



# BeiGene Global Manufacturing Facilities

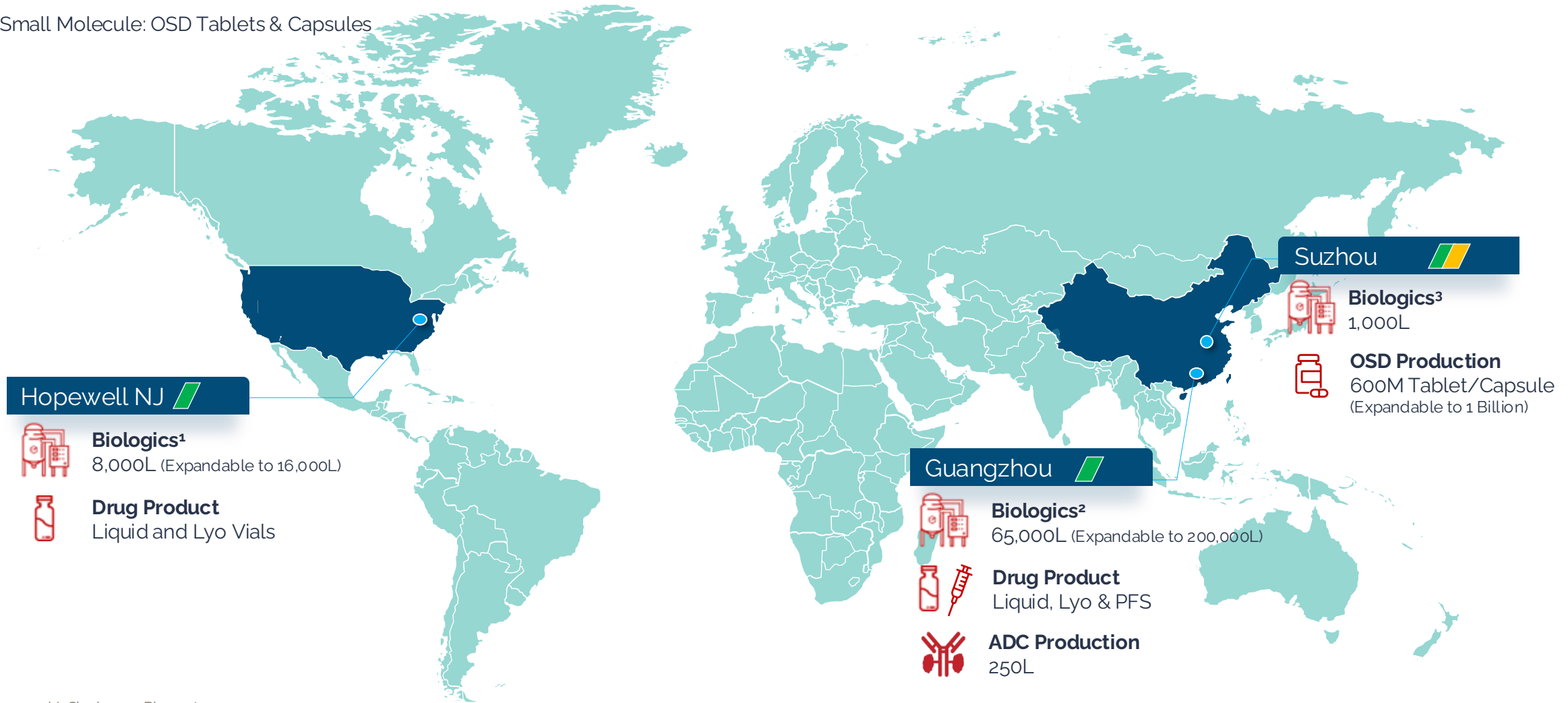
April 2024

# BeiGene Manufacturing



 **Biologics:** Mammalian (mAb, BsAb/TsAb) & Fabs, Fusion, Recombinant proteins

 **Small Molecule:** OSD Tablets & Capsules



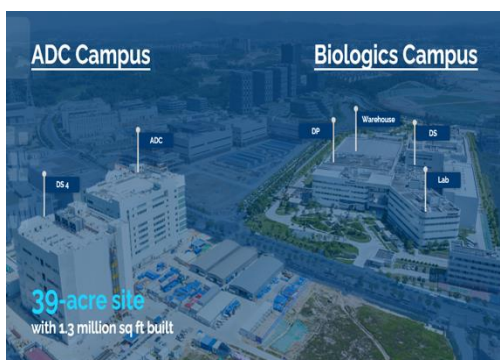
Note

1. DS1 - 4 x 2kL Single-use Bioreactors

2. DS1 - 4 x 2kL KU Bio, DS2 - 8 x 2kL Single-use Bioreactors, DS3 8 x 5kL Stainless-steel bioreactors, DS4 2 x 500L Single-use Bioreactor

3. DS Clinical - 2 x 500L Single-use Bioreactors

# Global Manufacturing Capabilities Overview



## Guangzhou



**Cell Culture**  
65,000L<sup>1</sup>

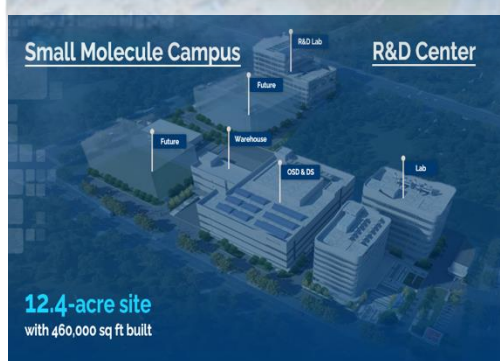
1. Expandable to 200,000L



**Drug Product**  
Liquid, Lyo & PFS



