



# ***Full year results 2018***

***1 March 2019***



***New frontiers in orthopaedics  
and bone diseases***

## ON THE CALL TODAY ARE:



***Thomas Lienard,  
CEO***



***Jean-Luc Vandebroek,  
CFO***



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# AGENDA

- **Welcome and introduction**
- **Operational and corporate highlights**
- **Financial highlights**
- **Outlook for 2019**
- **Q&A**

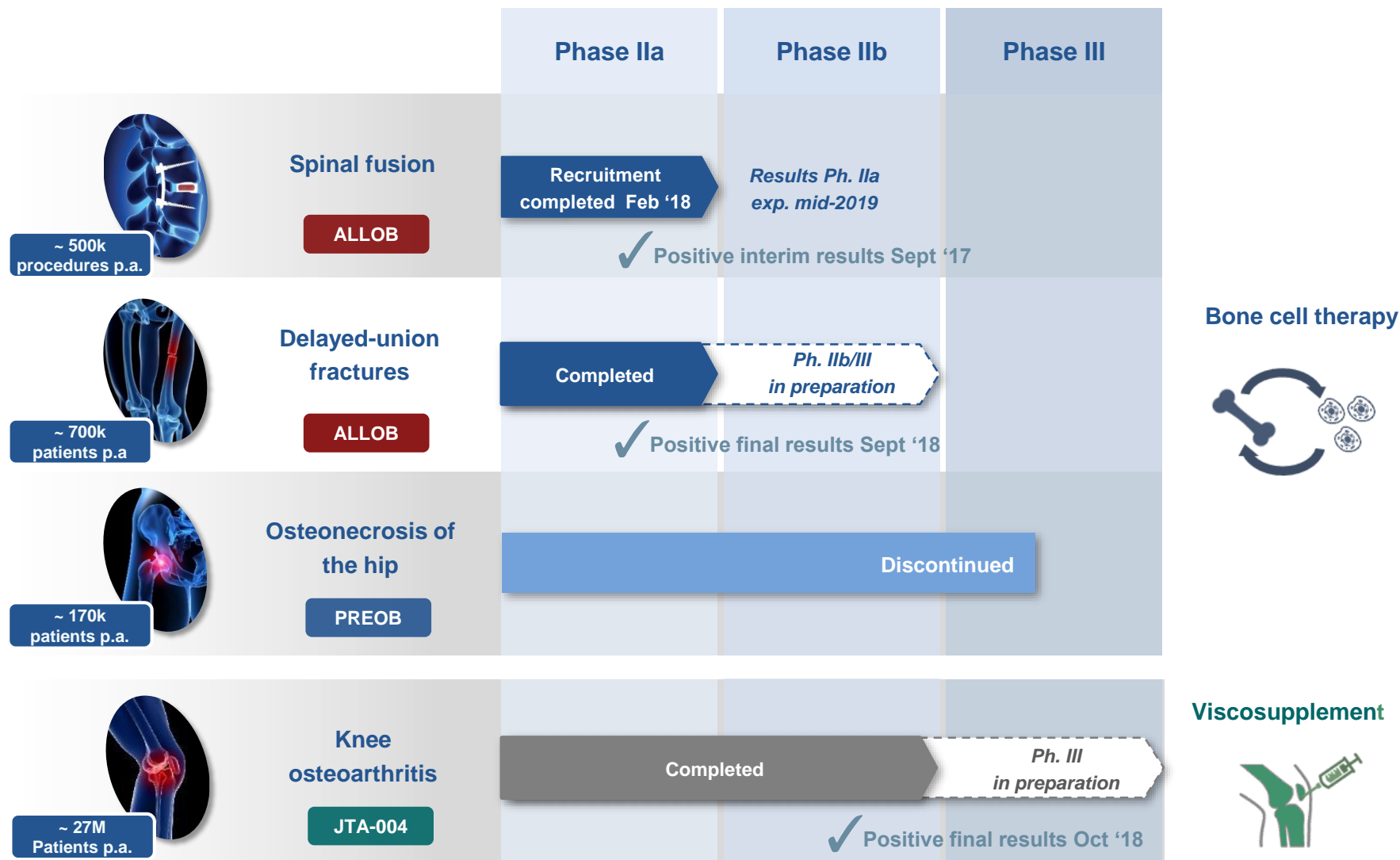




# OPERATIONAL & CORPORATE HIGHLIGHTS

# LATE-STAGE CLINICAL PIPELINE

## ADDRESSING HIGH UNMET NEEDS IN BONE DISORDERS



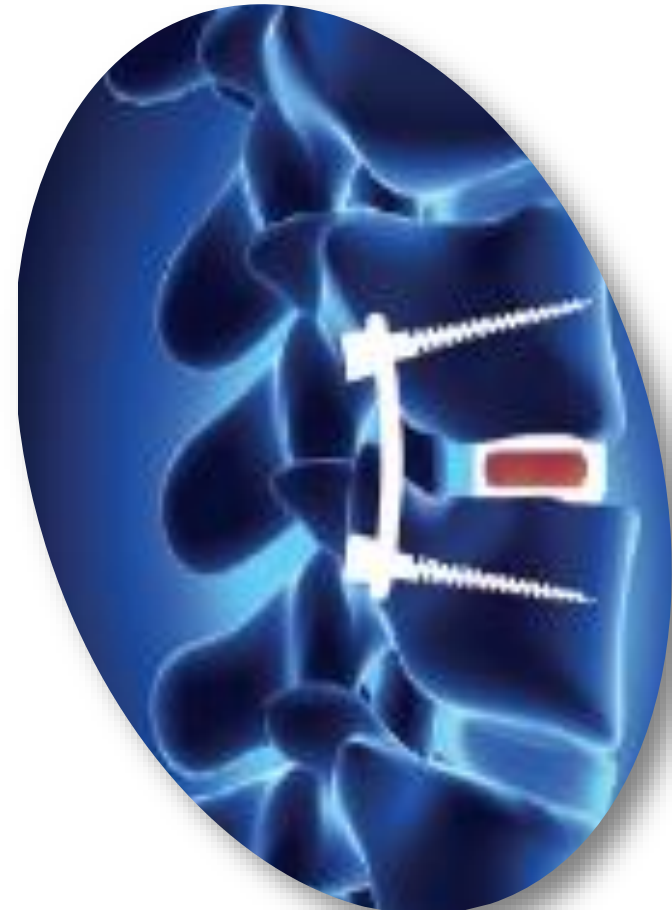
# SPINAL FUSION – ALLOB PHASE IIa CLINICAL STUDY ONGOING

## STATUS

- Open-label Phase IIa study ongoing
- **Patient recruitment completed** in February 2018
- **Positive interim results** for the **first 15 patients** announced in September 2017, reporting evidence of successful fusion and substantial clinical improvements

## NEXT STEPS

- **Efficacy and safety results** from **32 patients** expected **mid-2019** after a 12-month follow-up





# DELAYED UNION FRACTURES – PROMISING FINAL PHASE I/IIa RESULTS WITH ALLOB

## STATUS

- Phase I/IIa trial (non-controlled)
- All patients received one single injection of ALLOB at bone defect site
- **Final results** for 21 patients reported in September 2018 **confirmed** the **strong interim results**, which led to an early termination of the trial in September 2018
- **Preparations** for a **Phase IIb/III** study initiated

