
Enabling a Healthier World



Lonza

Leveraging a novel flexible facility concept to provide solutions to current and future manufacturing challenges

Charles Christy - Lonza | 19 July 2022

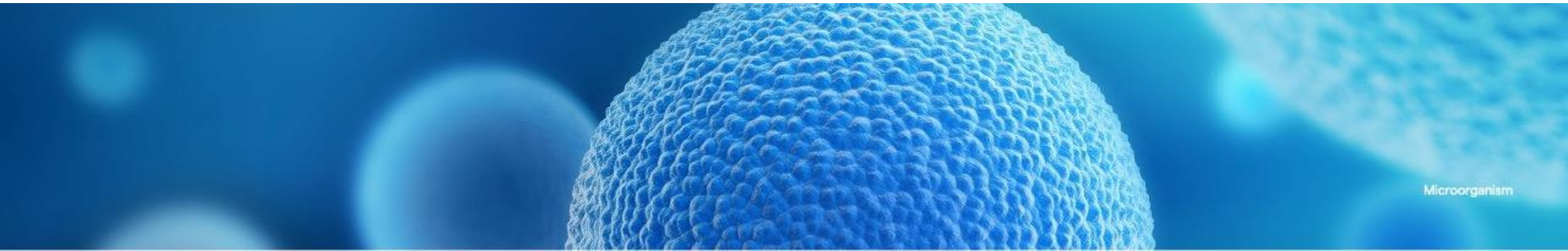
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Outline

Flexible Facility Concepts

- Who is Lonza ?
- Drivers for change
- Ibex® : Pre-investment concepts
- Advantages of approach
- Project examples

Motivated by a common purpose to

***Enable A
Healthier World***

Lonza is the preferred global partner to the pharmaceutical, biotech and nutrition markets.

We work to enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise and process excellence.

Our unparalleled breadth of offerings enables our customers to commercialize their discoveries and innovations in the healthcare sector.

~16,000

Full-time employees

125

Years of history

37

Global sites

Lonza experience to predict & adapt to changing modalities



1980s

Small molecules and APIs



1996

Mammalian cell culture and mAbs



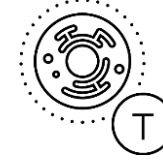
2006

Microbial fermentation



2007

ADCs



2007

Cell therapy



Viral vector gene therapy

2010



Small molecule drug product

2017



Microbiome¹

2019



Parenteral drug product²

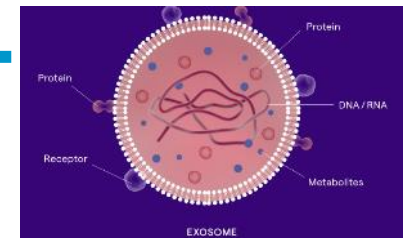
2019



mRNA

2020

Exosomes



Trends driving changes in the pharma & biotech industry



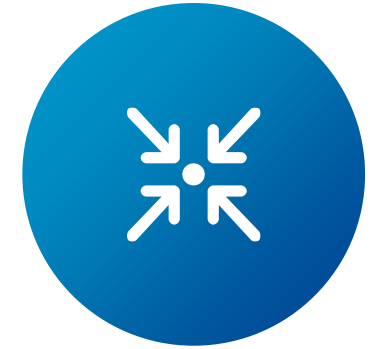
Societal trends

- Growing world population
- Aging population in Western countries
- Growing middle classes in BRIC-VISTA¹ countries



Health needs

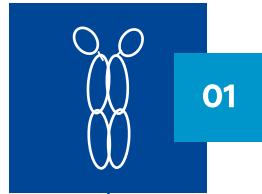
- Prevalence of chronic disease
- Rare & orphan diseases
- Pressure on healthcare budget
- Accelerated approval pathways
- Patient stratification



Impact on pharma & biotech Industry

- Uncertain demand
- More complex molecules
- High investment risk
- Accelerated timelines
- Therapeutic competition
- New drug pricing pressure

The manufacture of medicines is changing...



