



# Q3

## Third Quarter Report

Biovail Corporation 2001 Interim Report



## Dear fellow shareholders:

Biovail has continued its impressive performance in 2001, recording record financial results for the third quarter and nine months ending September 30, 2001. This ongoing strong performance is indicative of the Company's continuing evolution into one of the world's leading developers and marketers of pharmaceutical products utilizing advanced proprietary drug delivery technologies.

The Company achieved an exciting milestone immediately following the third quarter with the signing of significant multiple agreements with GlaxoSmithKline (GSK), one of the world's largest pharmaceutical companies. Biovail licensed worldwide marketing rights to GSK for its novel once-daily controlled-release formulation of bupropion HCl for all current and future indications. This successful treatment for depression is currently marketed by GSK under the Wellbutrin® and Zyban® brands. The agreement also provides for Biovail to manufacture and supply the new product to GSK, along with an option to co-promote the product in the US on approval. A New Drug Application (NDA) for Wellbutrin Once Daily will be co-filed with the US Food and Drug Administration (FDA) during the first half of 2002.

Biovail has also obtained the right to co-promote GSK's currently marketed twice-daily Wellbutrin® SR product in the US beginning in the fourth quarter of 2001.

In addition, Biovail obtained the rights to exclusively promote and distribute GSK's topical anti-viral product Zovirax® Ointment in the US and Puerto Rico. This agreement also covers Zovirax® Cream on FDA approval. GSK will re-instate an NDA for Zovirax® Cream previously filed with the FDA in the immediate future. Annual US sales of Zovirax® are currently in excess of \$60 million.

## Product sales

Revenue from product sales for the quarter increased by 157% over the third quarter 2000 to \$137 million. A major factor in this growth was the strong sales of the Cardizem® line of anti-hypertensive, anti-angina products in the US market realized by the Company's new US marketing operation, Biovail Pharmaceuticals USA. The Cardizem® line was acquired by Biovail at the end of 2000. The marketing initiatives of Cardizem® were further enhanced by the completion of the first stage of the Cardizem Patient Relationship Program®, which will allow the Company to target more than 600,000 patients in the US.

The excellent performance of Cardizem® was supplemented by solid growth in sales of the Company's generic products, marketed in the US by Biovail's marketing partner Teva Pharmaceutical and of our branded once daily diltiazem product Tiazac®, marketed in the US by Forest Laboratories and in Canada by Biovail's own Crystaal marketing division.

## Crystaal

Tiazac® was just one of Crystaal's success stories in the quarter. Market sales of Retavase®, Cardizem® CD and Celexa® also increased sharply. In fact, Celexa® is currently the fastest growing SSRI anti-depressant in the Canadian market, already achieving a 14% market share. Overall, Crystaal's pull through sales for the third quarter were up by 61% compared to third quarter 2000.

Over the next few months, the name Crystaal will be replaced with Biovail Pharmaceuticals Canada. This transition is being made to consolidate Biovail's presence and branding across North America.

## New product development

Third quarter 2001 was marked by a number of exciting milestones in Biovail's new product development. Among these was the filing of a New Drug Application (NDA) with the US Food and Drug Administration (FDA) for Cardizem® XL, a novel once-daily chronotherapeutic formulation of diltiazem. This filing follows completion of a highly successful trial that showed that Cardizem® XL significantly reduces diastolic and systolic blood pressure between the hours of 4 am and 12 noon – times when patients are at the greatest risk of suffering an adverse cardiac event, such as a non-embolic stroke or myocardial infarction. Biovail expects to launch Cardizem® XL – the first product of its kind – into the growing hypertension marketplace towards the end of 2002.

An NDA was also submitted to the FDA for a FlashDose® formulation of fluoxetine, a market leading anti-depressant with annual US brand sales in excess of \$1.6 billion. Work also progressed on FlashDose® versions of the anti-depressant paroxetine (Paxil®) and the insomnia medication zolpidem (Ambien®). Filings are anticipated in the near future.

