Half-year results 2016

30 August 2016

Bone Therapeutics

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
- Key highlights and financials of H1 2016
- Outlook for the remainder of 2016
- Q&A

ON THE CALL TODAY ARE:

Enrico Bastianelli, CEO

Wim Goemaere, CFO

KEY HIGHLIGHTS

Pipeline

- Significant progress across pipeline**:**
  - ALLOB® Phase IIA in **spinal fusion**: positive 12-month efficacy results of first patient; completion of recruitment; extension of the trial
  - ALLOB® Phase I/IIA in **delayed-union fractures**: 7 out of 8 patients achieved primary endpoints; extension of trial to multiple fractures
  - PREOB® Phase IIA in **severe osteoporosis**: positive efficacy results first patient cohort; transition of osteoporosis program to allogeneic development
  - PREOB® Phase IIB in **osteonecrosis**: data presented at the EULAR conference demonstrate superiority of a single administration over standard of care

Corporate & Financial

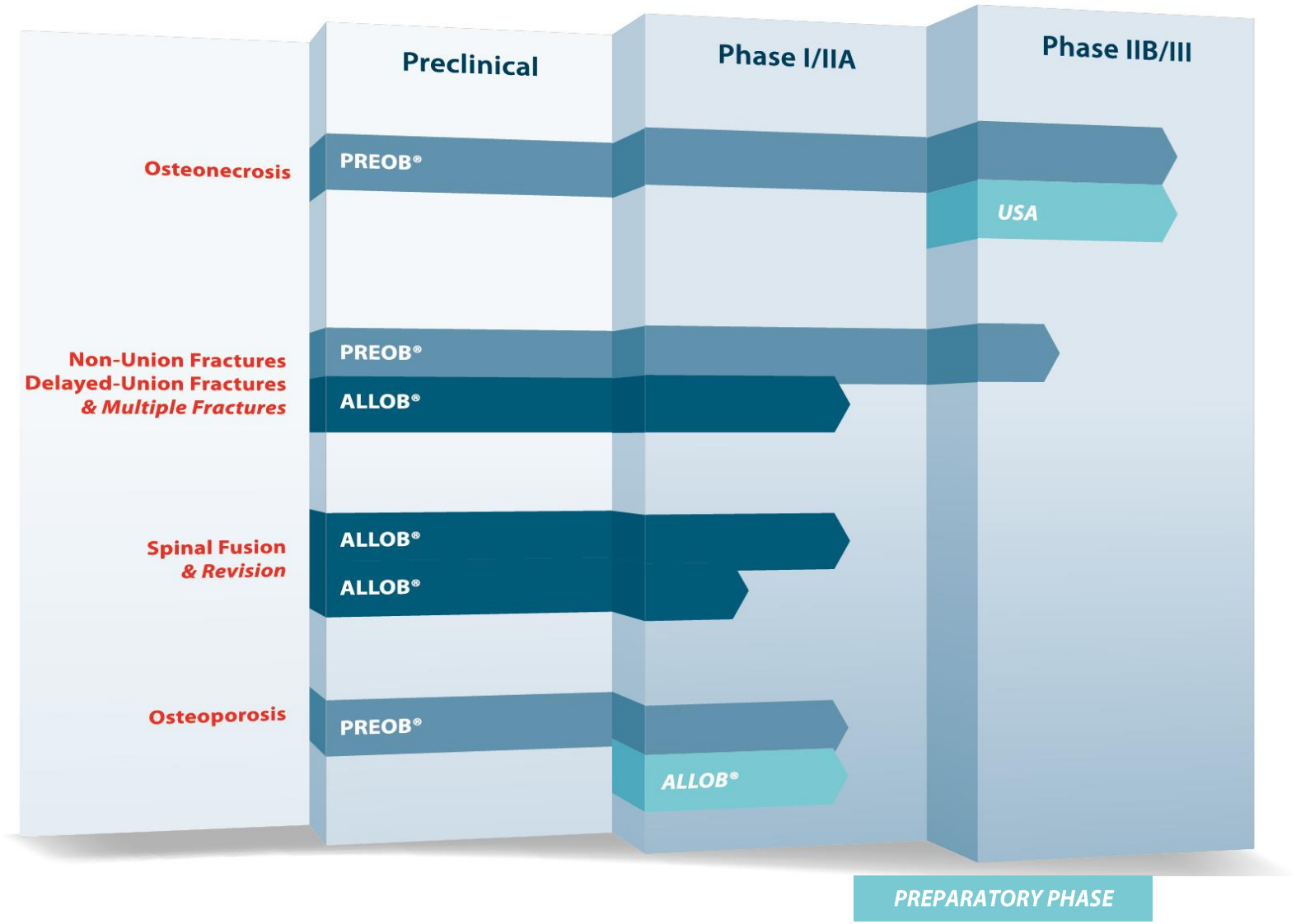
- Further strengthening of **management team** with appointment of Benoît Champluvier as Chief Technology & Manufacturing Officer as the company prepares for larger scale manufacturing
- Cash position at 30 June 2016 of **€26.6M**

