Bone Therapeutics Business Update for Third Quarter 2018

Positive efficacy and safety results in ALLOB Delayed Union Phase I/II trial, supporting next stage in clinical development

Manufacturing process optimisation implemented for allogeneic platform

Promising first efficacy data from JTA-004 viscosupplement support move to registration studies

Cell therapy development programmes to be focused fully on ALLOB platform following DSMB recommendation to discontinue PREOB trial in osteonecrosis of the hip

Gosselies, Belgium, 7 November 2018, 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 2018.

Thomas Lienard, Chief Executive Officer of Bone Therapeutics, commented: "*The third quarter was a period of significant clinical and strategic activity for Bone Therapeutics. We were delighted with the positive final readout in the Phase I/IIA delayed union study of the allogeneic bone cell therapy product ALLOB, which paves the way for the next stage of development. More recently, the promising results from our viscosupplement JTA-004 highlighted a complementary addition to our pipeline.*

Our focus is now on progressing the clinical development of the ALLOB platform in delayed union fractures and lumbar spinal fusion and of JTA-004 in knee osteoarthritis, following the recommendation of the DSMB to discontinue the PREOB trial in hip osteonecrosis. This will be supported by our ongoing manufacturing optimisation process, which will help us to lay a strong foundation for our future commercialisation strategy."

Business highlights (incl. post period end)

- In September, Bone Therapeutics announced a positive final readout in the Phase I/IIA delayed-union study of the allogeneic bone cell therapy product, ALLOB, adding to a growing body of clinical efficacy and safety data.

- Simultaneously, the Company also announced an optimised manufacturing process for ALLOB to improve consistency, scalability, cost effectiveness and ease of use, which are critical for development and commercialisation in cell therapy. The Company plans to implement this optimised process for all future clinical development programmes involving ALLOB and recently received positive feedback on the quality control programme and non-clinical strategy for ALLOB from a Regulatory Agency for the optimisation of the manufacturing process.

- Also in September, the Company presented preclinical *in vitro* and *in vivo* results at the 26th Annual Meeting of the European Orthopaedic Research Society (EORS) in which the scientific community acknowledged the potent bone-forming properties of its allogeneic platform.

- In October, post period, Bone Therapeutics announced results for a first efficacy study in knee osteoarthritis with the enhanced viscosupplement JTA-004. The study showed that a single intra-articular injection of JTA-004 delivered higher pain reduction than the reference product, a leading viscosupplement. The results support the move to registration studies, broadening the Company's advanced clinical pipeline.

- In October, post period, Linda Lebon was appointed Chief Regulatory Officer, joining Company's Executive Team. An industry veteran, Linda will play a crucial role in defining the regulatory pathway for clinical and development programmes.

- On 6 November, post period, the Company announced that the Data and Safety Monitoring Board recommended the discontinuation of the PREOB Phase III trial in osteonecrosis of the hip, as the interim results suggested that it is unlikely that the primary objective will be achieved at the final analysis. For more information, please see additional press release dated 6 November 2018.

Financial highlights

- Cash used in operating activities amounted to € 10.47 million for the first nine months of 2018, compared to € 10.14 million for the same period in 2017.

- Operating loss amounted to € 8.96 million compared to € 8.76 million for the same period last year.

- Net cash at the end of September 2018 amounted to € 8.41 million.

Outlook

- The Company's immediate focus is on submitting a new clinical trial application (CTA) with the regulatory authorities to allow the start of a Phase IIB trial in delayed union with its allogeneic product, utilising the optimised production process. Bone Therapeutics is currently generating the non-clinical data required for the application and expects to submit the CTA for a multi-centre, randomised, controlled study in H2 2019.

- Bone Therapeutics plans to report the top line results from 32 patients of the ALLOB Phase IIA spinal fusion study in mid-2019 after a 12-month follow-up.

- Good cash management will remain a key priority, with a strong focus on net cash burn. The Company confirms the expected cash burn (excluding proceeds from financing) for the full year 2018 to be in the range of € 15-16 million, in line with previous guidance. Based on its current priorities, the Company expects to have sufficient cash to carry out its objectives until the end of Q3 2019.

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.

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

The Company's primary clinical focus is ALLOB, an allogeneic "off-the-shelf" cell therapy platform derived from stem cells of healthy donors, which is in Phase II studies for the treatment of delayed-union fractures and spinal fusion. In addition, the Company also has JTA-004, a viscosupplement in development for the treatment of knee osteoarthritis.

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.

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