

The interim financial report is prepared in accordance with article 13 of the Royal Decree on the obligations of issuers of financial instruments admitted to trading on a regulated market and can be accessed on the website of Bone Therapeutics in the section 'Financial information'. Bone Therapeutics publishes its interim financial report in English. A French translation of the report will also be made available. In the event of differences between the English and the French version of the report, the original English version will prevail.

Bone Therapeutics reports half year 2021 results

Concentrating focus on the continued development and expansion of the mesenchymal stromal cell based allogeneic cell and gene therapy platform

Strengthens financial position with the release of the first tranche of EUR 8.0 million as part of the financing agreement with EIB

Management to host conference call today at 5pm CEST / 11am ET today - details provided below

Gosselies, Belgium, 8 September 2021, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, today announces a business update and its financial results for the six-month period ended 30 June 2021, prepared in accordance with IFRS as adopted by the European Union, and the outlook for the remainder of the year.

“At the end of the first half of 2021, Bone Therapeutics has now developed a clear route forward for the company, with a full focus on expanding its allogeneic differentiated MSC based cell therapy platform, beyond our current orthopedic focus for ALLOB, into other therapeutic indications. This expansion has been built on the evidence of our clinical progress on orthopedics, and demonstrated a foundation to broaden our focus to wider indications,” said Miguel Forte, MD, PhD, Chief Executive Officer of Bone Therapeutics. “Now we have concluded the current stage of clinical progress of JTA, this allows all financial, managerial and scientific resources to be focused on delivering therapeutic benefit from our core MSC technology. These resources include our appointments throughout 2021, including the appointments of stem cell therapy industry veteran, Anthony Ting, PhD, as Chief Scientific Officer and Dr. Anne Leselbaum as Chief Medical Officer. We look forward to the development of MSC based therapies to bring options to a wider group of patients.”

Operational and Corporate Highlights

- On [January 12, 2021](#), Bone Therapeutics initiated the treatment of patients in the Phase IIb study of its allogeneic cell therapy product, ALLOB, in patients with difficult tibial fractures. Early recruitment rates were very promising. As across the industry, the rate of recruitment has temporarily slowed in recent months due to short term pandemic-related factors, such as reduced site activities due to staff availability, and number of available patients due to less accidents. Bone Therapeutics has taken and will continue to take actions to intensify the recruitment through increased number of sites, training, information and best practices sharing between different sites. Even though the recruitment rate has been impacted, Bone Therapeutics continues to expect patient recruitment to be completed by the end of first half of 2022 and topline results by the end of 2022. Should the pandemic impact continue, Bone Therapeutics will have to re-evaluate these timelines and, in that eventuality, will communicate again to the markets.
- On [January 14, 2021](#), Bone Therapeutics signed an initial 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 therapeutic targets and explore new mechanisms of action with potential gene modifications for Bone Therapeutics' therapeutic portfolio.
- On [June 30, 2021](#), Bone Therapeutics published the positive results of its Phase I/IIa clinical trial with ALLOB in patients with delayed union fractures. The results were published in [Stem Cell Research & Therapy](#), the international peer-reviewed journal focusing on translational research in stem cell therapies. ALLOB was generally well-tolerated and that all patients met the primary endpoint.

- On [August 30, 2021](#), Bone Therapeutics announced topline results from the Phase III knee osteoarthritis study with its enhanced viscosupplement JTA-004, its legacy non-MSD product. Despite JTA's favorable safety profile, the study did not meet the primary and key secondary endpoints. No statistically significant difference in pain reduction could be observed between the treatment, placebo and comparator groups, with all treatment arms showing similar efficacy. In collaboration with existing and potential partners, Bone Therapeutics will evaluate the options for the future of JTA-004 development.
- On [March 30, 2021](#), Bone Therapeutics appointed the stem cell therapy industry veteran, Anthony Ting, PhD, as Chief Scientific Officer. Dr. Ting is now responsible for Bone Therapeutics' research activities. He was appointed to lead the expansion of Bone Therapeutics' pipeline into new therapeutic indications, leveraging internal know-how and external collaborations on novel, specialized cell therapy products with enhanced efficacy, using differentiated and modified MSCs.
- After 1H 2021, in [July 2021](#), Bone Therapeutics appointed Dr. Anne Leselbaum as Chief Medical Officer. Dr. Leselbaum brings three decades of experience in strategic international clinical development, clinical operations and medical affairs. As CMO, she will take responsibility for the leadership of all clinical development and medical affairs strategies and activities across the entire Bone Therapeutics' pipeline and will oversee the regulatory interactions.

