



Company presentation

Brussels

February, 2016



FORWARD-LOOKING STATEMENTS

This document and the accompanying oral presentation contain information on Bone Therapeutics SA' markets and competitive position, and more specifically, on the size of its markets. This information has been drawn from various sources or from Bone Therapeutics SA own estimates. Investors should not base their investment decision on this information. This document and the accompanying oral presentation also contain certain forward-looking statements. These statements are not guarantees of the Company's future performance. These forward-looking statements relate to the Company's future prospects, developments and marketing strategy and are based on analysis of estimates not yet determinable. Forward-looking statements are subject to a variety of risks and uncertainties as they relate to future events and are dependent on circumstances that may or may not materialize in the future.

Bone Therapeutics SA draws your attention to the fact that forward-looking statements cannot under any circumstance be construed as a guarantee of the Company's future performance and that the Company's actual financial position, results and cash flow, as well as the trends in the sector in which the Company operates may differ materially from those proposed or reflected in the forward-looking statements contained in this document and the accompanying oral presentation. Furthermore, even if Bone Therapeutics SA financial position, results, cash-flows and developments in the sector in which the Company operates were to conform to the forward-looking statements contained in this document and the accompanying oral presentation, such results or developments cannot be construed as a reliable indication of the Company's future results or developments. Certain figures and numbers appearing in this document and the accompanying oral presentation have been rounded. Consequently, the total amounts and percentages appearing in the tables are therefore not necessarily equal to the sum of the individually rounded figures, amounts or percentages.

AGENDA

- ▶ Welcome and introduction
- ▶ Operational highlights
- ▶ Corporate and financial highlights
- ▶ News flow
- ▶ Q&A



KEY HIGHLIGHTS OF 2015

Pipeline

Important advancements in the Phase II proof-of-concept trials

- ▶ ALLOB® Phase I/IIA delayed-union trial
 - **Positive efficacy** results in first patient cohort
 - Treated second patient cohort **without safety concerns**
 - Initiated new Phase IIA trial to extend delayed-union program to **multiple fractures**
- ▶ **Safety** results in ALLOB® Phase IIA spinal fusion trial
- ▶ Initiated **novel** Phase IIA trial for ALLOB® in **rescue spinal fusion**
- ▶ First **results** from PREOB® Phase IIA severe **osteoporosis** trial

Corporate

- ▶ Established a **US subsidiary** in Boston
- ▶ Opened **new headquarters** at the Gosselies Biopark
- ▶ Strengthened the Board of Directors and management team

Financial

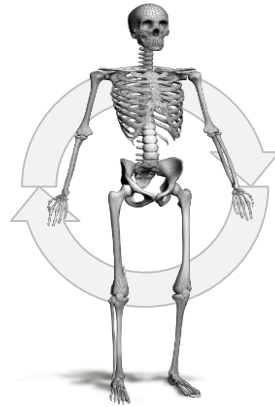
- ▶ Successful **€37M IPO** on Euronext Brussels and Euronext Paris
- ▶ Cash position at end of December 2015 of **€33.6M***
- ▶ Awarded **€5M** in funding from the Walloon Region in 2015

*Unaudited

A GAME CHANGER IN ORTHOPAEDICS

Rationale for bone cell therapy in orthopaedics and bone diseases

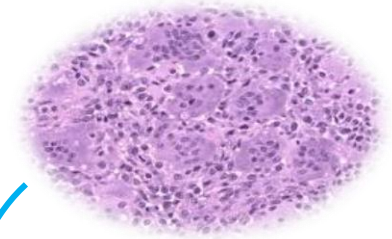
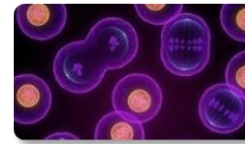
**Skeleton: a naturally
regenerative system**



**Limitations of standard
orthopaedic approaches**



Production of bone-forming cells



Minimally invasive administration

OUR TARGET MARKETS

FRACTURE REPAIR

Severe unhealed fractures



Non-union

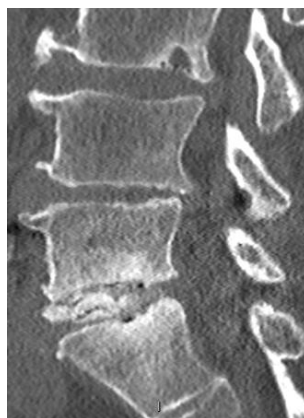
Delayed-union

Addressable Pop.
(~0.3M)