**Antibody Drug Conjugate**  
250L



## Suzhou

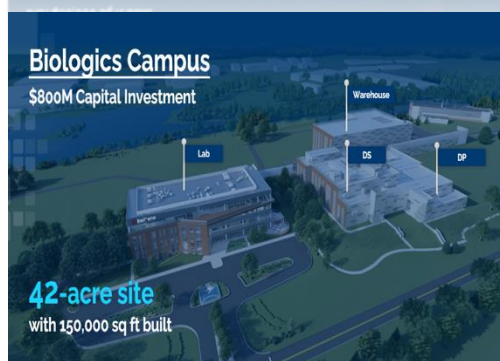


**Cell Culture**  
1,000L



**Drug Product (OSD)**  
600M Tablets & Capsules<sup>2</sup>

2. Expandable to 1 Billion Tablets & Capsules



## Hopewell

Expandable to Small Molecule & ADC

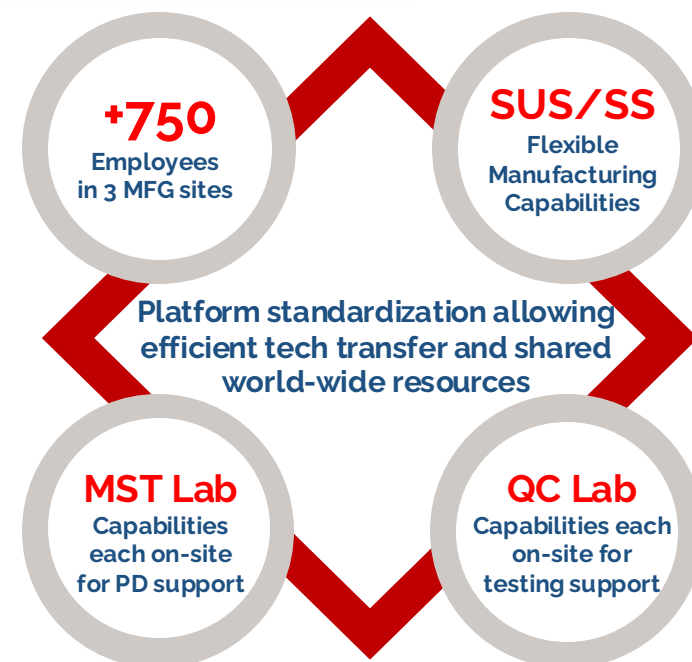


**Cell Culture**  
8,000L<sup>3</sup>

3. Expandable to 16,000L



**Drug Product**  
Liquid and Lyo Vials



PFS, Pre-filled Syringes; SUS, Single-Use System; SS, Stainless Steel

# Guangzhou - First Biologics Manufacturing Facility

## ADC Campus

ADC production capabilities and  
DS suite 4 with SUS 500L bioreactors

## Biologics Campus

DS Suite 1-3 with SUS 2kL and SS 5kL bioreactors.  
DP line (Liq., Lyo., PFS) including Label & Packaging



