

Q3 2016 Results

8 November 2016



 **Bone** Therapeutics

*New frontiers in orthopaedics
and bone diseases*

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KEY HIGHLIGHTS

Corporate & Financial

- Thomas Lienard appointed CEO
- Confirmed focus on allogeneic strategy in Europe and US, and on bringing a first product to market
- Positive decision on Belgian Patent Income Deduction
- 2016 cash burn anticipated EUR 14-15M; cash at end September EUR 22.58M
- Cash runway going into Q2 2018

Pipeline

- Phase II and Phase III programmes progressing
- Completion of recruitment for interim analysis of ALLOB® Phase I/IIA delayed union study expected in Q4 – interim analysis expected summer 2017
- ALLOB® phase IIA spinal fusion trial on track – results expected summer 2017

FINANCIAL HIGHLIGHTS

<i>Million € (YTD)</i>	Q3 2016	Q3 2015
Operating income	2.85	2.71
Operating expenses	(11.72)	(11.14)
R&D expenses	(9.32)	(8.51)
G&A expenses	(2.41)	(2.63)
Operating result	(8.87)	(8.43)
Net financial result	(0.19)	(1.79)
Net result	(9.00)	(10.23)
Net cash flow	(9.78)	24.20
Operating activities	(8.95)	(9.93)
Investing activities	(0.90)	(1.35)
Financing activities	0.07	35.48
Cash position	23.83 *	35.78

* Including 1.37M restricted cash

THOMAS LIENARD APPOINTED CEO

- ▶ Appointed Chief Business Officer in 2015
- ▶ Formerly MD, Belgium and Luxembourg, Lundbeck; Senior sales & marketing positions at Eli Lilly in Europe and US
- ▶ Consultant, McKinsey & Company
- ▶ MBA, Harvard Business School; Master in Business Engineering, Solvay Brussels School of Economics and Management
- ▶ Strong commercial background reflects evolving Company priorities



SKILLED MANAGEMENT TO TAKE COMPANY FORWARD

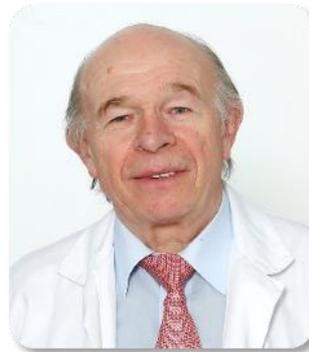
- ▶ Significant expansion of leadership team over past 2 years
- ▶ Skills and industry expertise to take Bone Therapeutics through to commercialisation of first products
- ▶ Focus on clinical, regulatory, business development and manufacturing



Wim Goemaere
Chief Financial Officer



Valérie Gangji, MD, PhD
Chief Medical Officer



Guy Heynen, MD
*Chief Clinical &
Regulatory Officer*



Benoit Champluvier, PhD
*Chief Technology &
Manufacturing Officer*



Nora Meskini
*Director
Clinical Operations*

CONFIRMATION OF STRATEGY TO MAXIMISE VALUE CREATION



Focus on:

The allogeneic platform ALLOB®:

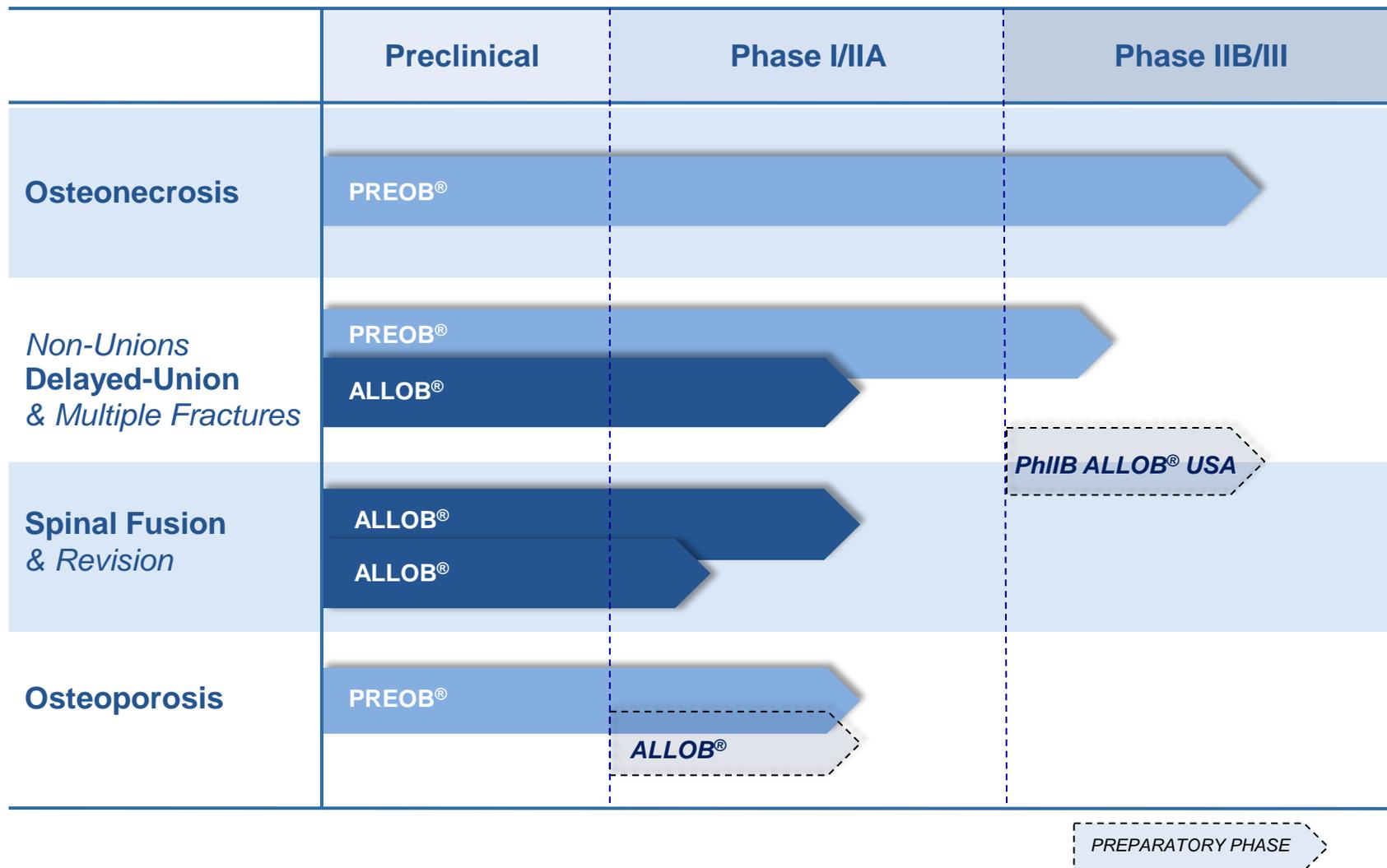
- A therapeutically attractive bone regenerative solution:
 - ✓ Industrial: scalable, cost-effective, off-the-shelf cell therapy product solution
 - ✓ Commercial: suited for larger markets
 - ✓ Business development: more attractive to partners
- Europe: maintain high-level investments in ALLOB® clinical programs
- US: prioritising clinical development of ALLOB®, to be prepared in 2017

Completing Phase III clinical trial in osteonecrosis to bring

1st commercial product to market

- Demonstrating and confirming high added value of Bone Therapeutics' bone-forming cell therapy products
- Propelling the company into commercialisation stage

ADVANCED AND DIVERSIFIED PIPELINE



CLINICAL TRIALS IN PROGRESS



OSTEONECROSIS

Validating Bone Therapeutics' bone-forming cell therapy products



SPINAL FUSION

Promising results for ALLOB[®] Phase IIA



DELAYED UNION (DU)

Promising results for ALLOB[®] Phase IIA



OSTEOPOROSIS (OP)

Allogeneic approach under evaluation

OSTEONECROSIS – BONE-FORMING CELL THERAPY PRODUCT VALIDATION

Product

PREOB®

Indication

- Osteonecrosis of the hip

Opportunity

- Orphan disease: 170.000 patients in EU, US & JP
- Affecting mostly young, active people (age 30-50) – c. 50% require prosthesis before 40
- High unmet medical need and very limited therapeutic options

Status

- Most advanced clinical program (Phase III)
- Currently recruiting patients

Next steps

- Recruitment update
- DSMB report (1 year following completion 1st cohort)

Upon completion Phase III:

- ▶ External validation of Bone Therapeutics' bone forming cell therapy products
- ▶ 1st product to market

SPINAL FUSION - PROMISING RESULTS FOR ALLOB® PHASE IIA

Product

ALLOB®

Indication

- Symptomatic lumbar degenerative disc disease requiring a spinal fusion procedure

Opportunity

- Large market: 500.000 annual lumbar spinal fusion procedures
- Growing market (5-6% p.a.) due to aging population and lifestyle
- Up to 35% failure rate from current approaches → demand for reliable solution
- Fusion promoting measures (BMP2) are in high demand

Status

- Phase IIA (non-controlled) ongoing
- 16 patients treated – results from full set of 8 first patients communicated Oct. 2016
- No treatment-related safety concerns
- Trial extended to 32 patients