More complex medicines



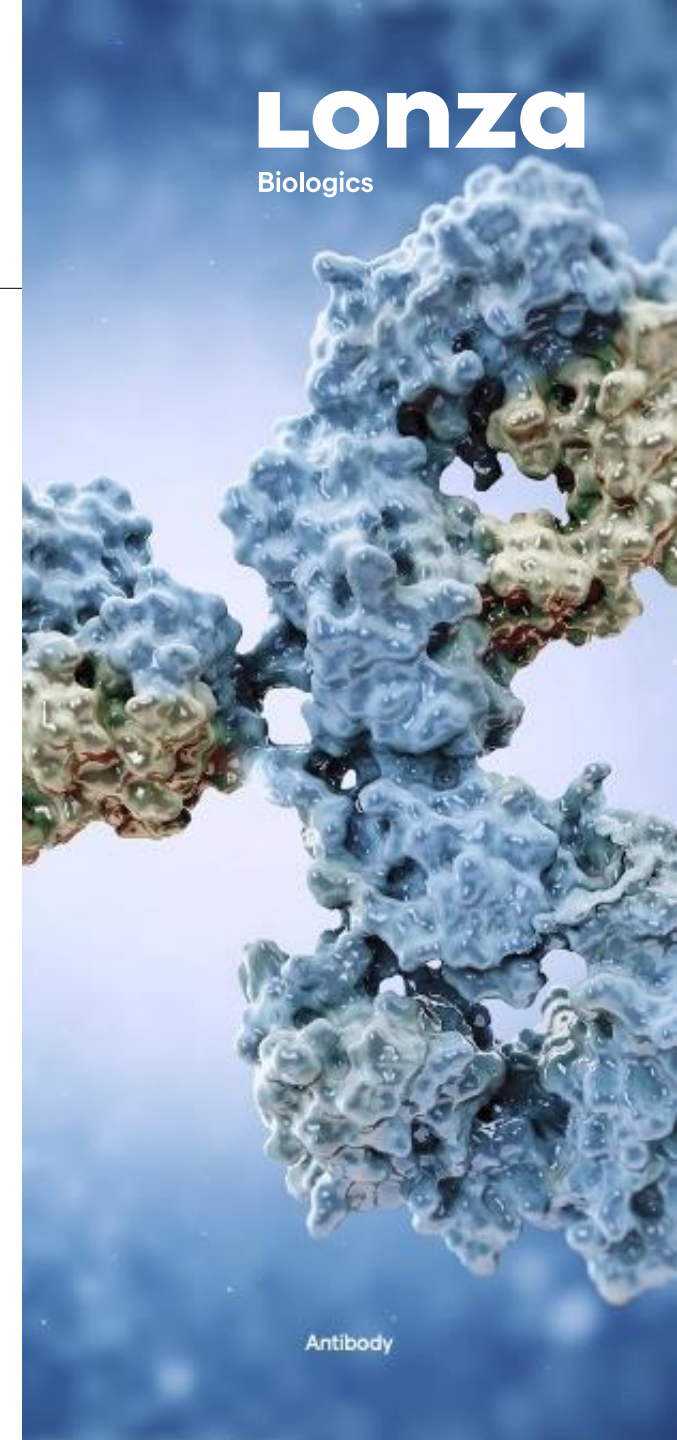
Shortened timelines



Innovation & Rise of Biotechnology



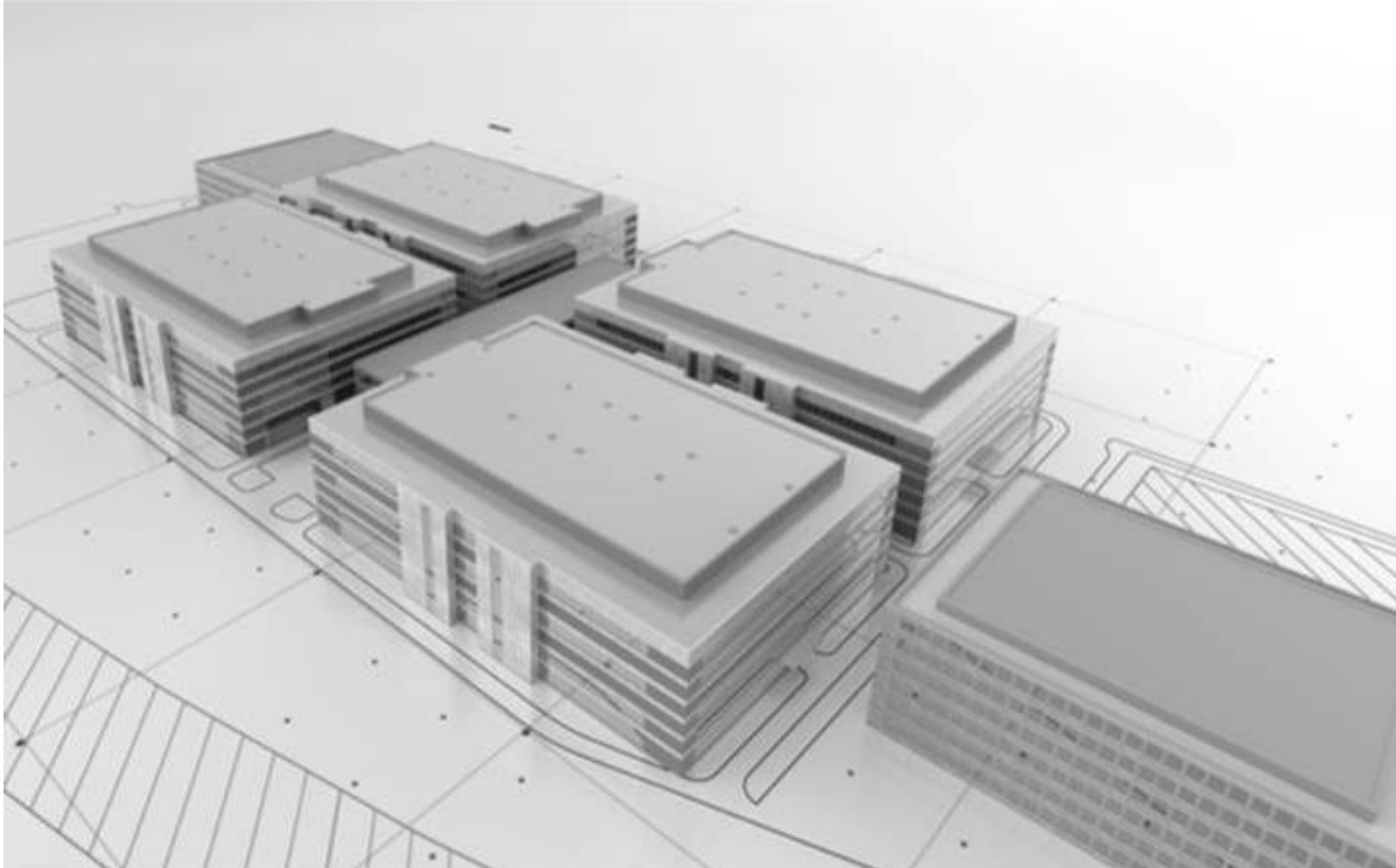
Pandemics



Antibody

The Lonza Biopark in Visp - the home of Ibex® Solutions

Up to 5 production complexes, laboratories and administration



Total area of about 100,000 m²

- > Infrastructure and operational buildings from the Visp site
- > Up to five production complexes
- > Central operations building
- > Warehouse and logistics
- > Main building with additional laboratories and offices

Ibex® Solutions BioPark – a generation project



Delivering the
medicines of
tomorrow, today®

- Customer benefits
- Speed
 - Flexibility
 - Simplicity
 - Risk mitigation



Flexible, modular and adaptable concept – Russian dolls

Leveraging the site of Visp to provide OPEX & CAPEX advantages



Site Visp



- Site infrastructure
- Site utilities
- Warehousing and logistics



Ibex® park 100,000 m²



- 5 manufacturing complexes
- Central utility building
- Central buffer and media
- Headblock with additional labs and offices



Manufacturing complexes

115 × 86 m (1.5 soccer fields)



- 2 manufacturing wings
- 1 gowning section
- 1 office section
- 1 utility section



Manufacturing wings

100 × 30 m



- 3 floors each 3000 m²
- Each floor can be divided into 3 units
- A total of 9 units per wing



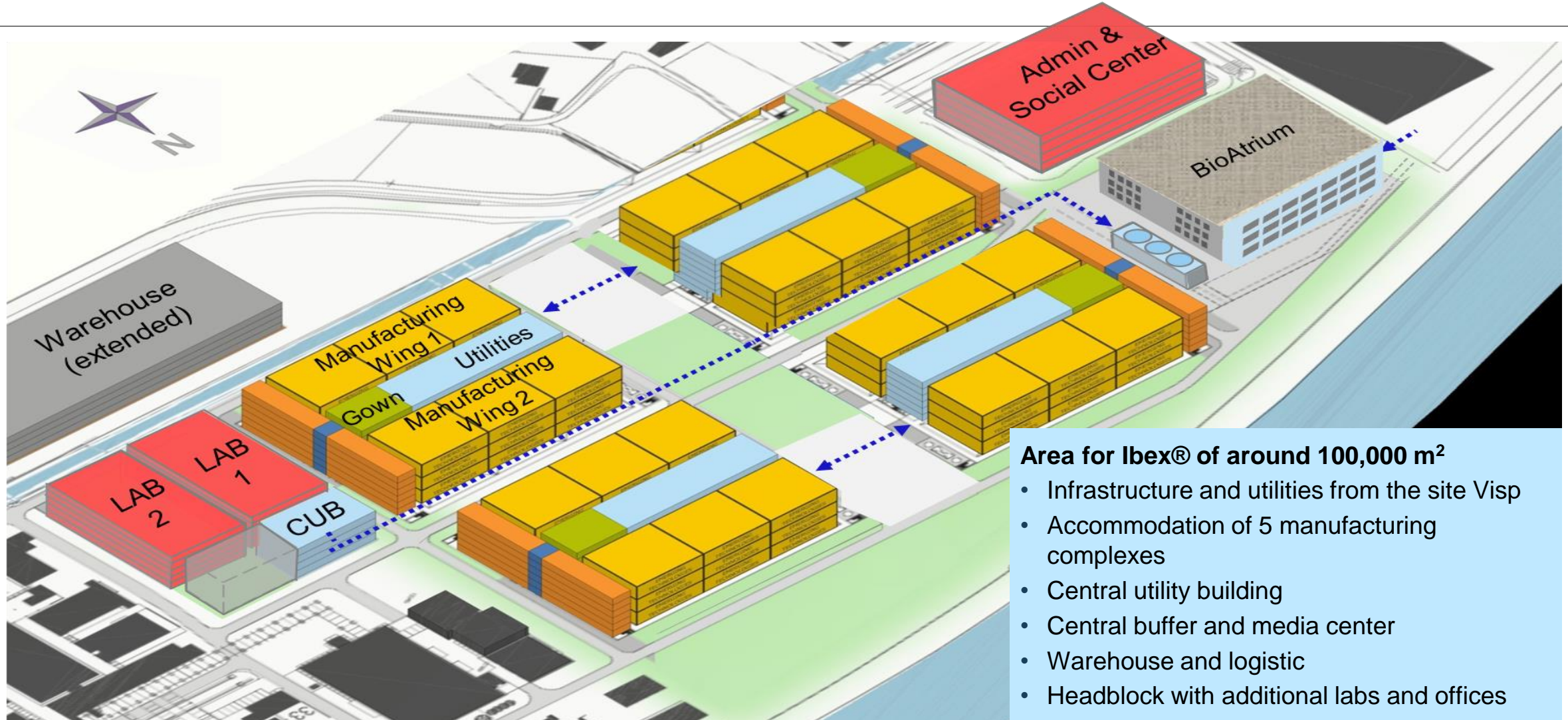
Dedicated suites



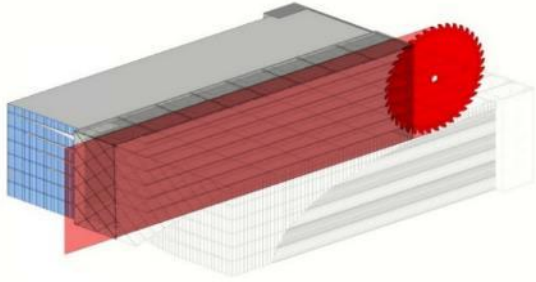
- Customer or technology dedicated suites
- Consist of 1 up to 9 units (entire wing)

