Bone Therapeutics Reports Full Year 2016 Results

- **Streamlined strategic priorities with primary focus on allogeneic pipeline**
- **Strong progress in clinical development of allogeneic platform ALLOB®**
- **Further demonstration of efficacy of autologous PREOB® in osteonecrosis**
- **Cash at end of 2016: EUR 20.3 million**
- **Management team strengthened with appointments of Thomas Lienard (CEO), Benoît Champluvier (CTMO) and Miguel Forte (CMO)**

Thomas Lienard, CEO, and Wim Goemaere, CFO, will host a conference call today at 10:00 CET / 09:00 GMT. To access the conference call, please dial one of the appropriate numbers below quoting the conference ID:

Belgium: +32 (0)81 70 00 61
France: +33 (0) 805 63 20 56
US: +1 (866) 966 9439
UK: +44 (0) 1452 555 566

Conference ID: 81483630

The presentation for the call will 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 +44 (0)1452 550 000 / +33 (0) 805 11 13 37 and by using the conference ID: 81483630#

Gosselies, Belgium, 16 March 2017, 7am CET – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in orthopaedic and bone diseases, today reports its full year results for the year ending 31 December 2016, prepared in accordance with IFRS as adopted by the European Union.

Thomas Lienard, CEO of Bone Therapeutics, commented: *"Over the past year Bone Therapeutics has undergone an important transition, during which we have seen a growing body of encouraging data around the safety and efficacy of our allogeneic bone cell therapy product ALLOB®, underpinning our confidence in the technology. Following a review of our portfolio and priorities, we have decided to focus our clinical strategy around our allogeneic platform, which we think offers significant commercial advantages due to its clinical benefits, scalability, cost-effectiveness and relevance for large addressable markets with high unmet need. During the year, the Company has maintained its strong focus on cash burn, ending 2016 with EUR 20.3 million, slightly ahead of expectations."*

"With the appointment of Benoît Champluvier as Chief Technology and Manufacturing Officer last year, we are also focusing on strengthening our in-house manufacturing expertise, ensuring that the Company is ready to take its products to market in the future. Together with the recent appointment of Miguel Forte as the new Chief Medical Officer to strengthen the leadership of our development capabilities, we believe we have the right team in place to focus on advancing our unique bone cell therapy programmes into late-stage trials and towards commercialisation."

"For 2017, we are expecting potential value inflection points in the second half of this year from our delayed-union fractures and spinal fusion clinical programmes. We look forward to moving ahead to bring this unique technology to patients and to deliver value for investors."

Key Highlights:

- Streamlining of strategic priorities following a review of the portfolio, to intensify focus on the development of the allogeneic pipeline. This strategy offers the most promising commercial opportunities and the greatest potential for partnerships, based on clinical benefits, scalability, cost-effectiveness and large addressable markets with unmet need
- Significant progress in clinical development of ALLOB®, our flagship allogeneic bone cell therapy technology, underpinning the potential of Bone Therapeutics' approach:
    - Positive safety and preliminary efficacy data reported in Phase IIA spinal fusion trial on first 8 patients treated
    - Completion of recruitment of the first 16 patients for the ALLOB® spinal fusion trial allowing for the completion of the interim analysis during late summer 2017
    - Positive safety and preliminary efficacy data reported for the first 8 patients treated in the delayed-union fractures Phase I/IIA trial. Seven out of eight patients met the primary endpoint at six months
    - Completion of recruitment of the first 16 patients for the ALLOB® delayed union trial post period
    - After the period end, the Safety Monitoring Committee confirms the safety of treatment for the 16 delayed-union patients. ALLOB has now been safely administered to over 40 patients across multiple programs with no clinical adverse effects
- Complete positive data from the proof-of-concept Phase IIB study of PREOB® in osteonecrosis presented at the Annual European Congress for Rheumatology (EULAR) conference

Financial and Corporate Highlights:

- Operating income of EUR 4.0 million for the full year 2016, compared to EUR 3.8 million in full year 2015
- Operating loss for the period amounted to EUR 12.8 million, compared to EUR 12.2 million in full year 2015
- EUR 20.3 million at 31 December in cash and cash equivalents
- Appointment of Thomas Lienard, as Chief Executive Officer and Benoit Champluvier as Chief Technology and Manufacturing Officer, ensuring that the Company has the right expertise to support the business as it strengthens its commercial manufacturing capabilities
- Miguel Forte, post the period end, appointed as Chief Medical Officer, completing the leadership team to focus on driving the business toward commercialisation

