



Third Quarter
Report 2004

Biovail
Corporation

Q3



Letter to Shareholders



Dear Fellow Shareholder:

The third quarter of 2004 was another important period for Biovail, as the company's current product portfolio continued to gain market share, and more milestones from our product-development pipeline were attained.

Biovail continued to demonstrate organic growth, as product sales in the third quarter of 2004 accounted for 94% of the company's total revenue. Key products performed very well, as total prescription volumes for core products were up 92% in the third quarter, compared with the corresponding period in 2003. Changes to wholesaler business models temporarily caused reductions in inventory that impacted revenues for promoted products. And the depth of Biovail's product-development pipeline was once again evident, as the company received marketing approval in Canada from the Therapeutic Products Directorate for Tiazac® XC and acceptance for review of its New Drug Submission for Glumetza™.

As part of Biovail's ongoing corporate-governance enhancement initiative, we effected the separation of the roles of Chairman and Chief Executive Officer. In October, the hiring of Dr. Douglas Squires as Biovail's new CEO was announced. Dr. Squires will assume full-time responsibility for the operations and general management of Biovail. The breadth and depth of his global pharmaceutical industry management experience over the past 29 years will strengthen the company's operational expertise – and help drive the expansion of our business in the U.S.

In my continuing role as Chairman of the Board, I will retain ongoing and strategy-setting responsibilities in conjunction with the Board and the CEO, in addition to furthering corporate responsibility and accountability at Biovail.

FINANCIAL PERFORMANCE

Biovail's product sales for the third quarter of 2004 were a record \$203.5 million, compared with \$180.0 million in the third quarter of 2003, an increase of 13%. This performance is largely attributable to the ongoing success of Wellbutrin XL®, Biovail Pharmaceuticals Canada (BPC) and Biovail's portfolio of generic products. Partially offsetting this growth was a reduction in wholesaler inventory levels for Biovail's promoted products, reflecting the wholesaler industry's ongoing shift towards a fee-for-service distribution model. It is important to note, however, that despite the revenue impact of this change in the third quarter of 2004, total prescriptions for Biovail's promoted products – the Cardizem® LA, Teveten® and Zovirax® product lines – have increased 18% relative to the same period a year ago.

Biovail's net income for the third quarter, calculated in accordance with United States Generally Accepted Accounting Principles, was \$49.6 million, compared with \$16.1 million for the corresponding 2003 period. Diluted earnings per share (EPS), for the third quarter of 2004 were \$0.31, versus \$0.10 for the third quarter of 2003.

PRODUCTS

Wellbutrin XL® continues to gain share in the U.S. anti-depressant market. Early in the third quarter of 2004, the net sales of Wellbutrin XL® exceeded the second-tier threshold of our agreement with GSK, thereby increasing Biovail's supply price to the third and highest tier of the manufacturing and supply agreement. Since the launch of Wellbutrin XL® in September 2003, bupropion's share of the anti-depressant market has expanded by 19%. In September 2004, Wellbutrin XL® had captured 52.2% of new prescriptions written for the Wellbutrin® brand (including generics).

Although ongoing changes in the U.S. wholesaler industry impacted revenues for our promoted brands in the third quarter of 2004, prescription trends for these products continue to increase steadily and speak to the growing effectiveness of Biovail's sales force.

Cardizem® LA prescription volume increased 40% for the third quarter of 2004, versus the comparable period in 2003, as it continued to reach gain market share in the once-daily diltiazem market. Cardizem® LA captured 7.8% of total prescription volume for the class in the third quarter of 2004, compared with 5.5% in the third quarter of 2003. Thus far in 2004, Cardizem® LA's share of the once-daily diltiazem market has increased 22.5%.

In Canada, a 10% year-over-year increase in total revenues was driven by the strong performance of Wellbutrin SR® and Tiazac®. Total prescription volume for Wellbutrin SR® increased 22.5% in the third quarter of 2004, versus the comparable 2003 period. Total prescription volume for Tiazac® – now in its seventh year on the market - increased 21.2% in the third quarter of 2004, compared with the same period in 2003.

REGULATORY HIGHLIGHTS

During the third quarter of 2004, Biovail received approval from the Therapeutic Products Directorate (TPD) for Tiazac® XC – a once-daily extended-release formulation of diltiazem for the treatment of hypertension. BPC will launch Tiazac® XC to Canadian physicians in early 2005.

In August, Biovail's New Drug Submission (NDS) for Glumetza™ – a novel formulation of metformin for the treatment of Type II diabetes developed in conjunction with our partner Depomed – was accepted for review by the TPD. Glumetza™ could potentially become the first once-daily metformin product in the Canadian diabetes market, where revenues in the 12 months ended September 2004 were \$215 million.

