
Biovail

Biovail Corp
7150 Mississauga Road
Mississauga, ON
L5N 8M5
Canada

Established 1981
Ownership Public
Research Focus Drug delivery
Total Sales (\$US) 624.1 (Dec 05)
Pharma Sales (\$US) 624.1 (Dec 05)
Scrip Ranking 73

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Principals

Chairman	Eugene N Melnyk	To retire June 2007. Previously Executive Chairman
CEO	Dr Douglas J P Squires	Joined November 2004. Previously President and CEO, MDS Pharma Services
CFO & Senior V-P	Kenneth G Howling	Promoted December 2006 from V-P, Finance & Corporate Affairs. Joined 1997. Also worked for Pharma Patch, SmithKline Beecham, Bencard Allergy Laboratories
Senior V-P, Business Development	Christine C Mayer	Joined May 2005. Previously V-P, Global Business Development, Sanofi-Aventis. Also worked for Johnson & Johnson (J&J)
Senior V-P, General Counsel & Corporate Secretary	Wendy A Kelley	Appointed July 2006. Previously with BMO Financial Group
Senior V-P, Medical & Scientific Affairs	Dr Peter Silverstone	Appointed May 2006. Previously CMO, Global IQ
Senior V-P, Technical Operations/Drug Delivery	Gilbert Godin	Appointed April 2006. Previously with MDS Pharma Services
COO, Biovail Laboratories SRL	Michel Chouinard	

Updated by NLO on 24/5/2007.

Licensing contact

Christine C Mayer, Senior V-P, Business Development

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Updated by NLO on 24/5/2007.

The company

Biovail Corporation specialises in the development, registration, manufacture and licensing of controlled-release products. Biovail seeks to apply its controlled-release technology to the treatment of chronic disorders such as cardiovascular, inflammatory, respiratory and gastro-intestinal conditions. Through its Contract Research Division, Biovail provides pharmaceutical companies with a broad range of pharmaceutical research services.

Mergers & acquisitions

1997	October	Biovail forms a spin-off company, Intelligent Polymers, to finance the development of a range of new controlled-release products
1999	November	Biovail acquires the drug delivery company Fuisz Technologies in a cash and stock transaction valued at Can\$245 million (\$163 million)
2000	February	Biovail agrees to acquire the Dorado, Puerto Rico, pharmaceutical manufacturing facility from McNeil Pharmaceuticals (Johnson & Johnson); included in the acquisition of this facility is the specialised production and packaging equipment that will be utilised for the company's future production requirements
	October	Biovail agrees to acquire DJ Pharma, a privately held speciality pharmaceutical sales and marketing company, for \$162.5 million in cash plus the assumption of approximately \$50 million of debt (pr 04-10-00)
2002	December	Biovail acquires Pharma PASS LLC, an Irvine, California company, and Pharma PASS SA, a company based in France, both of which belong to the Pharma PASS group (Pharma PASS). Both companies were purchased for approximately \$190 million
2005	November	Biovail intends to spin off most of its branded off-patent pharmaceutical products (including Cardizem CD, Ativan, Vaseretic, Vasotec, Isordil and Tiazac) as a new company, Crystaal Pharmaceuticals Corp (Press release, Biovail, 15 Nov 2005)

Updated by RW on 21/11/2005.

Operating locations/subsidiaries

Europe	Ireland (Biovail Technologies Ireland Ltd), Switzerland, UK (Biovail Technologies Ltd (BTL))
North America	Canada (Biovail Pharmaceuticals Canada, Biovail Ventures, Crystaal Crop), USA (Biovail Pharmaceuticals (USA) Inc, Biovail Laboratories, Biovail Technologies Ltd), West Indies (Biovail Laboratories Inc)

Updated by NLO on 24/5/2007.

Agreements

1996	Bristol-Myers Squibb (previously through DuPont)	whereby DuPont Merck will market Tiazac in the UK and Ireland
	Laboratorios Alter	whereby Alter will market Tiazac in Spain
	Pierre Fabre	whereby Pierre Fabre will market Tiazac in France
	Novopharm	where Novopharm acquires Canadian rights to Biovail's once-daily diltiazem
1997	Teva	through Biovail Laboratories, whereby Teva acquires US marketing rights to eight Biovail controlled-release generics, and to co-develop further generics. EXTENDED OCT 2004 , for four years (pr 01-10-04)
	Intelligent Polymers	to collaborate on the development of controlled-release products
1998	Gentium (previously Crinos)	for Italian marketing rights to Tiazac (once-daily diltiazem)
	Bayer	through Fuisz, to develop a Flash Dose tablet formulation of an undisclosed Bayer compound

