

Bone Therapeutics Reports Full Year 2015 Results

Dr Enrico Bastianelli, Chief Executive Officer and Wim Goemaere, Chief Financial Officer, will host a conference call today at 13:30 CEST / 12:30 BST / 07:30 EDT. The call will be conducted in English and a replay will be available for 7 days. To access the conference call, please dial one of the appropriate number below quoting the conference ID 72491662:

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The presentation will be made available on the Investors section of the Bone Therapeutics website shortly before the call (<http://bonetherapeutics.com/en/investors/presentations>). To ensure a timely connection, it is recommended that users register at least 10 minutes prior to the scheduled start timing.

Gosselies, Belgium, 29 March 2016 – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in the field of bone fracture repair, fracture prevention and spinal fusion, today reports its full year results for the year ending 31 December 2015, prepared in accordance with IFRS as adopted by the European Union.

Key Highlights

- Significant progress in ongoing clinical development, with positive safety and efficacy results from the ongoing Phase II trials
 - ALLOB[®] Phase I/IIA delayed-union trial: eight patients safely treated, with the first four patients achieving the primary efficacy endpoint
 - PREOB[®] Phase IIA trial for severe osteoporosis: demonstration of safety of intravenous administration of PREOB[®] and successful migration of the cells towards the bones most prone to osteoporosis-related fractures
- Initiation of a pioneering Phase IIA trial for the minimally invasive treatment of failed spinal fusions with ALLOB[®]
- Orphan Drug Designation granted to ALLOB[®] by the EMA and FDA for the treatment of osteogenesis imperfecta or brittle bone disease
- Successful € 37 million IPO on Euronext Brussels and Euronext Paris
- Creation of a US subsidiary in Boston and opening of new headquarters in Gosselies, Belgium
- Strengthening of the management team through the appointment of Thomas Lienard as Chief Business Officer
- Granted € 5 million in new funding from the Walloon Region to support the Company's preclinical research
- Ended 2015 with € 33.61 million in cash, well in line with company expectations

Post period highlights

- Extension of the delayed-union program for ALLOB[®] into multiple delayed-union fractures
- ALLOB[®] Phase IIA spinal fusion trial: 75% of patients now treated, with successful fusion demonstrated in the first patient
- Positive efficacy results from the PREOB[®] Phase IIA trial in severe osteoporosis after the 12-month follow-up of the first cohort of patients in the study, showing that a single administration of PREOB[®] had sustained beneficial effects on pain and bone turnover markers

Enrico Bastianelli, CEO of Bone Therapeutics, commented: "2015 has been a year of growth and progress for Bone Therapeutics and we ended the year poised for the next stage in our journey towards bringing our new unique bone cell therapies to market.

"We have made significant progress advancing our clinical pipeline, reporting key safety and efficacy data from the Phase II trials of our allogeneic bone cell therapy product ALLOB[®] and good progress in the ongoing Phase III programs of our autologous product, PREOB[®]. We also expanded our activities in spine medicine, an area of significant unmet need, with the initiation of a new trial for the minimally-invasive treatment of failed spinal fusions.

"In 2016, we expect more key clinical data including important efficacy results from the delayed-union and spinal fusion studies with ALLOB[®], and plan to complete recruitment for the spinal fusion study in the first half of this year. It is also our goal to initiate our first clinical trial in the US by the end of the year."

Key Financials

(€ million)	FY 2015	FY 2014
Operating income	3.82	3.68
Operating expenses	(16.05)	(9.30)
R&D	(12.91)	(7.96)
G&A	(3.14) ¹	(1.35)
Operating result	(12.22)	(5.63)
Net financial result	(1.80)	(0.19)
Net result	(14.09)	(5.81)
Net cash flow	22.04	9.14
Operating activities	(11.77)	(3.52)
Investing activities	(2.98)	(3.00)
Financing activities	36.78	15.67
Cash position at 31 December	33.61	11.58

¹ Including € 1.06 million of IPO costs

Operational Highlights

At the beginning of the year, the Company reported early efficacy results from the ALLOB[®] Phase I/IIA trial in delayed-union. Results from the first patient cohort showed that all four patients met the primary endpoints of the study and three patients had completely healed within six months. As communicated in September, eight patients had been treated in the trial without any safety concerns. The Safety Monitoring Committee reviewed the initial safety data and unanimously agreed that the trial can proceed as planned and can continue to enrol patients. Post-period, the Company announced the extension of the trial into multiple delayed-union fractures. This study will complement the ongoing trial and will allow the evaluation of safety and efficacy of higher doses of ALLOB[®].

