Bone Therapeutics Reports Full Year 2017 Results

- **Strong clinical progress in ALLOB® spinal fusion and delayed union trials**
- **Leadership team strengthened with appointments of Jean Stéphenne as Chairman of the Board (post period) and Jean-Luc Vandebroek as CFO**
- **Exclusive licensing agreement signed with Asahi Kasei for development and commercialization of PREOB® in Japan**
- **€ 19.45 million of commitment secured following private placement of convertible bonds (post period)**

Thomas Lienard, CEO, and Jean-Luc Vandebroek, CFO, will host a conference call today at 13:00 CET / 12:00 BST. 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: 9566757

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: 9566757#

Gosselies, Belgium, 25 April 2018, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in orthopaedics and bone diseases, today reports its full year results for the year ending 31 December 2017, prepared in accordance with IFRS as adopted by the European Union.

Thomas Lienard, CEO of Bone Therapeutics, commented: *"2017 was a year of important advances for Bone Therapeutics towards our goal of creating efficacious and commercially scalable bone cell therapy products to address large underserved markets. We have made significant progress in the development of our pipeline products with delivery of important clinical data for our allogeneic cell therapy product, ALLOB®, including strong interim efficacy and safety results for the Phase IIA lumbar spinal fusion study and early conclusion of the Phase I/IIA study for delayed-union fractures following positive interim efficacy data."*

"In line with our growth strategy, we have also strengthened our Board and management team with the appointment of Jean Stéphenne as Chairman and Jean-Luc Vandebroek as Chief Financial Officer. We have also made good progress in establishing our manufacturing infrastructure as we continue to mature and develop towards becoming a commercial stage company. In addition, we recently strengthened our balance sheet to enable continued execution of our strategy."

"With our strengthened balance sheet and our strong team, we look forward to further advancing our pipeline and driving our unique value proposition forward in the field of bone cell therapy."

Key Highlights:

- In 2017, we continued to make strong progress in the clinical development of ALLOB®, our flagship allogeneic bone cell therapy technology:
  - Completion of recruitment of the first 16 patients in the ALLOB® Phase I/IIA delayed-union study. Strong interim efficacy and safety results from this first cohort led to an early conclusion of the study as recommended by the DSMB. The Company plans to report final results of the study in mid-2018.
  - Positive efficacy and safety results reported for the first 15 patients in the Phase IIA lumbar spinal fusion trial. Post period, the Company completed patient recruitment of the full set of 32 patients for the Phase IIA lumbar spinal fusion study with efficacy and safety data expected in mid-2019.
  - European Patent Office notified the Company of its intention to grant a key patent for allogeneic bone cell therapy platform.
- Completion of the recruitment of the 44 treated patients required for the planned interim analysis of the Phase III trial for the treatment of osteonecrosis of the hip with the autologous bone cell therapy product, PREOB®. Conclusions from the interim analysis are expected in H2 2018.
- Exclusive license agreement signed with Asahi Kasei for the development and commercialisation of PREOB® in Japan.

Financial and Corporate Highlights (including post-period):

- The Company ended 2017 with € 8.4 million in cash and cash equivalents. Careful management of resources resulted in a cash utilization of € 11.9 million for the full year 2017 (below Company guidance), compared to € 13.3 million for the full year 2016.
- Operating income was € 4.2 million for the full year 2017, compared to € 4.0 million in full year 2016.
- Operating loss for the period amounted to € 12.3 million, compared to € 12.8 million in full year 2016
- Following a successful private placement of convertible bonds in March 2018, the Company secured a total of € 19.45 million in committed funds
- Appointment of Jean Stéphenne as the new Chairman of the Board of Directors (post period) and Damian Marron and Dirk Dembski as Non-Executive Directors.
- Appointment of Jean-Luc Vandebroek as Chief Financial Officer, supporting the Company's progress towards commercialisation.