FINANCIAL HIGHLIGHTS

Million €	H1 2016	H1 2015
Operating income	**1.95**	**1.98**
Operating expenses	**(7.69)**	**(7.34)**
R&D expenses	(6.01)	(5.27)
G&A expenses	(1.68)	(2.07)
Operating result	**(5.74)**	**(5.36)**
Net financial result	**(0.13)**	**(1.76)**
Net result	**(5.87)**	**(7.12)**
Net cash flow	**(7.01)**	**25.65**
Operating activities	(6.53)	(8.11)
Investing activities	(0.86)	(0.98)
Financing activities	0.38	34.74
Cash position	**26.60**	**37.22**

OVERVIEW CLINICAL HIGHLIGHTS H1 2016

BROAD AND DIVERSIFIED PIPELINE



OSTEONECROSIS – FINAL PHASE IIB RESULTS

Reference-controlled Phase IIB trial with PREOB® in early-stage osteonecrosis of the femoral head

Method: Core decompression and PREOB®/reference implantation

Reference: bone marrow concentrate (BMC)

Number of patients: 63 hips were treated, of which 60 were assessable* and included in the analyses (PREOB® n=30, BMC n=30)

Follow-up: 12, 24 & 36 months

Primary endpoints: proportion of responders at 24 months, defined as

- Absence of progression to fractural stage
- Clinically significant (>10mm) pain improvement

Responders

N=30 per group	PREOB® group	BMC group
24 months	70.0% (21/30)	36.7% (11/30)
36 months	60.0% (18/30)	33.3% (10/30)

At 24 months, responder rate to treatment was 70% in the PREOB® group vs. 37% in the BMC group (p=0.011; Fisher's exact test)

Progression to fracture

N=30 per group	PREOB® group	BMC group
24 months	20.0% (6/30)	40.0% (12/30)
36 months	20.0% (6/30)	50.0% (15/30)

*At 24 months, the proportion of hips that progressed to fracture in the PREOB® and BMC groups was respectively 20% and 40%, corresponding to a **50% reduction in fracture risk***

** 3 hips were not included in the analysis as, upon treatment, it was discovered that these hips had already evolved to stage III osteonecrosis*

