

Bone Therapeutics announces 2019 full year results

Management to host conference call today at 5pm CET / 11am EST / 8am PST - details provided below

Gosselies, Belgium, 11 March 2020, 7am CET – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in orthopaedics and bone diseases, today announces its business update and full year financial results for the year ending 31 December 2019, prepared in accordance with IFRS as adopted by the European Union.

“During the past year, Bone Therapeutics has laid a strong foundation for advancing our key assets, the allogeneic cell therapy platform ALLOB and the enriched protein solution JTA-004, into the next phase of clinical development and beyond,” said Miguel Forte, MD, PhD, CEO of Bone Therapeutics. “We have obtained additional clinical evidence supporting the safety and efficacy for ALLOB in patients undergoing spinal fusion procedures. We have also successfully implemented the optimised allogeneic cell therapy manufacturing process and additionally submitted the clinical trial applications for the crucial Phase III JTA-004 and Phase IIb ALLOB studies. With the preparation of both clinical trials complete, we are fully focussed on timely execution of our clinical programmes and delivering our business and partnering strategy in 2020. This will enable us to move toward our goal of creating innovation solutions that will make a true difference in the lives of patients suffering from debilitating orthopaedic conditions.”

Clinical and operational highlights during 2019

- Reported positive results for the Phase IIa study with the allogeneic off-the-shelf cell therapy platform, ALLOB in 30 patients undergoing lumbar spinal fusion procedures at 12 months post-treatment
- Renewed the GMP (Good Manufacturing Practices) certification of Bone Therapeutics’ own manufacturing site for the production of human cell therapy products
- Completed the Clinical Trial Application (CTA) submission to the competent authorities to initiate the pivotal Phase III study with the enhanced protein solution, JTA-004, in patients with knee osteoarthritis
- Started the CTA submission process in Europe for a Phase IIb clinical trial with its allogeneic bone cell therapy product, ALLOB, in patients with tibial fractures at risk for delayed healing
- Asahi Kasei and Bone Therapeutics agreed to formally end the PREOB licensing agreement, following the previously announced discontinuation of the autologous cell therapy program at the end of 2018.

Corporate highlights 2019

- Appointed Miguel Forte as Chief Executive Officer, Benoit Moreaux as Chief Scientific and Technology Officer and Olivier Godeaux as Chief Medical Officer
- Strengthened its Board of Directors with the appointment of Gloria Matthews, DVM, PhD, DACVS, as Independent Director.

Financial highlights 2019

- Secured a total of € 8.5 million through private placement of new shares and non-dilutive subordinated bonds
- Revenues and operating income of € 4.92 million
- Operating loss for the period amounted to € 9.58 million, compared to € 11.47 million for the full year 2018.
- Lower than anticipated net cash burn of € 11.48 million vs € 12-13 million previously guided
- Year-end cash position of € 8.63 million compared to € 8.17 million year-end 2018.

Outlook for the remainder of 2020

Bone Therapeutics anticipates starting patient recruitment for the Phase III study with JTA-004, for the treatment of pain in patients with knee osteoarthritis in Q1 2020, subject to the approval of the CTA by the regulatory authorities.

The company has started the CTA submission process in Europe for a Phase IIb clinical trial with its allogeneic bone cell therapy product, ALLOB, in patients with tibial fractures at risk for delayed healing, using its optimized production process. The company expects to enroll the first patient in Q2 2020.

In the second half of 2020, the company expects to report results from the 2-year follow-up period of the Phase IIa study with ALLOB in patients undergoing a spinal fusion procedure.

Good cost and cash management will remain a key priority. The net cash burn for the full year 2020 is expected to be in the range of € 15-17 million assuming normal operation 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 Q3 2020.

In this context, strengthening the cash position is a key priority. The company is currently evaluating and working on different financing options and plans to raise new funds from the capital markets and/or through alternative funding strategies.

Detailed clinical and operational review 2019

In June 2019, Bone Therapeutics announced the successful completion of the Phase IIa study of its allogeneic cell therapy product, ALLOB, in patients undergoing a lumbar spinal fusion procedure. The results at 12 months post-treatment demonstrated that treatment with ALLOB resulted in significant clinical and radiological improvements and that ALLOB was generally well-tolerated, consistent with previous reported results.

In October 2019, the Belgian Federal Agency for Medicines and Health Products (FAMHP) renewed the GMP (Good Manufacturing Practices) certification of the company's manufacturing site in Gosselies (Belgium) following a two-day site audit. This decision further validates the high production and quality standards of our allogeneic cell therapy platform.