Financial Highlights

- After 1H 2021, in [July 2021](#), Bone Therapeutics secured a loan agreement of up to EUR 16.0 million with the European Investment Bank (EIB). The EIB loan financing will be disbursed in two tranches of EUR 8.0 million each, subject to conditions precedent.
- Following the approval of the issuance of associated warrants by Bone Therapeutics' General Meetings at the end of [August 2021](#), Bone Therapeutics received a payment from the EIB for the first tranche of EUR 8.0 million and the EIB was granted 800,000 warrants approved by the Extraordinary General Meeting.
- Bone Therapeutics also renegotiated 800 convertible bonds issued on May 7, 2020 (for an amount of EUR 2 million) to Patronale Life into a loan subject to the same repayment terms as the agreement with the EIB, with the issuance of 200,000 additional warrants approved by the Extraordinary General Meeting.
- In [July 2021](#), Bone Therapeutics agreed a final settlement with the Belgian Financial Services and Markets Authority (FSMA) regarding clinical studies communication issues in 2016 and 2017 for a settlement amount of EUR 500,000.
- During the first six months of 2021, total operating income amounted to EUR 0.77 million, a slight increase compared to the same period in 2020 (EUR 0.73 million).
- Operating loss for the period amounted to EUR 5.72 million, compared to EUR 7.38 million in H1 2020.
- The Company ended the first six months of 2021 with EUR 6.01 million in cash and cash equivalents. Cash used for the period amounted to EUR 8.64 million, compared to EUR 8.86 million over the same period of 2020.
- Disciplined cost and cash management will remain a key priority. The net cash burn for the full year 2021 is expected to be in the range of EUR 16-18 million, assuming normal operation as the effect of the ongoing COVID-19 epidemic cannot be excluded.
- Based on existing cash resources and the disbursement of the first tranche of EUR 8.0 million from EIB in September 2021, Bone Therapeutics anticipates having sufficient cash to carry out its business objectives into Q2 2022. To further strengthen its cash position in the near term, the company is currently evaluating and working on different financing options and plans to raise new funds with existing and new investors as well as with strategic partners. Further information about the going concern is contained in the going concern statement section of the IFRS reporting.

Outlook for the remainder of 2021

- For the ongoing Phase IIb ALLOB clinical study in difficult tibial fractures, Bone Therapeutics' clinical team, in partnership with the clinical research organization, has instituted corrective measures to mitigate the impact of the pandemic. Given the early stage of the study conduct and recruitment and further to the initial mitigation actions,

Bone Therapeutics continues to expect patient recruitment to be completed by the end of first half of 2022 and topline results by the end of 2022. Should the pandemic continue, Bone Therapeutics may have to re-evaluate these timelines and, in that eventuality, will communicate again to the market.

- Bone Therapeutics will continue to expand its allogeneic differentiated MSC based cell therapy platform, beyond ALLOB, into other therapeutic indications. Bone Therapeutics is also intensifying its efforts to expand its preclinical and clinical pipeline with 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 (MSC) and the use of highly scalable and versatile cell sources such as induced pluripotent stem cells (iPSC).
- Bone Therapeutics will continue to hold discussions with potential partners to explore business opportunities while ALLOB is being evaluated in a double-blind, placebo-controlled, proof-of-concept Phase IIb study.
- Bone Therapeutics will continue its discussions with the US FDA (Food and Drug Administration) in preparation for the next steps in the clinical development of ALLOB in the US.
- LinkHealth and Pregene, Bone Therapeutics’ partners in Asia continue to drive the development of ALLOB towards the submission of Investigational New Drug Application (IND) with the Chinese National Medical Products Administration (NMPA). A successful IND application could result in new milestone payments to Bone Therapeutics.

