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BIOVAIL CORPORATION INTERNATIONAL  
Form 6-K  
August 08, 2001

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN ISSUER PURSUANT TO RULE 13a - 16 AND 15d - 16 OF  
THE SECURITIES EXCHANGE ACT OF 1934

AUGUST 7, 2001

COMMISSION FILE NUMBER 001-11145

BIOVAIL CORPORATION  
(TRANSLATION OF REGISTRANT'S NAME INTO ENGLISH)

2488 DUNWIN DRIVE, MISSISSAUGA, ONTARIO L5L 1J9, CANADA  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES AND ZIP CODE)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (416) 285-6000

INDICATE BY CHECK MARK WHETHER THE REGISTRANT FILES OR WILL  
FILE ANNUAL REPORTS UNDER COVER OF FORM 20-F OR FORM 40-F

Form 20-F  X  
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Form 40-F  \_\_\_\_

INDICATE BY CHECK MARK WHETHER FOR REGISTRANT BY FURNISHING THE INFORMATION  
CONTAINED IN THIS FORM IS ALSO THEREBY FURNISHING THE INFORMATION TO THE  
COMMISSION PURSUANT TO RULE 12g 3-2 (b) UNDER THE SECURITIES EXCHANGE ACT OF  
1934.

Yes  \_\_\_\_

No  X  
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BIOVAIL CORPORATION INTERNATIONAL  
QUARTERLY REPORT

THIS REPORT OF FOREIGN ISSUER ON FORM 6-K IS INCORPORATED BY REFERENCES INTO THE  
REGISTRATION STATEMENT ON FORM S-8 OF BIOVAIL CORPORATION (REGISTRATION NO.  
333-92229).

PART II - Other Information

99. A ON JULY 31, 2001, THE COMPANY ANNOUNCED SECOND QUARTER 2001 FINANCIAL  
RESULTS. THE PRESS RELEASE ISSUED BY THE COMPANY AND FILED WITH THE CANADIAN

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SECURITY ADMINISTRATORS AND STOCK EXCHANGES (NYSE / TSE) ATTACHED AS REFERENCE.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Biovail Corporation

August 7, 2001

By /s/John R. Miszuk

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John R. Miszuk  
Vice President, Controller

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[GRAPHIC OMITTED]

CONTACT: Ken Howling  
Vice President Finance  
(416) 285-6000

FOR IMMEDIATE RELEASE:

\* BIOVAIL REPORTS RECORD SECOND QUARTER 2001 RESULTS \*

- Product sales revenue increased 176% for the quarter -
- Second quarter diluted EPS of \$0.30 increased 76% versus prior year  
adjusted EPS of \$0.17 -
  - Raising 2001 revenue and earnings guidance -
- Cardizem(R)XL study analyzed and highly statistically significant  
results achieved -

TORONTO, Canada, July 31, 2001 - Biovail Corporation (NYSE, TSE:BVF) today reported record financial results for the three-month and six-month periods ending June 30, 2001. Total revenues for the second quarter of 2001 increased 105% to \$133.5 million, compared with \$65.2 million reported for the second quarter of 2000. Total revenues for the six months ended June 30, 2001 were \$252.7 million reflecting

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an increase of \$136.8 million or 118% over the six months ended June 30, 2000. Results were ahead of expectations primarily due to the resilience of the Cardizem(R) brands in the marketplace and strong sales of the Company's controlled-release generic product portfolio.

Net income increased 82% and was \$44.1 million for the second quarter 2001 versus second quarter 2000 net income of \$24.2 million. Net income for the six months ended June 30, 2001 of \$73.3 million increased 87% versus \$39.1 million for the prior year equivalent period excluding charges for an extraordinary item related to the early retirement of Senior Notes and the cumulative effect from the adoption of SAB 101. Second quarter 2001 diluted earnings per share increased 76% to \$0.30 per share versus \$0.17 per share for the second quarter 2000. For the six months ended June 30, diluted earnings per share increased 79% to \$0.50 per share for 2001 versus \$0.28 per share for 2000, excluding the charges outlined above.

