



CONCENTRATION DATA			
Sample	Concentration	Volume	Mass
1	1.0	1.0	1.0
2	2.0	2.0	2.0
3	3.0	3.0	3.0
4	4.0	4.0	4.0
5	5.0	5.0	5.0
6	6.0	6.0	6.0
7	7.0	7.0	7.0
8	8.0	8.0	8.0
9	9.0	9.0	9.0
10	10.0	10.0	10.0

# BONE THERAPEUTICS

**H1 2020 Results**

# PRESENTING TODAY ARE:



**Miguel FORTE, MD, PHD**  
Chief Executive Officer



**Jean-Luc VANDEBROEK**  
Chief Financial Officer

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# Agenda

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**Welcome and introduction**

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Highlights H1 2020

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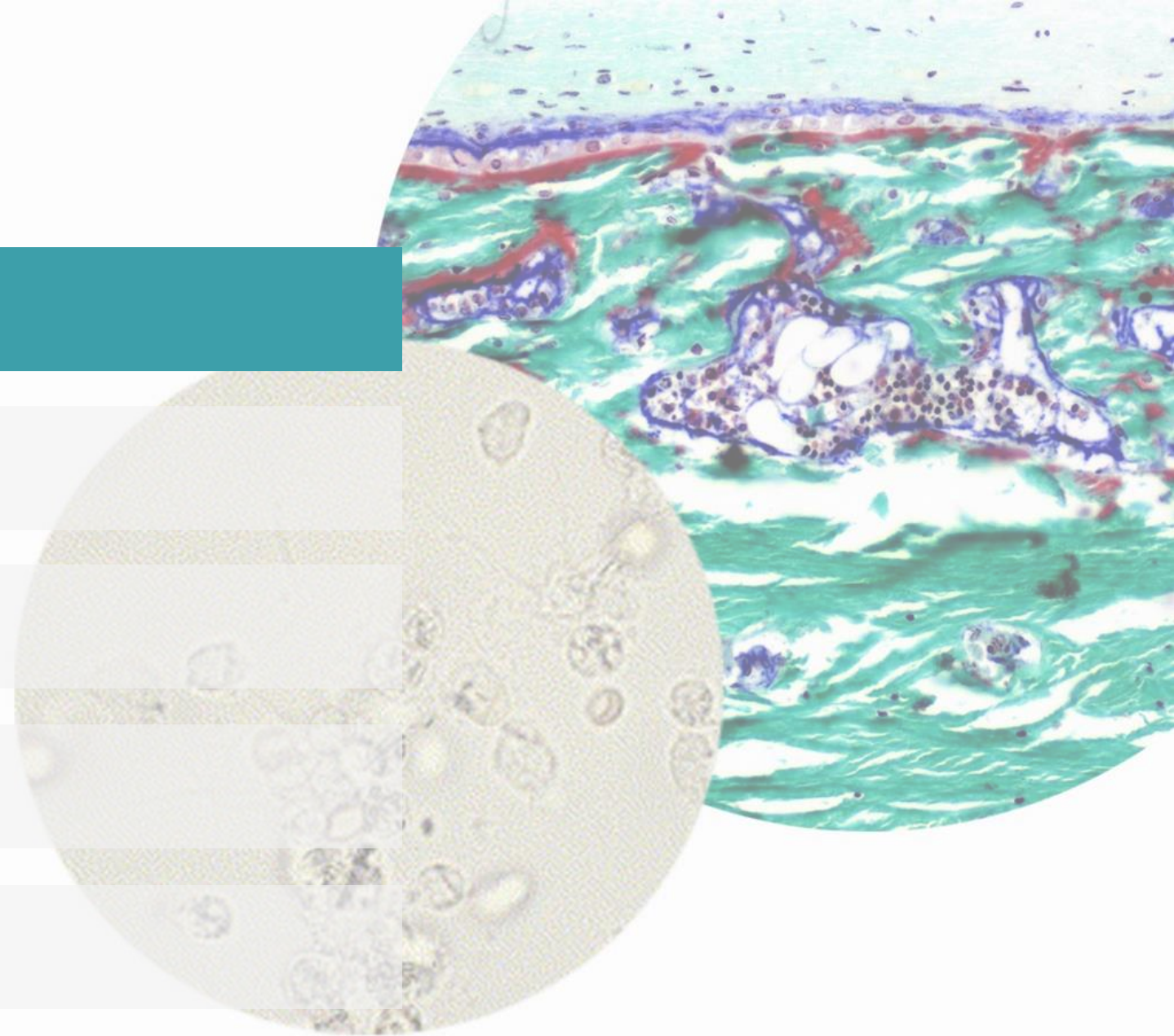
Financial Results H1 2020

04

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Q&A



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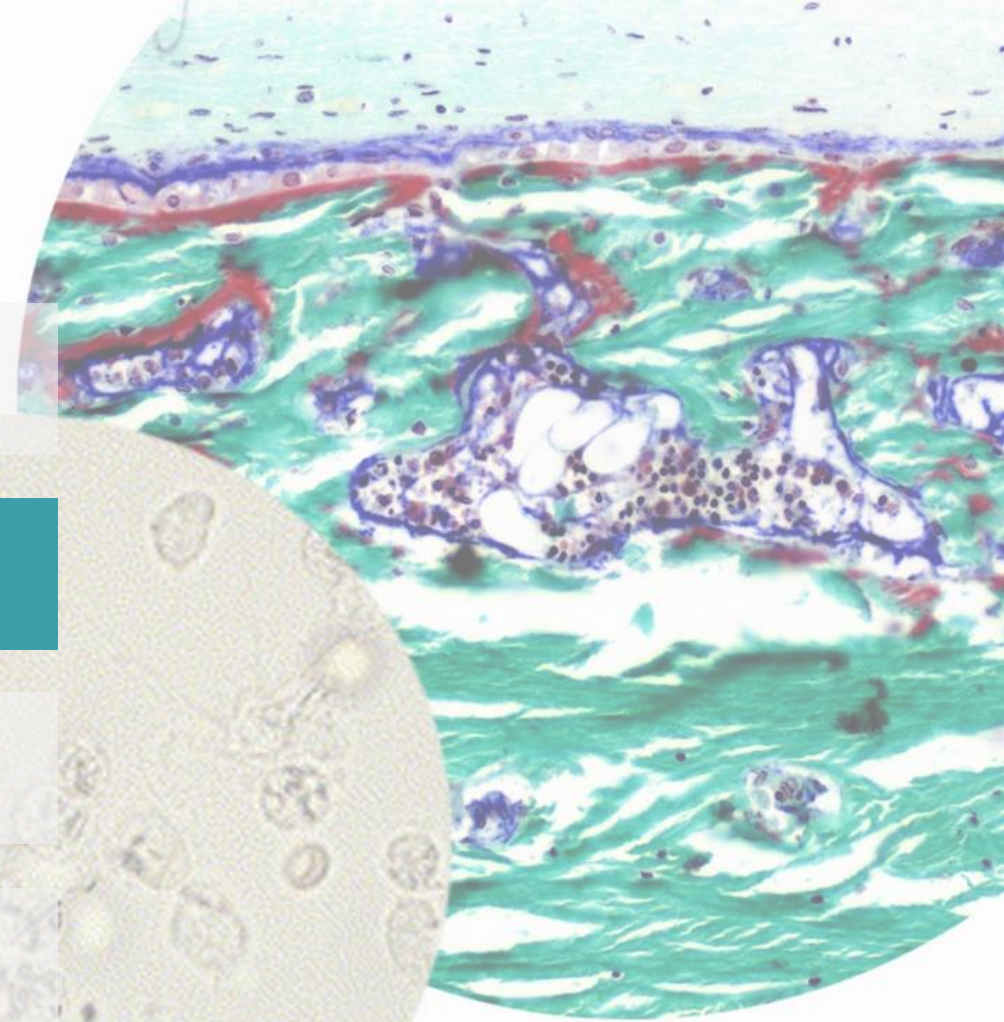
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# Recent strategic developments



