

Seeking Alpha α

Alpharma, Inc. Q1 2008 Earnings Call Transcript

Question-and-Answer Session

Operator

Thank you very much. (Operator Instructions). Our first question will from Gregg Gilbert, Merrill Lynch.

Gregg Gilbert - Merrill Lynch

Thanks, good morning. Starting with EMBEDA, Dean, can you provide more specific color on the technical issues around the data presentation that delayed the NDA? And secondly, I know you haven't decided on the specific launch strategy for EMBEDA yet, but is there any technical reason that you could not cease manufacturing KADIAN to accelerate and switch to EMBEDA, if that's what you chose to do?

Dean Mitchell

Good morning, Gregg. Thanks for the question. The technical issues really relate to the fact that we had certain agreements with the agency ahead of time, around how data would be presented, which in the context of a full review, would have been just fine. Once they decided it was going to be accelerated review, the agency made the policy decision that it had to be absolutely complete, and the data presented in every aspect that allowed them to do a full review within that compressed time, allowed under a priority review. So it's literally a matter of us reformatting and re-presenting some of the data, which is going to take us a couple of months that I talked about, that we expect to take and until we resubmit.

Then the second part of our question, you are absolutely right. We are still working on what our launch strategy is going to be. And I think part of the question is really, do we see a place in the market place for both KADIAN and EMBEDA? I think you can make a pretty good case that if EMBEDA is truly a less abusable product, the right ethical thing to do, probably would be, to withdraw KADIAN from the market. But we want to make sure that physicians are absolutely comfortable with using EMBEDA before making that decision around KADIAN.

Although there maybe a regulatory aspect to that, and we really don't know quite how the FDA is going to think about these products, I suspect, we are all going to learn a little bit more about that in the next 24 hours, as they review the product that our friends at Perdue have submitted.

Gregg Gilbert - Merrill Lynch

Thanks.

Dean Mitchell

Thanks Gregg.

Operator

Thank you. (Operator Instructions). Our next question will come from Ian Sanderson, Cowen and Company.

Ian Sanderson - Cowen and Company

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