

Bone Therapeutics Business Update for Third Quarter 2016

Thomas Lienard appointed Chief Executive Officer

Interim results from ALLOB[®] Phase IIA spinal fusion study announced post period

Confirmed focus on allogeneic strategy in Europe and the US

Thomas Lienard, Chief Executive Officer, and Wim Goemaere, Chief Financial Officer, will host a conference call today at 14:00 CET / 13:00 BST / 08:00 EDT.

To access the conference call, please dial one of the appropriate numbers below quoting the conference ID:

BE: +32 (0) 24 02 96 40
 FR : +33 (0) 1 72 00 15 10
 US: +1 (0) 8778 874 163
 UK: +44 (0) 2030 432 440

Conference ID: 92901655#

The presentation can be accessed by [clicking here](#) and will also be made available on the [Investors section](#) of the Bone Therapeutics website shortly before the call.

A replay will be available through dialling the following number +33(0)1 72 00 15 00 and by using the following reference code 304895#

Gosselies, Belgium, 8 November 2016, 7am CET – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing high unmet medical needs in bone fracture repair, fracture prevention and spinal fusion, today provides a business update for the third quarter ended 30 September 2016. The Company also announces that Thomas Lienard has been appointed Chief Executive Officer of Bone Therapeutics.

Commenting on the appointment of Thomas Lienard, Michel Helbig, Chairman, said *“Thomas Lienard’s appointment as CEO reflects the rapid maturing of our portfolio and pipeline as Bone Therapeutics continues to advance its key clinical programs and prepares for the commercialization of our first products. Thomas has extensive experience in the pharmaceutical industry and has demonstrated excellent strategic vision and leadership since his appointment as Chief Business Officer in 2015. We now have the right industry, commercial and clinical expertise to steer the Company through the next phase of growth.”*

Thomas Lienard, Chief Executive Officer of Bone Therapeutics, commented: *“We continued to see strong progress across our pipeline in the third quarter following encouraging efficacy and safety data from the Phase II and III programs in delayed-union fractures, spinal fusion, osteoporosis and osteonecrosis in the first half. We announced positive efficacy data for the ALLOB[®] Phase IIA spinal fusion trial shortly after the period end, strengthening our confidence in the potential of ALLOB[®] as an important new treatment option. We are focused on targeting our resources on those programs with the greatest commercial and partnering potential and on moving our key programs towards commercialization.”*

Operating and Financial Summary

The Company completed the analysis of data from the first 50% of patients in a non-controlled ALLOB[®] Phase IIA spinal fusion study, announcing results in early October. The data support product safety and indicate clinically relevant improvements in function, pain and general health as early as six months after treatment along with radiological signs of fusion.

In September, the Company received a positive ruling on Belgian Patent Income Deduction. Under this favourable regime 80% of all revenues from patents relating to PREOB[®] and ALLOB[®], plus two other earlier-stage products, will be exempt from Belgian income tax. The Company will benefit from this favourable tax regime for potential licensing revenues received up to 30 June 2021.

Cash used in operating activities amounted to EUR 8.95 million for the first nine months of 2016, compared to EUR 9.93 million for the same period in 2015. Cash at the end of September 2016 amounted to EUR 22.46 million (excluding EUR 1.37 million of restricted cash).

Corporate and strategic update – post period events

The Board has appointed Thomas Lienard as Chief Executive Officer. Mr. Lienard assumed the role of interim CEO in October 2016 following the decision of Enrico Bastianelli to step down after more than 10 years in the role. Thomas Lienard joined Bone Therapeutics in November 2015 as Chief Business Officer with extensive experience in pharmaceutical sales and marketing. Prior to joining Bone Therapeutics, Mr. Lienard worked at Lundbeck, where he was Managing Director for Belgium and Luxembourg and played a key role in the launch of several major products. Mr. Lienard has also held senior positions in sales and marketing at Eli Lilly and Company. Mr. Lienard and the management team will be able to rely on the continuous support of Mr. Bastianelli as needed during the coming months.

In order to maximize value creation and ensure the best use of resources, the Company has decided to focus on:

1. The allogeneic platform ALLOB[®], which the Company believes offers the strongest commercial and industrial perspectives and potential for partnerships based on clinical advantages and larger addressable markets. The Company will therefore focus resources on its allogeneic clinical programs in Europe. In the US, priority will also be given to the development of ALLOB[®], with clinical programmes to be prepared during 2017. The Company has therefore decided not to initiate the clinical development of its autologous product PREOB[®] in the US.
2. Completion of the Phase III clinical trial in osteonecrosis to bring its first product to market. The Company believes this will clearly demonstrate and confirm the high added value of Bone Therapeutics' bone forming cell therapy products and propel the Company to the commercialisation stage.

Outlook

In the fourth quarter of 2016, Bone Therapeutics expects to finalize recruitment for the interim analysis of the ALLOB[®] Phase I/IIA delayed-union study. The outcome of this interim analysis, expected in summer 2017, will determine whether the trial can be ended at this point and proceed towards the next phase of development.

Additional potential inflection points include efficacy results for the full set of patients in the ALLOB[®] Phase IIA spinal fusion trial, expected during summer 2017. Work will also continue on transitioning the osteoporosis study to ALLOB[®].

Bone Therapeutics reiterates its guidance on cash burn for the full year 2016, which will be in the range of EUR 14-15 million. Based on the current strategy, the Company estimates that it will be able to carry out its strategic objectives into Q2-2018, excluding any partnerships or other commercial agreements.

● 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.

Regulated information

8 November 2016

● For further information, please contact:

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