At the end of October, Biovail received an Approvable Letter from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for Ralivia ER™ – a once-daily formulation of the analgesic tramadol. The Approvable Letter involves the resolution of a number of items, including a request to provide further clinical information. Biovail believes that the current clinical package has sufficient data to address this request. Biovail is also in the process of determining what additional clinical data, if any, would be required. At this time, Biovail is committed to working closely with the FDA to resolve these as expeditiously as possible. We believe there is considerable opportunity in pain management – the analgesia market in the United States is worth approximately \$14 billion annually.

To date in 2004, Biovail has filed four NDAs for novel therapeutics with the U.S. FDA, completed one NDS with the TPD, and anticipates an additional regulatory filing by year-end. This is a remarkable achievement for any pharmaceutical company.

OTHER HIGHLIGHTS

On October 1, 2004, Biovail announced the amicable resolution of arbitration proceedings against our distribution partner, Teva Pharmaceutical Industries Ltd., and the extension and expansion of the exclusive marketing agreement between the two companies. Most notably, Biovail's selling price to Teva for the generic products portfolio was increased for the duration of the agreement. The financial impact of this increase will begin in the fourth quarter of 2004.

LOOKING AHEAD

Our performance to date in 2004 is evidence that the efforts of our people and the investments we have made in our business during the past couple of years are beginning to pay off.

Biovail's business model emphasizes the combination of established, commercial brands and a deep development pipeline underpinning long-term growth. To this end, our formulation operations in Chantilly, Virginia and Dublin, Ireland continue their R&D efforts for over 25 programs under development, including novel formulations of venlafaxine, bupropion, zolpidem, eprosartan, enalapril, metoprolol and combination products involving simvastatin. These products – along with others in earlier stages of development – support Biovail's long-term growth outlook.

Nearer term, with changes to the drug wholesaler industry now largely behind us, prescription demand for our core products will more closely match our reported revenues.

Thank you again for your continued support and confidence in Biovail.



Eugene N. Melnyk
Chairman Of The Board

Consolidated Balance Sheets

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

	<u>Sept 30</u>	<u>Dec 31</u>
	<u>2004</u>	<u>2003</u>
ASSETS		
Current		
Cash and cash equivalents	\$44,043	\$133,261
Accounts receivable	165,018	179,374
Inventories	97,919	84,058
Deposits and prepaid expenses	9,588	15,759
	316,568	412,452
Long-term investments	108,961	113,546
Property, plant and equipment, net	180,506	173,804
Goodwill, net	100,814	100,814
Intangible assets, net	998,502	1,049,475
Other assets, net	65,390	72,683
	\$1,770,741	\$1,922,774
LIABILITIES		
Current		
Accounts payable	\$44,907	\$67,932
Accrued liabilities	90,844	105,201
Minority interest	-	679
Income taxes payable	23,442	24,175
Deferred revenue	7,659	5,765
Current portion of long-term obligations	85,347	58,816
	252,199	262,568
Deferred revenue	17,550	14,500
Long-term obligations	504,556	764,111
	774,305	1,041,179
SHAREHOLDERS' EQUITY		
Common shares	1,452,040	1,448,353
Stock options outstanding	2,150	2,290
Deficit	(492,729)	(607,678)
Accumulated other comprehensive income	34,975	38,630
	996,436	881,595
	\$1,770,741	\$1,922,774

Consolidated Statements of Income

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

	Three Months Ended Sept 30		Nine Months Ended Sept 30	
	<u>2004</u>	<u>2003</u>	<u>2004</u>	<u>2003</u>
		(Restated [1])		(Restated [1])
REVENUE				
Product sales	\$203,457	\$179,985	\$575,767	\$464,629
Research and development	5,942	4,542	12,831	10,815
Co-promotion, royalty and licensing	6,326	30,787	20,066	148,543
	<u>215,725</u>	<u>215,314</u>	<u>608,664</u>	<u>623,987</u>
EXPENSES				
Cost of goods sold	51,835	40,079	163,028	88,823
Research and development	17,648	20,608	51,469	60,427
Selling, general and administrative	67,458	74,135	182,907	176,436
Amortization	16,330	28,243	49,169	114,650
Acquired research and development	-	18,409	8,640	102,609
Settlements	-	-	-	(34,055)
	<u>153,271</u>	<u>181,474</u>	<u>455,213</u>	<u>508,890</u>
Operating income	62,454	33,840	153,451	115,097
Interest income	186	1,191	757	5,893
Interest expense	(10,103)	(10,540)	(30,467)	(30,029)
Foreign exchange gain loss	(802)	531	(1,158)	(9,594)
Other income (expense)	-	(5,958)	(2,434)	706
Income before provision for income taxes	51,735	19,064	120,149	82,073
Provision for income taxes	2,100	2,950	5,200	13,300
Net income	\$49,635	\$16,114	\$114,949	\$68,773
Earnings per share				
Basic	<u>\$0.31</u>	<u>\$0.10</u>	<u>\$0.72</u>	<u>\$0.43</u>
Diluted	<u>\$0.31</u>	<u>\$0.10</u>	<u>\$0.72</u>	<u>\$0.43</u>
Weighted average number of common shares outstanding (000s)				
Basic	<u>158,801</u>	<u>158,704</u>	<u>159,060</u>	<u>158,428</u>
Diluted	<u>158,904</u>	<u>160,426</u>	<u>159,227</u>	<u>160,115</u>