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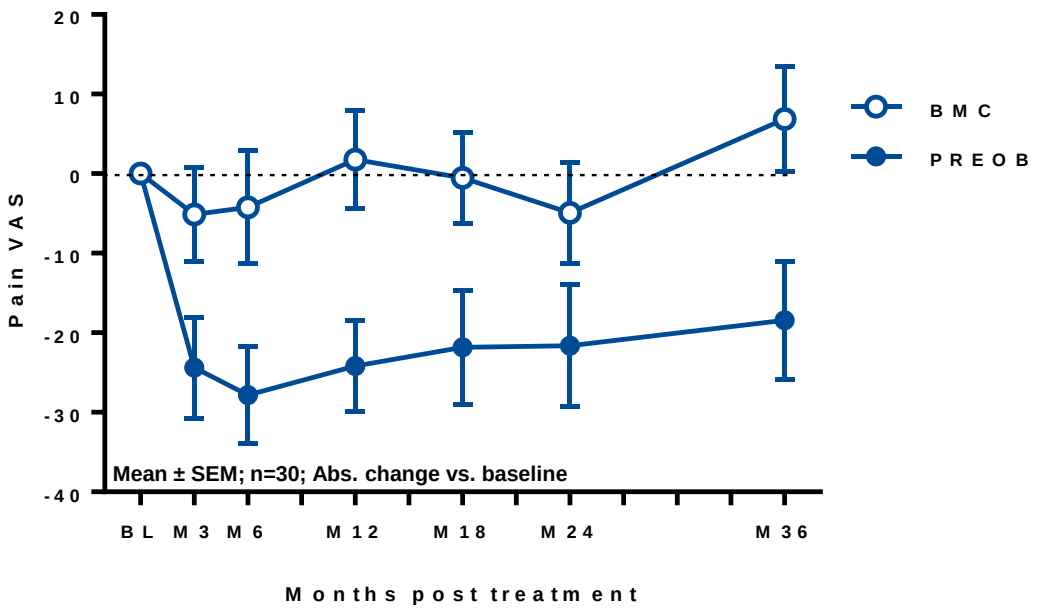
OSTEONECROSIS – FINAL PHASE IIB RESULTS



Patients treated with PREOB® had a **clinically (>10mm)** and **statistically significant improvement in joint pain** (VAS) and symptoms (WOMAC®) at all timepoints

	PREOB® group (n=33)	BMC group (n=30)	All (n=63)
AE	340	238	578
TEAE	327	226	553
SAE	71	57	128

Overall, 553 treatment emergent AE (TEAE) were reported, of which **2.7% (15 TEAE) were possibly related to the procedure or the cell therapy products**. The AEs reported as possibly related to study treatment were in accordance with the possible risks linked to study procedures (e.g., bone marrow aspiration) as described in the literature.

DELAYED-UNION – PROOF-OF-CONCEPT TRIAL

First-in-man, proof-of-concept Phase I/IIA open study

Method: Single ALLOB® administration in delayed-union fractures of long bones (femur, tibia, fibula, humerus, ulna, radius)

Number of patients: 32 patients (can be prematurely stopped at 16 patients based on efficacy)

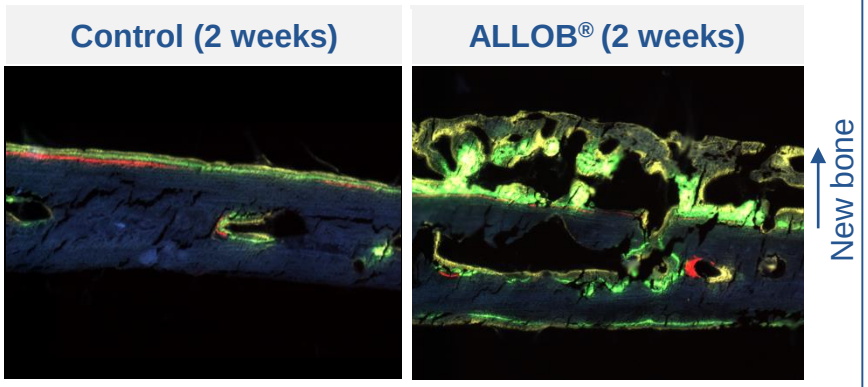
Follow-up: 6 months

Countries: Belgium, Germany & United Kingdom

Extension to multiple delayed-union fractures

Preclinical proof-of-concept

ALLOB® cells induce significant bone formation: subcutaneous injection over the skull of nude mice of ALLOB® cells *vs.* excipient (control)



