

BIOVAIL

CORPORATION INTERNATIONAL



INTERIM REPORT 1999

THIRD QUARTER

## **DEAR FELLOW SHAREHOLDERS**

Once again I am pleased to report an excellent performance by Biovail Corporation International in the third quarter of 1999. The Company achieved record third quarter and nine month financial results. These results were attributable to many factors, including continued growth in sales of Tiazac®, sales of a generic formulation of Verelan in the US, increased revenue from third party research and development, and the expansion of Crystaal, our Canadian sales and marketing division. The third quarter was also marked by strategic expansion, as the Company acquired Fuisz Technologies Ltd., an acquisition that will significantly expand Biovail's drug delivery technologies and platforms. This acquisition, along with other events during the quarter, will continue to fuel your Company's growth.

### **TIAZAC®**

Tiazac®, Biovail's once-daily diltiazem formulation for the treatment of angina and hypertension, continues to report increasing market penetration, both in the lucrative US diltiazem market, where Tiazac's® share now exceeds 16%, and in Canada, where it is marketed directly by Crystaal. Further expansion opportunities exist for Tiazac® in European and other world markets, where it is sold through a number of licensing agreements with local pharmaceutical companies.

### **GENERIC VERELAN**

During the third quarter, sales activity was reported following the late second quarter US launch of Biovail's generic version of the successful calcium channel blocker, Verelan, used in the treatment of hypertension. This product is being marketed by Teva Pharmaceuticals.

### **GENERIC ADALAT CC**

Towards the end of the quarter, Biovail announced the acquisition of exclusive US marketing rights to Elan Corporation's generic version of Adalat CC. This will allow Biovail, through its marketing partner Teva Pharmaceuticals, to launch Elan's 30mg dose of generic Adalat CC in the US six months earlier than scheduled and with six months of market exclusivity.

In addition, earlier in the year, Biovail received tentative FDA approval for its 30mg and 60mg dosage of a generic version of Adalat CC. On launch of the 60mg dose, Biovail will have six months of market exclusivity. Adalat CC, used in the treatment of hypertension, has annual US sales of approximately \$350 million.

## **GENERIC CARDIZEM CD**

Tentative FDA approval was received for Biovail's generic version of Cardizem CD. Indicated for the treatment of angina and hypertension, Cardizem CD had 1998 US sales in excess of \$700 million. Biovail is free to market its generic version in December 1999 upon expiry of a competitor's 180 day "first to file" statutory exclusivity period. Biovail's generic version of Cardizem CD will also be marketed in the US by Teva Pharmaceuticals.

## **CRYSTAAL CORPORATION**

Biovail's Canadian sales and marketing division, Crystaal, continued to gain market share and revenue, driven by sales of Tiazac® and the recent launches of Retavase, a clot dissolving medication; Brexidol, used for pain relief; the anti-depressant Celexa; and Cardiac STATus™, a rapid point-of-care diagnostic test for heart attacks. In addition Corlopam, an in-licensed product, has been submitted for approval to the Canadian regulatory authorities.

## **PRODUCT PIPELINE**

Progress continued in both the Company's ANDA and NDA pipelines during the quarter. In the ANDA pipeline, Biovail currently has several additional products awaiting FDA approval in the US. These include generic versions of: Dilacor XR, Procardia XL and Voltaren XR. The Company's NDA pipeline also continued to move forward with products being developed on behalf of Intelligent Polymers Ltd. and a proprietary controlled-release version of Celexa, a leading anti-depressant.

## **FUISZ ACQUISITION**

The most exciting news in the third quarter was Biovail's acquisition of Fuisz Technologies Ltd. Fuisz is a company specializing in advanced drug delivery technologies, including its patented CEFORM™ and Shearform™ technologies. It has modern research and manufacturing facilities in Chantilly, Virginia.

The acquisition of Fuisz further strengthens Biovail's position as a leader in drug delivery technology and offers numerous strategic benefits. These include the ability to apply an expanded variety of advanced drug delivery technologies and delivery formats to a broader range of drugs, and the synergies created by the sharing of scientific knowledge, expertise and technologies between the two companies. Biovail will also benefit from Fuisz's extensive

network of positive working relationships within the pharmaceutical industry. And finally, the acquisition has allowed Biovail to expand its US presence and provides a base for additional US expansion opportunities.

