



Aspect Medical Systems Business Update Call Transcript

Question-and-Answer Session

Operator

Thank you. (Operator Instructions) And we'll go to Tao Levy with Deutsche Bank.

Tao Levy - Deutsche Bank Securities

Hey, good morning.

Nassib Chamoun

Good morning, Tao.

Tao Levy - Deutsche Bank Securities

I'm having a few questions here. First, just maybe one a little bit quickly, I just want to make sure I got the points here. The start of the patient enrollment in the next trial will be second quarter of '08?

Nassib Chamoun

That's correct.

Tao Levy - Deutsche Bank Securities

And you said the trial will be half the size of the BRITE trial. So how long do you expect it to take to enroll, seems like it will be pretty short, right?

Nassib Chamoun

I will let Paul Manberg to answer that. He is putting all those pieces together.

Paul Manberg

Yeah. The current study, it took about 18 months from beginning to completion of the trial. So we expect this to be shorter than that, because we will probably be looking at an eight-week endpoint for this study. So it won't be as long of a tail. And since the number of patients will be about half, we are expecting about a year for this study to be completed. And that, based on our successful completion of the BRITE study on schedule, I think we are confident that we can accomplish that.

Tao Levy - Deutsche Bank Securities

And you are early to add, I assume you've had early discussions with the FDA, what type of regulatory process is this going to involve, they can require panel. Is it quicker than the standard 9 to 12 months regulatory review?

Paul Manberg

Right, we've held two meetings with the FDA about this and there was obviously a question as to which reviewing branch would get it. That's been worked out. This is being viewed as similar to a diagnostic type device where we are predicting response. So we are now expecting that we will probably go through 510K process or the de novo processes, that still under a discussion. And there is no requirement under those processes that it goes before a panel, I think it's still possible that the FDA would decide to do that.

Tao Levy - Deutsche Bank Securities

Okay.

Andrew Leuchter

So, we are hoping that the review process might be shorter than a year, but as you know with the FDA that it really depends on the strength of the evidence that you submit.

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