DELAYED-UNION - SUCCESS IN 7 (OUT OF 8) PATIENTS

Phase I/IIA delayed-union trial

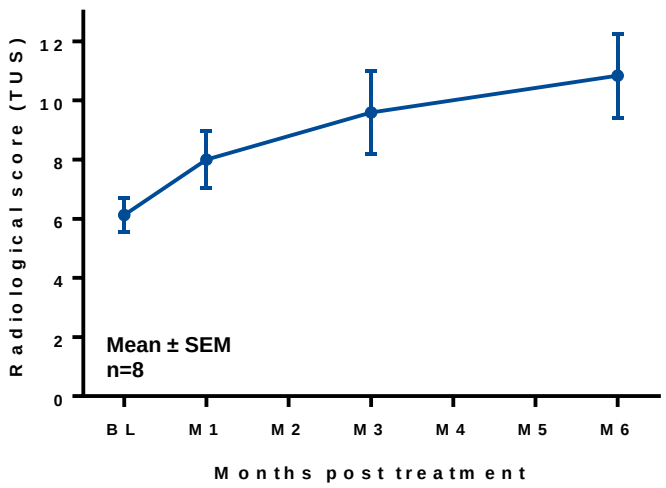
Primary endpoints:

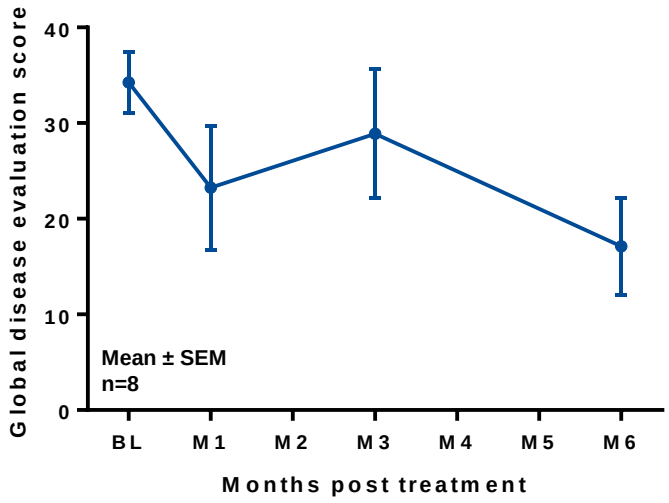
- Percentage of patients requiring rescue surgery
- Clinical symptoms (Global Disease Evaluation)
- Radiological symptoms
- Safety

Positive results at 6 months

7 out of 8 patients met primary endpoints

- 77% radiological improvement
- 68% improvement in pain
- 50% improvement of health status





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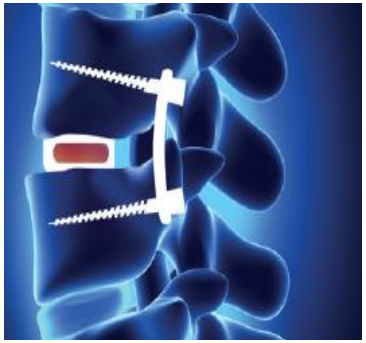
LUMBAR SPINAL FUSION

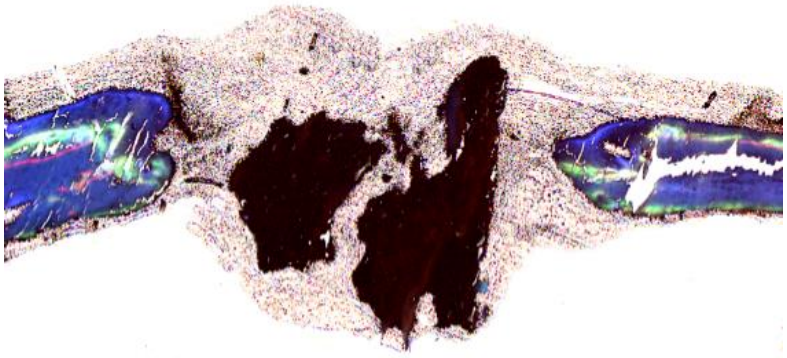
Standard of care
Interbody cages & granules