Overall concept / masterplan Ibex®

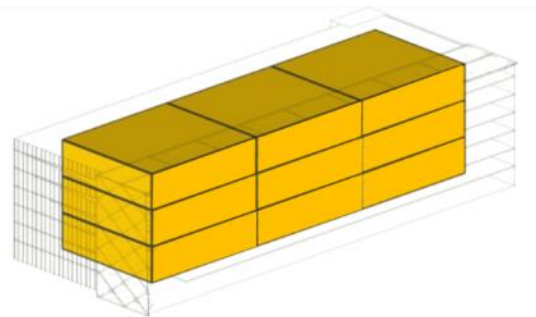
Pre-investment into super-shells & infrastructure (utilities, QC, warehouse ..)



Manufacturing wings

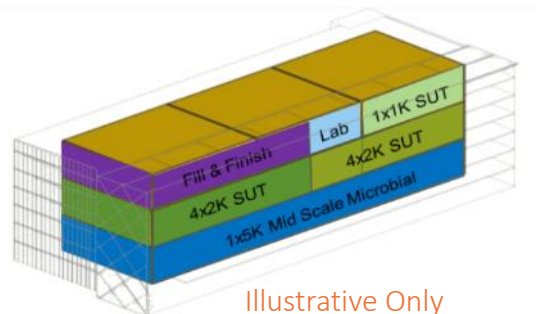


Each Complex can be split into 2 separate **manufacturing wings** for phasing



Each manufacturing wing contains:

- 3 floors each 3000 m²
- Each floor can be divided into 3 **Units** (1,000 m² each)
- A total of 9 units per wing



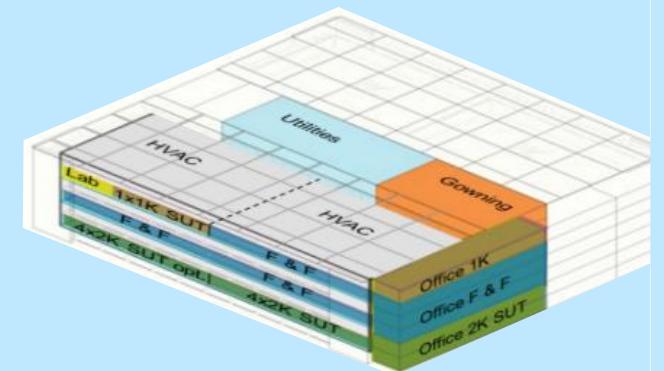
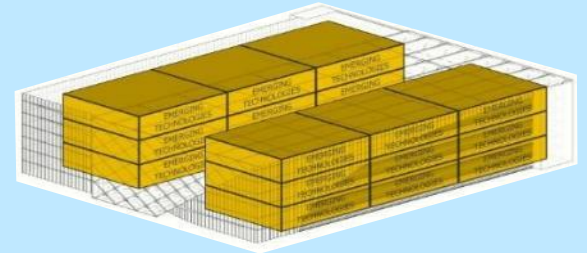
Dedicated suites are defined for customer/technologies and can consist of between 1 and 9 units (entire wing)

Manufacturing complex can host multiple biotechnologies



Manufacturing Complex is capable of hosting Lonza Platform Technologies

Lonza core technology	Required area	Units Required
• Mammalian large scale 4-6 x 20kL	9,000 m ²	9
• Mammalian Single-Use 2kL	1,500 m ²	1.5
• Viral Vector	1,000 m ²	1
• Microbial large scale 1x 15kL	6,000 m ²	6
• Microbial 3 to 5kL (medium scale)	3,000 m ²	3
• Process Development Labs, MSAT	500 m ²	0.5
• Drug Product Fill & Finish	1,500 m ²	3
• CGT (Cell and Gene Therapy)	1,000 m ²	1
• mRNA Drug Substance	500 m ²	0.5



Manufacturing complex = 2 wings
each wing is 9,000 m² of clean space (~100,000 ft²)

One Wing: Flexible & adaptable

3 Active Floors, 9,000 m² space

- 3,000 m² GMP per floor
 - Clean space ready for fit-out

2,000 m² support per floor

- Staging, logistics, controls

Full-service ground floor

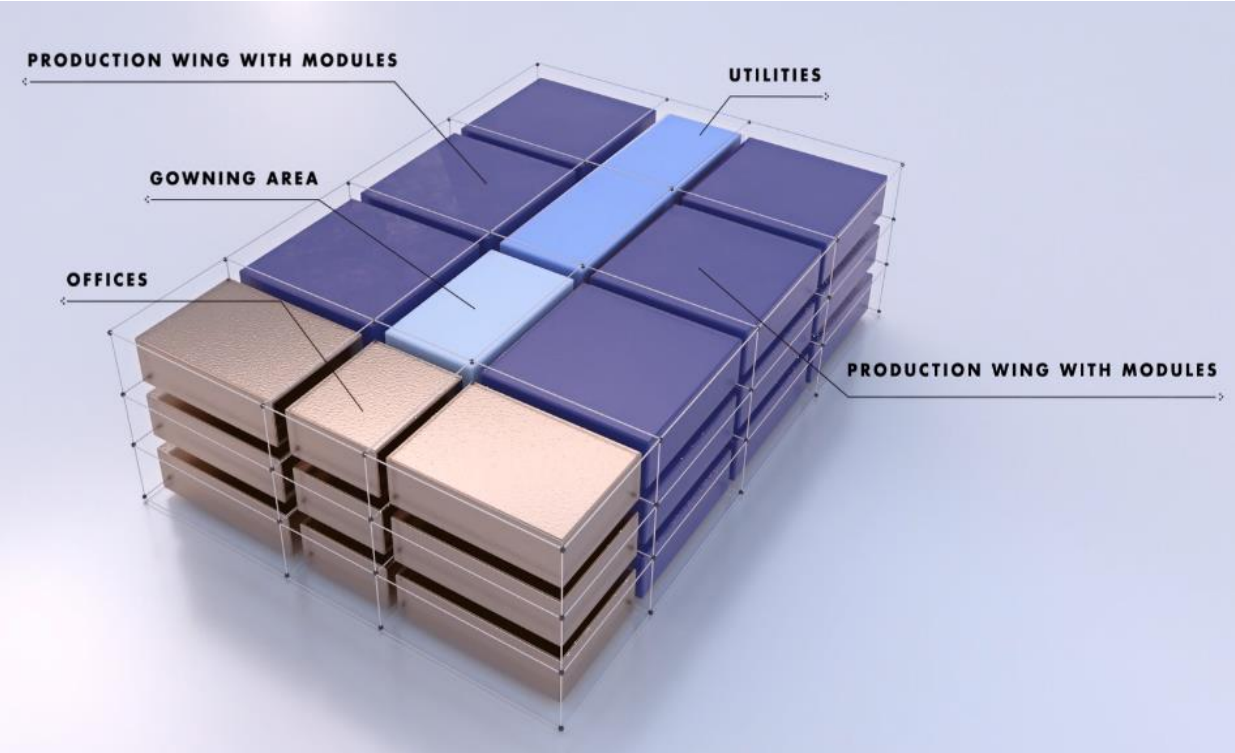
- Storage, WFI, Nitrogen, steam

Full site support (Russian doll)

