLE**

	<b>2004</b>	<b>2003</b>
Trade	\$ 139,576	\$ 159,656
Less allowances for doubtful accounts and sales discounts	4,716	3,954
	<b>134,860</b>	<b>155,702</b>
Royalties	7,011	16,089
Other	6,891	7,583
	<b>\$ 148,762</b>	<b>\$ 179,374</b>

A significant portion of the Company's product sales is made to its third-party licensees, as well as major drug wholesalers in the United States and Canada. The three largest customer balances accounted for 62% of trade receivables at December 31, 2004.

**8. INVENTORIES**

	<b>2004</b>	<b>2003</b>
Raw materials	\$ 48,801	\$ 25,937
Work in process	14,862	26,803
Finished goods	46,491	31,318
	<b>\$ 110,154</b>	<b>\$ 84,058</b>

## 9. LONG-TERM INVESTMENTS

	<u>2004</u>	<u>2003</u>
Ethypharm	\$ 30,000	\$ 67,802
Depomed, Inc.	23,646	30,562
Reliant Pharmaceuticals, LLC	8,929	8,929
Western Life Sciences Venture Fund	872	2,038
Other	4,599	4,215
	<u>\$ 68,046</u>	<u>\$ 113,546</u>

**Ethypharm**

In April 2002, Biovail invested \$67,802,000, including costs of acquisition, to acquire 9,794,118 common shares (15% of the issued and outstanding common shares) of Ethypharm. In addition, Biovail obtained a three-year option to purchase up to 4,080,882 additional common shares of Ethypharm for \$6.66 per share plus 10% per annum, compounded annually. Biovail has not exercised this option. The investment in Ethypharm is being accounted for using the cost method.

In September 2003 (as amended in February 2004), Biovail negotiated with Ethypharm for price protection on its initial equity investment in Ethypharm in the event of any private or public financing undertaken by Ethypharm; however, the likelihood of Biovail realizing the value of this investment through such a refinancing by Ethypharm is currently considered remote, as this price protection expires on June 9, 2005. Consequently, Biovail evaluated its investment in Ethypharm and determined that the carrying value of this investment may not be fully realized in the foreseeable future. In December 2004, Biovail recorded a \$37,802,000 write-down to the carrying value of its investment in Ethypharm to reflect an other-than-temporary decline in the estimated fair value of this investment.

**Depomed, Inc. ("Depomed")**

In July 2002, Biovail invested \$13,675,000, including costs of acquisition, to acquire 2,465,878 newly issued common shares (15% of the issued and outstanding common shares) of Depomed. In addition, Biovail obtained a three-year option to purchase additional common shares of Depomed, in an amount sufficient for Biovail to increase its investment up to 20% of Depomed's issued and outstanding common shares (calculated following the exercise of the option), for \$5.00 per share plus 20% per annum, compounded monthly. Biovail has not exercised this option.

In May 2002, Biovail obtained the rights to manufacture and market Depomed's 500 mg tablets of Glumetza (metformin HCl) under development (as described in note 23 Research and Development Collaborations).

In April 2003, in connection with a private placement by Depomed, Biovail acquired an additional 1,626,154 common shares of Depomed for \$3,533,000. Biovail also obtained warrants to acquire 569,154 shares of Depomed, which are exercisable from July 2003 until April 2008 at an exercise price of \$2.16 per share. Biovail has not exercised these warrants.

The investment in Depomed has been classified as being available-for-sale. At December 31, 2004 and 2003, Biovail's investment represented approximately 12% of the issued and outstanding common shares of Depomed. In 2004 and 2003, Biovail recorded an unrealized holding loss of \$6,916,000 and unrealized holding gain of \$20,752,000, respectively, in other comprehensive income to reflect changes in the fair value of this investment. In 2002, Biovail recorded an unrealized holding loss of \$7,398,000 in net income to reflect an other-than-temporary decline in the fair value of this investment.

**Reliant Pharmaceuticals, LLC ("Reliant")**

In December 2003, in connection with the collection of its loan receivable from Reliant (as described in note 22 Marketing and Distribution Agreements), Biovail subscribed to \$8,929,000 of Series D Preferred Units of Reliant. These units are convertible on a 1:1 basis into Reliant's common units and are senior to all existing preferred classes of units (Series A, B and C) of Reliant. These units do not entitle the holders to a preferred return (or dividends). In the case of a liquidation of Reliant,

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these units are entitled to a distribution, before any other distribution or payment is made to any unit ranking junior to these units, of an amount equal to the sum of: (i) \$20.00 per unit; and (ii) interest on such amount at a rate of 8.5% per annum from the date of contribution. These units are redeemable by Reliant at a redemption price equal to the preceding liquidation amount. These units have voting rights equal to the number of whole common units into which they are convertible. At December 31, 2004 and 2003, Biovail's investment represented less than 2% of the total issued and outstanding common and preferred units. This investment is being accounted for using the cost method.

### Western Life Sciences Venture Fund

In December 2001, Biovail committed to an aggregate capital contribution of approximately \$7,790,000 to a limited partnership under the name of Western Life Sciences Venture Fund. The purpose of this fund is to invest in early-stage biotechnology companies. Biovail has the exclusive right to negotiate for the distribution, sales, marketing or licensing rights to any products of the investee companies of this fund. This investment is denominated in Canadian dollars and is being accounted for using the equity method.

At December 31, 2004 and 2003, Biovail had invested a total of \$5,795,000 and \$3,162,000, respectively, to acquire Class A units of this fund. At December 31, 2004 and 2003, Biovail's investment represented approximately 28% and 26%, respectively, of the total issued and outstanding Class A units. In 2004 and 2003, Biovail's share of the net losses of this fund was \$4,179,000 and \$1,010,000, respectively.

## 10. PROPERTY, PLANT AND EQUIPMENT

	2004		2003	
	Cost	Accumulated depreciation	Cost	Accumulated depreciation
Land	\$ 11,764	\$	\$ 11,378	\$
Buildings	83,136	13,526	75,186	9,742
Machinery and equipment	102,099	36,575	88,594	26,269
Other equipment and leasehold improvements	71,851	32,193	56,083	21,426
	268,850	\$ 82,294	231,241	\$ 57,437
Less accumulated depreciation	82,294		57,437	
	\$ 186,556		\$ 173,804	

At December 31, 2004 and 2003, the cost of property, plant and equipment included \$18,389,000 and \$20,606,000, respectively, of assets under construction or awaiting FDA approval and not available for productive use. Interest capitalized amounted to \$222,000 and \$1,422,000 in 2004 and 2003, respectively.

Depreciation expense amounted to \$22,259,000, \$15,351,000 and \$9,794,000 in 2004, 2003 and 2002, respectively.

**11. INTANGIBLE ASSETS**

	2004		2003	
	Cost	Accumulated amortization	Cost	Accumulated amortization
Trademarks	\$ 703,698	\$ 116,453	\$ 703,698	\$ 81,371
Product rights	459,773	84,877	550,880	141,068
Technology	21,041	5,109	21,041	3,705
	1,184,512	\$ 206,439	1,275,619	\$ 226,144
Less accumulated amortization	206,439		226,144	
	\$ 978,073		\$ 1,049,475	

In 2004, the Company's participating interest in the gross profit on sales of generic omeprazole was fully amortized, as the Company had received all of the value from this interest by this date. Accordingly, the Company removed the cost and accumulated amortization of \$85,357,000 related to this interest from product rights.

Amortization expense amounted to \$66,048,000, \$139,357,000 and \$72,574,000 in 2004, 2003 and 2002, respectively. Annual amortization expense, related to intangible assets recorded at December 31, 2004, for each of the five succeeding years ending December 31 is as follows:

2005	\$ 64,809
2006	63,802
2007	63,802
2008	63,669
2009	62,736

Product rights have an estimated weighted average useful life of approximately 16 years. Total intangible assets have an estimated weighted average useful life of approximately 18 years.

**12. OTHER ASSETS**

	2004	2003
Deferred financing costs	\$ 18,661	\$ 17,311
Less accumulated amortization	9,396	6,274
	9,265	11,037
Zovirax distribution agreement	40,656	40,656
Deferred compensation trust fund	6,892	5,644
Interest rate swaps	6,002	14,746
Loan receivable	625	600
	\$ 63,440	\$ 72,683

**Deferred financing costs**

In March 2004, the Company recorded a \$1,200,000 write-down of deferred financing costs, as the result of a reduction in the borrowing capacity under its revolving term credit facility. Amortization expense related to deferred financing costs amounted to \$3,122,000, \$2,975,000 and \$2,267,000 in 2004, 2003 and 2002, respectively.





**Zovirax distribution agreement**

In consideration for certain amendments to the original Zovirax distribution agreement with GSK, Biovail agreed to pay GSK \$11,250,000 per year in four annual instalments on March 31 of each year beginning in 2004. The annual instalment payments were present valued using an imputed interest rate of 3.74%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$40,656,000, which was recorded in other assets. This amount will be amortized over the period of benefit from the amended terms beginning in 2005.

**Interest rate swaps**

The fair value of the Company's fixed rate 7<sup>7</sup>/<sub>8</sub>% Senior Subordinated Notes due April 1, 2010 ("Notes") is affected by changes in interest rates. The Company manages this exposure to interest rate changes through the use of interest rate swaps.

In June 2002, the Company entered into three interest rate swaps of aggregate \$200,000,000 notional amount, which were designated as a hedge of the Notes. These swaps involved the receipt of amounts based on a fixed rate of 7<sup>7</sup>/<sub>8</sub>% in exchange for floating rate interest payments, based on six-month London Interbank Offering Rate ("LIBOR") plus a spread of 2.69% to 2.99%, without an exchange of the underlying principal amount. On June 24, 2004, the Company terminated these swaps and received a cash settlement payment of \$6,300,000, of which \$4,478,000 was applied against the remaining fair value of these swaps and \$1,822,000 was applied against the accrued interest receivable related to these swaps at the date of termination. Prior to the termination of these swaps, the Company recognized other expense of \$2,307,000 in the period from January 1, 2004 to June 24, 2004, and other income of \$72,000 and \$3,408,000 in 2003 and 2002, respectively, related to the ineffective portion of this terminated hedging relationship.

On June 28, 2004, the Company entered into a new interest rate swap in a notional amount of \$200,000,000, which is designated as a hedge of the Notes. This swap involves the receipt of amounts based on a fixed rate of 7<sup>7</sup>/<sub>8</sub>% in exchange for floating rate interest payments, based on six-month LIBOR plus a spread of 3.26%, without an exchange of the underlying principal amount. This swap has a call feature and other terms that are consistent with those of the Notes; therefore, the Company can assume that there is no ineffectiveness present in this new hedging relationship, which permits it to apply the shortcut method of accounting in accordance with SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities". Accordingly, there was no ineffectiveness related to this new hedging relationship recorded in other income or expense in the period from June 28, 2004 to December 31, 2004. At December 31, 2004, the fair value of this swap was \$3,365,000 in favour of the Company.

At December 31, 2004, the Company reported a fair value adjustment to the carrying value of the Notes in long-term obligations of \$7,443,000. This adjustment comprised \$4,078,000 related to the terminated hedging relationship, which is being amortized to reduce interest expense over the remaining term of the Notes, and a \$3,365,000 offset to the fair value of the new interest rate swap.

**Loan receivable**

In March 2001, the Company made a \$600,000 relocation assistance loan to a former executive officer, which is secured by a charge on the former officer's personal residence. Effective March 1, 2004, this loan bears interest at a rate equal to the Company's rate of borrowing. Interest is accrued and added to the principal balance. Principal and accrued interest are due on March 31, 2008.

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13. ACCRUED LIABILITIES

	<u>2004</u>	<u>2003</u>
Product returns	\$ 30,421	\$ 43,289
Product rebates and chargebacks	12,409	21,601
Employee costs	16,052	16,796
Interest	9,148	9,209
Other	14,887	14,306
	<u>\$ 82,917</u>	<u>\$ 105,201</u>

14. DEFERRED REVENUE

	<u>2004</u>	<u>2003</u>
Up-front research and development fees	\$ 8,800	\$ 10,900
Up-front licensing fees and other	13,390	8,063
Customer prepayments	2,476	1,302
	<u>24,666</u>	<u>20,265</u>
Less current portion	8,141	5,765
	<u>\$ 16,525</u>	<u>\$ 14,500</u>

Effective January 1, 2000, the Company implemented the provisions of the U.S. Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements". Total revenue in 2004, 2003 and 2002 included \$3,400,000, \$5,200,000 and \$4,800,000, respectively, of amortization of revenue deferred on the implementation of SAB No. 101.

15. LONG-TERM OBLIGATIONS

	<u>2004</u>	<u>2003</u>
7 <sup>7</sup> / <sub>8</sub> % Senior Subordinated Notes due April 1, 2010	\$ 400,000	\$ 400,000
Unamortized discount	(1,916)	(2,281)
Fair value adjustment	7,443	10,401
	<u>405,527</u>	<u>408,120</u>
Revolving term credit facility		280,000
Zovirax obligation	32,230	42,198
Vasotec® and Vaseretic® obligation	27,704	45,376
Ativan® and Isordil® obligation	9,037	17,806
Wellbutrin® and Zyban® obligation		22,407
Deferred compensation	4,438	7,020
	<u>478,936</u>	<u>822,927</u>
Less current portion	33,465	58,816
	<u>\$ 445,471</u>	<u>\$ 764,111</u>

Interest expense on long-term obligations amounted to \$36,963,000, \$38,987,000 and \$28,564,000 in 2004, 2003 and 2002, respectively.

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### Notes

Pursuant to a supplement to its base shelf prospectus dated March 25, 2002, the Company issued, under an indenture dated March 28, 2002, \$400,000,000 aggregate principal amount of unsecured Notes. Interest on the Notes is payable semi-annually in arrears on April 1 and October 1 of each year. The Notes were issued at a price of 99.27% of their aggregate principal amount for an effective yield, if held to maturity, of 8%. Proceeds from the issue amounted to \$384,280,000, net of discount and financing costs.

At any time on or after April 1, 2006, the Company may redeem all or any of the Notes at the following prices, plus accrued and unpaid interest to the date of redemption, if redeemed during the 12 months beginning April 1 of the years indicated below:

Year	Percentage of principal amount
2006	103.938%
2007	101.969%
2008 and thereafter	100.000%

Before April 1, 2005, the Company may redeem up to 35% of the original principal amount of the Notes, with the net cash proceeds of certain sales of the Company's common shares, at 107.875% of the principal amount plus accrued and unpaid interest to the date of redemption.

At December 31, 2004 and 2003, the aggregate market values of the Notes, based on quoted market prices, were approximately \$412,000,000 and \$408,000,000, respectively.

### Revolving term credit facility

At December 31, 2004, the Company had no outstanding borrowings under its \$400,000,000 revolving term credit facility. At December 31, 2003, the Company had advances of \$280,000,000 borrowed under this credit facility. At December 31, 2004 and 2003, the Company had a letter of credit issued under this credit facility of \$36,666,000 and \$61,207,000, respectively, which secures the remaining semi-annual payments the Company is required to make under the Vasotec® and Vaseretic® agreement. At December 31, 2004 and 2003, the Company had remaining balances of \$363,334,000 and \$58,793,000, respectively, available to borrow under this credit facility.