Key Financials (IFRS)

(€ million)	FY 2017	FY 2016
Operating income	4.21	4.01
Operating expenses	(16.51)	(16.81)
R&D	(13.12)	(13.65)
G&A	(3.39)	(3.16)
Operating result	(12.29)	(12.80)
Net financial result	(0.48)	(0.28)
Net result	(12.77)	(13.02)
Net cash flow	(11.89)	(13.31)
Operating activities	(11.02)	(11.37)
Investing activities	(0.42)	(0.58)
Financing activities	(0.46)	(1.36)
Cash position at 31 December	8.41	20.30

Operational highlights (including post-period)

ALLOB®

In March 2017, Bone Therapeutics completed recruitment of the first 16 patients into the Phase I/IIA delayed-union study, a six-month, open-label clinical study designed to evaluate the safety and efficacy of ALLOB® in delayed-union fractures of long bones. Subsequently, at the six-month follow-up period in September 2017, the Company announced positive interim efficacy data. The six-month data showed that all patients treated met the primary endpoint and ALLOB® was well tolerated. Radiological evaluation of fracture healing showed an improvement of, on average, 4 points on the TUS (Tomographic Union Score) scale, twice the required minimum of 2 points. The health status of patients, as measured by the Global Disease Evaluation (GDE) score, improved by, on average, 48%, compared to the predetermined minimum of 25%. Based on the strong interim efficacy results, the Data and Safety Monitoring Board (DSMB) recommended concluding the trial early. The Company plans to report final results of the study in mid-2018.

Also in September 2017, Bone Therapeutics reported promising interim efficacy and safety results for the Phase IIA lumbar spinal fusion study. In addition to evidence of successful fusion shown by radiological data collected over a 12-month follow-up period (absence of motion in all patients and continuous bone bridges in 9 out of 15 patients), the interim results revealed substantial clinical improvement in function (55% improvement on the Oswestry Disability Index) and a strong reduction in back and leg pain (59% and 90% respectively). Treatment with ALLOB® was well tolerated in all patients.

In February 2018, the Company announced the completion of patient recruitment into the Phase IIA lumbar spinal fusion study and, following a follow-up period of 12 months, efficacy and safety data for the full set of 32 patients are expected in mid-2019.

Bone Therapeutics was notified by the European Patent Office (EPO) in June 2017 of its intention to grant a key patent covering Company's first-in-class allogeneic cell therapy technology. The patent will expand IP protection for both the manufacturing methods and the distinct cell type used in its allogeneic cell therapy technology into selected EU member states until 2029.

PREOB®

In June 2017, the Company announced completion of recruitment of the 44 treated patients required for the planned interim analysis of the Phase III trial for the treatment of osteonecrosis of the hip with its autologous bone cell therapy product, PREOB®. Conclusions of the interim analysis after a 12-month follow-up are expected in H2 2018.

In September, the Company signed an exclusive, royalty-bearing license agreement with one of Japan's leading industrial companies, Asahi Kasei Corporation. The license agreement covers the development and commercialisation of PREOB®, in Japan. Bone Therapeutics received an upfront payment of €1.7 million from Asahi Kasei and is eligible to receive up to €7.5 million from development and commercial milestone payments, as well as tiered royalties based on annual net sales of PREOB® in Japan.

Corporate highlights (including post-period)

In September 2017, the Company appointed Jean-Luc Vandebroek as Chief Financial Officer. With his extensive international finance experience from major public and privately-owned companies, Jean-Luc will oversee the Company's financial planning needs as it continues to mature and bring its innovative cell therapy products closer to the market.

In February 2018, Jean Stéphenne was appointed Chairman of the Board of Directors. Jean Stéphenne is a highly-experienced life sciences executive, who has served in senior leadership roles at a large number of biotechnology and pharmaceutical companies, most recently as Chairman of TiGenix. Together with the Board of TiGenix, he oversaw the clinical development and European marketing authorisation of its most advanced allogeneic cell therapy product for the treatment of complex perianal fistulas in Crohn's disease, resulting in the announced acquisition of the company for EUR 520 million by Takeda. Before joining TiGenix, Jean Stéphenne was a Member of the Corporate Executive Team of GlaxoSmithKline (GSK) and Chief Executive of GSK Biologicals (now GSK Vaccines). During his 40-year tenure at GSK Vaccines, he grew a company of 50 people into a fully integrated worldwide leader in vaccine development, with 12,000 employees.

The Company also welcomed Damian Marron and Dirk Dembski to its Board of Directors, further expanding its leadership experience in the fields of orthopaedics and cell therapy. Damian Marron is an experienced life sciences executive, having served as Chief Executive Officer at the biotech companies, Agalimmune and TxCell, specialists in immune-oncology and immune-cell therapy respectively. Dirk Dembski has held a variety of roles in biotechnology and orthopaedics companies.