Conference call

Miguel Forte, MD, PhD, Chief Executive Officer, and Jean-Luc Vandebroek, Chief Financial Officer, will host a conference call today at 5pm CEST / 11am ET. To participate in the conference call, please select your phone number below and use the conference ID 880 4181 7984#.

Belgium: +32 2 290 9360
France: +33 1 7095 0103
United Kingdom: +44 208 080 6592
United States: +1 646 876 9923

The conference call will also be webcast and can be attended via the following link:

<https://us06web.zoom.us/j/88041817984>

The presentation will be made available on the Investors section - Presentations of the Bone Therapeutics website shortly prior the call.

Consolidated statement of comprehensive income

<i>(in thousands of euros)</i>	For the six-months period ended	
	30/06/21	30/06/20
Revenues	0	0
Other operating income	773	732
Total revenues and operating income	773	732
Research and development expenses	(4,768)	(6,619)
General and administrative expenses	(1,726)	(1,494)
Operating profit/(loss)	(5,721)	(7,381)
Interest income	23	10
Financial expenses	(362)	(672)
Exchange gains/(losses)	(13)	(5)
Result Profit/(loss) before taxes	(6,072)	(8,048)
Income taxes	0	(11)
Result Profit/(loss) for the period	(6,072)	(8,059)
Income/(Loss) of discontinued operations	0	(1,781)
TOTAL COMPREHENSIVE INCOME/(LOSS) OF THE PERIOD	(6,072)	(9,840)
Basic and diluted loss per share (in euros) – continuing operations	(0.52)	(0.63)
Basic and diluted loss per share (in euros) – discontinued operations	0	(0.25)
Profit/(loss) for the period attributable to the owners of the Company	(6,072)	(9,830)
Profit/(loss) for the period attributable to the non-controlling interests	0	(10)
Total comprehensive income/(loss) for the period attributable to the owners of the Company	(6,072)	(9,830)
Total comprehensive income/(loss) for the period attributable to the non-controlling interests	0	(10)

Consolidated Balance Sheet

Consolidated Assets IFRS per: <i>(in thousands of euros)</i>	30/06/21	31/12/20
Non-current assets	5,664	6,019
Intangible assets	25	21
Property, plant and equipment	247	226
Investments in associates	12	12
Financial assets	1,296	1,296
Deferred tax assets	4,084	4,456
Current assets	8,665	18,817
Trade and other receivables	2,376	3,840
Other current assets	275	328
Cash and cash equivalents	6,014	14,648
TOTAL ASSETS	14,329	24,835
Consolidated Equity & Liabilities IFRS per: <i>(in thousands of euros)</i>	30/06/21	31/12/20
Equity attributable to owners of the parent	(2,849)	3,325
<i>Share capital</i>	3,813	8,415
<i>Share premium</i>	67,558	67,594
<i>Accumulated losses</i>	(74,600)	(73,080)
<i>Other reserves</i>	380	396
Non-controlling interests	0	0
Total Equity	(2,849)	3,325
Non-current liabilities	11,711	11,720
Financial liabilities	11,711	11,720
Other non-current liabilities	0	0
Current liabilities	5,467	9,790
Provisions	500	0
Interest bearing borrowings	836	3,077
Trade and other payables	2,996	5,514
Other current liabilities	1,35	1,199
Total liabilities	17,178	21,509
TOTAL EQUITY AND LIABILITIES	14,329	24,835

