

Bone Therapeutics

Price EUR11.58

ALLOB successfully boosts the spinal fusion process

Fair Value EUR30 (+159%)

BUY

Bloomberg	BONE.FP
Reuters	BONE.PA
12-month High / Low (EUR)	21.1 / 11.0
Market Cap (EURk)	79,289
Ev (BG Estimates) (EURk)	51,044
Avg. 6m daily volume (000)	4.20
3y EPS CAGR	ns

Bone Therapeutics has reported positive results for the first eight patients enrolled in the spinal fusion phase IIa trial. While a complete lumbar fusion process usually takes up to 24 months, we were pleased to see that all of the eight patients included in this first set of results fused at nine months (six of them as early as six months) while the endpoints which were at 12 months have all been met. The complete study results should be reported in Q2 2017.

ANALYSIS

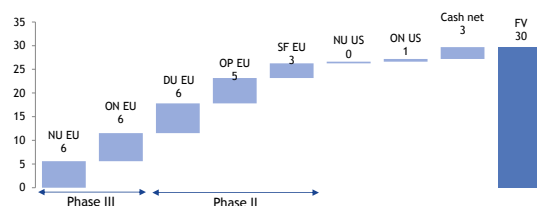
- Bone Therapeutics has reported positive results for the first eight patients enrolled in the spinal fusion phase IIa trial. In this first cohort, the trial met both primary radiological and clinical endpoints as well as secondary endpoints. With regards to primary radiological endpoint, we were pleased to see that the addition of ALLOB to the current SoC procedure (i.e. fusion via the implantation of a bioceramic interbody fusion cage to achieve lumbar fusion) resulted in a **complete fusion (absence of motion) in all of the eight patients at nine and 12 months**. We would also highlight the **rapid onset of action as six out of eight patients had no motion in vertebral bodies at six months**, which should be seen in the context of a traditional fusion process that can usually take up to 24 months. Hence, designing a clinical trial with all endpoints at 12 months was an ambitious challenge. Clinical evaluation showed **1/** a 33% and 40% improvement in the functional disability score at six and 12 months, **2/** an improvement in the patients' health status by 50% after six months, maintained through 12 months and **3/** a relief in back and leg pain by over 50% and 80% at six and 12 months. **Efficacy results in all of the 15 patients treated are expected towards Q2 2017.**
- These results bode well for the strategic use we see for the product in management of **degenerative disc diseases requiring a fusion procedure**. Indeed, the success rate of such operations in the lumbar spine is low with around 25% of patients undergoing lumbar spine fusion procedure needing a revision surgery which often leads to greater complication rates. The company's product has the **potential to boost the fusion process** with one single percutaneous administration and hence limit revision rates. Note that Bone Therapeutics is also evaluating ALLOB in the rescue lumbar surgery setting in a phase IIa. With complete results expected in Q2 2017, this might prompt deeper interactions with medical device and/or pharmaceutical companies with the aim of potentially licensing the product.

	1 M	3 M	6 M	31/12/15
Absolute perf.	-19.7%	-32.6%	-36.0%	-40.6%
Healthcare	-1.3%	-4.1%	3.4%	-8.7%
DJ Stoxx 600	-1.2%	4.9%	3.5%	-5.4%

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	30.1x	21.9x	39.0x	51.2x
EV/EBITDA	NS	NS	NS	NS
EV/EBIT	NS	NS	NS	NS



VALUATION

- We reiterate our BUY recommendation and EUR30 Fair Value. ALLOB in Spinal Fusion, both in the primary indication and in the rescue setting accounts for EUR3 of our Fair Value. Our PoS is unchanged at 20%.
- Our model points to sales in Europe of up to EUR170m at peak. The initiation of a US trial would be a free upside as we model EUR400m of sales in the region (not included in our valuation)

NEXT CATALYSTS

- 8th November: Q3 business update
- Q4 2016/Q1 2017: initiation of Osteonecrosis US trial and Osteoporosis phase II trial with ALLOB.
- H1 2017: interim efficacy results for 16 patients in the Delayed-Union phase II trial. Should 12 patients be qualified as responders, the study could be prematurely stopped and move onto phase III. Seven patients out of the eight for whom results have been reported have already responded.

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Distribution of stock ratings

BUY ratings 72%

NEUTRAL ratings 0%

SELL ratings 28%

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