

## **Bone Therapeutics Reports 2014 Financial and Operational Results**

*Transformational Year Culminating in Successful € 37 million IPO on Euronext Brussels and Euronext Paris*

**Gosselies, Belgium, 28 April 2015 - BONE THERAPEUTICS**, a leader in bone cell therapy addressing high unmet medical needs in the field of bone fracture repair and bone fracture prevention, today announces the publication of its annual report including the consolidated full year results for 2014, prepared in accordance with IFRS as adopted by the European Union.

**Enrico Bastianelli, CEO of Bone Therapeutics, commented:** *“The past year has been one of significant transformation in the development of Bone Therapeutics, with the initiation of two new Phase II studies, the acceleration of our Phase III programs and the transition to a public company. We look forward to the next steps in bringing our innovative cell therapies closer to commercialization.”*

### **Operational Highlights**

- Progressed its two ongoing Phase III trials for PREOB<sup>®</sup>, including authorization of patient enrolment in five new centres in the UK for the PREOB<sup>®</sup> Phase III osteonecrosis trial
- Initiation of first ever clinical trials with Bone Therapeutics' unique allogeneic bone cell therapy product ALLOB<sup>®</sup> for delayed-union fractures and use in spinal fusion procedures
- Positive efficacy results from the first four patients in a Phase I/IIA proof-of-concept trial of ALLOB<sup>®</sup> for the treatment of delayed-union fractures already reported post period end
- Safe treatment of the first four patients in a Phase I/IIA trial for ALLOB<sup>®</sup> in spinal fusion procedures reported post period end
- Management team strengthened to support clinical trial ramp up with the appointment of Guy Heynen as Chief Clinical and Regulatory Officer
- Increased total number of staff from 52 at the start of 2014 to 72 at the end of 2014, with the majority of new hires related to clinical development
- Strengthened the Board of Directors with three new Independent Directors: Roland Baron, Paul Magrez and Thierry François, adding valuable scientific, business development and corporate finance expertise

### **Financial Highlights**

- € 47.0 million of new funds raised, resulting in net proceeds of € 42.4 million through successful € 37.0 million IPO on Euronext Brussels and Euronext Paris post period end (not impacting the 2014 annual accounts) and the conversion of a € 10.0 million convertible bond issued in December 2014, securing a strong financial platform to execute its clinical and commercial strategy
- 2014 operating income, mainly resulting from the recognition of grant income, of € 3.7 million, representing an increase of 8% compared with the full year 2013

- Operating loss for the year of € 5.6 million, compared with € 4.0 million in 2013, due to planned increased investments in R&D and administrative expenses
- € 3.7 million of new Walloon Government grants secured to support the research projects
- € 2.0 million in cash raised during 2014 from existing shareholders
- Cash and cash equivalents at the end of 2014 amounted to € 11.6 million, due to the issue of a short term convertible bond at 18 December 2014 (converted on the date of the IPO, 6 February 2015)

**-Ends-**

### **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<sup>®</sup>, 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<sup>®</sup>, 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. 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 9 patent families. Further information is available at [www.bonetherapeutics.com](http://www.bonetherapeutics.com).*

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## **Operational Review**

### ***Introduction***

Bone Therapeutics aims to be a leading regenerative company providing innovative cell products for high unmet medical needs in the fields of bone fracture repair and prevention. These areas represent a significant market opportunity due to the lack of efficacious and safe, non-invasive, treatments and limited competition, despite large markets. The Company is creating a new and unique treatment approach using differentiated bone-forming cells administered via a minimally invasive percutaneous procedure, expected to offer significant benefits over the current standard-of-care.

Bone Therapeutics has two complementary, first-in-class product platforms, the autologous PREOB<sup>®</sup> and the allogeneic ALLOB<sup>®</sup>, targeting five indications and protected by nine families of patents. The Company is seeking to advance its autologous osteoblastic product, PREOB<sup>®</sup>, currently in the final stages of clinical development, for the treatment of osteonecrosis and non-union fractures, with a view to obtaining marketing approvals from the EMA and FDA. Additionally, PREOB<sup>®</sup> is being evaluated in a Phase I/IIA trial for severe osteoporosis. Bone Therapeutics' allogeneic bone cell product, ALLOB<sup>®</sup> is currently in two proof-of-concept trials for delayed-union fractures and spinal fusion.

