Evaluate Vantage

August 03, 2017

Initial success for Rewalk’s soft suit

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Rewalk Robotics was doubtless delighted by new clinical data suggesting that a prototype exosuit it has developed helped partially paralysed patients walk. With its flagship exoskeleton, approved in the US in 2014, the subject of FDA demands for a new post-marketing trial and having great difficulty obtaining reimbursement, smooth development of a second system will be welcome news.

Smooth maybe, but early. The trial was conducted in just nine patients, and the study write-up describes the suit as “first-generation”. Rewalk says it is working to develop lightweight designs for clinical studies as well as pursuing regulatory clearance and commercialisation, but this could be years away – and the new device could run into the same reimbursement headwinds as the approved one.

The new exosuit is called Restore, and contains less plastic and metal hardware than the approved system, Rewalk Personal. Instead the cables and motors are attached to the patient using fabric. It is initially geared towards patients recovering from stroke who have hemiparetic gait – they are partially paralysed on one side of their body. There are around three million stroke survivors with lower limb disability in the US.

According to analysts from Oppenheimer, the soft suit will now go for final testing and adjustments, with the first commercial design slated for the fourth quarter of this year. Should it succeed in stroke patients Rewalk intends to develop the suit for those with multiple sclerosis and other conditions.

In the latest stroke trial the researchers stated the suit's action was “sufficient to facilitate more normal walking” in post-stroke patients.

Tempered

The results were welcomed by Rewalk’s shareholders, who pushed the stock up 6%. But at $1.40 the shares are still down 88% from the float price and 95% from their peak value of $31 nearly three years ago (*IPOs heat up in summer but fall in autumn, October 13, 2014*).

Perhaps investors had unrealistic expectations of what powered exoskeletons could deliver: certainly anyone picturing Ripley’s power loader from the film Aliens would be sorely disappointed. But even those with more tempered ideas might admit feeling a little chagrined.

Back in 2014, analysts from Canaccord forecast product revenues of $143.8m for Rewalk in 2018. According to *EvaluateMedTech*’s consensus data these now stand at just $5m.

By early 2015 Canaccord analysts were starting to admit that both sales and pricing of the exoskeletons were lower than they had expected. Come early 2016 Barclays analysts were pointing to reimbursement and the slow pace of trial enrolment as the sources of Rewalk’s woes.

Then it emerged that the FDA had demanded a further post-approval trial (*Rewalk draws the FDA’s ire, March 3, 2016*). This is ongoing, and the suit remains on the market, but is still only reimbursed on a case-by-case basis, and until the post-market data come in, allowing broader reimbursement coverage, sales will remain moribund. The study results are not expected until 2018.

Next year will also bring FDA approval studies on the Restore exosuit, with a target launch date by the end of 2018. But if Rewalk cannot secure broad reimbursement for Rewalk Personal’s use in patients with spinal cord injury – a much more severe condition than post-stroke hemiparesis – chances of gaining coverage for Restore seems just as uncertain.

Restore is simpler and therefore likely to be priced lower than the flagship product; perhaps this will help it find traction with payers. The question is whether the company can wait that long; it finished the second quarter with just $16.3m in cash; Barclays analysts estimate that at the current burn rate of $6-7m it has only two or three quarters of liquidity left.

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