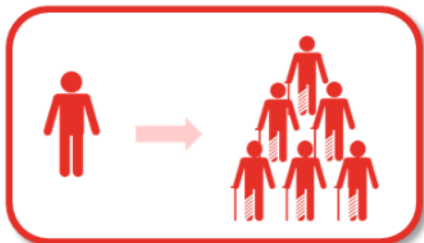
## NEXT STEPS

- **CTA submission** in EU and the US expected in **H2 2019**





# OPTIMISED PRODUCTION PLATFORM TO ALLOW SUCCESSFUL MANUFACTURING OF A COMMERCIAL CELL THERAPY



Increasing yield  
(100,000 doses)



Cryopreserved  
final product



Scale-up &  
automation

## CRITICAL SUCCESS FACTORS



Scalable to address  
large patient populations

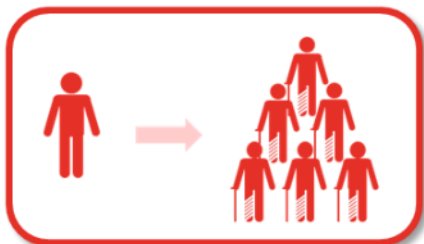


Consistent quality



Reduced cost

# OPTIMISED PRODUCTION PLATFORM TO ALLOW SUCCESSFUL MANUFACTURING OF A COMMERCIAL CELL THERAPY



Increasing yield  
(100,000 doses)



Cryopreserved  
final product



Scale-up &  
automation

## CRITICAL SUCCESS FACTORS



Streamlined  
supply chain



Broad accessibility



Off-the-shelf solution

# KNEE OSTEOARTHRITIS – STRONG RESULTS WITH JTA-004 IN FIRST EFFICACY STUDY

## STATUS

- 164 patients in the Phase II study were randomly assigned to receive either one of the 3 doses of JTA-004 or the reference product hylan G-F20
- Results, reported in October 2018, showed a **statistically significant superior pain relief** in the pooled JTA-004 group compared to the reference group and demonstrated that JTA-004 was generally well tolerated

## NEXT STEPS

- **CTA submission** in EU and the US expected in **H2 2019**



# HIP OSTEONECROSIS – PREOB PHASE III STUDY DISCONTINUED

- Based on interim results in November 2018, **DSMB recommended discontinuing** the study as the primary objective of the study was expected not to be achieved
- PREOB was generally **well-tolerated**
- **Subsequent analysis of unblinded data** demonstrated:
  - Clinical effect of PREOB in line with previous reported efficacy
  - Control arm, consisting of core decompression alone, performed much better than anticipated based on historical clinical studies
  - Which may have led to a reduced difference in responder rate between PREOB and the control arm





# STRENGTHENING THE BOARD OF DIRECTORS

February  
2018



**Jean St  phenne**  
*Chairman of the Board*



**BNP PARIBAS  
FORTIS**

- > 40y biotech and pharma experience. During his 40-year tenure at GSK Vaccines, he grew the company of 50 people into a fully integrated worldwide leader in vaccine development, with 12,000 employees
- Currently serves on board of various life sciences companies including Vaxxilon, OncoDNA, CureVac and Bepharbel. Previous board positions include TiGenix, Besix Group, BNP Paribas Fortis, GBL and IBA.

April  
2018



**Claudia D'Augusta, PhD**  
*Independent Director*



- >20y of international experience in corporate finance, capital markets and M&A
- Currently Venture Partner at Ysios Capital and previously CFO at TiGenix. Prior to that, she held various other senior financial positions across a number of international public and private companies.

June  
2018



**Jean-Luc Vandebroek, CFO**  
*Executive Director*



- >20y of international finance experience at major public and privately-owned corporations
- Formerly CFO at Moteo Two Wheels/Bihr (Alcoba) and Fluxys, and Corporate Director Finance Europe & US and VP Finance BeLux at Ahold Delhaize

# STRENGTHENING THE EXECUTIVE MANAGEMENT TEAM

October  
2018



**Linda Lebon**  
*Chief Regulatory Officer*



- Strategic regulatory expert with >25 years of experience in regulatory affairs
- Held positions in several large pharmaceutical companies as well as senior positions in regulatory CROs and advisory firms

