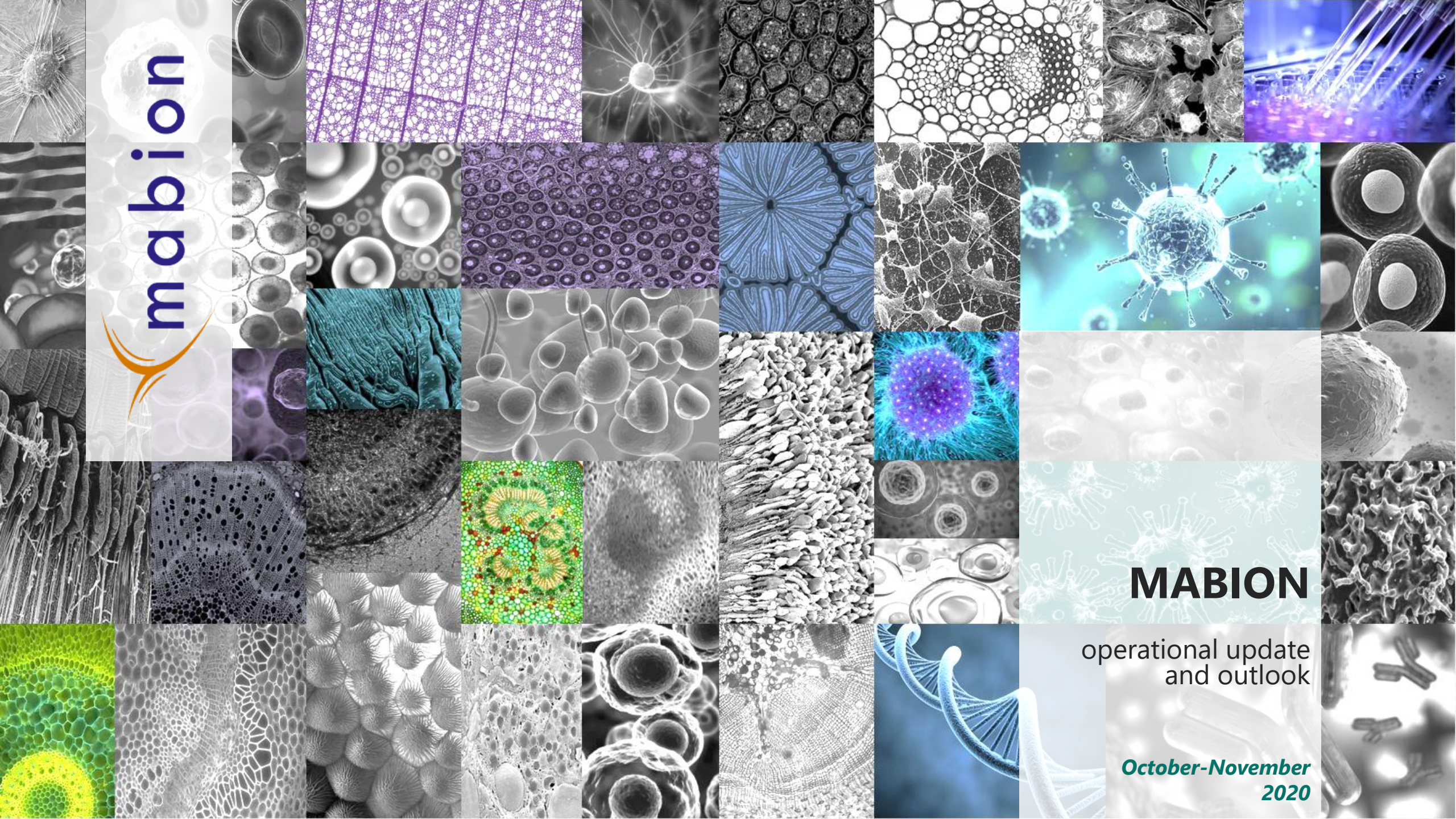
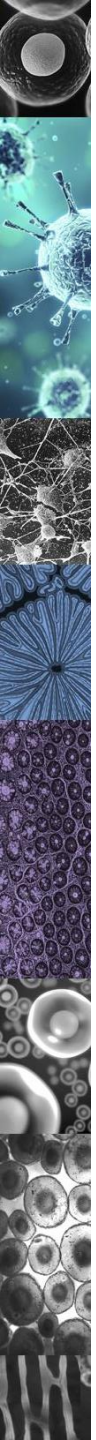


