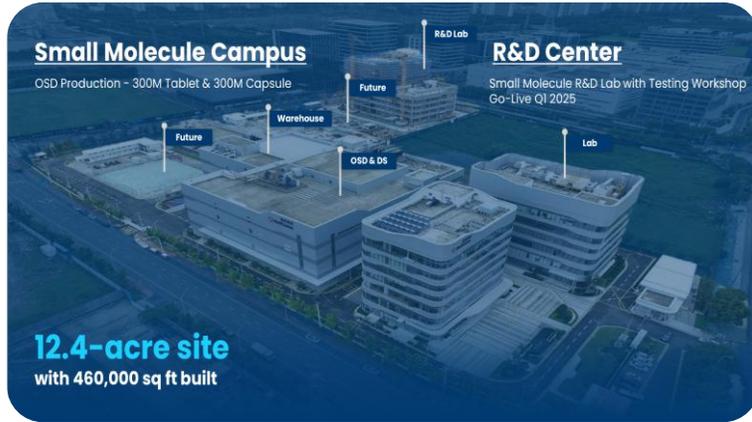




BeOne Medicines Suzhou Manufacturing Campus

Suzhou, China Site | Small Molecule Campus



Suzhou, China Site



Oral Solid Dosage

- 600M Capsule & Tablet Production Capacity (Expandable to 1B)
- Blending & Sieving, Wet & Dry Granulations, Capsule Filling & Tableting, and Film Coating
 - Primary Packaging (Bottle & Blister)
 - Secondary Packaging



Warehouse

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



QC & CMC

- QC: Analytical Method Validation & Transfer and Testing
 - Raw Material, IPC, Release, Environmental Monitoring, Utility Monitoring
 - Stability & Reference Standard Management
- CMC: Drug Substance, Drug Product and Analytical Research & Development
- TS: Tech Transfer to Continuous Process Verification



BeOne Medicines | Global Manufacturing Capabilities Overview

Biologics Campus

Hopewell NJ US Site

42-acre site
with 400,000 sq ft built

First U.S. Biologics Manufacturing Facility



Drug Substance

- Total 8kL Cell Culture Capacity - Single-use System (4 X 2kL)
 - Batch, Fed-batch, And Perfusion
- Mammalian (Mab, Bsab/Tsab, Fabs, Fusion, Recombinant Proteins)
- Expansion Plan:** 2nd Line Cell Culture (4x2kL), ADC Conjugation



Drug Products

- Isolators
- Liquid Vials (Clinical & Commercial)
 - Labeling & Packaging
- Lyophilized Vials (Clinical & Commercial)
 - Expansion Plan:** Small Molecule & ADC



Global Quality Track Record

30+ of Approvals and Inspections in 5+ Years (US FDA, EMA, China NMPA, ANVISA, TGA, MFDS, and more)

ADC Campus

Biologics Campus

Guangzhou China Site

39-acre site
with 1.3 million sq ft built

Clinical & Commercial Biologics and ADC Production



Drug Substance

- Total 65kL Cell Culture Capacity - Single-use System (2 x 500L, 12 x 2kL), Stainless System (8 x 5kL)
 - Fed-batch Cell Culture And Purification
- Mammalian (Mab, BsAb/TsAb, Fabs, Fusion, Recombinant Proteins)
- ADC** (PD and Manufacturing)



Drug Products

- Liquid Vials (Clinical & Commercial)
 - Pre-filled Syringes (Clinical & Commercial)
- Lyophilized Vials (Clinical & Commercial)
 - Labeling & Packaging



QC & MST Lab with Global Platform

Analytical Method Validation & Transfer

Global Stability & Reference Standard Center

Small Molecule Campus

Suzhou China Site

12.4-acre site
with 460,000 sq ft built

Clinical & Commercial Small Molecule Production



Oral Solid Dosage

- 600M Capsule & Tablet Production Capacity (Expandable To 1B)
- Primary Packaging (Bottle & Blister)
- Labeling & Packaging



Global PD Lab & CMC Mgmt.

Cell Line & Process Development (incl. Formulation)

CMC & Project Management



Thanks

