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Biovail Reports First-Quarter 2009 Financial Results

May 06, 2009

GAAP EPS of $0.25; Cash EPS of $0.42;

Wellbutrin XL® Acquisition Expected to Add $200-$220 Million to Cash Flows through 2010;

Additional $480 Million Cash Expected through 2010 to Accelerate New Strategic Focus;

Pimavanserin and Tetrabenazine CR Build on Specialty CNS Pipeline;

Annual Cost Savings Target Raised to $40-$60 Million

TORONTO--(BUSINESS WIRE)--May. 6, 2009-- Biovail Corporation (NYSE/TSX: BVF) today announced its financial results for the three-month period ended March 31, 2009.

To the extent that this news release contains forward-looking statements, investors are cautioned that these are based on the Company's current views, and actual outcomes are not certain. For more information, see the note on forward-looking information following the conference-call details below.

"We are ahead of schedule with our New Strategic Focus and have proven our ability to execute," said Biovail Chief Executive Officer Bill Wells. "We acquired and launched our first specialty CNS product, tetrabenazine for Huntington's Chorea, which is performing ahead of our expectations. We have begun building a promising pipeline of specialty CNS products. On the business-development front, we are hard at work on a number of interesting opportunities. We have reinforced our base business in order to provide additional resources to accelerate our strategy through the acquisition of U.S. rights to Wellbutrin XL® , which is expected to add $200 million to $220 million in cash flow through 2010 and create substantial value for the Company. We have strengthened our senior management team and established an outstanding External Advisory Board. Perhaps most importantly, we have become a recognized and credible participant in the specialty CNS market."

Mr. Wells added, "We are making excellent progress toward implementing our New Strategic Focus and shifting Biovail to high growth, but we still have work to do. Given the current global financial environment, we are seeing numerous and unique opportunities to in-license or acquire CNS products and also have been introduced to corporate acquisition targets that might not have been otherwise available. Business development remains a top priority. We must ensure we have the resources to pursue these opportunities by reinforcing our cash flows in the base business, increasing efficiencies and ensuring we have the right capital structure. Including the incremental cash anticipated from Wellbutrin XL® and the announced change in our dividend policy, we expect additional available cash of approximately $480 million through 2010. We must also continue to build our capabilities and steadily increase our presence in the specialty CNS market. The challenges are great, but we believe the opportunities are equally large. Everyone at Biovail

is highly motivated to tackle these challenges and succeed. If we are successful, Biovail will be a leader in the specialty CNS market and a high-growth company."

First-Quarter 2009 Financial Results

Total revenues for the three months ended March 31, 2009 were $173.3 million, compared with $208.5 million for the first quarter of 2008. First-quarter 2009 net income, in accordance with United States Generally Accepted Accounting Principles (GAAP), was $39.0 million, compared with $56.4 million for the corresponding 2008 period. GAAP diluted earnings per share (EPS) for the first quarter of 2009 were $0.25, versus $0.35 for the first quarter of 2008.

Specific Items Affecting First-Quarter Results

GAAP net income and EPS figures for the first quarter of 2009 were negatively impacted by a $2.7-million loss on the impairment of investments related to the Company's investment in auction-rate securities, $1.4 million in costs associated with the Securities and Exchange Commission (SEC) consultant hired as a result of the settlement of the legacy SEC proceeding, a $1.3-million restructuring charge related to the implementation of the Company's New Strategic Focus, and $0.2 million in legal settlements. In aggregate, these items negatively impacted net income and EPS in the first quarter of 2009 by $5.7 million and $0.04, respectively.

GAAP net income and EPS figures for the first quarter of 2008 were negatively impacted by a $3.6-million loss on the impairment of investments primarily related to the Company's investments in auction-rate securities, a $1.2-million equity loss related to an investment in Western Life Sciences Venture Fund and an accrual of $7.9 million for the estimated contractual obligations to terminate the long-term safety study for BVF-146 (combination of once-daily tramadol with an anti-inflammatory agent).