ALLOB®



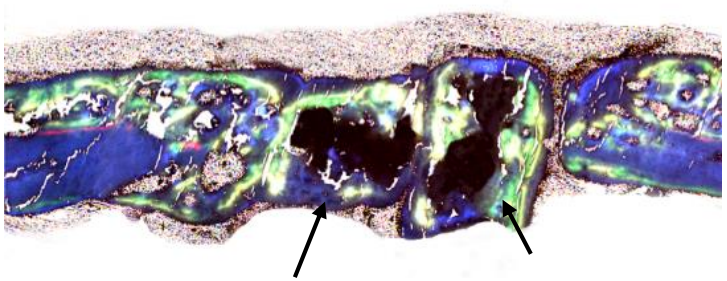
Sub-critical circular cranial bone defect in Nude mice: administration of ceramic scaffold alone or combined with ALLOB®, mimicking a fusion procedure

Ceramics + Control



No continuity between bone edges and ceramics
→ No fusion

Ceramics + ALLOB®



Continuity between bone edges and ceramics
→ Fusion

LUMBAR SPINAL FUSION - POSITIVE PRELIMINARY RESULTS

Phase IIA spinal fusion trial

Recruitment completed

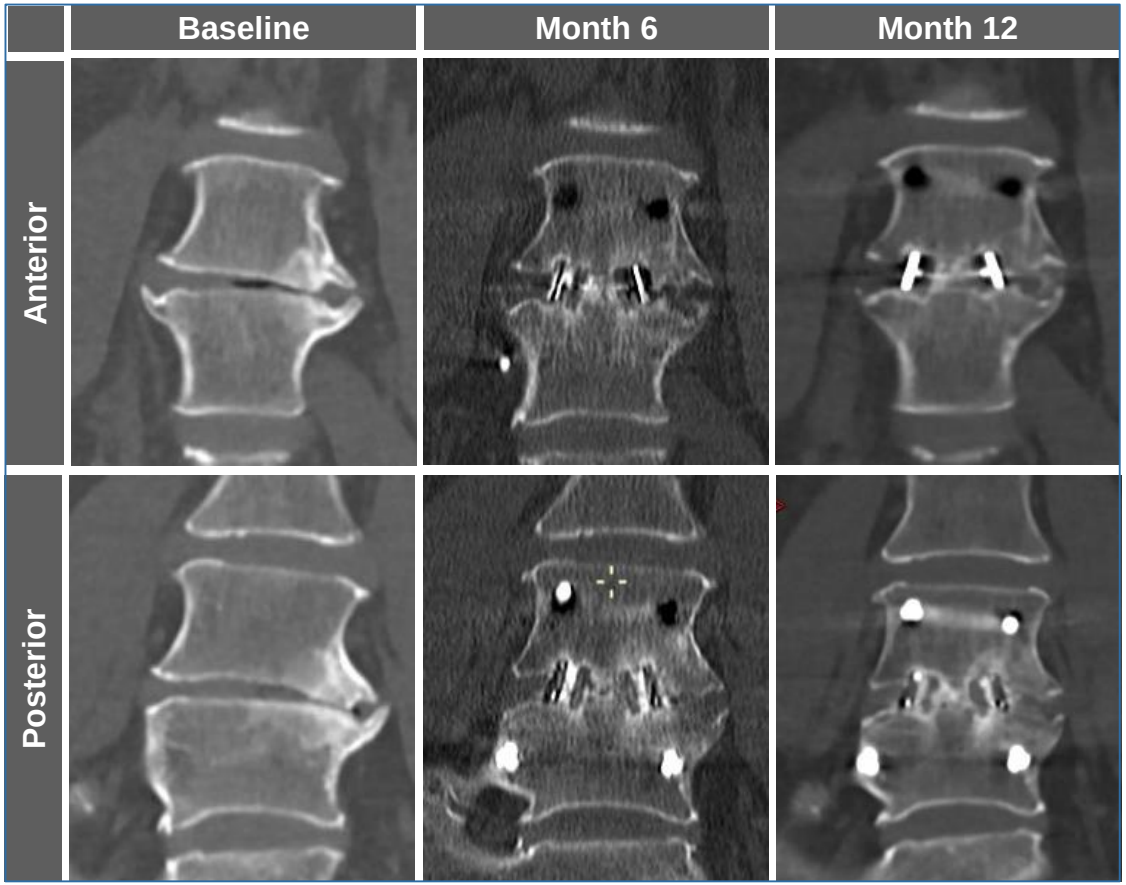
No safety issues on 16 patients

Positive preliminary results of first patient (as from month 6):