Due to the resilience demonstrated by the Cardizem(R) brands, and the strong level of sales of the Company's controlled-release generic product portfolio, Biovail is revising upwards its previous level of revenue and earnings guidance. Biovail currently forecasts the following revenue and earnings per share ranges, excluding charges, for the balance of 2001.

	Q3 2001		Q4 2001		2001
	Revised	Previous	Revised	Previous	Revised
Total Revenues (\$US Millions)	\$145 - \$160	\$135 - \$150	\$160 - \$180	\$150 - 170	\$560 - \$590
Diluted EPS	\$0.35-\$0.40	\$0.30-\$0.40	\$0.45-\$0.50	\$0.40-\$0.50	\$1.25-\$1.33

Also completed during the quarter were significant Phase III clinical trials involving Biovail's novel once-daily chronotherapeutic formulation of diltiazem. The results have demonstrated that the product, named Cardizem(R) XL, dosed at night, results in a highly significant statistical reduction in both diastolic blood pressure (DBP) and systolic blood pressure (SBP) between 6 a.m. and 12 noon compared to equivalent morning dosing. Dr. Joel Neutel, lead investigator for the Cardizem(R) XL Study and Chief of Clinical Pharmacology and Hypertension at the VA Medical Center in Long Beach California, commented, "This is the first time a study has demonstrated that a chronotherapeutic agent given at night results in clinically meaningfully and highly statistically significant reductions in blood pressure during the early morning period than the identical agent dosed in the morning. Cardizem(R) XL was shown to achieve peak efficacy between the hours of 6 a.m. and 12 noon which is desirable since this is when the greatest incidence of non-embolic strokes and myocardial

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infarctions occur."

### Financial Results

Product sales revenue of \$125.4 million increased 176% during the second quarter 2001 versus second quarter 2000 and increased 192% to \$237.3 million for the first half of 2001 versus first half 2000 primarily due to sales of the Cardizem(R) line in North America, Tiazac sales in the US and sales of a number of branded products by Biovail Pharmaceuticals, Inc., the Company's US sales and marketing organization. Excluding product sales revenue associated

with the acquisition of the Cardizem(R) brands and Biovail Pharmaceuticals, Inc., product sales revenue increased over 60% for the three months ended June 30, 2001.

Research and development revenues were approximately \$2 million and \$3.5 million for the second quarter and first half of 2001 respectively compared to 2000 levels of \$16.6 million and \$28.3 million respectively. The reduction in research and development revenues is due to the termination of Biovail's research and development arrangement with Intelligent Polymers Limited (IPL) at the end of September 2000.

Royalty and licensing revenue of \$6.1 million and \$11.9 million for the second quarter and first half of 2001 reflect increases in excess of 85% versus comparable 2000 levels primarily due to royalties associated with the sale of a Cardizem(R) product by a third party.

Gross margins were approximately 78% for the second quarter and first half of 2001 versus approximately 70% for the comparable 2000 periods. The improvement in gross margins was primarily due to sales of higher margin products such as the Cardizem(R) brands and a favourable sales mix. Sales of branded pharmaceutical products accounted for more than 60% of product sales revenue for both the second quarter and first half of 2001.

Research and development expenses were \$13.9 million and \$25.3 million for the second quarter and first half of 2001. Selling, general and administrative expenses for the second quarter and first half of 2001 of \$34.9 million and \$71.8 million reflect increases of 142% and 172% versus 2000 levels primarily due to the selling and marketing expenses associated with Biovail Pharmaceuticals, Inc. acquired in the fourth quarter 2000 and the amortization expenses associated with the acquisition of Biovail Pharmaceuticals, Inc. and the Cardizem(R) brands.

Operating income for second quarter 2001 increased to \$57.1 million versus \$23.2 million earned in the second quarter of 2000. Operating income was \$101.5 million for the first half of 2001 versus \$39.3 million for the first half of 2000.

Net interest expense was \$9.7 million for the second quarter 2001 and approximately \$22.2 million for the first half of 2001. The increase in net interest expense for the second quarter and first half of 2001 versus 2000 levels was primarily due to the convertible preferred securities issued in March of 2000 and advances made against

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the Company's revolving term

credit facility established at the end of 2000. This facility was recently syndicated and was increased from \$300 million to \$400 million due to the favourable response received from the debt capital markets. The revolving term credit facility has received a BB- rating from Standard & Poors and a Ba3 rating from Moody's Investor Services.