Acquisition of U.S. Rights to Wellbutrin XL®

Biovail also announced today that it has entered into an agreement to acquire the U.S. commercialization rights to Wellbutrin XL® (extended-release bupropion hydrochloride tablets) from GlaxoSmithKline (GSK) for total consideration of $510 million. Wellbutrin XL® , which GSK has distributed in the U.S. since September 2003, was developed by Biovail and is manufactured at the Company's Steinbach, Manitoba manufacturing facility. The agreement is subject to Hart-Scott-Rodino regulatory clearance in the U.S. For more information, see separate news release issued May 6, 2009, *Biovail Announces Acquisition of U.S. Rights to Wellbutrin XL® .* Biovail intends to finance this acquisition through the use of available cash and the Company's credit facility.

Pimavanserin License & Collaboration Agreement with ACADIA Pharmaceuticals

Earlier this week, Biovail announced a collaboration and license agreement with ACADIA Pharmaceuticals Inc. for the U.S. and Canadian rights to develop manufacture and commercialize pimavanserin tartrate, a new chemical entity (NCE) currently in development for the treatment of Parkinson's disease psychosis (PDP). Under the terms of the agreement, Biovail has paid to ACADIA an upfront amount of $30 million and will make additional milestone payments as pimavanserin progresses towards commercialization. For more information, see news release issued May 4, 2009, *Biovail Enters Into Collaboration and License Agreement with ACADIA for Pimavanserin.*

Tetrabenazine CR for Tourette Syndrome

Biovail today announced that, in partnership with Cambridge Laboratories (Ireland) Limited, a controlled-release formulation of tetrabenazine for the treatment of Tourette Syndrome (BVF-

018) has been added to the Biovail's specialty CNS pipeline. Biovail is targeting a mid-2009 pre-IND meeting with the U.S. Food and Drug Administration (FDA) for this program. Tourette Syndrome is a central nervous system (CNS) disorder estimated to affect approximately 200,000 people in the U.S.

Commercial Launch of Aplenzin™

In April 2009, Biovail announced the U.S. commercial launch of Aplenzin™ (bupropion hydrobromide) extended-release tablets by sanofi-aventis US. Aplenzin™ was approved by the FDA in April 2008 at dosage strengths of 174mg, 348mg and 522mg for the treatment of major depressive disorder (MDD). The 522mg dosage strength of Aplenzin™ represents the only FDA-approved single-tablet, once-daily treatment option equivalent to 450mg of bupropion hydrochloride therapy, which requires two or three tablets daily.

Establishment of External Advisory Board

In March 2009, Biovail announced the formation of an External Advisory Board (EAB) to oversee and provide medical, scientific, and commercial input into the Company's development-pipeline efforts in specialty CNS disorders.

Biovail's EAB is comprised of Franklin M. Berger, Dr. Mark A. Cochran, Dr. Kathleen Clarence-Smith, Dr. Robert H. Lenox, Dr. Karoly Nikolich and Dr. Ian Ragan. These exceptional professionals bring a wealth of academic, business and product-development expertise and acumen to Biovail. For more information, please see news release issued March 27, 2009, *Biovail Announces Establishment of External Advisory Board.*

Restructuring Update

In consideration of the Company's shift in its research-and-development focus from reformulation opportunities to the in-licensing and development of specialty CNS programs, Biovail has decided to close its research and development (R&D) site in Mississauga, Ontario, and to streamline its R&D operations in Chantilly, Virginia. The Chantilly operation, currently housed in two buildings, will be consolidated into a single building and will assume the Pharmaceutical Science and Technology Transfer functions currently performed at Biovail's Mississauga R&D site. This initiative, which will retain our strong expertise in formulation, clinical development and regulatory affairs, will reduce headcount by approximately 50 employees, and is expected to reduce R&D overhead by approximately $8 million annually. Restructuring charges of approximately $4 million and other costs of approximately $2.2 million are expected to be incurred largely in the second quarter of 2009. Biovail continues to target an investment in R&D of $600 million in the 2008 to 2012 timeframe.

