BAUSCH Health

Biovail Announces Filing of ANDA for Fenofibrate Tablets

September 03, 2008

TORONTO--(BUSINESS WIRE)--Sept. 3, 2008--Biovail Corporation (NYSE:BVF) (TSX:BVF) today announced that the United States Food and Drug Administration (FDA) has accepted the Company's abbreviated new drug application (ANDA) for a generic formulation of 145mg and 48mg strengths of fenofibrate tablets (sold under the brand name Tricor by Abbott Laboratories).

"This represents the second successful ANDA filing in the past six months," said Biovail Chief Executive Officer Bill Wells. "While our primary focus remains the implementation of our New Strategic Focus, we continue to make progress with our existing pipeline products."

Tricor is a lipid-lowering agent used to treat abnormal lipid levels in the bloodstream, including cholesterol and triglycerides. The product is available in 145mg and 48mg strengths. According to IMS Health, Tricor generated U.S. revenues of approximately $1.45 billion in the twelve-month period ended June 30, 2008, with the 48mg strength accounting for $69.5 million of the total.

Caution Regarding Forward-Looking Information and "Safe Harbor" Statement

To the extent any statements made in this press release contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and may be forward-looking information under applicable Canadian provincial securities legislation (collectively, "forward-looking statements"). These forward-looking statements relate to, among other things, our objectives, goals, strategies, intentions, plans, beliefs, estimates and outlook, including, without limitation, statements concerning the successful filing of abbreviated new drug applications with the U.S. Food and Drug Administration, the implementation of the Company's New Strategic Focus, progress being made with development-pipeline products, and can generally be identified by the use of words such as "believe", "anticipate", "expect", "intend", "plan", "will", "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements.

Although Biovail believes that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Certain material factors or assumptions are applied in making forward-looking statements, and actual results may differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from these expectations include, among other things: the results of continuing safety and efficacy studies by industry and government agencies; the patient's dosage regime; the particular attributes, traits and health of the patient; the regulatory environment; acceptance and demand for new pharmaceutical products and new indications for existing products; the impact of competitive products and pricing; regulatory matters including compliance with pharmaceutical regulations; and other risks detailed from time to time in the Company's filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, as well as the Company's ability to anticipate and manage the risks associated with the foregoing. Additional information about these factors and about the material factors or assumptions underlying such

forward-looking statements may be found in the body of this news release, as well as under the heading "Risk Factors" contained in Item 3(D) of Biovail's most recent Annual Report on Form 20-F.

Biovail cautions that the foregoing list of important factors that may affect future results is not exhaustive. When relying on our forward-looking statements to make decisions with respect to the Company, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. We undertake no obligation to update or revise any forward-looking statement.

About Biovail Corporation

Biovail Corporation is a specialty pharmaceutical company engaged in the formulation, clinical testing, registration, manufacture, and commercialization of pharmaceutical products. The Company is focused on the development and commercialization of medicines that address unmet medical needs in niche specialty central nervous system (CNS) markets. For more information about Biovail, visit the Company's Web site at
www.biovail.com
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