February  
2019  
(Post  
period)



**Benoit Moreaux, PhD**  
*Chief Technology and  
Manufacturing Officer*



- Experienced executive with 20y expertise in strategic operation planning and leading drug development
- Former CSO and Managing Director Nikkiso Belgium, Senior Portfolio and R&D positions at Baxter and Johnson & Johnson



# FINANCIAL HIGHLIGHTS

# KEY FINANCIAL FIGURES

(€ million)	FY 2018	FY 2017
<b>Operating income</b>	<b>5.08</b>	<b>4.21</b>
<b>Operating expenses</b>	<b>(16.54)</b>	<b>(16.51)</b>
R&D expenses	(12.88)	(13.12)
G&A expenses	(3.66)	(3.39)
<b>Operating result</b>	<b>(11.47)</b>	<b>(12.29)</b>
<b>Net financial result</b>	<b>(2.67)</b>	<b>(0.48)</b>
<b>Net result</b>	<b>(14.14)</b>	<b>(12.77)</b>
<b>Net cash flow</b>	<b>(0.24)</b>	<b>(11.89)</b>
Operating activities	(12.90)	(11.02)
Investing activities	(0.30)	(0.42)
Financing activities	12.96	(0.46)
<b>Net cash position (at end of period)</b>	<b>8.17</b>	<b>8.41</b>

- **Cash burn** (excl. proceeds from financing) of **€13.9M** for FY2018
- Private placement of **convertible bonds** with a total commitment of **EUR 19.45M** and **EUR 1M regulatory milestone payment from Asahi**, giving runway into **end of 2019**
- **Net financial result** includes transaction costs of €0.5M and fair value of bond/warrant discounts of €1.7M