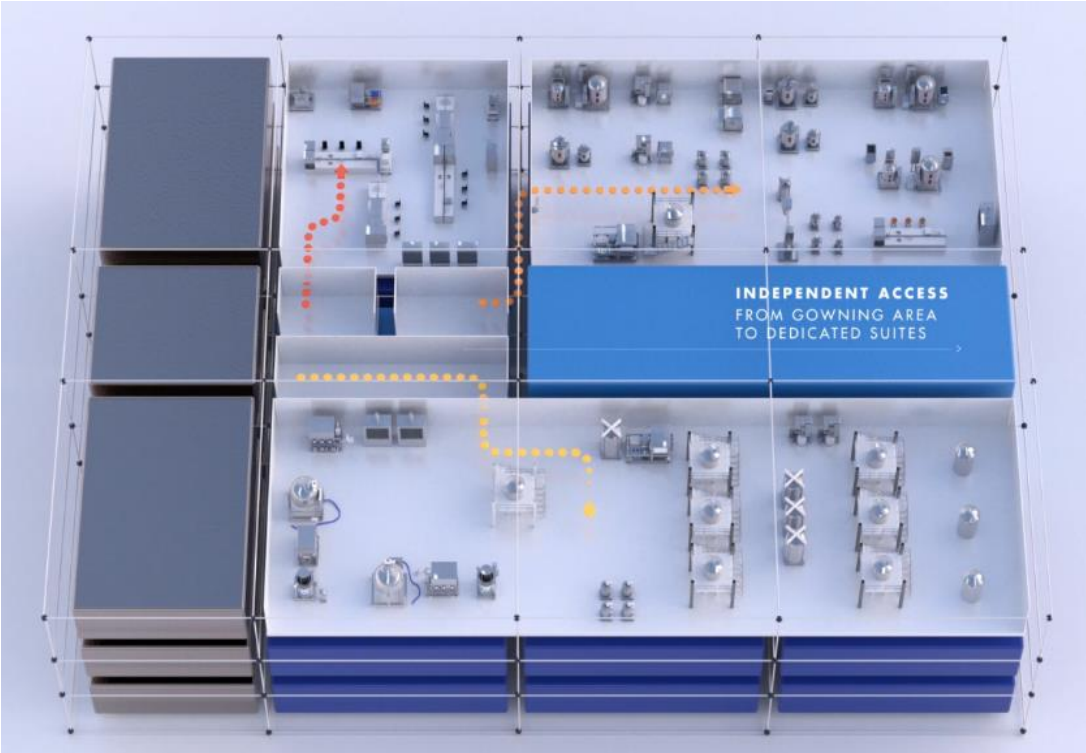
- Utilities, QC, warehousing, automation, training, hiring ...



Internal modular structure



Each customer has their **own dedicated facility access**, with independent routes from the locker entrance to production modules with independent HVAC, final utilities ..





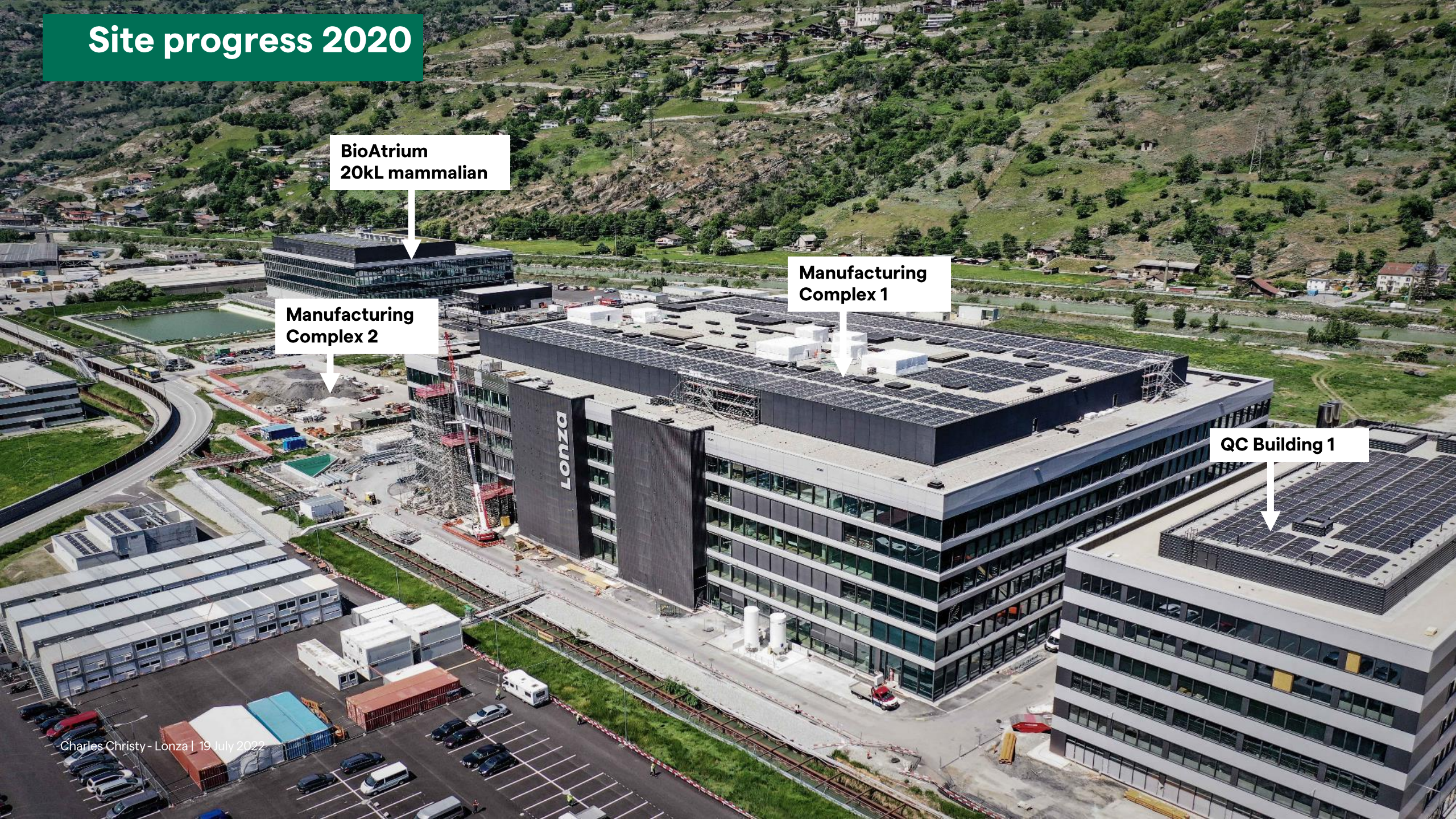
Site progress 2020

BioAtrium
20kL mammalian

Manufacturing
Complex 2

Manufacturing
Complex 1

QC Building 1



Pre-Investment allows agile & flexible responses

Case study Ibex® Solutions BioPark



2017 – 2018
Start of construction



2020 – 2021
Start of operation



2021+
Investment in a new large-scale
mammalian manufacturing facility



Selected Customer Projects



KODIAK

moderna

Multiple undisclosed biotech
and pharma clients

Legend: White color – built; orange color – under construction; green color – potential future development

Limited pre-investment allows full flexibility

Ibex® Dedicate

- Pre-Built Shells & Infrastructure
- Single customer in “dedicated” facility
- Minimized pre-investment
- Maximum flexibility and agility
 - Tailored offer for specific situation
 - CapEx sharing, ramp-up, scale, speed, operational model ...
- Manages customer challenges and risks
 - Clinical risk, capacity and size required, exits/re-purposing, any technology, any scale