Next steps

- Results from 16 patients expected summer 2017
- Development in US under evaluation subject to positive Phase IIA results

DELAYED UNION (DU) – PROMISING RESULTS FOR ALLOB® PHASE IIA

Product

ALLOB®

Indication

- Severe fractures of long bones with delayed healing (3-7 months post fracture)

Opportunity

- Up to 1M DU cases p.a. – 1/3 evolve to non-union
- Relatively young patients
- Underserved market with very limited therapeutic options
- High disease burden with important direct and indirect costs for society

Status

- Phase IIA trial ongoing
- All patients receive one single injection of ALLOB® at bone defect site
- 7 out of 8 first patients met primary endpoints within 6 months
- No treatment-related safety concerns

Next steps

- Completion of recruitment of first 16 patients
- Interim data analysis planned for summer 2017
- Study could be stopped early on the basis of efficacy after interim analysis

OSTEOPOROSIS (OP) – ALLOGENIC APPROACH UNDER EVALUATION

Product

PREOB® / ALLOB®

Indication

- Severe Osteoporosis

Opportunity

- Large market: 30M patients with established OP in EU, US and JP
- Growing market (CAG 4-5%) due to aging population
- Last-line treatment : underserved market with very limited therapeutic options
- Unmet needs in severely affected patients

Status

- First 7 patients treated with PREOB® in Phase IIA trial
- Positive effects observed on pain and bone turnover markers
- No treatment-related safety concerns

Next Steps

- Evaluation of the opportunity and feasibility of initiating a Phase II trial with ALLOB®

BUSINESS DEVELOPMENT



Focus on

- ▶ Partnership in the US for co-development and commercialisation
- ▶ Licensing of portfolio in Japan and SE Asia

BELGIAN PATENT INCOME DEDUCTION (PID)

- ▶ Highly favourable tax regime
- ▶ 80% of all revenues from patents relating to PREOB[®] and ALLOB[®] exempt from Belgian income tax up to June 2021
- ▶ Includes upfront payments, milestone payments, royalties
- ▶ Results in net effective tax rate of 6.8% before incorporation of losses carried forward and tax credits

UPCOMING CLINICAL NEWS

Indication	Milestones	2016				2017					2018	
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
Osteonecrosis (Phase III)	PREOB®	Site update	✓									
		Study status for Interim/DSMB										
		Patient update										
		DSMB Report										
Spinal fusion (Phase II)	ALLOB®	Completion recruitment		✓								
		Efficacy 4-8 patients										
		Efficacy 16 patients			✓							
		Initiation Phase IIB study										
Revision (Phase II)	ALLOB®	Safety 4 patients										
Delayed-Union (Phase I/II)	ALLOB®	Efficacy 8 patients	✓									
		Completion of recruitment										
		Efficacy 16 patients – interim										
Non-Union (Phase IIB/III)	PREOB®	Study status for Interim/DSMB										
Osteoporosis (Phase II)	PREOB®	Efficacy 8 patients	✓									
	ALLOB®	Initiation ALLOB® trial										

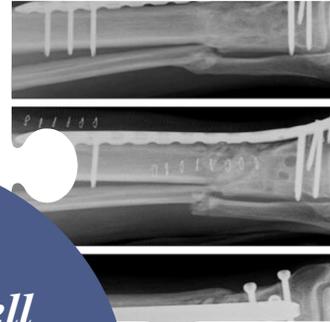
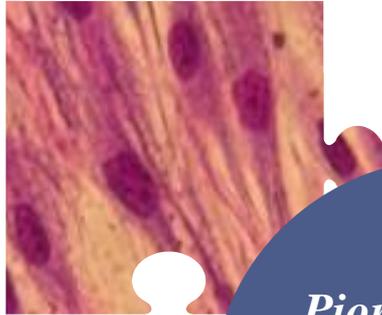
Under Evaluation

INVESTMENT HIGHLIGHTS

1

FIRST-IN-CLASS / BEST-IN-CLASS

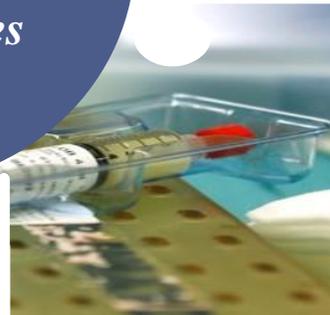
Unique technologies
for orthopaedics &
bone diseases



*Pioneering cell
therapy for
orthopaedics &
bone diseases*

4

LARGE MARKETS WITH HIGH UNMET MEDICAL NEEDS



2

MINIMALLY INVASIVE

Significant potential
benefits over current
standard of care

3

ADVANCED CLINICAL PIPELINE

Multiple indications

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