

Bone Therapeutics announces 2021 full year results

Strategic focus revised and fully focused on achieving topline results of the ALLOB Phase IIb study in tibial fractures.

Discussions for ALLOB global partnership still ongoing.

Board of Directors and Management exploring all strategic options to protect shareholder value.

Strengthening financial position with EIB agreement and private placement in 2021 and a new bond issuance foreseen in May 2022

Management to host conference call today at 3pm CEST / 9am EST - details provided below

Mont-Saint-Guibert, Belgium, 29 April 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 and full year financial results for the year ending 31 December 2021, prepared in accordance with IFRS as adopted by the European Union.

“Incomplete fracture healing remains a seriously unmet medical need affecting hundreds of thousands of patients worldwide. Despite the pandemic and subsequent seriously geopolitical and economic global events, Bone Therapeutics still remains on target for delivery of topline results for its Phase IIb study of its allogeneic cell therapy product, ALLOB, in patients with difficult tibial fractures,” said Miguel Forte, MD, PhD, CEO of Bone Therapeutics. “We believe ALLOB could provide difficult tibial fracture patients a convenient treatment option with a potentially superior outcome. Having successfully completed two clinical studies showing promising safety profile and efficacy signals in more than 60 patients, we firmly believe that ALLOB has the highest potential of near-term value creation and is focused on completing the current Phase IIb study. In addition, Bone Therapeutics has made a serious contribution for the future into the use of Induced Pluripotent Stem Cell (iPSC) derived, genetically engineered MSCs. Bone Therapeutics is continuing its efforts to establish value adding business collaborations and to strengthen its financial position.”

Clinical and operational highlights (including post-period events)

In January 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. Bone Therapeutics anticipates finalizing patient recruitment of this study in 2022. This recruitment 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 subsequent 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 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 and the improving recruitment rate, Bone Therapeutics continues to currently expect the release of topline data by Q1 2023.

In January 2021, Bone Therapeutics signed an initial agreement for a process development partnership with the mesenchymal stromal cell (MSC) specialist, Rigenrand. This collaboration focused on further developing and enhancing Bone Therapeutics' bone-forming platform.

In June 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.

In August 2021, Bone Therapeutics announced topline results from the Phase III knee osteoarthritis study with its enhanced viscosupplement JTA-004, its legacy non-MSc product. JTA-004 had a favorable safety profile. However, 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 September 2021, Bone Therapeutics signed a research evaluation agreement with Implant Therapeutics, the developer of hypoimmunogenic and safe harbor engineered iPSC derived cells. The agreement enables Bone Therapeutics to access, evaluate and materially transfer Implant Therapeutics' Induced Pluripotent Stem Cell (iPSC) derived, genetically engineered MSCs, including lines, media, differentiation protocols and expertise.

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). 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 Q2 2022.

Corporate highlights (including post-period events)

In March, 2021, Bone Therapeutics appointed the stem cell therapy industry veteran, Anthony Ting, PhD, as Chief Scientific Officer. Dr. Ting is responsible for Bone Therapeutics' research activities.

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 takes 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.

In September 2021, Bone Therapeutics appointed Lieve Creten, as interim Chief Financial Officer (CFO), succeeding Jean-Luc Vandebroek. Lieve's extensive financial experience ensures the continued optimal financial control, oversight and compliance.

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.

In March 2022, Bone Therapeutics announced it was redefining its strategic priorities to concentrate specifically on the development of its most advanced clinical asset, ALLOB. As a result, Bone Therapeutics will focus its R&D activities to support the clinical development of ALLOB and all activities related to the development of the pre-clinical iMSCg platform as well as all other non ALLOB related activities, were stopped. In this context, some members of Bone Therapeutics' management team will depart Bone Therapeutics in the following months in alignment with the refocus in activity. This includes Miguel Forte (CEO), Tony Ting (CSO), Stefanos Theoharis (CBO) and Lieve Creten (CFO). During the transition, CEO, Miguel Forte, will remain in function. The Scientific Advisory Board was also dissolved.

Financial highlights (including post-period events)

In July 2021, Bone Therapeutics secured a loan agreement of up to €16.0 million with the European Investment Bank (EIB). The EIB loan financing will be disbursed in two tranches of €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 €8.0 million and the EIB was granted 800,000 warrants approved by the Extraordinary General Meeting.