In December 2019, the company started the CTA submission to the competent authorities to initiate the pivotal Phase III study with the enhanced protein solution, JTA-004, in patients with knee osteoarthritis. The JTA-004 Phase III study is a placebo and active-controlled, randomized, double-blind study to evaluate the potential of a single, intra-articular injection of JTA-004 to reduce osteoarthritic pain in the knee compared to placebo or Hylan G-F 20, the leading osteoarthritis treatment on the market. The study is expected to enrol 676 patients with mild to moderate symptomatic knee osteoarthritis in 6 European countries and Hong Kong SAR. The first results of the study are anticipated in the second quarter of 2021 after a follow-up period of 3 months.

In December 2019, following the previously announced discontinuation of the autologous cell therapy program, PREOB, at the end of 2018, Asahi Kasei and Bone Therapeutics agreed to formally end the PREOB licensing agreement. As a result, Bone Therapeutics and the Walloon Region agreed to terminate the related reimbursable grant agreements under the form of Recoverable Cash Advances, thereby reducing cash reimbursements and associated interest payments that were due by the company by € 1.4M over the next 5 years.

Corporate developments 2019

In March 2019, Olivier Godeaux, MD was appointed as Chief Medical Officer. Benoit Moreaux, DVM was appointed as Chief Scientific and Technology Officer. Dr. Olivier Godeaux is a seasoned biopharmaceutical industry executive with a proven track record in advancing drug candidates through to regulatory approval and

commercial launch. With 20 years of experience, Dr. Benoit Moreaux brings extensive industry expertise in strategic operations planning and execution, as well as global quality assurance.

In June 2019, the significantly strengthened its Board of Directors with the appointment of Gloria Matthews, DVM, PhD, DACVS, as Independent Director. Gloria has more than 20 years of research and clinical experience in orthopaedics, osteoarthritis, rheumatology and cartilage repair with extensive expertise in medical devices, biologicals, and regenerative medicine. She has built an impressive business and medical network over the years and her knowledge will be invaluable as the company is entering a next stage in its corporate development.

In December 2019, Miguel Forte, MD, PhD was appointed as Chief Executive Officer to lead the company into the next phase of development. Miguel has over 20 years of experience in regenerative medicine and cell therapy, latterly as Chief Executive Officer of Zelluna Immunotherapy, a biopharma company focusing on developing transformative T cell receptors (TCR) based cellular immunotherapies for the treatment of cancers. He is currently also serving as Chief Commercialization Officer and Chair of the Commercialization Committee of the International Society of Cellular Therapy (ISCT).

Detailed financial review 2019

Income statement

The total revenues and operating income for 2019 amounted to € 4.92 million compared to € 5.08 million in 2018. Other operating income is mainly as a result of grants from the Walloon Region ("Recoverable Cash Advances - RCAs") which in total amounted to € 3.51 million in 2019 (including an impact of € 1.60 million for the stop of PREOB). In addition, the company benefited from the special regime employing scientific staff through the recovery of company withholding tax for an amount of € 0.59 million, an investment tax credit for an amount of € 0.58 million and € 0.24 million in patent and other subsidies. In 2018, the company recognized a success fee payment from licensee Asahi Kasei, after reaching a regulatory milestone following a successful consultation with the Japanese Regulatory Authority for PREOB for an amount of € 1.00 million.

R&D expenses in 2019 were at € 11.19 million compared to € 12.88 million in 2018. The decrease is mainly related to the decrease in R&D operating expenses from clinical operation and to the decrease in the number of R&D employees.

General and administrative expenses for the full year 2019 amounted to € 3.31 million compared to € 3.66 million over the same period last year. The decrease is mainly the result of a good costs management.

The operating loss in 2019 was at € 9.58 million. Last year, the company reported an operating loss of € 11.47 million.

The net financial loss amounted to € 0.72 million compared with € 2.55 million in 2018. The net financial expenses are mainly impacted by the interests paid for € 0.37 million and by the adaptation of the valuation of the PUT option for € 0.28 million. Last year, the net financial loss were mainly impacted by the recognition of the discount given on the committed capital from the private placement of the convertible bonds and related bond warrants (impact of € 1.69 million) and by the recognition of transaction costs of € 0.58 million related to the corresponding private placement.

