

## Bone Therapeutics Business Update for Third Quarter 2017

**Strong interim results for ALLOB® Phase IIA spinal fusion trial**

**All patients met primary endpoint in ALLOB® Phase I/IIA delayed-union study interim analysis, leading to early conclusion of the study**

**Exclusive licensing agreement signed with Asahi Kasei for the development and commercialization of PREOB® in Japan**

**Gosselies, Belgium, 9 November 2017, 7am CET – BONE THERAPEUTICS** (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in orthopaedics and bone diseases, today provides a business update for the third quarter ended 30 September 2017.

**Thomas Lienard, Chief Executive Officer of Bone Therapeutics, commented:** *“During the Third Quarter, Bone Therapeutics has delivered several key milestones that further validated our unique, minimally invasive bone cell technology, bringing us closer to potentially game-changing treatments in the large and growing orthopaedic and bone disease markets. We were delighted to report the positive interim results for our allogeneic product ALLOB® in both spinal fusion and delayed-union fracture trials. Moreover, demonstrating the international appeal and potential of our unique bone cell therapy products, we are pleased to partner with Asahi Kasei for the development and commercialization of PREOB® in Japan, with the potential to expand to other countries in Asia.”*

*“Preparations for further clinical development of ALLOB® in delayed union fractures are well under way, as well as a continued focus on process optimization and scale up to ensure a truly commercially viable product. We also look forward to announcing the completion of recruitment in our Phase IIA spinal fusion study at end of 2017 or early 2018.”*

### Business highlights

- In September, Bone Therapeutics reported strong interim efficacy and safety results for the Phase IIA lumbar spinal fusion study with its allogeneic cell therapy product, ALLOB®. In addition to evidence of successful fusion shown by radiological data collected over a 12-month follow-up period (absence of motion in all patients and continuous bone bridges in 9 out of 15 patients), the interim results revealed substantial clinical improvement in function (55% improvement on the Oswestry Disability Index) and a strong reduction in back and leg pain (59% and 90% respectively). From a safety perspective, treatment with ALLOB® was well tolerated in all patients. Further details are available in the press release of September 14, 2017.
- The Company also announced positive interim efficacy data for its ALLOB® Phase I/IIA study for delayed-union fractures. At 6 months post administration, all patients treated met the primary endpoint. Radiological evaluation of fracture healing showed an improvement of, on average, 4 points on the TUS (Tomographic Union Score) scale, twice the required minimum of 2 points. The health status of patients, as measured by the Global Disease Evaluation (GDE) score, improved by, on average, 48%, compared to the predetermined minimum of 25%. Based on these interim efficacy results, the Data and Safety Monitoring Board (DSMB) has recommended stopping the trial early due to efficacy results. ALLOB® was shown to be well tolerated. Further details are available in the press release of September 20, 2017.
- The Company signed an exclusive, royalty-bearing license agreement with one of Japan’s leading industrial companies, Asahi Kasei Corporation. The license agreement covers the development and commercialisation of Bone Therapeutics’ autologous bone cell therapy product, PREOB®, in Japan with the option to extend into additional Asian territories. Further details are available in the press release of September 22, 2017.

- At the beginning of September, Jean-Luc Vandebroek was appointed Chief Financial Officer. With his extensive international finance experience from major public and privately-owned companies, he will oversee the Company's financial planning needs as it continues to mature and bring its innovative cell therapy products closer to the market.

### Financial highlights

- Cash used in operating activities amounted to EUR 10.13 million for the first nine months of 2017, compared to EUR 8.95 million for the same period in 2016.
- Operating loss amounted to EUR 8.76 million compared to EUR 8.87 million for the same period last year.
- Net cash at the end of September 2017 amounted to EUR 9.11 million.

### Outlook

- Bone Therapeutics expects to complete recruitment of patients into the ALLOB<sup>®</sup> Phase IIA study in spinal fusion at the end of 2017 or early 2018.
- The Company plans to initiate the Phase IIB trial with ALLOB<sup>®</sup> for delayed-union fractures in the second half of 2018.
- Ongoing recruitment for the pivotal Phase III study in osteonecrosis for PREOB<sup>®</sup> with interim analysis expected in the second half of 2018. The interim analysis will determine whether the trial could be stopped at this stage.
- Good cash management will remain a key priority, with a strong focus on net cash burn. Cash burn for the full year 2017 is expected to be approximately EUR 13-14 million, below the previous guidance of EUR 15 million. Based on its strategic priorities, the Company provides guidance that it has sufficient cash to carry out its strategic objectives into Q2 2018. In order to pursue the development of its promising bone-forming cell therapy platform the Company plans to raise funds with existing and new investors to strengthen its cash position.

### ● About Bone Therapeutics

*Bone Therapeutics is a leading cell therapy company addressing high unmet needs in orthopaedics and bone diseases. Based in Gosselies, Belgium, the Company has a broad, diversified portfolio of bone cell therapy products in clinical development across a number of disease areas targeting markets with large unmet medical needs and limited innovation.*

*Our technology is based on a unique, proprietary approach to bone regeneration which turns undifferentiated stem cells into "osteoblastic", or bone-forming cells. These cells can be administered via a minimally invasive procedure, avoiding the need for invasive surgery.*

*Our primary clinical focus is ALLOB<sup>®</sup>, an allogeneic "off-the-shelf" cell therapy product derived from stem cells of healthy donors, which is in Phase II studies for the treatment of delayed-union fractures and spinal fusion. The Company also has an autologous bone cell therapy product, PREOB<sup>®</sup>, obtained from patients' own bone marrow and currently in Phase III development for osteonecrosis and is also partnered with Asahi Kasei Corporation for the development and commercialisation of PREOB<sup>®</sup> in Japan.*

*Bone Therapeutics' cell therapy products are manufactured to the highest GMP standards and are protected by a rich IP estate covering nine patent families. Further information is available at: [www.bonetherapeutics.com](http://www.bonetherapeutics.com).*

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