MABION

operational update
and outlook

October-November 2020



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CEO
President of the MB

Sławomir Jaros, PhD, MBA
CSO, COO
Member of the MB

Grzegorz Grabowicz, MBA
CFO
Member of the MB

Adam Pietruszkiewicz
Member of the Supervisory Board delegated to perform duties as Member of the MB

MABION AS INTEGRATED BIOPHARMACEUTICAL COMPANY WITH A GROWING AND DIVERSIFIED PORTFOLIO BASED ON SOPHISTICATED COMPETENCIES IN BIOLOGICAL DRUGS

research & development
(up & downstream, up-scale & characteristics, analytics, validation, comparability, similarity)

manufacturing
GMP-certified facility

mabion

clinical development
(analytics, sample logistics, immunometric assays)

regulatory
(dossier preparation, application filing, regulatory review and sample exam, scientific review)

biosimilars & ethical pharmaceuticals

- **CD20 in NHL and RA**
- **other biosimilars in development**
- **CD20 orphan drug program**

COVID-19 response projects

- antibody COVID-19 therapeutic
- recombinant protein-based vaccine

partnering

Mylan
agreement signed for the EU

Taxon Therapeutics
memo of understanding signed

Icano MAB
letter of intent signed

vaxine
memo of understanding signed

MABION'S DIVERSIFIED R&D PORTFOLIO

molecule/drug	clinical indication	characteristics	status	commercialization approach	partner
rituximab (MabionCD20)	oncology (NHL) and autoimmunology (RA)	biosimilar drug in approved therapies	registration phase in the EU and clinical phase I in the US	partnered for the EU	Mylan *United Kingdom*
rituximab (MabionMS)	CNS disease (MS)	innovative therapy	product ready for preclinical and clinical phase	active business development	Available for partnering
cetuximab (MabionEGFR)	oncology (CRC and squamous cell carcinoma in the head and neck)	biosimilar drug in approved therapies	optimization of the cell line	pre-commercialization stage	Available for partnering
denosumab, omalizumab	autoimmunity, metabolic diseases and oncology	biosimilar drug in approved therapies	active development of the respective cell lines	pre-commercialization stage	Potential partners identified
rituximab (MabionCD20)	orphan diseases (autoimmunology)	innovative therapies	product ready for clinical phase	MoU signed	Taxon Therapeutics *Israel*
vaccine	COVID-19	innovative therapy	Material Transfer Agreement signed	MoU signed	vaxine *Australia*
IL-1R7 mAb	COVID-19	innovative therapy	preparing for initiation of technology transfer	Letter of Intent signed	Icano MAB *Germany*

Our foundation towards EMA and FDA registration: developing relationship with Agencies by frequent regulatory consultations and harmonization of FDA and EMA recommendations

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Paul-Ehrlich-Institut

- ✓ 4 departments and key personnel involved
- ✓ numerous analytical laboratory studies performed
- ✓ professional consultancy firms involved (different areas of expertise)

EU regulators interactions outcomes/requests:

- ✓ **MabionCD20 analytical approach confirmed by EMA/German Agency – addressing the afucosylation question**
- ✓ **Analytical comparison between MabionCD20 from clinical-scale with commercial-scale product**
- ✓ **Bridging PK study design endorsed**
- ✓ Full-scale process introduced and reviewed

EMA Scientific Advice Response (CMC, clinical)

German Agency (PEI) meeting (CMC, clinical)

January *February* *March* *April* *May* *June* *July* *August* *September* *October* *November* *December*

2020 **2021**

FDA BPD Meeting Type III (CMC, clinical)

FDA BPD Meeting Type II (clinical)

Submission of briefing materials for 2021 FDA BPD Meeting Type II (clinical, regulatory)

U.S. FOOD & DRUG ADMINISTRATION

FDA interactions outcomes:

- ✓ **Following FDA review, no questions were raised regarding afucosylation**
- ✓ A few different registration avenues are available for the US market, including a possible early market entry
- ✓ **Upcoming clinical trial data can be used for any of these registration scenarios**
- ✓ **Analytical comparison between MabionCD20 from clinical scale with commercial-scale product**
- ✓ In case of early entry, additional data required for approval in all Rituxan label indications