	Pfizer	to use Fuisz' Ceform Taste Isolation and Shearform technologies to produce a flash dose tablet formulation of an undisclosed new Pfizer drug
	Laboratorios Richmond	for Argentinian marketing rights to Tiazac
	Boehringer Ingelheim	whereby Fuisz develops Ceform EA microspheres for use in preclinical studies of an undisclosed new Boehringer Ingelheim compound
	Whitehall-Robins (Wyeth)	to acquire certain exclusive rights, including US rights, to Fuisz' Ceform EA rapid absorption ibuprofen
	Elan	whereby Crystaal acquires Canadian marketing rights to Elan's dopamine D ₁ -agonist, Corlopam (fenoldopam)
	Berrenne Industria Farmaceutica	for Brazilian marketing rights to Tiazac
	Novopharm	to develop controlled-release formulations of two undisclosed compounds, using Fuisz' Ceform CR technology
	Centocor (Johnson & Johnson)	through Crystaal, for exclusive Canadian distribution rights to Centocor's thrombolytic, Retavase (reteplase, licensed from Roche)
	Elan	whereby Elan acquires manufacturing rights to Fuisz' products
1999	Lundbeck	to develop and supply to Lundbeck a controlled-release formulation of the SSRI antidepressant, citalopram
	Fidia	through Crystaal, for a distribution deal for Hyalart in Canada
	Schering-Plough	(previously through DJ Pharma) to market and distribute Cedax (ceftibuten), an oral third-generation cephalosporin antibiotic, in the US. TERMINATED AUG 2004 , whereby Shionogi USA begins marketing and distributing Cedax in the US (pr 27-08-04)
2000	Hemispherx Biopharma	whereby Biovail acquires the exclusive rights to market Ampligen in Canada from Hemispherx in return for an initial undertaking by Biovail to purchase approximately US\$2 million in Hemispherx common shares from treasury
	Ambrilia Biopharma (formerly known as Procyon Biopharma)	whereby Biovail acquires the Canadian rights to Fibrostat, a topical cream for the treatment of scars resulting from surgery or burns
2001	Sanofi-Aventis (previously through Aventis)	for North American rights to Aventis' Cardizem (diltiazem) product line, in a deal worth around \$409.5 million. The agreement covers once-daily diltiazem (Cardizem CD), twice-daily Cardizem SR and Cardizem tablets and injectable products, whose sales were about \$240 million last year, although they are declining because of generic competition
	Dov Pharmaceutical	whereby Biovail acquires the rights to a patent on a combination of immediate- and extended-release diltiazem, to treat hypertension and angina. Biovail will make an up-front payment of \$7.5 million and will pay R&D costs. TERMINATED APR 2003 whereby Dov reacquires the licence for \$1 million plus additional payments if the drug is approved
	Procyon Biopharma	to license US marketing rights to Fibrostat, its topical therapeutic for scar management, to Biovail, which is already the licensee for Canada
	GlaxoSmithKline	in October, whereby GlaxoSmithKline licenses from Biovail the worldwide rights to a once-daily formulation of the antidepressant, bupropion (Wellbutrin XL). In December 2003, GSK exercises its option to develop and register the product in the European Union and other key world markets
2002	Watson Pharmaceuticals (previously through Andrx)	to settle a long-standing US patent litigation on extended-release diltiazem, with Andrx gaining a non-exclusive licence to a Biovail patent in exchange for royalties
	Ethypharm	whereby drug delivery technologies will be shared and products developed