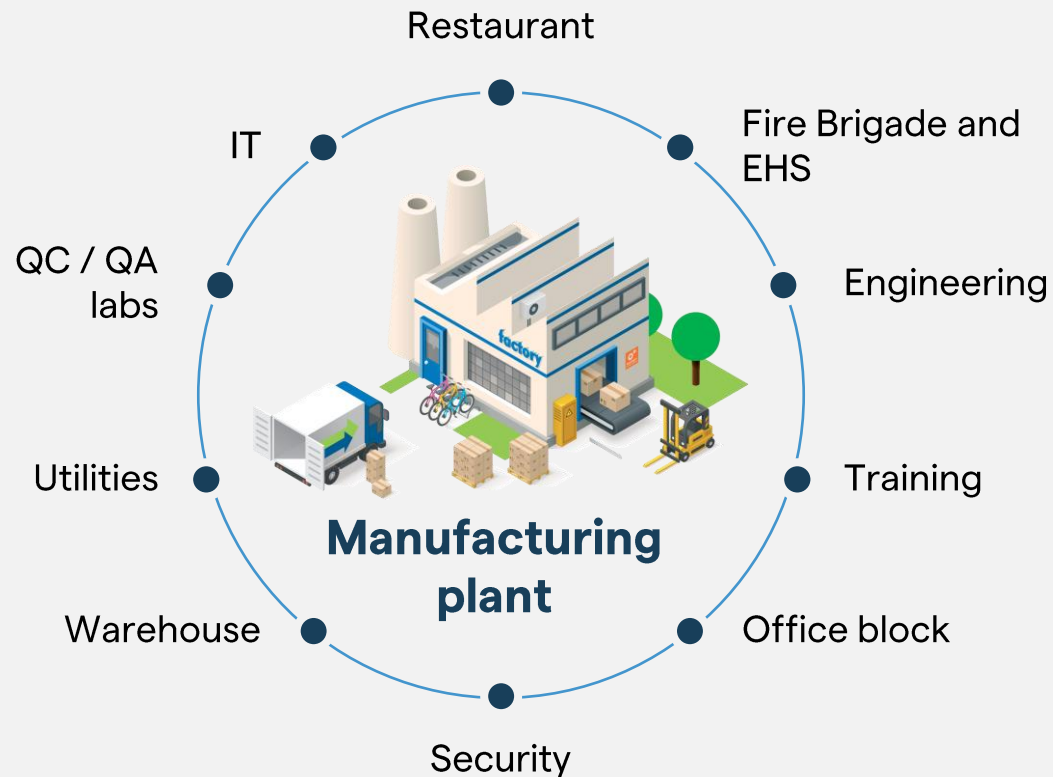


Competitive advantage:

- Faster than greenfield (or brownfield)
- Lower OPEX via Visp site
- Shared utilities and infrastructure
- Always a wing available
- De-risks for clinical failure or demand change

OPEX and CAPEX advantage

Leveraging the existing Visp site & pre-investments



- | | |
|---|---|
| 01 Infrastructure and Utilities from the site Visp | 04 Warehouse and Logistic |
| 02 Central Utility Building | 05 Head-block with additional Labs and Offices |
| 03 Central buffer and media center | 06 Training programs and center for New Hires |

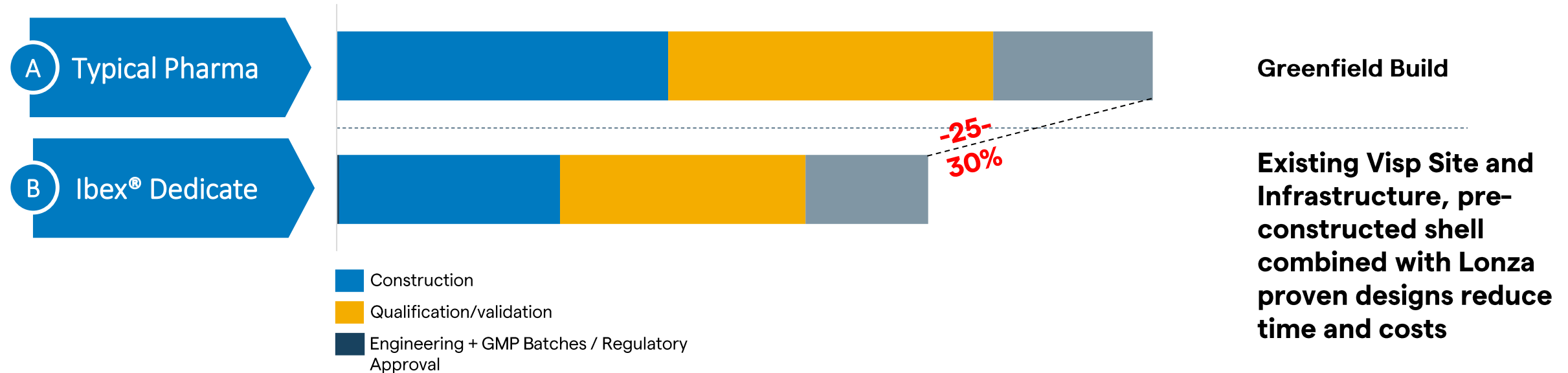


CapEx Optimization of up to 25-30%

How does the investment needed for Ibex® Dedicate build compare to a typical Pharma build?

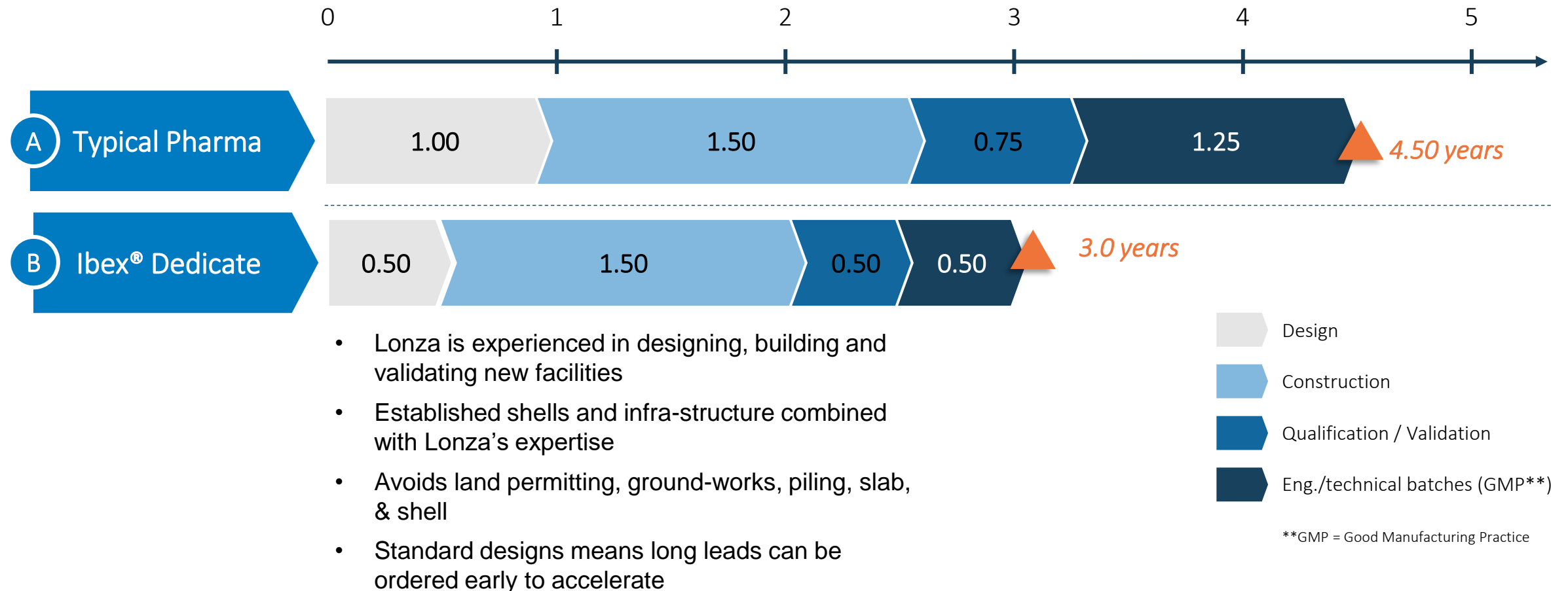
CapEx Breakdown by Project Phase (mCHF)

(Illustrative Example: Typical Mammalian Large-scale Capacity Addition)



A dedicated manufacturing capacity saving up to in total 18+ months time to market*

How does an Ibex® Dedicate build compare to a typical Pharma build?