MABION „BACK ON TRACK" WITH MABIONCD20 TO ENTER VERY ATTRACTIVE MARKETS

MabionCD20 – making further crucial steps towards registration, in line with plan outlined in July 2020

- signed agreement with a top global CRO for the clinical bridging study in RA (necessary for the EU registration and first key step in the US registration)
- details of the study continuously discussed and agreed with regulators
- initial proposal of the regulatory strategy as well as the scope of required data for the US market acknowledged by the FDA
- full–scale process validation completed
- promising data from the stability, analytical similarity and comparability studies proving high quality of the commercial-scale MabionCD20 product

Large and attractive EU and US market

- The current total worldwide annual value of the rituximab market including biosimilars is EUR 6.5 bn, of which **EUR 4.7 bn** is the market for the combined **NHL and RA indications**. The EU and the US markets account for **80%** of the global market.
- Rituximab biosimilars are expected to grow at a **CAGR of 10% from 2020 to 2024** in the NHL and RA indications, taking share from the reference products Mabthera/Rituxan

TOP-NOTCH CRO CONTRACTED TO SUPPORT HIGH-QUALITY DATA GENERATION

contract research organization	parexel
preparatory tasks	**4Q 2020 – 2Q 2021**
est date of CTA filings	**1Q 2021**
clinical indication	**rheumatoid arthritis**
first patient dosed	**2Q 2021**
est date of the final report	**mid 2022**
target population	**210 (ca 70 per arm)**
endpoints	**PK (primary), Efficacy (secondary)**
countries	**5**
no of sites	**27**
CRO contract value	**ca 25 mPLN**

Phase 1/2 trial to demonstrate the biosimilarity between MabionCD20 and comparators: MabThera (EU reference product) and Rituxan (US reference product) – clinical „bridging" study

estimated duration of the clinical trial discussed with Parexel and taking into account market conditions

DEVELOPMENT OF THE FULL-SCALE PROCESS IN LINE WITH THE PREVIOUSLY COMMUNICATED PLAN

1. **validation of manufacturing process** ☑ **validation completed**

   confirming that it is feasible to repeatedly achieve the required quality of the product by using defined process control parameters

2. **stability study** ☑ **Started / in process**

   controlling natural differences in structure of the biological product and potential undesired immunogenicity due to impact of physical conditions (particularly temperature influencing time and storage method)

3. **analytical similarity and comparability assessment** ☑ **Started / in process**

   in vitro assays aimed at comparing biological and physicochemical attributes of biosimilar and reference drug through statistical analysis of results based on qualified analytical methods with verified sensitivity. Analytical similarity assessment involves identification of critical quality attributes (CQAs) that are relevant to clinical outcomes.

these studies are conducted in parallel with the clinical PK study (therefore not on the critical path)

