



# MABION S.A.

**Investor meeting  
November 2018**



## Financial results Q32018



# Main factors influencing Company's financial results and financial standing in the third quarter of 2018

- Lack of sales
- Receipt of filing milestone from Mylan
- Continued R&D works on MabionCD20 (closure of of clinical trials, preparing answers to EMA questions, scaling-up production process of MabionCD20 to 2500 L, preparing protocol for clinical trials for FDA purposes)
- Pre-clinical stage R&D works on MabionEGFR and MabionMS
- Development of workforce from 172 to 182 – growth mainly in production department
- Interest income on deposits
- Continued works on conceptual design of a new plant
- CAPEX financed mainly through leasing
- Foreign exchange gains due to strengthening zloty
- Increases in prices of electricity and gas

# The Company's financial results for first nine months of 2018 [PLN thousands]

	9 months 2018	9 months 2017
Sales of research and development services	0	0
Research and development costs	(35 039)	(30 759)
General and administrative expenses	(15 784)	(13 053)
Other operating income and expenses, net	2 130	1 603
Operating loss	(48 693)	(42 209)
Financial income and expenses, net	(3 593)	3 609
Loss before tax	(52 286)	(38 600)
Net loss	(52 286)	(38 600)
Loss per share [PLN]	(4)	(3)
Cash flow from operating activities, net	(32 726)	(44 517)
Cash flow from investing activities, net	(3 608)	(5 371)
Cash flow from financing activities, net	103 286	37 418
Net increase / (decrease) in cash and cash equivalents	66 952	(12 471)
	<b>30.09.2018</b>	<b>31.12.2017</b>
Total assets	154 261	82 445
Total liabilities	96 252	136 603
Non-current liabilities	32 881	16 233
Current liabilities	63 371	120 370
Equity	58 009	(54 158)
Share capital	1 372	1 180
Book value per share [PLN]	13.74	6.99

## Sources of financing during next 12 months

Management assumes that the Company's activities will be financed during next 12 months from the following funds:

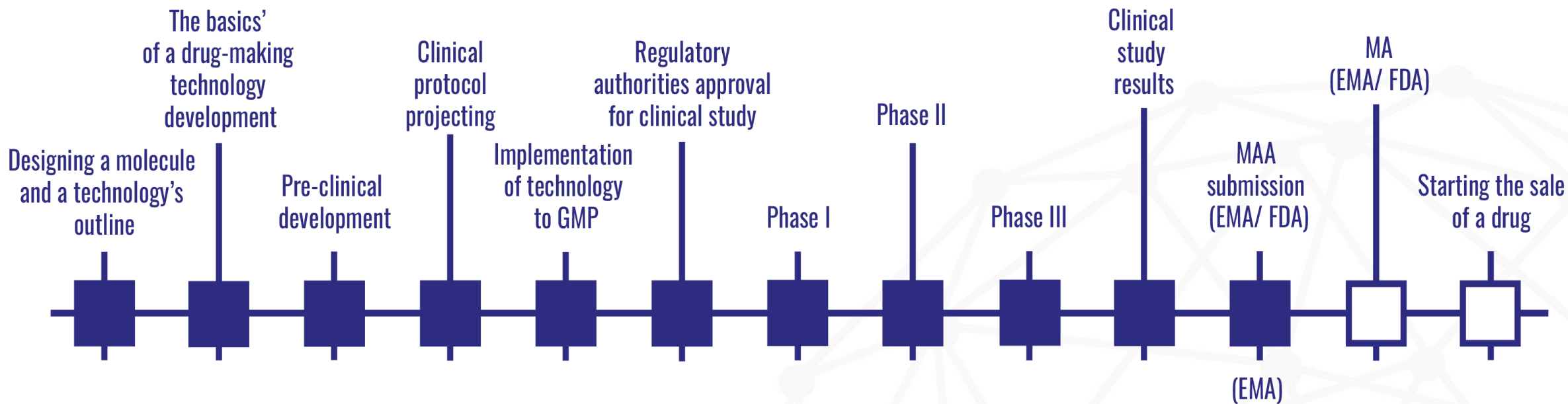
- Own funds (ca. PLN 58 million as of today)
- Subsidies from EU-financed projects (Szybka ścieżka, InnoNeuroPharm, CBR)
- Milestone payments from new distribution partners for MabionCD20 on markets, that are not signed yet
- Leasing
- Long-term investment loan