The ongoing closure of Biovail's manufacturing facilities in Puerto Rico remains on track to be completed by early 2010. The two Puerto Rico facilities, and the previously closed R&D facility in Dublin, Ireland, remain on the market to be sold.

Biovail's restructuring and expense reduction opportunities have proven to be greater than originally anticipated. Consequently, Biovail is increasing its cost reduction target to $40 million to $60 million annually beginning in 2010. Total write-offs and restructuring charges associated with this effort are now expected to be in the range of $100 million to $120 million (previously $80 million to $100 million), of which the estimated cash component remains in the range of $20 million to $40 million. To date, $75.6 million of these charges have been incurred.

Balance Sheet & Cash Flow

At the end of the first quarter of 2009, Biovail had cash and cash equivalents of $297.7 million, marketable securities valued at $20.7 million, and no borrowings under its $250-million committed credit facility.

Cash flow from operations was $47.0 million in the first quarter of 2009, compared with $92.7 million in the first quarter of 2008 ($66.9 million and $73.9 million, respectively, before changes in operating assets and liabilities), which primarily reflects lower net income in 2009 and a decrease of $21.7 million related to the change in accounts receivable, reflecting a higher level of receipts in the first quarter of 2008. Net capital expenditures in the first quarter of 2009 amounted to $0.8 million, compared with $9.7 million in the prior-year period. Going forward, capital expenditures are expected to remain significantly below historical levels as a result of the closure or consolidation of the Company's facilities in Puerto Rico, Ireland, Mississauga and Chantilly, and the availability of capacity in Biovail's Steinbach manufacturing facility. In 2009, Biovail anticipates capital expenditures to be in the range of $5 million to $10 million.

First-Quarter 2009 Financial Performance

Product revenues for the first quarter of 2009 were $165.4 million, compared with $196.9 million in the first quarter of 2008. This decline is primarily due to lower revenues from Wellbutrin XL® , the Zovirax® line, Ultram® ER, Cardizem® LA and the impact of a weaker Canadian dollar on the sales of Biovail Pharmaceuticals Canada (BPC). Partially offsetting factors include the strong performance of Biovail's Legacy products, and the inclusion of revenues from Xenazine® /Nitoman® and Aplenzin™ in the first quarter of 2009. Excluding Wellbutrin XL® , total product revenues were $145.3 million in the first quarter of 2009, compared with $138.1 million in the prior-year period, an increase of 5%.

Launched in November 2008 by Biovail's marketing partner Ovation Pharmaceuticals, Inc, (acquired by H. Lundbeck A/S in February 2009), Xenazine® generated first-quarter 2009 revenues of $6.7 million. Through April 9, 2009, the product's total prescription volume and average daily dose remain above initial expectations. In Canada, Nitoman® generated revenue of $1.0 million in the first quarter of 2009, which is included in Biovail Pharmaceutical Canada's revenues.

Aplenzin™ generated revenues of $3.8 million in the first quarter of 2009, which represented launch quantities and samples shipped to Biovail's marketing partner sanofi-aventis US prior to the product's April 2009 U.S. commercial launch.

Product revenues for Wellbutrin XL® were $20.1 million in the first quarter of 2009, compared with $58.9 million in the first quarter of 2008. This decrease reflects the introduction of a generic formulation of the 150mg strength of the product in May 2008.

First-quarter 2009 revenues for Biovail's Zovirax® franchise were $32.9 million, compared with $37.1 million in the prior-year period, reflecting a 5% decrease in prescription volume and a reduction in inventories at the wholesaler level, partially offset by price increases. In the first quarter of 2009, Zovirax® Ointment and Zovirax® Cream held a combined 75% share of the topical herpes market, an increase of 1.2 percentage points in market share versus first-quarter 2008 levels.