**Phase III – JTA-004** – Authorities clearance to proceed in 7/7 countries in June 2020  
- 164 patients recruited as of 13 of August 2020

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**Phase IIb – ALLOB** – EU clearance to proceed in 6/7 countries in August 2020  
- first patient expected in H2 2020

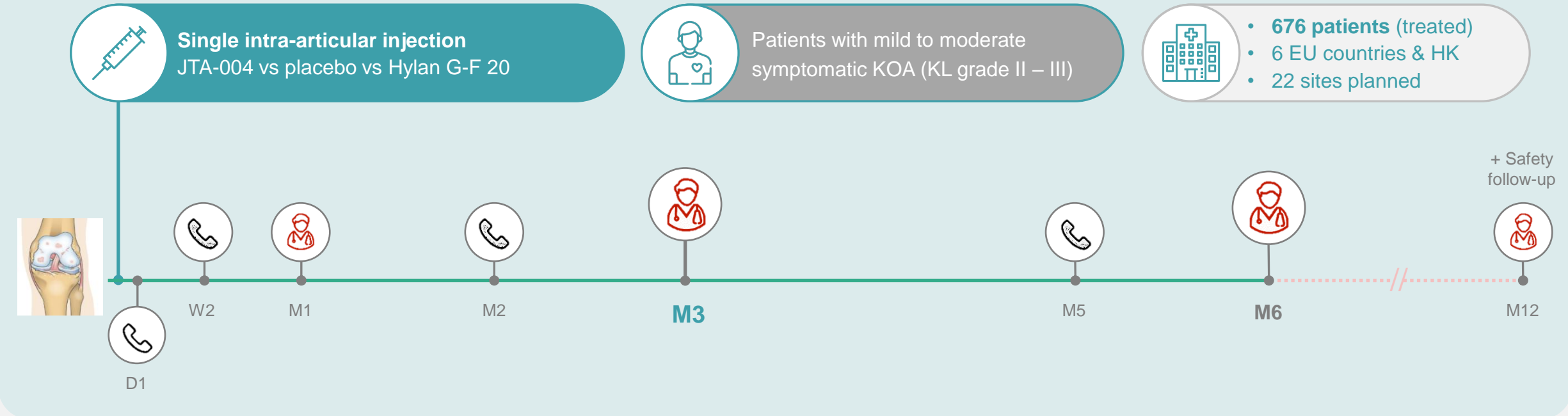
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**BT-20** – Expanding existing pipeline from orthopedics into inflammatory conditions, including COVID-19, leveraging Bone Therapeutics platform of differentiated MSCs



# JTA-004 is currently evaluated in the ongoing pivotal Phase III placebo controlled, randomized, double-blind, multicenter study



## Primary objective

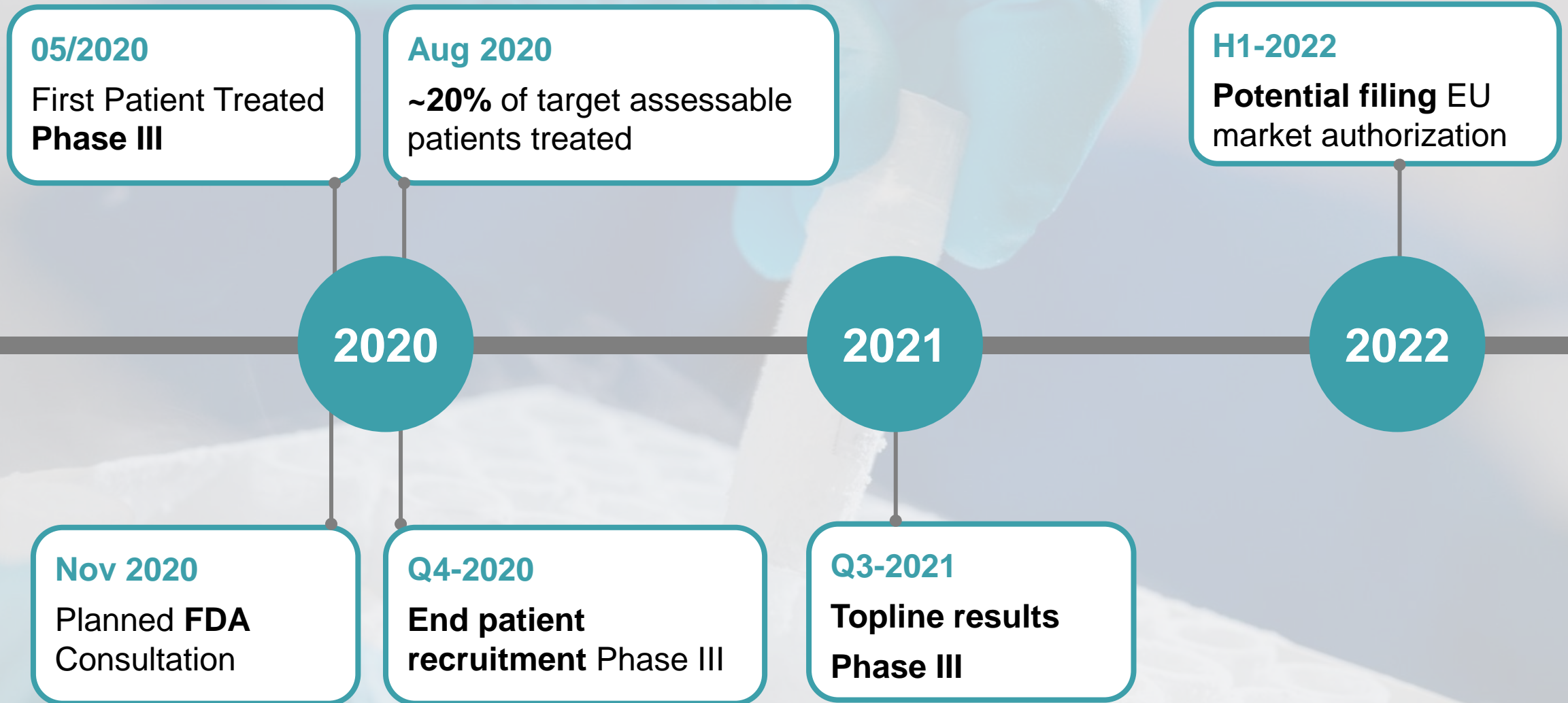
- **Reduction in knee pain at month 3** compared to placebo

