

18th January 2016

Healthcare

Bone Therapeutics

Price EUR16.98

Initiation of a Phase IIa in multiple delayed-union fractures

Fair Value EUR29 (+71%)

BUY-Top Picks

Bloomberg	BONE.FP
Reuters	BONE.PA
12-month High / Low (EUR)	24.1 / 16.0
Market Cap (EURk)	116,279
Avg. 6m daily volume (000)	4.00

	1 M	3 M	6 M	31/12/14
Absolute perf.	-5.7%	-17.8%	-21.4%	ns
Healthcare	-6.3%	-4.4%	-15.4%	4.3%
DJ Stoxx 600	-8.3%	-8.6%	-17.5%	-3.7%

	2014	2015e	2016e	2017e
P/E	x	x	x	x
Div yield (%)	NM	NM	NM	NM

ANALYSIS

- Bone Therapeutics has announced this morning the initiation of a phase IIa study in patients suffering from multiple delayed-union fractures. The trial aims to assess both efficacy and safety of two to four minimally invasive percutaneous doses of ALLOB at two to four sites on either the same or different long bones and should enrol 12 patients. Recruitment of the 12 patients with 9 sites opened in Belgium and Germany is expected to be completed towards the year-end with a readout by mid-2017. Patients are to be evaluated at six months by CT-scan or X-ray. We believe that a >2 points improvement has been retained as has been the case for the ongoing phase IIa non-union trial.
- This extension of the phase IIa trial in delayed-union patients should offer additional data on the use of ALLOB at higher doses i.e. up to 200⁶ cells while 100⁶ cells has been the maximum studied so far. As such, we are not ruling out the prospect of patients suffering from multiple fractures being included in the phase III trial, potentially broadening the label of Bone Therapeutics' allogeneic product upon approval.

VALUATION

- We are reiterating our BUY recommendation and EUR29 Fair Value.
- We are making no change to our estimates and will wait for the DSMB review in delayed-union patients to include multiple delayed union fractures in our estimates. Note that we estimate the multiple delayed-union fracture market represents 10-20% of the monofocal delayed-union market

NEXT CATALYSTS

- Q1 2016: interim efficacy analysis for the first patients' cohort suffering from severe Osteoporosis
- Q1 2016: Results from the second patients' cohort from the delayed-union phase IIa trial followed by DSMB's interim review on the first 16 patients. Note that the study could be stopped prematurely should 12 out of 16 patients be responders. Four patients (first cohort) have already been qualified as responders.

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Distribution of stock ratings

BUY ratings 72%

NEUTRAL ratings 0%

SELL ratings 28%

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