The Company also completed a successful osteoarthritis Phase III study of its extended-release once-daily formulation of tramadol for the treatment of moderate to moderately severe pain. At present, tramadol is only marketed in a multiple daily dose formulation by Johnson and Johnson under the brand name Ultram®. Annual US sales of Ultram® exceeded \$590 million US in 2000, with an annual sales growth of approximately 15%.

Also in the quarter, Biovail, in cooperation with Celgene Corporation, submitted a New Drug Submission to the Canadian Therapeutics Products Program (TTP) for d-methylphenidate, a treatment for Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD). On approval, Biovail will market this product exclusively in Canada.

## Other operations

Manufacturing operations continue to expand to meet increased demand. The Company produced, packaged and shipped 23% more products in the first nine months of this year compared to the same period last year. Overall output for the third quarter 2000 is up 38%. In addition, Biovail's new Dorado, Puerto Rico facility received FDA approval for its QC operations and approval for packaging is expected shortly.

In September, the Board of Directors approved a stock repurchase program, authorizing the Company to repurchase up to \$120 million of its issued and outstanding common stock, dependant on market conditions and other factors.

### **Financial results**

Biovail reported record financial results for the three-month and nine-month periods ending September 30, 2001. Total revenues for the third quarter of 2001 increased 63% to \$152.2 million, compared with \$93.4 million reported for the third quarter of 2000. Total revenues for the first nine months of 2001 were \$404.9 million, an increase of \$195.6 million, or 93%, over the same period last year. A \$141.5 million charge was recorded in third quarter 2000 relating to a write-off of acquired research and development associated with products developed for Intelligent Polymers Limited.

Net income, excluding charges, increased 37% to \$55.8 million for the third quarter 2001 compared to \$40.7 million for third quarter, 2000. Net income, excluding charges, for the nine months ended September 30, 2001 was \$129.1 million was an increase of 62% over \$79.8 million for the same period of last year.

Diluted earnings per share, excluding charges, increased to \$0.37 per share, versus \$0.28 per share for the third quarter 2000. For the nine months ended September 30, 2001, diluted earnings per share, excluding charges, increased 54% to \$0.86 per share compared to \$0.56 per share for 2000.

On behalf of the Board of Directors, I would like to thank the Company's shareholders for their continued support and our employees for their ongoing hard work and dedication.

(Signed)

### **Eugene Melnyk**

Chief Executive Officer  
Chairman of the Board

## Consolidated Balance Sheets

In accordance with U.S. generally accepted accounting principles

	September 30 2001	December 31 2000
<b>Assets</b>		
<b>Current</b>		
Cash and cash equivalents	\$ 27,769	\$ 125,144
Accounts receivable	119,409	105,850
Inventories	40,878	24,108
Deposits and prepaid expenses	5,617	5,347
	<b>193,673</b>	260,449
Long-term investments	1,593	1,561
Property, plant and equipment, net	81,758	52,541
Goodwill, net	97,849	103,105
Intangible assets, net	647,653	667,431
Other assets, net	14,338	22,180
	<b>\$ 1,036,864</b>	<b>\$ 1,107,267</b>
<b>Liabilities</b>		
<b>Current</b>		
Accounts payable	\$ 23,981	\$ 34,683
Accrued liabilities	96,822	35,452
Income taxes payable	13,434	6,711
Deferred revenue	23,775	26,334
Current portion of long-term obligations	54,640	182,564
	<b>212,652</b>	285,744
Deferred revenue	24,300	27,900
Long-term obligations	214,814	256,180
Convertible Subordinated Preferred Equivalent Debentures	134,515	299,985
	<b>586,281</b>	869,809
<b>Shareholders' Equity</b>		
Common shares, no par value, unlimited shares authorized, 138,783,811 and 131,461,060 issued and outstanding at September 30, 2001 and December 31, 2000, respectively	<b>698,862</b>	482,842
Stock options outstanding	9,823	9,891
Warrants	6,246	7,912
Deficit	(261,082)	(261,819)
Accumulated other comprehensive loss	(3,266)	(1,368)
	<b>450,583</b>	237,458
	<b>\$ 1,036,864</b>	<b>\$ 1,107,267</b>

