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## Auxilium Pharmaceuticals Q4 2008 Earnings Call Transcript

### Question-and-Answer Session

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#### **Operator**

(Operators Instructions). Your first question comes from the line of Marshall Urist from Morgan Stanley. Please proceed.

#### **Marshall Urist - Morgan Stanley**

Yeah, hey guys Good morning. First question is, can you just give us any kind of updates from the ... now that the safety database is locked any, can you give us any new comments on new, any new adverse ... serious adverse events or any kind of updates that you could give us there would be helpful?

#### **Armando Anido**

Yeah, I think as you heard Tony talk about the databases were locked back in December and I think that there are no new events to really discuss. We are in the process of finalizing the BLA at this particular point. And you should expect that we will talk about safety at a later point after the BLA is submitted. Right now we don't have an exact timeframe or an exact location where that will be released.

#### **Marshall Urist - Morgan Stanley**

Great, thanks. And then on the filing timeline for priority review, is there something that gives you confidence there or are you just planning that that could be the soonest date and so you don't want to be caught flat footed if that does happen?

#### **Armando Anido**

Well I think that as we have been talking about, I think preparing for the upside, which would be a ... as a priority review with the six month clock versus a ten months standard review, I think is something that we have to be ready for. I think that we are not a 100% sure that it's going to happen. I think that when you take a look at the requirements for a priority review we hit on two out of the three criteria that the FDA kind of sets for it. The one that we miss on is a life threatening disorder and, but we are not sure what the FDA is going to react to when we submit it. But we will be requesting it.

#### **Marshall Urist - Morgan Stanley**

Okay. Great, thanks. I'll jump back in the line.

**Armando Anido**

Thanks.

**Operator**

Your next question comes from the line of Thomas Wei from Piper Jaffray. Please proceed.

**Thomas Wei - Piper Jaffray**

Thanks. With 12 months of follow-up data in hand now, can you share with us any information on what the disease progression rate looks like for patients who were treated with XIAFLEX in the first year?

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