In March, the Company announced the treatment of the first four patients in the ALLOB[®] Phase IIA spinal fusion trial. By the end of the year, in December, eight patients had been treated without any safety concerns and post-period it was announced that 12 patients out of a total of 16 were safely treated, reaching 75% of the trial recruitment target. Additionally, after the 12-month follow-up of the first patient treated early 2015, preliminary efficacy results showed spinal fusion on CT scans and absence of intervertebral motion on dynamic x-rays.

In June, preliminary results from the PREOB[®] Phase IIA study for severe osteoporosis were communicated, demonstrating migration of intravenously-injected cells to the bones and absence of treatment-related safety concerns.

In September, the Company initiated a pioneering trial for the minimally invasive treatment of failed spinal fusion. In about 25% of lumbar spinal fusion cases, patients remain unsatisfied with the results of this procedure. In this trial, patients suffering from a failed spinal fusion surgery will be treated with a single injection of ALLOB[®] into the failed fusion area without the need for open surgery.

In November, ALLOB[®] received orphan drug designation for osteogenesis imperfecta from the EMA (European Medicines Agency) and FDA (Food and Drug Administration in the US). Osteogenesis imperfecta, also known as brittle bone disease, is a rare genetic disorder that causes bone fragility, fractures and deformities. Although the Company has not yet started clinical trials in this area, the orphan drug designation provides the opportunity for the future to develop a more effective treatment that, contrary to the available treatments, could eventually target the cause.

Corporate Highlights

On 13 April, the Company announced the creation of its US subsidiary, Bone Therapeutics USA Inc., with headquarters in Boston, Massachusetts. This was the first milestone in a process that will lead to the initiation of clinical trials in the US. On 24 April, Bone Therapeutics officially opened its new headquarters in Gosselies, south of Brussels. This was an important step to underpin the Company's continued growth and commercial readiness. The state-of-the-art production facility will secure first commercial cell therapy production, helping to support the further growth of the Company.

In November, Thomas Lienard was appointed as Chief Business Officer, assuming responsibility for activities in business development, business operations and strategic planning.

By 31 December 2015, the Company employed 101 people, up from 72 at the end of December 2014.

Outlook for 2016

In line with the strategy outlined at the time of the Company's IPO, Bone Therapeutics is accelerating the development of PREOB[®], currently in the last clinical phase for the treatment of osteonecrosis and non-union fractures. During 2016, the Company will provide an update on its osteonecrosis trial, now underway in five European countries. Preparations are in progress to initiate a first clinical trial in the US by the end of 2016.

In 2016, the Company will continue its promising Phase I/II trials for ALLOB[®] and plans to communicate on important efficacy results. Efficacy results for the first eight patients in the Phase I/IIA ALLOB[®] delayed-union trial are expected during the first half of 2016, as well as efficacy results for the first four patients in the Phase I/IIA ALLOB[®] spinal fusion trial. The Company also expects to communicate on safety in the first four patients treated in the recently initiated rescue spinal fusion trial.

Good cash management will remain a key priority for the Company, with a strong focus on net cash burn. The Company maintains its guidance, given at the time of the IPO that it has sufficient cash to carry out its strategic objectives until the end of 2017.

Financial review

Income statement

In 2015, total (other) operating income amounted to € 3.82 million compared to € 3.68 million in 2014. Other operating income results from grants from the Walloon Region (refundable grants) totalling € 2.12 million in 2015. In addition, the Company benefited from the special regime allowing for the employment of scientific staff with the recovery of company withholding tax for an amount of € 0.71 million, an investment tax credit for an amount of € 0.74 million and € 0.20 million in patent and other subsidies.

R&D expenses in 2015 were € 12.91 million compared to € 7.96 million in 2014. The increase, as anticipated at the time of the IPO, mainly resulted from the increase in activity with respect to clinical programmes, both existing programmes (Phase III) and newly initiated Phase II programmes, but also from strengthening the research and development team.

G&A expenses in 2015 were € 3.14 million compared to € 1.35 million in 2014. Of this total increase amounting to € 1.79 million, € 1.06 million was on account of IPO-expenditure directly impacting the statement of comprehensive income. The remaining € 0.73 million relates to the strengthening of the G&A team but also to comply with the new context of operating as a public company.