* Based on a large-scale mammalian or microbial facility

Technology & Scale Agnostic

Lonza
Biologics



Any technology, any scale

Flexible Super-shell concept

Lonza
Biologics



From Single Use (SUT) to 20kL Stainless

Lonza
Biologics



Typical Installations - Drug Product Line & Single Use Suite



Lonza Visp Switzerland Site Autumn 2021



Significant Efficiencies by Leveraging Lonza Visp BioPark



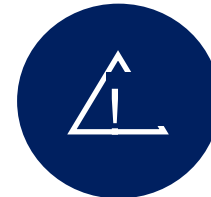
Excellent COG's – Leverage Visp Super-site for shared services (utilities, warehouse, QC etc)
→ lowers CAPEX & OPEX significantly



Flexible Business Models - CAPEX & capacity sharing options available



Reduced Timeline – Leverage existing Manufacturing Complex & BioPark (Utilities, QC, warehouse ..)



Reduced Risk – As a CDMO Lonza can re-purpose unused capacity if required



Lonza Visp Site Autumn 2021



**Existing 15kL
Microbial Assets**

**QC Building &
MSAT & Pilot
Mab Facility**

**Manufacturing
Complex 1
1 & 2 kL Mab & DP
4kL Microbial**

**Manufacturing
Complex 2
Orca 20kL &
Wing 2 for
Clients**

**BioAtrium JV
20kL
Mab Facility**

Project Examples

Lonzo



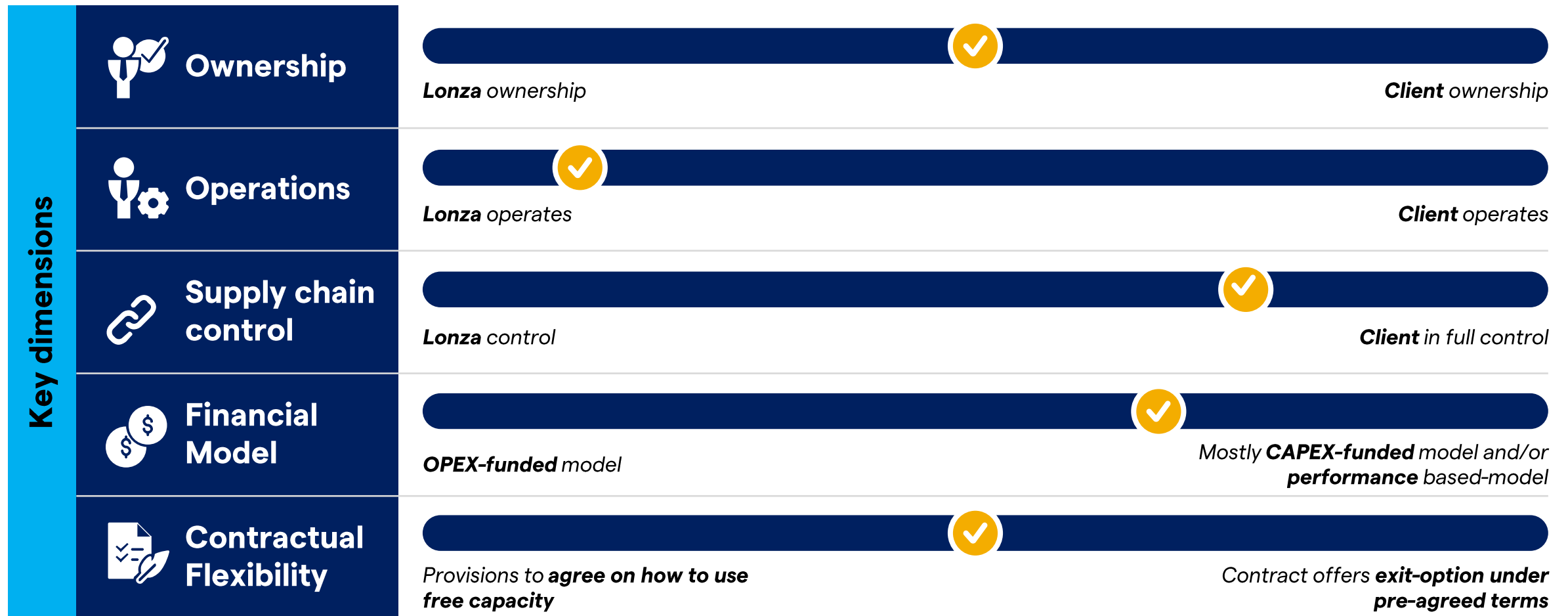
Components of a partnership

ibex | the agile advantage®

Lonza
Biologics

Flexibility in business model is key to modern partnerships

Illustrative



Current Ibex® Dedicate customers



Our diverse customers cover a wide range of scales , technologies & business models



Ibex® Dedicate
Technology-agnostic offering for products in late clinical or commercial stages

Production Q3 2020	Production December 2020	Production 2021	Commissioning H2 2021	Production H2 2022	Commissioning Q4 2022
Sanofi	Moderna	Undisclosed	Servier	Kodiak	Undisclosed
<ul style="list-style-type: none">• Joint Venture with Sanofi• Large-scale mammalian cell culture facility for monoclonal antibody production• Investment of CHF 290 million• Approx. 200 new jobs	<ul style="list-style-type: none">• Vaccine candidate COVID-19• mRNA Technology• Investment of CHF 200 million (Lonza and Moderna)• Approx. 200 new jobs	<ul style="list-style-type: none">• Major multinational pharmaceutical company• Manufacturing of commercial-derived product	<ul style="list-style-type: none">• Mid-scale microbial facility to supply Servier with active pharmaceutical ingredient for acute lymphoblastic leukemia• Approx. 100 new jobs	<ul style="list-style-type: none">• Late-stage clinical antibody-biopolymer conjugate• Innovative medication against retinal diseases	<ul style="list-style-type: none">• Two new bioconjugation suites for commercialization of antibody-drug conjugates• Highly potent material for cancer therapy• Approx. 200 new jobs