## Key secondary objectives

- **Reduction in knee pain at month 6** compared to placebo
- Reduction in knee pain vs reference (Hylan G-F 20) at M3-6-12
- Improvement in physical function, Patient Global Assessment and quality of life

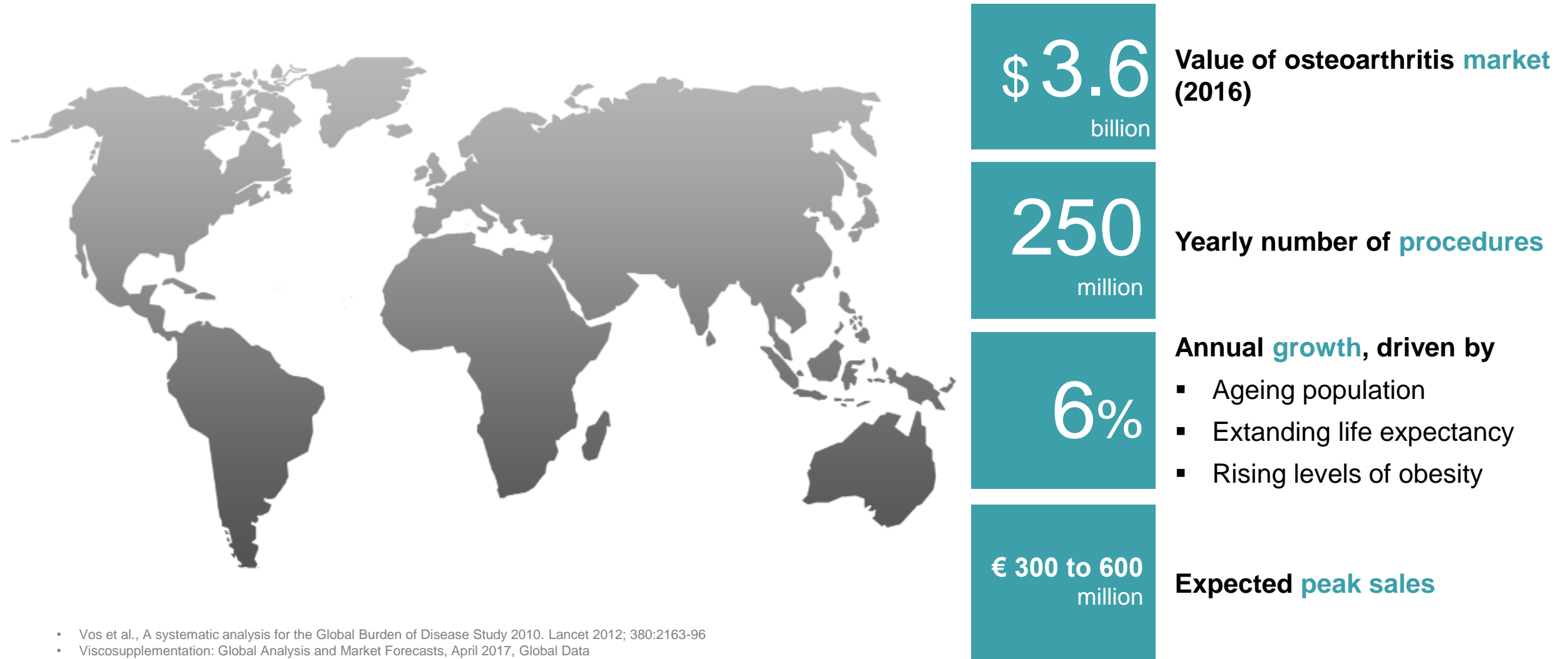
KL: Kellgren-Lawrence  
KOA: Knee Osteoarthritis

# Recent developments and anticipated next steps for JTA



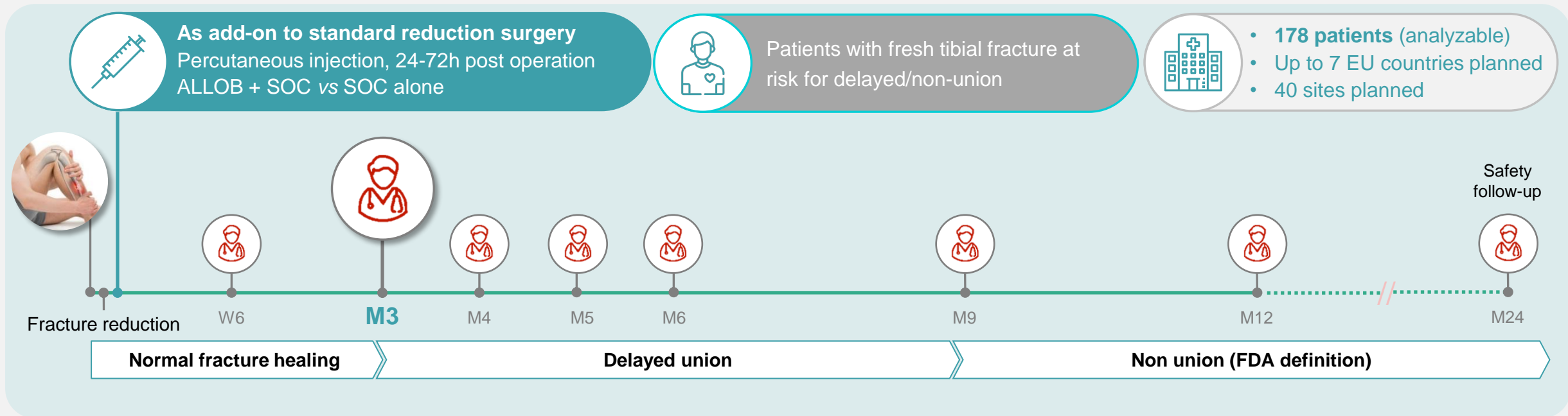


# JTA is addressing a large and growing market



- Vos et al., A systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012; 380:2163-96
- Viscosupplementation: Global Analysis and Market Forecasts, April 2017, Global Data
- Opportunity Analyzer: Osteoarthritis - Analysis and Forecasts to 2026, September 2017, Global Data
- Analyst's estimates

