Bone Therapeutics Provides Third Quarter 2020 Business Update

Manufacturing collaboration with Catalent to streamline future ALLOB production

Catalent to acquire Bone Therapeutics' cell therapy manufacturing facility for €12 million

Exclusive license agreement with Link Health and Pregene for €55 million total in upfront and milestone payments to develop and commercialize ALLOB in Greater China and adjacent Asian countries

Expansion of the product portfolio from orthopedics into inflammatory conditions

Gosselies, Belgium, 30 October 2020, 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 third quarter, ending 30 September 2020.

"*Bone Therapeutics has completed considerable achievements on a number of different fronts in the past few months, in spite of the ongoing pandemic,*" **said Miguel Forte, MD, PhD, Chief Executive Officer of Bone Therapeutics**. "*Regarding developments of our clinical pipeline, Bone Therapeutics has made strong progress in the pivotal Phase III study with our lead asset, JTA-004. In addition, we have continued to build on our innovative allogeneic cell therapy platform which expands its application from orthopedics and bone diseases to inflammatory conditions with limited treatment options. Regarding commercial progress over the past quarter, Bone Therapeutics has now forged a partnership with Link Health, Pregene and sale and supply agreements with Catalent in relation to ALLOB development and production.*"

Clinical highlights – Q3 2020 to date

- Since the initiation of the recruitment in mid-May 2020, Bone Therapeutics has completed now over 60% of the patient recruitment in the ongoing Phase III clinical study with the improved viscosupplement, JTA-004, in patients with knee osteoarthritis.
- The Phase IIb study of Bone Therapeutics' allogeneic cell therapy product, ALLOB, in patients with difficult tibial fractures has received approval from regulatory authorities in all seven European countries in which Bone Therapeutics has applied for the study, with preparations ongoing for study initiation.
- 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 – Q3 2020 to date

- 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 include €55 million total in upfront and milestone payments, with €10 million expected in next 24 months as well as tiered double-digit royalties on net sales.
- Bone Therapeutics signed a manufacturing collaboration with Catalent, Inc. to streamline the production of ALLOB. Under the terms of the share purchase agreement, Catalent will acquire Bone Therapeutics' cell therapy manufacturing subsidiary, Skeletal Cell Therapy Support SA (SCTS), for gross proceeds of €12 million. The transaction is expected to close in November 2020, subject to conditions precedent. The equity purchase price, net of SCTS's debt (€3 million), cash adjustments, and taking into account the restructuring of some Bone Therapeutics' existing liabilities (€3 million), will generate net proceeds of approximately €6 million. The acquired manufacturing

entity will continue to service the production of ALLOB for Bone Therapeutics and its partners. This enables Bone Therapeutics to focus its attention on the development of products from its differentiated MSC platform of cell and gene therapeutic targets for orthopedics and other indications.

- In August, Bone Therapeutics received in total €1.6 million in grants and non-dilutive funding from the Walloon Region, subject to conditions precedent. Bone Therapeutics will use the additional financial support to advance its current Phase III clinical study with JTA-004 as well as for research and preparation of clinical development of BT-20, a new allogeneic and off-the-shelf cell therapy product. BT-20 will enable Bone Therapeutics to expand its portfolio from orthopedics and bone diseases to inflammatory conditions.

Financial highlights – Q3 2020 (1)

- Net cash at the end of September 2020 amounted to €5.6 million.
- Prudent cost and cash management will remain a key priority for Bone Therapeutics, as already reflected in its operating expenses. The net cash burn for the full year 2020 is expected to be approximately €15-16 million. Taking into account the total committed gross proceeds raised through the Private Placements in April and May of this year, the convertible bonds, the recoverable cash advances granted by the Walloon Region, the agreements signed with Link Health, Pregene and Catalent and the reimbursement of part of the bank loans, Bone Therapeutics anticipates having sufficient cash to carry out its business objectives until early Q3 2021. This assumes normal operation, as there may be further effects of the ongoing COVID-19 epidemic.

Outlook for the remainder of 2020.

- At the current recruitment rate, and assuming no further significant disruption of health care systems worldwide due to the continuing COVID-19 pandemic, Bone Therapeutics expects to complete patient enrollment in the Phase III JTA-004 study before year-end. Topline results are anticipated on the 3-month primary endpoint and 6-month follow-up period in the second half of 2021.
- Bone Therapeutics expects to initiate clinical trial activities and patient recruitments for the ALLOB Phase IIb study in patients with difficult tibial fractures in European clinical centers before the end of the year.
- As the effects of the pandemic continue to evolve globally, it is possible that both studies may encounter a delay compared to the anticipated schedule. Bone Therapeutics and partners will continue to actively and closely monitor the situation in Europe and Hong Kong on an ongoing basis.
- In November, Bone Therapeutics plans to initiate discussions with the US FDA (Food and Drug Administration) in preparation for the next steps in the clinical development of JTA-004 in the US, a large, important market.
- Part of the €12 million proceed received for the acquisition of Bone Therapeutics' cell therapy manufacturing subsidiary, SCTS will be used for SCTS debt payment, resulting in net proceeds of €9 million. Bone Therapeutics plans to reimburse an additional €3 million of debts, substantially reducing its debt burden while strengthening its balance sheet. The final proceeds following this operation amount to approximately €6 million. The manufacturing collaboration with Catalent will streamline and economize ALLOB's production and is estimated to result in a €2 million annual reduction of fixed costs.
- Based on current developments and recently signed agreements, the Company has decided to terminate the convertible bond program issued in April 2020.
- Bone Therapeutics continues to hold discussions with potential partners to explore business opportunities. It also intends to prepare a fundraise in Q4 of 2020. Existing shareholders have already taken a pre-commitment to participate.

(1) Unaudited numbers

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 is ready to start 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 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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