In March 2018, the Company successfully secured € 19.45 million of commitment via a private placement of convertible bonds, subscribed by international and local investors. Each subscribed convertible bond is accompanied by 19 bond warrants, exercisable to a convertible bond each. Several investors decided to immediately exercise warrants resulting in immediate gross proceeds of approximately € 6.58 million. The remaining warrants will be exercised providing additional proceeds of € 12.87 million over a maximum period of 19 months.

Outlook for 2018

Bone Therapeutics plans to report the final results from the ALLOB® Phase I/IIA delayed-union study in mid-2018.

A value inflection point is anticipated in the second half of 2018, as the Company expects to present the conclusions of the interim analysis after a one-year follow-up period of the first 44 patients in the Phase III study of PREOB® in osteonecrosis of the hip.

Additionally, the Company has started making preparations for a multicentre, controlled Phase IIB study for the treatment of difficult fractures with ALLOB®.

Cash burn for the full year of 2018 is expected to be in the range of € 15-16 million. Based on its current priorities, the Company will have sufficient cash to carry out its objectives until end Q3 2019.

Financial review

Income statement

In 2017, the Company received a non-refundable upfront payment from Asahi Kasei Corporation for € 1.67 million. The Company recognized this upfront payment over a period of 10 years and only € 0.04 million in 2017. The total (other) operating income amounted to € 4.18 million compared to € 4.00 million in 2016. Other operating income is mainly as a result of grants from the Walloon Region ("Recoverable Cash Advances - RCAs") which in total amounted to € 2.46 million in 2017. In addition, the Company benefited from the special regime employing scientific staff through the recovery of company withholding tax for an amount of € 0.73 million, an investment tax credit for an amount of € 0.74 million and € 0.24 million in patent and other subsidies.

R&D expenses in 2017 were at € 13.12 million compared to € 13.65 million in 2016. The decrease has been the result of lower R&D costs in ongoing trials and an increase in efficiency of the Company's clinical operations.

General and administrative expenses for the full year 2017 amounted to € 3.39 million compared to € 3.16 million over the same period last year. The slight increase is mainly explained by the development of our activities.

The operating loss in 2017 was at € 12.29 million. In 2016, the Company reported an operating loss of € 12.80 million. The Company had net financial expenses of € 0.29 million in 2017 in line with last year.

The reported net loss in 2017 amounted to € 12.77 million or € 1.86 loss per share (on an undiluted basis). In 2016, the Company had a net loss of € 13.02 million, equivalent to a loss per share of € 1.90 (on an undiluted basis).

Balance sheet

Total assets at the end of December 2017 amounted to € 25.17 million compared to € 38.59 million at the end of December 2016, mainly impacted by the current assets.

The current assets decreased from € 28.47 million to € 14.62 million at the end of December 2017. The decrease is mainly related to the variation of the cash position which amounted to € 8.41 million compared to € 20.30 million in 2016.

The trade and other receivables showed a decrease of € 2.08 million compared to last year as a result of:

- New RCAs recognized during 2017 for an amount of € 1.18 million (increase)
- Amounts received during the course of 2017 for RCAs in progress (upfront amounts and amounts received following expense declarations in function of the progress of the works) for a total of € 3.42 million (decrease)
- The remaining increase of € 0.15 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 increased from € 10.11 million to € 10.56 million at the end of December 2017. The increase is mostly related to deferred tax assets. Deferred tax assets totaling € 3.61 million represent a tax credit on investment in R&D reimbursable in the foreseeable future (spread over the next seven years), partly offset by the decrease of the property, plant and equipment. The Company invested an amount of € 0.40 million for the new production facility at Gosselies and for the laboratory and production equipment related to the new production facility. The Company recorded an amount of € 0.60 million as net depreciation.

Equity amounted to € 2.38 million at the end of December 2017 compared to € 15.27 million at the end of December 2016.

- The share capital decreased due to the incorporation of the loss carried forward and amounted to € 14.66 million at the end of 2017
- The retained earnings were impacted by the loss for the period of € 12.77 million.
- Other reserves decreased by € 0.11 million related to share-based payments.

The non-controlling interest in the Company's affiliate SCTS has been set at "0" and has been represented as a liability on the balance sheet for an amount of € 1.64 million on 31 December 2017. This represents the value of the put option that the parties representing the non-controlling have and which allows them to sell their interest to the Company.

Liabilities amounted to € 22.79 million at the end of December 2017 compared to € 23.32 million at the end of December 2016 with the main decrease coming from both the non-current and current liabilities.