# ALLOB is being prepared for a Phase IIb placebo controlled, randomized, double-blind, multicenter study



## Primary objective

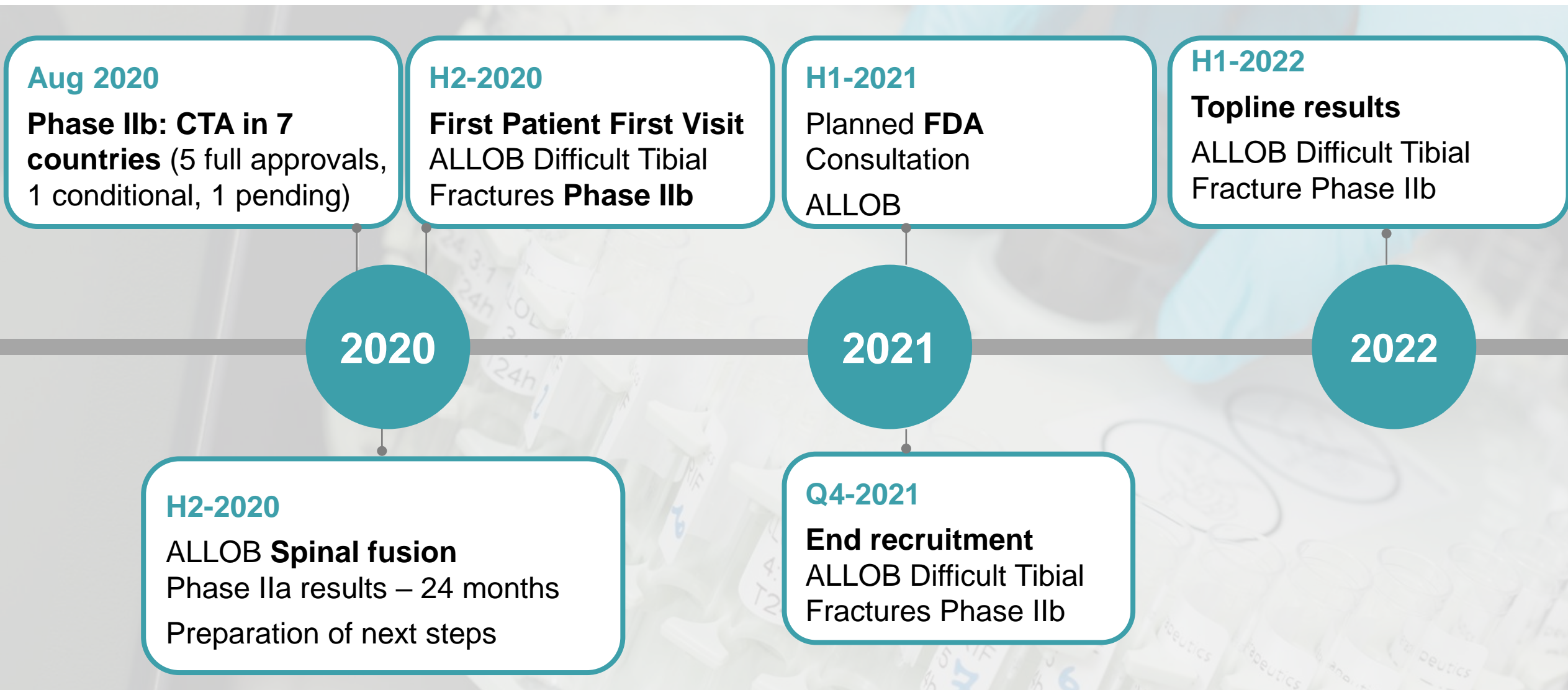
- % patients with RUST\* at month 3 above a defined threshold, predictive of future fracture healing after treatment with ALLOB compared to placebo.

## Key secondary objectives

- Speed and rate of healing (including full weight bearing and pain at palpation)
- Rate of rescue intervention
- Leg function
- Return to normal activities

\* RUST: Radiological Union Score for Tibia  
SOC (Standard of care): wait-and-see