Ultram® ER generated revenues of $20.6 million in the first quarter of 2009, compared with $24.1 million in the first quarter of 2008. Ultram® ER's performance in the first quarter of 2009 reflects a 9% year-over-year decrease in prescription volume and a reduction in Biovail's supply price from 37.5% to 35% of net sales, which were partially offset by price increases and a $1.1-million reduction to the $6.5-million provision related to the December 2008 voluntary recall of certain lots of Ultram® ER 100mg strength tablets.

Revenues from BPC were $15.3 million in the first quarter of 2009, compared with $16.2 million in the first quarter of 2008, a 6% decrease that reflects the impact of a weaker Canadian dollar, partially offset by the inclusion of Nitoman® revenues and higher volumes of Wellbutrin® XL, Tiazac® XC and Ralivia™. In Canadian dollar terms, BPC revenues in the first quarter of 2009 increased 17%, compared with the corresponding period in 2008.

In the first quarter of 2009, Cardizem® LA generated revenues of $8.2 million, compared with $10.2 million for the corresponding period in 2008, a 20% decrease that reflects lower prescription volumes. The amortization of deferred revenues associated with the May 2005 Kos transaction positively impacted Cardizem® LA revenues by $3.8 million in the first quarters of both 2008 and 2009. Pursuant to an agreement with Watson Pharmaceuticals, Inc. a generic formulation of Cardizem® LA can be launched upon Watson's receipt of FDA approval. Biovail will receive a royalty based on sales of Watson's generic version of Cardizem® LA.

Legacy products generated revenues of $40.6 million for the first quarter of 2009, compared with $33.1 million in the first quarter of 2008. This strong performance reflects the positive impact of price increases, and higher volumes of generic Tiazac® as a result of the recent withdrawal of a competing formulation from the market, which more than offset declining prescription volumes for these mature products.

Product revenue for Biovail's portfolio of generic products was $16.9 million in the first quarter of 2009, compared with $17.2 million in the first quarter of 2008. This performance reflects lower prescription volumes and a decrease in pricing to remain competitive in the market.

The following table summarizes Biovail's product revenue performance in the first quarter of 2009:

($000s)	**Q1/09 Revenues**	**Q1/08 Revenues**	**Change (%)**
Xenazine®	6,683	-	NA
Aplenzin™	3,821	-	NA
Wellbutrin XL®	20,120	58,856	(66)
Zovirax®	32,911	37,130	(11)
Ultram® ER	20,596	24,104	(15)
Biovail Pharmaceuticals Canada	15,308	16,240	(6)
Cardizem® LA	8,187	10,207	(20)
Legacy	40,579	33,147	22
Generics	16,871	17,230	(2)
Glumetza® (U.S.)	317	-	NA
Total Product Revenues	165,393	196,914	(16)

Research-and-development revenue was $3.7 million in the first quarter of 2009, compared with $7.4 million in the corresponding period in 2008. This 49% decrease reflects lower volume of clinical research and laboratory testing services provided to external customers by Biovail's Contract Research Division (CRD), as well as the negative impact of the weakening Canadian dollar relative to the U.S. dollar.

Royalty and other revenue was $4.2 million in the first quarter of 2009, which was consistent with the level recorded in the first quarter of 2008.

Cost of goods sold for the first quarter of 2009 was $44.8 million, compared with $53.7 million in the first quarter of 2008. Gross margins on product revenues were 73% in each of the first quarters of 2009 and 2008. A number of offsetting factors drove this result, including improvements from price increases across several product lines and lower costs in Biovail's Puerto Rico manufacturing facilities, partially offset by lower Wellbutrin XL® volumes, lower pricing on Biovail's generic products and the lower gross margins associated with Xenazine® / Nitoman® .

