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

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

Microbiome
2019

Parenteral drug product
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-VISTA\(^1\) 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

\(^1\)BRIC - Brazil, Russia, China and India
VISTA - Vietnam, Indonesia, South Africa, Turkey, Argentina.
Charles Christy - Lonza | 19 July 2022
The manufacture of medicines is changing...

01 More complex medicines

02 Shortened timelines

03 Innovation & Rise of Biotechnology

04 Pandemics
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

<table>
<thead>
<tr>
<th>Site Visp</th>
<th>Ibex® park 100,000 m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Site infrastructure</td>
<td>• 5 manufacturing complexes</td>
</tr>
<tr>
<td>• Site utilities</td>
<td>• Central utility building</td>
</tr>
<tr>
<td>• Warehousing and logistics</td>
<td>• Central buffer and media</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturing complexes</th>
<th>Headblock with additional labs and offices</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 2 manufacturing wings</td>
<td>• 1 gowning section</td>
</tr>
<tr>
<td>• 1 office section</td>
<td>• 1 utility section</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacturing wings</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• 3 floors each 3000 m²</td>
<td>• Each floor can be divided into 3 units</td>
</tr>
<tr>
<td>• A total of 9 units per wing</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dedicated suites</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Customer or technology dedicated suites</td>
<td>• Consist of 1 up to 9 units (entire wing)</td>
</tr>
</tbody>
</table>
Overall concept / masterplan Ibex®

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

- Infrastructure and utilities from the site Visp
- Accommodation of 5 manufacturing complexes
- Central utility building
- Central buffer and media center
- Warehouse and logistic
- Headblock with additional labs and offices

Area for Ibex® of around 100,000 m²
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).

Illustrative Only
### Lonza core technology

<table>
<thead>
<tr>
<th>Technology</th>
<th>Required area</th>
<th>Units Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammalian large scale 4-6 x 20kL</td>
<td>9,000 m²</td>
<td>9</td>
</tr>
<tr>
<td>Mammalian Single-Use 2kL</td>
<td>1,500 m²</td>
<td>1.5</td>
</tr>
<tr>
<td>Viral Vector</td>
<td>1,000 m²</td>
<td>1</td>
</tr>
<tr>
<td>Microbial large scale 1x 15kL</td>
<td>6,000 m²</td>
<td>6</td>
</tr>
<tr>
<td>Microbial 3 to 5kL (medium scale)</td>
<td>3,000 m²</td>
<td>3</td>
</tr>
<tr>
<td>Process Development Labs, MSAT</td>
<td>500 m²</td>
<td>0.5</td>
</tr>
<tr>
<td>Drug Product Fill &amp; Finish</td>
<td>1,500 m²</td>
<td>3</td>
</tr>
<tr>
<td>CGT (Cell and Gene Therapy)</td>
<td>1,000 m²</td>
<td>1</td>
</tr>
<tr>
<td>mRNA Drug Substance</td>
<td>500 m²</td>
<td>0.5</td>
</tr>
</tbody>
</table>

**Manufacturing Complex** is capable of hosting Lonza Platform Technologies.
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 ...
Each customer has their own dedicated facility access, with independent routes from the locker entrance to production modules with independent HVAC, final utilities...
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

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

Charles Christy - Lonza | 19 July 2022
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

1. Infrastructure and Utilities from the site Visp
2. Central Utility Building
3. Central buffer and media center
4. Warehouse and Logistic
5. Head-block with additional Labs and Offices
6. Training programs and center for New Hires
How does the investment needed for Ibex® Dedicate build compare to a typical Pharma build?

CapEx Optimization of up to 25-30%

CapEx Breakdown by Project Phase (mCHF)
(Illustrative Example: Typical Mammalian Large-scale Capacity Addition)

- **Typical Pharma**
  - Construction
  - Qualification/validation
  - Engineering + GMP Batches/ Regulatory Approval

- **Ibex® Dedicate**
  - Construction
  - Qualification/validation
  - Engineering + GMP Batches/ Regulatory Approval

Greenfield Build

Existing Visp Site and Infrastructure, pre-constructed shell combined with Lonza proven designs reduce time and costs

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Business Use Only
Ibex® Dedicate

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?

<table>
<thead>
<tr>
<th>Time (years)</th>
<th>Typical Pharma</th>
<th>Ibex® Dedicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1.00</td>
<td>0.50</td>
</tr>
<tr>
<td>1</td>
<td>1.50</td>
<td>1.50</td>
</tr>
<tr>
<td>2</td>
<td>0.75</td>
<td>0.50</td>
</tr>
<tr>
<td>3</td>
<td>1.25</td>
<td>0.50</td>
</tr>
<tr>
<td>4</td>
<td>4.50</td>
<td>3.0 years</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Lonza is experienced in designing, building and validating new facilities
- Established shells and infra-structure combined with Lonza’s expertise
- Avoids land permitting, ground-works, piling, slab, & shell
- Standard designs means long leads can be ordered early to accelerate

