Bone Therapeutics Provides Business Update for the First Quarter of 2016

Positive early efficacy results from Phase IIA spinal fusion and osteoporosis studies

Addition of new sites in ongoing Phase III osteonecrosis trial

Osteonecrosis Phase IIB data to be presented at the upcoming EULAR conference

EUR 30.4 million cash position at the end Q1 2016

Gosselies, Belgium, 10 May 2016 – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in the field of bone fracture repair, fracture prevention and spinal fusion, today provides operational and financial update for the first quarter of 2016. The Company also provides an update on positive momentum of its ongoing Phase III osteonecrosis trial with PREOB®, its autologous osteoblastic cell product, extending recruitment at a number of new trial sites.

Enrico Bastianelli, Chief Executive Officer of Bone Therapeutics, commented: *"The first quarter of 2016 has seen continued momentum for Bone Therapeutics across our pipeline of products, PREOB® and ALLOB®, as we build upon a strong year of trading in 2015.*

"So far this year, we have already communicated positive efficacy results from our spinal fusion and osteoporosis trials. In particular, we announced positive 12-month efficacy results from the first cohort of patients treated with PREOB® in the Phase IIA severe osteoporosis trial. In addition, we made progress in the landmark Phase III studies with PREOB®, accelerating recruitment in the osteonecrosis study with the addition of new sites and the submission to Israel.

"We have continued to focus on tight cash management, which remains in line with expectations, whilst maximising the potential of our bone cell therapy product portfolio and look forward to reporting on efficacy results in our delayed-union fracture and spinal fusion trials."

Business highlights

- Extension of the delayed-union program for ALLOB® into multiple delayed-union fractures to evaluate safety and efficacy of higher doses of ALLOB®.
- Positive efficacy results from the PREOB® Phase IIA trial in severe osteoporosis on the first patient cohort, showing that a single administration of PREOB® had sustained beneficial effects on pain and bone turnover markers.
- Successful fusion in the first patient of the ALLOB® Phase IIA spinal fusion trial, with substantial pain relief as early as six months after treatment.

Post-period highlights

- Recruitment of the ALLOB® Phase IIA study in spinal fusion completed, and trial extension to respond to high clinical demand and to study the early onset of the spinal fusion process.
- Four more sites approved in the ongoing PREOB® Phase III osteonecrosis trial since the IPO, and submission in Israel for four additional sites.
- Presentation of the 36-month efficacy and safety data of the PREOB® Phase IIB trial in osteonecrosis at the upcoming EULAR (Annual European Congress of Rheumatology) conference in London on 8–11 June.
- Validation and extension of patent portfolio, with sixteen awards, notices of allowance or positive opinions received mainly for PREOB® and ALLOB®-related patents and two additional patents filed since the IPO.

Financial highlights

- Cash used in operating activities amounts to EUR 2.9 million for the first three months of 2016, compared to EUR 2.7 million for the first three months of 2015 (excluding IPO expenses paid in Q1 2015).
- Operating loss amounts to EUR 2.4 million compared to EUR 2.8 million for the same period last year (including EUR 1.1 million of IPO costs).
- Cash at the end of March 2016 amounts to EUR 30.4 million.

Outlook

In line with the strategy outlined at the time of the Company's IPO, the Company will continue its promising Phase II proof-of-concept trials with ALLOB® and plans to communicate on important efficacy results for the first eight patients in the Phase I/IIA ALLOB® delayed-union trial during the first half of 2016, as well as efficacy results for the first four patients in the Phase IIA ALLOB® spinal fusion trial.

Preparations are in progress to initiate Bone Therapeutics' first clinical trial in the US.

Good cash management will remain a key priority for the Company, with a strong focus on net cash burn. The Company maintains its guidance, given at the time of the IPO that it has sufficient cash to carry out its strategic objectives until the end of 2017.

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®, 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®, 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 11 patent families. Further information is available at: www.bonetherapeutics.com.

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