Addressable Pop.
(~1.0M)

SPINAL FUSION

Degenerative diseases of the spine



Spinal fusion

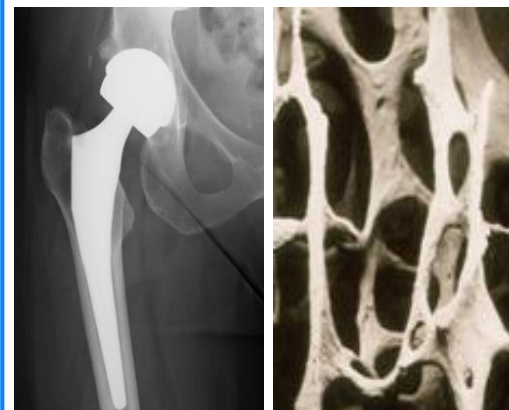
Revision spinal fusion

Addressable Pop.
(~0.5M*)

Addressable Pop.
(~0.12M*)

FRACTURE PREVENTION

Bone fragility conditions at increased fracture risk



Osteonecrosis

Severe osteoporosis







Addressable Pop.
(~0.2M)

Addressable Pop.
(~10M)

**Only lumbar spine fusion procedures*

PIPELINE

Two products: autologous (PREOB®) & allogeneic (ALLOB®) in six indications

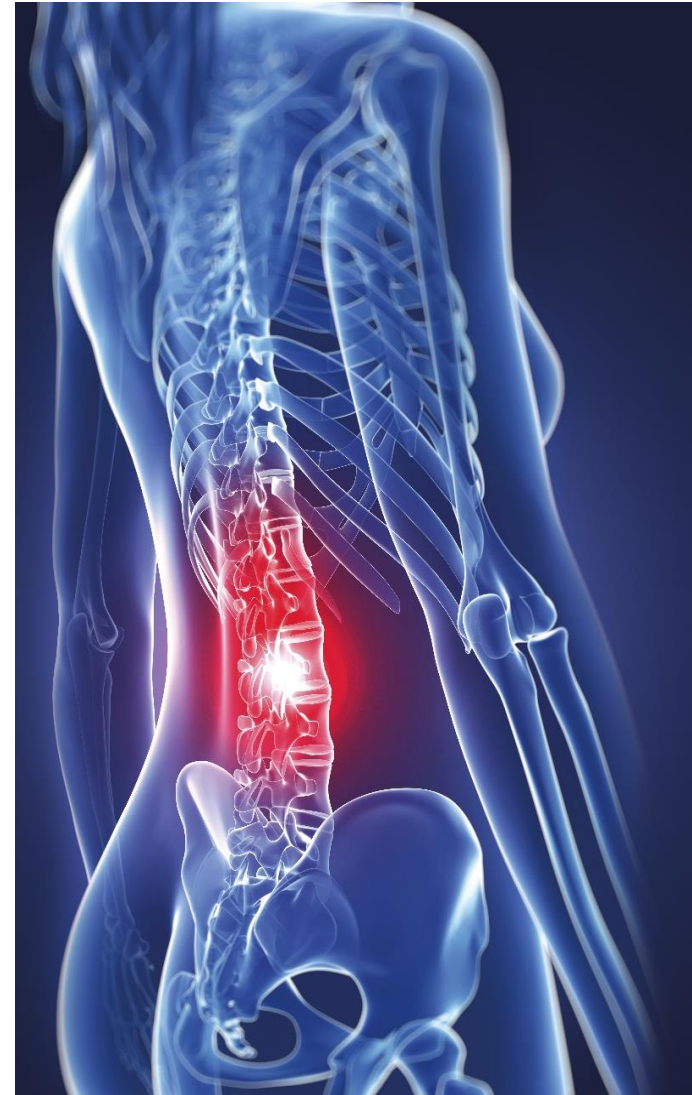
<i>Indication</i>	<i>Platform</i>	Preclinical	Phase I/IIA	Phase IIB/III
Non-Unions	PREOB®			
Delayed-Unions and Multiple Fractures	ALLOB®			
Spinal Fusion	ALLOB®			
Rescue Spinal Fusion	ALLOB®			
Osteonecrosis	PREOB®			
Osteoporosis	PREOB®			