2014 was a year of significant growth and progress for Bone Therapeutics, with an emphasis on broadening our pipeline and accelerating our clinical trials.

### ***Authorizations in additional countries to significantly accelerate clinical programs***

Key to Bone Therapeutics' ramp up of clinical development of its unique product pipeline has been the successful expansion of its trials into additional countries. This is a significant achievement considering the high level of scrutiny for advanced therapy medicinal products (ATMP), which applies to both PREOB<sup>®</sup> and ALLOB<sup>®</sup>. The Company successfully received authorisation from the Competent Authorities and Central Ethics Committee in the UK to enrol patients through five centres into our pivotal Phase III trial for PREOB<sup>®</sup> in osteonecrosis. This will add to the acceleration of the recruitment into the program, as was observed after the enrolment of German specialized centres. Currently, the trial is running in 37 centres across Europe.

In line with the Phase III programs, significant effort is being put into the acceleration of our Phase II trials. Extension of the delayed-union trial to Germany was approved by the Paul-Ehrlich Institute in October 2014. In the beginning of 2015, the trial was further extended to the UK.

### ***Initiation of first clinical trials with ALLOB<sup>®</sup> yielding promising results***

In 2014, the first patient was treated with our unique allogeneic cell therapy product, ALLOB<sup>®</sup>. ALLOB<sup>®</sup> is the first ever allogeneic differentiated osteoblastic cell therapy product developed for the treatment of orthopaedic conditions and has the potential to become a first-line treatment for

impaired fracture healing, thanks to its minimally invasive percutaneous administration. We initiated two important proof-of-concept trials with this product, one in the treatment of delayed-union fractures and one in spinal fusion procedures.

The first results of the delayed-union and spinal fusion trials were reported in 2014 and in the beginning of 2015, after the period end. Safety was confirmed in both studies following the treatment of the first patients in these studies. In addition, the Company reported that all four patients in the delayed-union trial met the primary endpoints of the study. These initial results give us confidence that ALLOB<sup>®</sup> could offer significant benefit to patients who currently have to wait until the treating surgeon decides they can be treated with current techniques, which involve highly invasive surgery and long and painful recovery.

### ***Appointment of Chief Clinical and Regulatory Officer, staff and Directors to strengthen the team***

To support our clinical operations and further strengthen the management team, Guy Heynen was appointed in November as Chief Clinical and Regulatory Officer. His long-standing experience in the field of regulatory affairs and clinical trials with major international pharmaceutical companies will play an important role in advancing the Company's broad product pipeline through the clinic in preparation for bringing its products to market.

During 2014, Bone Therapeutics continued to further expand its operations. By 31 December 2014 the total number of staff employed amounted to 72, up from 52 at the end of December 2013, with the majority of new hires in support of its clinical development. The Board of Directors was strengthened with the appointment of three new Independent Directors: Roland Baron, Paul Magrez and Thierry François, adding scientific expertise, business development and corporate finance skills, respectively, to the Board.

### **Outlook for 2015**

In line with our strategy outlined at the time of the Company's recent IPO, it is Bone Therapeutics' aim to further complete the development of PREOB<sup>®</sup>. During 2015, site recruitment updates and patient recruitment updates can be expected.

Bone Therapeutics also aims to accelerate development of its Phase I/IIA trials for ALLOB<sup>®</sup> in delayed union fractures and spinal fusion, and the Phase I/IIA PREOB<sup>®</sup> osteoporosis trial. Safety and efficacy results for the first 8 patients in the Phase I/IIA ALLOB<sup>®</sup> delayed-union trial are expected during 2015. The Company also expects results on safety for the first 8 patients in the Phase I/IIA PREOB<sup>®</sup> osteoporosis trial, and safety results for the first 8 patients in the Phase I/IIA ALLOB<sup>®</sup> spinal fusion trial. The Company expects to further exploit the potential of its allogeneic product ALLOB<sup>®</sup> in the untapped market of rescue spine fusion with the initiation of a Phase I/IIA clinical trial.

As stated at the time of its IPO, the Company plans to scale up its manufacturing capability and during 2015 will prepare to relocate its manufacturing facility to the Gosselies BioPark, near Brussels, Belgium with the aim to be fully operational at this new location by mid-2016 after

obtaining GMP accreditation. Bone Therapeutics plans to expand its activities into the US, in order to lay the foundations for advancing its US clinical trial programme in this important market as of 2016.