Earnings before interest, taxes, depreciation and amortization (EBITDA) increased 157% to \$71.1 million for the quarter ended June 30, 2001 versus \$27.7 million for the equivalent prior year period. EBITDA increased 161% to \$128.9 million for the first half 2001 versus \$49.3 million for the first half of 2000 and operating cash flow was \$137.4 million for the first half of 2001.

Eugene Melnyk, Chairman of the Board, commented, "Biovail continues to implement its strategic initiatives and therefore expand its business base. We currently enjoy excellent growth from the sales of our Tiazac brands, sales of our once-daily generic products, sales from the Cardizem(R) brands in North America, sales of branded pharmaceutical products in the Canadian market and sales from the recently acquired Biovail Pharmaceuticals, Inc. brands. Our focus continues to be on the execution of our revenue diversification and multi-stage growth strategies. We will continue to expand in the area of directly promoted branded pharmaceutical products that are both acquired and internally developed. The Cardizem(R) XL studies have been analyzed and we are excited by these results and the opportunity to bring this innovative, chronotherapeutic cardiovascular medication to the market next year."

The Company's conference call to review the second quarter and first half 2001 results will be broadcast live at 8:30 a.m. E.S.T. on the world wide web at [www.biovail.com](http://www.biovail.com) and a replay of the conference call will be available on this website shortly after the call.

Biovail Corporation is an international full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture, sale and promotion of pharmaceutical products utilizing advanced drug delivery technologies.

"SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995.

TO THE EXTENT ANY STATEMENTS MADE IN THIS RELEASE CONTAIN INFORMATION THAT IS NOT HISTORICAL, THESE STATEMENTS ARE ESSENTIALLY FORWARD LOOKING AND ARE SUBJECT TO RISKS AND UNCERTAINTIES, INCLUDING THE DIFFICULTY OF PREDICTING FDA 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 SECURITIES AND EXCHANGE COMMISSION.

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CONSOLIDATED BALANCE SHEETS  
 IN ACCORDANCE WITH U.S. GENERALLY ACCEPTED ACCOUNTING PRINCIPLES  
 (All dollar amounts are expressed in thousands of U.S. dollars)  
 (Unaudited)

	JUNE 30 2001	December 31 2000
	-----	-----
<b>ASSETS</b>		
<b>CURRENT</b>		
Cash and cash equivalents	\$ 68,276	\$ 125,144
Accounts receivable	88,377	105,850
Inventories	39,156	24,108
Deposits and prepaid expenses	4,565	5,347
	-----	-----
	200,374	260,449
Long-term investments	2,413	1,561
Property, plant and equipment, net	76,712	52,541
Goodwill, net	98,823	103,105
Intangible assets, net	647,945	667,431
Other assets, net	20,900	22,180
	-----	-----
	\$ 1,047,167	\$ 1,107,267
	-----	-----
<b>LIABILITIES</b>		
<b>CURRENT</b>		
Accounts payable	\$ 30,425	\$ 34,683
Accrued liabilities	46,778	35,452
Income taxes payable	9,899	6,711
Deferred revenue	38,413	26,334
Current portion of long-term obligations	95,923	182,564
	-----	-----
	221,438	285,744
Deferred revenue	25,500	27,900
Long-term obligations	174,487	256,180
Convertible Subordinated Preferred Equivalent Debentures	299,985	299,985
	-----	-----
	721,410	869,809
	-----	-----
<b>SHAREHOLDERS' EQUITY</b>		
Common shares	507,369	492,733
Warrants	7,912	7,912
Deficit	(188,550)	(261,819)
Accumulated other comprehensive loss	(974)	(1,368)
	-----	-----
	325,757	237,458
	-----	-----
	\$ 1,047,167	\$ 1,107,267
	-----	-----