Speed is key

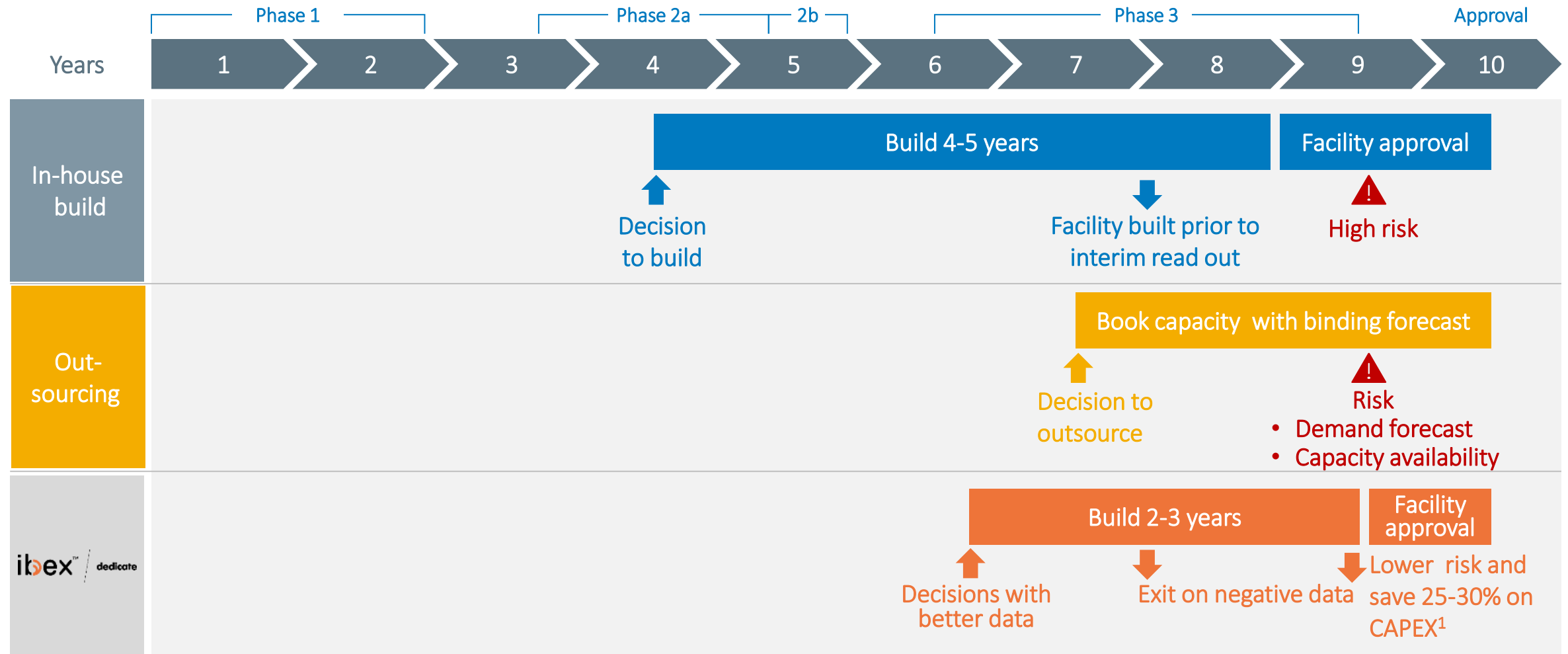
Allows to reduce risk based on better clinical data

Or, be faster to market if rapid approval is anticipated



Scenario 1: potential blockbuster large-scale capacity

How to secure capacity while reducing investment risk



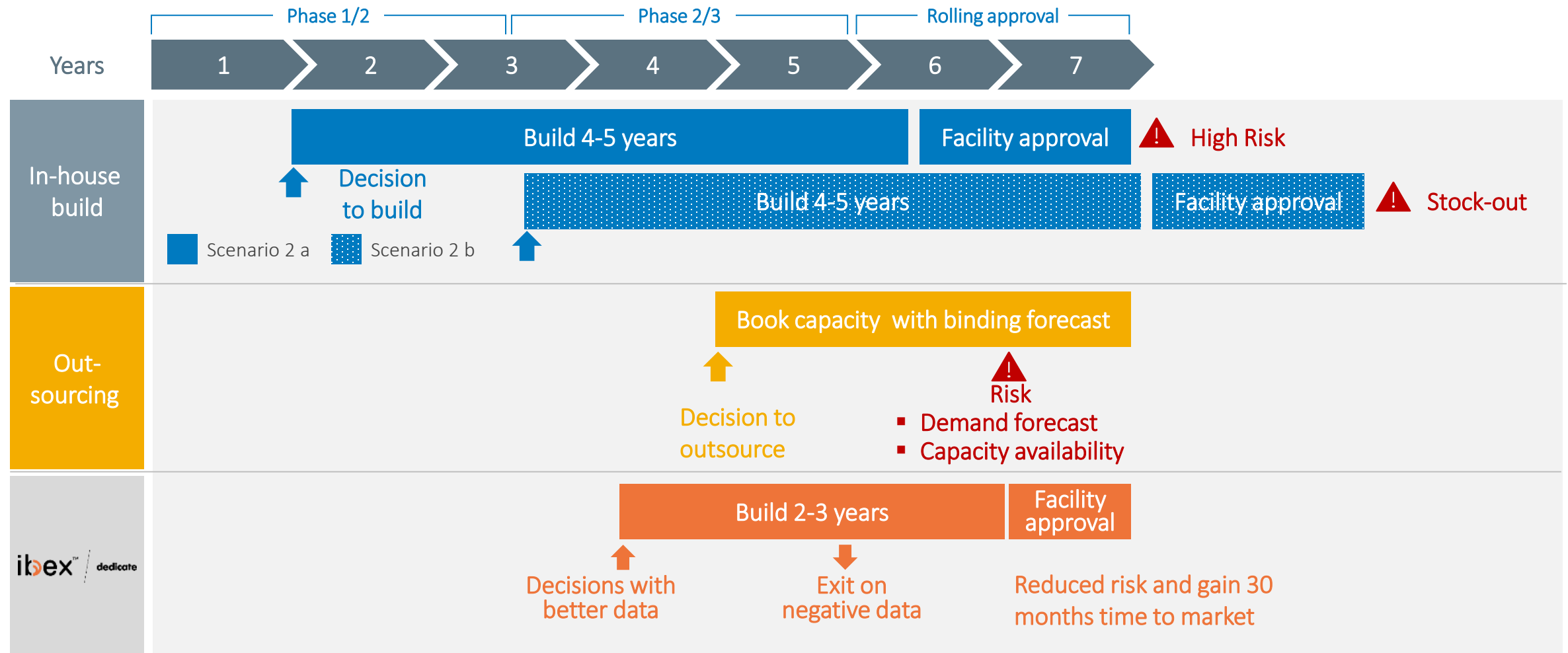
¹ Compare to typical large scale capacity