## Details of the 2014 financial results

### *Profit & loss statement*

<i>(in thousands of euros)</i>	<b>Year ended 31 December</b>	
Summary P&L statement	<b>2014</b>	<b>2013</b>
Total operating income	3,677	3,394
R&D expenses	(7,957)	(6,816)
G&A expense	(1,345)	(621)
<b>Operating profit/(loss)</b>	<b>(5,626)</b>	<b>(4,043)</b>
<b>PROFIT/(LOSS) FOR THE PERIOD</b>	<b>(5,808)</b>	<b>(4,066)</b>

Operating income, mainly resulting from the recognition of grant income amounted to € 3.68 million representing an increase of 8% compared to last year. Higher R&D and administrative expenses (+25% overall) compared to last year resulting from an acceleration of the clinical trial activity and strengthening the teams and the management are offsetting the increase in operating income. Operating loss over 2014 amounts to € 5.63 million compared to € 4.04 million last year.

### *Statement of financial position*

<i>(in thousands of euros)</i>	<b>31/12/2014</b>	<b>31/12/2013</b>
Non-current assets	4,942	4,724
Current Assets	19,259	8,087
<b>Total Assets</b>	<b>24,202</b>	<b>12,811</b>
Equity	(9,485)	63
Non-current liabilities	7,328	6,502
Current liabilities	26,359	6,246
<b>Total Equity &amp; Liabilities</b>	<b>24,202</b>	<b>12,811</b>

Non-current assets amounting to € 4.94 million remained in line with last year's amount which was at € 4.72 million at the end of 2013. New investments in property, plant and equipment for the new facilities under construction at the Biopark in Gosselies were offset by an equivalent amount recorded following confirmation from the Walloon Region that the company will receive of a capital grant for an amount of € 2.90 million.

Current assets on 31 December 2014 amounted to € 19.26 million versus € 8.09 million at the same time last year. The increase in cash and cash equivalents, due to the issue of a short term convertible bond at the end of 2014 for a gross amount of € 10.00 million, explains to a large extent this increase in current assets. The increase in trade receivables further explains the increase in current assets.

Equity on 31 December 2014 amounted to a negative amount of € 9.49 million compared to € 0.1 million at the end of the previous year. Equity was impacted by:

- The loss for the period amounting to € 5.81 million
- The issue of a derivative instrument together with the convertible bond at the end of 2014 for an amount of € 5.32 million
- Transaction costs related to the IPO (6 February 2015) recognized in 2014 for an amount of € 0.48 million
- Partially offset by € 2.02 million resulting from capital increases earlier in the year

Non-current liabilities at 31 December 2014 showed a limited increase compared to last year coming in at € 7.33 million with the increase coming on the account of a supplementary long term loan for an amount of € 0.37 million which the Company has taken to finance the construction of its new facilities at Gosselies.

Current liabilities increased with € 20.11 million amounting to € 26.36 million mainly due to:

- The issue of a short term convertible bond for a gross amount of € 10.00 million which together with the impact of the related derivative instrument (also impacting on equity – see above) resulted in an increase of current financial liabilities of € 14.92 million
- A straight loan taken for an amount of € 2.9 million to pre-finance the investment grant awarded but to be received at a later date
- An increase in trade payables of € 1.76 million (in line with the increased activity and the IPO preparations)

### ***Cash flow statement***

<i>(in thousands of euros)</i>	<b>2014</b>	<b>2013</b>
Net cash used in operating activities	-3,524	-3,274
Net cash used in investing activities	-3,004	-1,748
Net cash provided by financing activities	15,665	2,641
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>9,137</b>	<b>-2,381</b>

The consolidated cash flow statement shows a net increase of € 9.14 million compared to a net decrease of € 2.39 million over 2013. Net cash provided by financing activities amounting to € 15.67 million offset the cash used in operating activities for an amount of € 3.52 million (in line with last year's € 3.27 million) and the net cash used in investing activities (mainly related to the infrastructure project at Gosselies) amounting to € 3.00 million.

Cash flow from financing activities resulted from two capital increases for a total amount of € 2.02 million less IPO costs incurred in 2014 for an amount of € 0.33 million. Further, the net proceeds of the convertible bond issue at the end of 2014 amount to € 9.53 million, loans concluded with related parties and commercial banks offset by reimbursements and interest payments are resulting in a net positive impact of € 4.45 million.