

KV Pharmaceuticals Doubtful about their Future

KV Pharmaceuticals has "substantial doubt" about its ability to "continue as a going concern," according to a financial statement filed last week. In the Form 10-Q, the troubled drugmaker lists its 2009 manufacturing consent decree and items related to the decree among the chief causes of doubt.

In assessing KV's current business status, management articulated the consent-decree-related causes imperiling company viability: suspension of product shipments, the unknown timing of FDA approvals allowing shipments to resume and the likelihood KV will have to seek additional capital to compensate for lost revenue. Exec thinking was further colored by the company's fiscal 2010 net loss of almost \$284 million, according to the filing.

The FDA has allowed KV to resume shipping just two drugs--the extended-release potassium chloride capsule, Micro-K, and a generic version of that product--since the consent decree went into effect. In addition, KV said in the filing it's still in the ramp-up stage of sales of Makena, a hormone to prevent preterm labor, and is not yet generating the "significant sales" it expects from the drug. Makena began shipping last March after a February FDA approval.

KV said in the filing that it continues preparing other products for FDA inspection but doesn't foresee resuming shipments until fiscal year 2012--at the earliest.

Here's a link to KV's filing of the Form 10-Q

<http://www.sec.gov/Archives/edgar/data/57055/000119312511333946/d263611d10qa.htm>