

The logo for Seeking Alpha, with the text 'Seeking Alpha' in white and a Greek letter alpha symbol in orange on a dark red background.

Acorda Therapeutics, Inc., Q3 2008 Earnings Call Transcript

Question-and-Answer Session

Operator

(Operator Instructions). Our first question will come from the line of Matt Roden with J.P. Morgan.

Matt Roden - J.P. Morgan

I have a couple of questions on the European regulatory discussions. First, just to clarify, should we assume that no additional clinical trials would be required for filing an approval of Fampridine in Europe? Secondly, can you talk a little bit more about what led to your decision to file through the central route rather than the country-by-country basis? And then thirdly, can you narrow down a little bit in 2009 whether be it the first half or second half?

Ron Cohen

At this point, we don't believe that we'll need to conduct additional studies based on the meetings that we've had. Obviously, the final decision is going to be up to the EMEA as a whole, but based on where we are, we plan to file based on the trials that we have, which are, as you know, the 2 placebo controlled phase III trials primarily. With respect to how we arrived at this decision, we don't generally get into specifics of our conversations with regulators. We discussed several topics with them as I mentioned in terms of the overall adequacy of the package that we have. Typically, as you know, a decentralized filing is used when you don't necessarily plan to launch in every country. Typically, a centralized filing I would say is preferred if you do want to have the flexibility to launch throughout Europe, it's a more efficient process, and if there is no apparent reason not to do it, typically companies will opt for centralized procedure, and based on our current information we think a centralized procedure is the way to go. We are not at this point prepared to give more specifics than to say that it's in 2009, hopefully we'll be able to narrow that down as we get into the New Year.

Operator

Our next question will come from the line of Joel Sendek with Lazard Capital Markets.

Joel Sendek - Lazard Capital Markets

Two questions, first you mentioned that you might request a priority review, I'm wondering why you wouldn't.

Ron Cohen

Yes, I think Joel it's a new environment right now at the FDA. We monitor these things as closely as we can as I think everyone else does in the industry, and it's clear I think to everyone who has been watching that the agency has been under increasing stresses, mostly induced by staffing issues which in turn were induced by lack of funding until very recently. That puts a huge amount of pressure on the existing staff at the FDA, and we've seen that in terms of the output lately in terms of PDUFA dates and meetings being delayed or postponed and so forth. So, we're reviewing whether or not priority review in this environment actually is going to be advantageous as opposed to, for example, possibly putting more pressure on an already stressed situation. That's something we're assessing and we'll make the decision as we get to the filing, which is the time we would ask for priority review.

Copyright © 2008 CNET Networks, Inc. All Rights Reserved.