19th May 2016

Healthcare

Bone Therapeutics

Price EUR18.70

Switching to allogeneic platform in Osteoporosis, a strategic move maximizing value!

Fair Value EUR30 (+60%) **BUY**

Bloomberg	BONE FP
Reuters	BONE.PA
12-month High / Low (EUR)	23.0 / 15.2
Market Cap (EURk)	128,095
Ev (BG Estimates) (EURk)	99,850
Avg. 6m daily volume (000)	2.70
3y EPS CAGR	ns

	1 M	3 M	6 M	31/12/15
Absolute perf.	5.6%	13.4%	-6.2%	-4.1%
Healthcare	-2.4%	1.1%	-12.1%	-11.0%
DJ Stoxx 600	-2.4%	1.8%	-11.9%	-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	46.9x	42.9x	69.7x	83.9x
EV/EBITDA	NS	NS	NS	NS
EV/EBIT	NS	NS	NS	NS

This morning, Bone Therapeutics has announced its intention to switch its osteoporosis phase II program from the autologous platform (PREOB) to the allogeneic one (ALLOB). Trial should be initiated in early 2017, with no delay incurred from this move which we view has strategic.

ANALYSIS

- Management has stated that it intends to discontinue the ongoing phase IIa trial in severe osteoporosis to switch it from the autologous to the allogeneic platform. The initial program was designed to enroll approximately 20 patients, of which 7 have already been treated (their follow-up will continue). In early 2017, management expects to initiate a randomized multi-centered placebo-controlled phase II trial in severe osteoporosis with the allogeneic platform. To date, the company accumulated meaningful data on both the safety and the efficacy of the allogeneic platform which motivated the switch. Indeed, ALLOB and PREOB have shown similar profile and we benefit from necessary hindsight to support this strategic decision.
- The dose escalation trial that should be initiated in early 2017 will assess the safety and efficacy of ALLOB on top of bisphosphonate in severe osteoporotic patients non-responders to the latter versus bisphosphonate + placebo. Moreover, Bone Therapautics should target patients with a low bone turnover. We believe that 60 to 80 patients should be enrolled to give to the trial enough robustness for statisticall analysis (vs. 20 for the osteoporosis PREOB study). With regards to the multiple delayed-union fractures trial initiated earlier this year (please see here), we believe that Bone Therapeutics should not be limited by dosage for escalation as: 1/ the 200^6 cells dose still offer a confortable safety margin and 2/ first effects have been reported in other trials at the 100^6 cells dose. The unknown at this stage being the safety of the IV route for the allogeneic platform, we would highlight that lead center has supported the switch.
- We would expect no delay to be incurred from the change of platform. Expansion of the number of centers to be opened (~15/20 vs. 1 in the discontinued trial) and less extensive use of medical imaging in the short term follow-up post infusion should ease recruitement.
- Value creation should arise upon positive results from this phase II as the cost structure of the company will not be able to handle a commercialisation on a stand-alone basis, hence the need for a partnership. Indeed, economics from a potential licensing deal are likely to be revised upwards once considering that the production and logistic is higly simplified with an allogeneic platform. Morevover, switching from an autologous to an allogeneic product administrated via IV (likely to be a once a year treatment regimen) might trigger interests from pharma cie.
- Turning to the US, while management has communicated on its intention to initiate a trial in Osteonecrosis before the end of the year, it also stated before that that it has budgeted the initiation of two trials. With the strategic move announced today, we would not expect another US trial to be initiated in 2016. However, we do not rule out that this could occur next year and would tend to favour the Spine or osteoporosis indication for whom clinical guidelines as to the design of the trial already exist.

VALUATION

- We reiterate our BUY rating and EUR30 fair value and would not expect any impact on the cash burn in 2016 (BGe EUR10-12m).
- Our peak sales for the product stands at EUR1bn and EUR1.7bn in Europe and in the US respectively. Note that in our valuation, we only include European sales, adjusted with a 20% probability of Success. Hence contribution form the project to our fair value is EUR5.

NEXT CATALYSTS

- Today: Paris' roadshow with CEO (Enrico Bastianelli) and CFO (Wim Goemaere)

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