THOROUGH EXECUTION OF THE PREVIOUSLY COMMUNICATED PLAN

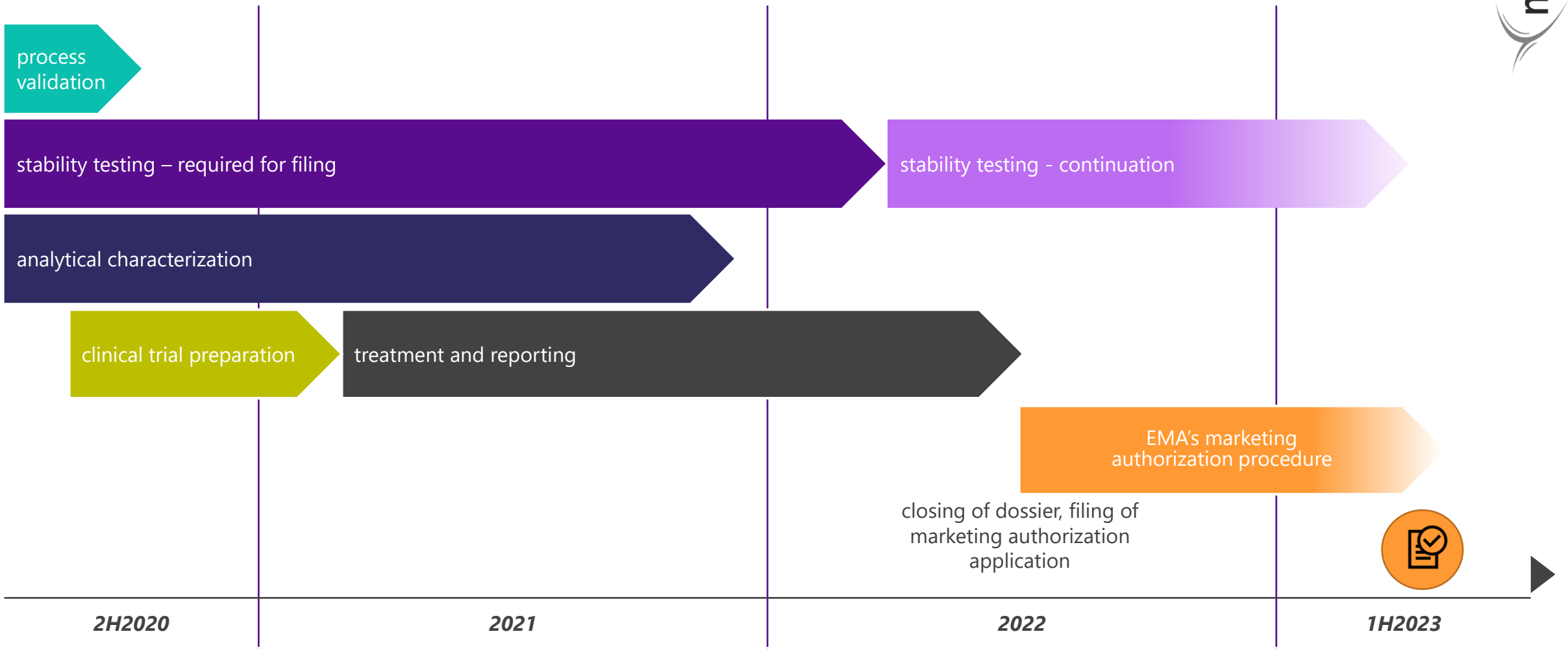
accomplished

- ☑ scientific advice procedures completed for the EU
- ☑ full-scale validation completed
- ☑ clinical PK study protocol finalized
- ☑ application for public grant submitted
- ☑ stability study started
- ☑ analytical characterization started
- ☑ agreement with CRO signed