# Recent developments and anticipated next steps for ALLOB



# ALLOB is addressing a large and growing market

## Difficult fractures

**\$2.6**  
billion

**Value of bone graft substitutes market (2016)**

**1.7**  
million

**Number of procedures in EU5, US & JP (2016)**

**5%**

**Annual growth, driven by**

- Ageing population
- Rising levels of obesity
- Product innovation

**€ 280 to 500**  
million

**Expected peak sales**

## Spinal fusion

**\$7.1**  
billion

**Value of spinal fusion market (2016)**

**1**  
million

**Number of procedures in EU5, US, JP & CN (2020)**

**3%**

**Annual growth, driven by**

- Ageing population
- Sedentary lifestyle
- Innovation

**€ 270 to 800**  
million

**Expected peak sales**



# Stefanos Theoharis appointed as CBO to accelerate strategic discussions for the commercialization of ALLOB and JTA-004



**Stefanos THEOHARIS, PhD**  
Chief Business Officer

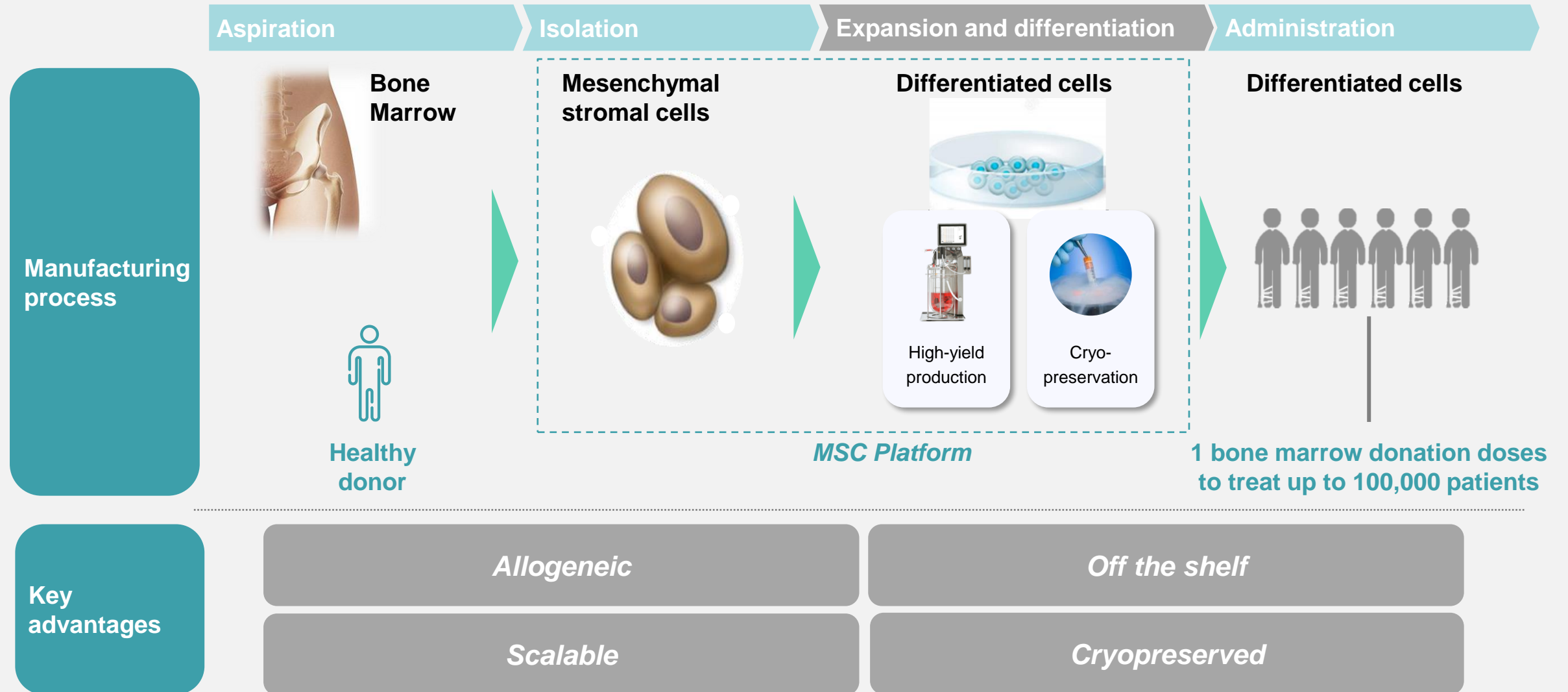
- Stefanos brings **more than 15 years of business development experience** in the pharma and biotech industry, specifically in the **cell and gene therapy space**
- Previously Senior Vice-President at **Cell Medica** (allogeneic T-cell immunotherapy), Chief Business Officer at **apceth GmbH**, (genetically-engineered mesenchymal stromal (MSC) cell products), Head of Business Development at the antisense RNA drug specialist **Antisense Pharma** (now **Isarna**), and Director Business Development at **Roche**. Stefanos also worked at **Lazard**.



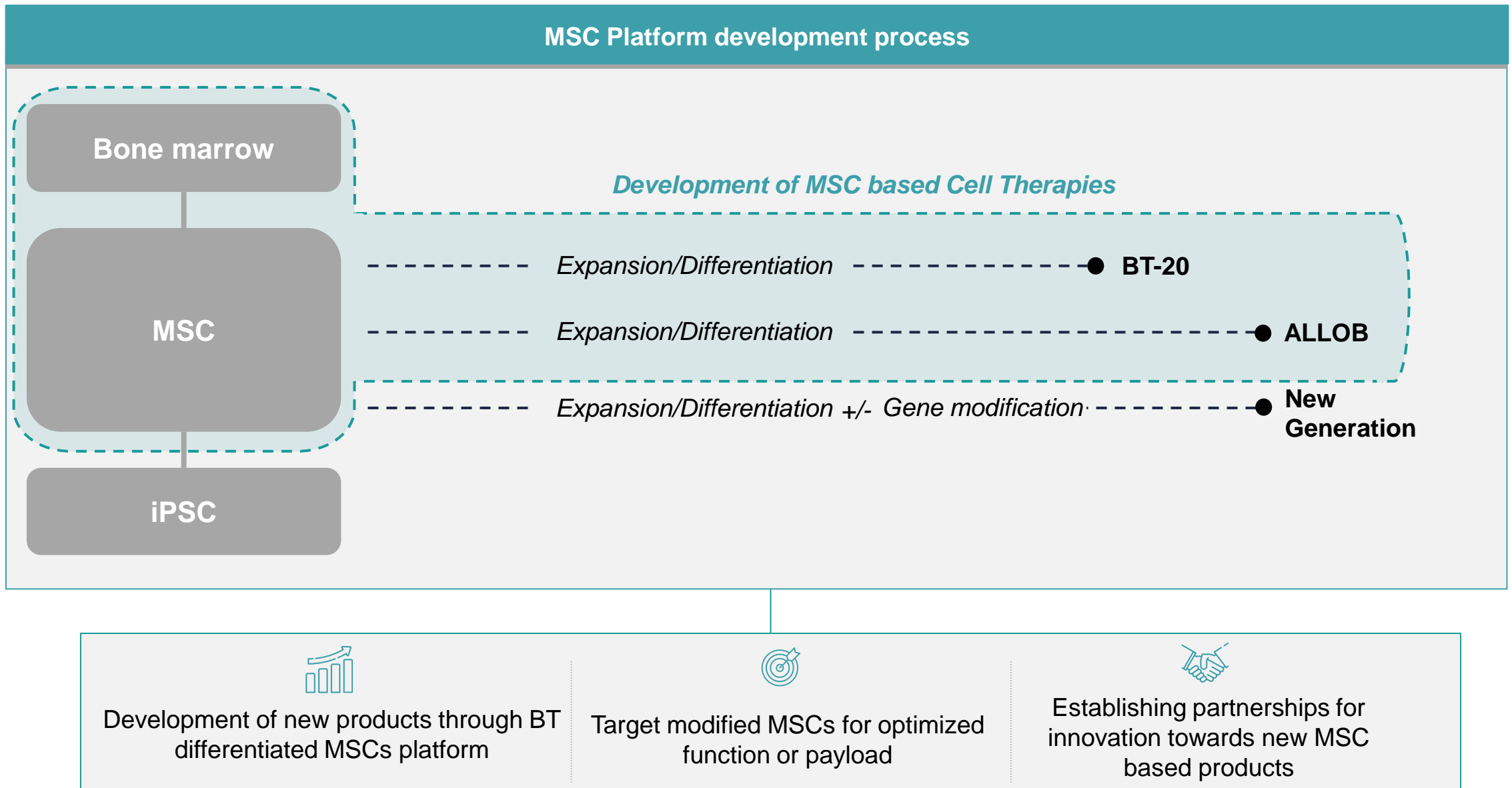


# Next Generation MSC

# Leveraging Bone Therapeutics platform of differentiated MSC platform into a broader range of conditions



# Multiple sources of MSC allow various developments





# BT-20 is an immunomodulatory MSC derived product



**Immunomodulatory** partially differentiated MSC Cell Therapy Product



Integrated in BT differentiated **MSC platform IP**



Amenable to **large scale production**



**Pre-clinical package** with safety data and immunomodulatory in progress



Performed **Scientific Advice with AFMPS** – Belgian Regulatory Competent Authority