#### **PUBLIC OFFERING**

Subsequent to the third quarter, Biovail completed a successful public offering of 5,000,000 common shares. A total of 4,545,000 shares were sold in the US and outside of Canada, and 455,000 shares were sold in Canada. Gross proceeds from this offering were \$255 million. These proceeds will allow Biovail to capitalize on exciting opportunities that present themselves in the pharmaceutical industry.

#### **RECORD RESULTS**

The Company reported record third quarter and year-to-date financial results for the period ended September 30, 1999.

Revenue for the third quarter and first nine months increased by 57% and 44% respectively to \$45.6 million and \$110.0 million, compared to 1998 third quarter revenue of \$29.0 million and first nine months revenue of \$76.1 million. Operating income for the third quarter 1999 was \$21.3 million and for the first nine months was \$48.4 million, representing increases of 53% and 49% respectively over the same periods of 1998. Net income for the third quarter was \$17.1 million, or \$0.70 per share, a 30% increase over net income of \$13.2 million or \$0.49 per share for third quarter 1998. For the first nine months of 1999, net income was \$37.5 million, or \$1.53 per share, a 23% increase over net income of \$30.6 million, or \$1.14 per share, for the first nine months of 1998.

I would like to take this opportunity to thank the employees who continue to work hard on behalf of the Company and shareholders for their support.

(signed) Eugene Melnyk

**Eugene Melnyk**

*Chairman of the Board*

# consolidated balance sheets

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

	September 30, 1999 <i>(Unaudited)</i>	December 31, 1998 <i>(Audited)</i>
<b>A S S E T S</b>		
<b>Current</b>		
Cash and short-term deposits	\$ 22,938	\$ 78,279
Accounts receivable	48,060	42,768
Inventories	14,053	10,542
Executive stock purchase plan loans	2,320	2,924
Deposits and prepaid expenses	3,425	3,357
	90,796	137,870
<b>Long-term investments</b>	10,055	10,055
<b>Investment in Fuisz Technologies Ltd.</b>	77,118	-
<b>Capital assets, net</b>	26,930	23,677
<b>Other assets, net</b>	28,574	28,317
	\$ 233,473	\$ 199,919
<b>L I A B I L I T I E S</b>		
<b>Current</b>		
Accounts payable	\$ 17,013	\$ 12,244
Accrued liabilities	8,163	4,129
Income taxes payable	2,007	1,004
Customer prepayments	17,443	4,516
Current portion of long-term debt	747	653
	45,373	22,546
<b>Long-term debt</b>	125,478	126,182
	170,851	148,728
<b>S H A R E H O L D E R S ' E Q U I T Y</b>		
Share capital	21,797	19,428
Warrants	8,244	8,244
Retained earnings	32,275	24,748
Cumulative translation adjustment	306	(1,229)
	62,622	51,191
	\$ 233,473	\$ 199,919

# c o n s o l i d a t e d   s t a t e m e n t s o f   i n c o m e

*(All dollar amounts except per share data are expressed  
in thousands of U.S. dollars)*

	Three Months Ended September 30,	
<i>(Unaudited)</i>	<b>1999</b>	1998
<b>Revenue</b>	\$ 45,607	\$ 28,990
<b>Expenses</b>		
Cost of goods sold	8,946	6,946
Research and development	7,699	4,047
Selling, general and administrative	7,678	4,067
	<b>24,323</b>	15,060
<b>Operating income</b>	21,284	13,930
<b>Equity in loss of Fuisz Technologies Ltd.</b>	(361)	-
<b>Interest expense, net</b>	(2,722)	(97)
<b>Income before income taxes</b>	18,201	13,833
<b>Provision for income taxes</b>	1,062	629
<b>Net income</b>	\$ 17,139	\$ 13,204
<b>Earnings per share</b>	\$ 0.70	\$ 0.49
<b>Weighted average number of common shares outstanding</b>	24,451,000	26,899,000

## S E G M E N T E D   I N F O R M A T I O N

<b>Revenue from external customers</b>			
Product sales	\$ 28,730	\$	16,540
Research and development	12,240		8,974
Royalty and licensing	4,637		3,476
	<b>\$ 45,607</b>	<b>\$</b>	<b>28,990</b>
<b>Segment operating income (loss)</b>			
Product sales	\$ 14,421	\$	6,960
Research and development	4,015		4,406
Royalty and licensing	4,651		3,417
Unallocated	(1,803)		(853)
	<b>\$ 21,284</b>	<b>\$</b>	<b>13,930</b>