# STRENGTHENING CASH POSITION VIA SUCCESSFUL CONVERTIBLE BOND PLACEMENT

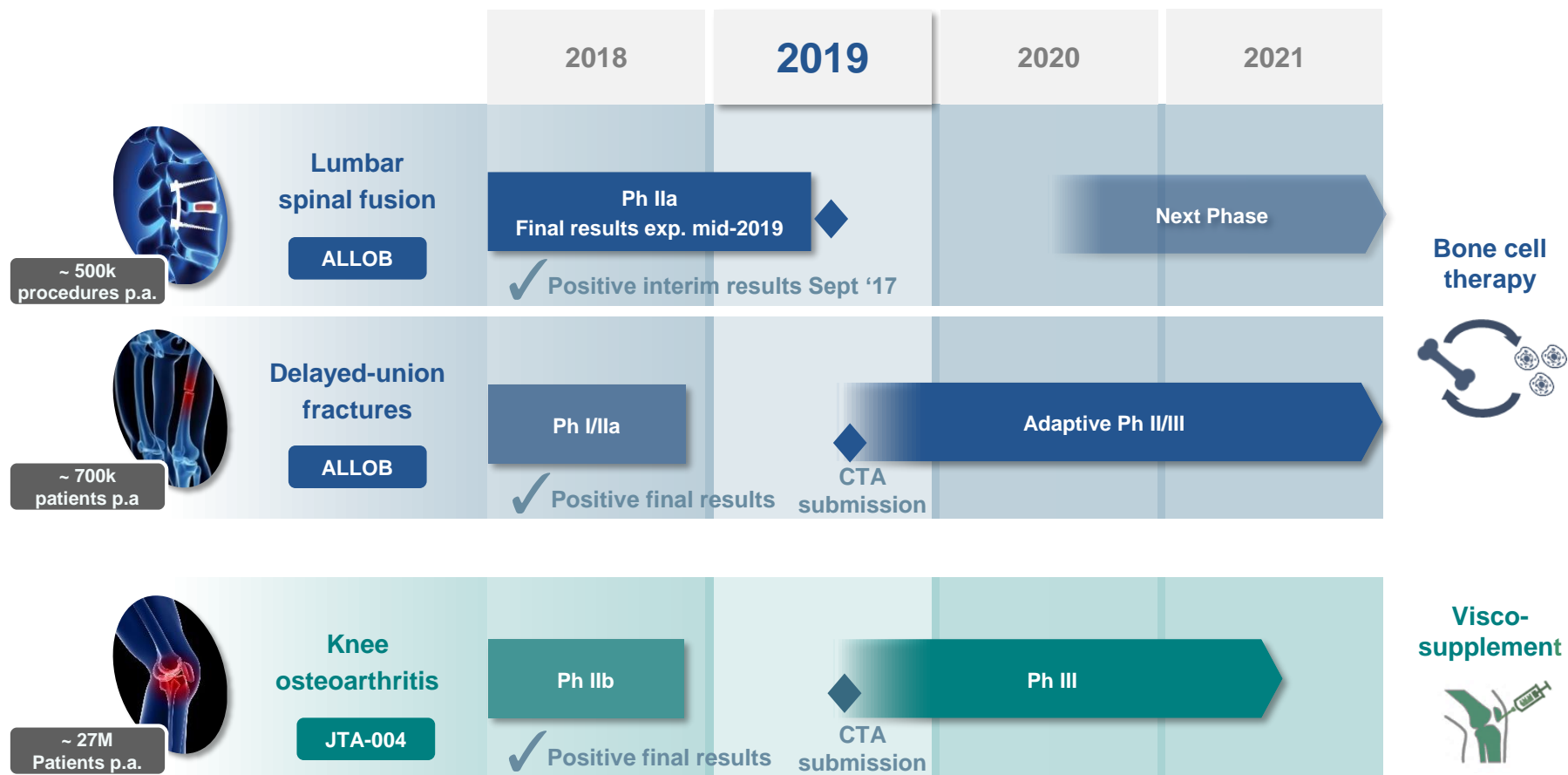


- Secured € 19.45M of committed funds via private placement of convertible bonds in March 2018
- Convertible bonds with 19 bond warrants offering flexibility to different types of investors
- Total gross proceeds for the period of € 14.28 million made up of
  - Initial gross proceeds of € 6.58 million
  - Additional 3,080 bond warrants exercised in the remainder of the year resulting in a supplementary proceeds of € 7.70 million
- Additional proceeds of € 5.18 million over a maximum period of 10 months ending October 2019



# OUTLOOK 2019

# CLINICAL OUTLOOK 2019



## 2 PRODUCTS ENTERING PHASE III<sup>(1)</sup> END 2019

### ALLOB



Bone  
cell therapy

- **Differentiated, active bone-forming cells**
- **Allogeneic** (from donor bone marrow)
- **Injectable** (minimally invasive)
- **Economical, large scale manufacturing**
- **Off-the-shelf** (ready to use)
- Market :
  - **Fractures** at high risk of DU & NU (>1M cases p.a.)
  - **Spinal fusion** procedures (**500K patients p.a.**)

### JTA-004



Visco-  
supplement

- **Patented** composition of **3 active substances**
- Convenient, **single injection**
- **Anti-inflammatory & lubricating** properties
- **Better pain reduction vs market leader**
- **Simple manufacturing process**
- Market : **Knee osteoarthritis**  
(**27M patients p.a.** in EU/USA/JAP)