Scenario 2: your drug is on an accelerated approval pathway

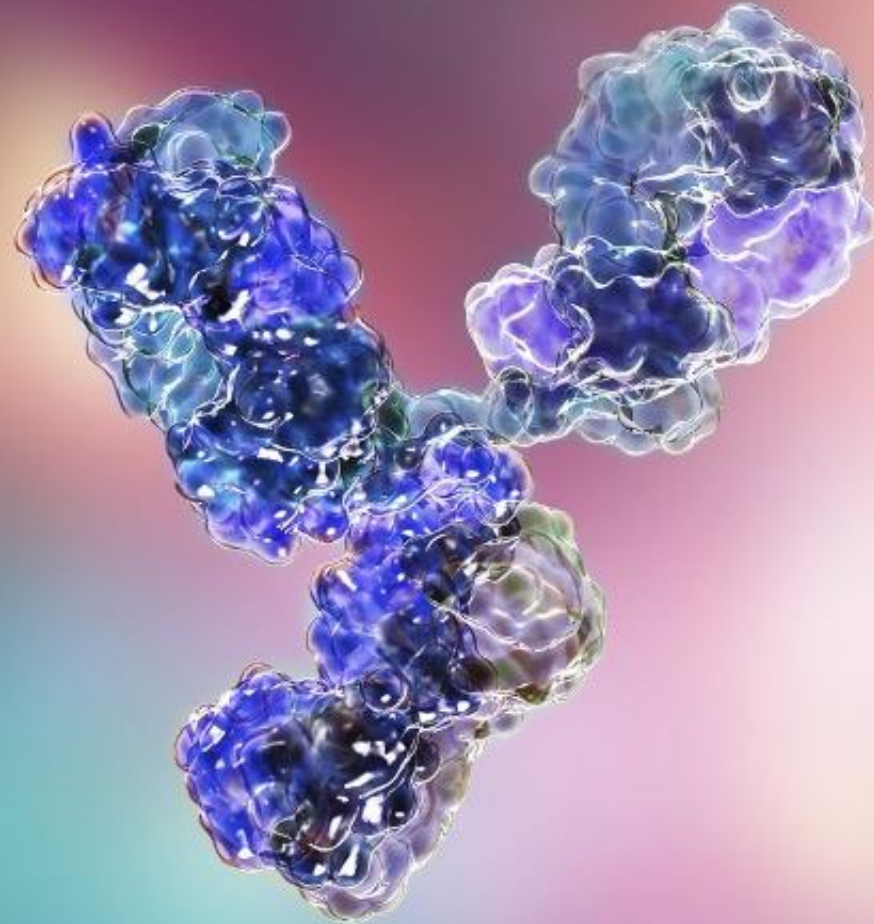
Lonza

Pharma & Biotech

How to secure capacity when timelines are shortened - **speed is key**



COVID-19 vaccines



Antibody

mRNA in Ibex®: Supplying Global Society with Covid-19-Vaccine

Eight months from Project Start to Operational start-up

June 2020



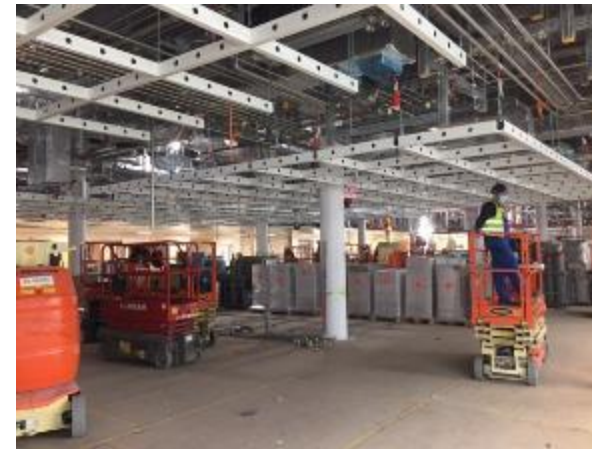
- Approval of Layouts
- Ordering of long-lead equipment
- Floor finished

July / August 2020



- Start construction of the facility and utilities

September 2020



- Installation of ceiling
- Piping and duct work on-going
- FAT execution of equipment

October 2020



- Installation of cleanroom walls
- Equipment deliveries and installation

mRNA in Ibex®: Supplying Global Society with Covid-19-Vaccine

Eight months from Project Start to Operational start-up

December 2020



- Qualification of the equipment and cleanrooms
- Operational start-up

Jan / Feb 2021



- 1st Line (Kit 4) started on 09. Jan
- 2nd Line (Kit 5) started on 22. Feb

March 2021



- Swissmedic manufacturing license granted for Ibex® facility
- Kit 6 handed over

May Jun Jul



- Layouts frozen
- Equipment list frozen

Phase II (Kit 11-13, buffer prep)

Large-Scale mammalian



Enabling a Healthier World



Large Scale Mammalian manufacturing

Ibex® BioPark, Lonza Visp

Charles Christy - Lonza | 19 July 2022

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MC2 20kL Mammalian Overview

MC2, 2nd Manufacturing Complex in Ilex

- MC2 is an integrated Manufacturing Complex with utilities and logistics to support both wings
- Wing 1 dedicated to large scale Mammalian Cell Culture
 - 6x20kL Mammalian Cell culture with Integrated Downstream to Bulk Drug Substance fill & freeze

This slide deck:

- Site Overview/Update
- MC2 Overview
- Site progress photos



MC2: 20kL Mammalian facility Wing 1

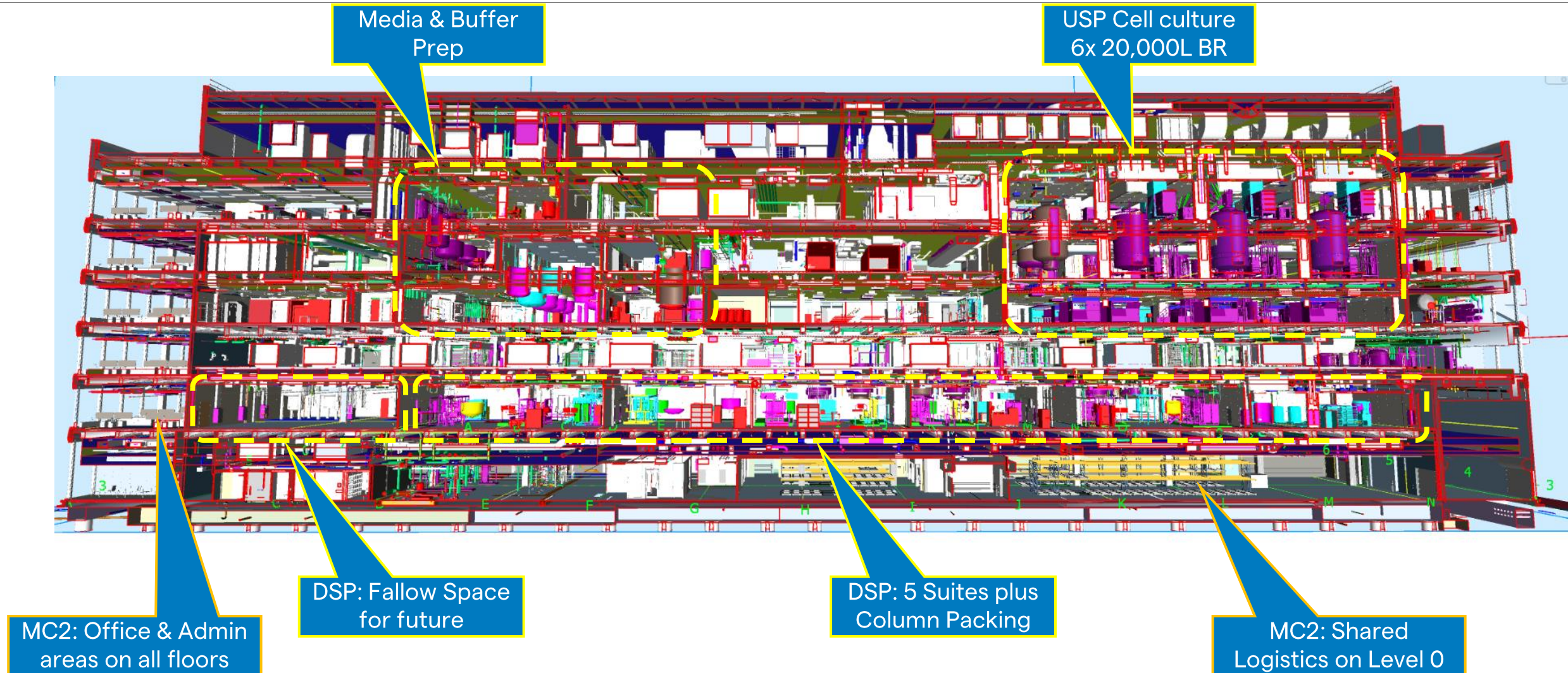
Manufacturing Complex 2: Ibex Biopark Visp



- MC2 is being constructed next to MC1
- The building design is identical, but mirrored
- Wing 1 is dedicated to large scale 6 x 20,000L Mammalian Cell Culture
- 6 by 20kL at 6 g/L, 70 % recovery can produce approx. 10 tons of Mab annually



Wing 1 Orca: 3D section



An aerial photograph of a city nestled in a valley, surrounded by mountains. The city is densely packed with buildings, and a river flows through it. The mountains in the background are covered in autumn foliage, and some peaks are snow-capped. The sky is clear and blue. The text "the next project..." is overlaid in large white letters, and "Let's work on it together" is overlaid in smaller white letters below it.

the next project...

Let's work on it together