# c o n s o l i d a t e d   s t a t e m e n t s o f   i n c o m e

*(All dollar amounts except per share data are expressed  
in thousands of U.S. dollars)*

	Nine Months Ended September 30,	
<i>(Unaudited)</i>	1999	1998
<b>Revenue</b>	<b>\$ 110,002</b>	<b>\$ 76,135</b>
<b>Expenses</b>		
Cost of goods sold	21,833	18,956
Research and development	19,482	12,179
Selling, general and administrative	20,282	12,521
	61,597	43,656
<b>Operating income</b>	<b>48,405</b>	<b>32,479</b>
<b>Equity in loss of Fuisz Technologies Ltd.</b>	<b>(361)</b>	<b>-</b>
<b>Interest expense, net</b>	<b>(8,171)</b>	<b>(254)</b>
<b>Income before income taxes</b>	<b>39,873</b>	<b>32,225</b>
<b>Provision for income taxes</b>	<b>2,370</b>	<b>1,629</b>
<b>Net income</b>	<b>\$ 37,503</b>	<b>\$ 30,596</b>
<b>Earnings per share</b>	<b>\$ 1.53</b>	<b>\$ 1.14</b>
<b>Weighted average number of common shares outstanding</b>	<b>24,451,000</b>	<b>26,899,000</b>

## S E G M E N T E D   I N F O R M A T I O N

<b>Revenue from external customers</b>		
Product sales	\$ 66,271	\$ 45,303
Research and development	27,592	20,927
Royalty and licensing	16,139	9,905
	\$ 110,002	\$ 76,135
<b>Segment operating income (loss)</b>		
Product sales	\$ 30,255	\$ 17,797
Research and development	6,590	7,363
Royalty and licensing	15,928	9,711
Unallocated	(4,368)	(2,392)
	\$ 48,405	\$ 32,479

# c o n s o l i d a t e d   s t a t e m e n t s

## o f   c a s h   f l o w s

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

	Nine Months Ended September 30,			
<i>(Unaudited)</i>	1999		1998	
<b>Net inflow (outflow) of cash related to the following activities</b>				
<b>Operating</b>				
Net income for the period	\$	37,503	\$	30,596
Depreciation and amortization		4,960		3,534
Equity in loss of Fuisz Technologies Ltd.		361		-
		42,824		34,130
Changes in non-cash operating items:				
Increase in accounts receivable		(5,174)		(3,659)
Increase in inventories		(3,432)		(1,462)
Increase in deposits and prepaid expenses		(68)		(521)
Increase in accounts payable and accrued liabilities		8,999		1,033
Increase in income taxes payable		1,026		809
Increase in customer prepayments		12,927		2,995
		14,278		(805)
		57,102		33,325
<b>Investing</b>				
Additions to capital assets, net		(5,281)		(2,505)
Executive stock purchase plan loans		719		66
Acquisition of product rights		(2,203)		-
Investment in Fuisz Technologies Ltd.		(77,479)		-
Acquisition of long-term investments		-		(10,000)
Acquisition of royalty interest		-		(15,000)
Increase in other assets		-		(4,165)
		(84,244)		(31,604)
<b>Financing</b>				
Acquisition of share capital		(30,593)		(22,598)
Issuance of share capital		2,985		3,776
Reduction in other long-term debt		(667)		(8,455)
Increase in other long-term debt		-		19,141
		(28,275)		(8,136)
<b>Effect of exchange rate changes on cash</b>				
		76		(19)
<b>Decrease in cash and cash equivalents</b>				
		(55,341)		(6,434)
<b>Cash and cash equivalents, beginning of period</b>				
		78,279		8,275
<b>Cash and cash equivalents, end of period</b>				
	\$	22,938	\$	1,841
<b>Represented by:</b>				
Cash and short-term deposits	\$	22,938	\$	11,892
Bank indebtedness		-		(10,051)
	\$	22,938	\$	1,841



## s h a r e h o l d e r   i n f o r m a t i o n

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*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 or visit our web site.*

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## c o r p o r a t e   i n f o r m a t i o n

### **S T O C K   L I S T I N G**

New York Stock Exchange  
Toronto Stock Exchange  
Symbol: BVF

### **R E G I S T R A R S   A N D**

### **T R A N S F E R   A G E N T S**

CIBC Mellon Trust Company  
Toronto, Ontario

ChaseMellon

Shareholder Services

New York, USA

To the extent any statements made in this report contains 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.

**BIOVAIL**

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