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Biovail's alleged Cardizem CD will not reverse sales and earnings decline.

Biovail Corp. (Symbol: BVF) (Price: 28.625) International has announced Hoechst Marion Roussel ("HMR") did not challenge its ANDA filing for a generic Cardizem CD product within the required 45-day time limit under Waxman Hatch. This has led to claims that Biovail's product does not infringe on HMR's patents and to predictions that Biovail will be the first, or at worst one of only two, companies competing for a share of the Cardizem CD market. These reports, which appear to have been confirmed by Biovail in a recent press release, are incomplete and incorrect. The claim that Biovail's filing is assured of FDA approval before its competitors is baseless and false. Furthermore, the widespread reports that Biovail can be the first to market a Cardizem CD generic product in the fall of 1998 is completely false and untrue. Below is a detailed description of the status of the pending Cardizem CD ANDA application and the possible outcome.

In September 1995, Andrx Corporation ("Andrx") filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") requesting approval for a generic version of Cardizem CD, a diltiazem hydrochloride prescription drug for hypertension. In January 1996 Carderm Capital L.P., which licensed the Cardizem CD patent to HMR, and HMR filed a lawsuit against Andrx alleging that Andrx's generic product infringed upon one of six patents listed as covering Cardizem CD. This lawsuit was filed within a 45-day period after Andrx notified HMR of the ANDA filing and resulted in an injunction. The Andrx injunction permits the FDA to give tentative approval of the ANDA, but prevents full marketing approval of the ANDA until either a final judgement in the lawsuit has been rendered or a 30-month period has expired. The 30-month period has been in effect since January 1996 and will expire on July 2, 1998.

Andrx was the first company to file an ANDA for a generic version of Cardizem CD. As a result, under certain circumstances Andrx has the right to 180 days of market exclusivity. The FDA can not grant ANDA marketing approval to any other competitor who subsequently filed until after Andrx's exclusivity period has expired. This 180 day exclusivity begins on either the first day of commercial marketing of the product or the date the lawsuit between Andrx and HMR finds the application to be invalid or not infringing, whichever is earlier.

Faulding, Inc. ("Faulding") was the second company to file an ANDA with the FDA for approval of a generic version of Cardizem CD. On February 3, 1997 HMR also filed a lawsuit against Faulding within 45 days of receiving notification. As a result, Faulding can receive tentative ANDA approval but is restricted from receiving final marketing approval until there is either a final judgement in its lawsuit or its own 30 month restriction period expires. Should Andrx withdraw its application, Faulding could inherit Andrx's 180-day exclusivity period.

In early spring 1997 Biovail filed an ANDA for a generic version of Cardizem CD. HMR did not file a lawsuit against Biovail within the 45-day period that would cause the automatic 30-month stay on final approval. HMR still reserves the right to file a lawsuit. The fact that Hoechst did not sue Biovail within the 45-day period does not mean that Biovail's generic formula of Cardizem CD does not infringe on the patent. It also does not mean that their application will be approved by the FDA, let alone before either the Andrx or Faulding applications are approved. Furthermore, it does not in any way indicate that Biovail is assured of being first to the market. In fact, Andrx's 180 days of market

exclusivity could begin after the expiration of its 30 month injunction period. This would prevent any other marketing approval until early 1999.

Generic bioequivalent drugs are difficult to develop without infringing on existing patents. Biovail has no experience with ANDA approvals and there is no assurance that their Cardizem CD ANDA will be approved. It takes the FDA 18 to 24 months on average to approve an ANDA application. Andrx's application could receive tentative approval at any time. Andrx's defense litigation is well developed and is expected to commence marketing no later than July 1998 subject to final approval. Faulding has a great deal of experience with ANDA filings and a track record of successfully obtaining ANDA approvals very efficiently. Faulding believes it may be able to obtain a favorable judgement before its injunction expires, and also is expected to commence marketing as soon as possible.

As stated above, Biovail has never obtained an ANDA approval. Biovail was able to obtain a New Drug Application ("NDA") approval for Tiazac, a once-daily diltiazem prescription drug, through an extremely unique set of circumstances, which were beyond its control. Hoechst Roussel Pharmaceuticals, Inc. ("Hoechst Roussel") had licensed Tiazac from Biovail and had filed its NDA application. Marion Merrell Dow, Inc. ("MMD") and Elan had sued claiming alleged patent infringement. In an unrelated event Hoechst Roussel and MMD subsequently agreed to merge. The FTC charged that the merger violated Federal anti-trust laws by substantially reducing competition in several drug markets including the diltiazem market. As a result, Hoechst Roussel agreed to a FTC final consent order before gaining approval of the merger. This FTC consent decree was extremely beneficial to Biovail. It ordered the dismissal of a citizen's petition filed with the FDA and the patent infringement lawsuit filed by MMD. In addition, Biovail was given the right to refer to the toxicology and pharmacology data used by MMD for their Cardizem CD NDA on Biovail's own Tiazac NDA. Independent of the consent decree, Biovail also received a cash payment of \$7.5 million from HMR as settlement for Biovail's withdraw of a complaint filed against MMD.

By coincidence Biovail benefited greatly from the \$7 billion merger of Hoechst and MMD. Not only were a complaint and a lawsuit dropped against the company, but HMR was also prevented from filing any further complaints with the FDA that might delay the approval of Biovail's Tiazac NDA. As a result, Biovail received approval to market Tiazac on September 11, 1995. Prior to the merger between Hoechst AG and MMD, the license was returned to Biovail. Assured of FDA approval Biovail was then freed to enter into a new, far more lucrative licensing and supply agreement with Forest Laboratories, Inc. ("Forest") for Tiazac. The effects of this one-time event have now completely expired.

In the last nine months of 1996 and for the six months ended June 30, 1997 Biovail reported total net income of \$31 million. This cumulated net income included \$26 million, equal to over 82% of reported earnings, of deferred income amortization. These deferred revenues that totaled over \$27 million as recently as March 31, 1996 have now been completely exhausted. We believe that this lost "income," increased competition for Tiazac, and the complete lack of sales growth will result in substantially lower earnings in the fourth quarter. We see no reason to buy or hold Biovail shares at over a tax-adjusted 48 times LTM EPS. We believe that Biovail shares will soon trade below \$12 per share.

Short selling involves a risk not associated with the purchase of stock including, but not only limited to, unlimited loss and stock borrowing risks. Additional information is available upon request.