The operating loss in 2015 was € 12.22 million. In 2014, Bone Therapeutics reported an operating loss of € 5.63 million. Bone Therapeutics had net financial expenses of € 1.80 million 2015 compared to € 0.19 million in 2014 mainly explained by the non-cash impact of the derivative of the convertible bonds amounting to € 1.33 million and the transaction costs related to the convertible bonds of € 0.28 million.

The net result for the period amounted to € 14.09 million compared to € 5.81 million in 2014.

Balance sheet

Total assets at the end of December 2015 amount to € 50.38 million compared to € 24.20 million at the end of December 2014, with the main increase due to cash and cash equivalents and on property, plant and equipment, resulting from the investments related to the new facilities.

Deferred tax assets totalling € 2.33 million represent a tax credit on investment in R&D, reimbursable by the administration in the foreseeable future (one to seven years). The trade and other receivables amounting to € 7.91 million mainly relate to the amount receivable in respect of an investment grant from the Walloon Region for an amount of € 1.31 million, and to an amount of € 5.68 million in forgivable loans (being the amount receivable of the so called "avances récupérables"). The remaining amount refers to patent grants to be received for an amount of € 0.17 million and VAT to receive for an amount of € 0.57 million.

Cash and cash equivalents at the end of December 2015 amount to € 33.61 million, in comparison with € 11.58 million in 2014. The increase is mainly due to the proceeds of the IPO in February 2015.

Equity amounts to € 28.15 million at the end of December 2015 compared to the negative amount of € 9.49 million at the end of December 2014.

- The share capital and the share premium accounts increased by € 37.03 million coming from the gross proceeds of the IPO (6 February 2015).
- The share capital and the share premium accounts increased by € 10.35 million as a result of the conversion of the Convertible Bonds issued at the end of December 2014 and the beginning of 2015.
- The share premium account decreased by € 2.29 million as a result of the transaction costs related to the IPO.
- The share premium further increased by € 6.65 million through the impact of the recognition of the derivative instrument related to the Convertible Bonds which were issued on 18 December 2014 and on 8 January 2015.
- The retained earnings were impacted by the loss of the period for an amount of € 14.09 million.
- Other reserves increased by € 0.49 million related to the share-based payments.

Liabilities amount to € 22.24 million at the end of December 2015 compared to € 33.69 million at the end of December 2014 with the main decrease due to the current liabilities (conversion of the Convertible Bonds on 6 February 2015).

The non-current liabilities increased from € 7.33 million at the end of 2014 to € 11.69 million on 31 December 2015. They are composed as follows:

- Long term investment credit facilities to finance the infrastructure project (new building at Gosselies) for an amount of € 2.66 million (€ 0 at the end of 2014),
- Reimbursable part of the forgivable loans as recognized at the start of the contracts ("avances récupérables" from the Walloon Region) for an amount € 5.67 million (€ 4.31 million in 2014),
- Loans from related parties (regional investment offices) for an amount of € 1.71 million (€ 1.70 million in 2014),
- Other non-current liabilities for an amount of € 1.58 million represent the put option held by the minority shareholders of SCTS SA, affiliate company of Bone Therapeutics SA, to sell their shares to Bone Therapeutics SA (€ 1.50 million in 2014),
- Other items accounting for € 0.08 million.

Current liabilities amount to € 10.54 million at 31 December 2015 compared to € 26.36 million at the end of December 2014, representing a decrease of € 15.82 million. The financial liabilities amount to € 2.31 million which decreased by € 16.12 million. This is mainly on account of the conversion of the Convertible Bonds and the related derivative, which were both transferred to equity for an amount of € 15.07 million and due the reimbursement of part of the straight loan facility provided by ING and BNP Paribas Fortis for an amount of € 1.23 million following the receipt of this amount from the Walloon Region (pre-financing of an investment grant).

Trade and other payables amounted to € 2.58 million which represented a decrease with € 0.63 million compared to the end of December 2014 mainly accrued IPO-expenses at the end of December 2014.

Other current liabilities amount to € 5.59 million at the end of December 2015 compared to € 4.71 million at the end of December 2014, showing an increase of € 0.88 million due to deferred income related to new grants the Company obtained from the Walloon Region during 2015.

