

Bone Therapeutics provides fourth quarter 2020 business update and 2021 outlook

Clinical programs running on schedule, including Phase III trial of JTA-004 and Phase IIb trial of ALLOB

Extensive achievements in collaborations and partnerships to enhance development, manufacturing and commercialization capabilities

Strong financial position following fundraising, licencing agreement and optimisation of manufacturing assets

Gosselies, Belgium, 20 January 2021, 7am CET – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, today provides a business update for the fourth quarter, ending 31 December 2020 as well as a business outlook for 2021.

“Bone Therapeutics managed to achieve a highly productive period in the last few months. We have made major advances in nearly all aspects of our activities while executing on our business strategy,” said Miguel Forte, Chief Executive Officer, Bone Therapeutics. “We recently started treating patients in the Phase IIb study with our allogeneic bone cell therapy product ALLOB. We also completed patient recruitment in the pivotal Phase III trial with the enriched viscosupplement, JTA-004, ready to provide topline data in the third quarter of this year. This will be a critical milestone in the history of Bone Therapeutics. In addition to our clinical programs, we have strongly improved our manufacturing capabilities with a partnership with Catalent, a leading global cell and gene CDMO, and extended the geographic reach of our bone cell therapies into Asia thanks to the licensing agreement with our Chinese partners Link Health and Pregene. We also have explored new grounds in the collaborations with Rigenerand and BioWin consortium. These collaborations will further expand the application of our innovative cell therapy platform and broaden our advanced clinical pipeline with potential new breakthrough developments. Building on the strong foundation of these recent achievements and a strengthened cash position, we are confident for 2021, continuing the progress we have already made and moving our allogeneic cell therapy and advanced biological products through clinical development while exploring new innovations that meet critical needs of patients.”

Clinical highlights – Q4 2020 to date

- Bone Therapeutics treated the first patient in the Phase IIb study of its allogeneic cell therapy product, ALLOB, in patients with difficult tibial fractures, following receiving regulatory approval in all seven European countries designated for the trial. The study is expected to enroll 178 patients in over 40 sites. Bone Therapeutics anticipates finalizing patient recruitment in H1 2022 and reporting topline results in second half of 2022 subject to the evolution of the COVID-19 pandemic.
- Bone Therapeutics succeeded in completing the patient recruitment and treatment in the pivotal Phase III clinical study with the improved viscosupplement, JTA-004, in patients with knee osteoarthritis. As this was completed on schedule, despite the COVID-19 pandemic, topline results maintain to be expected in Q3 2021.
- Bone Therapeutics announced positive 24-month results for the Phase IIa study with the allogeneic cell therapy product, ALLOB, in patients undergoing lumbar spinal fusion procedures. 90% of patients showed bone fusion as well as strong clinical improvements in function and pain at 24 months follow-up period with a good product safety profile.

Corporate highlights – Q4 2020 to date

- Bone Therapeutics signed a manufacturing collaboration with Catalent, Inc. to streamline the production of ALLOB. Under the terms of the share purchase agreement, Catalent acquired Bone Therapeutics' cell therapy manufacturing subsidiary, Skeletal Cell Therapy Support SA (SCTS), for gross proceeds of €12 million.

- Bone Therapeutics signed an exclusive license agreement with Link Health Pharma Co., Ltd and Shenzhen Pregene Biopharma Company, Ltd for the manufacturing, clinical development and commercialization of ALLOB in Greater China, Taiwan, Singapore, South Korea, and Thailand. Terms of the agreement included €55 million total in upfront and milestone payments, with €10 million expected in next 2 years as well as tiered double-digit royalties on net sales.
- Bone Therapeutics also signed a first agreement for a process development partnership with the mesenchymal stromal cell (MSC) specialist, Rigenrand. This first collaboration will focus on further developing and enhancing Bone Therapeutics' bone-forming cells with the potential to broaden their therapeutic targets and explore new mechanisms of action with potential gene modifications for Bone Therapeutics' therapeutic portfolio.
- In November, Bone Therapeutics joined a research collaboration with expert industry and academic partners to develop biologically active, patient-tailored, 3D printed, bioresorbable implants enriched with Bone Therapeutics' allogeneic bone forming cells, ALLOB. The consortium, now named Bonerec, was established under the "Competitiveness Clusters" framework of the Belgian Walloon Health Association, BioWin, and received €3 million non-dilutive funding from the Walloon Government.
- Bone Therapeutics appoints Sven Kili, MD as interim Chief Medical Officer, effective as of 15 January 2021. Dr. Kili is a highly experienced pharmaceutical physician specializing in the development and commercialization of cell and gene therapies. Previously, Dr. Kili was vice president & head of cell and gene therapy development at GSK, where he oversaw the approval and the launch of the first in man *ex vivo* gene therapy. He also held senior executive positions in global medical affairs for Sanofi-Genzyme's biosurgery franchise and cell therapy and regenerative medicine activities. Dr. Kili is orthopedic surgeon by training at the National Health Service, UK. He will replace Olivier Godeaux, MD until June 2021, who has decided to leave Bone Therapeutics to pursue other ventures. Dr. Godeaux will remain available to the Company for the next 3 months to support the succession during the transition period.