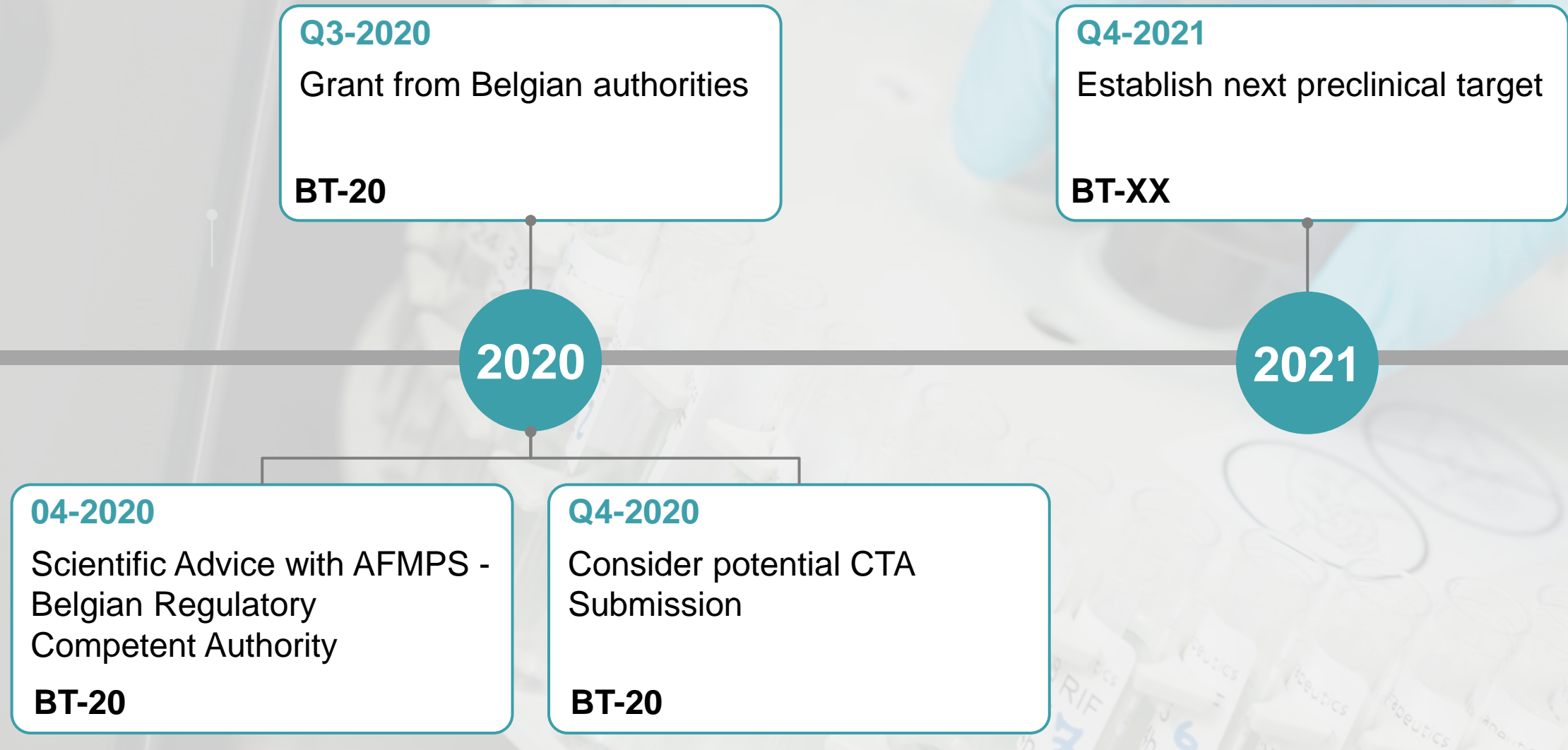


**Grant** from the Walloon Region for **pre-clinical research** and **Phase I clinical study**

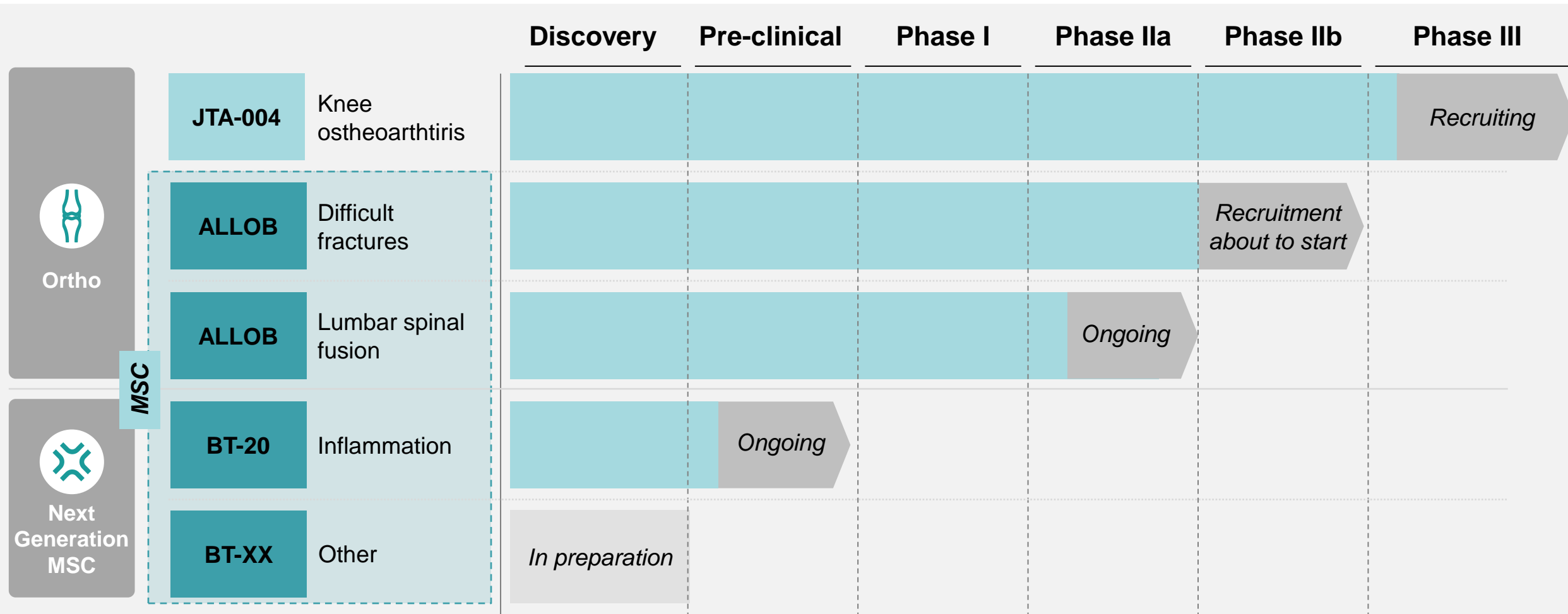


Product optimization **targeting broad ARDS** or **CTA submission** in view of emerging C-ARDS (Covid) associated unmet medical needs