## Consolidated Statements of Income (Loss)

In accordance with U.S. generally accepted accounting principles

(All dollar amounts except per share data are expressed in thousands of U.S. dollars) (Unaudited)	Three Months Ended September 30		Nine Months Ended September 30	
	2001	2000	2001	2000
<b>Revenue</b>				
Product sales	\$ 137,147	\$ 53,318	\$ 374,472	\$ 134,555
Research and development	6,588	34,434	10,117	62,730
Royalty and licensing	8,455	5,663	20,332	12,076
	<u>152,190</u>	<u>93,415</u>	<u>404,921</u>	<u>209,361</u>
<b>Expenses</b>				
Cost of goods sold	36,621	16,786	90,283	41,333
Research and development	12,018	22,392	36,863	47,457
Selling, general and administrative	26,422	13,162	77,675	38,196
Amortization	11,107	1,022	32,558	3,049
Acquired research and development	-	141,500	-	141,500
	<u>86,168</u>	<u>194,862</u>	<u>237,379</u>	<u>271,535</u>
<b>Operating income (loss)</b>	<b>66,022</b>	<b>(101,447)</b>	<b>167,542</b>	<b>(62,174)</b>
Interest income (expense), net	(6,465)	3,102	(28,656)	5,219
Debt conversion premium	(22,731)	-	(22,731)	-
	<u>36,826</u>	<u>(98,345)</u>	<u>116,155</u>	<u>(56,955)</u>
<b>Income (loss) before income taxes</b>	<b>36,826</b>	<b>(98,345)</b>	<b>116,155</b>	<b>(56,955)</b>
Provision for income taxes	3,725	2,478	9,785	4,735
	<u>33,101</u>	<u>(100,823)</u>	<u>106,370</u>	<u>(61,690)</u>
<b>Income (loss) before extraordinary item and cumulative effect of change in accounting principle</b>	<b>33,101</b>	<b>(100,823)</b>	<b>106,370</b>	<b>(61,690)</b>
Extraordinary item	-	-	-	(20,039)
	<u>33,101</u>	<u>(100,823)</u>	<u>106,370</u>	<u>(81,729)</u>
<b>Income (loss) before cumulative effect of change in accounting principle</b>	<b>33,101</b>	<b>(100,823)</b>	<b>106,370</b>	<b>(81,729)</b>
Cumulative effect of change in accounting principle	-	-	-	(43,500)
	<u>33,101</u>	<u>(100,823)</u>	<u>106,370</u>	<u>(125,229)</u>
<b>Net income (loss)</b>	<b>\$ 33,101</b>	<b>\$ (100,823)</b>	<b>\$ 106,370</b>	<b>\$ (125,229)</b>
<b>Basic earnings (loss) per share</b>				
Income (loss) before extraordinary item and cumulative effect of change in accounting principle	\$ 0.24	\$ (0.78)	\$ 0.80	\$ (0.48)
Extraordinary item	-	-	-	(0.16)
Cumulative effect of change in accounting principle	-	-	-	(0.34)
	<u>\$ 0.24</u>	<u>\$ (0.78)</u>	<u>\$ 0.80</u>	<u>\$ (0.98)</u>
<b>Diluted earnings (loss) per share</b>				
Income (loss) before extraordinary item and cumulative effect of change in accounting principle	\$ 0.22	\$ (0.78)	\$ 0.71	\$ (0.48)
Extraordinary item	-	-	-	(0.16)
Cumulative effect of change in accounting principle	-	-	-	(0.34)
	<u>\$ 0.22</u>	<u>\$ (0.78)</u>	<u>\$ 0.71</u>	<u>\$ (0.98)</u>
<b>Weighted average number of common shares outstanding (000s)</b>				
Basic	<u>137,011</u>	<u>129,739</u>	<u>133,713</u>	<u>128,285</u>
Diluted	<u>152,428</u>	<u>146,377</u>	<u>149,308</u>	<u>143,402</u>