	Merck & Co	whereby Biovail pays US\$155 million for the US rights to Merck & Co's ACE-inhibitor, Vasotec (enalapril) and the combination product Vaseretic (enalapril plus hydrochlorothiazide)
	Merck & Co	whereby Biovail will develop, license and supply a new dosage form of an undisclosed product in Merck & Co's pipeline using its Ceform Microsphere oral drug delivery technology`
	DepoMed	whereby Biovail licenses North American rights to DepoMed's once-daily metformin product, metformin GR. AMENDED MAY 2004 , Depomed gains royalty rights to Biovail's 1000 mg tablet for metformin HC1 for sales in the US and Canadian territories in exchange for allowing Biovail to use Depomed's clinical data on 500 mg metformin HC1 tablets to support and accelerate regulatory submissions for Biovail's 1000 mg tablet and establish equivalence between the two dosage forms. In July 2005, Depomed receives a \$25 million milestone payment from Biovail Corp based on the US Food and Drug Administration approval of Glumetza, once-daily extended release metformin, for the treatment of Type II diabetes (Press release, Depomed, 6 Jul 2005). REVISED DEC 2005 , whereby Depomed gains the marketing and distribution rights to the 500mg and 1,000mg formulations of Glumetza in the US; the NDA for the 500mg formulation of Glumetza is transferred to Depomed; and Biovail relinquishes its option on metformin combination products utilising Depomed technology (Press release, Depomed, 13 Dec 2005)
	GlaxoSmithKline	whereby Biovail acquires the Canadian rights to Wellbutrin SR and Zyban. Through this agreement and upon marketing approval from Canadian authorities, Biovail has the option to market Wellbutrin XL
	GlaxoSmithKline	for the marketing rights to Zovirax ointment and Zovirax cream to twenty years from ten years for a payment of \$40 million
	Reliant Pharmaceuticals	to co-promote a number of Biovail products including Teveten, Cedax and Rondec. EXPANDED NOV 2002 for three years. TERMINATED DEC 2003 . In addition Biovail extinguishes its trailing royalty obligation to Reliant through a \$62 million payment (<i>Scrip</i> S00827918)
2003	Flamel	in April, whereby Flamel licenses Biovail the exclusive North American rights to their oral solid control release formulation of aciclovir for the treatment of episodic and recurrent genital herpes infections. Biovail is responsible for all the development, clinical and regulatory costs associated with the filing and approval of the product in the US and Canada. TERMINATED MAR 2005 (pr 05-03-05)
	Athpharma	in May, to acquire four cardiovascular products under development by Athpharma to complement its hypertension product, Cardizen LA (BVV B00800934) TERMINATED JUL 2006 (Press release, Biovail, 24 Jul 2006)
	Wyeth	in June, whereby Biovail acquires US rights to the Ativan (lorazepam) and Isordil (isosorbide dinitrate) oral product lines from Wyeth for \$130 million and annual payments pursuant to a three year supply agreement

2005	Kos Pharmaceuticals (Abbott Laboratories)	in May, whereby Kos acquires Teveten (eprosartan mesylate) and Teveten HCT (eprosartan mesylate/hydrochlorothiazide), and obtains exclusive sales and marketing rights to Cardizem LA (diltiazem hydrochloride) in the US, commercial rights to the combination product of Cardizem LA and enalapril (ace-inhibitor), and the right of first negotiation to two other research and development projects in the cardiovascular/metabolic disease area. Kos intends to offer employment to approximately 200 Biovail employees, including 150 sales representatives. Kos pays approximately \$104 million in cash (Press release, Kos Pharmaceuticals, 3 May 2005)
	MedPointe	in October, for MedPointe to promote Biovail's Zovirax (acyclovir) cream and Zovirax (acyclovir) ointment for the topical treatment of herpes simplex virus (HSV) infections (Press release, MedPointe, 4 Oct 2005)
	Ortho-McNeil (Johnson & Johnson)	in November, for the marketing and distribution of a once-daily, extended-release (ER) formulation and an orally disintegrating (ODT), immediate-release formulation of tramadol hydrochloride in the US and Puerto Rico. Ortho-McNeil retains an option for Ultram ER for other jurisdictions, excluding Canada and Europe (Press release, Biovail, 3 Nov 2005)
2006	AstraZeneca Pharmaceuticals (AstraZeneca)	in May, through Biovail Pharmaceuticals (BPI), under which BPI's sales force promotes Zoladex 3.6mg (goserelin acetate implant) to obstetricians and gynecologists for the treatment of endometriosis in the US and Puerto Rico (Press release, Biovail, 2 May 2006)
	Novartis Pharmaceuticals Canada (Novartis)	in May, through Biovail Pharmaceuticals Canada (BPC), to market Novartis' Lescol (fluvastatin sodium) capsules and once-daily Lescol XL (fluvastatin sodium extended-release) tablets, for the treatment of hypercholesterolemia and mixed hyperlipidemia, in Canada (Press release, Biovail, 19 May 2006)
	Sciele Pharma	in December, for five years, whereby Sciele Pharma provides US promotional support for Zovirax (acyclovir), for the treatment of herpes simplex virus (HSV) infections (Press release, Sciele Pharma, 20 Dec 2006)
2007	Depomed	in February, through Biovail Laboratories International SRL, which receives an option to license Depomed's AcuForm technology to develop and commercialise up to two pharmaceutical products. Biovail pays Depomed an upfront fee of \$500,000 (Press release, Depomed, 12 Feb 2007)

Updated by EW on 13/2/2007.