# Recent developments and anticipated next steps for New Generation of MSC Therapies



# Balanced portfolio composed of products in late and early development stages



# Agenda

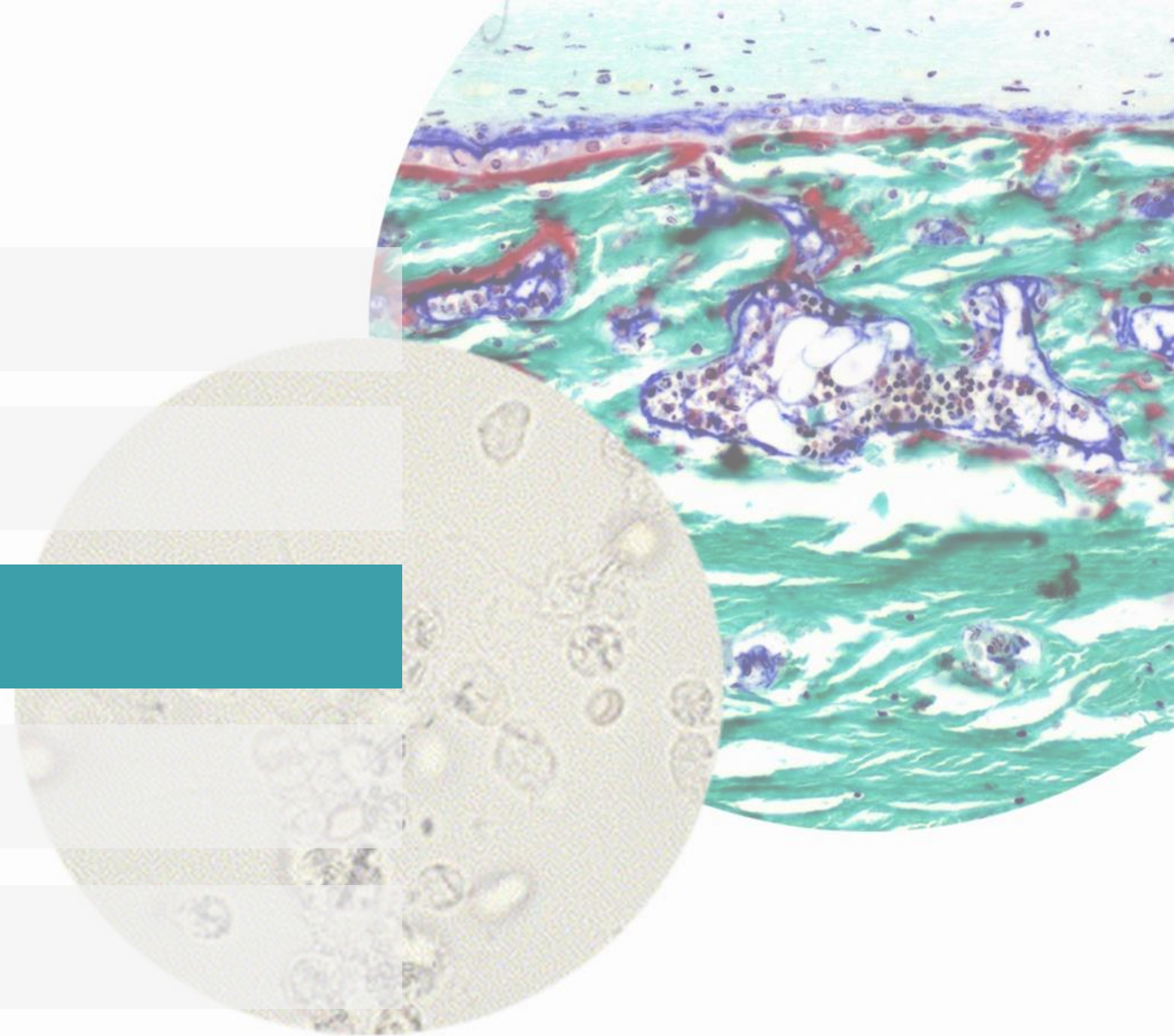
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# Key financial figures for the period ended 30 June 2019

## Key financial

- Net cash as of 30 June 2020: € 10.0M
- In Q2 2020, secured total committed value of € 15M in two successful funding operations to support clinical progress
- Anticipated net cash burn for FY2020: ~ € 15-16M (versus € 11.5M in 2019)
- Anticipated runway into Spring 2021
- Pre-commitment from existing shareholders to participate in the next fundraise planned in H2 2020
- Post period, awarded non-dilutive funding (RCA) and 2 grants from the Walloon Region to advance JTA-004 PhIII study and for research and initial preparatory steps towards clinical development of BT-20

(€ million)	H1 2020	H1 2019
<b>Operating income</b>	<b>1.04</b>	<b>1.68</b>
<b>Operating expenses</b>	<b>(10.13)</b>	<b>(7.12)</b>
R&D expenses	(8.53)	(5.47)
G&A expenses	(1.61)	(1.64)
<b>Operating result</b>	<b>(9.10)</b>	<b>(5.44)</b>
<b>Net result</b>	<b>(9.84)</b>	<b>(5.59)</b>
<b>Net cash flow</b>	<b>(1.41)</b>	<b>4.99</b>
Operating activities	(8.28)	(4.87)
Investing activities	(0.09)	(0.27)
Financing activities	9.78	10.12
<b>Net cash position (at end of period)</b>	<b>10.04</b>	<b>13.16</b>