The revolving period of this credit facility extends to May 25, 2005, following the lenders' consent to extend the renewal date from March 25, 2004. The revolving period may be extended at the request of the Company and at the sole discretion of the lenders for additional periods of up to 364 days. If the lenders elect not to further extend the revolving period of this credit facility, the Company may elect to convert amounts then outstanding into a one-year term facility, repayable in four equal quarterly instalments.

Borrowings under this credit facility are secured by a charge over substantially all of the assets and undertakings, including intellectual property, of the Company. The credit agreement includes certain financial and non-financial covenants. The financial covenants require the Company to meet or exceed certain minimum thresholds for shareholders' equity and interest coverage, and not to exceed a maximum threshold in respect of the ratio of debt to earnings before interest, taxes, depreciation and amortization. Non-financial covenants include, but are not limited to, restrictions on investments and dispositions, as well as capital and debt-restructuring activities, exceeding established thresholds. On a change in control, the lenders have the right to require the Company to settle this entire credit facility, plus accrued and unpaid interest at the date of settlement.

Borrowings may be by way of U.S. dollar, LIBOR or U.S. base rate advances or Canadian dollar prime rate or bankers' acceptance ("BA") advances or letters of credit. Interest is charged at the Bank's quoted rate plus a borrowing margin of 1.375% to 2% in the case of LIBOR and BA advances, and 0.375% to 1% in the case of base rate and prime rate advances, depending on the Company's financial covenant ratios at the time of such borrowing.

**Zovirax obligation**

The Zovirax obligation relates to the amendments to the Zovirax distribution agreement. This non-interest bearing obligation was discounted based on an imputed interest rate of 3.74%. The three remaining annual payments of \$11,250,000 each are due on March 31 of each year, from 2005 to 2007.

**Vasotec® and Vaseretic® obligation**

This obligation reflects the minimum fixed royalty payments assumed on the acquisition of Vasotec® and Vaseretic®. This non-interest bearing obligation was discounted based on an imputed interest rate of 5.75%. The remaining payments are due semi-annually, on April 1 and October 1 of each year, in the following annual amounts: 2005 \$15,256,000; and 2006 \$14,011,000.

**Ativan® and Isordil® obligation**

This obligation reflects the remaining fixed annual payments related to the acquisition of Ativan® and Isordil®. This non-interest bearing obligation was discounted based on an imputed interest rate of 3.00%. The final payment of \$9,150,000 is due on May 31, 2005.

**Wellbutrin® and Zyban® obligation**

This obligation relates to the acquisition of the Canadian rights to Wellbutrin® and Zyban®. This non-interest bearing obligation was discounted based on an imputed interest rate of 3.74%. The final payment was made on March 1, 2004.

**Maturities**

Aggregate maturities of long-term obligations for the years ending December 31 are as follows:

	<b>Notes</b>	<b>Other</b>	<b>Total</b>
	<b>_____</b>	<b>_____</b>	<b>_____</b>
2005	\$	\$ 35,656	\$ 35,656
2006		25,261	25,261
2007		11,250	11,250
2010	400,000		400,000
	<b>_____</b>	<b>_____</b>	<b>_____</b>
<b>Total gross maturities</b>	<b>400,000</b>	<b>72,167</b>	<b>472,167</b>
	<b>_____</b>	<b>_____</b>	<b>_____</b>
Unamortized discounts	(1,916)	(3,196)	(5,112)
Fair value adjustment	7,443		7,443
Deferred compensation <sup>(1)</sup>		4,438	4,438
	<b>_____</b>	<b>_____</b>	<b>_____</b>
<b>Total long-term obligations</b>	<b>\$ 405,527</b>	<b>\$ 73,409</b>	<b>\$ 478,936</b>
	<b>_____</b>	<b>_____</b>	<b>_____</b>

(1)

The deferred compensation obligation is repayable to the participants in the deferred compensation plan upon their retirement or earlier withdrawal from this plan and, consequently, this obligation does not have a defined maturity.

## 16. SHAREHOLDERS' EQUITY

**Stock Option Plans**

In June 2004, the Company adopted a new stock option plan (the "2004 Stock Option Plan") in replacement of its previous stock option plan and pursuant to which the Company will grant options to purchase common shares of the Company to selected employees, directors, officers and consultants of the Company. The 2004 Stock Option Plan provides that a maximum of 5,000,000 common shares are issuable pursuant to the exercise of options. The options are granted at the fair market value of the underlying common shares at the date of grant and expire no later than 10 years from that date.

Under the Company's previous stock option plan established in 1993, as amended (the "1993 Stock Option Plan"), a maximum of 28,000,000 common shares were issuable pursuant to the exercise of options. The options were granted at the fair market value of the underlying common shares at the date of grant and expire no later than seven years from that date. On approval of the 2004 Stock Option Plan, the 1993 Stock Option Plan was frozen and no further grants of stock options will be made under that plan. The remaining 409,112 common shares that were reserved for the issuance of stock options under the 1993 Stock Option Plan were removed from the reserve. At December 31, 2004, there were 7,390,762 outstanding options that are or may become exercisable under the terms of the 1993 Stock Option Plan.

The following table summarizes the Company's stock option activity for the three years ended December 31, 2004:

	<b>Options (000s)</b>	<b>Weighted average exercise price</b>
<b>Outstanding balance, January 1, 2002</b>	6,253	\$ 18.53
Granted	2,068	36.84
Exercised	(2,197)	8.71
Forfeited	(199)	28.48
	<b>5,925</b>	<b>28.23</b>
<b>Outstanding balance, December 31, 2002</b>	5,925	28.23
Granted	2,304	27.66
Exercised	(663)	17.50
Forfeited	(234)	31.93
	<b>7,332</b>	<b>28.91</b>
<b>Outstanding balance, December 31, 2003</b>	7,332	28.91
Granted	1,241	18.75
Exercised	(561)	13.51
Forfeited	(300)	26.40
	<b>7,712</b>	<b>\$ 28.49</b>
<b>Outstanding balance, December 31, 2004</b>	7,712	\$ 28.49

The weighted average fair values per stock option granted during 2004, 2003 and 2002 were \$8.09, \$11.48 and \$13.58, respectively.

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The following table summarizes information about options outstanding at December 31, 2004:

Range of exercise prices	Outstanding (000s)	Weighted average remaining contractual life (years)	Weighted average exercise price	Exercisable (000s)	Weighted average exercise price
\$ 0.81 \$ 3.52 <sup>(1)</sup>	44	5.0	\$ 3.06	44	\$ 3.06
8.75 12.77	76	1.1	9.67	76	9.67
17.50 25.00	3,362	3.2	20.40	1,834	21.77
27.72 39.00	2,918	2.9	32.42	1,946	32.82
40.00 48.07	1,312	2.3	42.41	1,026	42.36
	<b>7,712</b>	<b>2.9</b>	<b>\$ 28.49</b>	<b>4,926</b>	<b>\$ 30.07</b>

(1)

These options represent the converted DJ Pharma invested employee stock options pursuant to the merger agreement.

### Employee Stock Purchase Plan ("EPP")

The Company's EPP was established in 1996 to provide a convenient method for full-time employees of the Company to participate in the share ownership of the Company or to increase their share ownership in the Company via payroll or contractual deduction. Directors, senior officers or insiders of the Company are not eligible to participate in the EPP. A maximum of 1,200,000 common shares are issuable under the EPP. At the discretion of a committee of the Board of Directors that administers the EPP, the Company may issue directly from treasury or purchase shares in the market from time to time to satisfy the obligations under the EPP. A participant may authorize a payroll or contractual deduction up to a maximum of 10% of the base salary or remuneration to be received during any purchase period. The purchase price is 90% of the fair market value of the common shares on the date on which the eligible period ends. At December 31, 2004, a total of 88,698 common shares have been issued under the EPP.

### Stock repurchase programs

In November 2003, the Company implemented a stock repurchase program pursuant to which it was able to repurchase up to 10% of its issued and outstanding common shares on or before November 25, 2004. No common shares were repurchased under this program.

In February 2002, the Company implemented a stock repurchase program pursuant to which it was able to repurchase up to 5% of its issued and outstanding common shares. In May 2002, the Company increased the amount to 10% of its issued and outstanding common shares. An aggregate of 12,872,300 common shares were repurchased under this program, through open market transactions on the NYSE and TSX, at an average purchase price of \$39.08 per share, for total consideration of \$503,100,000. The excess of the cost of the common shares acquired over the stated capital thereof, totaling \$388,204,000, was charged to deficit. This program was terminated with no further common shares repurchased.

### Warrants outstanding

At September 30, 1999, the Company had 3,737,500 warrants issued and outstanding. Each warrant entitled the holder to purchase four common shares of the Company. The warrants were exercisable at a per share price of \$10.00 from October 1, 1999 until September 30, 2002.

During 2002, substantially all of the remaining outstanding warrants were exercised, resulting in the issue of 11,282,284 common shares, on the exercise of 2,820,571 warrants, for proceeds of \$112,823,000. On September 30, 2002, any remaining warrants expired.

**Executive Stock Purchase Plan ("ESPP") loans**

In September 2001, the Company made ESPP loans in an aggregate amount of \$9,988,000 to certain executive officers in order to finance the acquisition of common shares of the Company on the open market. These loans were full recourse and were secured by the common shares purchased pursuant to these loans and bore interest at a rate equal to the Company's rate for borrowings. Interest was payable quarterly in arrears. These loans were due and payable on September 30, 2003.

At December 31, 2003, four executive officers were indebted to the Company in an aggregate amount of \$7,990,000 in connection with the ESPP loans. To facilitate repayment of these loans, on December 31, 2003, Eugene Melnyk, Chairman of the Board of Biovail, in his individual capacity, made loans to these executives in an amount equal to the amount of their indebtedness to the Company and the ESPP loans were repaid. These executives pledged to Mr. Melnyk, as collateral for their loans, an aggregate of 176,080 shares of the Company and their interest in 200,000 options to acquire shares of the Company having a strike price of \$31.00 per share. The loan arrangements provide that there will be no recourse to these executives in addition to the collateral pledged by them, except in certain instances.

**17. WRITE-DOWN OF ASSETS, NET OF GAIN ON DISPOSAL**

**Year ended December 31, 2004**

In 2004, the Company recorded a net charge of \$40,685,000 related to the write-down or gain on disposal of the following assets:

In December 2004, Biovail recorded a \$37,802,000 write-down to the carrying value of its investment in Ethypharm (as described in note 9 Long-Term Investments).

In November 2004, the Company decided not to reformulate the Rondec product line and to discontinue all related marketing and sales efforts, as the result of a continuing decline in market share for these products due to generic competition. The Company evaluated the fair value of the Rondec product rights and determined that they had been permanently impaired. Accordingly, the Company recorded a charge of \$4,354,000 to write off the remaining carrying value of these product rights.

In July 2004, the Company disposed of the Cedax product rights, which resulted in a gain on disposal of \$1,471,000 (as described in note 3 Disposition and Acquisitions of Intangible Assets).

**Year ended December 31, 2003**

In 2003, the Company recorded a charge of \$45,081,000 related to the write-down of the following assets:

In December 2003, the Company evaluated its future interest in its Cedax and Rondec product lines. The Company intended to focus its therapeutically aligned sales efforts on cardiovascular products, such as Cardizem® LA and Teveten®, as well as Zovirax. Without continued promotion the economic viability of Cedax and Rondec was substantially lower, as these products required significant marketing and sales efforts in order to maintain market share. The Company evaluated the current and forecasted market shares at the time for Cedax and Rondec and determined that the undiscounted future cash flows from these products were below the carrying values of the related product rights. Accordingly, the Company recorded a charge of \$43,400,000 to write down the carrying values of these product rights to their estimated fair values.

In December 2003, the Company recorded a charge of \$1,681,000 related to the write-down of goodwill associated with its Swiss subsidiary, Biovail S.A, due to a decline in royalties earned on the sales of products out-licensed by this subsidiary.

**Year ended December 31, 2002**

In 2002, the Company recorded a charge of \$31,944,000 related to the write-down of the following assets:

In June 2002, the Company, Elan Corporation, plc ("Elan") and the U.S. Federal Trade Commission ("FTC") entered into a settlement with respect to the introduction of generic versions of Adalat CC. As a result of the FTC settlement, the agreements between the Company and Elan related to the Company's in-licensing of Elan's generic versions of Adalat CC were dissolved.



Consequently, the Company's long-term obligation to make minimum license payments to Elan under these agreements was terminated. The Company had been in negotiations to have Elan reacquire the rights to its generic versions of Adalat CC that had been sold to Biovail. As there had been no meaningful progress to these negotiations as at December 31, 2002, and as Biovail was unable to ascertain the eventual outcome of these negotiations, Biovail determined that the net book value of the generic Adalat CC product rights of \$55,787,000, net of the corresponding long-term obligation to Elan of \$33,381,000, should be written off. In December 2002, the Company recorded a related charge of \$22,406,000. In June 2003, the Company settled with Elan (as described in note 18 - Settlements).

In 2002, the Company recorded other-than-temporary declines in the values of its investment in Depomed and other investments of \$7,398,000 and \$676,000, respectively, and recorded other asset write-downs of \$1,464,000.

## 18. SETTLEMENTS

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

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

### **Elan**

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

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

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

### **Mylan**

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

During 2003, in relation to the matters described above, the Company recorded settlement payments of \$34,055,000, mainly related to the Company's lost profits on sales of Nifedical XL, Keftab and its generic version of Verelan, and additional payments of \$16,229,000, mainly related to a reduction in cost of goods sold, a reimbursement of legal and other expenses, and interest income. In addition, the Company recorded \$14,554,000 of the settlement payment from Lilly as a reduction to assets related to the recoverable value of the Keftab product right and the value of the destroyed Keftab inventory.

**19. INCOME TAXES**

The components of the provision for (recovery of) income taxes are as follows:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Current</b>			
Domestic	\$ 485	\$ 400	\$ 1,250
Foreign	8,465	(4,400)	20,250
	<u>          </u>	<u>          </u>	<u>          </u>
	8,950	(4,000)	21,500
<b>Deferred</b>			
Domestic			
Foreign			
	<u>          </u>	<u>          </u>	<u>          </u>
	<u>          </u>	<u>          </u>	<u>          </u>
	\$ 8,950	\$ (4,000)	\$ 21,500
	<u>          </u>	<u>          </u>	<u>          </u>

The reported provision for, or recovery of, income taxes differs from the expected amount calculated by applying the Company's Canadian statutory rate to income or loss before provision for, or recovery of, income taxes. The reasons for this difference and the related tax effects are as follows:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
	<u>          </u>	<u>          </u>	<u>          </u>
Income (loss) before provision for (recovery of) income taxes	\$ 169,944	\$ (31,265)	\$ 109,295
Expected Canadian statutory rate	36.5%	34.1%	39.4%
	<u>          </u>	<u>          </u>	<u>          </u>
Expected provision for (recovery of) income taxes	62,030	(10,661)	43,084
<b>Non-deductible amounts</b>			
Amortization	23,472	45,343	26,130
Acquired research and development	3,154	42,530	66,125
Equity loss	1,525	344	
	<u>          </u>	<u>          </u>	<u>          </u>
Foreign tax rate differences	(163,648)	(143,719)	(126,862)
Unrecognized income tax benefit of losses	78,991	56,606	9,347
Other	3,426	5,557	3,676
	<u>          </u>	<u>          </u>	<u>          </u>
	\$ 8,950	\$ (4,000)	\$ 21,500
	<u>          </u>	<u>          </u>	<u>          </u>

The Company has provided for foreign withholding taxes on the portion of undistributed earnings of foreign subsidiaries expected to be remitted.