## Consolidated Statements of Cash Flows

In accordance with U.S. generally accepted accounting principles

### Nine Months Ended September 30

(All dollar amounts are expressed in thousands of U.S. dollars) (Unaudited)	2001	2000
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ 106,370	\$ (125,229)
Depreciation and amortization	41,730	14,926
Amortization of discount on long-term obligations	9,467	-
Debt conversion premium	22,731	-
Interest paid through the issuance of common shares	1,238	-
Deferred income taxes	1,450	-
Compensation cost for employee stock options	1,499	-
Acquired research and development	-	141,500
Extraordinary item	-	20,039
Cumulative effect of change in accounting principle	-	43,500
	<u>184,485</u>	<u>94,736</u>
Change in non-cash operating items	(16,350)	(48,529)
<b>Cash provided by operating activities</b>	<u>168,135</u>	<u>46,207</u>
<b>Cash flows from investing activities</b>		
Additions to property, plant and equipment, net	(37,851)	(11,074)
Additions to intangible assets	(27,767)	-
Reduction in intangible assets	14,748	333
Acquisition of long-term investments	(238)	(2,273)
Investment in IPL Acquireco 2000 Ltd.	-	(141,500)
Maturity of short-term investments, net	-	16,725
Proceeds from sale of assets held for disposal	-	20,000
<b>Cash used in investing activities</b>	<u>(51,108)</u>	<u>(117,789)</u>
<b>Cash flows from financing activities</b>		
Issuance of common shares	14,913	104,093
Repurchase of common shares	(78,715)	-
Proceeds from the exercise of warrants	28,648	-
Repayments under revolving term credit facility	(32,320)	-
Reduction in other long-term obligations	(146,866)	(11,432)
Issuance of Convertible Subordinated Preferred Equivalent Debentures, net of financing costs	-	288,500
Repurchase of U.S. Dollar Senior Notes	-	(141,017)
Collection of warrant subscription receivable	-	2,287
<b>Cash provided by (used in) financing activities</b>	<u>(214,340)</u>	<u>242,431</u>
Effect of exchange rate changes on cash and cash equivalents	(62)	(233)
<b>Increase (decrease) in cash and cash equivalents</b>	<u>(97,375)</u>	<u>170,616</u>
Cash and cash equivalents, beginning of period	125,144	178,086
<b>Cash and cash equivalents, end of period</b>	<u>\$ 27,769</u>	<u>\$ 348,702</u>

Presentation for the three months and six months ended September 30, 2001 and 2000, reflects the retroactive adoption of SAB 101, and the reclassification of certain figures.

## Shareholder Information

### Head office

Biovail Corporation  
2488 Dunwin Drive  
Mississauga, Ontario  
Canada L5L 1J9

### 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 Symbols

Common Shares:	<b>BVF</b>
Common Share Warrants:	<b>BVF_w</b>
Convertible Subordinated Preferred Equivalent Debentures:	<b>BVF_p</b>

### Registrars and Transfer Agents

CIBC Mellon Trust Company  
Toronto, Canada  
ChaseMellon Shareholder Services  
New York, New York

The following words and logos are trademarks for the company and may be registered in Canada, the United States and certain other jurisdictions: Biovail, Cardizem®, Tiazac®, Viazem, CEFORM®, FlashDose®, Shearform® and Crystaal.

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 of predicting FDA and TPP 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, 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.

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



Biovail Corporation  
2488 Dunwin Drive  
Mississauga, Ontario  
Canada L5L 1J9

**T:** (416) 285-6000

**F:** (416) 285-6499

**E:** [ir@biovail.com](mailto:ir@biovail.com)

**W:** [www.biovail.com](http://www.biovail.com)