Evaluate Vantage

December 20, 2016

Penny stock Amedica tries again

Elizabeth Cairns

Refiling an approval application for a spinal implant with the FDA sent Amedica's shares up 6% yesterday, but at 67 cents the orthopaedics group is still mired in penny stock territory.

US clearance of the device, a tweaked version of the Valeo C+CsC, might improve the share price incrementally, should it be granted, but it is unlikely to make a vast difference to Amedica's standing in the spinal device market. It is currently the 14th-biggest player, and last week's launch of a spinal allograft by Zimmer Biomet, which has been aggressively consolidating in this space, will not help it climb the ranks (see table below).

Bioceramic

In November Amedica said the FDA declined to award 510(k) clearance for Valeo C+CsC, a cancellous structured ceramic (CsC) cervical implant made of porous silicon nitride and intended for spinal fusion procedures. This is designed to encourage the patient's own bone to grow into the porous structure, knitting together in the manner of broken bones. Amedica claims that it is the world's first structural porous bioceramic – it is CE marked and on sale in Europe.

European approval was based on the Cascade study, which compared outcomes of cervical fusion using the Valeo C+CsC with the existing standard, polyether ether ketone plastic spacers filled with bone autograft. Results showed comparable clinical and radiographic performance between the two, and of course Amedica's device has the advantage of not requiring an initial bone harvesting procedure elsewhere in the patient's body to supply the autograft.

The FDA's rejection was by no means the start of Amedica's troubles. Just a month earlier it had made nearly 40% of its staff redundant to save around $2m in annual operating costs. But the company has been performing poorly for much longer than that.

Its $20m Nasdaq IPO in February 2014 – at the very beginning of that year's sudden medtech IPO boom – was little short of a disaster. Before floating Amedica lowered its projected price range from $10-12 down to $8-10, but eventually priced at just $5.75. A slow and steady decline followed, and over the course of 2014 the stock had slipped 86%.

Allograft

And regardless of how new and differentiated Amedica believes its C+CsC technology to be, taking market share in a segment dominated by huge companies, many of which are working to become bigger still, will not be an easy task.

Zimmer Biomet, for instance, has just launched an autograft substitute of its own, PrimaGen, in the US. This contains a combination of demineralised cortical bone fibres with cancellous bone, again with the aim of providing a trabecular structure for natural bone in-growth.

The product is mouldable and delivered via a syringe rather than being a solid implant like Amedica's. It is indicated for use beyond the spine, and may be used in the repair, replacement, reconstruction or supplementation of tissue in other musculoskeletal defects. The defects may be surgically created or arise from traumatic injury.

Zimmer has been aggressive in its determination to climb the ranks of orthopaedics companies, and thanks to its merger with Biomet and its later acquisition of LDR is forecast to jump from the sixth-largest spinal company last year to fourth in 2022. Amedica's projected sales will not allow it to trouble the top of this table.

The spinal device market				
		Global sales ($m)		
Rank	**Company**	**2015**	**2022**	**CAGR**
1	Medtronic	2,221	2,146	0%
2	Johnson & Johnson	1,825	2,007	+1%
3	NuVasive	679	1,059	+7%
4	Zimmer Biomet	404	962	+13%
5	Stryker	740	909	+3%
6	Globus Medical	528	780	+6%
7	K2M	216	441	+11%
8	InVivo Therapeutics	-	241	N/A
9	Alphatec Holdings	185	128	-5%
10	RTI Surgical	77	88	+2%
11	SeaSpine	66	82	+3%
12	Orthofix International	76	80	+1%
13	Vexim	15	46	+17%
14	Amedica	19	34	+8%
15	Aurora Spine	5	27	+27%
16	SpineGuard	7	24	+19%
17	Exactech	8	12	+6%
-	Biomet*	249	-	N/A
-	LDR**	164	-	N/A
*Bought by Zimmer in June 2015; **bought by Zimmer Biomet in July 2016. Source: EvaluateMedTech.*				

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com or follow @LizEPVantage on Twitter