Financial highlights – Q4 2020 ⁽¹⁾

- Bone Therapeutics successfully raised €10 million through a private placement with current and new institutional investors both in Europe and in the US.
- Bone Therapeutics continues to place a strong focus on cash management. Net cash utilization of €16.4 million ⁽¹⁾ for the full year 2020 is in line with the company's guidance of €15-16 million. The net cash position totaled €14.7 million ⁽¹⁾ for the year ended December 31, 2020. Following the Link Health-Pregene licensing agreement, the acquisition of Bone Therapeutics' manufacturing subsidiary SCTS by Catalent and a successful fundraise of €10M in gross proceeds in the fourth quarter of 2020, the company anticipates having sufficient cash to carry out its business objectives until end Q4 2021. This assumes normal operation, as there may be further effects of the ongoing COVID-19 epidemic.

Outlook for 2021

- Bone Therapeutics anticipates reporting on topline results for the 3-month primary endpoint and 6-month follow-up period in the third quarter of 2021 for its pivotal Phase III clinical study with the improved viscosupplement, JTA-004, in patients with knee osteoarthritis. This follows the completion of patient recruitment.
- Bone Therapeutics continues to hold discussions with potential partners to explore business opportunities as JTA-004 is approaching the announcement of pivotal Phase III topline results and ALLOB is being evaluated in a double-blind, placebo-controlled, proof-of-concept Phase IIb study.
- Over the course of H1 2021, Bone Therapeutics plans to continue discussions with the US FDA (Food and Drug Administration) in preparation for the next steps in the clinical development of JTA-004 and ALLOB in the US.
- Bone Therapeutics plans to continue to expand its allogeneic differentiated MSC based cell therapy platform, beyond ALLOB, into other therapeutic indications.

Financial Calendar 2021

29 April – Full Year Results & Annual Report 2020
26 May – Q1 2021 Business and Financial Highlights
9 June – Annual General Meeting 2021
8 September – Half Year Results 2021
26 October – Q3 2021 Business and Financial Highlights

The financial calendar is communicated on an indicative basis and may be subject to change.

(1) Unaudited number

About Bone Therapeutics

Bone Therapeutics is a leading biotech company focused on the development of innovative products to address high unmet needs in orthopedics and other diseases. The Company has a diversified portfolio of cell and biologic therapies at different stages ranging from pre-clinical programs in immunomodulation to mid-to-late stage clinical development for orthopedic conditions, targeting markets with large unmet medical needs and limited innovation.

Bone Therapeutics is developing an off-the-shelf next-generation improved viscosupplement, JTA-004, which is currently in Phase III development for the treatment of pain in knee osteoarthritis. Consisting of a unique combination of plasma proteins, hyaluronic acid - a natural component of knee synovial fluid, and a fast-acting analgesic, JTA-004 intends to provide added lubrication and protection to the cartilage of the arthritic joint and to alleviate osteoarthritic pain and inflammation. Positive Phase IIb efficacy results in patients with knee osteoarthritis showed a statistically significant improvement in pain relief compared to a leading viscosupplement.

Bone Therapeutics' core technology is based on its cutting-edge allogeneic cell therapy platform with differentiated bone marrow sourced Mesenchymal Stromal Cells (MSCs) which can be stored at the point of use in the hospital. Currently in pre-clinical development, BT-20, the most recent product candidate from this technology, targets inflammatory conditions, while the leading investigational medicinal product, ALLOB, represents a unique, proprietary approach to bone regeneration, which turns undifferentiated stromal cells from healthy donors into bone-forming cells. These cells are produced via the Bone Therapeutics' scalable manufacturing process. Following the CTA approval by regulatory authorities in Europe, the Company has initiated patient recruitment for the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB continues to be evaluated for other orthopedic indications including spinal fusion, osteotomy, maxillofacial and dental.

Bone Therapeutics' cell therapy products are manufactured to the highest GMP (Good Manufacturing Practices) standards and are protected by a broad IP (Intellectual Property) portfolio covering ten patent families as well as knowhow. The Company is based in the BioPark in Gosselies, Belgium. Further information is available at www.bonetherapeutics.com.

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