In August 2021, Bone Therapeutics also renegotiated 800 convertible bonds issued on May 7, 2020 (for an amount of €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 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 total revenues and operating income for 2021 amounted to €2.7 million compared to €3.7 million in 2020. As a result of the reduced clinical activities following the completion of the Phase III JTA-004 study, and the slower pace of patient enrollment for the ALLOB TF2 Phase IIb study due to the COVID-19 pandemic, operating loss for the period decreased to €12.0 million from €15.0 million for the full year 2020. Consequently, cash used for operating activities amounted to €12.8 million for the full year 2021. Year-end cash position amount to €9.5 million compared to €14.7 million year-end 2020.

In April 2022, Bone Therapeutics signed a binding term sheet for a €5 million convertible bonds (CBs) facility arranged by ABO Securities. The proceeds of the financing will be used to advance the clinical development of Bone Therapeutics' lead asset, the allogeneic bone cell therapy, ALLOB. ABO Securities, on behalf of the CB investor, commits to subscribe to up to €5 million in CBs. Subject to the fulfillment of condition precedents, Bone Therapeutics and ABO Securities aim to agree on and execute the final subscription agreement for the CBs and to issue the first tranche of CBs by the beginning of May 2022.

Outlook for the remainder of 2022

In 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 and the improving recruitment rate due to the gradual lifting of COVID-19 related measures in Europe, Bone Therapeutics expects 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.

The negotiations for ALLOB, with one of Bone Therapeutics' current Chinese partners, for the global rights agreement are still ongoing but are taking longer than originally anticipated. The potential completion of a final binding agreement has been delayed into Q2 2022.

Subsequent to some preliminary contacts, the board of directors of Bone Therapeutics is currently examining various opportunities to combine certain activities within Bone Therapeutics, taking into account the interests of its shareholders and other stakeholders. Further announcements will be made in due course, if and when circumstances so allow or require.

Following the restructuring of the management team announced on 12 April 2022, Bone Therapeutics has initiated the search for a new CEO and CFO.

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 €8-10 million, assuming normal operations as the effect of the ongoing COVID-19 epidemic cannot be excluded. The situation will 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. Bone Therapeutics refers to the going concern statement in the Annual Report 2021 for all key assumptions taken.

Conference call

Miguel Forte, MD, PhD, Chief Executive Officer will host a webcast with conference call today at 3:00 pm CEST / 9:00 am EST. To participate in webcast or the conference call, please use the following link:

<https://us06web.zoom.us/j/81633950602>

Or select your dial-in number from the list below quoting the conference ID 816 3395 0602#:

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

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

Consolidated statement of comprehensive income

<i>(in thousands of euros)</i>	2021	2020
Revenues	1,000	1,000
Other operating income	1,745	2,666
Total revenues and operating income	2,745	3,666
Research and development expenses	(11,684)	(15,416)
General and administrative expenses	(3,087)	(3,267)
Operating profit/(loss)	(12,026)	(15,017)
Financial income	333	0
Interest income	25	24
Financial expenses	(1,147)	(747)
Exchange gains/(losses)	(20)	(13)
Result Profit/(loss) before taxes	(12,836)	(15,754)
Income taxes	(89)	(78)
Net Income (Loss) from continuing operations	(12,925)	(15,832)
Net Income (Loss) from discontinued operations	0	3,891
TOTAL COMPREHENSIVE INCOME/(LOSS) OF THE PERIOD	(12,925)	(11,940)
Basic and diluted loss per share (in euros) – continuing operations	(0.77)	(1.35)
Basic and diluted loss per share (in euros) – discontinued operations	0.00	0.33
Profit/(loss) for the period attributable to the owners of the Company	(12,925)	(11,940)
Total comprehensive income/(loss) for the period attributable to the owners of the Company	(12,925)	(11,940)

Consolidated Balance Sheet

Consolidated Assets IFRS per: <i>(in thousands of euros)</i>	31/12/21	31/12/20
Non-current assets	5,481	6,019
Intangible assets	24	28
Property, plant and equipment	863	226
Investments in associates	12	12
Other non-current assets	96	1,296
R&D Tax Credits	4,486	4,456
Current assets	14,291	18,817
Trade and other receivables	2,581	3,840
Other current assets	1,000	328
Financial assets	1,200	0
Cash and cash equivalents	9,510	14,648
TOTAL ASSETS	19,772	24,835