The reported net loss in 2019 amounted to € 10.34 million or € 1.08 loss per share (on an undiluted basis). In 2018, the company had a net loss of € 14.14 million, equivalent to a loss per share of € 1.86 (on an undiluted basis).

Balance sheet

Total assets at the end of December 2019 amounted to € 22.39 million compared to € 25.75 million at the end of December 2018, mainly impacted by the current assets.

The current assets decreased from € 15.00 million to € 11.73 million at the end of December 2019. The decrease is mainly related to the variation of trade and other receivables which showed a decrease of € 3.70 million compared to last year as a result of:

- The milestone payment from Asahi Kasei received in 2019 for an amount of € 0.90 million net of taxes (decrease);
- Amounts received during the course of 2019 for RCAs in progress (upfront amounts and amounts received following expense declarations in function of the progress of the works) for a total of € 2.74 million (decrease);
- The remaining increase of € 0.06 million in trade and other receivables is on account of the VAT receivable, patent grants receivable and tax credit to be received within one year.

The non-current assets decreased from € 10.75 million to € 10.66 million at the end of December 2019. The decrease is mostly related to the property, plant and equipment and by the financial assets, partly offset by the deferred tax assets. Deferred tax assets totaling € 4.06 million represent a tax credit on investment in R&D reimbursable in the foreseeable future (spread over the next seven years). The company invested an amount of € 0.64 million for the laboratory and production equipment related to the production facility and for the cars and IT equipment (in relation with the new IFRS16 rule). The company recorded an amount of € 0.74 million as net depreciation

Equity decreased from € 4.49 million at the end of December 2018 to € 2.05 million at the end of December 2019, as a result of the share capital and share premium's increase (amounting € 8.52 million) and recognition of the transaction costs the equity transaction for an amount of € 0.46 million, by the loss of 2019 for an amount of € 10.34 million, for the reduction in the share-based payment reserve for € 0.48 million and by the recognition of a specific reserve linked to the convertible bonds and warrants and other reserves for € 0.32 million

Liabilities amounted to € 20.34 million in 2019 compared to € 21.26 million at the end of December 2018, representing a decrease of € 0.92 million.

Current liabilities remained stable compared to last year. The Put Option has been reclassified in the other current liabilities for an amount of € 1.96 million, mostly offset by the recognition of the deferred income related to the recoverable cash advances and patent subsidies into the comprehensive income statement (for an amount of € 1.88 million).

The non-current liabilities decreased compared to last year and amounted to € 11.01 million the end of December 2019. The non-current liabilities are impacted by the recognition of the non-dilutive subordinated loan for an amount of € 3.33 million and offset by a reclassification of the Put Option in the other current liabilities (for € 1.68 million in 2018) and by the decrease of the debts related the recoverable cash advances explained by the repayments and by the stop of PREOB (for a total decrease of € 2.13 million).

Cash flow statement

Cash used for operating activities amounted to € 10.40 million for the full year 2019 compared to € 12.90 million for the full year 2018.

Total operating loss for the period amounted to a loss of € 9.58 million compared to a loss of € 11.47 million over the same period in 2018. The decrease of the net loss in 2019 is mainly explained by an increase of the operating profit and a decrease of a net financial loss.

Adjustments for non-cash items amounted to € 3.89 million compared to € 2.73 million during the previous year relating to depreciation, share based payments and recognition of grant income from RCA's, patent subsidies and tax credit. Working capital was negatively impacted for the full year 2019 for an amount of € 0.19 million mainly

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explained by a decrease of trade and payables.

Actual cash received in 2019 for the grants and regulatory milestones amounted to € 3.25 million compared to € 1.70 million in 2018.

Cash flow from investing activities showed a net use of € 0.30 million for the full year 2019 compared to € 0.30 million in 2018. This mainly represents investments made in the laboratory equipment.

Cash flow from financing activities amounted to € 11.16 million for 2019 compared with € 12.96 million in 2018.

Financial cash inflows during 2019 are as follows:

- Net cash in from private placement (convertible bonds and related warrants) and from non-dilutive subordinated loan for a total amount of € 11.99 million;
- Recoverable cash advances provided to the company by the Walloon Region (R&D project financing) for an amount of € 0.82 million in 2019 which corresponds to the part for which reimbursement is turnover-independent.

Financial cash outflows during 2019 are as follows:

- Reimbursements of recoverable cash advances for an amount of € 0.74 million in 2019 (€ 0.58 million in 2018);
- Other reimbursements (lease contracts and bank loans and interest) paid for an amount of € 0.91 million.

