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TransEnterix knockback could mean a Titan advantage

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It is not often that a race for second place commands this kind of interest. The FDA's denial of TransEnterix's 510(k) application for its robotic surgery system this week has made the group's silver-medal competition with Titan Medical much harder to call. It also scythed the North Carolina-based company's shares in half.

The two companies are each developing surgical robotics systems intended to be smaller and cheaper than the only such product on the US market, Intuitive Surgical's da Vinci. Titan's device is not expected to be cleared for sale until next year – and if TransEnterix resubmits its application they could be neck and neck.

Controversy

At the end of March the FDA delayed the approval decision date for TransEnterix's SurgiBot, a single-port laparoscopic system designed to perform general abdominal surgery. Analysts did not greet the news with dismay, with Stifel writing that "this modestly delayed decision date does not suggest anything incrementally concerning about the ultimate approvability of SurgiBot".

Judging by the 52% share price crash yesterday, it was not just analysts who had expected a positive decision. Management seems to have been sideswiped too; TransEnterix has not outlined what its next steps will be, instead saying it would issue an update on the regulatory strategy during its first quarter results conference call on May 10.

TransEnterix had used a previously cleared surgical device, its Spider system, as the predicate for the 510(k). Analysts at BTIG wrote at the time of the application that this device was similar enough to SurgiBot that there was an 80% chance of approval without any additional clinical studies – despite the fact that when Intuitive had sought approval for single-site cholecystectomy approval, the FDA made exactly this request.

In the event, the FDA said that SurgiBot did not meet the criteria for substantial equivalence to Spider. It is not clear whether the FDA has asked for additional clinical work, but if this is necessary clearance could be delayed by up to 12 months.

That would put TransEnterix roughly on a par with Titan's Sport system for market entry to the US.

New Power Generation

Sport is a similar single-port system also aiming for approval for general abdominal, urologic and gynaecologic surgery. It is larger than SurgiBot, with the surgeon operating the device from a console away from the patient, rather than at the patient's side.

There is expected to be a price differential, too, with a Sport system coming in at around $1m, roughly twice as much as SurgiBot (*The new generation of surgical robots aims for economy, July 21, 2015*).

If TransEnterix had had a year or so on the market before Titan entered, it might have been able to build a following for a system quite far removed from the dominant da Vinci, especially considering its much lower price – da Vinci platforms go for around $2m. If SurgiBot and Sport hit roughly together, though, surgeons might prefer the more familiar-seeming Sport system.

And the prospect of a takeout, never far from medtech investors' minds, has also buoyed TransEnterix's shares over the past few months. Johnson & Johnson is collaborating with Google's healthcare arm, Verily, on a robotic surgical venture Verb Surgical, and both that company and Intuitive itself have at one time or another been mooted as potential buyers of TransEnterix.

Perhaps such a deal is more likely now that TransEnterix is half the price it was a few days ago. On the other hand, buyers tend to like to step in after regulatory approval. This is another reason why TransEnterix needs to communicate its plan for securing 510(k) clearance as soon as possible.

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