

## **Regulated information**

11 May 2017

# **Bone Therapeutics Business Update for First Quarter 2017**

- Completion of recruitment of first 16 patients in ALLOB<sup>®</sup> Phase I/IIA delayed-union study
- Over 40 patients have now been treated safely with ALLOB®
  - Dr. Miguel Forte appointed as Chief Medical Officer to strengthen Bone Therapeutics' clinical leadership team

**Gosselies, Belgium, 11 May 2017, 7am CEST – 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 first quarter ended 31 March 2017.

**Thomas Lienard, Chief Executive Officer of Bone Therapeutics, commented:** "During the first quarter of 2017 we have continued to execute on our new business strategy, focused around advancing our allogeneic bone cell therapy platform and strengthening the Company's clinical capabilities in preparation for commercialisation. Over 40 patients have now been treated safely with our allogeneic product ALLOB<sup>®</sup>, giving us strong confidence in the potential of our approach.

We look forward to reporting on key inflection points later this year, with interim data from our delayed-union fractures and spinal fusion clinical programmes in September as we move ahead to bring this unique technology to patients and to deliver value for investors."

## **Business highlights**

- Completion of recruitment of 16 patients for an interim analysis in the ALLOB<sup>®</sup> Phase I/IIA delayed-union study. In this six month, open-label clinical study, the safety and efficacy of the Company's allogeneic cell therapy product ALLOB<sup>®</sup> is being evaluated in the treatment of delayed-union fractures of long bones.
- Safety for these first 16 patients was subsequently confirmed by the Safety Monitoring Committee. To date, Bone Therapeutics has treated over 40 patients in different clinical trials with its allogeneic bone cell therapy product ALLOB<sup>®</sup> without clinical adverse effect.
- Study is targeting the recruitment of 32 patients, but is flexible and could be stopped prematurely after a positive evaluation of the interim data analysis of the first 16 patients, expected in September.

## **Corporate highlights**

• In March 2017, Dr Miguel Forte was appointed Chief Medical Officer, strengthening Bone Therapeutics' leadership team. His expertise in clinical development and regulatory affairs, particularly in the field of regenerative medicine, will help advance the Company's promising pipeline of bone cell therapy products.

### **Financial highlights**

- Cash used in operating, investment and financing activities amounted to EUR 3.8 million for the first three months of 2017, compared to EUR 3.3 million for the first quarter of 2016.
- Operating loss amounted to EUR 3.0 million compared to EUR 2.4 million for the same period last year.
- Cash at the end of March 2017 amounted to EUR 16.5 million.



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### Outlook

Two potential inflection points are expected in the second half of 2017, with clinical efficacy and safety data expected from ALLOB<sup>®</sup> studies in delayed-union fractures and spinal fusion.

Additionally, Bone Therapeutics is expected to provide a recruitment update for the Phase III clinical trial of the autologous product, PREOB<sup>®</sup> for the treatment of osteonecrosis.

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 15 million. Based on its new strategic priorities, the Company provides guidance that it has sufficient cash to carry out its strategic objectives into Q2 2018.

### 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 patient's own bone marrow and currently in Phase III development for osteonecrosis and non-union fractures.

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: <u>www.bonetherapeutics.com</u>.

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