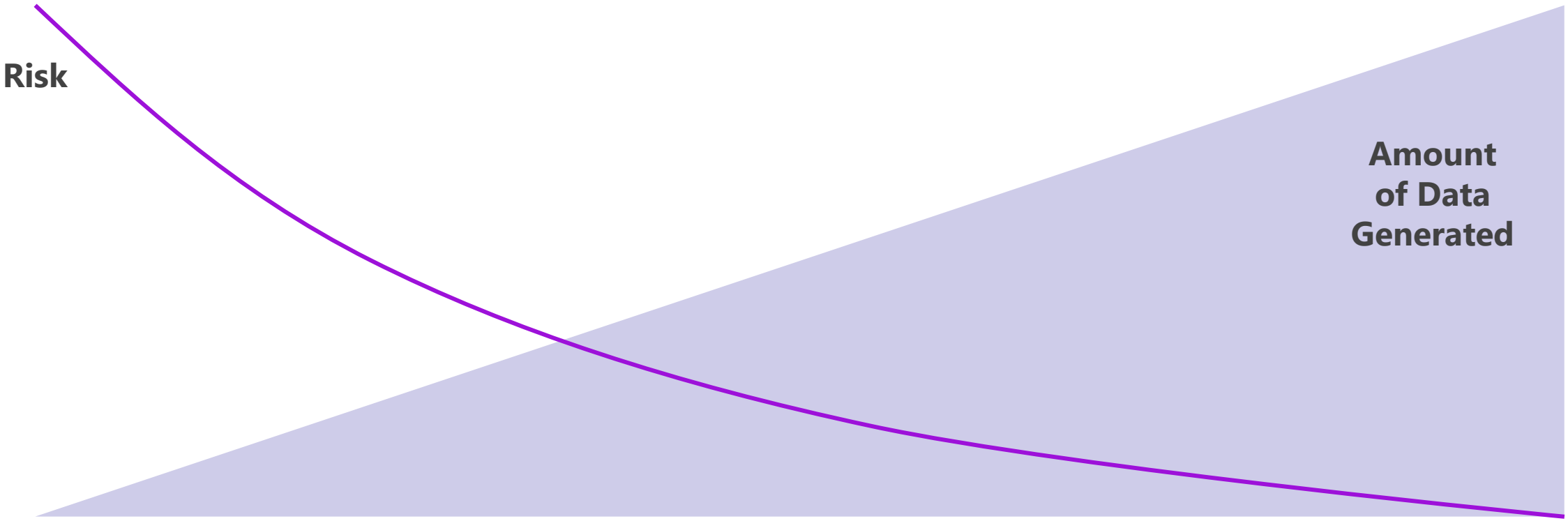
near-term activities

- ☐ filing clinical trial application
- ☐ commencing clinical PK study

ASSUMED TIMELINE OF THE CD20 FULL-SCALE APPLICATION PROCESS IN EMA



MABIONCD20: AS DATA IS GENERATED, THE LIKELIHOOD OF SUCCESS IS INCREASING



Cell line development	Clone selection	Initial characteriza-tion	Establishment of in-vitro models and assays	Preclinical	Phase I BE study	Phase III study	Submission and Regulatory Review	Additional data generation	Resubmission, Review and Approval
☑	☑	☑	☑	☑	☑	☑	☑	WORK IN PROGRESS	

advancement in biosimilar development

REGULAR ONGOING COLLABORATION WITH MYLAN

- Uninterrupted and engaged day-to-day **collaboration**
- Dedicated **Mylan teams** from several countries are engaged in several workstreams in the Mabion-Mylan cooperation
- **Mylan is actively contributing** to frequent interactions with regulators, working hand-in-hand with Mabion
- Continued preparations for the **planned launch** of **MabionCD20**
- Contractually-defined **Joint Steering Committee (JSC)** ensuring communication of the partners on a top Management level

ROBUST LONG-TERM PROSPECTS FOR THE RITUXIMAB

L.E.K. L.E.K. Consulting

mabion

- Key findings from the L.E.K. Consulting report
  - Rituximab is a well-established molecule with volumes forecast to remain stable; biosimilars are expected to continue to take share from the reference products Mabthera/Rituxan
  - **Total rituximab** molecule **market** value is estimated at ca **6.5bn EUR** in 2020, whereas the EU and U.S. rituximab **market in NHL and RA** accounts for ca **3.8bn EUR**
  - **Rituximab** molecule volumes have remained stable over 2017-20F with biosimilars **capturing** between app. **72-93%** of the total volumes **in the EU** and app. **30% in the U.S.**
  - U.S. and EU rituximab biosimilar market value in NHL and RA is expected to grow at a CAGR of **10% between 2020 and 2024**

Existing Capabilities and Capacity Allow Mabion to Extend its Pipeline

Mabion has started to initiate new projects leveraging its assets, based on a solid foundation of strong competencies,

- Complementary projects **do not affect the core activities**
- **Financed from independent sources**, obtaining targeted financing is a sine qua non for advancing and accelerating the new projects
- Mabion's established manufacturing technology can be quickly and cost-effectively adapted to new projects, with reduced risk of contamination through the use of **disposable technology**
- Existing and additional agreements in negotiation with **international partners** confirm the **attractiveness of the company's assets on a global market**, of both commercial-scale MabionCD20 as well as capabilities, location, and assets
- **New portfolio management strategy** allows for **better asset utilization** and will translate into applying the company's manufacturing capacity even before the market authorization of MabionCD20

team of dedicated and experienced employees with solid and long-term know how

high-quality and certified assets: laboratory (GLP) and manufacturing facility (GMP) located centrally in the EU, including access to an attractive plot of land for expansion in a special economic zone

proprietary technology enabling high productivity and cost-effectiveness translating into cost advantage

CD20 ORPHAN DRUG PROGRAM

Mabion's collaboration with a biopharmaceutical company focused on the development and commercialization of pharmaceuticals for rare diseases with unmet needs offers additional attractive opportunities for the commercialization of MabionCD20.

