

CO.DON

Pharma & biotech

Building roll-out momentum in Europe

CO.DON is a manufacturer of autologous cell therapies for the treatment of cartilage defects. The main product, Spherox, is based on the core spheroid technology and can repair cartilage defects of the knee via a minimally invasive procedure. After accumulating supportive data from the Phase III (ongoing) and the Phase III (co.dis' (successfully Completed this year) trials, CO.DON obtained marketing authorisation from the EMA in July 2017 and is now rolling out Spherox in several European markets. This has been slower than initially expected due to the transition period from the older product and reimbursement issues, but the company expects progress by the end of Q318 and guides break-even by 2021.

EMA's approval opens multiple European markets

CO.DON specialises in the regenerative treatment of articular cartilage defects. During a biopsy procedure, healthy cartilage cells are taken from the patient's own cartilage as well as a blood sample. This is cultivated in a laboratory outside the body using CO.DON's innovative biological techniques to create cartilage, which is then transplanted back into the defect area. Although CO.DON's products have been sold in Germany since 1997 and some 14,000 patients have already been treated, the EMA authorisation was required for EU-wide distribution and was received in July 2017 based on accumulated data from the clinical trials.

Expansion beyond Germany home market is ongoing

Another milestone for Spherox was the Final Appraisal Determination published by the UK's NICE in January 2018, which recommended the use of autologous chondrocyte implantation for adult patients with knee cartilage defects larger than 2cm², as a cost-effective therapy. The first UK-based patient was treated in May 2018 and CO.DON is working to roll out Spherox in other European markets, at the same time investing in capacity expansion with planned capex of €10m to build a state-of-the-art human cell therapy production site in Leipzig. Leveraging its experience in cell therapies, CO.DON plans to establish a <u>JV with Xintela</u>, a listed Swedish biotech, to co-develop a stem cell product for osteoarthritis, which was supported by CO.DON's <u>largest investor</u>, which acquired a 26% stake in Xintela.

Break-even guided in 2021; EV of €80m

H118 revenue of €3.0m was flat y-o-y, while operating loss was €3.8m vs -€2.4m, due to product roll-out and associated costs. Lack of sales growth was explained by CO.DON as a transition phase from its older product (co.don chondrosphere) to Spherox after the EMA approval, and reimbursement issues. This should be resolved by end-Q318. The company guides break-even in 2021. CO.DON reported H118 cash of €20.3m (net cash: €5.3m), resulting in an EV of €80m.

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
				٠,	(24)	(70)
12/16	5.6	(3.7)	(0.23)	0.0	N/A	N/A
12/17	6.0	(7.1)	(0.36)	0.0	N/A	N/A
12/18e	6.7	(7.6)	(0.33)	0.0	N/A	N/A
12/19e	8.4	(5.3)	(0.27)	0.0	N/A	N/A

Source: CO.DON data, Thomson Reuters



Share details Code CNWK Shares in issue 19.7m Net cash (€m) at end-H118 5.3

Business description

CO.DON is a biopharmaceutical company focused on commercialising regenerative treatments for cartilage repair. Its main product, Spherox, is based on the core spheroid technology and can repair cartilage defects of the knee using patients' own cells via a minimally invasive procedure. Spherox has received EMA marketing authorisation for knee cartilage repair and is being launched in multiple European countries.

Bull

- Established market base and distribution in Germany.
- Substantial expansion possible after the EUwide marketing authorisation.
- Positive findings from clinical trials support efficacy and safety.

Bear

- Visibility increased after EMA authorisation, which could invite competition (although product development can be lengthy).
- Although well financed now, any unexpected operational setbacks could lead to the need for additional capital.
- Dependent on positive reimbursement decisions in EU countries.

Analysts	
Jonas Peciulis	+44 (0) 20 3077 5728

healthcare@edisongroup.com