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BIOVAIL CORPORATION  
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 JUNE 30		SIX MONTHS END JUNE 30	
	2001	2000	2001	2000
<b>REVENUE</b>				
Product sales	\$ 125,398	\$ 45,384	\$ 237,325	\$ 100,000
Research and development	1,963	16,645	3,529	10,000
Royalty and licensing	6,143	3,135	11,877	10,000
	-----	-----	-----	-----
	133,504	65,164	252,731	120,000
	-----	-----	-----	-----
<b>EXPENSES</b>				
Cost of goods sold	27,534	13,538	54,088	10,000
Research and development	13,913	13,942	25,320	10,000
Selling, general and administrative	34,925	14,456	71,803	10,000
	-----	-----	-----	-----
	76,372	41,936	151,211	10,000
	-----	-----	-----	-----
<b>OPERATING INCOME</b>	57,132	23,228	101,520	10,000
Interest income (expense), net	(9,719)	2,383	(22,191)	10,000
	-----	-----	-----	-----
Income before income taxes	47,413	25,611	79,329	10,000
Provision for income taxes	3,310	1,444	6,060	10,000
	-----	-----	-----	-----
<b>INCOME BEFORE EXTRAORDINARY ITEM AND CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE</b>	44,103	24,167	73,269	10,000
Extraordinary item	-	-	-	(10,000)
	-----	-----	-----	-----
<b>INCOME BEFORE CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE</b>	44,103	24,167	73,269	10,000
Cumulative effect of change in accounting principle	-	-	-	(10,000)
	-----	-----	-----	-----
<b>NET INCOME (LOSS)</b>	\$ 44,103	\$ 24,167	\$ 73,269	\$ 10,000
	-----	-----	-----	-----
<b>BASIC EARNINGS (LOSS) PER SHARE</b>				
Income before extraordinary item and cumulative effect of change in accounting principle	\$ 0.33	\$ 0.19	\$ 0.55	\$ 0.10
Extraordinary	-	-	-	-
Cumulative effect of change in accounting principle	-	-	-	-
	-----	-----	-----	-----
Net income (loss)	\$ 0.33	\$ 0.19	\$ 0.55	\$ 0.10
	-----	-----	-----	-----
<b>DILUTED EARNINGS (LOSS) PER SHARE</b>				
Income before extraordinary item and cumulative effect of change in accounting principle	\$ 0.30	\$ 0.17	\$ 0.50	\$ 0.10
Extraordinary item	-	-	-	-
Cumulative effect of change in accounting principle	-	-	-	-

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Net income (loss)	\$ 0.30	\$ 0.17	\$ 0.50	\$
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING (000s)				
Basic	132,297	129,530	132,037	1
Diluted	147,933	143,118	147,735	1

BIOVAIL CORPORATION  
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)

	SIX MONTHS ENDED JUNE 30	
	2001	2000
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	\$ 73,269	\$ (24,406)
Depreciation and amortization	27,357	10,018
Amortization of discount on long-term obligations	7,115	-
Deferred income taxes	1,450	-
Compensation cost for employee stock options	999	-
Extraordinary item	-	20,039
Cumulative effect of change in accounting principle	-	43,500
	110,190	49,151
Change in non-cash operating items	27,222	(38,959)
CASH PROVIDED BY OPERATING ACTIVITIES	137,412	10,192
CASH FLOWS FROM INVESTING ACTIVITIES		
Additions to property, plant and equipment, net	(28,939)	(5,791)
Additions to intangible assets	(13,954)	-
Reduction in intangible assets	11,352	261
Acquisition of long-term investments	(209)	(2,285)
Maturity of short-term investments, net	-	4,218
Proceeds from sale of assets held for disposal	-	20,000
CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	(31,750)	16,403
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common shares	13,617	102,822
Proceeds from the exercise of warrants	20	-
Repayments under revolving term credit facility	(75,790)	-



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Reduction in other long-term obligations	(100,365)	(10,657)
Issuance of Convertible Subordinated Preferred Equivalent Debentures, net of financing costs	-	289,410
Repurchase of U.S. Dollar Senior Notes	-	(141,017)
Collection of warrant subscription receivable	-	2,287
	-----	-----
CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	(162,518)	242,845
	-----	-----
Effect of exchange rate changes on cash and cash equivalents	(12)	(73)
	-----	-----
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(56,868)	269,367
Cash and cash equivalents, beginning of period	125,144	178,086
	-----	-----
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 68,276	\$ 447,453
	-----	-----