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King Pharmaceuticals Inc. Q3 2008 Earnings Call Transcript

Question-and-Answer Session

Thank you, Mr. Squicciarino. The floor is now open for questions. [Operator Instructions]. Our first question is from Corey Davis from Natixis. Please go ahead.

Corey Davis - Natixis Bleichroeder

Thanks very much. I just wanted to ask a couple of questions about the Alpharma acquisition. Just kidding. I wanted to ask about REMOXY, two things. First is, if you were to get final approval on your PDUFA date, how soon after that could you launch considering things like sales force preparation and especially thinking about manufacturing supply?

Brian A. Markison - Chairman of the Board, President and Chief Executive Officer

Corey that was one question. Was there a second as well?

Corey Davis - Natixis Bleichroeder

It concerns the risk management program.

Brian A. Markison - Chairman of the Board, President and Chief Executive Officer

Okay.

Corey Davis - Natixis Bleichroeder

Do you have one developed; have you developed it within interaction of the FDA? Do you expect to need one at all for REMOXY?

Brian A. Markison - Chairman of the Board, President and Chief Executive Officer

That's four questions. But we'll? I'll let Eric Carter to talk a little bit about the risk map and then I'll come back to the launch planning that we have for REMOXY. And by the way we were going to answer your first questions.

Joseph Squicciarino - Chief Financial Officer

Only kidding. Eric?

Eric G. Carter - Chief Science Officer

Yes, the expectation is that REMOXY will be approved under REMS, Risk Evaluation and Mitigation Strategy. And indeed we have explored the work that's been done by others and what we anticipate is required to put together a comprehensive appropriate REMS which we are presenting to the advisory committee next week and has been presented of course as part of the? filing of the NDA to FDA. It is a proposed REMS at this point in time. FDA will need to approve it. But we are confident that we have in the REMS addressed all of the key issues that are important to assure the safe use of REMOXY.

Brian A. Markison - Chairman of the Board, President and Chief Executive Officer

And Corey, with regard to launch preparedness, should we get approval on our PDUFA date, we're going through a number of scenarios now where we certainly expect to launch as early as possible in the first quarter of 2009, if not even a tiny bit sooner. But we're tightening up all of those plans as we speak.

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