

# CO.DON

## Green light for Spherox from the EMA

CO.DON is a leading manufacturer of autologous cell therapies for the treatment of cartilage defects. The company's main product, Spherox, is based on the core spheroid technology and can repair cartilage defects of the knee of up to 10cm<sup>2</sup> in a minimally invasive procedure. The Phase III clinical trial allowed CO.DON to obtain marketing authorisation from the European Medicine Agency (EMA) in July 2017, which opened access to all European markets. The company is preparing for the roll-out of Spherox and has already received a green light from the UK's National Institute for Health and Care Excellence (NICE).

### Autologous cell-based transplants for cartilage repair

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. Following the EMA approval, Spherox is currently the only authorised advanced therapy medicinal product (ATMP).

### EMA's approval opens multiple European markets

Although CO.DON's products have been sold in Germany since 1997, the EMA authorisation was required for EU-wide distribution. The efficacy and safety of Spherox from a [Phase III trial](#) (n=102) are expected later this year. Meanwhile, three-year follow-up interim data from the [Phase II trial](#) (n=75) have shown significant improvements across two outcomes (patient-reported and imaging-based). Accumulated data from the trials supported the EMA's approval in July 2017.

### Valuation: EV of €183m

H117 revenues of €3.0m were flat y-o-y, while operating loss was €2.4m vs -€1.2m a year ago due to product roll-out and regulatory expenditure. Consensus estimates are for positive EBIT of €2.1m on sales of €20.7m in 2020. In October, CO.DON raised €15.5m gross and will invest in the expansion. Current estimated net cash is €20.1m, resulting in an EV of €183m; this appears undemanding given the opportunity to expand into multiple European markets. Especially encouraging is the recommendation of the method by the UK's NICE and a wholesale licence granted by the UK Medicines & Healthcare products Regulatory Agency (MHRA).

#### Consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/15	5.1	(2.9)	(0.18)	0.0	N/A	N/A
12/16	5.6	(3.7)	(0.23)	0.0	N/A	N/A
12/17e	6.2	(5.8)	(0.29)	0.0	N/A	N/A
12/18e	8.6	(5.8)	(0.29)	0.0	N/A	N/A

Source: Company data, Thomson Reuters

#### Pharma & biotech

14 November 2017

**Price** €10.43  
**Market cap** €203m

#### Share price graph



#### Share details

Code CNWK  
 Listing Xetra  
 Shares in issue 19.5m

#### Business description

CO.DON is a biopharmaceutical company, focused on commercialising regenerative treatments for cartilage repair. Spherox, has received EMA marketing authorisation for knee cartilage repair and is on track to be launched in multiple European countries.

#### Bull

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

#### Bear

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

#### Analysts

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