The financial information in the press release has not been audited by the Auditor.

Conference call

Miguel Forte, MD, PhD, CEO, and Jean-Luc Vandebroek, CFO, will host a conference call today at 5pm CET / 11am EST / 8am PST. To participate in the conference call, please select your dial-in number from the list below quoting the conference ID 7547944#:

Belgium: +32 (0)800 48 740 / +32 (0)2 400 98 74
France: +33 (0)805 103 028 / +33 (0)1 76 70 07 94
United Kingdom: +44 (0)800 376 7922 / +44 (0)844 571 8892
United States: +1 (866) 966 1396 / +1 (631) 510 7495

Shortly prior to the call, the presentation will be made available on the Investors section of the Company's website. A replay will be available by dialling the following number +44 (0)333 300 9785 / +33 (0)1 70 95 03 48 and by using the conference ID: 7547944#

● **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 bone diseases. The Company has a broad, diversified portfolio of bone cell therapies and an innovative biological product in later-stage clinical development, which target markets with large unmet medical needs and limited innovation.

Bone Therapeutics is developing an off-the-shelf protein solution, JTA-004, which is entering Phase III development for the treatment of pain in knee osteoarthritis. Positive Phase IIb efficacy results in patients with knee osteoarthritis showed a statistically significant improvement in pain relief compared to a leading viscosupplement. The clinical trial application (CTA) to start the pivotal Phase III program has been submitted to the regulatory authorities in Europe and Hong Kong SAR. The trial is expected to start in Q1 2020.

Bone Therapeutics' other core technology is based on its cutting-edge allogeneic cell therapy platform (ALLOB) which can be stored at the point of use in the hospital, and uses a unique, proprietary approach to bone regeneration, which turns undifferentiated stem cells from healthy donors into bone-forming cells. These cells can be administered via a minimally invasive procedure, avoiding the need for invasive surgery, and are produced via a proprietary, scalable cutting-edge manufacturing process. Following the promising Phase IIa efficacy and safety results for ALLOB, the Company has started the CTA submission procedure with the regulatory authorities in Europe to start the Phase IIb clinical trial with ALLOB in patients with difficult-to-heal fractures, using its optimized production process.

The ALLOB platform technology has multiple applications and will continue to be evaluated in other indications including spinal fusion, osteotomy and maxillofacial and dental applications.

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.

● **For further information, please contact:**

Bone Therapeutics SA

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Consolidated statement of comprehensive income

<i>(in thousands of euros)</i>	2019	2018
Revenue	0	1,000
Other operating income	4,918	4,079
Total operating income	4,918	5,079
Research and development expenses	(11,185)	(12,884)
General and administrative expenses	(3,310)	(3,660)
Operating profit/(loss)	(9,577)	(11,466)
Interest income	26	66
Financial expenses	(738)	(2,609)
Exchange gains/(losses)	(15)	(18)
Share of profit/(loss) of associates	6	16
Result Profit/(loss) before taxes	(10,298)	(14,011)
Income taxes	(38)	(131)
PROFIT/(LOSS) FOR THE PERIOD	(13,336)	(14,142)
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	(10,336)	(14,142)
Basic and diluted loss per share (in euros)	(1.08)	(1.86)
Profit/(loss) for the period attributable to the owners of the Company	(10,461)	(14,218)
Profit/(loss) for the period attributable to the non-controlling interests	125	77
Total comprehensive income for the period attributable to the owners of the Company	(10,461)	(14,218)
Total comprehensive income for the period attributable to the non-controlling interests	125	77

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Consolidated Balance Sheet

ASSETS <i>(in thousands of euros)</i>	31/12/2019	31/12/2018
Non-current assets	10,660	10,754
Intangible assets	28	22
Property, plant and equipment	6,100	6,203
Investments in associates	332	326
Financial assets	140	323
Deferred tax assets	4,059	3,881
Current assets	11,733	15,000
Trade and other receivables	3,025	6,724
Other current assets	75	102
Cash and cash equivalents	8,633	8,174
TOTAL ASSETS	22,393	25,753
EQUITY AND LIABILITIES <i>(in thousands of euros)</i>	31/12/2019	31/12/2018
Equity		
Equity attributable to owners of the parent	2,048	4,491
<i>Share capital</i>	5,454	12,532
<i>Share premium</i>	58,026	53,478
<i>Retained earnings</i>	(61,586)	(62,136)
<i>Other reserves</i>	154	618
Non-controlling interests	0	0
Total equity	2,048	4,491
Non-current liabilities	11,006	11,925
Financial liabilities	11,006	10,247
Other non-current liabilities	0	1,678
Current liabilities	9,339	9,337
Financial liabilities	2,709	2,606
Trade and other payables	3,841	3,996
Current tax liabilities	0	11
Other current liabilities	2,788	2,725
Total liabilities	20,344	21,262
TOTAL EQUITY AND LIABILITIES	22,393	25,753

