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Thoratec Corporation Q1 2009 Earnings Call Transcript

Question-and-Answer Session

Operator

(Operator instructions) We will take the first question from Mimi Pham with JMP Securities.

Mimi Pham – JMP Securities

Hi good morning, good afternoon.

Gary Burbach

Hi, Mimi.

Mimi Pham – JMP Securities

Can you just clarify your CAP with 30 patients, are you through the end of that now that, you know since you had rolled I guess 85 patients in the three-month period?

Gary Burbach

So the 30 patient CAP that I mentioned is a new CAP that we just received two weeks ago. So the previous CAP we had enrolled that CAP, yes.

Mimi Pham – JMP Securities

So you still have 30 patients, I mean 30 people left on this new 30 patient CAP.

Gary Burbach

Close to. Yes.

Mimi Pham – JMP Securities

Do you have a sense from the FDA, like in terms of, you know last quarter you talked about just potential restrictions on the CAP, is that somewhat related to them allowing you to file earlier or do you have any more clarity or color on that that you can provide in terms of future potential restrictions?

Gary Burbach

Yes. I mean at this point there are restrictions other than that it's only 30 patients. You can see from the pace that we enrolled in the trial in the last quarter that centers are enrolling patients quickly

relative to that size. So, it necessitates us going back fairly frequently and the side is going through their IRB process, which for this kind of a change is quick, but nevertheless it does make for a bit of a cumbersome process.

It also maintains uncertainty as to will they continue to provide CAPs in that kind of an approach. So our focus is certainly to try to maintain access to our trial centers through the review and approval process. So, at this point, we certainly are pleased that the FDA gave us another CAP and you know we will look to continue that process going forward.

Mimi Pham – JMP Securities

Okay. And just one last question, in terms of the questions received from the FTC regarding the HeartWare transaction would you say that you're more confident or less confident about the transaction closing in the second half of this year based on your review of the questions?

Gary Burbach

Yes. We are not going to discuss the specifics of the second request, you know we are, as we mentioned, we are actively working to respond to those questions and continue to expect to close in the second half of the year.

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