

Bone Therapeutics provides fourth quarter 2021 business update and 2022 outlook

Recruitment for ALLOB tibial fracture Phase IIb study ongoing and on schedule to release topline data in Q1 2023, despite COVID slowdown

New scientific advisory board appointments to bolster the further development of the next generation iMSCg platform

Discussions for ALLOB global partnership still ongoing. Completion of potential global partnership delayed and now anticipated in Q1 2022

Financial position strengthened following equity fundraising in Q4 2021 with runway expected into Q3 2022

Gosselies, Belgium, 19 January 2022, 7am CET – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, announces today a business update for the fourth quarter, ending 31 December 2021 as well as a business outlook for 2022.

“Bone Therapeutics’ activity in Q4 2021 has resulted in a broadened pipeline and stronger therapeutic potential for the company. The pandemic continues to be a concern across the cell and gene therapy, biopharma and healthcare industries. Bone Therapeutics has, however, put measures in place to reduce the impact of the pandemic on its clinical development,” said **Miguel Forte, Chief Executive Officer, Bone Therapeutics**. *“In addition, the deal for the global rights for the allogeneic osteoblastic cell therapy product ALLOB, when and if completed, will allow Bone Therapeutics, together with its partners, to ensure the development of ALLOB towards commercialization, while at the same time continue to explore options to expand the iMSCg platform. This includes the development of a next generation of genetically engineered mesenchymal stromal cells and the use of highly scalable and versatile cell sources such as induced pluripotent stem cells. Bone Therapeutics has expanded its Scientific Advisory Board purely for this purpose.”*

Operational highlights

- Bone Therapeutics’ allogeneic bone cell therapy product, ALLOB is currently being evaluated in a randomized, double-blind, placebo-controlled Phase IIb study in patients with high-risk tibial fractures. Bone Therapeutics anticipates finalizing patient recruitment of this study in 2022. This finalization is subject, as across the industry, to evolution of the ongoing COVID-19 pandemic and the associated containment measures. Although early recruitment rates were very promising, the recruitment rates have temporarily slowed in recent months due to pandemic-related factors, such as reduced site activities due to staff availability and the number of available patients due to less occurrence of accidents. Bone Therapeutics has already implemented several mitigating measures in collaboration with the involved clinical research organization to improve and facilitate recruitment. These measures include site expansion, training, information, best practices sharing and close monitoring of progress. As a result of these measures Bone Therapeutics continues to currently expect the release of topline data by Q1 2023.
- In November 2021, Bone Therapeutics signed a non-binding term sheet for the global rights for ALLOB, Bone Therapeutics’ allogeneic osteoblastic cell therapy product, with one of its current Chinese partners, Link Health Pharma Co., Ltd (Link Health). If the licensing deal is concluded, the partner would be responsible for all future costs of development of ALLOB, including the ongoing ALLOB TF2 Phase IIb trial and costs related to development, process development (scale up) and manufacturing of the product. In this non-binding agreement, no upfront or development milestones are expected but Bone Therapeutics would receive commercial milestone payments of up to €60 million in total and tiered royalties on net sales of up to 25%. The negotiations for the global rights agreement are still ongoing but take longer than expected. The envisaged completion of a final binding agreement has been delayed and is now contemplated over the course of Q1 2022.

Corporate highlights

- In October 2021, Bone Therapeutics appointed key experts to its Scientific Advisory Board (SAB). The members of the SAB consist of world-recognized scientists and clinicians in the cell and gene therapy field. The additional members of the SAB have been added to provide additional expert guidance on the development of Bone Therapeutics' novel, next generation induced pluripotent stem cell-derived mesenchymal stromal cell (iMSCg) platform.
- Bone Therapeutics has relocated its corporate offices to the Louvain-la-Neuve Science Park in Mont-Saint-Guibert (Louvain-la-Neuve), Belgium. Louvain-la-Neuve is home to the Catholic University of Louvain (UCLouvain), one of Belgium's premier academic research institutes. Bone Therapeutics will be part of a vibrant biotech ecosystem with a high concentration of cell therapeutic companies.

Financial highlights ⁽¹⁾

- In December 2021, Bone Therapeutics raised additional €3.3 million funding through a private placement with current and new institutional investors to advance its lead orthopedic asset, ALLOB, through mid-stage clinical development. The funds will also support the development of the new iMSCg cell and gene therapy platform to address a broader array of underserved clinical indications outside orthopedics.
- Disciplined cost and cash management will remain a key priority. Net cash burn for the full year 2021 is anticipated to be €16-18 million ⁽¹⁾. The net cash position totaled €9.5 million ⁽¹⁾ for the year ended December 31, 2021. Taking into consideration the €3.3M in gross proceeds from the private placement in the fourth quarter of 2021 and anticipated milestone payments, Bone Therapeutics expects to have sufficient cash to carry out its business objectives into Q3 2022. This assumes normal operation, as there may be further effects of the ongoing COVID-19 pandemic.

Outlook for 2022

- Bone Therapeutics will continue to explore options to develop its allogeneic differentiated MSC based cell therapy platform, beyond ALLOB, into other therapeutic indications. If financing so allows, Bone Therapeutics is also aiming to expand its preclinical and clinical pipeline to additional indications by enhancing and "professionalizing" the therapeutic capacity of its cell and gene therapy platform. This activity includes the development of a next generation of genetically engineered mesenchymal stromal cells (MSCs) and the use of highly scalable and versatile cell sources such as induced pluripotent stem cells (iPSC).
- For the ongoing Phase IIb ALLOB clinical study in difficult tibial fractures, Bone Therapeutics' clinical team, in partnership with its clinical research organization, is continuing to institute measures to mitigate the impact of the pandemic and will closely monitor the recruitment progress. As a result of the initial mitigation actions, Bone Therapeutics continues to expect to report topline results as scheduled by the first quarter of 2023. However, a delay cannot be excluded. Should the pandemic continue to have impact on patient availability, Bone Therapeutics may have to re-evaluate this timeline and, in that eventuality, will communicate again to the market.
- Bone Therapeutics will continue to prepare its discussions with the US FDA (Food and Drug Administration) in anticipation of the next steps in the clinical development of ALLOB in the US.
- Bone Therapeutics is in the process of considering mandating a third party organization to explore partnership, M&A opportunities and alternative sources of funding for the iMSCg platform.
- Link Health and Pregene, Bone Therapeutics' partners in Asia, continue to drive the development of ALLOB towards the approval of the Investigational New Drug Application (IND) with the Chinese National Medical Products Administration (NMPA).
- Bone Therapeutics continues to hold ALLOB business discussions with partners and aims to complete and to fully execute an agreement for the global rights for ALLOB over the course of Q1 2022.

Financial Calendar 2022

- 27 April – Full Year Results & Annual Report 2021
- 25 May – Q1 2022 Business and Financial Highlights
- 8 June – Annual General Meeting 2022
- 7 September – Half Year Results 2022
- 25 October – Q3 2022 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 therapies at different stages ranging from pre-clinical programs in immunomodulation to mid stage clinical development for orthopedic conditions, targeting markets with large unmet medical needs and limited innovation.

Bone Therapeutics' core technology is based on its cutting-edge allogeneic cell and gene 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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