Key Financials

(€ million)	FY 2016	FY 2015
Operating income	4.01	3.82
Operating expenses	(16.81)	(16.05)
R&D	(13.65)	(12.91)
G&A	(3.16)	(3.14)[1]
Operating result	(12.80)	(12.22)
Net financial result	(0.28)	(1.80)
Net result	(13.02)	(14.09)
Net cash flow	(13.31)	22.04
Operating activities	(11.37)	(11.77)
Investing activities	(0.58)	(2.98)
Financing activities	(1.36)	36.78
Cash position at 31 December	20.30	33.61

[1] *Including € 1.06 million of IPO costs*

Operational highlights

ALLOB®

During 2016, Bone Therapeutics made significant progress in the clinical development of ALLOB®, with evidence of a very good safety profile and preliminary efficacy accumulating from two ongoing studies.

Data from a Phase IIA study for the treatment of delayed-union fractures with ALLOB®, published in May, showed that seven out of eight patients treated met the study's primary endpoints, with a 77% improvement in radiological and 68% in clinical parameters demonstrated. After the period end, the Company announced that it had completed recruitment of the first 16 patients in this trial, with no significant safety concerns.

The Safety Monitoring Committee, after the period end on 14 March 2017, confirmed these findings and recommended the continuation of the trial as planned. ALLOB® has so far delivered a very good safety profile, with no safety issues reported in the three Phase II trials underway.

Bone Therapeutics also reported positive safety and preliminary efficacy data from the ALLOB® Phase IIA spinal fusion trial. These data demonstrated evidence of successful fusion and important clinical improvements in function, pain and general health as early as six months after treatment. The Company also presented preclinical and early clinical efficacy data from the first patient in the trial at the Clinical Applications of Stem Cells Conference in Singapore in February, showing spinal fusion on CT scans and absence of intervertebral motion on dynamic x-rays.

PREOB®

In June, Bone Therapeutics presented data from the PREOB® Phase IIB osteonecrosis study at the Annual European Congress for Rheumatology (EULAR) in London. These data demonstrate the superiority of a single administration of PREOB® over standard of care in halting or reversing the progression of osteonecrosis of the hip.

PREOB® is in an ongoing Phase III trial for the treatment of osteonecrosis across a number of European centers.

In March, the Company reported initial efficacy data from the first cohort of seven patients treated with PREOB®, its autologous bone cell therapy product, in its Phase IIA severe osteoporosis trial. These initial data demonstrate positive effects on pain and osteoporosis blood markers of a single administration of PREOB®. Early in 2017, after the period end, Bone Therapeutics announced that following consultation with the Company's Scientific Advisory Board and in line with its new priorities, the Company has decided not to pursue the clinical development of ALLOB® in severe osteoporosis without a partner, due to the nature and the complexity of the disease and its market.

Corporate highlights

As part of a drive to strengthen its commercialisation capabilities, Bone Therapeutics appointed Thomas Lienard, formerly Chief Business Officer, as Chief Executive Officer of the Company. Thomas has extensive international sales and marketing experience gained from a long career in global pharmaceutical companies including Lundbeck and Eli Lilly.

The Company also appointed Benoît Champluvier as Chief Technology and Manufacturing Officer. Mr Champluvier joined from GlaxoSmithKline Vaccines, where he has more than 20 years' experience driving innovative and complex bioprocesses and supporting the development and launch of a number of new products. He will be responsible for production and quality control, playing a key role in streamlining production processes and gearing up Bone Therapeutics' capacity to manufacture both commercial-scale and clinical trial batches at its specialist facility in Gosselies.

In addition, after the period end, Bone Therapeutics announced the appointment of Miguel Forte as Chief Medical Officer with a focus on the Company's clinical development strategy and advancing its products to market. Dr. Forte has significant regenerative medicine and cell therapy industry experience, latterly as Chief Operating and Medical Officer at TxCell, a French biotechnology company specializing in immune cell therapy, and as Chief Commercialization Officer and Chair of the Commercialization Committee at the International Society of Cellular Therapy (ISCT). He has 20 years' industry experience.

Outlook for 2017

Two potential inflection points are expected in the second half of 2017, with clinical efficacy and safety data anticipated from ALLOB® studies in delayed-union fractures and spinal fusion. Bone Therapeutics expects to present the results of the interim analyses of these two ALLOB® studies in the second half of 2017.

Additionally, Bone Therapeutics is expected to provide a recruitment update for the osteoneocrosis Phase III clinical trial.

Good cash management will remain a key priority, with a strong focus on net cash burn. Cash burn for the full year 2017 is expected to be in the order of EUR 15 million. Based on its new strategic priorities, the company provides guidance that it has sufficient cash to carry out its strategic objectives into Q2 2018.

