

## Bone Therapeutics Provides Business Update for Q4 2016

**Positive efficacy data for the ALLOB® Phase IIA spinal fusion trial**

**Allogeneic platform ALLOB® and osteonecrosis Phase III study main strategic focus**

**Thomas Lienard appointed Chief Executive Officer**

**EUR 2.3 Million in Non-Dilutive Funding granted by the Walloon Region**

**Cash and cash equivalents of EUR 20.3 million<sup>(1)</sup> on 31 December 2016,  
in line with expectations**

**Gosselies, Belgium, 17 January 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 fourth quarter ended 31 December 2016.

**Thomas Lienard, CEO of Bone Therapeutics, commented:** *“We continued to make good progress in the final quarter of the year. In particular, highly encouraging data from our Phase IIA study of the allogeneic product ALLOB® in spinal fusion has further increased our confidence in the broad applicability of our unique approach to the regeneration of bone cells in a range of orthopaedic conditions and bone diseases. In order to deliver the full potential of our pipeline, the Board, working with guidance from our Scientific Advisory Board, has made the strategic decision to focus resources on the development of ALLOB® in those areas with the greatest unmet need, particularly our most advanced programmes in spinal fusion and delayed union. We look forward to a number of key data announcements on these during 2017. With a clearly differentiated portfolio, carefully targeted resources and an excellent leadership and scientific team, we look forward to 2017 with renewed vigour and confidence.”*

### Operational and corporate highlights

In October, Bone Therapeutics reported positive efficacy data for the ALLOB® Phase IIA spinal fusion trial after completing the analysis of data from the first 8 patients enrolled in the study. The data support product safety and demonstrate clinically relevant improvements in function, pain and general health as early as six months after treatment, along with radiological signs of fusion.

In order to maximize value creation and ensure the best use of resources, the Board has reviewed its portfolio and priorities. The Company has therefore decided to focus on the allogeneic platform ALLOB®. The Company believes that ALLOB® offers the most promising commercial opportunities and the greatest potential for partnerships, based on clinical benefits, scalability, cost-effectiveness and large addressable markets with unmet need. The Company will also pursue the Phase III clinical trial of PREOB® in osteonecrosis, its closest product to commercialisation and which has shown promising results in Phase II studies as presented earlier this year at the Annual European Congress for Rheumatology (EULAR) in London (June 2016).

In order to further optimize the allocation of its resources, after careful evaluation of the preliminary clinical results and extensive consultations with Bone Therapeutics' Scientific Advisory Board, the Company has also decided not to pursue the clinical development of ALLOB® in severe osteoporosis without a partner at this time. The Company believes that, given the nature and the complexity of the disease and its market, significant additional development work will be required to fully validate the relevance and applicability of systemic administration of cell therapy products in osteoporosis. Therefore, the Company has decided to concentrate resources on the development of locally-administrated treatments for osteonecrosis, spine diseases and unhealed fractures, which are at more advanced stages of clinical development and have significant commercial potential.

Also in October, the Board appointed Thomas Lienard as Chief Executive Officer following the decision of Enrico Bastianelli to step down. The Company entered into a contractual arrangement with Enrico Bastianelli SPRL whereby the management team will be able to rely on his continued support until mid-April 2017. Mr Bastianelli was further granted, in the execution of prior contractual arrangements, an exclusive right to use certain intellectual property rights of the Company for some specific

non-bone applications which the Company has opted not to develop (amongst others these include non-bone related diseases such as osteoarthritis and rheumatoid arthritis, and veterinarian applications of JTA<sup>(2)</sup>).

### Financial highlights

During the fourth quarter of 2016, the Company was awarded EUR 2.3 million in new funding from the Walloon Region to support its preclinical research projects. This financial support will contribute to the exploration of the use of its allogeneic product ALLOB<sup>®</sup> in additional indications and patient populations, and to the further optimization of the production and logistics of its cell therapy products over the next two years.

The Company ended the fourth quarter of 2016 with EUR 20.3 million<sup>(1)</sup> in cash, well in line with Company expectations. Careful management of resources resulted in a net cash burn<sup>(3)</sup> of EUR 13.3 million<sup>(1)</sup> for the full year 2016, compared to EUR 15.0 million (excluding EUR 1.1 million IPO expenses) for the full year 2015.

### Outlook for 2017

Two potential inflection points are expected in the second half of 2017, with clinical efficacy data anticipated from ALLOB<sup>®</sup> studies in delayed-union fractures and spinal fusion. Bone Therapeutics expects to finalize recruitment for the interim analysis of the ALLOB<sup>®</sup> Phase I/IIA delayed-union study shortly and to present the results of this interim analysis in the second half of 2017. The Company also expects to provide further results from the first set of 16 patients in the ALLOB<sup>®</sup> Phase IIA spinal fusion trial.

Additionally, Bone Therapeutics is expected to provide a recruitment update for the osteonecrosis Phase III clinical trial.

The full 2016 Annual Results will be announced on March 16, 2017.

<sup>(1)</sup> Unaudited figure

<sup>(2)</sup> JTA is an enhanced viscosupplement for intra-articular administration into the osteoarthritic joint

<sup>(3)</sup> Net cash burn = the sum of cash used/generated in operational, investment and financing activities

## About Bone Therapeutics

*Bone Therapeutics is a leading biotechnology company specializing in the development of cell therapy products intended for orthopaedics and bone diseases. 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, 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 10 patent families. Further information is available at: [www.bonetherapeutics.com](http://www.bonetherapeutics.com).*

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