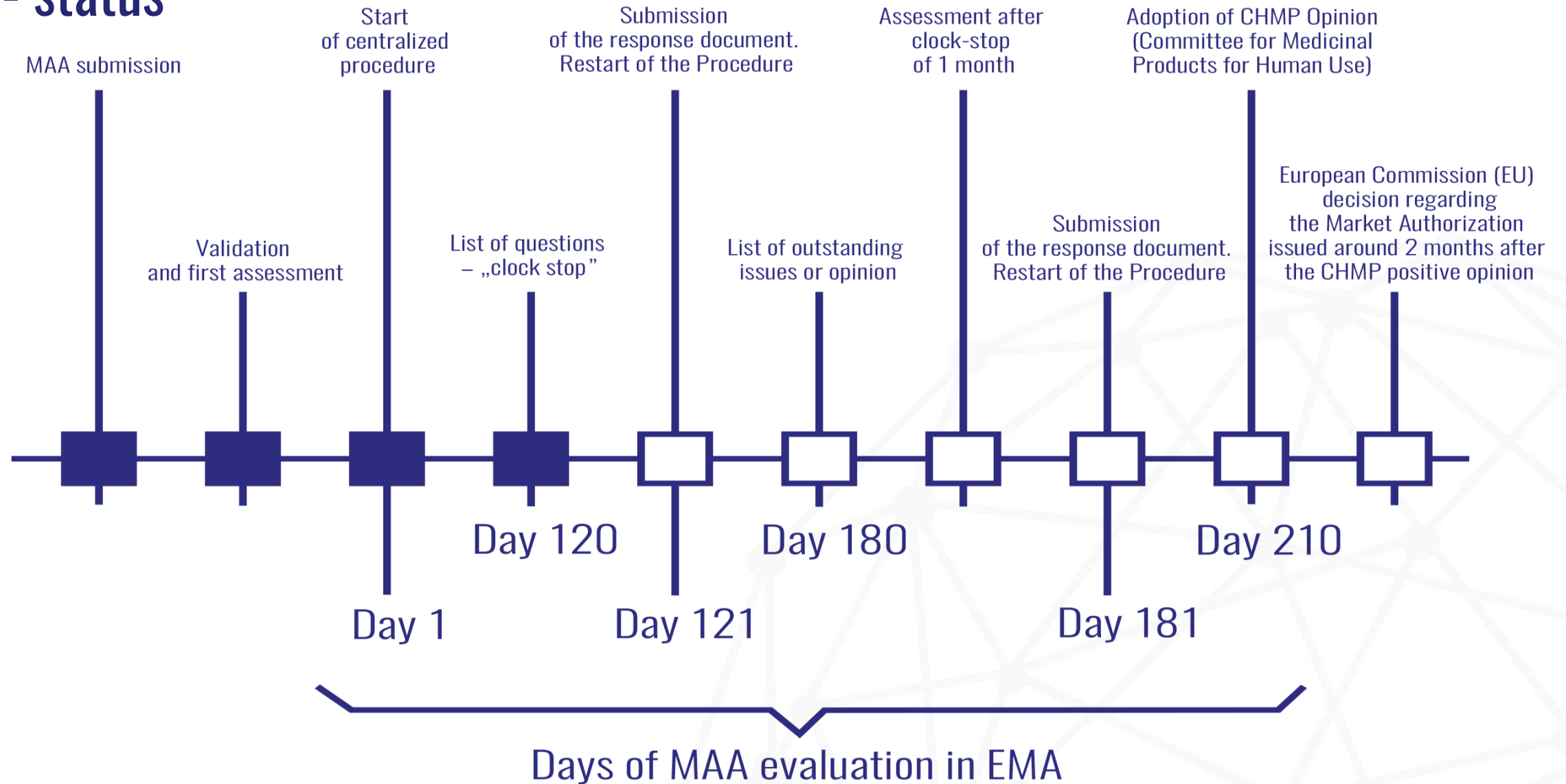
EMA - MAA



# MabionCD20 - project progress

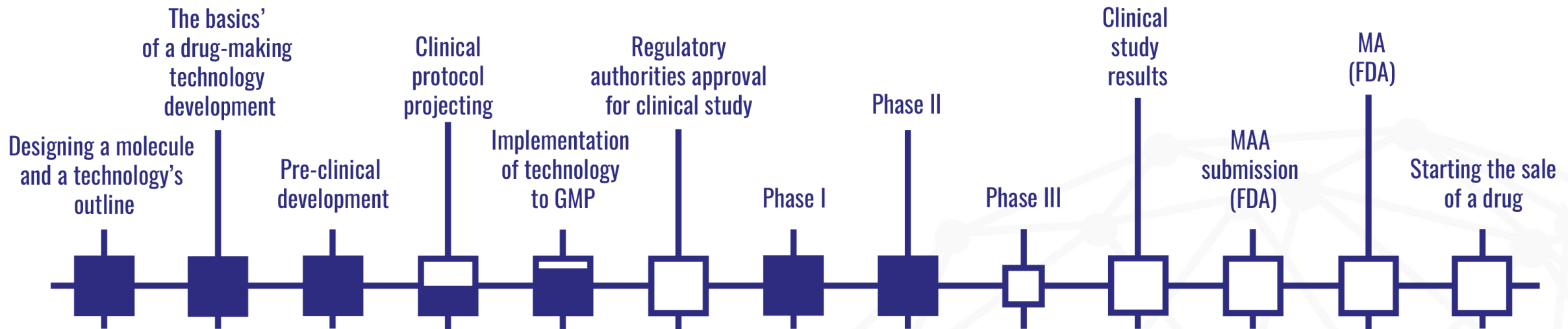


# EMA - status





# FDA - strategy





# Competition



- **Celltrion** - have already introduced the drug on the market in the EU and submitted supplemented registration documentation in the US
- **Sandoz** - strategic withdrawal with Rituximab biosimilar from US market

## What does it mean for Mabion?

Submission of documentation to the FDA is still one of the most important strategic goals for Mabion S.A.

