

Bone Therapeutics

Price EUR18.64

Major update in Delayed-Union! Allogeneic platform further backed by clinical data

Fair Value EUR30 (+61%)

BUY

Bloomberg	BONE.FP
Reuters	BONE.PA
12-month High / Low (EUR)	23.0 / 15.2
Market Cap (EURk)	127,684
Ev (BG Estimates) (EURk)	99,439
Avg. 6m daily volume (000)	2.70
3y EPS CAGR	ns

Bone therapeutics reported positive results for three patients included in the second four patient's cohort of the Delayed Union phase IIa trial. To date, 7 patients out of 8 followed over 6 months have been qualified as responders. Note that a DSMB is expected to take place in H2 2016 could prematurely stop the trial. Over the last months, Bone Therapeutic has accumulated more and more clinical data backing its allogeneic platform.

	1 M	3 M	6 M	31/12/15
Absolute perf.	5.3%	13.0%	-3.3%	-4.4%
Healthcare	-2.5%	2.6%	-9.6%	-11.1%
DJ Stoxx 600	-2.4%	4.5%	-9.7%	-8.5%

YEnd Dec. (EURk)	2014	2015e	2016e	2017e
Sales	2,908	2,327	1,591	1,489
% change		-20.0%	-31.6%	-6.4%
EBITDA	-4,678	-6,646	-9,598	-12,762
EBIT	-5,277	-7,367	-10,401	-13,646
% change		-39.6%	-41.2%	-31.2%
Net income	-5,891	-10,600	-10,441	-13,686
% change		-79.9%	1.5%	-31.1%

	2014	2015e	2016e	2017e
Operating margin	NM	NM	NM	NM
Net margin	NM	NM	NM	NM
ROE	NM	NM	NM	NM
ROCE	NM	NM	NM	NM
Gearing	NM	NM	NM	NM

(EUR)	2014	2015e	2016e	2017e
EPS	NM	NM	NM	NM
% change	-	ns	ns	ns
P/E	x	x	x	x
FCF yield (%)	%	%	%	%
Dividends (EUR)	0.00	0.00	0.00	0.00
Div yield (%)	NM	NM	NM	NM
EV/Sales	46.7x	42.7x	69.5x	83.7x
EV/EBITDA	NS	NS	NS	NS
EV/EBIT	NS	NS	NS	NS

- Bone therapeutics reported this morning's results from the second four patient's cohort enrolled in the Delayed-Union phase IIa trial. At 6 months, three out of the four patients treated by a single percutaneous administration of ALLOB (allogeneic platform) met the co-primary endpoint of the study, set in accordance with the EMA. As a reminder, the latter are an improvement in the global disease evaluation score as perceived by patients of at least 25% and an improvement in the CT-scan of at least two points. This brings the total number of responders from 4 to 7 out of 8 patients followed over 6 months so far. Pooled results from these eight patients are encouraging with a statistically significant improvement of radiological scores of 77%. Overall pain at the fracture site and health status have been improved by 68% and 50% respectively, statistically significant as well.
- The trial initiated in June 2014 aims at assessing the efficacy and safety of ALLOB in 32 patients suffering from unhealed fractures after a minimum of three months and a maximum of seven months after a single percutaneous injection at the fracture site. We would remind that the study benefits from an open label design which enables the group to update on a regular basis. Main value creating event from this study should be the DSMB results (efficacy and safety) expected in H2 this year. Indeed, this Board has been granted the authorization by regulatory agency to prematurely stop the trial upon positive results in 12 patients out of the 16 that should be evaluated. As for now, 7 patients have reported positive results.
- These results strongly support the use of an allogeneic product for the reconstruction of bone, key in the setting of fracture healing (off the shelf availability in hospital?). Moreover, while immune rejection issues might have trigger cautiousness in the use of the platform, we are pleased to read that an additional follow-up of the first patients confirms the efficacy and good health status at 12 months.
- Since it became a public company in early 2015, Bone Therapeutics accumulated clinical data backing both of its platforms. Recently, 1/ osteoporosis IV route has been proven safe and 2/ a trial has been initiated in multiple fractures with the allogeneic platform. This translate in our view the willingness of management to further put the emphasis on the development of ALLOB, keeping PREOB for orphan diseases. We do not rule out that this strategy might enable the company to increase its visibility and trigger interest from pharma.

VALUATION

- We do not change our PoS linked to the project and set at 30%. Upon positive results in 12 out of 16 patients included in the DSMB's efficacy and safety update, we would raise our PoS from 30% to 50% (+EUR5.5/share to our fair value).

NEXT CATALYSTS

- Q2 2016: Group strategy update (US clinical trials)
- H2 2016: Spinal fusion results in 4 patients and DSMB in Delayed-Union

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