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Deferred income taxes have been provided for on the following temporary differences:

	<u>2004</u>	<u>2003</u>
<b>Deferred tax assets</b>		
Tax loss carryforwards	\$ 165,113	\$ 101,132
Scientific Research and Experimental Development pool	37,991	32,471
Provisions	33,982	25,576
Investment tax credits	27,552	23,739
Plant, equipment and technology	12,457	7,710
Deferred financing and share issue costs	6,701	14,125
Intangible assets	4,667	4,687
Other	4,667	4,079
	<u>288,463</u>	<u>213,519</u>
Total deferred tax assets	288,463	213,519
Less valuation allowance	(284,080)	(207,932)
	<u>4,383</u>	<u>5,587</u>
Net deferred tax assets	4,383	5,587
<b>Deferred tax liabilities</b>		
Prepaid expenses	2,642	2,729
Intangible assets	1,043	1,147
Other	698	1,711
	<u>4,383</u>	<u>5,587</u>
Total deferred tax liabilities	4,383	5,587
	<u>\$</u>	<u>\$</u>
Net deferred income taxes	\$	\$

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 2004 and 2003, the valuation allowance increased by \$76,148,000 and \$91,411,000, respectively. The increases in the valuation allowance were mainly related to accumulated tax losses and tax credit carryforwards.

At December 31, 2004, the Company had accumulated tax losses of approximately \$3,300,000 available for federal purposes and approximately \$29,900,000 available for provincial purposes in Canada, which expire in 2008 and 2009. The Company also had approximately \$27,500,000 of unclaimed Canadian investment tax credits, which expire from 2005 to 2014. These losses and investment tax credits can be used to offset future years' taxable income and federal tax, respectively.

In addition, the Company has pooled Scientific Research and Experimental Development ("SR&ED") expenditures amounting to approximately \$104,400,000 available to offset against future years' taxable income from its Canadian operations, which may be carried forward indefinitely.

The eventual settlement of the Company's U.S. dollar denominated 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 dollars at the time the Notes are settled. At December 31, 2004, the unrealized foreign exchange gain on the translation of the Notes to Canadian dollars for Canadian income tax purposes was approximately \$130,000,000. If the Notes had been settled at December 31, 2004, one-half of this foreign exchange gain would have been included in the Company's taxable income, which would have resulted in a corresponding reduction in the Company's available Canadian operating losses, SR&ED pool and/or investment tax credit carryforward balances disclosed above. The eventual settlement of the 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.

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At December 31, 2004, the Company has accumulated tax losses of approximately \$409,600,000 for federal and state purposes in the United States, which expire from 2007 to 2024. 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.

### 20. EARNINGS OR LOSS PER SHARE

Earnings (loss) per share were calculated as follows:

	2004	2003	2002
Net income (loss)	\$ 160,994	\$ (27,265)	\$ 87,795
Basic weighted average number of common shares outstanding (000s)	159,115	158,516	151,960
Dilutive effect of stock options (000s)	143		2,511
Dilutive effect of warrants (000s)			5,992
Diluted weighted average number of common shares outstanding (000s)	159,258	158,516	160,463
Basic earnings (loss) per share	\$ 1.01	\$ (0.17)	\$ 0.58
Diluted earnings (loss) per share	\$ 1.01	\$ (0.17)	\$ 0.55

In 2003, all stock options were excluded from the calculation of diluted loss per share, as the effect of including them would have been anti-dilutive. The potential dilutive effect of stock options on the weighted average number of common shares outstanding was as follows:

	2003
Basic weighted average number of common shares outstanding (000s)	158,516
Potential dilutive effect of stock options (000s)	1,403
Adjusted weighted average number of common shares outstanding (000s)	159,919

### 21. CASH FLOW INFORMATION

#### Changes in operating assets and liabilities

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

	2004	2003	2002
Accounts receivable	\$ 29,396	\$ 15,926	\$ (93,241)
Inventories	(26,108)	(30,023)	(14,643)
Deposits and prepaid expenses	(636)	3,156	(12,265)
Accounts payable	(26,281)	(3,590)	35,717
Accrued liabilities	(21,375)	(649)	47,578
Income taxes payable	428	(10,958)	17,618
Deferred revenue	4,401	(7,166)	(22,699)
	\$ (40,175)	\$ (33,304)	\$ (41,935)

**Non-cash investing and financing activities**

There were no non-cash investing and financing activities in 2004. In 2003, non-cash investing and financing activities included the long-term obligation of \$17,497,000 related to the acquisition of Ativan® and Isordil®, and the subscription to \$8,929,000 Series D Preferred Units of Reliant in repayment of a portion of the loan receivable from Reliant. In 2002, non-cash investing and financing activities included long-term obligations of \$99,620,000 and \$69,961,000 related to the acquisitions of Vasotec® and Vaseretic®, and Wellbutrin® and Zyban®, respectively, as well as the long-term obligation of \$80,656,000 related to the amendments to the Zovirax distribution agreement.

**Cash paid during the year**

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Interest	\$ 32,594	\$ 31,187	\$ 14,899
Income taxes	8,195	7,862	5,063

**22. MARKETING AND DISTRIBUTION AGREEMENTS****Teva**

In September 2004, Biovail resolved its pending arbitration with Teva and its affiliates related to a dispute over its existing distribution agreement with Teva. Under the terms of the settlement agreements entered into, Biovail granted Teva a four-year extension to the 10-year supply term for each of Biovail's generic products currently marketed by Teva and Biovail sold Teva two extended-release generic products under development. In consideration, Biovail's selling price to Teva for each generic product will be increased for the remainder of the extended supply term. In addition, Teva will pay Biovail up to \$9,300,000, subject to certain milestones. At the date of settlement, Biovail was entitled to receive \$6,800,000 of this amount, of which \$6,300,000 was deferred and is being recognized over the remaining extended supply term. Biovail will only recognize the remaining \$2,500,000 if the milestones are achieved.

Biovail also granted Teva an option to acquire one additional generic product under development. If Teva elects to exercise this option, it will pay Biovail up to \$2,500,000, subject to certain milestones. Biovail will only recognize this amount if the milestones are achieved. Biovail will complete the development of this product and will retain the exclusive manufacturing rights to this product. Subject to approval by the FDA, Biovail will be entitled to a share of the profit on Teva's net sales of this product for 10 years from the date of first commercial sale.

Biovail also entered into an agreement with Teva that provides for the supply of diltiazem HCl (the active ingredient in Cardizem® and Tiazac®) by Teva to Biovail until December 31, 2009.

**GSK**

In October 2001, Biovail and GSK entered into an agreement for the development and license of Wellbutrin XL and the co-promotion of Wellbutrin SR. Under the terms of this agreement, Biovail licensed Wellbutrin XL to GSK for sale and distribution on a worldwide basis, excluding Canada. Biovail and GSK collaborated to complete the development of Wellbutrin XL and to obtain FDA approval for this product. In addition, GSK and Biovail co-promoted GSK's Wellbutrin SR in the United States during the period from January 1, 2002 to March 31, 2003. In consideration for the activities undertaken by Biovail under this agreement, GSK committed to pay Biovail up to \$61,500,000 in six quarterly increments. The first increment of \$11,500,000 was related to the development of Wellbutrin XL. During 2002, Biovail completed the development of Wellbutrin XL and recognized the first increment in research and development revenue. The five remaining quarterly increments, of up to \$10,000,000 each, related to the co-promotion of Wellbutrin SR in the United States. The receipt of each of these increments was dependent on Biovail performing prescribed detailing activity related to the co-promotion of Wellbutrin SR, and the amount was determined based on a percentage of net sales of Wellbutrin SR in the United States during each quarter. Biovail received the full amount of these increments in each of the four quarters of 2002 and the first quarter of 2003.

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GSK filed an NDA for Wellbutrin XL in August 2002 and received FDA approval for this product in August 2003. Biovail is the exclusive manufacturer and supplier of Wellbutrin XL to GSK on a worldwide basis. The supply price for trade product during each calendar year is determined based on an increasing tiered percentage of GSK's net selling prices (after taking into consideration GSK's provisions for estimated discounts, returns, rebates and chargebacks). The supply prices for sample product are fixed based on contractually agreed prices.

### Reliant

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

Commencing on June 30, 2003, each of Biovail and Reliant had the right to terminate this agreement for any reason. In the event that either party terminated this agreement, Biovail could elect to either pay Reliant a termination fee, or continue to pay Reliant trailing royalties on sales of the co-promoted products through to December 31, 2008. In the event that Biovail elected to continue to pay Reliant these royalties, Reliant could elect to terminate the payment of these royalties on the withdrawal from the market or sale of any of the products, in which case Biovail would pay Reliant the termination fee. This agreement was to expire on December 31, 2008.

Effective April 1, 2003, Biovail and Reliant amended certain terms of this agreement, such that Reliant was responsible for one-half of certain advertising and sales promotion costs incurred during 2003 related to the co-promoted products. Accordingly, Biovail's selling, general and administrative expenses in 2003 were recorded net of a reimbursement of \$25,000,000 received from Reliant. The amended terms also increased the tiered co-promotion fee payable to Reliant.

Effective December 31, 2003, Biovail and Reliant mutually agreed to terminate the co-promotion agreement (as amended). Consequently, Biovail recorded a charge of \$61,348,000 to extinguish its trailing royalty obligation to Reliant.

In connection with the co-promotion agreement, Biovail, together with certain of Reliant's existing lenders, established a \$115,000,000 secured credit facility in favour of Reliant. Biovail committed to fund up to \$70,000,000 of this credit facility. Interest was calculated daily on the outstanding advances at U.S. prime plus a margin of 2%. Coincident with the termination of the co-promotion agreement, Reliant elected to prepay all of the outstanding advances, plus accrued interest of \$3,195,000. In December 2003, Reliant paid Biovail \$64,266,000 in cash and, in exchange for the remaining \$8,929,000 owing, Biovail agreed to subscribe to Series D Preferred Units of Reliant (as described in note 9 Long-Term Investments).

### 23. RESEARCH AND DEVELOPMENT COLLABORATIONS

In the ordinary course of business, the Company enters into research and development collaborations with third parties to provide formulation and other services for its products under development. These collaborations target the Company's therapeutic areas of focus cardiovascular (including Type II diabetes), pain management and central nervous system, and typically include formulation and product-development services being rendered by the developer. The developer may utilize its own technology, and, in other cases, the Company will allow access to its technology for the formulation and development of the product(s). In some cases, the Company has an ownership interest or an option to take an ownership position in the developer. In no case is the Company responsible for any of the developers' third-party liabilities, nor has the Company guaranteed any debts, nor is the Company required under any circumstances to exercise any of its options.

These third-party developers are typically compensated on the basis of fees for service, milestone payments, royalties from the future sales of the products under development, or some combination of these bases. In addition, in the ordinary course of business, the Company may enter into research and development collaborations with third parties whereby the Company may provide contract research, formulation development and other services to those third parties. The Company is typically

compensated on the basis of fees for service, milestone payments, royalties from future sales of the product(s), or some combination of these bases.

**Ethypharm**

In April 2002 (as amended in September 2003 and February 2004), Biovail licensed from Ethypharm the rights to market Tramadol ODT and Tramadol/APAP, as well as four other products in the United States, Canada and Mexico. Biovail will pay Ethypharm a milestone payment of \$1,000,000 if Tramadol ODT is approved by the FDA, and a royalty on any future sales of Tramadol/APAP. Biovail will also pay up to \$45,000,000 in milestone payments on the first regulatory approval of the four other products within the United States, Canada or Mexico, as well as royalties on any future sales of these products. Biovail has also entered into a cross-license agreement with Ethypharm, whereby the two companies grant to each other non-exclusive licenses to use Biovail's CEFORM technology and Ethypharm's Flashtab technology, respectively, relating to the development of new rapid dissolve pharmaceutical products. Biovail has not made any milestone payments to Ethypharm.

**Depomed**

In May 2002, Biovail obtained from Depomed the rights to manufacture and market 500 mg tablets of Glumetza in the United States and Canada. Glumetza is a once-daily, extended-release formulation of metformin HCl for the treatment of Type II diabetes. The 500 mg tablets utilize Depomed's Gastric Retention drug delivery technology. Depomed is responsible for completing the clinical development program in support of this product. If this product is approved by the FDA, Biovail will pay Depomed a \$25,000,000 milestone fee, as well as royalties on any future sales of this product. Biovail has the option to reduce certain of those royalties for a one-time payment to Depomed of \$35,000,000. Biovail has not made any milestone payments to Depomed.

In April 2004, Biovail and Depomed amended certain terms of the license agreement. Under the amended agreement, Biovail will pay Depomed a royalty on any future sales of Biovail's 1000 mg tablets of Glumetza, which utilize Biovail's Smartcoat drug delivery technology. In exchange, Depomed allowed Biovail to use Depomed's clinical data on the 500 mg tablets to support and accelerate regulatory submissions for Biovail's 1000 mg tablet. In June 2004, the FDA accepted Biovail's NDA submission for Glumetza 500 mg and 1000 mg tablets for review. In August 2004, Biovail's New Drug Submission for Glumetza was accepted for review by the Canadian Therapeutic Products Directorate. In February 2005, Biovail received an Approvable Letter from the FDA for Glumetza, which indicated that approval is pending completion of discussions with regard to a manufacturing issue.

**Procyon Biopharma Inc. ("Procyon")**

In January 2002 (as amended in January 2004), the Company licensed from Procyon the rights to manufacture and market Fibrostat in the United States. Fibrostat is a topical therapeutic for scar management. The Company will pay aggregate fees of approximately \$7,650,000 to Procyon for the development of Fibrostat, subject to the attainment of certain milestones. If Fibrostat is approved by the FDA, the Company will pay a licensing fee to Procyon of approximately \$4,200,000, as well as royalties on any future sales of Fibrostat. Biovail has not paid any fees to Procyon.

In January 2005, Procyon announced the results of a Phase IIb clinical trial with Fibrostat, which indicated that although Fibrostat was safe and well tolerated, it did not have the desired efficacy. Biovail is currently reviewing the results of the Phase IIb study.

**Flamel Technologies S.A. ("Flamel")**

In February 2003, Biovail licensed from Flamel the rights to manufacture and market an oral solid controlled-release formulation of acyclovir, for the treatment of episodic and recurrent genital herpes infections, in the United States and Canada. Biovail paid Flamel a non-refundable up-front payment of \$500,000, and Biovail was to pay Flamel up to \$6,500,000 on the achievement of certain developmental milestones, as well as royalties on any future sales of this product. Biovail did not make any milestone payments to Flamel.

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Under the license agreement, Biovail was responsible for the clinical program required for FDA approval of the product. After meeting with the FDA on several occasions, it was determined that the extent of the clinical program and the resultant costs increased substantially relative to Biovail's original estimate and, for this reason, Biovail elected not to initiate this program. Biovail was in discussions with Flamel regarding the clinical program when, in March 2005, Flamel decided to terminate the license agreement with Biovail.