Consolidated Cash Flow Statement

Consolidated Statements of Cash Flows (in thousands of euros)	For the six-months period ended	
	30/06/21	30/06/20
CASH FLOW FROM OPERATING ACTIVITIES		
Operating profit/(loss)	(5,721)	(9,096)
Adjustments for:		
Depreciation, Amortisation and Impairments	64	351
Share-based compensation	(17)	8
Grants income related to recoverable cash advances	(294)	(315)
Grants income related to patents	(13)	(3)
Grants income related to tax credit	(205)	(452)
Other	78	29
Movements in working capital:		
(Increase)/Decrease in Trade and other receivables (excluding government grants)	(139)	(40)
Increase/(Decrease) in Trade and other Payables	(2,053)	(1)
Increase/(Decrease) in Other current liabilities (excluding government grants)	0	0
Cash used by operations	(8,301)	(9,519)
Cash received from licensing agreement	933	0
Cash received from grants related to recoverable cash advances	639	725
Cash received from grants related to patents	56	27
Cash received from other grants	0	117
Cash received from grants related to tax credit	459	394
Income taxes paid	0	(26)
Net cash used in operating activities	(6,215)	(8,282)
CASH FLOW FROM INVESTING ACTIVITIES		
Interests received	29	1
Purchases of property, plant and equipment	(75)	(88)
Purchases of intangible assets	(6)	0
Net cash used in investing activities	(52)	(87)
CASH FLOW FROM FINANCING ACTIVITIES		
Proceeds from government loans	274	311
Repayment of government loans	(142)	0
Proceeds received from related parties	0	1,550
Reimbursements of loan from related parties	(629)	(51)
Reimbursements of lease liabilities	(17)	(63)
Proceeds from bank institutions	0	4,000
Reimbursements of bank loans	(1,500)	(63)
Interests paid	(354)	(187)
Payments to acquire financial investments	0	(1,234)
Transaction costs	0	(200)
Proceeds from issue of equity instruments of the Company	0	1,450
Proceeds received from convertible loan and subordinated loan	0	4,263
Net cash generated from financing activities	(2,367)	9,776
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(8,635)	1,407
CASH AND CASH EQUIVALENTS at beginning of the period	14,648	8,633
CASH AND CASH EQUIVALENTS at end of the period	6,014	10,040

Consolidated statement of changes in equity

<i>(in thousands of euros)</i>	Attributable to owners of the parent					TOTAL EQUITY
	Share capital	Share premium	Accumulated Losses & other reserves	Total equity attributable to owners of the parent	Non-controlling interests	
BALANCE AT 1 JANUARY 2020	5,454	58,026	(61,432)	2,048	0	2,048
Total comprehensive income of the period	0	0	(9,830)	(9,830)	(10)	(9,840)
Issue of share capital	506	2,269	0	2,775	0	2,775
Equity component for Convertible Bonds	0	0	199	199	0	199
Specific reserve for convertible bonds	0	0	219	219	0	219
Allocation to the legal reserve	0	0	3	3	0	3
Share-based payment	0	0	8	8	0	8
Movement non-controlling interests	0	0	(10)	(10)	10	0
Other	0	0	10	10	0	10
BALANCE AT 30 JUNE 2020	5,959	60,296	(70,833)	(4,578)	0	(4,578)
BALANCE AT 1 JANUARY 2021	8,415	67,594	(72,684)	3,325	0	3,325
Total comprehensive income of the period	0	0	(6,072)	(6,072)	0	(6,072)
Issue of share capital	0	0	0	0	0	0
Decrease of share capital	(4,602)	0	4,602	0	0	0
Transaction costs for equity issue	0	(36)	0	(36)	0	(36)
Specific reserve for convertible bonds	0	0	(60)	(60)	0	(60)
Share-based payment	0	0	(17)	(17)	0	(17)
Other	0	0	11	11	0	11
BALANCE AT 30 JUNE 2021	3,813	67,558	(74,220)	(2,849)	0	(2,849)

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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