Orphan diseases - key characteristics

- **Definition** – disease that affects fewer than **200k patients in the US** (<6.37 in 10k, based on the US population of 314m), in the **EU app. 250k patients** (less than 5 patients in 10k, based on EU population of 514m)
- **Marketing Incentives** - **7-10 years of market exclusivity** for for the product, Tax credits, R&D grants, public funding
- **Regulatory Fast-track -** Fast track in EMA / FDA, relatively high success rate at each phase, shorter time-to-market
- **Market Potential** - Average cost per patient per year of an orphan drug was **$147k vs $30k for a non-orphan drug** in 2017; 30m people in the US, 30m people in Europe and approx. 350m people worldwide suffer from rare diseases

Taxon Therapeutics collaboration – key facts

- **MoU** - an intent to develop the terms of potential long-term collaboration in scope of research, development, and subsequent global commercialization of the medicinal products **based on MabionCD20** in certain clinical indications, in particular rare diseases
- **Potential commitment** - Mabion will contribute its assets in form of the CD20 antibody production technology, quality and regulatory documentation, as well as the (existing) medicinal product for clinical trials, **Mabion will be the sole manufacturer, in scope of commercialization**.
- **Next steps –** agreement on contractual terms and execution of the agreement

Taxon's internal expertise and know-how in regulatory affairs will expedite product approval

Taxon Therapeutics will seek new indications for the use of MabionCD20 and conduct clinical trials

Collaboration shall benefit from the advanced status of Mabion CD20:
- developed process, analytical methods developed and validated
- availability of equipment, technology and know-how
- Mabion's team familiar with the product

→ Attractive opportunity requiring minimal investment by Mabion!

COVID-19 OPPORTUNITIES – VACCINE

Vaxine project	
Partner	Vaxine is an Australian biotechnology company focused on the development of innovative vaccines against seasonal and pandemic viruses. Vaxine develops vaccine based on recombinant protein (unlike competitors based on mRNA, DNA, inactivated virus etc.) utilizing an insect cell-based recombinant spike protein in combination with its proprietary Advax™ adjuvant.
Mabion's role	Use of the company's competencies in the field of protein engineering as well as GMP-certified production facility. Mabion will manufacture and commercialize the vaccine for the agreed markets once approved.
Current status	Signed MoU extended until November 30, 2020. Parties have entered into an agreement which governs the transfer of materials from Vaxine to Mabion to conduct training at Mabion laboratories as well as exploratory studies with recombinant SARS-CoV-2 spike protein (vaccine antigen). Collaboration ongoing.
Next steps	Securing funding for the project from several different governmental institutions at the European Commission level as well as individual member states. Agreements to be closed on development, production, and commercialization. After positive Ph1 results - next phases of clinical trials to be conducted.

COVID-19 OPPORTUNITIES – THERAPEUTIC ANTIBODY

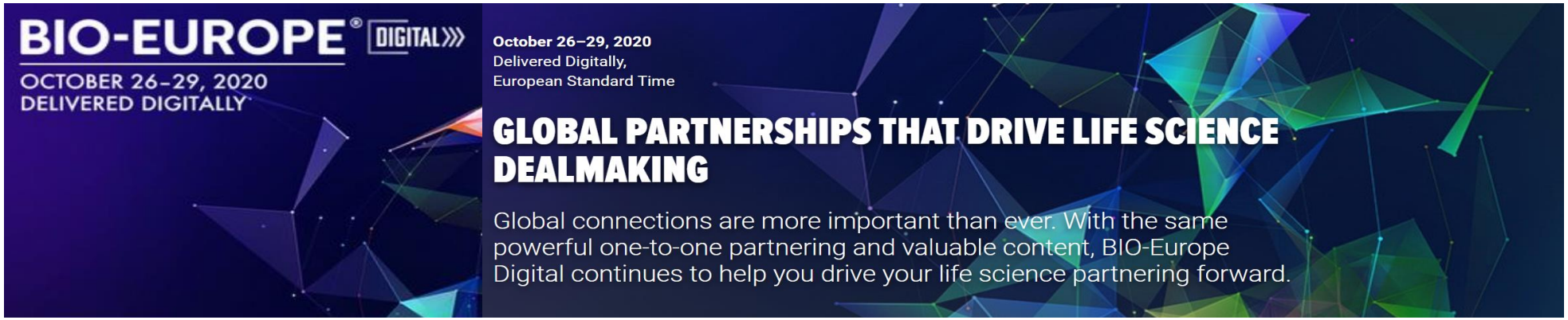
IcanoMAB project

Partner	IcanoMAB is a private biotech company headquartered in Germany focusing on the pre-clinical stages and development of antibodies for the treatment of cancer, immune-system and inflammation-related-diseases including COVID-19. The company is developing its proprietary clinical candidates to use novel approaches for improving clinical outcomes in immuno-oncology, solid tumors and immunology and inflammation.
Mabion's role	Possible collaboration in the areas of Chemistry, Manufacturing and Controls (CMC) and process development work as well as GMP production of the human IL-1R7 Antibody developed by IcanoMAB. The proposed product is being developed as a potential treatment in oncology, immune-modulation (incl. the so-called cytokine storm, one of the most serious complications of COVID-19)
Current status	Signed Letter of Intent valid until 31 March 2021
Next steps	Definitive agreement to be worked out, including agreement on the financial conditions of the collaboration of the parties; The agreement is to be concluded by 31 March 2021, with the provision that the agreement and collaboration will enter into force in the event and after the partners have secured additional financing for the development program related to the product.