### 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.

Because it cannot currently predict or foresee the outcome of the legal proceedings it is involved in, or reasonably estimate the amount of any losses that may result from these proceedings, the Company has not accrued for any loss contingencies related to these proceedings at December 31, 2004. An adverse outcome in certain of these proceedings could have a material adverse effect on the Company's results of operations, financial position and cash flows.

#### Intellectual property

RhoxalPharma Inc. ("RhoxalPharma") has filed an Abbreviated New Drug Submission ("ANDS") in Canada, seeking approval of a generic version of Tiazac® (120 mg, 180 mg, 240 mg, 300 mg and 360 mg). The Company has two patents listed in the Patent Registry and has instituted legal proceedings that will prohibit the issuance of a Notice of Compliance to RhoxalPharma until said proceedings are concluded, or until the expiry of 24 months from the date of the Notice of Allegation, whichever is earlier.

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

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

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

Torpharm, Inc. ("Torpharm") has filed an Abbreviated New Drug Application ("ANDA") in the United States, seeking approval for a generic version of Cardizem® CD (120 mg, 180 mg, 240 mg and 300 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a court decision of non-infringement or patent invalidity or a court decision to abbreviate the 30-month stay.

Torpharm has filed an ANDA in the United States, seeking approval for a generic version of Tiazac® (120 mg, 180 mg, 240 mg, 300 mg and 360 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Torpharm until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.



Anchen Pharmaceuticals Inc. ("Anchen") has filed an ANDA in the United States, seeking approval for a generic version of Wellbutrin XL (150 mg and 300 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Anchen until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

Abrika LLLP ("Abrika") has filed an ANDA in the United States, seeking approval for a generic version of Wellbutrin XL (150 mg and 300 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Abrika until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

Impax Laboratories Inc. ("Impax") has filed an ANDA in the United States, seeking approval for a generic version of Wellbutrin XL (150 mg and 300 mg). The Company has instituted legal proceedings pursuant to the Hatch-Waxman Act that preclude the FDA from granting approval to Impax until the earliest of 30 months after the filing of the legal suit, a final court decision of non-infringement or patent invalidity, or a court decision to abbreviate the 30-month stay.

#### **Product liability**

Biovail Pharmaceuticals, Inc. ("BPI") has been named in two Complaints alleging personal injuries arising from Plaintiffs' use of Dura-Vent, a product containing phenylpropranolamine ("PPA") and formerly marketed by BPI. One case has been dismissed without prejudice while the Company has never been served with a summons in the second case, which is not being prosecuted against the Company. The Company believes that these claims are without merit and, in the event these actions proceed further, they will be vigorously defended.

#### **Antitrust**

Several class action complaints have been filed against the Company in which the Plaintiffs have alleged that Biovail has improperly impeded the approval of a generic form of Tiazac®. The Company believes that the complaints are without merit and that the Company's actions were in accordance with its rights as contained in the Hatch-Waxman Amendments and the law. Moreover, the position of the Company is that it is not responsible for Andrx Corporation's ("Andrx") inability to receive timely final marketing approval from the FDA for its generic Tiazac® considering that the Andrx product did not receive FDA approval for a lengthy period following the removal of all legal or regulatory impediments by the Company. The Company has filed its Motion for Summary Judgment seeking to dismiss those of the actions pending in federal court. In the meantime, similar cases pending in the state court in California have been stayed.

Several class action suits have been commenced jointly against the Company, Elan and Teva relating to an agreement between the Company and Elan for the in-licensing of Adalat CC products from Elan. The agreement in question has since been dissolved as a result of a settlement agreement with the FTC. Biovail believes these suits are without merit since, among other things, any delay in the marketing or out-licensing of the Company's Adalat CC product was due to manufacturing difficulties the Company encountered and not because of any improper activity on its part. The Company has filed an extensive Motion for the summary dismissal of these actions. The Court has denied the Company's motion to dismiss the damage claims brought on behalf of a purported class of so-called "direct purchasers", generally consisting of distributors and large chain drug stores, but dismissed the claims of a class of consumers and "end-payers" without prejudice. The consumer and "end-payer" claims were re-filed in California state court. The actions will proceed on their merits through normal legal process.

#### **Securities Class Actions**

In the fourth quarter of 2003, a number of Securities Class Action Complaints were filed naming Biovail and certain officers. The Complaints allege the Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. More specifically the Complaints allege that Biovail and certain of its officers made materially false and misleading statements during certain specified periods of time.

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The Plaintiffs filed a Consolidated Amended Class Action Complaint to which the Company responded by filing a Motion to dismiss. The Court has denied the Company's motion to dismiss. The action will proceed on its merits through normal legal process.

### **Defamation and tort**

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

The Company filed a motion for summary dismissal of this action. The Court has dismissed a number of claims, with the remaining claims to proceed through the litigation process on the merits.

### **General civil actions**

Complaints have been filed by the City of New York, the State of Alabama and the New York State Counties of Onondaga, Rockland, Erie and Westchester, claiming that the Company, and numerous other pharmaceutical companies, made fraudulent misstatements concerning the "average wholesale price" of their prescription drugs, resulting in overpayments by the plaintiffs for pharmaceutical products sold by the companies. However, given the paucity of Biovail products at issue and the very brief time frame in respect of such sales, the Company anticipates that even if the actions were successful, any recovery against Biovail would likely not be material.

### **Governmental and regulatory enquiries**

The Company has received notification from the U.S. Attorney, District of Massachusetts, on behalf of the U.S. Office of the Inspector General ("OIG") of Health and Human Services that a preliminary administrative inquiry has been initiated into the Company's clinical experience and marketing programs related to Cardizem® LA. The Company is providing the OIG its full cooperation in this inquiry.

On November 20, 2003, the Company received a notification from the SEC indicating that the Commission would be conducting an informal inquiry relating to the Company's financial performance for the fiscal year 2003. On March 3, 2005, the Company received a subpoena from the SEC. The subpoena reflects the fact that the Commission has entered a formal order of investigation. The subpoena seeks information about the Company's financial performance for the fiscal year 2003, but the scope of the investigation is broader, and the period under review now goes back to June 2001. The Company is providing the SEC with its full cooperation.

The Company received requests for information from the Ontario Securities Commission ("OSC") as part of the OSC's continuous disclosure review of public companies. The Company cooperated with the OSC in providing the requested information in respect of these enquiries. In addition, the Company received notification that the OSC "is conducting a routine enquiry into the trading of Biovail Corporation" securities prior to the issuance of press releases on October 3, 2003, which provided guidance for the third quarter, and October 30, 2003, which reported the financial results for the third quarter. Subsequently, the Company has received further requests for information and documentation. The Company is providing the OSC with its full cooperation.

## **25. CONTRACTUAL OBLIGATIONS**

### **Operating lease commitments**

The Company leases certain facilities, vehicles and equipment under operating leases. Rental expense was approximately \$10,300,000, \$7,800,000 and \$5,000,000 in 2004, 2003 and 2002, respectively.

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Minimum future rental payments under non-cancelable operating leases for the years ending December 31 are as follows:

2005	\$ 9,900
2006	9,200
2007	8,100
2008	6,600
2009	4,700
Thereafter	20,100
	<hr style="border: 1px solid black;"/>
<b>Total minimum future rental payments<sup>(1)</sup></b>	<b>\$ 58,600</b>
	<hr style="border: 1px solid black;"/>

(1)

Minimum future rental payments have not been reduced by the following sublease rentals due under a non-cancelable sublease:

2005 \$188,000; 2006 \$288,000; 2007 \$301,000; and 2008 \$102,000.

### Contingent milestone payments

The Company may be required to make the following milestone payments under research and development collaborations with third parties. These payments are contingent on the achievement of specific developmental, regulatory and/or commercial milestones. Because it is uncertain if and when these milestones will be achieved, the Company has not accrued for these payments at December 31, 2004.

	<b>Third-party collaborator</b>	<b>Amount</b>
		<hr style="border: 1px solid black;"/>
Tramadol ODT, and four other products	Ethypharm	\$ 46,000
Glumetza	Depomed	25,000
Athpharma products	Athpharma	24,200
Pharma Pass products	PPII	14,235
Fibrostat	Procyon	11,850
Colonic Delivery System products	PPII	10,000
Other	Other	2,400
		<hr style="border: 1px solid black;"/>
		<b>\$ 133,685</b>
		<hr style="border: 1px solid black;"/>

### Purchase obligations

In connection with the acquisition of Ativan® and Isordil® (as described in note 3 Disposition and Acquisitions of Intangible Assets), Biovail will pay Wyeth a \$20,000,000 additional rights payment, increasing at 10% per annum, on the approval by the FDA of the first Ativan® line extension product that may be developed by Biovail. This payment has not been recorded as a liability at December 31, 2004, and it is in addition to the Ativan® and Isordil® fixed annual payments recorded in long-term obligations.

In connection with the manufacture and supply of Vasotec® and Vaseretic®, Biovail is obligated to make semi-annual payments to Merck for minimum product quantities (regardless of the actual product supplied). The remaining payments are due semi-annually, on April 1 and October 1 of each year, in the following gross annual amounts: 2005 \$3,810,000; and 2006 \$3,589,000. These payments have not been recorded as liabilities at December 31, 2004, and they are in addition to the Vasotec® and Vaseretic® minimum fixed royalty payments recorded in long-term obligations.

**26. SEGMENT INFORMATION**

The Company operates in one operating segment – the development and commercialization of pharmaceutical products. Management assesses performance and makes resource decisions based on the consolidated results of operations of this operating segment. Substantially all of the operations of the Company are directly engaged in or support this operating segment. Other operations are not material and share many of the same economic and operating characteristics as pharmaceutical products and, accordingly, they are included with pharmaceutical products for purposes of segment reporting.

**Geographic information**

The following table displays revenue and long-lived assets by geographic area:

	Revenue <sup>(1)</sup>			Long-lived assets <sup>(2)</sup>		
	2004	2003	2002	2004	2003	2002
Canada	\$ 110,511	\$ 124,800	\$ 62,848	\$ 108,988	\$ 114,660	\$ 94,519
United States and Puerto Rico	767,562	692,853	713,615	184,793	182,495	271,122
Barbados and other Caribbean			9,533	1,007,448	1,071,082	1,039,868
Other countries	8,470	6,069	2,029	27,134	28,539	27,340
	<b>\$ 886,543</b>	<b>\$ 823,722</b>	<b>\$ 788,025</b>	<b>\$ 1,328,363</b>	<b>\$ 1,396,776</b>	<b>\$ 1,432,849</b>

(1) Revenue is attributed to countries based on the location of the customer.

(2) Consists of property, plant and equipment, goodwill, intangible and other assets, net of depreciation and amortization. Property, plant and equipment are attributed to countries based on their physical location, goodwill is attributed to countries based on the location of the related acquired business, and intangible and other assets are attributed to countries based on ownership rights.

**Major customers**

The following table identifies external customers that accounted in 2004 for 10% or more of the Company's total revenue:

	Percentage of total revenue		
	2004	2003	2002
Customer A	36%	9%	7%
Customer B	17	13	23
Customer C	13	17	11

**27. COMPARATIVE FIGURES**

Certain of the prior years' figures have been reclassified to conform to the presentation adopted in 2004.

## MANAGEMENT REPORT

The Company's management is responsible for preparing the accompanying consolidated financial statements in conformity with Canadian generally accepted accounting principles ("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.

The consolidated financial statements and information contained in the Management's Discussion and Analysis ("MD&A") necessarily includes amounts based on informed judgments and estimates of the expected effects of current events and transactions with appropriate considerations to materiality. In addition, in preparing the financial information management must interpret the requirements described above, make determinations as to the relevancy of information to be included, and make estimates and assumptions that affect reported information. The MD&A also includes information regarding the estimated impact of current transactions and events, sources of liquidity and capital resources, operating trends, risks and uncertainties. Actual results in the future may differ materially from our present assessment of this information because future events and circumstances may not occur as expected.

The Company maintains a system of internal accounting controls designed to provide reasonable assurance, at a reasonable cost, that assets are safeguarded and that transactions are executed and recorded in accordance with the Company's policies for doing business. This system is supported by written policies and procedures for key business activities; the hiring of qualified, competent staff; and by a continuous planning and monitoring program.

Ernst & Young LLP has been engaged by the Company's shareholders to audit the consolidated financial statements. During the course of their audit, Ernst & Young LLP reviewed the Company's system of internal controls to the extent necessary to render their opinion on the consolidated financial statements. However, Ernst & Young LLP was not engaged to audit the Company's internal controls over financial reporting.

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.

**DOUGLAS J. P. SQUIRES**  
Chief Executive Officer

**CHARLES A. ROWLAND, JR.**  
Senior Vice President and  
Chief Financial Officer  
F-48

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**AUDITORS' REPORT**

To the Shareholders of  
Biovail Corporation

We have audited the consolidated balance sheets of **Biovail Corporation** as at December 31, 2004 and 2003 and the consolidated statements of income (loss), shareholders' equity and cash flows for each of the years in the three-year period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, these consolidated financial statements present fairly, in all material respects, the financial position of the Company as at December 31, 2004 and 2003 and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2004 in accordance with Canadian generally accepted accounting principles.

On March 8, 2005, we reported separately to the shareholders of **Biovail Corporation** on the consolidated financial statements for the same periods, prepared in accordance with United States generally accepted accounting principles.

