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Acusphere Inc. Q3 2008 Earnings Call Transcript

Question-and-Answer Session

Operator

(Operator Instructions) Your first question comes from Jason Napodano – Zacks Investment Research.

Jason Napodano - Zacks Investment Research

I appreciate the update, you actually answered a lot of the questions that I was going to ask, but I've got a couple here. The comment in the press release about the potential off-label concerns by the FDA, you spoke on that in your prepared remarks, Sherri, but I'm wondering do you think that the FDA is more concerned with the patient population and the patients that are contraindicated or the potential use of the drug for alternative diagnostic uses?

Sherri Oberg

I'm trying to be very careful to keep my remarks limited to Acusphere thoughts rather than FDA thoughts on this topic and that's for obvious regulatory reasons, but I think if you look at the June advisory committee with other agents and just look at other meetings that FDA has with other drugs that aren't in our class, off-label usage is always a consideration. We're focusing more on off-label usage within the cardiology field because we think that's where the more likely risk is. We've never studied this drug in radiology applications or in fields outside of cardiology so there's no publication on dosing or how to do this, and so that's really not the risk we're focused on. We're more focused on other types of cardiology patients that cardiologists would be treating, that we have not studied.

Jason Napodano - Zacks Investment Research

What kind of post approval commitment do you think that the FDA would potentially be looking for in terms of either a Phase IV study, or an open label study, or a long-term safety program?

Sherri Oberg

It's premature for me to comment on that because I just really don't know the answer to that. It was clear from the advisory committee meeting in June with the other agents that there's post marketing studies that the FDA is working with those agents on, and so, as a part of that they're developing their thought process as to what they want those post marketing studies to look like. We don't know what that is yet, other than very high level information.

I'd say on the positive side of this is that given the changes in FDA guidelines, these risk management plans and post marketing studies are new ways for the FDA to look positively at drugs

because they now have the authority to enforce these types of studies it creates a reason to say, okay, I can say yes to this because I know that there is a plan forward to address risks that in the past when they haven't been able to enforce this it was of a bigger concern, so we're hopeful this is going to work to our favor, but we really don't have any input from FDA. I don't want to comment for FDA on this. This is really just our view.

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