Financial review

Income Statement

In 2016, total (other) operating income amounted to EUR 4.01 million compared to EUR 3.82 million in 2015. Other operating income came from grants from the Walloon Region (*"avances récupérables"*) which totalled EUR 2.45 million in 2016. In addition, the Company benefited from a special regime of employing scientific staff through the recovery of withholding tax for an amount of EUR 0.75 million, an investment tax credit for an amount of EUR 0.75 million and EUR 0.06 million in patent and other subsidies.

R&D expenses in 2016 were at EUR 13.65 million compared to EUR 12.91 million in 2015. The increase is mainly due to the strengthening of the Company's clinical research team to support ongoing trials.

General and administrative expenses for the full year 2016 amounted to EUR 3.16 million compared to EUR 3.14 million over the same period last year. During 2015, EUR 1.06 million was accounted for as IPO-expenditure directly impacting the statement of comprehensive income. The net increase, disregarding IPO-expenditure in 2015, amounted to EUR 1.08 million. The increase mainly resulted from the full impact of a strengthening of the G&A team during 2015 (EUR 0.4 million), increase of activities for business development and investor relations (EUR 0.3 million) and fees (EUR 0.3 million) paid or to be paid (2017) to the former CEO for services rendered and to be rendered during a 12-month period post his departure (including a non-compete arrangement).

The operating loss in 2016 was EUR 12.80 million. In 2015, Bone Therapeutics reported an operating loss of EUR 12.22 million.

The Company had net financial expenses of EUR 0.27 million in 2016 compared to EUR 1.80 million in 2015 which was mainly explained by the non-cash impact of the derivative of the convertible bonds amounting to EUR 1.33 million and the transaction costs related to the convertible bonds of EUR 0.28 million.

The reported net loss in 2016 amounted to EUR 13.02 million or EUR 1.90 loss per share (on an undiluted basis). In 2015, the Company made a net loss of EUR 14.09 million, equivalent to a loss per share of EUR 2.14 (on an undiluted basis).

Balance Sheet

Total assets at the end of December 2016 amount to EUR 38.59 million compared to EUR 50.38 million at the end of December 2015 with the main decrease due to cash and cash equivalents offset by an increase in property, plant and equipment and by the deferred tax assets.

The Company's cash position at the end of December 2016 amounted to EUR 20.30 million, a reduction of EUR 13.31 million mainly due to cash used in operating activities.

Non-current assets increased from EUR 8.68 million to EUR 10.11 million at the end of December 2016. This increase is related to property plant and equipment and to deferred tax assets. Property, plant and equipment increased by EUR 0.60

million in 2016. The Company invested an amount of EUR 0.57 million for this new production facility at Gosselies and EUR 0.53 million for the laboratory and production equipment related for this new production facility. The Company has recorded an amount of EUR 0.48 million as net depreciation. Deferred tax assets totalling EUR 3.08 million are representing a tax credit on investment in R&D, reimbursable in the foreseeable future (spread over the next 7 years).

Trade and other receivables slightly increased to EUR 0.10 compared to 2015.

Equity amounted to EUR 15.27 million at the end of December 2016 compared to EUR 28.15 million at the end of December 2015.

- Retained earnings were impacted by the loss for the period amounting to EUR 13.02 million
- Other reserves increased with an amount of EUR 0.14 million related to share-based payments

Liabilities amounted to EUR 23.32 million at the end of December 2016 compared to EUR 22.24 million at the end of December 2015, with the main increase due to non-current liabilities.

Non-current liabilities increased from EUR 11.69 million at the end of 2015 to EUR 12.80 million on 31 December 2016.

Current liabilities amounted to EUR 10.51 million at 31 December 2016 compared with EUR 10.54 million at the end of December 2015.

The financial liabilities amount to EUR 1.24 million and did decrease with EUR 1.07 million. This is mainly due to the reimbursement of the straight loan facility provided by ING and BNP Paribas Fortis for an amount of EUR 1.68 million following the receipt of this amount from the Walloon Region through an investment grant.

Trade and other payables amounted to EUR 3.12 million which represented an increase of EUR 0.54 million compared to the end of December 2015. This increase is mainly related to non-recurring items.

Other current liabilities amount to EUR 6.15 million at the end of December 2016 compared to EUR 5.59 million at the end of December 2015, showing an increase of EUR 0.56 million due to deferred income related to new grants the Company obtained from the Walloon Region during 2016.