Toronto, Canada,  
March 8, 2005

Chartered Accountants

F-49

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## BIOVAIL CORPORATION

## CONSOLIDATED BALANCE SHEETS

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

	As at December 31	
	2004	2003
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents ( <i>note 5</i> )	\$ 34,324	\$ 133,261
Marketable securities ( <i>note 6</i> )	5,020	
Accounts receivable ( <i>note 7</i> )	148,762	179,374
Inventories ( <i>note 8</i> )	110,154	84,058
Deposits and prepaid expenses	16,395	15,759
	<u>314,655</u>	<u>412,452</u>
Long-term investments ( <i>note 9</i> )	54,270	92,756
Property, plant and equipment, net ( <i>note 10</i> )	186,556	173,804
Goodwill	102,909	103,429
Intangible assets, net ( <i>note 11</i> )	1,296,352	1,457,226
Other assets, net ( <i>note 12</i> )	57,438	57,937
	<u>\$ 2,012,180</u>	<u>\$ 2,297,604</u>
<b>LIABILITIES</b>		
<b>Current</b>		
Accounts payable	\$ 41,120	\$ 67,932
Accrued liabilities ( <i>note 13</i> )	82,917	105,201
Minority interest ( <i>note 4</i> )		679
Income taxes payable	24,594	24,175
Deferred revenue ( <i>note 14</i> )	8,141	5,765
Current portion of long-term obligations ( <i>note 15</i> )	33,465	58,816
	<u>190,237</u>	<u>262,568</u>
Deferred revenue ( <i>note 14</i> )	16,525	14,500
Deferred leasehold inducements	4,914	
Long-term obligations ( <i>note 15</i> )	442,186	753,710
	<u>653,862</u>	<u>1,030,778</u>
<b>SHAREHOLDERS' EQUITY</b>		
Common shares, no par value, unlimited shares authorized, 159,383,402 and 158,796,978 issued and outstanding at December 31, 2004 and 2003, respectively ( <i>notes 2 and 16</i> )	1,523,021	1,469,627
Contributed surplus ( <i>note 2</i> )	65,505	2,290
Deficit ( <i>note 2</i> )	(258,518)	(222,931)

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	As at December 31	
Cumulative translation adjustment	28,310	17,840
	1,358,318	1,266,826
	\$ 2,012,180	\$ 2,297,604
Commitments and contingencies (notes 2, 3, 24 and 25)		

F-50



On behalf of the Board:

**EUGENE N. MELNYK**

Chairman of the Board

**MICHAEL VAN EVERY**

Director

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

F-51

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## BIOVAIL CORPORATION

## CONSOLIDATED STATEMENTS OF INCOME (LOSS)

In accordance with Canadian generally accepted accounting principles  
(All dollar amounts expressed in thousands of U.S. dollars, except per share data)

	Years ended December 31		
	2004	2003	2002
<b>REVENUE</b>			
Product sales	\$ 841,446	\$ 632,898	\$ 645,986
Research and development	20,452	14,239	28,425
Co-promotion, royalty and licensing	24,645	176,585	113,614
	<u>886,543</u>	<u>823,722</u>	<u>788,025</u>
<b>EXPENSES</b>			
Cost of goods sold (notes 2 and 3)	229,528	139,456	164,706
Research and development (note 2)	72,500	86,570	52,150
Selling, general and administrative (note 2)	274,553	242,771	166,397
Amortization	163,088	240,650	125,849
Write-down of assets, net of gain on disposal (note 17)	40,685	82,189	31,944
Extinguishment of royalty obligation (note 22)		61,348	
Settlements (note 18)		(34,055)	
	<u>780,354</u>	<u>818,929</u>	<u>541,046</u>
Operating income	106,189	4,793	246,979
Interest income	1,034	7,165	3,608
Interest expense (note 15)	(40,783)	(41,286)	(32,005)
Foreign exchange gain (loss)	(564)	(14,007)	700
Equity loss (note 9)	(4,179)	(1,010)	
	<u>61,697</u>	<u>(44,345)</u>	<u>219,282</u>
Income (loss) before provision for (recovery of) income taxes	61,697	(44,345)	219,282
Provision for (recovery of) income taxes (note 19)	8,950	(4,000)	11,729
	<u>52,747</u>	<u>(40,345)</u>	<u>207,553</u>
Net income (loss)	\$ 52,747	\$ (40,345)	\$ 207,553
<b>Earnings (loss) per share (note 20)</b>			
Basic	\$ 0.33	\$ (0.25)	\$ 1.37
Diluted	\$ 0.33	\$ (0.25)	\$ 1.29
<b>Weighted average number of common shares outstanding (000s) (note 20)</b>			
Basic	159,115	158,516	151,960
Diluted	159,258	158,516	160,463

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

## BIOVAIL CORPORATION

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

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

## Common shares

	Shares (000s)	Amount	Contributed surplus	Executive Stock Purchase Plan loans	Warrants outstanding	Deficit	Cumulative translation adjustment	Total
<b>Balance, January 1, 2002</b>	157,496	\$ 1,430,457	\$ 3,391	\$ (9,988)	\$ 6,221	\$ (1,935)	\$ (2,729)	\$ 1,425,417
Issued on the exercise of stock options (note 16)	2,197	20,480	(1,184)					19,296
Issued under Employee Stock Purchase Plan (note 16)	17	463						463
Cancelled under stock repurchase program (note 16)	(12,872)	(114,896)				(388,204)		(503,100)
Issued on exercise of warrants (note 16)	11,282	119,044			(6,221)			112,823
Stock-based compensation (note 2)			1,999					1,999
Net income						207,553		207,553
Foreign currency translation adjustment							336	336
<b>Balance, December 31, 2002</b>	158,120	1,455,548	4,206	(9,988)		(182,586)	(2,393)	1,264,787
Issued on the exercise of stock options (note 16)	663	13,597	(2,000)					11,597
Issued under Employee Stock Purchase Plan (note 16)	14	482						482
Stock-based compensation (note 2)			84					84
Repayment of Executive Stock Purchase Plan loans				9,988				9,988
Net loss						(40,345)		(40,345)
Foreign currency translation adjustment							20,233	20,233
<b>Balance, December 31, 2003</b>	158,797	1,469,627	2,290			(222,931)	17,840	1,266,826
Cumulative effect of change in accounting policy (note 2)		40,945	47,389			(88,334)		
Issued on the exercise of stock options (note 16)	561	12,016	(4,437)					7,579
Issued under Employee Stock Purchase Plan (note 16)	25	433						433
Stock-based compensation (note 2)			20,403					20,403
Cancellation of employee stock options			(140)					(140)
Net income						52,747		52,747
Foreign currency translation adjustment							10,470	10,470
<b>Balance, December 31, 2004</b>	159,383	\$ 1,523,021	\$ 65,505	\$	\$	\$ (258,518)	\$ 28,310	\$ 1,358,318



## BIOVAIL CORPORATION

## CONSOLIDATED STATEMENTS OF CASH FLOWS

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

	Years ended December 31		
	2004	2003	2002
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net income (loss)	\$ 52,747	\$ (40,345)	\$ 207,553
<b>Adjustments to reconcile net income (loss) to cash provided by operating activities</b>			
Depreciation and amortization (notes 10 and 11)	186,419	257,072	136,718
Amortization and write-down of deferred financing costs (note 12)	4,322	2,975	2,267
Amortization of discounts on long-term obligations (note 15)	3,897	7,427	5,329
Stock-based compensation (note 2)	20,403	84	1,999
Write-down of assets (note 17)	42,156	82,189	31,944
Gain on disposal of intangible assets (note 17)	(1,471)		
Equity loss (note 9)	4,179	1,010	
Receipt of leasehold inducements	5,232		
Future income taxes (note 19)			(9,771)
Other	(619)	4,871	
Changes in operating assets and liabilities (note 21)	(40,175)	(33,304)	(41,935)
<b>Net cash provided by operating activities</b>	<b>277,090</b>	<b>281,979</b>	<b>334,104</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Additions to property, plant and equipment	(28,029)	(36,923)	(61,382)
Acquisitions of businesses, net of cash acquired (note 4)	(9,319)	(25,741)	(240,581)
Purchases of marketable securities (note 6)	(5,038)		
Acquisitions of long-term investments (note 9)	(2,877)	(4,555)	(85,119)
Proceeds on disposal of intangible assets (note 3)	3,000	10,000	
Acquisitions of intangible assets (note 3)		(242,298)	(375,385)
Advance of loan receivable (note 22)		(40,000)	(30,000)
Repayment of loan receivable (note 22)		61,071	
<b>Net cash used in investing activities</b>	<b>(42,263)</b>	<b>(278,446)</b>	<b>(792,467)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Advances (repayments) under revolving term credit facility, including financing costs (note 15)	(282,550)	169,800	107,895
Repayments of other long-term obligations (note 15)	(66,288)	(119,344)	(41,980)
Issuance of common shares, net of issue costs (note 16)	8,012	12,079	19,615
Proceeds on termination of interest rate swaps (note 15)	6,300		
Repayment of Executive Stock Purchase Plan loans (note 16)		9,988	
Repurchase of common shares (note 16)			(503,100)
Issuance of Senior Subordinated Notes, net of financing costs (note 15)			384,280
Proceeds from exercise of warrants (note 16)			112,823

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	Years ended December 31		
	2020	2019	2018
<b>Net cash provided by (used in) financing activities</b>	(334,526)	72,523	79,533
Effect of exchange rate changes on cash and cash equivalents	762	1,125	19
<b>Net increase (decrease) in cash and cash equivalents</b>	(98,937)	77,181	(378,811)
Cash and cash equivalents, beginning of year	133,261	56,080	434,891
<b>Cash and cash equivalents, end of year</b>	\$ 34,324	\$ 133,261	\$ 56,080

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

**BIOVAIL CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**In accordance with Canadian generally accepted accounting principles  
(All tabular dollar amounts expressed in thousands of U.S. dollars, except per share data)**

**December 31, 2004**

**1. GOVERNING STATUTE AND NATURE OF OPERATIONS**

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

**2. SIGNIFICANT ACCOUNTING POLICIES**

**Basis of presentation**

The consolidated financial statements have been prepared by the Company in U.S. dollars and in accordance with Canadian generally accepted accounting principles ("GAAP"), applied on a consistent basis. Consolidated financial statements prepared in U.S. dollars and in accordance with U.S. GAAP are separately made available to all shareholders and filed with necessary regulatory authorities.

**Principles of consolidation**

The consolidated financial statements include the accounts of the Company and those of all its wholly-owned and majority-owned subsidiaries. All significant intercompany transactions and balances have been eliminated.

**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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Under certain agreements, management relies on estimates and assumptions made by the Company's third-party licensees. Significant estimates made by management include allowances for accounts receivable and inventories, provisions for product returns, rebates and chargebacks, the useful lives of long-lived assets, the expected future cash flows used in evaluating long-lived assets and investments for impairment, the realizability of future tax assets, and the allocation of the purchase price of acquired assets and businesses. 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 financial position and results of operations could be materially impacted.

**Fair value of financial instruments**

Fair value of a financial instrument is defined as the amount at which the instrument could be exchanged in a current transaction between willing parties. The estimated fair values of cash equivalents, marketable securities, accounts receivable, accounts payable, accrued liabilities and income taxes payable approximate their carrying values due to their short maturity periods. The fair values of marketable securities, long-term investments, long-term obligations and derivative financial instruments are based on quoted market prices, if available, or estimated discounted future cash flows.

**Cash and cash equivalents**

Cash and cash equivalents include highly liquid investments with original maturities of 90 days or less when purchased.

**Marketable securities**

Marketable securities comprise investment-grade debt securities with original maturities greater than 90 days when purchased and are accounted for as being available-for-sale. These securities are reported at amortized cost, which approximates fair value. Realized gains and losses on the sale of these securities are recognized in net income or loss. The amortization of acquisition premiums or discounts is recorded as a deduction from or addition to interest income earned on these securities.





**Accounts receivable**

The Company performs ongoing credit evaluations of customers and generally does not require collateral. Allowances are maintained for potential credit losses based on the aging of accounts receivable, historical bad debts experience and changes in customer payment patterns.

**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 and rejected product are written off to cost of goods sold.

**Long-term investments**

Long-term investments, where the Company does not have the ability to exercise significant influence, are accounted for using the cost method. Declines in the fair value of these investments below their cost basis that are considered to be other-than-temporary are recognized in net income or loss.

A long-term investment over which the Company has the ability to exercise significant influence is accounted for using the equity method. The Company's share of the losses of this investee is recognized in net income or loss.

On an ongoing basis, the Company evaluates its long-term investments to determine if a decline in fair value is other-than-temporary. Factors that the Company considers include general market conditions, the duration and extent to which the fair value of an investment is below its cost basis and the Company's ability and intent to hold the investment.

**Property, plant and equipment**

Property, plant and equipment are reported at cost, less accumulated depreciation. Cost includes interest costs attributable to major capital projects prior to the related assets becoming available for productive use. 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

**Goodwill**

Goodwill represents the excess of the purchase price of acquired businesses over the fair value of the identifiable net assets acquired. Goodwill is not amortized but is tested for impairment by comparing the fair value of the reporting unit to which the goodwill relates to the carrying value of the reporting unit. The Company tests goodwill for impairment on an annual basis and between annual tests whenever events or changes in circumstances indicate that the fair value of the reporting unit may be below its carrying value.

**Intangible assets**

Intangible assets acquired through asset acquisitions or business combinations are initially recognized at fair value based on an allocation of the purchase price. Intangible assets with finite lives are amortized over their estimated useful lives. The Company

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does not have any indefinite-lived intangible assets. Intangible assets are reported at cost, less accumulated amortization. Amortization is generally calculated using the straight-line method based on the following estimated useful lives:

Trademarks	20 years
Acquired research and development	5-15 years
Product rights	8-20 years
Technology	15 years

### Acquired research and development

The costs of assets that are purchased through asset acquisitions or business combinations for a particular research and development project are capitalized as acquired research and development at the time of acquisition and amortized over their estimated useful lives. The amount allocated to acquired research and development is determined by identifying those specific in-process research and development projects that the Company intends to continue, and for which: (i) technological feasibility had not been established at the date of acquisition; and (ii) there was no alternative future use.

The efforts required to develop the acquired research and development into commercially viable products include the completion of the development stages of these projects, clinical-trial testing, regulatory approval and commercialization. The principal risks relating to these projects include the outcomes of the formulation development, clinical studies and regulatory filings. Since pharmaceutical products cannot be marketed without regulatory approvals, the Company will not receive any benefits unless regulatory approval is obtained. The completion of these projects may require significant amounts of future time and effort, as well as additional development costs, which may be incurred by the Company. Consequently, there is significant technological and regulatory approval risk associated with these projects at the date of acquisition.

The research being undertaken on these projects relates specifically to developing novel formulations of the associated molecules. Consequently, the Company does not foresee any alternative future benefit from the acquired research and development other than specifically related to these projects.

The fair value of acquired research and development is determined using an income approach on a project-by-project basis. The estimated future net cash flows related to these projects include the costs to develop these projects into commercially viable products, and the projected revenues to be earned on commercialization of these projects when complete. The discount rates used to present value the estimated future net cash flows related to each of these projects are determined based on the relative risk of achieving each of these project's net cash flows. The discount rates reflect the project's stage of completion and other risk factors, which include the nature and complexity of the product, the projected costs to complete, market competition and the estimated useful life of the product.

### Impairment of long-lived assets

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

The Company's evaluation of long-lived assets is based on management's assessment of potential indicators of impairment, such as damage or obsolescence, plans to discontinue use or restructure, and poor financial performance compared with original plans. While there were no significant indications of impairment at December 31, 2004, the Company is currently reviewing its strategic approach to commercializing its products in the United States. The outcome of this review is not presently determinable, but it could result in a write-down in the carrying values of certain of the Company's long-lived assets.

**Deferred financing costs**

Deferred financing costs are reported at cost, less accumulated amortization. Amortization is calculated using the straight-line method over the term of the related long-term obligations. Amortization expense related to deferred financing costs is included in interest expense.

**Deferred compensation plan**

The Company maintains a deferred compensation plan to provide certain employees with the opportunity to supplement their retirement income through the deferral of pre-tax income. The assets of this plan are placed in trust, and are recorded in other assets with a corresponding liability recorded in long-term obligations. The terms of the trust agreement state that the assets of the trust are available to satisfy the claims of general creditors of the Company in the event of bankruptcy, thereby qualifying this trust as a rabbi trust for U.S. income tax purposes. Changes in the value of the assets held by this trust, and a corresponding charge or credit to compensation expense (to reflect the fair value of the amount owed to the participants), are recognized in net income or loss.

**Derivative financial instruments**

The Canadian Institute of Chartered Accountants ("CICA") Accounting Guideline ("AcG") 13, "Hedging Relationships" establishes the criteria for identification, designation, documentation and effectiveness of hedging relationships, for the purpose of applying hedge accounting. AcG-13 does not specify hedge-accounting methods. AcG-13 is to be applied to hedging relationships in effect in fiscal years beginning on or after July 1, 2003. The Company adopted the new guideline effective January 1, 2004. The adoption of AcG-13 had no effect on the Company's financial position or results of operations.