Consolidated Statements of Cash Flows

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

	Nine Months Ended Sept 30	
	<u>2004</u>	<u>2003</u>
		(Restated [1])
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$114,949	\$68,773
Add (deduct) items not involving cash		
Depreciation and amortization	65,919	126,645
Amortization of deferred financing costs	3,510	2,103
Amortization of discounts on long-term obligations	2,438	5,461
Acquired research and development	8,640	102,609
Gain on disposal of intangible assets	(1,471)	-
Other	(823)	5,569
	193,162	311,160
Net change in non-cash operating items	(27,792)	(67,100)
Cash provided by operating activities	165,370	244,060
CASH FLOWS FROM INVESTING ACTIVITIES		
Additions to property, plant and equipment	(20,190)	(28,283)
Acquisition of business, net of cash acquired	(9,319)	-
Acquisitions of long-term investments	(2,877)	(34,596)
Proceeds on disposal of intangible asset	3,000	10,000
Acquisitions of intangible assets	-	(203,052)
Increase in loan receivable	-	(40,000)
Cash used in investing activities	(29,386)	(295,931)
CASH FLOWS FROM FINANCING ACTIVITIES		
Advances (repayments) under revolving term credit facility, including financing costs	(182,550)	114,800
Repayments of other long-term obligations	(52,796)	(88,261)
Proceeds on termination of interest rate swaps	6,300	-
Issuance of common shares, net of issue costs	3,687	11,419
Cash provided by (used in) financing activities	(225,359)	37,958
Effect of exchange rate changes on cash and cash equivalents	157	1,122
Net decrease in cash and cash equivalents	(89,218)	(12,791)
Cash and cash equivalents, beginning of period	133,261	56,080
Cash and cash equivalents, end of period	\$44,043	\$43,289

[1]As disclosed in Biovail Corporation's amended Form 6-K for the quarterly period ended September 30, 2003, financial results for the three months and nine months ended September 30, 2003 have been restated for non-cash foreign exchange translation adjustments, which resulted in an increase in the net income for the three months ended September 30, 2003 from \$12,985,000 (basic and diluted income per share of \$0.08) as previously reported to \$16,114,000 (basic and diluted income per share of \$0.10) as restated, and a decrease in net income for the nine months ended September 30, 2003 from \$74,964,000 (basic and diluted earnings per share of \$0.47) as previously reported to \$68,773,000 (basic and diluted earnings per share of \$0.43) as restated. Current and prior years' figures reflect the reclassification of foreign exchange gains and losses from selling, general and administrative expenses.

Shareholder Information

BIOVAIL CORPORATION

7150 Mississauga Road
Mississauga, Ontario
Canada L5N 8M5

T: (905) 286-3000

F: (905) 286-3050

E: ir@biovail.com

W: www.biovail.com

HOW TO REACH US FOR MORE INFORMATION

For additional copies of this report, the annual report on Form 20-F as filed with the United States Securities and Exchange Commission, for quarterly reports or for further information, please contact Investor Relations.

Corporate Information

TRADING SYMBOL – BVF

New York Stock Exchange
Toronto Stock Exchange

REGISTRARS AND TRANSFER AGENTS

CIBC Mellon Trust Company
Toronto, Ontario, Canada
Mellon Investor Services, LLC
New York, New York, USA

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To the extent any statements made in this report contain information that is not historical, these statements are essentially forward-looking. As such, they are subject to risks and uncertainties, including the difficulty in predicting FDA and 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, the regulatory environment, legislative amendments and / or changes, 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 and Canadian securities authorities. Biovail Corporation undertakes no obligation to update or revise any forward-looking statement.

Financial Statements prepared in accordance with Canadian Generally Accepted Accounting Principles are made available to all shareholders.