Cash Flow Statement

Cash used for operating activities amounts to EUR 11.37 million for the full year 2016 and EUR 11.77 million for the full year 2015. Total operating loss for the period amounts to a loss of EUR 12.80 million compared with a loss of EUR 12.22 million over the same period in 2015.

Adjustments for non-cash items amounted to EUR 2.57 million, compared with EUR 2.21 million in 2015 relating to depreciation, share based payments and recognition of grant income from RCA's, patent subsidies and tax credit. Actual cash received in 2016 for the grant related items amounted to EUR 2.75 million compared with EUR 2.23 million in 2015.

Working capital was positively impacted for the full year 2016 by EUR 1.92 million mainly following a reduction in trade receivables (disbursement of the outstanding amount for the investment grant of EUR 1.31 million) and an increase of trade and other payables for an amount of EUR 0.34 million.

Cash flow from investing activities shows a net use of cash for EUR 0.58 million for the full year 2016 and EUR 2.98 million for the year 2015. This mainly represents investments made in property, plant and equipment related to the finalization of the construction of the new facilities in Gosselies.

Cash flow used in financing activities amounts to EUR 1.36 million compared to a cash generated from financing activities of EUR 36.78 million in 2015. In 2015 the Company benefited from the proceeds of the IPO and proceeds of new loans exceeding the amount of loans reimbursed during the period. In 2016 the amounts reimbursed for existing loans were more important than the amounts received for new loans, resulting in the use of cash for financing activities of EUR 1.36 million, in particular, a reimbursement of a short-term credit facility for an amount of EUR 1.40 million.

The Company is currently finalizing its financial statements for the year ended 31 December 2016. The Auditor has confirmed that his audit procedures, which are substantially completed, have not revealed any material corrections required to be made to the financial information included in this press release. Should any material changes arise during the audit finalization, an additional press release will be issued. The Company expects to be able to publish its fully audited Annual Report for the full year 2016 on 20 April 2017.

About Bone Therapeutics

Bone Therapeutics is a leading cell therapy company addressing high unmet needs in orthopaedic and bone diseases. Based in Gosselies, Belgium, the Company has a broad, diversified portfolio of bone cell therapy products in clinical development across a number of disease areas targeting markets with large unmet medical needs and limited innovation.

Our technology is based on a unique, proprietary approach to bone regeneration which turns undifferentiated stem cells into "osteoblastic", or bone-forming cells. These cells can be administered via a minimally invasive procedure, avoiding the need for invasive surgery.

Our primary clinical focus is ALLOB®, an allogeneic "off-the-shelf" cell therapy product derived from stem cells of healthy donors, which is in Phase II studies for the treatment of delayed-union fractures and spinal fusion. The Company also has an autologous bone cell therapy product, PREOB®, obtained from patient's own bone marrow and currently in Phase III development for osteonecrosis and non-union fractures.

Bone Therapeutics' cell therapy products are manufactured to the highest GMP standards and are protected by a rich IP estate covering 9 patent families. Further information is available at: www.bonetherapeutics.com.

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Consolidated Statement of Comprehensive Income

(in thousands of euros)	2016	2015
Revenue	0	0
Other operating income	4,007	3,824
Total operating income	**4,007**	**3,824**
Research and development expenses	(13,649)	(12,910)
General and administrative expenses	(3,157)	(3,138)
Operating profit/(loss)	**(12,799)**	**(12,224)**
Interest income	173	194
Financial expenses	(379)	(1,966)
Exchange gains/(losses)	(60)	(26)
Share of profit/(loss) of associates	(15)	(1)
Result Profit/(loss) before taxes	**(13,081)**	**(14,025)**
Income taxes	60	(61)
PROFIT/(LOSS) FOR THE PERIOD	**(13,021)**	**(14,085)**
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	**(13,021)**	**(14,085)**
Basic and diluted loss per share (in euros)	**(1.90)**	**(2.14)**
Profit/(loss) for the period attributable to the owners of the Company	(12,989)	(14,144)
Profit/(loss) for the period attributable to the non-controlling interests	(32)	59
Total comprehensive income for the period attributable to the owners of the Company	(12,989)	(14,144)
Total comprehensive income for the period attributable to the non-controlling interests	(32)	59

Consolidated Balance Sheet

ASSETS *(in thousands of euros)*	31/12/2016	31/12/2015
Non-current assets	**10,114**	**8,682**
Intangible assets	56	69
Property, plant and equipment	6,385	5,793
Investments in associates	291	282
Financial assets	299	205
Deferred tax assets	3,083	2,333
Current assets	**28,471**	**41,701**
Trade and other receivables	8,013	7,912
Other current assets	158	178
Cash and cash equivalents	20,300	33,611
TOTAL ASSETS	**38,585**	**50,383**