The Company manages its exposure to interest rate risks through the use of derivative financial instruments that are designated as a hedge of an identified portion of a recognized long-term obligation. The Company does not utilize derivative financial instruments for trading or speculative purposes. Net receipts or payments relating to the derivative financial instruments are recorded as an adjustment to interest expense. The Company does not recognize unrealized gains or losses resulting from changes in the marked-to-market values of the derivative financial instruments, or from changes in the fair values of the underlying hedged item.

**Deferred leasehold inducements**

Leasehold inducements comprise free rent and leasehold improvement incentives. Leasehold inducements are deferred and amortized to reduce rental expense on a straight-line basis over the term of the related lease.

**Foreign currency translation**

The financial statements of the Company's operations having a functional currency other than U.S. dollars 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 shareholders' equity. Foreign currency gains and losses related to the translation of the Company's Irish operation into its U.S. dollar functional currency are recognized in net income or loss.

Foreign currency exchange gains and losses on transactions occurring in a currency other than an operation's functional currency are recognized in net income or loss.

**Revenue recognition**

Revenue is deemed to be realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the Company's price to the customer is fixed or determinable, and collectibility is reasonably assured. Management evaluates revenue arrangements with multiple deliverables to determine whether the deliverables

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represent one or more units of accounting. A delivered item is considered a separate unit of accounting if the following separation criteria are met: (i) the delivered item has standalone value to the customer; (ii) the fair value of any undelivered items can be reliably determined; and (iii) the delivery of undelivered items is probable and substantially in the Company's control. The relevant revenue recognition accounting policy is applied to each separate unit of accounting.

### **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 reported as deferred revenue.

Revenue from product sales is recognized net of provisions for estimated discounts and allowances, returns, rebates and chargebacks. In connection with these provisions related to sales of products manufactured by the Company for distribution by third-party licensees, the Company relies on estimates and assumptions made by these licensees. The Company offers discounts for prompt payment and other incentive allowances to customers. Provisions for these 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 these returns are estimated based on historical return and exchange levels, and third-party data with respect to inventory levels in the Company's distribution channels. The Company is subject to rebates and chargebacks on sales made under governmental and managed care pricing programs. Provisions for these rebates and chargebacks are estimated based on historical experience, contractual sales terms with wholesalers and indirect customers, and relevant statutes with respect to governmental pricing programs.

### **Research and development**

Research and development revenue attributable to the performance of contract services is recognized as the services are performed, in accordance with the terms of the specific development contracts. On long-term research and development collaborations, revenue is recognized on a proportionate basis relative to the total level of effort necessary to meet all regulatory and developmental requirements. Costs and profit margin related to these collaborations that are in excess of amounts billed are recorded in accounts receivable, and amounts billed related to these collaborations that are in excess of costs and profit margin are recorded in deferred revenue. Contingent revenue attributable to the achievement of regulatory or developmental milestones is recognized only on the achievement of the applicable milestone. Non-refundable, up-front fees for access to the Company's proprietary technology in connection with certain research and development collaborations are deferred and recognized as revenue on a systematic basis over the term of the related collaboration.

### **Co-promotion**

Co-promotion revenue is recognized based on the terms of the specific co-promotion contracts, and is generally determined based on a percentage of the net sales of the co-promoted products. Sales and marketing costs related to co-promotion revenue are recorded in selling, general and administrative expenses. The Company did not earn any co-promotion revenue in 2004.

### **Royalty and licensing**

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. Licensing revenue is deferred and recognized on a systematic basis over the licensing period.

### **Shipping and handling costs**

Shipping and handling costs comprising freight-out are included in cost of goods sold. The Company does not charge customers for shipping and handling costs.

**Research and development expenses**

Research costs related to proprietary research and development programs are expensed as incurred. Development costs related to proprietary research and development programs are expensed as incurred unless they meet the criteria for deferral. The Company did not have any deferred development costs at December 31, 2004 or 2003. Milestone payments made to third parties in connection with research and development collaborations are expensed as incurred prior to the receipt of regulatory approval. Milestone payments made to third parties after regulatory approval is received are capitalized and amortized over the estimated useful lives of the related products.

Costs associated with revenue generated from research and development collaborations, and with providing contract research services are included in research and development expenses and were \$12,956,000, \$9,503,000 and \$11,570,000 in 2004, 2003 and 2002, respectively.

**Advertising costs**

Advertising costs comprise product samples, print media and promotional materials. Advertising costs related to new product launches are expensed on the first showing of the product. The Company did not have any deferred advertising costs at December 31, 2004 or 2003.

Advertising costs expensed in 2004, 2003 and 2002 were \$29,040,000, \$23,013,000 and \$18,795,000, respectively. These costs are included in selling, general and administrative expenses.

**Co-promotion fees**

Co-promotion fees payable by the Company are accrued based on a percentage of the net sales of the co-promoted products. Co-promotion fees are included in selling, general and administrative expenses. The Company did not incur any co-promotion fees in 2004.

**Stock-based compensation**

CICA Handbook Section 3870, "Stock-Based Compensation and Other Stock-Based Payments" established standards for the recognition, measurement and disclosure of stock-based compensation, and other stock-based payments. Under the provisions of CICA Handbook Section 3870, prior to January 1, 2004, companies could either measure the compensation cost of equity instruments issued under employee compensation plans using a fair value-based method or could recognize compensation cost using another method, such as the intrinsic value-based method. However, if another method was applied, pro forma disclosure of net income or loss and earnings or loss per share was required in the financial statements as if the fair value-based method had been applied. Effective January 1, 2004, CICA Handbook Section 3870 required that all stock-based compensation be measured and expensed using a fair value-based methodology.

Prior to January 1, 2004, the Company recognized employee stock-based compensation cost under the intrinsic value-based method and provided pro forma disclosure of net income or loss and earnings or loss per share as if the fair value-based method had been applied. Effective January 1, 2004, the Company adopted the fair value-based method for recognizing employee stock-based compensation on a retroactive basis to January 1, 1996, without restatement of prior periods. At January 1, 2004, the cumulative effect of the change in accounting policy on prior periods resulted in a charge to deficit of \$88,334,000 relating the fair value of stock options vested since January 1, 1996, an increase to common shares of \$40,945,000 related to the fair value of stock options exercised since January 1, 1996, and an increase of \$47,389,000 to contributed surplus related to the fair value of options vested but unexercised since January 1, 1996.

In 2004, the Company recorded total stock-based compensation expense of \$20,403,000, of which \$1,250,000 was included in cost of goods sold, \$2,007,000 was included in research and development expenses, and \$17,146,000 was included in selling, general and administrative expenses. No compensation expense for stock options granted to employees at fair market value was included in the determination of net income or loss in 2003 or 2002; however, the Company recorded compensation expense in those years for stock options granted (at the date of acquisition in October 2000) to the employees of DJ Pharma, Inc. ("DJ Pharma"). For

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2003 and 2002, the following table presents the Company's pro forma net income or loss and earnings or loss per share as if the fair value-based method of CICA Handbook Section 3870 had been applied in those years for all stock options granted:

	<b>2003</b>	<b>2002</b>
Net income (loss) as reported	\$ (40,345)	\$ 207,553
Pro forma stock-based compensation expense determined under fair value-based method	(16,903)	(14,254)
<b>Pro forma net income (loss)</b>	<b>\$ (57,248)</b>	<b>\$ 193,299</b>
<b>Basic earnings (loss) per share</b>		
As reported	\$ (0.25)	\$ 1.37
Pro forma	\$ (0.36)	\$ 1.27
<b>Diluted earnings (loss) per share</b>		
As reported	\$ (0.25)	\$ 1.29
Pro forma	\$ (0.36)	\$ 1.20

The weighted average fair values of all stock options granted during 2004, 2003 and 2002 were \$8.09, \$11.48 and \$13.58, respectively, estimated as of the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Expected option life (years)	4.0	4.0	3.8
Volatility	55.8%	54.7%	46.8%
Risk-free interest rate	3.7%	3.9%	4.5%
Dividend yield	%	%	%

The Black-Scholes option-pricing model used by the Company to calculate option values, was developed to estimate the fair value of freely tradeable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. This model also requires highly subjective assumptions, including future stock price volatility and expected time until exercise, which greatly affect the calculated values.

### Income taxes

Income taxes are accounted for under the liability method. Future 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 future tax assets that is more likely than not to remain unrealized. Future tax assets and liabilities are measured using substantively enacted tax rates and laws expected to apply when these assets or liabilities are expected to be realized or settled.

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### Earnings or loss per share

Basic earnings or loss per share are calculated by dividing net income or loss by the weighted average number of common shares outstanding during the reporting period. Diluted earnings or loss per share are calculated by dividing net income or loss by the weighted average number of common shares outstanding during the reporting period after giving effect to dilutive potential common shares. The dilutive effects of stock options and warrants are determined using the treasury stock method. The dilutive effects of convertible securities are determined using the if-converted method.

### Year ended December 31, 2004

#### Disposition of Cedax

In July 2004, Biovail terminated its sub-license and manufacturing agreements with Schering-Plough Corporation ("Schering") to market and distribute Cedax in the United States. Biovail had obtained the co-exclusive rights to Cedax through its acquisition of DJ Pharma in October 2000. Shionogi & Co., Ltd. of Japan and its affiliates ("Shionogi") assumed the marketing and distribution of Cedax in the United States from Schering. Shionogi agreed to pay Biovail \$3,000,000 in consideration for the conveyance of Biovail's rights under the sub-license agreements, and Shionogi may pay Biovail up to an additional \$3,000,000 contingent on the achievement of certain target annual gross sales of Cedax. Biovail will only recognize this contingent consideration if Shionogi realizes the sales targets. Shionogi also acquired Biovail's remaining Cedax inventories and promotional materials. This transaction resulted in a gain on disposal of \$1,471,000, which is netted against write-down of assets.

### Year ended December 31, 2003

#### Acquisitions of intangible assets

During 2003, the Company acquired the following intangible assets. Total consideration related to each of these acquisitions was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition:

	<b>Tramadol products</b>	<b>Ativan® and Isordil®</b>	<b>Athpharma products</b>	<b>Generic omeprazole</b>	<b>Other</b>	<b>Total</b>
<b>Acquired assets</b>						
Acquired research and development	\$ 16,000	\$ 38,100	\$ 44,200	\$	\$	\$ 98,300
Trademarks		107,542				107,542
Product rights		16,041		35,500	256	51,797
Technology		2,156				2,156
	<u>\$ 16,000</u>	<u>\$ 163,839</u>	<u>\$ 44,200</u>	<u>\$ 35,500</u>	<u>\$ 256</u>	<u>\$ 259,795</u>
<b>Consideration</b>						
Cash paid	\$ 16,000	\$ 146,342	\$ 44,200	\$ 35,500	\$ 256	\$ 242,298
Long-term obligation		17,497				17,497
	<u>\$ 16,000</u>	<u>\$ 163,839</u>	<u>\$ 44,200</u>	<u>\$ 35,500</u>	<u>\$ 256</u>	<u>\$ 259,795</u>

#### Tramadol products

In April 2002, Biovail obtained the rights to market six products under development by Ethypharm S.A. ("Ethypharm") (as described in note 23 Research and Development Collaborations). The products under development included Ethypharm's orally disintegrating tablet ("ODT") formulations of tramadol hydrochloride ("HCl") ("Tramadol ODT"), and a combination of tramadol HCl and acetaminophen ("Tramadol/APAP"). Tramadol is indicated for the treatment of moderate to moderately severe pain.

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In September 2003 (as amended in February 2004 to confirm conditions that existed at December 31, 2003), Biovail acquired Ethypharm's remaining interest in Tramadol ODT (including all relevant patents) for \$16,000,000. Through this acquisition, Biovail extinguished any future milestone or royalty obligations that it may have had to Ethypharm related to Tramadol ODT, except for a \$1,000,000 milestone payment if Tramadol ODT is approved by the U.S. Food and Drug Administration ("FDA"). In addition to Tramadol ODT, Biovail acquired Ethypharm's remaining interest in Tramadol/APAP (including all relevant patents). Biovail will pay Ethypharm a royalty on any future sales of Tramadol/APAP.

### Acquired research and development

At the dates of acquisition, Tramadol ODT was in a late-stage clinical phase of development and Tramadol/APAP was in a pre-clinical phase of development, and neither of these products had been submitted for approval by the FDA. In May 2004, the FDA accepted Biovail's New Drug Application ("NDA") submission for Tramadol ODT for review. In January 2005, Biovail received an Approvable Letter from the FDA for Tramadol ODT, which indicated that approval is pending resolution of labeling issues. The acquired research and development is being amortized over its estimated useful life of five years.

### Ativan® and Isordil®

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

The purchase price for Ativan® and Isordil® was \$163,839,000 comprising cash consideration, including costs of acquisition, of \$146,342,000, and the two remaining fixed annual payments. The remaining fixed annual payments were present valued using an imputed interest rate of 3.00%, which was comparable to Biovail's available borrowing rate at the date of acquisition. Accordingly, the present value of the remaining fixed annual payments was determined to be \$17,497,000.

The fair values of the acquired assets were determined using an income approach. The discount rates used to present value the estimated future cash flows related to each acquired asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were in the range of 10.5% to 35%.

The trademarks are being amortized over their estimated useful lives of 20 years. The product rights and technology are being amortized over their estimated useful lives of 15 years.

### Acquired research and development

At the date of acquisition, the Ativan® line extension products were in pre-clinical phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 30% to 35% and the costs to complete the development of these products were estimated to be up to \$23,500,000. An ODT formulation of Ativan®, for the treatment of anxiety, is in an early clinical phase of development. The acquired research and development is being amortized over its estimated useful life of five years.

### Athpharma products

In April 2003, Biovail entered into an agreement with Athpharma Limited ("Athpharma") to acquire four cardiovascular products under development for \$44,200,000, including costs of acquisition. The four products under development are Bisochron (bisoprolol), a beta-1 selective beta-blocker formulation for the treatment of hypertension, Isochron (isosorbide-5-mononitrate),



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a long acting nitrate formulation for the treatment of angina, and Hepacol I (pravastatin) and Hepacol II (simvastatin), two liver-selective statin formulations for the treatment of high cholesterol. Athpharma will complete the development of these products. Biovail will pay a portion of the development costs, and may make aggregate payments of \$24,200,000 to Athpharma subject to the attainment of certain milestones. Biovail will also pay Athpharma royalties on any future sales of these products.

### Acquired research and development

At the date of acquisition, Bisochron and Isochron were both entering Phase III clinical studies, and Hepacol I and Hepacol II were both in pre-clinical phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 45% to 70% and Biovail's share of the costs to complete the development of these products was estimated to be \$20,000,000. The following values were assigned to these products: Bisochron \$21,550,000, Isochron \$13,100,000, Hepacol I \$6,985,000 and Hepacol II \$2,565,000. Biovail and Athpharma are currently in discussions to either substitute certain new products in place of Bisochron, Isochron, Hepacol I and Hepacol II or to terminate the development and license agreement. The acquired research and development is being amortized over its estimated useful life of five years.