Financial figures

Summary (US\$ million)	
Year ended Dec	2006
Revenues	1,070.53
R&D expenditure	95.48
Operating profit (loss)	229.55
Net profit (loss)	203.95
EPS (\$)	1.27
Cash & cash equivalents	834.54
Total assets	2,175.11

Summary (US\$ million)

Year ended Dec	2005	2004	2003	2002	2001	2000
Revenues	935.54	886.54	823.72	788.03	537.14	309.17
R&D expenditure	88.44	70.49	86.57	52.15	51.02	52.66
Operating profit (loss)	301.87	216.06	16.94	134.28	171.16	(78.03)
Net profit (loss)	236.22	160.99	(27.27)	87.80	87.45	(147.98)
EPS (\$)	1.48	1.01	(0.17)	1.77	0.58	(1.16)
Cash & cash equivalents	445.29	-	-	-	-	-
Total assets	2,028.81	1,711.06	1,922.77	1,833.80	1,331.48	1,107.27

Key Product Sales (US\$ million)

Year ended Dec	2006	2005	2004	2003
Biovail Pharmaceuticals Canada (BPC) products	68.72	99.51	101.87	85.20
Cardizem LA	59.32	59.67	53.63	-
Core products	-	-	565.84	172.40
Generics	141.08	135.21	149.68	101.50
Legacy products	139.85	133.42	125.93	208.90
Teveten	(1.32)	6.39	17.60	-
Ultram ER	53.72	-	-	-
Wellbutrin XL	450.33	354.21	317.30	64.90
Zovirax	112.39	95.86	75.45	-
Total product sales	1,024.09	884.27	841.45	632.90

In June 2006, Biovail amended and renewed its revolving term credit facility with its banking syndicate (Press release, Biovail, 16 Jun 2006).

Updated by NLO on 29/3/2007.

Number of Projects in R&D (summary)

Launched	4	Phase III Clinical Trial	3	Preclinical	11
Registered	1				
Pre-registration	3				

Number of Projects in R&D (detail)

Drug Name	Main therapy	Main therapy status
Biotechnology Products (1)		
Ampligen	Oligonucleotide, non-antisense, non-RNAi	Phase III Clinical Trial
Cardiovascular Products (1)		
BVF-239	Cardiovascular	Preclinical

Drug Name	Main therapy	Main therapy status
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Formulations (18)

bupropion, Biovail	Formulation, modified-release, <=24hr	Launched
metformin AcuForm HCl	Formulation, modified-release, <=24hr	Launched
tramadol SR, Ethypharm	Formulation, modified-release, <=24hr	Launched
tramadol, Biovail	Formulation, modified-release, <=24hr	Launched
citalopram hydrobromide, Biova	Formulation, oral, orally-disintegrating	Registered
bupropion EA salt, Biovail	Formulation, fixed-dose combinations	Pre-registration
zolpidem tartrate, Flash Dose	Formulation, optimized, microparticles	Pre-registration
fluoxetine, Flash Dose	Formulation, oral, solubility-enhanced	Pre-registration
tramadol + NSAID, Biovai	Formulation, fixed-dose combinations	Phase III Clinical Trial
sumatriptan, Biovail	Formulation, oral, orally-disintegrating	Phase III Clinical Trial
bupropion + SSRI, Biovail	Formulation, fixed-dose combinations	Preclinical
metformin + ACE inhib, Biovail	Formulation, fixed-dose combinations	Preclinical
metformin + CCB, Biovail	Formulation, fixed-dose combinations	Preclinical
metoprolol ER + ACE inhib, Bio	Formulation, fixed-dose combinations	Preclinical
carvedilol, Biovail	Formulation, modified-release, <=24hr	Preclinical
lorazepam, Flash Dose	Formulation, oral, orally-disintegrating	Preclinical
venlafaxine, Biovail	Formulation, oral, other	Preclinical
BVF-300	Formulation, other	Preclinical

Neurological Products (2)

BVF-065	Neurological	Preclinical
BVF-087	Neurological	Preclinical

Marketed pharmaceutical products (originated)

Drug Name	Brand Name	Main therapy
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Formulations (16)

bupropion, Biovail	bupropion CR, Biovail	Formulation, modified-release, <=24hr
clonidine, Biovail	Tenso-Timelets	Formulation, modified-release, <=24hr
delivery technology, Biovail	CEFORM	Formulation technology
diethylpropion, Biovail	Regenon retard	Formulation, modified-release, <=24hr
dihydrocodeine, Biovail	DHC-Continus	Formulation, modified-release, multi