– Health status improvement & back/leg pain relief

– No vertebral motion on dynamic x-rays & evidence of fusion on CT scan

Extension to assess bone fusion at earlier timepoints



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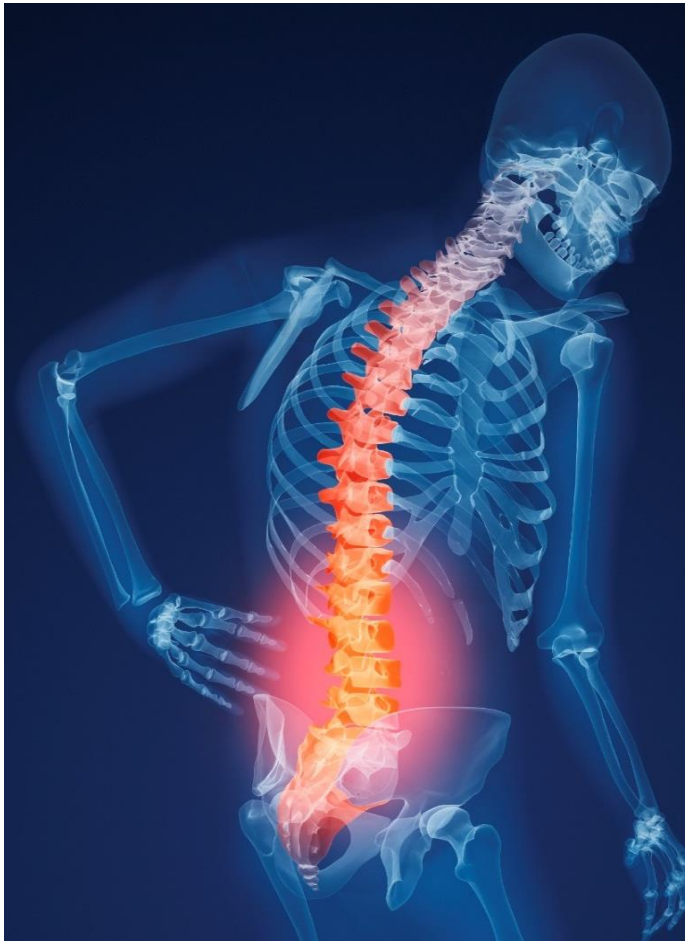
SEVERE OSTEOPOROSIS - STRATEGY

Proof-of-concept

Initial results of severe osteoporosis proof-of-concept trial show that a single intravenous administration of PREOB® has beneficial effects on pain and bone turnover through a novel mechanism-of-action

Strategy – capitalize on allogeneic approach

- Initiate ALLOB® severe osteoporosis trial
- Intravenous administration of ALLOB®
- Increasing doses (i.e., dose-escalation)
- Randomized and controlled (against placebo)
- Double-blind trial



STRATEGY UPDATE AND OUTLOOK

DELIVERING CORPORATE GROWTH STRATEGY

Further strengthening of strategic leadership

- **Chief Technology and Manufacturing Officer – appointment of Benoît Champluvier**
  - 20+ years of experience at GlaxoSmithKline Vaccines driving innovative and complex bioprocesses, supporting development and launch of new products
  - Responsibility for production & quality control in preparation for commercial-scale and larger clinical trial manufacturing
- **Chief Business Officer - Thomas Lienard appointed November 2015**
  - 15+ years pharmaceutical industry experience incl. Lundbeck, Eli Lilly
  - Responsibility for business development, business operations, strategic planning

OUTLOOK

Clinical results

– Efficacy results for the Phase IIA **spinal fusion** trial with ALLOB®

– Complete recruitment for interim analysis Phase I/IIA ALLOB® **delayed-union** trial