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Consolidated Cash Flow Statement

Consolidated Statements of Cash Flows <i>(in thousands of euros)</i>	2019	2018
CASH FLOW FROM OPERATING ACTIVITIES		
Operating profit/(loss)	(9,577)	(11,466)
Adjustments for:		
Depreciation, Amortisation and Impairments	753	580
Share-based compensation	(472)	52
Grants income related to recoverable cash advances	(3,505)	(2,523)
Grants income related to patents	(6)	(229)
Grants income related to tax credit	(578)	(612)
Other	(77)	1
Movements in working capital:		
Trade and other receivables (excluding government grants)	(5)	(810)
Trade and Other Payables	(183)	405
Cash generated from operations	(13,650)	(14,602)
Cash received from licensing agreement	900	0
Cash received from grants related to recoverable cash advances	1,901	1,580
Cash received from grants related to patents	141	20
Cash received from grants related to tax credit	344	232
Income taxed paid	(38)	(131)
Net cash used in operating activities	(10,400)	(12,901)
CASH FLOW FROM INVESTING ACTIVITIES		
Interests received	8	1
Purchases of property, plant and equipment	(289)	(277)
Purchases of intangible assets	(21)	(19)
Net cash used in investing activities	(302)	(295)
CASH FLOW FROM FINANCING ACTIVITIES		
Proceeds from government loans	815	677
Repayment of government loans	(736)	(573)
Reimbursements of financial lease liabilities	(432)	(366)
Reimbursements of other financial loans	(250)	(250)
Interests paid	(228)	(225)
Transactions costs	(632)	(580)
Proceeds from issue of equity instruments of the Company	8,520	13,512
Proceeds received from convertible bond	605	763
Proceeds received from subordinated loans	3,500	0
Net cash provided by financing activities	11,162	12 958
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	459	(237)
CASH AND CASH EQUIVALENTS at beginning of year	8,174	8,411
CASH AND CASH EQUIVALENTS at end of year	8,633	8,174

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Consolidated statement of changes in equity

(in thousands of euros)	Attributable to owners of the parent			Total equity attributable to owners of the parent	Non-controlling interests	TOTAL EQUITY
	Share capital	Share premium	Retained earnings			
Balance at 31 December 2017	14,662	42,665	(54,944)	2,382	0	2,382
Impact of restatement based on IFRS 15	0	0	1,501	1,501	0	1,501
Balance at 1 January 2018	14,662	42,665	(53,443)	3,883	0	3,883
Total comprehensive income of the period	0	0	(14,218)	(14,218)	77	(14,142)
Issue of share capital	2,699	10,813	0	13,512	0	13,512
Decrease of share capital	(4,829)	0	4,829	0	0	0
Specific reserve for convertible bonds	0	0	1,175	1,175	0	1,175
Allocation to the legal reserve	0	0	5	5	0	5
Share-based payment	0	0	52	52	0	52
Movement non-controlling interests	0	0	77	77	(77)	0
Other	0	0	6	6	0	6
Balance at 31 December 2018	12,532	53,478	(61,518)	4,491	0	4,491
Balance at 1 January 2019	12,532	53,478	(61,518)	4,491	0	4,491
Total comprehensive income of the period	0	0	(10,461)	(10,461)	125	(10,336)
Issue of share capital	3,514	5,006	0	8,520	0	8,520
Decrease of share capital	(10,592)	0	10,592	0	0	0
Transaction costs for equity issue	0	(457)	0	(457)	0	(457)
Specific reserve for convertible bonds	0	0	306	306	0	306
Allocation to the legal reserve	0	0	6	6	0	6
Share-based payment	0	0	(472)	(472)	0	(472)
Movement non-controlling interests	0	0	125	125	(125)	0
Other	0	0	(11)	(11)	0	(11)
Balance at 31 December 2019	5,454	58,027	(61,432)	2,048	0	2,048