Drug Name	Brand Name	Main therapy
diltiazem once-daily, Biov	Tiazac	Formulation, modified-release, <=24hr
diltiazem once-daily,Biovail-2	Cardizem LA	Formulation, modified-release, <=24hr
disopyramide, Biovail	Norpace CR	Formulation, modified-release, <=24hr
ibuprofen, Biovail	Novogent	Formulation, modified-release, <=24hr
ibuprofen, Flash Dose	ibuprofen, Flash Dose	Formulation, modified-release, immediate
isosorbide dinitrate, Biovail	Isoket Retard 120	Formulation, modified-release, <=24hr
ketoprofen, Biovail	Oruvail	Formulation, modified-release, other
metoclopramide, Biovail	Gastromax	Formulation, modified-release, <=24hr
propranolol, Biovail	Beta-Timelets	Formulation, modified-release, <=24hr
theophylline, Biovail	Theo-24	Formulation, modified-release, other
tramadol, Biovail	Ultram ER	Formulation, modified-release, <=24hr

Marketed pharmaceutical products (licensed in)

Drug Name	Brand Name	Main therapy
Alimentary/Metabolic Products (1)		
magaldrate	Dynese	Antacid/Antiflatulent
Anti-infective Products (1)		
aciclovir	Zovirax	Antiviral, other
Cardiovascular Products (4)		
diltiazem	Cardizem	Antianginal
enalapril maleate	Xanef	Antihypertensive, renin system
enalapril maleate + HCTZ	Vaseretic	Antihypertensive, renin system
fluvastatin	Lescol	Hypolipaeamic/Antiatherosclerosis
Formulations (9)		
diltiazem once-daily, Elan	Cardizem CD	Formulation, modified-release, <=24hr
diltiazem SR, Ethypharm	diltiazem SR, Ethypharm	Formulation, modified-release, other
diltiazem twice-daily, Elan	Cardizem SR	Formulation, modified-release, <=24hr
fluvastatin, extended release	Lescol XL	Formulation, modified-release, other
metformin AcuForm HCl	Glumetza	Formulation, modified-release, <=24hr
naproxen, Biovail	naproxen, Biovail	Formulation, modified-release, <=24hr
pHEMS delivery system, Verex	pHEMS delivery system, Verex	Formulation technology

Drug Name	Brand Name	Main therapy
piroxicam betadex	Brexidol	Formulation, conjugate, carbohydrate
tramadol SR, Ethypharm	Ultram ODT	Formulation, modified-release, <=24hr

Hormonal Products (excluding sex hormones) (1)

goserelin	Zoladex	Releasing hormone
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Neurological Products (1)

citalopram hydrobromide	Celexa	Antidepressant
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2004 Additional news

March

- Biovail renews its Revolving Term Credit Facility with its syndicate of Canadian and American banks. Biovail identified its cash flow expectations and capital requirements for 2004 along with its strategy to focus its business development activities on out-licensing, not acquisitions, and therefore has renewed the Credit Facility at US\$400 million (pr 23-03-04).

2005 Additional news

February

- Biovail announces a \$27.6 million expansion project to further enhance the manufacturing capability of the company's largest manufacturing facility located in Steinbach, Manitoba (pr 22-02-05).

May

- As a result of Biovail's decision to realign its commercial approach to the US primary-care market, Biovail will be reducing its global headcount of 2,200 by approximately 20%. Kos Pharmaceuticals will offer employment to approximately 200 members of Biovail's US commercial group as part of the companies' recent agreement. Transitional support will be offered to Biovail employees who are not transferring to Kos and affected by these decisions (pr 03-05-05).

2006 Additional news

March

- Biovail effects changes to its business infrastructure to create, maintain and extend its competitive advantage in the key markets for which it produces medicines. Biovail reorganises its business into three business units: Biovail Drug Delivery (BDD), comprising Biovail's drug-delivery technologies, its drug-development capabilities and its strategic partnerships; Biovail Pharmaceuticals US (BPUS), focusing the promotion of products to specialists in niche therapeutic markets; and Biovail Pharmaceuticals Canada (BPC), a Canadian business unit, which promotes products to both to specialist and primary-care physicians in Canada (Press release, Biovail, 7 Mar 2006).

- *Updated by DS on 27/3/2006.*