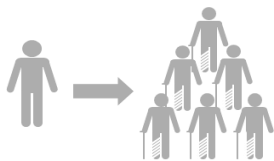


# DRIVERS FOR FUTURE VALUE CREATION



*Exploring new frontiers in orthopedics and bone diseases*

## Off-the-shelf solutions



## Large, underserved patient populations



Fusion promoting  
500k patients



Wait & See  
700k patients



Better pain relief  
27M patients

## Clinical validation



Strong Ph. IIa  
interim results



Early stop Ph. IIa  
due to efficacy –  
Promising Ph. IIa  
final results



Higher pain  
reduction vs market  
leader in Ph. IIb

## Commercial readiness



Cell therapy  
know-how



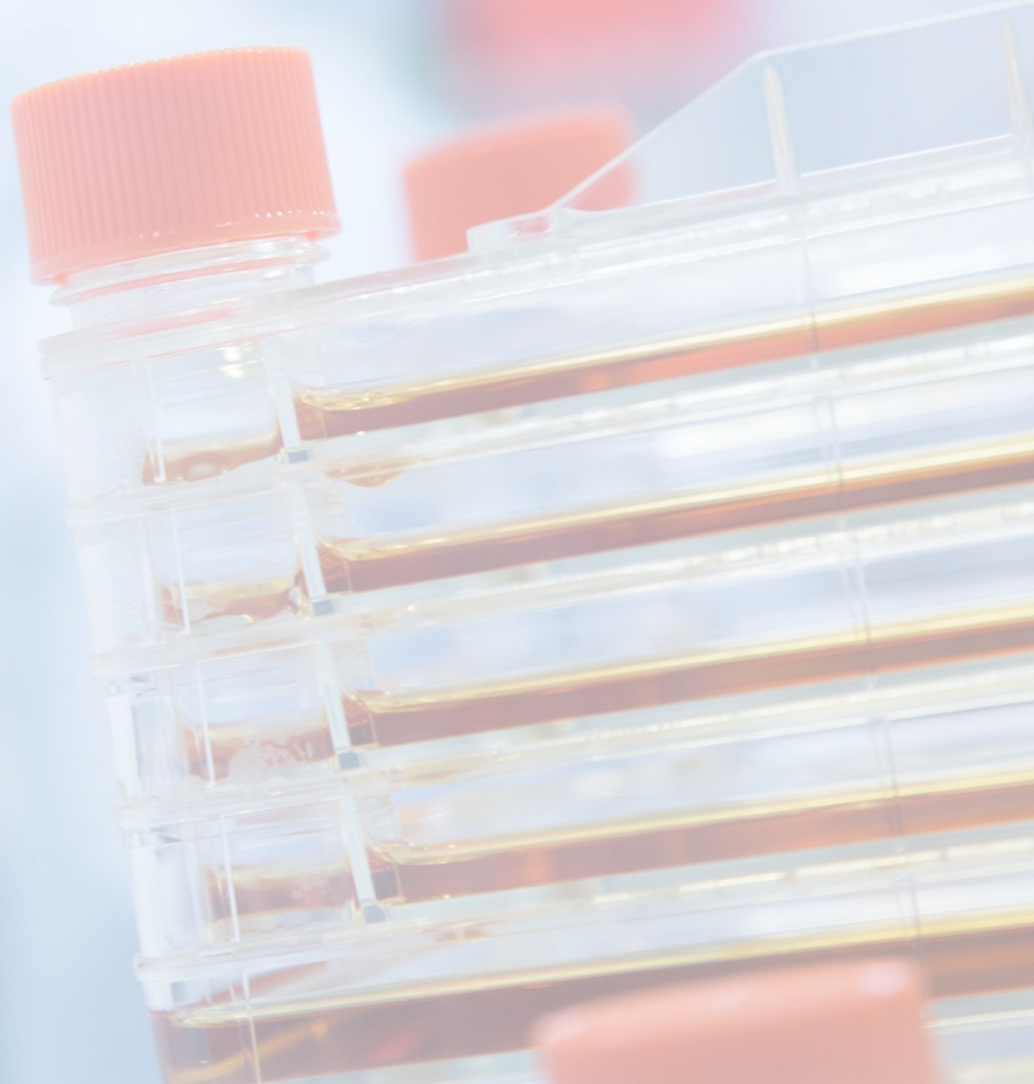
Optimization  
& scale-up



Simple  
production



# Questions ?



# Thank you

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