2015 HIGHLIGHTS

NEW OPPORTUNITIES IN ORTHOPAEDICS – SPINAL FUSION

- ▶ Orthopaedics market characterized by:
 - Large & growing market (~4% p.a.)
 - Limited innovation & high unmet medical need
- ▶ Bone Therapeutics' innovative bone-forming cell therapies can potentially enhance current treatments
- ▶ Seizing the opportunity in spinal fusion (18% of orthopaedics market)
 - Characterized by strong growth (5-6% p.a.) and large unmet need
 - Current standard-of-care applied with limited success
 - Up to 25% of patients unsatisfied with their surgery
- ▶ Creating a market in spinal fusion
 - Now in Phase IIA trials with ALLOB®
 - No safety issues so far and first efficacy results due



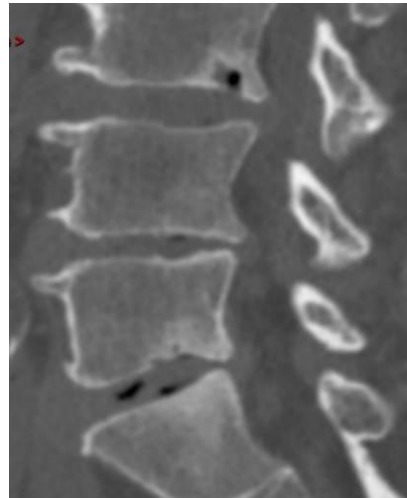
PHASE IIA ALLOB[®] SPINAL FUSION TRIAL

1,000,000 surgeries p.a. in EU & US, of which 500,000 at lumbar level

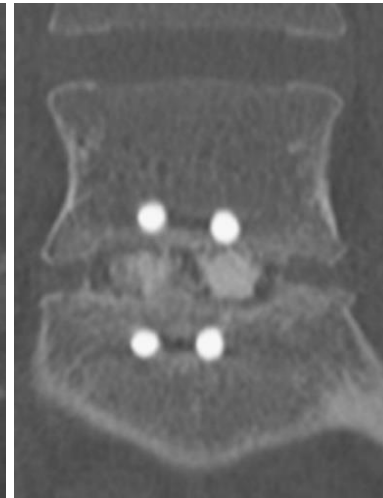
Slow progression to fusion and treatment failure (no fusion) in 5% to 35% of procedures

Declining sales of Infuse (BMP2) – FDA warning and safety concerns

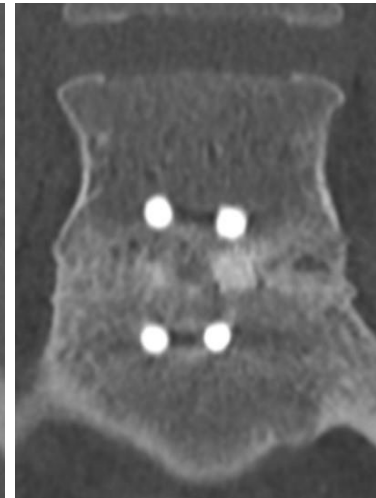
- ▶ Phase IIA proof-of-concept
- ▶ 16 patients with symptomatic lumbar degenerative disc disease, requiring a spinal fusion procedure
- ▶ Objectives: safety & efficacy (functional disability and fusion)
- ▶ Duration: 12 months follow-up



pre-op



1 year post-op



4 years post-op

PHASE IIA ALLOB[®] SPINAL FUSION TRIAL

Local administration of ALLOB[®]
intended to promote faster & better
bone formation in lumbar interbody
fusion



ALLOB[®]



Standard-of-Care

Interbody cages
Bioceramic granules



- ▶ Standard-of-care surgical approach combining cage and bioceramic granules/ALLOB[®] mix
- ▶ Single application (add-on to standard-of-care)
- ▶ 75% of patients treated
- ▶ **No safety issues** reported