Consolidated Equity & Liabilities IFRS per: <i>(in thousands of euros)</i>	31/12/21	31/12/20
Share capital	4,924	8,415
Share premium	69,499	67,594
Accumulated losses	(81,488)	(73,080)
Other reserves	301	396
Total Equity	(6,765)	3,325
Non-current liabilities	19,864	11,720
Interest bearing borrowings	19,752	11,720
Other non-current liabilities	112	0
Current liabilities	6,673	9,790
Interest bearing borrowings	1,046	3,077
Trade and other payables	4,822	5,514
Other current liabilities	804	1,199
Total liabilities	26,537	21,510
TOTAL EQUITY AND LIABILITIES	19,772	24,835

Consolidated Cash Flow Statement

<i>(in thousands of euros)</i>	2021	2020
CASH FLOW FROM OPERATING ACTIVITIES		
Operating profit/(loss)	(12,026)	(17,448)
Adjustments non-cash:		
Depreciation, Amortization and Impairments	186	601
Share-based compensation	(99)	266
Grants income related to recoverable cash advances	(590)	(1,450)
Grants income related to patents	(69)	(52)
Grants income related to tax credit	(594)	(853)
Other	(65)	(88)
Movements in working capital:		
Trade and other receivables (excluding government grants)	(624)	(1,014)
Trade and other Payables	(684)	1,723
Cash used by operations	(14,565)	(18,315)
Cash received from grants related to recoverable cash advances	468	1,745
Cash received from non-refundable Subventions	331	0
Cash received from grants related to patents	47	56
Cash received from other grants	0	117
Cash received from grants related to tax credit	1,024	394
Income taxes paid	(89)	(78)
Net cash used in operating activities	(12,784)	(16,082)
CASH FLOW FROM INVESTING ACTIVITIES		
Interests received	3	2
Purchases of property, plant and equipment	(193)	(78)
Purchases of intangible assets	(14)	(15)
Proceed from the sale of SCTs	0	12,000
Net cash used in investing activities	(204)	11,908
CASH FLOW FROM FINANCING ACTIVITIES		
Proceeds from government loans	201	748
Repayment of government loans	(372)	(122)
Proceeds from loans from related parties	0	1,550
Reimbursements of related parties' loans	(675)	(1,864)
Reimbursements of financial lease liabilities	(89)	(267)
Proceeds from bank	8,000	4,000
Reimbursements of other financial loans	(1,500)	(4,625)
Interests paid	(724)	(679)
Guarantee facilities	0	(1,200)
Payments to acquire non-controlling interests	0	(1,956)
Transaction costs	(277)	(1,180)
Proceeds from issue of equity instruments of the Company	3,286	11,793
Proceeds received from convertible loan	0	4,000
Net cash generated from financing activities	7,850	10,188
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(5,138)	6,015
CASH AND CASH EQUIVALENTS at beginning of the year	14,648	8,633
CASH AND CASH EQUIVALENTS at end of the year	9,510	14,648

Consolidated statement of changes in equity

<i>(in thousands of euros)</i>	Share capital	Share premium	Accumulated Losses & other reserves	TOTAL EQUITY
BALANCE AT 1 JANUARY 2020	5,454	58,026	(61,432)	2,048
Total comprehensive income of the period	0	0	(11,940)	(11,940)
Issue of share capital	2,961	10,534	0	13,495
Transaction costs for equity issue	0	(966)	0	(966)
Equity component for Convertible Bonds	0	0	466	466
Allocation to the legal reserve	0	0	3	3
Share-based payment	0	0	266	266
Other	0	0	(48)	(48)
BALANCE AT 31 DECEMBER 2020	8,415	67,594	(72,684)	3,325
BALANCE AT 1 JANUARY 2021	8,415	67,594	(72,684)	3,325
Total comprehensive income of the period	0	0	(12,925)	(12,925)
Issue of share capital	1,111	2,175	0	3,286
Incorporation of losses	(4,602)	0	4,602	0
Transaction costs for equity issue	0	(277)	0	(277)
Equity component for Convertible Bonds	0	0	(89)	(89)
Allocation to the legal reserve	0	0	0	0
Share-based payment	0	0	(99)	(99)
Other	0	7	7	14
BALANCE AT 31 DECEMBER 2021	4,924	69,499	(81,188)	(6,765)

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.

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