**39-acre site**  
with **1.3 million sq ft** built

*SUS, Single-Use System; SS, Stainless Steel; PFS, Pre-filled Syringes; ADC, Antibody Drug Conjugates*

*BeiGene Confidential*

# Biologics and ADC Campus



## Drug Substance

### Flexible Manufacturing Capabilities

- Total 65kL Cell Culture Capacity
- Single-use System (2 x 500L, 12 x 2kL)
- Stainless System (8 x 5kL)
- Batch and Fed-batch



## Drug Products

### End-to-End DP Production Lines

- Liquid Vials (clinical & commercial)
- Lyophilized Vials (mAb)
- Pre-filled Syringes (clinical & commercial)
- Label and Packaging



## ADCs

### Clinical & Commercial Production

- ADC Conjugation room (250L stainless-steel tank)
  - Partnership with CMOs for Linker & Payload supply
- ADC Purification with Chromatograph & UF/DF
- DP Lyophilized Vials and Label & Packaging



## Warehouse

### Equipped with Latest Technology

- ASRS (Automatic Search & Retrieval System)
- Storage Conditions:
  - 15 - 25°C, 2 - 8°C, - 40°C, - 70°C

# Suzhou – Small Molecule Manufacturing Facility

## Small Molecule Campus

OSD Production - 300M Tablet & 300M Capsule  
DS Clinical with SUS 500L bioreactors

## R&D Center

Small Molecule R&D Lab with Testing Workshop  
Go-Live Q1 2025

Future

Warehouse

Future

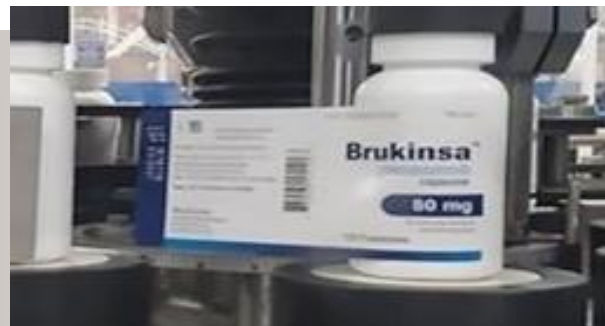
OSD & DS

R&D Lab

Lab

**12.4-acre site**  
with 460,000 sq ft built

# Small Molecule Production and R&D Campus



## Oral Solid Dosage

### Flexible Manufacturing Capabilities

- Total 300M Tablet & 300M Capsule Capacity (clinical & commercial)
- Primary Packaging (bottle & blister)
- Label & Packaging



## Biological Drug Substance

### Clinical and Pilot DS Production

- Total 1kL Cell Culture Capacity
  - Single-use System (2 x 500L)
  - Batch and Fed-batch
- Bispecific Antibody Production