The non-current liabilities decreased from € 12.80 million at the end of 2016 to € 12.19 million on 31 December 2017. They are composed as follows:

- Long term investment credit facilities to finance the infrastructure project for an amount of € 2.38 million (€ 2.63 million at the end of 2016),
- Reimbursable part of the RCAs from the Walloon Region as recognized at the start of the contract for an amount € 6.58 million (€ 6.58 million in 2016),
- Loans from related parties (regional investment offices) for an amount of € 1.51 million (€ 1.77 million in 2016),
- Other non-current liabilities for an amount of € 1.64 million represent the put option explained above (€ 1.64 million in 2016),
- Other items accounting for € 0.08 million.

Current liabilities amounted to € 10.60 million at 31 December 2017 compared to € 10.51 million at the end of December 2016. The financial liabilities remained stable compared to last year and amounted to € 1.25 million.

Trade and other payables amounted to € 3.56 million which represented an increase with € 0.46 million compared to the end of December 2016. The increase is mainly related to regular activities.

Other current liabilities amounted to € 5.76 million at the end of December 2017 compared to € 6.15 million at the end of December 2016, showing a net decrease of € 0.39 million due to the recognition of deferred income related to existing contracts for an amount of € 2.02 million into the comprehensive income. In addition, the Company also recognized an amount of € 1.63 million in relation to the upfront payment received from Asahi Kasei.

Cash flow statement

Cash used for operating activities amounted to € 11.02 million for the full year 2017 compared to € 11.37 million for the full year 2016.

Total operating loss for the period amounted to a loss of € 12.29 million compared to a loss of € 12.80 million over the same period in 2016. The decrease of the net loss in 2017 is mainly explained by the decrease of the R&D expenses over the year.

Adjustments for non-cash items amounted to € 2.96 million compared to € 2.57 million during the previous year relating to depreciation, share based payments and recognition of grant income from RCA's, patent subsidies and tax credit. Actual cash received in 2017 for the grant related items amounted to € 2.60 million compared to € 2.75 million in 2016. The Company also received € 1.67 million of upfront payment in relation of the licensing agreement with Asahi Kasei.

Working capital was positively impacted for the full year 2017 for an amount of € 0.15 million mainly following an increase of trade and other payables for an amount of € 0.46 million and a reduction of trade and receivables of € 0.31 million. Last year, the working capital was positively impacted by the disbursement of the outstanding amount for the investment grant of € 1.31 million.

Cash flow from investing activities showed a net use of € 0.42 million for the full year 2017 compared to € 0.58 million in 2016. This mainly represents investments made in property, plant and equipment related to the finalization of the construction of the facilities at the BioPark in Gosselies.

Cash flow from financing activities amounted to net cash used of € 0.46 million for 2017. In 2017 the amounts reimbursed for existing loans was lower compared to 2016. In particular, a short-term credit facility for an amount of € 1.40 million which served to fund the investments of the new facilities at Gosselies was reimbursed in 2016.

About Bone Therapeutics

Bone Therapeutics is a leading cell therapy company addressing high unmet needs in orthopaedics 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.

Bone Therapeutics' 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.

The Company's 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 of the hip.

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

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Consolidated statement of comprehensive income

(in thousands of euros)	**2017**	**2016**
Revenue	41	0
Other operating income	4,172	4,007
Total operating income	**4,213**	**4,007**
Research and development expenses	(13,122)	(13,649)
General and administrative expenses	(3,385)	(3,157)
Operating profit/(loss)	**(12,294)**	**(12,799)**
Interest income	197	173
Financial expenses	(489)	(448)
Exchange gains/(losses)	*(12)*	(15)
Share of profit/(loss) of associates	*7*	(9)
Result Profit/(loss) before taxes	**(12,591)**	**(13,081)**
Income taxes	(178)	60
PROFIT/(LOSS) FOR THE PERIOD	**(12,769)**	**(13,021)**
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	**(12,769)**	**(13,021)**
Basic and diluted loss per share (in euros)	**(1.86)**	**(1.90)**
Profit/(loss) for the period attributable to the owners of the Company	(12,752)	(12,989)
Profit/(loss) for the period attributable to the non-controlling interests	(18)	(32)
Total comprehensive income for the period attributable to the owners of the Company	(12,752)	(12,989)
Total comprehensive income for the period attributable to the non-controlling interests	(18)	(32)