Cash flow statement

Cash used for operating activities amounts to € 11.77 million for the full year 2015 and € 3.52 million for the full year 2014. Higher operational cash outlays are driven by higher research and development expenditures and higher general and administrative expenditures, but also by one-off payments related to the IPO process. Cash received from the Walloon Region relating to grants and subsidies amounted to € 2.29 million in 2015 compared to € 3.51 million in 2014.

Total operating loss for the period amounts to € 12.23 million compared to a loss of € 5.63 million over the same period in 2014.

Cash flow from investing activities shows a net use of cash for € 2.98 million for the full year 2015 and € 3.00 million for the year 2014. This mainly represents investments made through the Company's affiliate SCTS SA in respect of the construction of the new facilities at the BioPark in Gosselies.

Cash flow generated from financing activities amounts to € 36.78 million for 2015 compared to € 15.67 million in 2014. The difference primarily relates to cash inflow from the capital increase (IPO) for an amount of € 37.38 million during 2015.

The Company ended 2015 with € 33.61 million in cash, which was well in line with company expectations.

● **About Bone Therapeutics**

Bone Therapeutics is a leading biotechnology company specializing in the development of cell therapy products intended for bone fracture repair and fracture prevention. The current standard-of-care in this field involves major surgeries and long recovery periods. To overcome these problems, Bone Therapeutics is developing a range of innovative regenerative products containing osteoblastic/bone-forming cells, administrable via a minimally invasive percutaneous technique; a unique proposition in the market.

PREOB[®], Bone Therapeutics' autologous bone cell product, is currently in pivotal Phase IIB/III clinical studies for two indications: osteonecrosis and non-union fractures, and in Phase II for severe osteoporosis. ALLOB[®], its allogeneic "off-the-shelf" bone cell product, is in Phase II for the treatment of delayed-union fractures and lumbar fusion for degenerative disease of the spine, including a minimally invasive therapy for failed spinal fusions. The Company also runs preclinical research programs and develops novel product candidates.

Founded in 2006, Bone Therapeutics is headquartered in Gosselies (South of Brussels, Belgium). Bone Therapeutics' regenerative products are manufactured to the highest GMP standards and are protected by a rich IP estate covering 11 patent families. Further information is available at: www.bonetherapeutics.com.

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Regulated information

29 March 2016

Consolidated Statement of Comprehensive Income

<i>(in thousands of euros)</i>	2015	2014
Revenue	0	0
Other operating income	3,824	3,677
Total operating income	3,824	3,677
Research and development expenses	(12,910)	(7,957)
General and administrative expenses	(3,138)	(1,345)
Operating profit/(loss)	(12,224)	(5,626)
Interest income	194	130
Financial expenses	(1,966)	(310)
Exchange gains/(losses)	(26)	(4)
Share of profit/(loss) of associates	(1)	1
Result Profit/(loss) before taxes	(14,025)	(5,808)
Income taxes	(61)	0
PROFIT/(LOSS) FOR THE PERIOD	(14,085)	(5,808)
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	(14,085)	(5,808)
Basic and diluted loss per share (in euros)	(1,91)	(1,69)
Profit/(loss) for the period attributable to the owners of the Company	(14,144)	(5,734)
Profit/(loss) for the period attributable to the non-controlling interests	59	(74)
Total comprehensive income for the period attributable to the owners of the Company	(14,144)	(5,734)
Total comprehensive income for the period attributable to the non-controlling interests	59	(74)

Regulated information

29 March 2016

Consolidated Balance Sheet

ASSETS <i>(in thousands of euros)</i>	31/12/2015	31/12/2014
Non-current assets	8,682	4,942
Intangible assets	69	54
Property, plant and equipment	5,793	2,667
Investments in associates	282	283
Financial assets	205	181
Deferred tax assets	2,333	1,759
Current assets	41,701	19,259
Trade and other receivables	7,912	7,498
Other current assets	178	186
Cash and cash equivalents	33,611	11,576
TOTAL ASSETS	50,383	24,202
EQUITY AND LIABILITIES <i>(in thousands of euros)</i>	31/12/2015	31/12/2014
Equity		
Equity attributable to owners of the parent	28,147	(9,485)
<i>Share capital</i>	20,708	10,466
<i>Share premium</i>	42,670	1,671
<i>Retained earnings</i>	(35,752)	(21,670)
<i>Other reserves</i>	520	48
Non-controlling interests	0	0
Total equity	28,147	(9,485)
Non-current liabilities	11,693	7,328
Financial liabilities	10,118	5,827
Deferred tax liabilities	0	0
Other non-current liabilities	1,575	1,501
Current liabilities	10,543	26,359
Financial liabilities	2,313	18,437
Trade and other payables	2,579	3,213
Current tax liabilities	61	0
Other current liabilities	5,590	4,710
Total liabilities	22,236	33,687
TOTAL EQUITY AND LIABILITIES	50,383	24,202