### Generic omeprazole

In May 2003, Biovail paid \$35,500,000 to the previous owners of Pharma Pass LLC (a company acquired by Biovail in December 2002, as described in note 4 Acquisitions of Businesses) related to an additional participating interest in the gross profit on sales of generic omeprazole owned by those parties. The generic omeprazole product right was being amortized on a proportionate basis relative to the revenue received from this interest. Amortization expense of \$1,121,000 and \$34,379,000 was recorded in 2004 and 2003, respectively, as Biovail had received all of the value from this interest by March 31, 2004.

### Year ended December 31, 2002

#### Acquisitions of intangible assets

During 2002, the Company acquired the following intangible assets. Total consideration related to each of these acquisitions was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition:

	Wellbutrin® and Zyban®	Vasotec® and Vaseretic®	Teveten®	Zovirax	Total
<b>Acquired assets</b>					
Prepaid expenses	\$ 2,609	\$	\$	\$	\$ 2,609
Trademarks	24,349	165,804			190,153
Product rights	45,000	79,500	94,340	173,364	392,204
	<b>\$ 71,958</b>	<b>\$ 245,304</b>	<b>\$ 94,340</b>	<b>\$ 173,364</b>	<b>\$ 584,966</b>
<b>Consideration</b>					
Cash paid, net of gross profit on acquired assets	\$ 1,997	\$ 145,684	\$ 94,340	\$ 133,364	\$ 375,385
Long-term obligations	69,961	99,620		40,000	209,581
	<b>\$ 71,958</b>	<b>\$ 245,304</b>	<b>\$ 94,340</b>	<b>\$ 173,364</b>	<b>\$ 584,966</b>

#### Wellbutrin® and Zyban®

In December 2002, Biovail acquired from GlaxoSmithKline plc ("GSK") the rights to Wellbutrin® SR and Zyban® (bupropion HCl) in Canada. Biovail also acquired the right to market its bupropion HCl extended-release tablets ("Wellbutrin

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XL") in Canada if regulatory approval is received. Wellbutrin® SR is indicated for the treatment of depression and Zyban® is administered for the treatment of nicotine addiction as an aid to smoking cessation. Biovail obtained the beneficial rights to Wellbutrin® SR and Zyban® effective December 1, 2002, and obtained full legal rights on March 2, 2004, following the completion of the payments described below.

GSK will continue to manufacture and supply Wellbutrin® SR and Zyban® to Biovail for four years from the date of acquisition. GSK continued to market Wellbutrin® SR and Zyban® in Canada during the period from December 1, 2002 to December 31, 2003 and, in consideration, Biovail paid GSK a tiered royalty on the net sales of these products during this period. Effective January 1, 2004, Biovail began to actively promote Wellbutrin® SR in Canada.

The purchase price for Wellbutrin® and Zyban® comprised cash consideration, including costs of acquisition, of \$3,320,000, less GSK's gross profit on the acquired assets from December 1, 2002 (the effective date of the transaction) to December 26, 2002 (the closing date of the transaction) of \$1,323,000, plus remaining payments of \$72,072,000 paid in four quarterly instalments from June 1, 2003 to March 1, 2004. These payments were present valued using an imputed interest rate of 3.74%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$69,961,000. Biovail will also pay GSK a royalty on any future sales of Wellbutrin XL in Canada for a period of 20 years from the date of commercial launch of this product.

The prepaid expenses were amortized over a one-year period from January 1, 2003. These expenses related to the minimum amount that GSK committed to spend on the marketing of Wellbutrin® SR and Zyban® in Canada during that period. The trademarks and product rights are being amortized over their estimated useful lives of 20 years and 15 years, respectively.

### **Vasotec® and Vaseretic®**

In May 2002, Biovail acquired from Merck & Co., Inc. ("Merck") the rights to Vasotec® (enalapril maleate) and Vaseretic® (enalapril maleate and hydrochlorothiazide) in the United States. Vasotec® and Vaseretic® are indicated for the treatments of hypertension and congestive heart failure. Biovail also acquired the fixed-dose combination NDA of enalapril and diltiazem maleate. Merck will continue to manufacture and supply Vasotec® and Vaseretic® to Biovail for five years from the date of acquisition. Biovail will make semi-annual payments to Merck over a five-year term for minimum product quantities and a minimum fixed royalty (regardless of the actual product supplied). Biovail will also pay Merck royalties on any future sales of any life cycle products developed and marketed in the United States.

Biovail also entered into a separate agreement with Merck to develop, license and supply a new dosage format of a Merck product under development. Utilizing CEFORM technology, Biovail and Merck will conduct the development program and, subject to approval by the FDA, Biovail will manufacture and supply this new dosage format to Merck for commercialization. Biovail is entitled to receive a milestone payment on regulatory approval of \$250,000, as well as royalties on any future sales of this new dosage format.

The purchase price for Vasotec® and Vaseretic® comprised cash consideration, including costs of acquisition, of \$155,634,000, less Merck's gross profit on the acquired assets from April 1, 2002 (the effective date of the transaction) to May 10, 2002 (the closing date of the transaction) of \$9,950,000, plus the minimum fixed royalty payments required to be made by Biovail to Merck of \$109,276,000. These payments were present valued using an imputed interest rate of 5.75%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$99,620,000.

The trademarks and product rights are being amortized over their estimated useful lives of 20 years and 15 years, respectively.

### **Teveten®**

In March 2002, Biovail acquired from Solvay Pharmaceuticals Marketing & Licensing AG ("Solvay") the rights to Teveten® (eprosartan mesylate) and Teveten® HCT (eprosartan mesylate and hydrochlorothiazide) in the United States. Teveten® is an angiotensin-II receptor blocker for the treatment of hypertension and is indicated for use either alone or in conjunction with other antihypertensive medications.

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The purchase price for Teveten® comprised cash consideration of \$94,340,000, including costs of acquisition. The product rights are being amortized over their estimated useful life of 20 years.

Solvay will continue to manufacture and supply Teveten® and Teveten® HCT to Biovail for up to 12 years from the date of acquisition, and will assist in qualifying a Biovail facility to achieve the transition of the manufacturing process. Solvay will continue to manufacture and market Teveten® and Teveten® HCT in areas outside of the United States. Solvay paid Biovail a \$20,000,000 marketing allowance to reimburse Biovail for the agreed upon direct costs related to the re-launch and marketing of Teveten® and Teveten® HCT in the United States. Biovail recorded one-half of the marketing allowance each year in 2003 and 2002 as a reduction of selling, general and administrative expenses. Biovail formed a joint business development committee with Solvay to discuss future clinical and product-development options that could enhance the performance or expand the utilization of Teveten®. Solvay has the option to acquire, for worldwide markets excluding the United States, all potential future modifications and innovations developed by Biovail for Teveten®.

### **Zovirax**

Effective January 1, 2002, Biovail acquired from GSK the exclusive distribution rights for Zovirax Ointment and Zovirax Cream in the United States. Zovirax (acyclovir) is a topical anti-viral product. Zovirax Ointment is indicated for the treatment of herpes, and Zovirax Cream is indicated for the treatment of cold sores. GSK will continue to manufacture and supply Zovirax Ointment and Zovirax Cream to Biovail over the term of the distribution agreement.

The purchase price for Zovirax comprised cash consideration of \$133,364,000, including costs of acquisition. The product rights were being amortized over their estimated useful life of 10 years, based on the original term of the distribution agreement.

In the event of the termination of the Wellbutrin XL agreement (as described in note 22 Marketing and Distribution Agreements) by either Biovail or GSK, Biovail would be required to pay GSK additional payments for the rights to Zovirax of \$22,000,000 per year in calendar years 2005 and 2006, and in calendar years 2007 through 2011, Biovail would be required to pay GSK additional payments based on a percentage of Biovail's gross sales of Zovirax during the immediately preceding calendar year.

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

In December 2002, Biovail and GSK agreed to extend the Zovirax distribution agreement from 10 to 20 years. In consideration for this extension, Biovail paid GSK \$40,000,000 in March 2003. This amount was added to the value of the unamortized Zovirax product rights and, subsequent to the date of amendment, these product rights are being amortized over their revised estimated remaining useful life of 19 years.

## **4. ACQUISITIONS OF BUSINESSES**

### **Years ended December 31, 2004 and 2003**

#### **BNC-PHARMAPASS**

##### **Description of acquisition**

In July 2003, Biovail and Pharma Pass II, LLC ("PPII") formed BNC-PHARMAPASS, LLC ("BNC-PHARMAPASS") to advance the development of three products. These products were carvedilol (Coreg), a beta-blocker indicated for the treatment

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of congestive heart failure, eprosartan (Teveten®), indicated for the treatment of hypertension, and tamsulosin (Flomax), indicated for the treatment of benign prostatic hyperplasia. On the formation of BNC-PHARMAPASS, PPII contributed all of its intellectual property relating to these products, which was fair valued at an amount of \$31,350,000, for a 51% interest in this company, and Biovail contributed cash in the amount of \$30,060,000, for a 49% interest in this company. PPII agreed to complete the formulation work in connection with these products. Biovail agreed to pay the cost of all clinical trials and certain other development costs related to these products. Biovail had an option to acquire PPII's interest in BNC-PHARMAPASS for cash consideration plus a royalty on any future sales of these products.

Subsequent to date of formation, PPII reduced its capital in BNC-PHARMAPASS through the withdrawal of \$25,741,000 of cash from BNC-PHARMAPASS. As a result, PPII's interest in BNC-PHARMAPASS was reduced to 16%, and Biovail's interest in BNC-PHARMAPASS increased to 84% at December 31, 2003.

At December 31, 2003, Biovail's investment in BNC-PHARMAPASS was recorded as follows:

Cash	\$	4,319
Minority interest		(679)
Acquired research and development		26,420
		<hr/>
Cash contributed	\$	30,060
		<hr/>

In January 2004, PPII further reduced its interest in BNC-PHARMAPASS through the withdrawal of the remaining \$4,319,000 of cash from BNC-PHARMAPASS. In February 2004, Biovail acquired PPII's remaining interest in BNC-PHARMAPASS for \$5,000,000. Biovail and PPII also agreed to terminate the development of tamsulosin, and the intellectual property related to this product was returned to PPII. The increase in Biovail's share of the fair values of the two remaining products (carvedilol and eprosartan) after the withdrawal of cash, together with the consideration paid to acquire PPII's remaining interest in BNC-PHARMAPASS, resulted in an additional \$8,640,000 capitalized to acquired research and development in 2004.

### Acquired research and development

At the dates of acquisition, the carvedilol, eprosartan and tamsulosin products were in pre-formulation and formulation phases of development, and none of these products had been submitted for approval by the FDA. The discount rates used to present value the estimated future cash flows related to these products were in the range of 30% to 45% and the costs to complete the development of these products were estimated to be \$50,000,000. Biovail is continuing the development programs for carvedilol and eprosartan, which are in early clinical phases of development. The acquired research and development is being amortized over its estimated useful life of five years.

### Year ended December 31, 2002

During 2002, Biovail completed the acquisitions of Pharmaceutical Technologies Corporation ("Pharma Tech") and Pharma Pass LLC and Pharma Pass S.A. (collectively, "Pharma Pass"). These acquisitions were accounted for under the purchase

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method of accounting. Total consideration, including costs of acquisition, was allocated based on the estimated fair values of the acquired assets on the respective dates of acquisition as follows:

	<b>Pharma Tech</b>	<b>Pharma Pass</b>	<b>Total</b>
<b>Acquired assets</b>			
Acquired research and development	\$ 60,558	\$ 107,187	\$ 167,745
Product rights	5,000	63,800	68,800
Technology		7,700	7,700
Current liabilities	(3,664)		(3,664)
	\$ 61,894	\$ 178,687	\$ 240,581
Consideration, net of cash acquired	\$ 61,894	\$ 178,687	\$ 240,581

### Pharma Tech

#### Background

Pharma Tech was a development-stage company engaged in the application of drug delivery technologies to the formulation and development of a portfolio of products. Pharma Tech contracted directly with third parties, including Biovail, to conduct the contract research and development services. Biovail provided contract research and advisory services consistent with contractual relationships it had with other third parties. On the completion of the development of Biovail's products, Biovail had the right to manufacture and sell the products and Pharma Tech was entitled to royalties from the net sales of each product for a period of 10 years from the date of launch of each product. Biovail had options to acquire Pharma Tech's interest in the products or to acquire Pharma Tech.

Prior to the acquisition, Biovail earned revenue from providing advisory and contract research services to Pharma Tech of \$2,844,000 and \$2,189,000 in 2002 and 2001, respectively. The costs of providing these services to Pharma Tech were \$2,053,000 and \$1,679,000 in 2002 and 2001, respectively, and Biovail was reimbursed amounts at cost of \$2,509,000 and \$1,395,000 in 2002 and 2001, respectively. In 2002, Biovail also recorded \$6,689,000 of up-front fees in research and development revenue. These fees had been received from Pharma Tech in 2001, at which time they were deferred for subsequent amortization to revenue. The deferred revenue was fully amortized at December 31, 2002.

#### Description of acquisition

On December 17, 2002, Biovail paid \$43,080,000 to Pharma Tech to terminate the development by Pharma Tech of one of the products under development and the associated royalties on future sales of this product if approved by the FDA. At the date of termination, this product had not been submitted for approval by the FDA. Accordingly, the termination payment was capitalized as acquired research and development and is being amortized over its estimated useful life of five years.

On December 31, 2002, Biovail acquired 100% of the outstanding shares of Pharma Tech for \$22,600,000, including costs of acquisition. Through the acquisition of Pharma Tech, Biovail extinguished any future milestone or royalty obligations that Biovail may have had to Pharma Tech resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements previously entered into between Biovail and Pharma Tech.

The acquired assets of Pharma Tech were fair valued using an income approach. The discount rates used to present value the estimated future cash flows related to each asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were in the range of 30% to 45%.

#### Acquired research and development

At the date of acquisition, Pharma Tech was involved in a number of product-development projects that were in various stages of completion and had not been submitted for approval by the FDA. At the date of acquisition, an additional product had received

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an Approvable Letter from the FDA; however, significant technical issues required resolution before final approval would be granted. Therefore, the technological feasibility of this product had not been established at the date of acquisition. Biovail is continuing to work to resolve these issues. Subsequent to the date of acquisition, Biovail discontinued one of the product-development projects and it received an Approvable Letter from the FDA for one of the remaining products. The acquired research and development is being amortized over its estimated useful life of five years.

### **Product rights**

At the date of acquisition, Pharma Tech was involved with a product-development project that had been submitted for approval by the FDA. This product has received an Approvable Letter from the FDA, which raised only routine matters. Biovail believes that these matters can be successfully resolved and that final approval will be granted. However, since pharmaceutical products cannot be marketed without regulatory approvals, Biovail will not receive any benefits until regulatory approval is obtained. The product rights are being amortized over their estimated useful life of 15 years.

### **Pharma Pass**

#### **Background**

Pharma Pass was a developer of advanced oral controlled-release technologies and formulations for pharmaceutical companies, including Biovail, in Europe and the United States. On the completion of the development of Biovail's products, Biovail had the right to manufacture and sell the products and Pharma Pass was entitled to royalties from the net sales of each product for a period of 15 years from the date of launch of each product.

