

## Bone Therapeutics Provides Business Update for the Third Quarter of 2015

**Gosselies, Belgium, 18 November 2015 - BONE THERAPEUTICS** (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in the field of bone fracture repair and bone fracture prevention, today announces the publication of its trading statement for the third quarter ending 30 September 2015.

**Enrico Bastianelli, CEO of Bone Therapeutics, commented:** *“During the third quarter of 2015, we made good progress across the pipeline. We have been able to progress our ALLOB<sup>®</sup> product platform with the initiation of our Phase IIA trial for the treatment of failed spinal fusions; the first ever minimally invasive revision spinal fusion procedure using a bone cell therapy product. In addition, I am delighted that Thomas Lienard has joined our team as Chief Business Officer. His experience will be invaluable to Bone Therapeutics as it moves toward market approval and commercialization of our products.”*

### Pipeline Highlights

- Second patient cohort in the ALLOB<sup>®</sup> Phase I/IIA delayed-union trial treated successfully without safety concerns. Recommendation by the Safety Monitoring Committee to continue the trial as planned. This Phase I/IIA study is a six-month open-label trial to evaluate the safety and efficacy of Bone Therapeutics' allogeneic bone cell therapy product, ALLOB<sup>®</sup>, in the treatment of delayed-union fractures of long bones
- Pioneering Phase IIA trial initiated for the minimally invasive treatment of failed spinal fusion procedures with ALLOB<sup>®</sup>. This pilot, open, proof-of-concept trial is the first that involves the administration of a bone cell therapy product percutaneously directly into the failed fusion area without open surgery. The implantation of bone-forming cells is intended to promote the fusion process through stimulation of bone formation.

### Financial Highlights

- Cash used in operating activities amounts to EUR 9.93 million for the first nine months of 2015, compared to EUR 3.91 million for the first nine months of 2014. The increase is on account of higher R&D expenses related to the Company's ongoing pipeline development and higher G&A expenses. Overall the teams were strengthened to address the challenges ahead and G&A expenses were impacted by costs of operating as a public company, an increase in infrastructure expenditure and IPO expenses (EUR 1.06 million) directly charged to profit and loss. Operating loss, amounting to EUR 8.43 million compared to EUR 3.74 million for the same period last year. Working capital movements explain the remaining increase. An amount of EUR 0.95 million related to forgivable loans and patent subsidies were received during the first nine months. The net result for the period amounts to a loss of EUR 10.23 million (EUR 3.89 million in 2014).
- Cash at the end of September 2015 amounted to EUR 35.78 million, including EUR 0.3 million restricted cash.

### Post-Period Highlights

- Appointment of Thomas Lienard as Chief Business Officer. Mr Lienard has over 15 years of sales and marketing experience working in Belgium and the US with international pharmaceutical companies. He will take up responsibility for activities in business development, business operations and strategic planning.

- ALLOB<sup>®</sup> granted Orphan Drug Designation (ODD) from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) for the treatment of the genetic bone disorder osteogenesis imperfecta (brittle bone disease).

## Outlook

In the coming months, we expect to:

- report additional safety results from our trials in spinal fusion procedures and expect the ALLOB<sup>®</sup> Phase IIA spinal fusion trial to reach 50% of patients treated.
- receive additional grants from the Walloon Region to further support our preclinical research activities.

The cash burn for the full year 2015 is expected to be in line with the Company's previously stated expectations.

**-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 I/IIA 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 11 patent families. Further information is available at [www.bonetherapeutics.com](http://www.bonetherapeutics.com).*

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