Regulated information

29 March 2016

Consolidated Cash Flow Statement

Consolidated Statements of Cash Flows <i>(in thousands of euros)</i>	2015	2014
CASH FLOW FROM OPERATING ACTIVITIES		
Operating profit/(loss)	(12,224)	(5,626)
Adjustments for :		
Depreciation, Amortisation and Impairments	394	371
Share-based compensation	486	48
Grants income related to forgivable loans	(2,123)	(2,472)
Grants income related to patents	(207)	(166)
Grants income related to tax credit	(736)	(426)
Other	(24)	29
Movements in working capital:		
Trade and other receivables (excluding government grants)	1,171	(547)
Trade and Other Payables	(788)	1,746
Other current liabilities (excluding government grants)	0	7
Cash generated from operations	(14,052)	(7,035)
Cash received from grants related to forgivable loans	2,267	3,338
Cash received from grants related to patents	19	173
Net cash used in operating activities	(11,765)	(3,524)
CASH FLOW FROM INVESTING ACTIVITIES		
Interests received	143	20
Purchases of property, plant and equipment	(3,048)	(2,999)
Purchases of intangible assets	(52)	(25)
Payments to acquire financial investments	(24)	0
Net cash used in investing activities	(2,982)	(3,004)
CASH FLOW FROM FINANCING ACTIVITIES		
Proceeds from government loans	972	1,430
Repayment of government loans	(283)	(203)
Reimbursements of other non-current liabilities	0	0
Proceeds from loans from related parties	500	370
Reimbursements of financial lease liabilities	(188)	(49)
Proceeds from other financial loans	1,437	2,900
Interests paid	(279)	(6)
Proceeds received from convertible loan (net of transaction costs)	0	9,533
Proceeds from issue of equity instruments of the Company (net of issue costs)	34,622	1,690
Net cash provided by financing activities	36,781	15,665
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	22,035	9,137
CASH AND CASH EQUIVALENTS at beginning of year	11,577	2,440
CASH AND CASH EQUIVALENTS at end of year	33,611	11,577

Regulated information

29 March 2016

Consolidated statement of changes in equity

<i>(in thousands of euros)</i>	<i>Attributable to owners of the parent</i>					<i>Non-controlling interests</i>	<i>TOTAL EQUITY</i>
	<i>Share capital</i>	<i>Share premium</i>	<i>Retained earnings</i>	<i>Total equity attributable to owners of the parent</i>			
Balance at 1 January 2014	9,288	6,635	(15,860)	63	0	63	
<i>Total comprehensive income of the period</i>	0	0	(5,734)	(5,734)	(75)	(5,809)	
<i>Issue of share capital</i>	1,179	852	0	2,031	0	2,031	
<i>Transaction costs for equity issue</i>	0	(340)	0	(340)	0	(340)	
<i>Equity transaction of convertible bond</i>	0	(5,321)	0	(5,321)	0	(5,321)	
<i>Transaction costs related to equity transaction of convertible bond</i>	0	(154)	0	(154)	0	(154)	
<i>Share-based payment</i>	0	0	48	48	0	48	
<i>Movement non-controlling interests</i>	0	0	(75)	(75)	75	0	
<i>Other</i>	0	0	1	1	0	1	
Balance at 31 December 2014	10,466	1,671	(21,621)	(9,485)	0	(9,485)	
<i>Total comprehensive income of the period</i>	0	0	(14,144)	(14,144)	59	(14,085)	
<i>Issue of share capital</i>	6,990	30,390	0	37,380	0	37,380	
<i>Transaction costs for equity issue</i>	0	(2,788)	0	(2,788)	0	(2,788)	
<i>Conversion of Convertible Bonds</i>	3,253	13,397	0	16,650	0	16,650	
<i>Share-based payment</i>	0	0	486	486	0	486	
<i>Movement non-controlling interests</i>	0	0	59	59	(59)	0	
<i>Other</i>	0	0	(13)	(13)	0	(13)	
Balance at 31 December 2015	20,708	42,670	(35,232)	28,147	0	28,146	