Mabion's business development activities at bio-Europe 2020

- 2020 business development activities:
  - supported by Plexus Ventures
  - two dozen meetings with potential customers and partners
  - several follow up meetings scheduled, and NDA's closed
  - collaboration with "PolishBiotech" sponsored by Polish Ministry of Economic Development

- **BIOEurope 2020** (one of the world's most prominent partnering events in the life science industry)
  - numerous meetings with big pharma and biotech representatives
  - meetings on MabionCD20, other biosimilar assets, and Mabion's capabilities (CDMO business)



CASH FLOW OUTLINE FOR THE UPCOMING PERIODS UNTIL EXPECTED MARKET AUTHORIZATION BY EMA

	activities (estimated needs)		2H 2020	1H 2021	2H 2021	1H 2022	2H 2022	2023
MabionCD20	- R&D (clinical development, stability, analytical similarity, comparability assessment) (70% of indicated amount) - maintenance & manufacturing - quality assurance & quality control & regulation	max 75-85 mPLN (with savings potental)	proportionally					
MabionCD20	manufacturing capacity CAPEX (not including Mabion II, tbd)	35 mPLN		20			15	
	OPEX	annual average from the previous periods	proportionally					

sources (estimated inflow and time)

secondary public offering	50 mPLN +
founders' loans (upon written request)	15 mPLN + 15 mPLN + ...
public grants (awarded and potential)	application for public grant submitted
EIB loan - open talks	up to ca 135 mPLN in tranches

- estimated expenditure related to the clinical trial will amount to 5,4 mEUR (ca 25 mPLN) – included in the 75-85 mPLN amount presented above, which potentially can be further optimized
- additional projects (orphan drugs and COVID-19 response) to be financed independently from the current balance sheet and will be pursued once funding is secured and could bring in additional revenues prior to MabionCD20 authorization and market launch
- additional sources of funding being explored including
  - partnering options - including commercialization of MabionCD20 in the US market and
  - various strategic options

FOUNDERS CONTINUE TO STRONGLY SUPPORT THE BUSINESS, CONFIRMED WITH INCREASING FINANCIAL INVOLVEMENT

- **As previously declared (in March'20) Founding Fathers strongly support Mabion with additional funding, having deep faith in Mabion's fundamental value and near-term value growth potential**

- July 2020 Glatton sp. z o.o. refinanced Mabion's 15m PLN banking loan from Santander

- August 2020 Mabion entered into loan agreements with Glatton sp. z o.o. and Twiti Investments Ltd. up to the amount of 15m PLN
  - the loan is distributed to Mabion in tranches upon the written request from the Company
  - based on the agreements the Lenders disbursed ca 10 mPLN to the Company until 30th October 2020

- **Glatton sp. z o.o., Twiti Investments Ltd. and Polfarmex S.A. declare further support for the Company and are also involved in several strategic initiatives targeting strengthening of the Company's capital structure**

MABION TRANSFORMING INTO A FULLY-FLEDGED INTEGRATED BIOPHARMACEUTICAL COMPANY UNLEASHING ADDITIONAL GROWTH POTENTIAL

- Mabion is transforming from a one-product biotech company into a fully integrated biopharmaceutical company with an expanding portfolio
- MabionCD20 project is on track for submission and market authorization for the EU market
- Rituximab market growth potential and market structure quickly developing towards higher share of biosimilars – the L.E.K. study shows that a new entrant to the market in 2023 could capture a mid-teens market share
- New projects (potential use of CD20 in orphan diseases, potential anti-COVID-19 vaccine and development of an antibody as potential therapy in COVID-19) poised to improve utilization of resources while MabionCD20 is moving forward
- Highly attractive company valuation - Mabion is soon to be executing a share issue