**GMP = Good Manufacturing Practice

* Based on a large-scale mammalian or microbial facility

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Business Use Only
Technology & Scale Agnostic
Any technology, any scale

Flexible Super-shell concept
From Single Use (SUT) to 20kL Stainless
Typical Installations - Drug Product Line & Single Use Suite
**Ibex® Client Dedicated Facilities**

**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 & 2 kL Mab & DP 4kL Microbial
- Manufacturing Complex 2 Orca 20kL & Wing 2 for Clients
- BioAtrium JV 20kL Mab Facility
Project Examples
## Components of a partnership

### Flexibility in business model is key to modern partnerships

<table>
<thead>
<tr>
<th>Key dimensions</th>
<th>Ownership</th>
<th>Operations</th>
<th>Supply chain control</th>
<th>Financial Model</th>
<th>Contractual Flexibility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lonza</td>
<td>Client</td>
<td>Lonza</td>
<td>OPEX-funded</td>
<td>Contract offers</td>
</tr>
<tr>
<td></td>
<td>ownership</td>
<td>operates</td>
<td>control</td>
<td>model</td>
<td>exit-option under</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>pre-agreed terms</td>
</tr>
</tbody>
</table>
### Current Ibex® Dedicate customers

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

<table>
<thead>
<tr>
<th>Production Q3 2020</th>
<th>Production December 2020</th>
<th>Production 2021</th>
<th>Commissioning H2 2021</th>
<th>Production H2 2022</th>
<th>Commissioning Q4 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sanofi</strong></td>
<td><strong>Moderna</strong></td>
<td><strong>Undisclosed</strong></td>
<td><strong>Servier</strong></td>
<td><strong>Kodiak</strong></td>
<td><strong>Undisclosed</strong></td>
</tr>
<tr>
<td>• Joint Venture with Sanofi</td>
<td>• Vaccine candidate COVID-19</td>
<td>• Major multinational pharmaceutical company</td>
<td>• Mid-scale microbial facility to supply Servier with active pharmaceutical ingredient for acute lymphoblastic leukemia</td>
<td>• Late-stage clinical antibody-biopolymer conjugate</td>
<td>• Two new bioconjugation suites for commercialization of antibody-drug conjugates</td>
</tr>
<tr>
<td>• Large-scale mammalian cell culture facility for monoclonal antibody production</td>
<td>• mRNA Technology</td>
<td>• Manufacturing of commercial-derived product</td>
<td>• Innovative medication against retinal diseases</td>
<td>• Highly potent material for cancer therapy</td>
<td>• Approx. 200 new jobs</td>
</tr>
<tr>
<td>• Investment of CHF 290 million</td>
<td>• Investment of CHF 200 million (Lonza and Moderna)</td>
<td>• Approx. 200 new jobs</td>
<td>• Approx. 100 new jobs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Approx. 200 new jobs</td>
<td></td>
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</tr>
</tbody>
</table>

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**Ibex® Dedicate**

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

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

### In-house build

- **1st year (Phase 1)**: Decision to build
- **2nd year (Phase 2a)**: Facility approval
- **3rd year (Phase 2b)**: Facility built prior to interim read out

- **High risk**
- **Risk**
  - Demand forecast
  - Capacity availability

### Outsourcing

- **2nd year (Phase 2a)**: Decision to outsource
- **3rd year (Phase 2b)**: Book capacity with binding forecast

- **Risk**
  - Demand forecast
  - Capacity availability

### ibex®

- **10th year**: Facility approval
- **9th year**: Lower risk and save 25-30% on CAPEX

### Notes

1. Compare to typical large scale capacity

Charles Christy - Lonza | 19 July 2022
Scenario 2: your drug is on an accelerated approval pathway

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

<table>
<thead>
<tr>
<th>Years</th>
<th>Phase 1/2</th>
<th>Phase 2/3</th>
<th>Rolling approval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In-house build

- Decision to build
- Build 4-5 years
- Facility approval
- High Risk

Outsourcing

- Decision to outsource
  - Demand forecast
  - Capacity availability
- Build 2-3 years
- Facility approval
- Reduced risk and gain 30 months time to market

Book capacity with binding forecast

Decisions with better data
Exit on negative data

Scenario 2 a
Scenario 2 b

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COVID-19 vaccines
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

• Layouts frozen

Jun

• Equipment list frozen

Jul

Phase II (Kit 11-13, buffer prep)
Large-Scale mammalian
Large Scale Mammalian manufacturing

Ibex® BioPark, Lonza Visp

Charles Christy - Lonza | 19 July 2022
MC2 20kL Mammalian Overview

MC2, 2nd Manufacturing Complex in Ibex

- 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

- Media & Buffer Prep
- USP Cell culture 6x 20,000L BR
- DSP: Fallow Space for future
- DSP: 5 Suites plus Column Packing
- MC2: Office & Admin areas on all floors
- MC2: Shared Logistics on Level 0
the next project...

Let's work on it together