# Agenda

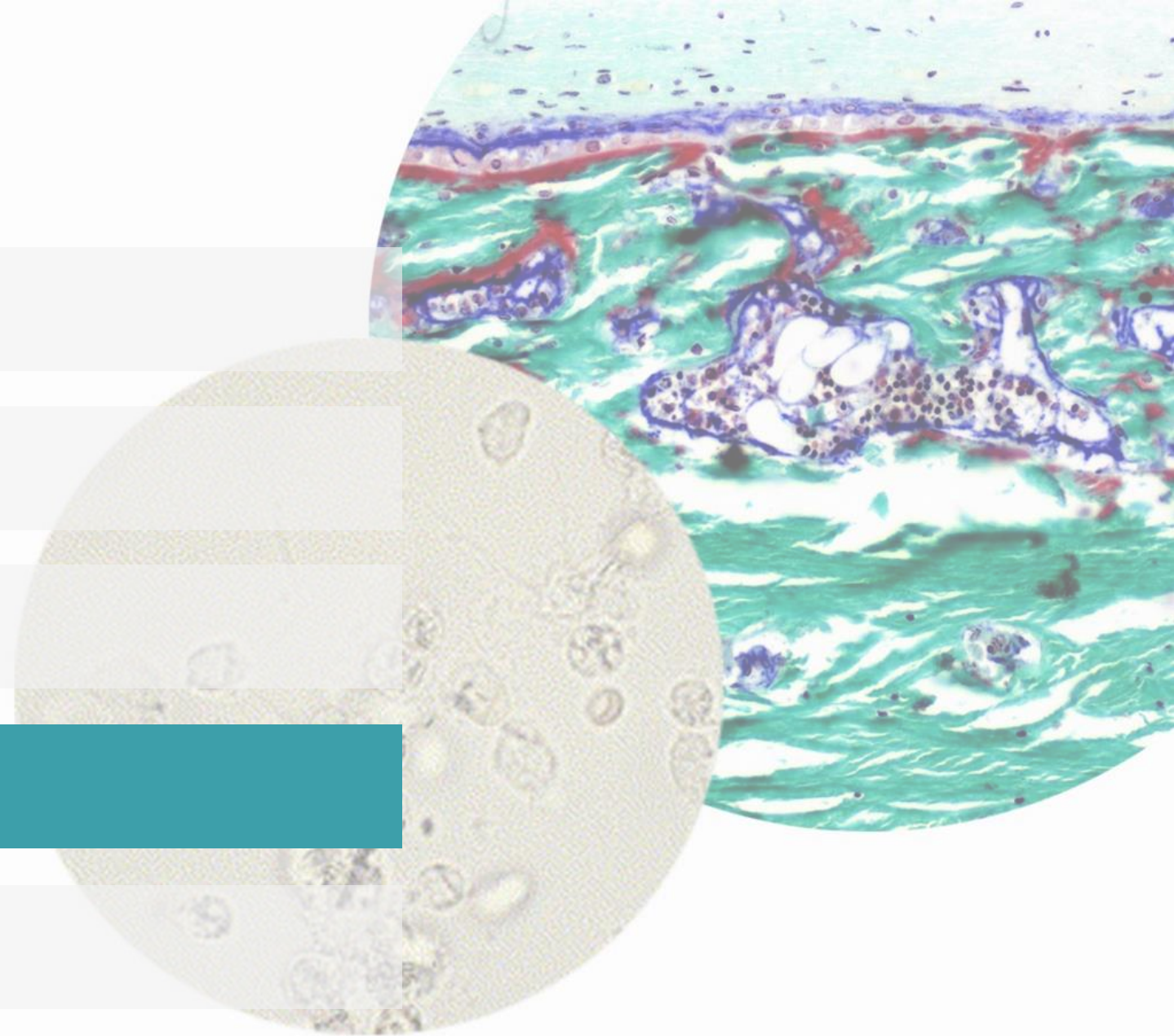
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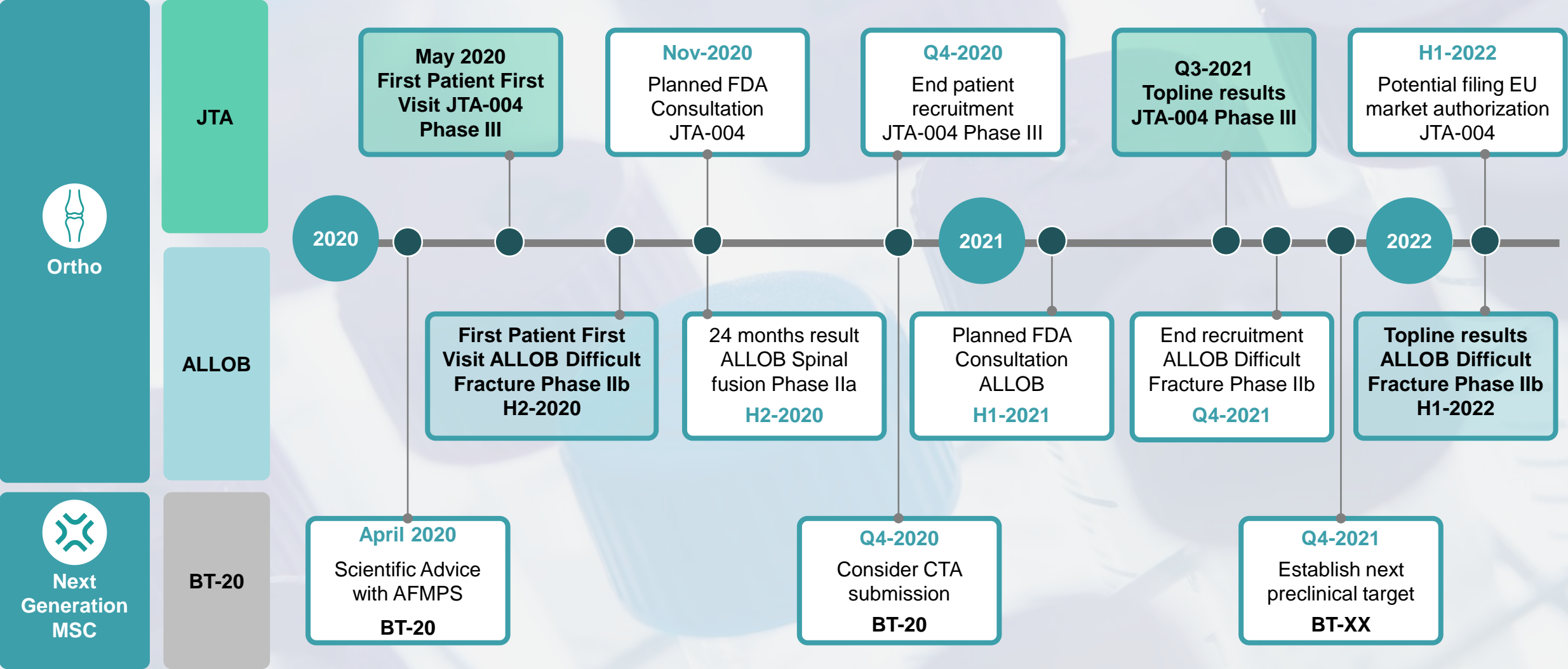
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# Overview of recent developments and anticipated next steps



# Summary



Focused on **execution of JTA Phase III** and **ALLOB Phase IIb** for clinical results in 2021 and 2022



Accelerating strategic discussions regarding the **commercialization of both our clinical assets** with potential business partners

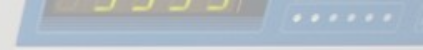


Leveraging the synergies of its allogeneic MSC platform to target a **broad range of additional conditions**





CONCENTRATION DATA			
NAME	CONC.	UNIT	REMARKS
1	100	µg/ml	Stock
2	10	µg/ml	Working
3	1	µg/ml	Working
4	0.1	µg/ml	Working
5	0.01	µg/ml	Working
6	0.001	µg/ml	Working
7	0.0001	µg/ml	Working
8	0.00001	µg/ml	Working
9	0.000001	µg/ml	Working
10	0.0000001	µg/ml	Working



Q&A