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Human Genome Sciences Inc. Q3 2008 Earnings Call Transcript

Question-and-Answer Session

Operator

Thank you very much. [Operator Instructions]. Our first question is from Geoffrey Porges from Sanford Bernstein. Please proceed with your question sir.

Geoffrey Porges

Thanks very much. Tom, first of all, obviously, we need to, I think understand a little bit more about what's going on with ABthrax and are you absolutely certain that you will get paid for this in 2009, as it merely a sort of procedure, administrative procedural issue here? Or are there substantive issues being reviewed by both the DoD and by the FDA? And then I'd just like to come back with a follow up question if I may? Thanks.

H. Thomas Watkins

Jim, why don't you start with that question.

Jim Davis

Yeah, sure. Let me just clarify one thing, DoD is not involved in this contract. The approval authority through HHS, the BARDA division. And we have no substitute issue with BARDA. What has happened with FDA is that we have submitted substantial number of reports and our reports are back the same reports that we eventually submit for our BLA. FDA is doing a very thorough review of each of those reports, quite similar if not identical to what they would do for our BLA. As a result that review is taking a fair amount of time. As is usual FDA comes back, ask questions, we give them data, we give them reformulated data, we give them new charts and tables. But, I think the process is one of a typical response back and forth with FDA as they review the data. And we do remain confident that we will get this approval in the near term and that we will receive our revenue in 2009.

Geoffrey Porges

Could I ask a follow up question to that then? When was it apparent to you Tom that you were not going to get the revenue because quite recently you were still saying that you were going to be reporting the revenue beginning in October or beginning in the fourth quarter with the substantial chunk of revenue, so when was this known?

H. Thomas Watkins

Just very recently, Geoffrey the answer to that, at FDA, this is not an approval. As we have stated, it's a clearance to ship. And it has always been our belief and remains our belief that as soon as we get that clearance we will be shipping very promptly. BARDA and Jim stated this, working very closely with us here. They are anxious to stock a product. We've got it manufactured; we've got it ready to ship. So, the answer to your question is, the timing change, which is really this year to next year sort of thing, has just become apparent to us in the very recent past, and that's why we are taking the steps that we are. Jim, anything to add to that?

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