Consolidated Balance Sheet

ASSETS *(in thousands of euros)*	**31/12/2017**	**31/12/2016**
Non-current assets	**10,558**	**10,114**
Intangible assets	30	56
Property, plant and equipment	6,302	6,385
Investments in associates	297	291
Financial assets	317	299
Deferred tax assets	3,611	3,083
Current assets	**14,615**	**28,471**
Trade and other receivables	5,938	8,013
Other current assets	266	158
Cash and cash equivalents	8,411	20,300
TOTAL ASSETS	**25,173**	**38,585**

EQUITY AND LIABILITIES *(in thousands of euros)*	**31/12/2017**	**31/12/2016**
Equity		
Equity attributable to owners of the parent	**2,383**	**15,270**
Share capital	14,663	20,708
Share premium	42,665	42,670
Retained earnings	(55,501)	(48,773)
Other reserves	557	665
Non-controlling interests	0	0
Total equity	**2,383**	**15,270**
Non-current liabilities	**12,192**	**12,802**
Financial liabilities	10,551	11,167
Other non-current liabilities	1,641	1,635
Current liabilities	**10,598**	**10,512**
Financial liabilities	1,251	1,242
Trade and other payables	3,583	3,120
Current tax liabilities	0	0
Other current liabilities	5,764	6,150
Total liabilities	**22,791**	**23,315**
TOTAL EQUITY AND LIABILITIES	**25,173**	**38,585**

Consolidated Cash Flow Statement

Consolidated Statements of Cash Flows *(in thousands of euros)*	**2017**	**2016**
CASH FLOW FROM OPERATING ACTIVITIES		
Operating profit/(loss)	(12,294)	(12,799)
Adjustments for:		
Depreciation, Amortisation and Impairments	524	537
Share-based compensation	(89)	123
Grants income related to recoverable cash advances	(2,459)	(2,454)
Grants income related to patents	(201)	(56)
Grants income related to tax credit	(754)	(750)
Other	16	35
Movements in working capital:		
Trade and other receivables (excluding government grants)	(309)	1,586
Trade and Other Payables	463	338
Other current liabilities (excluding government grants)	(3)	(4)
Cash generated from operations	**(15,105)**	**(13,445)**
Cash received from licensing agreement	1,670	0
Cash received from grants related to recoverable cash advances	2,390	1,976
Cash received from grants related to patents	88	62
Cash received from grants related to tax credit	117	37
Income taxed paid	(178)	0
Net cash used in operating activities	**(11,018)**	**(11,369)**
CASH FLOW FROM INVESTING ACTIVITIES		
Interests received	0	28
Purchases of property, plant and equipment	(406)	(579)
Purchases of intangible assets	(9)	(26)
Net cash used in investing activities	**(415)**	**(578)**
CASH FLOW FROM FINANCING ACTIVITIES		
Proceeds from government loans	1,024	847
Repayment of government loans	(510)	(402)
Dividends paid	(60)	0
Proceeds from loans from related parties	0	300
Reimbursements of financial lease liabilities	(434)	(426)
Reimbursements of other financial loans	(250)	(1,396)
Interests paid	(227)	(286)
Net cash provided by financing activities	**(456)**	**(1,363)**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(11,889)**	**(13,310)**
CASH AND CASH EQUIVALENTS at beginning of year	**20,300**	**33,611**
CASH AND CASH EQUIVALENTS at end of year	**8,411**	**20,300**

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 2016	***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*
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***
Total comprehensive income of the period	*0*	*0*	*(12,752)*	***(12,752)***	*(18)*	*(12,769)*
Issue of share capital	*0*	*0*	*0*	***0***	*0*	*0*
Decrease of share capital	*(6,046)*	*0*	*6,046*	***0***	*0*	*0*
Transaction costs for equity issue	*0*	*(5)*	*0*	***(5)***	*0*	*(5)*
Allocation to the legal reserve	*0*	*0*	*3*	***3***	*0*	*3*
Share-based payment	*0*	*0*	*(89)*	***(89)***	*0*	*(89)*
Movement non-controlling interests	*0*	*0*	*(18)*	***(18)***	*18*	*0*
Other	*0*	*0*	*(27)*	***(27)***	*0*	*(27)*
Balance at 31 December 2017	***14,663***	***42,665***	***(54,944)***	***2,382***	***0***	***2,382***