#### **Description of acquisition**

On December 6, 2002, Biovail acquired 100% of the outstanding interests of Pharma Pass LLC and 100% of the outstanding shares of Pharma Pass S.A. for \$178,687,000, including costs of acquisition. Through the acquisition of Pharma Pass, Biovail extinguished any future milestone or royalty obligations that Biovail may have had to Pharma Pass resulting from the approval and successful commercialization of any of the products under development, pursuant to the research and development agreements previously entered into between Biovail and Pharma Pass.

The acquired assets of Pharma Pass were fair valued using an income approach. The discount rates used to present value the estimated future cash flows related to each asset were determined based on the relative risk of achieving each asset's estimated future cash flows and were generally in the range of 9% to 45%.

#### **Acquired research and development**

At the date of acquisition, Pharma Pass was involved in approximately 20 product-development projects for a number of pharmaceutical companies including Biovail. At the date of acquisition, a number of these products had been submitted for approval by the FDA and the remaining products were in various stages of completion. Subsequent to the date of acquisition, one of these products (bupropion HCl) received FDA approval and another (tramadol HCl) received an Approvable Letter from the FDA. Two other products were sold to Teva Pharmaceuticals Industries Ltd. ("Teva") (as described in note 22 Marketing and Distribution Agreements). Biovail is continuing the development programs for the remaining products. The acquired research and development is being amortized over its estimated useful life of five years.

### **Product rights**

Biovail obtained interests in certain licensed products including Tricor (fenofibrate) and generic omeprazole. Biovail is entitled to receive royalties on sales of Tricor and was entitled to a participating interest in the gross profit on sales of generic omeprazole. The Tricor product right is being amortized over its estimated useful life of eight years. The generic omeprazole product right was being amortized on a proportionate basis relative to the revenue received from the participating interest. The

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generic omeprazole product right was fully amortized in 2003, as Biovail had received all of the value from this interest by December 31, 2003.

### Technology

Biovail obtained the patents related to Pharma Pass's Zero Order Release System, a drug delivery technology that controls the rate of release of a drug and/or significantly enhances the systemic absorption of a drug molecule. Biovail believes this technology has application to products currently in formulation and to the future development of controlled-release products. Biovail also obtained Pharma Pass's oral Colonic Delivery System, a drug delivery technology designed for the targeted release of medication into the lower intestine and upper colon. Biovail has the option to continue the development of four products utilizing this technology. Biovail will pay PPII up to \$10,000,000 in milestone fees subject to the successful completion of the development of these products. Biovail will obtain ownership of the related patents following the net payment of \$10,000,000 less the sum of the milestone fees paid. Biovail is currently in the process of selecting the four products to be developed. The technology is being amortized over its estimated useful life of 15 years.

### 5. CASH AND CASH EQUIVALENTS

	2004	2003
Cash and bank certificates of deposit	\$ 33,562	\$ 72,928
Money market funds	762	54,914
Canadian government securities		5,419
	\$ 34,324	\$ 133,261

### 6. MARKETABLE SECURITIES

The amortized cost and estimated fair value of marketable securities held at December 31, 2004 were as follows:

	Amortized cost	Unrealized losses	Fair value
Debt securities	\$ 5,020	(4)	\$ 5,016
	\$ 5,020	(4)	\$ 5,016

All marketable securities held at December 31, 2004 mature within one year.

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7. ACCOUNTS RECEIVABLE

	<u>2004</u>	<u>2003</u>
Trade	\$ 139,576	\$ 159,656
Less allowances for doubtful accounts and sales discounts	4,716	3,954
	<u>134,860</u>	<u>155,702</u>
Royalties	7,011	16,089
Other	6,891	7,583
	<u>\$ 148,762</u>	<u>\$ 179,374</u>

A significant portion of the Company's product sales is made to its third-party licensees, as well as major drug wholesalers in the United States and Canada. The three largest customer balances accounted for 62% of trade receivables at December 31, 2004.

8. INVENTORIES

	<u>2004</u>	<u>2003</u>
Raw materials	\$ 48,801	\$ 25,937
Work in process	14,862	26,803
Finished goods	46,491	31,318
	<u>\$ 110,154</u>	<u>\$ 84,058</u>

9. LONG-TERM INVESTMENTS

	<u>2004</u>	<u>2003</u>
Ethypharm	\$ 30,000	\$ 67,802
Depomed, Inc.	9,810	9,810
Reliant Pharmaceuticals, LLC	8,929	8,929
Western Life Sciences Venture Fund	872	2,038
Other	4,659	4,177
	<u>\$ 54,270</u>	<u>\$ 92,756</u>

**Ethypharm**

In April 2002, Biovail invested \$67,802,000, including costs of acquisition, to acquire 9,794,118 common shares (15% of the issued and outstanding common shares) of Ethypharm. In addition, Biovail obtained a three-year option to purchase up to 4,080,882 additional common shares of Ethypharm for \$6.66 per share plus 10% per annum, compounded annually. Biovail has not exercised this option.

In September 2003 (as amended in February 2004), Biovail negotiated with Ethypharm for price protection on its initial equity investment in Ethypharm in the event of any private or public financing undertaken by Ethypharm; however, the likelihood of Biovail realizing the value of this investment through such a refinancing by Ethypharm is currently considered remote, as this price protection expires on June 9, 2005. Consequently, Biovail evaluated its investment in Ethypharm and determined that the carrying value of this investment may not be fully realized in the foreseeable future. In December 2004, Biovail recorded a \$37,802,000 write-down to the carrying value of its investment in Ethypharm to reflect an other-than-temporary decline in the estimated fair value of this investment.



**Depomed, Inc. ("Depomed")**

In July 2002, Biovail invested \$13,675,000, including costs of acquisition, to acquire 2,465,878 newly issued common shares (15% of the issued and outstanding common shares) of Depomed. In addition, Biovail obtained a three-year option to purchase additional common shares of Depomed, in an amount sufficient for Biovail to increase its investment up to 20% of Depomed's issued and outstanding common shares (calculated following the exercise of the option), for \$5.00 per share plus 20% per annum, compounded monthly. Biovail has not exercised this option.

In May 2002, Biovail obtained the rights to manufacture and market Depomed's 500 mg tablets of Glumetza (metformin HCl) under development (as described in note 23 Research and Development Collaborations).

In April 2003, in connection with a private placement by Depomed, Biovail acquired an additional 1,626,154 common shares of Depomed for \$3,533,000. Biovail also obtained warrants to acquire 569,154 shares of Depomed, which are exercisable from July 2003 until April 2008 at an exercise price of \$2.16 per share. Biovail has not exercised these warrants.

At December 31, 2004 and 2003, Biovail's investment represented approximately 12% of the issued and outstanding common shares of Depomed. At December 31, 2004 and 2003, the fair values of this investment, based on quoted market prices, were \$23,646,000 and \$30,562,000, respectively. In 2002, Biovail recorded an unrealized holding loss of \$7,398,000 in net income to reflect an other-than-temporary decline in the fair value of this investment.

**Reliant Pharmaceuticals, LLC ("Reliant")**

In December 2003, in connection with the collection of its loan receivable from Reliant (as described in note 22 Marketing and Distribution Agreements), Biovail subscribed to \$8,929,000 of Series D Preferred Units of Reliant. These units are convertible on a 1:1 basis into Reliant's common units and are senior to all existing preferred classes of units (Series A, B and C) of Reliant. These units do not entitle the holders to a preferred return (or dividends). In the case of a liquidation of Reliant, these units are entitled to a distribution, before any other distribution or payment is made to any unit ranking junior to these units, of an amount equal to the sum of: (i) \$20.00 per unit; and (ii) interest on such amount at a rate of 8.5% per annum from the date of contribution. These units are redeemable by Reliant at a redemption price equal to the preceding liquidation amount. These units have voting rights equal to the number of whole common units into which they are convertible. At December 31, 2004 and 2003, Biovail's investment represented less than 2% of the total issued and outstanding common and preferred units.

**Western Life Sciences Venture Fund**

In December 2001, Biovail committed to an aggregate capital contribution of approximately \$7,790,000 to a limited partnership under the name of Western Life Sciences Venture Fund. The purpose of this fund is to invest in early-stage biotechnology companies. Biovail has the exclusive right to negotiate for the distribution, sales, marketing or licensing rights to any products of the investee companies of this fund. This investment is denominated in Canadian dollars and is being accounted for using the equity method.

At December 31, 2004 and 2003, Biovail had invested a total of \$5,795,000 and \$3,162,000, respectively, to acquire Class A units of this fund. At December 31, 2004 and 2003, Biovail's investment represented approximately 28% and 26%, respectively, of the total issued and outstanding Class A units. In 2004 and 2003, Biovail's share of the net losses of this fund was \$4,179,000 and \$1,010,000, respectively.

**10. PROPERTY, PLANT AND EQUIPMENT**

	2004		2003	
	Cost	Accumulated depreciation	Cost	Accumulated depreciation
Land	\$ 11,764	\$	\$ 11,378	\$
Buildings	83,136	13,526	75,186	9,742
Machinery and equipment	102,099	36,575	88,594	26,269
Other equipment and leasehold improvements	71,851	32,193	56,083	21,426
	<u>268,850</u>	<u>\$ 82,294</u>	<u>231,241</u>	<u>\$ 57,437</u>
Less accumulated depreciation	82,294		57,437	
	<u>\$ 186,556</u>		<u>\$ 173,804</u>	

At December 31, 2004 and 2003, the cost of property, plant and equipment included \$18,389,000 and \$20,606,000, respectively, of assets under construction or awaiting FDA approval and not available for productive use. Interest capitalized amounted to \$222,000 and \$1,422,000 in 2004 and 2003, respectively.

Depreciation expense amounted to \$22,259,000, \$15,351,000 and \$9,794,000 in 2004, 2003 and 2002, respectively.

**11. INTANGIBLE ASSETS**

	2004		2003	
	Cost	Accumulated amortization	Cost	Accumulated amortization
Trademarks	\$ 703,698	\$ 116,453	\$ 703,698	\$ 81,371
Acquired research and development	569,717	265,813	561,077	170,201
Product rights	484,773	95,502	575,880	149,193
Technology	21,041	5,109	21,041	3,705
	<u>1,779,229</u>	<u>\$ 482,877</u>	<u>1,861,696</u>	<u>\$ 404,470</u>
Less accumulated amortization	482,877		404,470	
	<u>\$ 1,296,352</u>		<u>\$ 1,457,226</u>	

In 2004, the Company's participating interest in the gross profit on sales of generic omeprazole was fully amortized, as the Company had received all of the value from this interest by this date. Accordingly, the Company removed the cost and accumulated amortization of \$85,357,000 related to this interest from product rights.

Amortization expense amounted to \$164,160,000, \$239,112,000 and \$126,924,000 in 2004, 2003 and 2002, respectively.

**12. OTHER ASSETS**

	<b>2004</b>	<b>2003</b>
Deferred financing costs	\$ 18,661	\$ 17,311
Less accumulated amortization	9,396	6,274
	<u>9,265</u>	<u>11,037</u>
Zovirax distribution agreement	40,656	40,656
Deferred compensation trust fund	6,892	5,644
Loan receivable	625	600
	<u>\$ 57,438</u>	<u>\$ 57,937</u>

**Deferred financing costs**

In March 2004, the Company recorded a \$1,200,000 write-down of deferred financing costs, as the result of a reduction in the borrowing capacity under its revolving term credit facility. Amortization expense related to deferred financing costs amounted to \$3,122,000, \$2,975,000 and \$2,267,000 in 2004, 2003 and 2002, respectively.

**Zovirax distribution agreement**

In consideration for certain amendments to the original Zovirax distribution agreement with GSK, Biovail agreed to pay GSK \$11,250,000 per year in four annual instalments on March 31 of each year beginning in 2004. The annual instalment payments were present valued using an imputed interest rate of 3.74%, which was comparable to Biovail's available borrowing rate at the date of the transaction. Accordingly, the present value of these payments was determined to be \$40,656,000, which was recorded in other assets. This amount will be amortized over the period of benefit from the amended terms beginning in 2005.

**Loan Receivable**

In March 2001, the Company made a \$600,000 relocation assistance loan to a former executive officer, which is secured by a charge on the former officer's personal residence. Effective March 1, 2004, this loan bears interest at a rate equal to the Company's rate of borrowing. Interest is accrued and added to the principal balance. Principal and accrued interest are due on March 31, 2008.

**13. ACCRUED LIABILITIES**

	<b>2004</b>	<b>2003</b>
Product returns	\$ 30,421	\$ 43,289
Product rebates and chargebacks	12,409	21,601
Employee costs	16,052	16,796
Interest	9,148	9,209
Other	14,887	14,306
	<u>\$ 82,917</u>	<u>\$ 105,201</u>

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14. DEFERRED REVENUE

	<u>2004</u>	<u>2003</u>
Up-front research and development fees	\$ 8,800	\$ 10,900
Up-front licensing fees and other	13,390	8,063
Customer prepayments	2,476	1,302
	<u>24,666</u>	<u>20,265</u>
Less current portion	8,141	5,765
	<u>\$ 16,525</u>	<u>\$ 14,500</u>

Effective January 1, 2000, the Company implemented the provisions of the U.S. Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements" retroactively to January 1, 1998. These policies are generally accepted under Canadian GAAP. Total revenue in 2004, 2003 and 2002 included \$3,400,000, \$5,200,000 and \$4,800,000, respectively, of amortization of revenue deferred on the implementation of SAB No. 101.

15. LONG-TERM OBLIGATIONS

	<u>2004</u>	<u>2003</u>
7 <sup>7</sup> / <sub>8</sub> % Senior Subordinated Notes due April 1, 2010	\$ 400,000	\$ 400,000
Unamortized discount	(1,916)	(2,281)
Fair value adjustment	4,158	
	<u>402,242</u>	<u>397,719</u>
Revolving term credit facility		280,000
Zovirax obligation	32,230	42,198
Vasotec® and Vaseretic® obligation	27,704	45,376
Ativan® and Isordil® obligation	9,037	17,806
Wellbutrin® and Zyban® obligation		22,407
Deferred compensation	4,438	7,020
	<u>475,651</u>	<u>812,526</u>
Less current portion	33,465	58,816
	<u>\$ 442,186</u>	<u>\$ 753,710</u>

Interest expense on long-term obligations amounted to \$36,963,000, \$38,987,000 and \$28,564,000 in 2004, 2003 and 2002, respectively.

Notes

Pursuant to a supplement to its base shelf prospectus dated March 25, 2002, the Company issued, under an indenture dated March 28, 2002, \$400,000,000 aggregate principal amount of unsecured 7<sup>7</sup>/<sub>8</sub>% Senior Subordinated Notes due April 1, 2010 ("Notes"). Interest on the Notes is payable semi-annually in arrears on April 1 and October 1 of each year. The Notes were issued at a price of 99.27% of their aggregate principal amount for an effective yield, if held to maturity, of 8%. Proceeds from the issue amounted to \$384,280,000, net of discount and financing costs.

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At any time on or after April 1, 2006, the Company may redeem all or any of the Notes at the following prices, plus accrued and unpaid interest to the date of redemption, if redeemed during the 12 months beginning April 1 of the years indicated below:

<b>Year</b>	<b>Percentage of principal amount</b>
2006	103.938%
2007	