## Warehouse

### Supports various product types

- Storage Conditions:  
15 - 25°C, 2 - 8°C, - 40°C, - 80°C

# Hopewell – First U.S. Biologics Manufacturing Facility



## Biologics Campus Expandable to Small Molecule & ADC

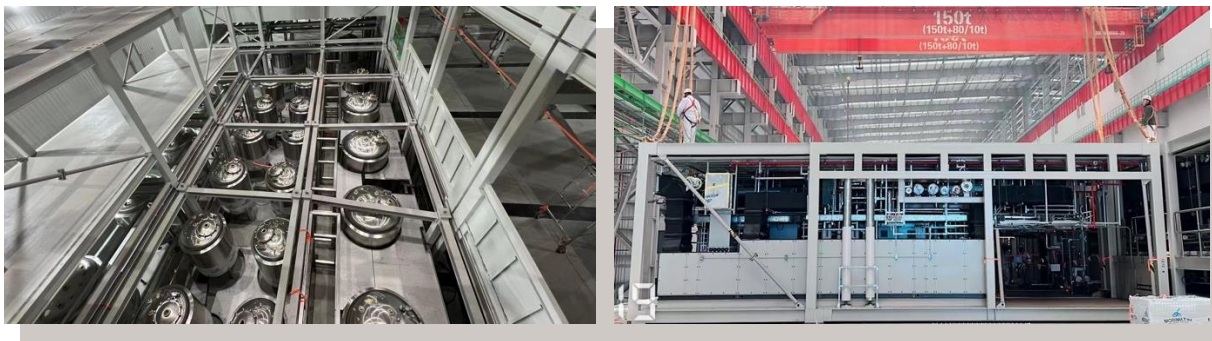
DS Suite with SUS 2kL bioreactors  
DP line (Liquid & Lyophilized vials)



**42-acre site**  
with 150,000 sq ft built



# Expansion of State-of-the-Art Manufacturing Facility



## Drug Substance

### Manufacturing Capabilities

- Total 8kL Cell Culture Capacity
  - Single-use System (4 x 2kL)
  - Batch, Fed-batch, and Perfusion
- Faster expansion through modular system
- Room reserved for additional 4 x 2kL line



## Drug Products

### DP Production Lines

- Isolators
- Liquid vials (clinical & commercial)
- Lyophilized Vials (clinical & commercial)
- Label & Packaging



## Warehouse

### Equipped with Latest Technology

- ASRS (Automatic Search & Retrieval System)
- Storage Conditions:
  - 2 - 8°C, - 20°C, - 70°C

# High Standard Quality Management System



*Benchmarking ICH and US, European, and Chinese GMP standards to provide accessible and affordable good drugs for patients around the world*

**Quality System:  
Internationally Recognized Top Standards**

**30+ Approvals And Inspections In 5+ Years  
(US FDA, EMA, TGA, China NMPA, ANVISA, and more)**



➤ **Successful Regulatory Approvals**

➤ **Inspections With Zero Critical Observations**

# QC Lab- Comprehensive Testing Capability

Global Stability Center

Global Reference Standard  
Management Center

Global Sterility Assurance



QC Lab

**Established BeiGene's Global Testing Platform**  
Focuses on Analytical Method Validation/Transfer and QC Testing

Raw  
Material

In-Process  
Control (IPC)

DS/DP  
Release

DS/DP  
Stability

Environmental  
Monitoring

Utility  
Monitoring

Reference  
Standard  
Management

- **Globalized Quality System** enables the quick and efficient biologics CMC development
- **Phase-appropriate strategy** which meet international GMP regulatory requirement

# Bio PD/CMC and MST Capabilities



## BIO PD & CMC

### Established Large Molecule Development Platform

End to End (IND to Commercial)

#### Cell Line & Process Development

- Cell Line Development
- Upstream & Downstream Development
- Analytical Development
- Formulation Development (Liquid, Lyo, PFS)
- Media Development
  - Proprietary Media (2x Titer output)

mAbs, BsAb/TsAb,  
ADC, Fabs, Fusion,  
Recombinant protein

#### CMC Strategies and Management

- Fast to IND, BLA Strategies
- Ensure Timeline and Meet BLA Requirement (Global HA)
- Internal & External Programs Management

#### Due Diligence

- Assess CMC aspect of potential collaboration
- Contract negotiation around CMC Terms



## MST Lab

### Established BeiGene's Global Lab Capabilities

Well-equipped MST Lab With Expansion Opportunities

#### Technical Support

- Tech Transfer
- Process Validation
- Continuous Process Verification
- On The Floor Support

#### Lab Capability

- Deviation Analysis

**CANCER HAS  
NO BORDERS.  
NEITHER  
DO WE<sup>®</sup>**

# Thank You

Contacts:

Business Development  
[BDnotices@beigene.com](mailto:BDnotices@beigene.com)