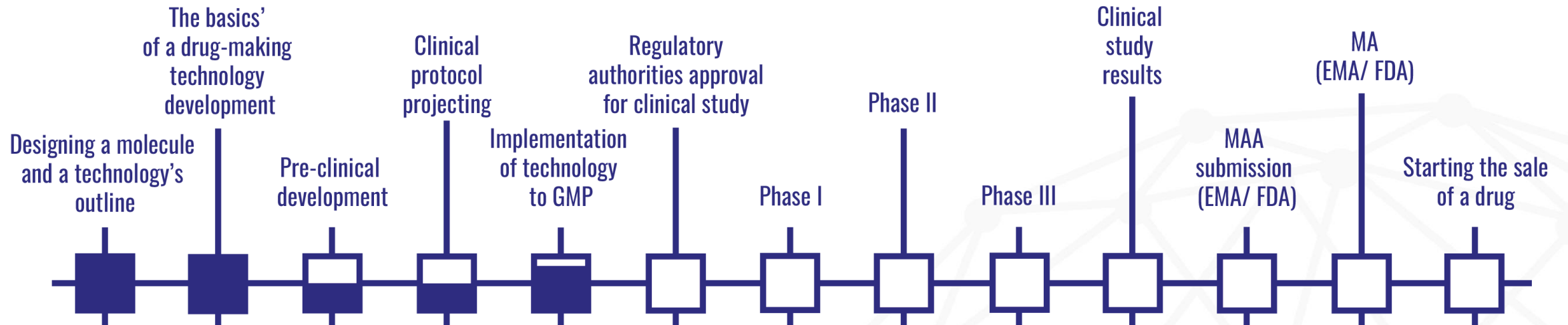


# MabionCD20 in Multiple Sclerosis

A new, yet validated application for Rituxan/MabThera



# Mabion MS - project status



- **Combination Therapy of Multiple Sclerosis comprising a CD20 Ligand**  
application number EP17461640.9, submission date: 05.12.2017
  - **Low aggregate anti CD20 ligand formulation**  
application number EP18461619,1 submission date: 26.10.2018