Next steps

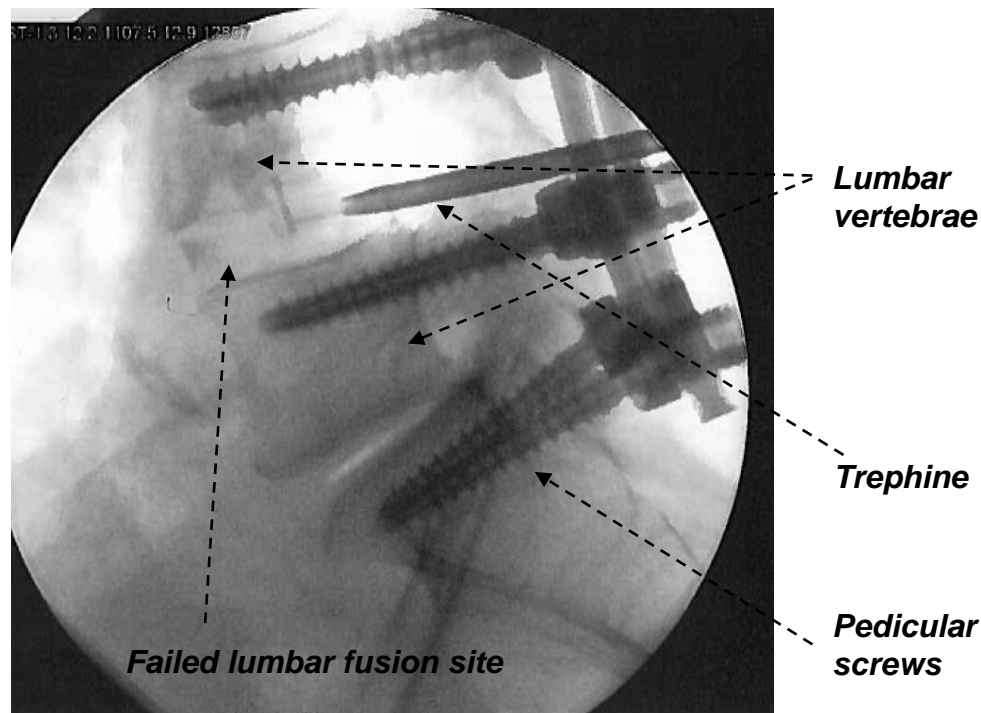
Efficacy results of first 4 patients and completion of recruitment

PHASE IIA ALLOB[®] RESCUE SPINAL FUSION TRIAL

Up to 25% failure after initial spinal fusion surgery with non-union and persistent pain

Standard-of-care revision surgery: open, additional difficulties and associated with complications

- ▶ Phase IIA, open, multicentre, proof-of-concept
- ▶ Single minimally invasive (percutaneous) implantation into the failed fusion site
- ▶ 16 patients with a failed lumbar spinal fusion (15 months after the initial fusion procedure)
- ▶ 12-month study follow-up
- ▶ Study endpoints: clinical symptoms (pain & disability) and radiological healing



Next step

Interim safety results of first 4 patients

PHASE I/IIA ALLOB[®] DELAYED-UNION TRIAL

- ▶ Open – continuous follow-up of safety and efficacy
- ▶ Single percutaneous implantation of ALLOB[®] into delayed-union site
- ▶ Positive results from first cohort - **All 4 patients met primary endpoints** within 6 months
- ▶ Second cohort of patients treated **without safety issues**