VALUE FUNDAMENTALS OF MABION

PLNm

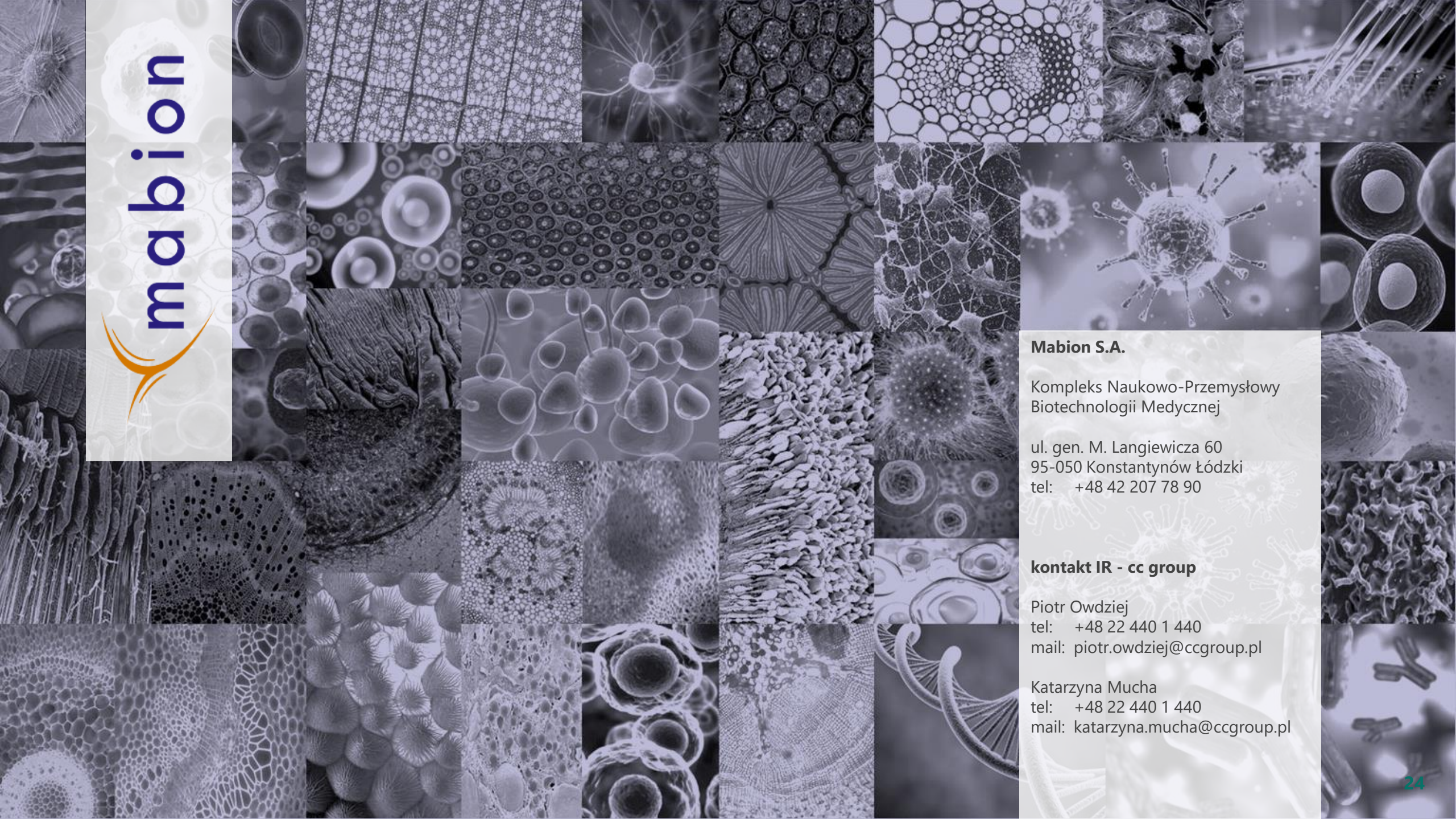
high-quality certified assets: laboratory (GLP) and manufacturing facility (GMP) located in the EU

proprietary technologies enabling high productivity and cost-effectiveness translating into cost advantage

team of dedicated and seasoned employees with extensive know-how

critical competences in bioengineering and manufacturing allowing broadening of R&D portfolio in additional markets

MabionCD20 asset moving towards marketing authorization



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