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Bone Therapeutics publishes its interim financial report in English. A French translation of the report will also be made available. In the event of differences between the English and the French versions of the report, the original English version will prevail.

## **Bone Therapeutics announces half-year results for 2015**

*Positive first results from three ongoing proof-of-concept Phase II trials*

*US subsidiary established and opening of new headquarters in Belgium*

*Successful 2.5x oversubscribed EUR 37 million Initial Public Offering on Euronext Brussels and Euronext Paris*

**Gosselies, Belgium, 22 September 2015 - BONE THERAPEUTICS** (Euronext Brussels and Paris: BOTHE), a leader in bone cell therapy addressing high unmet medical needs in the field of bone fracture repair and bone fracture prevention, today provides a business update and its financial results for the six-month period ended 30 June 2015, prepared in accordance with IFRS as adopted by the European Union.

**Enrico Bastianelli, CEO of Bone Therapeutics, said:** *“The first half of 2015 has been transformational for the Company starting with our successful Initial Public Offering on Euronext Brussels and Euronext Paris, which has given us a strong financial runway to continue to progress and develop our innovative clinical programs.*

*“The year has already seen significant progress across our pipeline with positive efficacy results reported in our ALLOB<sup>®</sup> Phase I/IIA delayed-union trial and the announcement of first results from the PREOB<sup>®</sup> Phase IIA trial in severe osteoporosis.”*

### **Operational Highlights**

- Positive efficacy results for the novel allogeneic bone cell product ALLOB<sup>®</sup> in the Phase I/IIA study for delayed-union fractures. All treated patients in the first patient cohort met the primary endpoints of the study.
- Extension of this trial to the UK, adding two prestigious sites, King’s College Hospital in London and the Norfolk and Norwich University Hospitals NHS Foundation Trust.
- Demonstration of safety in the ALLOB<sup>®</sup> Phase IIA spinal fusion trial following treatment of the first four patients.
- First results from the Phase IIA trial for PREOB<sup>®</sup> in severe osteoporosis demonstrated the migration of intravenously injected bone-forming cells to the bones most prone to osteoporotic fractures. No treatment-related safety issues were reported in the first patient cohort.
- US subsidiary, Bone Therapeutics USA Inc., established in the biotechnology cluster of Boston.
- Opening of the Company’s new headquarters at the Gosselies Biopark to ensure initial commercial production capacity as well as continued growth of the Company.
- Strengthened the Board of Directors with the addition of three new Independent Directors.

### **Post-Period Operational 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.

### **Financial Highlights**

- Completion of a EUR 37.03 million IPO on Euronext Brussels and Euronext Paris.
- Cash used in operating activities amounting to EUR 8.11 million, compared to EUR 2.38 million for the first six months of 2014. Higher operating loss amounting to EUR 5.36 million (EUR 2.66 million for the first half of 2014), resulting from higher R&D and G&A expenses (including EUR 1.06 million IPO expenses charged to profit and loss), are at the basis of this increase. Working capital movements (amongst others IPO expenses provided for in 2014 paid in 2015) explain the remaining increase.
- Cash balance of EUR 37.22 million at the end of June 2015.

### **Outlook for the remainder of 2015**

The Company will continue to progress its ongoing Phase II and III studies with PREOB<sup>®</sup> and ALLOB<sup>®</sup> in fracture prevention, fracture healing and spinal fusion, in line with the strategy outlined at the time of the IPO. In the coming months, the Company expects to:

- Update the market on the study status of the Phase III osteonecrosis trial, currently running in five European countries;
- Report on safety in eight patients in the Phase IIA spinal fusion trial.

Based on the positive results announced during H1 2015, the Company expects to report further positive news with respect to efficacy for its ongoing phase II trials.

Guidance for the net cash burn (net of net equity raised during the year) for the full year 2015 is €10-12 million.

**-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 II 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 9 patent families. Further information is available at [www.bonetherapeutics.com](http://www.bonetherapeutics.com).*

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