Before treatment



+ 3 months



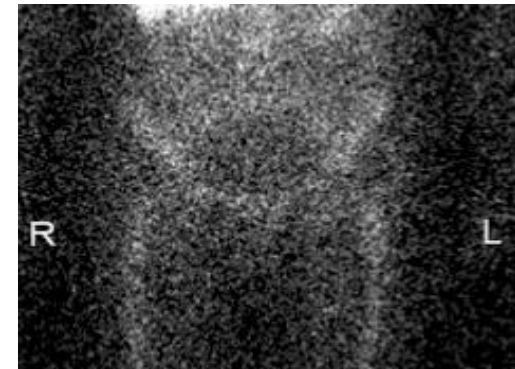
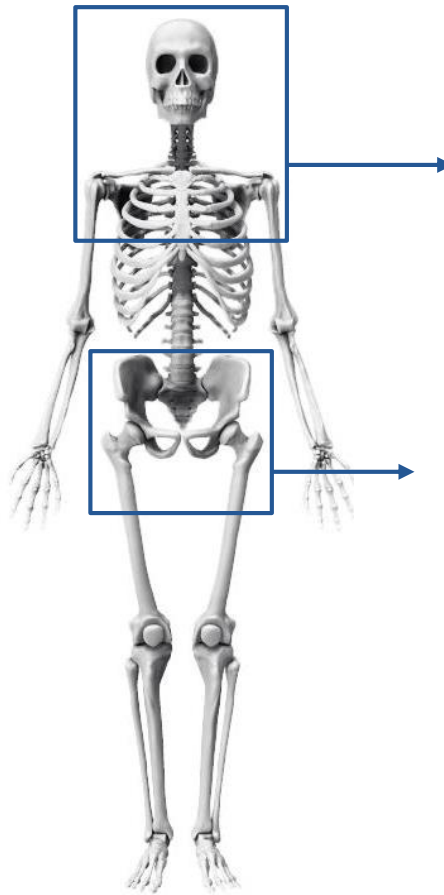
+ 6 months



Next steps Interim efficacy results of first 8 patients & safety results of first 12 patients

PHASE IIA PREOB[®] OSTEOPOROSIS TRIAL

- ▶ Phase IIA proof-of-concept
- ▶ Patients suffering from severe osteoporosis not responding to anti-osteoporotic treatment (i.e., losing bone mass)
- ▶ Objectives: to determine (i) the body distribution of PREOB[®] after intravenous infusion and (ii) the effect on bone markers
- ▶ 20 patients; 12-month follow-up
- ▶ 8 patients included
- ▶ No treatment-related **safety concerns** reported



48h

Next step

Efficacy results of first patient cohort (8 patients)

CORPORATE HIGHLIGHTS 2015

► Established a **US subsidiary**

- Bone Therapeutics USA Inc., in Boston, Massachusetts
- First step in the development of its US clinical trials program
- Approval US clinical trials by the end of 2016

► Opened **new headquarters** at the Gosselies Biopark

- Administrative and R&D departments have now moved to the new facilities
- Production activities to be transferred start of 2017 after obtaining GMP accreditation
- State-of-the art production facility will secure first commercial cell therapy production capacity and ensure continued growth of the Company



► Strengthened **management** team

- Thomas Lienard appointed as Chief Business Officer

FINANCIAL HIGHLIGHTS 2015

- ▶ Cash position on 31 December, 2015 of **€33.6 million**
 - Well in line with company expectations
- ▶ **€5 million** funding granted by the Walloon Region in 2015
 - Equals 13.5% of IPO proceeds
- ▶ Full Annual Results 2015 on **14 April 2016**

NEWS FLOW 2016

UPCOMING CLINICAL NEWS

Indication	Phase	Platform	Actions	2015				Q1	2016				2017			
				Q1	Q2	Q3	Q4		Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Non-Union	IIB/III	PREOB®	Study status for Interim/DSMB													
			Launch of US clinical trial	✓												
Delayed-Union	I/IIA	ALLOB®	Efficacy 4 patients			✓										
			Safety 8 patients													
			Efficacy 8 patients													
			Safety 12 patients													
			Efficacy 12 patients													
			Safety 4 patients													
Spinal Fusion	IIA	ALLOB®	Safety 8 patients													
			Safety 12 patients													
			Efficacy 4 patients													
			Efficacy 8 patients													
Revision Spinal Fusion	IIA	ALLOB®	Initiation of study			✓										
			Safety 4 patients													
			Safety 8 patients													
			Efficacy 4 patients													
Osteonecrosis	III	PREOB®	Site update													
			Study status for Interim/DSMB													
			Launch of US clinical trial													
			Safety 8 patients			✓										
Osteoporosis	IIA	PREOB®	Efficacy 8 patients													
			Safety 16 patients													

Q&A

Enrico BASTIANELLI, MD, MBA
Chief Executive Officer

Wim GOEMAERE, MAE
Chief Financial Officer

Phone: +32 (0)2 529 59 90

Fax: +32 (0)2 529 59 93

E-mail address: info@bonetherapeutics.com

Postal address: Rue Auguste Piccard 37, 6041 Gosselies

Website: www.bonetherapeutics.com



Wallonie

