

Bone Therapeutics provides Third Quarter 2022 Business Update

Mont-Saint-Guibert, Belgium, 21 October 2022, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, today announces its business update for the third quarter, ended 30 September 2022.

“If approved by its shareholders, Bone Therapeutics’ acquisition of Medsenic majority participation will combine the allogeneic cell therapy product, ALLOB with Medsenic’s dedicated best-in-class autoimmune disease platform as well as the respective teams, intellectual property and know-how. This will enable BioSenic, the combined company, to develop an expanded product portfolio across multiple therapeutic indications and thus limit shareholder risk, offer multiple treatments to patients, and increase the potential for growth and value creation for all shareholders,” said Jean Stéphenne, President of Bone Therapeutics. “In addition, Bone Therapeutics remains on target for delivery of topline interim results for the Phase IIb study ALLOB, in patients with difficult tibial fractures. Bone Therapeutics has now regained full global rights to ALLOB, and this will enable BioSenic to explore opportunities for the platform across the world.”

Key highlights

- Bone Therapeutics continues to advance the patient recruitment of the ongoing Phase IIb study with its allogeneic cell therapy product, ALLOB, in patients with high-risk tibial fractures. In July 2022, Bone Therapeutics announced an optimized statistical analysis and the implementation of an interim analysis for the ALLOB Phase IIb study. With the improved statistical analysis, the number of required patients can be reduced by 20%. The interim analysis will be added to the study providing an early assessment of ALLOB’s efficacy based on radiological data of the first 66 evaluable patients and more stringent efficacy end point criteria.
- In August 2022, Bone Therapeutics announced the acquisition of a majority participation in Medsenic, a privately held, clinical stage biopharmaceutical company incorporated in France and specializing in the development of optimized formulations of arsenic salts and their application in inflammatory conditions and other potential new indications. The acquisition will result in the business combination of Bone Therapeutics and Medsenic, creating BioSenic, a speciality biopharma company. This acquisition was achieved through the signature of a binding contribution agreement to combine the operations of both companies by means of a share for share exchange, subject to the approval of the shareholders' meeting. Subject to the realization of various conditions precedent, the final validation for the merger will be decided at a Bone Therapeutics Extraordinary General Meeting (EGM) on 24 October 2022.
- In October 2022, Bone Therapeutics regained worldwide rights to ALLOB, via a unilateral termination notice received from Shenzhen Pregene Biopharma Co., Ltd. Bone Therapeutics, Pregene and Link Health Pharma Co., Ltd signed an exclusive license agreement in October 2020 for the manufacturing, clinical development and commercialization of Bone Therapeutics’ allogeneic, off-the-shelf, bone cell therapy platform ALLOB in China (including Hong Kong and Macau), Taiwan, Singapore, South Korea, and Thailand. Bone Therapeutics has now regained all development manufacture and commercialization rights of ALLOB from Pregene. This will also now enable Bone Therapeutics to negotiate rights for ALLOB with LinkHealth, and other partners. Pregene shall transfer data to Bone Therapeutics and not participate in any future development or commercialization activities for the product.

Financial highlights

- Net cash at the end of September 2022 amounted to €2.8 million ⁽¹⁾.
- Disciplined cost and cash management will remain a key priority. The operating cash burn for the full year 2022 is expected to be in the range of EUR 8-10 million and a financing cash burn of approximately EUR 1.3 million, assuming normal operation as we continue to feel the effects of the COVID-19 pandemic. The situation continues to be actively and closely monitored. The company anticipates having sufficient cash to carry out its business objectives into Q1 2023, assuming, amongst other, full issuance of the new convertible bond facility.

⁽¹⁾ Unaudited number

Outlook for the remainder of 2022 and 2023

- Subject to the realization of various conditions precedent, Bone Therapeutics will hold an Extraordinary General Meeting (EGM) on 24 October 2022 to validate and complete the acquisition of a majority participation in Medsenic and name change of Bone Therapeutics into BioSenic.
- In the ongoing Phase IIb ALLOB clinical study in difficult tibial fractures, Bone Therapeutics expects to report interim topline results as scheduled by the first half of 2023. However, a delay still cannot be excluded. Should the COVID pandemic continue to have an impact on patient availability, Bone Therapeutics may have to re-evaluate this timeline and, in that eventuality, will communicate again to the market.
- Following regaining worldwide rights for ALLOB, Bone Therapeutics will now continue partnering conversations with Link Health and other partners for the manufacturing, clinical development and commercialization of Bone Therapeutics' allogeneic, off-the-shelf, bone cell therapy platform ALLOB.
- Bone Therapeutics is continuing negotiations and conversations with a range of partners and potential partners for the global rights of the manufacturing, clinical development and commercialization of Bone Therapeutics' ALLOB and in different local regions.
- The Medsenic Phase II clinical study with arsenic trioxide in the first-line treatment of cGvHD (chronic GvH) is complete and provided positive results. A phase IIa clinical trial for Lupus had previously established proof of concept of safety for the patient and efficacy on the course of the autoimmune disease: a Phase 2b clinical trial for severe Lupus is in the planning stage. A Phase III study of cGvHD is also currently anticipated to start in 2023. Also, positive preclinical work gives good grounds for a Phase 2 clinical trial on systemic sclerosis.
- After the acquisition of a majority participation in Medsenic and the name change of Bone Therapeutics into BioSenic, the new company plans to accelerate its development-mainly based upon clinical research, and will raise funds, in the form of a first private placement of new shares towards the end of 2022, in order to finance its combined activities.

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. Currently Bone Therapeutics is concentrating specifically on the development of its most advanced clinical asset, the allogeneic cell therapy platform, ALLOB.

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. Its 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 Louvain-la-Neuve Science Park in Mont-Saint-Guibert, Belgium. Further information is available at www.bonetherapeutics.com

About Medsenic SAS

Medsenic innovates and exploits the new possibilities offered by the therapeutic use of arsenic trioxide in several autoimmune diseases and is currently in clinical trials in Europe. The company was founded in 2010 by François Rieger, former Director of Research at the CNRS (French National Centre for Scientific Research) and author of more than 170 international scientific publications, and Véronique Pomi-Schneiter, former founder and manager of a consulting company specializing in human resources, communication and development strategy. Under the aegis of a high-level scientific board, chaired by the 2011 Nobel Prize in Medicine Jules Hoffmann, a specialist in innate immunology, and supported by selected private investors, Medsenic accelerated its development in 2016 with the arrival of professional investors. Further information is available at www.medsenic.com.

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