Total research-and-development (R&D) expenditures for the first quarter of 2009 were $14.5 million, compared with $36.3 million for the first quarter of 2008. Excluding expenses associated with CRD, R&D expenses were $11.1 million in the first quarter of 2009, compared with $30.2 million in the first quarter of 2008. The decrease reflects reduced overhead costs as a result of the closure of the Company's Ireland facility, and lower expenses associated with feasibility programs in Biovail's development pipeline as the Company rebalances its development priorities towards specialty CNS programs. In addition, in the first quarter of 2008, Biovail accrued $7.9 million for the estimated contractual obligations to terminate the long-term safety study for BVF-146. Going forward, R&D expenses are expected to increase relative to first-quarter 2009 levels as a result of the collaboration and license agreement with ACADIA for pimavanserin (see separate news release issued May 4, 2009, *Biovail Enters Into Collaboration and License Agreement with ACADIA for Pimavanserin*), the planned initiation of the Phase 3 clinical program for BVF-324, an undisclosed drug for the treatment of premature ejaculation, and the ongoing development of a controlled-release formulation of tetrabenazine (BVF-018).

Selling, general and administrative (SG&A) expenses for the first quarter of 2009 were $43.2 million, compared with $43.6 million in the first quarter of 2008, a 1% decrease. Included in SG&A expenses for the first quarter of 2009 were $5.8 million in indemnity obligations to certain former officers ($1.2 million in the first quarter of 2008), and $1.4 million in respect of SEC consultant costs. After taking account of these expenditures, SG&A costs declined $6.3 million, or 15%, over the same quarter in 2008. In addition, sales and marketing costs declined over the same quarter in 2008 by $5.9 million, primarily reflecting the net cost reduction due to the change to a contract sales organization for Zovirax® effected in January of 2009.

Amortization expense in the first quarter of 2009 was $15.5 million, compared with $11.7 million in the first quarter of 2008. The increase in 2009 reflects the inclusion of amortization of intangible assets related to the September 2008 acquisition of Prestwick Pharmaceuticals, Inc.

Cash EPS

As previously disclosed, in the fourth quarter of 2008, as a result of a change in the Company's assessment of the realizability of a portion of its deferred tax assets related to approximately $350 million of net operating loss (NOL) carry-forwards in the U.S., Biovail reduced the valuation allowance against a portion of the deferred tax asset in respect of the U.S. NOLs. This reduction has resulted in the recording of the related deferred tax expense and a corresponding increase in the Company's GAAP tax rate commencing in this quarter. However, as the use of NOLs reduces cash taxes otherwise payable, Biovail does not anticipate any significant changes to its cash tax rate in 2009. In addition, amortization expense is likely to vary considerably between periods as Biovail executes its New Strategic Focus, which assumes significant business-development

activity. Accordingly, to facilitate a more appropriate comparison between periods, Biovail will now report Cash EPS, which it calculates as cash flows from operating activities excluding changes in operating assets and liabilities divided by the weighted-average number of shares outstanding, with its quarterly financial results. Cash EPS excludes changes in operating assets and liabilities because they are subject to timing variability that could result in fluctuations not reflective of operating results.

In the first quarter of 2009, Cash EPS was $0.42 compared with $0.46 in the first quarter of 2008. Excluding specific items in the first quarter of 2009, comprised of $1.4 million in costs associated with the SEC consultant, $1.3 million in restructuring costs and $0.2 million in legal settlements, Cash EPS was $0.44. For more information concerning Cash EPS, please refer below to *"Use of non-GAAP Financial Measures."*

Use of Non-GAAP Financial Measures

Cash EPS has been provided as Biovail believes such measures provide investors with additional information to assist in understanding critical components of Biovail's financial results and they are useful measures for investors and management that facilitate, on an aggregate and on a per-share basis, respectively, operating comparisons between periods. Such measures do not have any standardized meanings prescribed by GAAP, and are therefore unlikely to be comparable to similar measures presented by other companies. Cash EPS is not a measure of performance under GAAP, and should not be considered in isolation of or as a substitute for net income or earnings per share prepared in accordance with GAAP. Biovail has provided a reconciliation of Cash EPS to GAAP net income and to GAAP EPS in the table below.

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