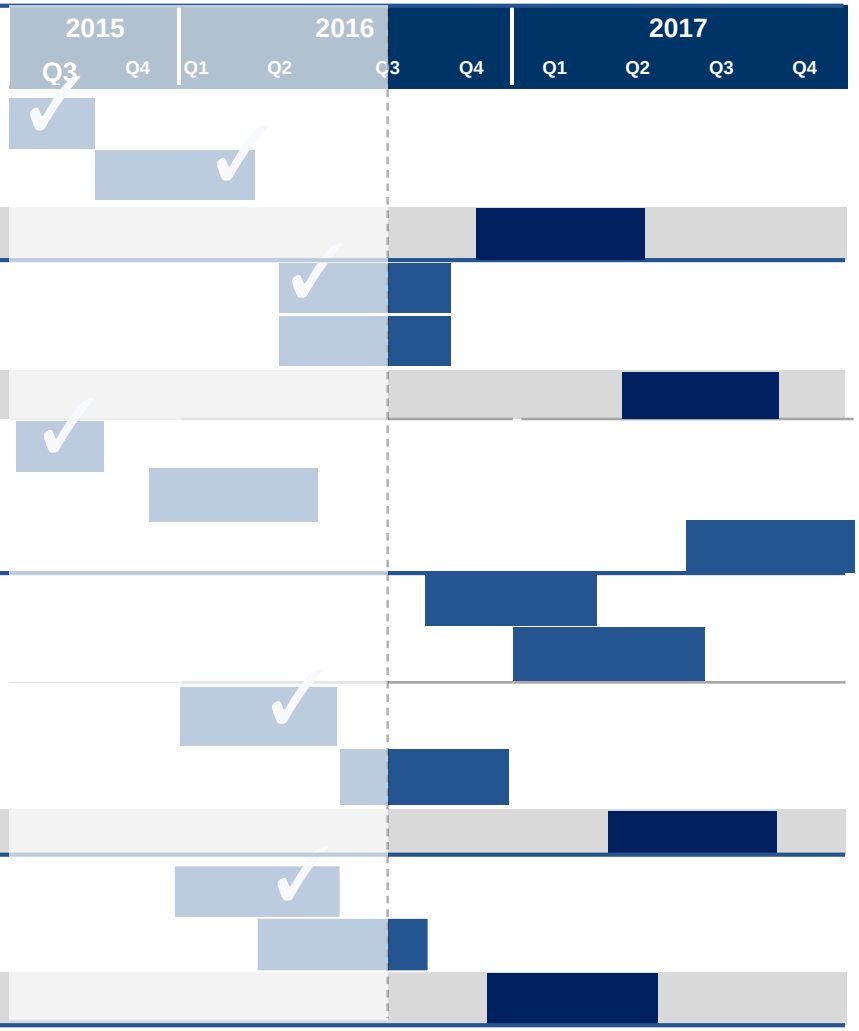
– Preparation of first **US clinical trial**

Cash flow

Careful cash management will remain a key priority for the Company, with a strong focus on net cash burn. The Company has sufficient cash to carry out its strategic objectives until early 2018.

UPCOMING CLINICAL NEWS

Indication		Milestones
	PREOB®	*Safety 8 patients*
		Efficacy 8 patients
Osteoporosis (II)	**ALLOB®**	**Initiation ALLOB® trial**
		Completion recruitment
Spinal fusion (II)	**ALLOB®**	Efficacy 4-8 patients
		Efficacy 16 patients
		Initiation of study
Revision (II)	**ALLOB®**	Safety 4 patients
		Efficacy 4 patients
		Study status for Interim/DSMB
Non-Union (IIB/III)	PREOB®	Launch of US clinical trial
		Efficacy 8 patients
Delayed-Union (I/II)	**ALLOB®**	Completion of recruitment
		Efficacy 16 patients – interim
		Site update
Osteonecrosis (III)	**PREOB®**	Study status for Interim/DSMB
		Launch of US clinical trial



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Questions

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