EQUITY AND LIABILITIES *(in thousands of euros)*	31/12/2016	31/12/2015
Equity		
Equity attributable to owners of the parent	15,270	28,147
Share capital	20,708	20,708
Share premium	42,670	42,670
Retained earnings	(48,773)	(35,752)
Other reserves	665	520
Non-controlling interests	0	0
Total equity	**15,270**	**28,147**
Non-current liabilities	**12,802**	**11,693**
Financial liabilities	11,167	10,118
Deferred tax liabilities	0	0
Other non-current liabilities	1,635	1,575
Current liabilities	**10,513**	**10,543**
Financial liabilities	1,242	2,313
Trade and other payables	3,120	2,579
Current tax liabilities	0	61
Other current liabilities	6,150	5,590
Total liabilities	**23,315**	**22,236**
TOTAL EQUITY AND LIABILITIES	**38,585**	**50,383**

Consolidated Cash Flow Statement

Consolidated Statements of Cash Flows *(in thousands of euros)*	2016	2015
CASH FLOW FROM OPERATING ACTIVITIES		
Operating profit/(loss)	(12,799)	(12,224)
Adjustments for :		
Depreciation, Amortisation and Impairments	537	394
Share-based compensation	123	486
Grants income related to recoverable cash advances	(2,454)	(2,123)
Grants income related to patents	(56)	(207)
Grants income related to tax credit	(750)	(736)
Other	35	(24)
Movements in working capital:		
Trade and other receivables (excluding government grants)	1,586	1,171
Trade and Other Payables	338	(788)
Other current liabilities (excluding government grants)	(4)	0
Cash generated from operations	**(13,445)**	**(14,052)**
Cash received from grants related to recoverable cash advances	1,976	2,267
Cash received from grants related to patents	62	19
Cash received from grants related to tax credit	37	0
Net cash used in operating activities	**(11,369)**	**(11,765)**
CASH FLOW FROM INVESTING ACTIVITIES		
Interests received	28	143
Purchases of property, plant and equipment	(579)	(3,048)
Purchases of intangible assets	(26)	(52)
Payments to acquire financial investments	0	(24)
Net cash used in investing activities	**(578)**	**(2,982)**
CASH FLOW FROM FINANCING ACTIVITIES		
Proceeds from government loans	847	972
Repayment of government loans	(402)	(283)
Proceeds from loans from related parties	300	500
Reimbursements of financial lease liabilities	(426)	(188)
Reimbursements of other financial loans	(1,396)	1,437
Interests paid	(286)	(279)
Proceeds received from convertible loan (net of transaction costs)	(1)	0
Proceeds from issue of equity instruments of the Company (net of issue costs)	0	34,622
Net cash provided by financing activities	**(1,363)**	**36,781**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(13,310)**	**22,035**
CASH AND CASH EQUIVALENTS at beginning of year	**33,611**	**11,577**
CASH AND CASH EQUIVALENTS at end of year	**20,300**	**33,611**

Consolidated statement of changes in equity

(in thousands of euros)	Attributable to owners of the parent					
	Share capital	Share premium	Retained earnings	Total equity attributable to owners of the parent	Non-controlling interests	TOTAL EQUITY
Balance at 1 January 2015	**10,466**	**1,671**	**(21,621)**	**(9,485)**	**0**	**(9,485)**
Total comprehensive income of the period	0	0	(14,144)	**(14,144)**	59	(14,085)
Issue of share capital	6,990	30,390	0	**37,380**	0	37,380
Transaction costs for equity issue	0	(2,788)	0	**(2,788)**	0	(2,788)
Conversion of Convertible Bonds	3,253	13,397	0	**16,650**	0	16,650
Share-based payment	0	0	486	**486**	0	486
Movement non-controlling interests	0	0	59	**59**	(59)	0
Other	0	0	(13)	**(13)**	0	(13)
Balance at 31 December 2015	**20,708**	**42,670**	**(35,232)**	**28,147**	**0**	**28,146**
Total comprehensive income of the period	0	0	(12,989)	**(12,989)**	(32)	(13,021)
Issue of share capital	0	0	0	**0**	0	0
Transaction costs for equity issue	0	0	0	**0**	0	0
Conversion of Convertible Bonds	0	0	0	**0**	0	0
Share-based payment	0	0	123	**123**	0	123
Movement non-controlling interests	0	0	(32)	**(32)**	32	0
Other	0	0	23	**23**	0	23
Balance at 31 December 2016	**20,708**	**42,670**	**(48,108)**	**15,270**	**0**	**15,270**