## MabionEGFR Biosimilar to Erbitux (cetuximab)



## Current Erbitux (cetuximab) Market<sup>(1)</sup>

- Global sales of Erbitux were ~US\$ 1.6B globally in 2017 (Lilly in US and Merck KGaA ex-US)
- Cetuximab is a chimeric antibody with a high barrier due to glycosylation site characteristics
- Despite the loss of patent protection in 2014 (Europe) and 2016 (US), no cetuximab biosimilars have been launched in any market
- Mabion is not aware of any active pivotal biosimilar studies for cetuximab in major markets
  - Celltrion (CT-P15) and Amgen/Allergan (ABP 494) reference pipeline cetuximab biosimilars
- Mabion has a US\$ 8M grant to support Mabion EGFR clinical development over five years



## Manufacturing Capability

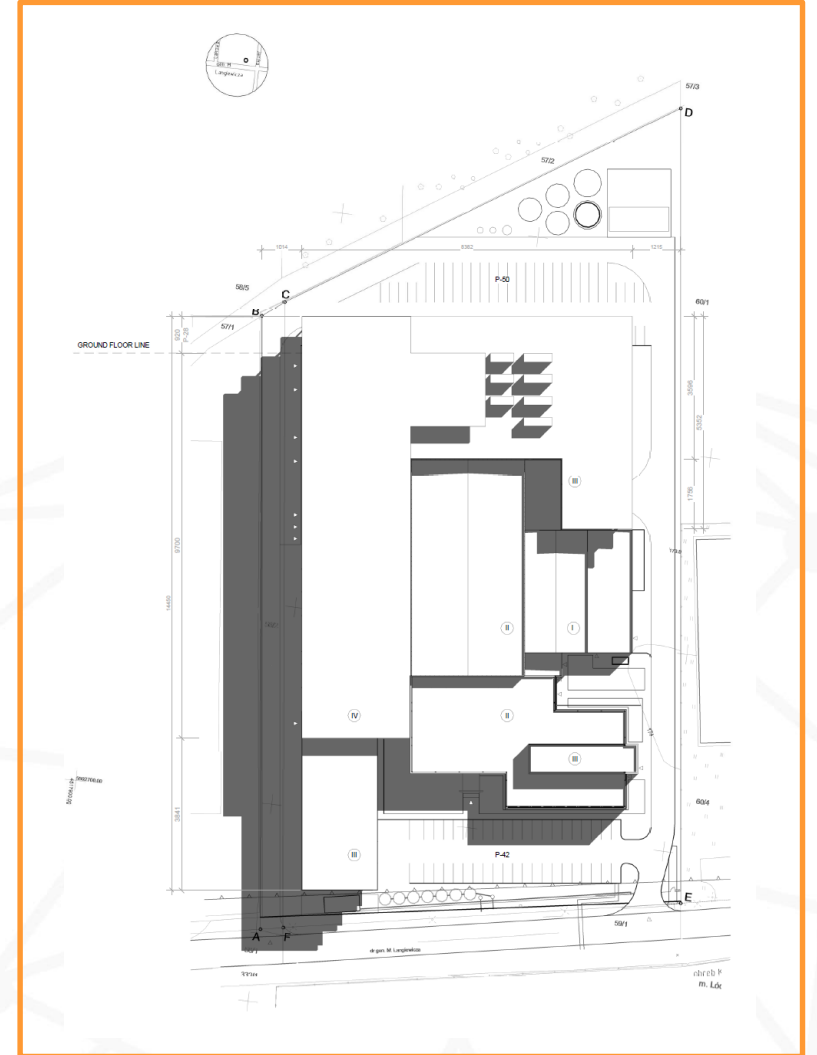




# Planned Expansion – Stage 2

## Stage 2: Investing in new manufacturing building

- Purpose: Fully support US commercialization of MabionCD20 as a biosimilar, potential MabionCD20 MS commercialization and commercialization of future biosimilar assets
- Facility to house up to 12 2,500L bioreactors









# MABION S.A.

Q&A