



# **Diversified Modalities**



Biologics | Mammalian (mAb, BsAb/TsAb), **Fusion. Recombinant Proteins** 



# Hopewell **Manufacturing Site**

**Princeton West Innovation Center, NJ USA** 

**42**-acre of state-of-the-art U.S. biologics

manufacturing site with \$800 million capital investment that complement BeOne's existing capabilities around the world

# **Global Manufacturing Footprint**



# Hopewell Site

Flagship U.S. Biologics Manufacturing Center Since 2024

- 42-acre site
  - 350,000 sq ft built
- Total 8kL cell culture capacity
- Phase II + for Small Molecule, ADC & Other

# **Guangzhou Site**

**Biologics & ADC Manufacturing** 

- Since 2019
- 39-acre site
- 1.3 million sq ft built
- · 65kL total cell culture capacity
- Liquid, Lyo, PFS capability

#### **Suzhou Site**

Small Molecule Manufacturing

- Since 2017
- 12.4-acre site
- 460.000 saft built
- Total 600M Tablet/Capsule capacity

# **Hopewell Manufacturing Site**

Expansion of State-of-the Art Manufacturing Facility



#### **Manufacturing Capabilities**

- Total 8kL Cell Culture Capacity
  - Single-use System (4 x 2kL)
  - Batch, Fed-batch, & Perfusion
- Drug **Substance**
- Shell for additional 4 x 2kL line (Phase II+)
  - Faster expansion through modular system



#### **DP Production Lines**

- Isolators
- Liquid vials
- Drug **Products**
- Lyophilized vials
  - Label & Packaging



#### Lab Capabilities

- Analytical Method Development, Validation, and Transfer
- QC & MST Labs
- QC Testing (Release, IPC, Stability and more)
- Tech Transfer. Process Validation. MFG tech support



#### **Equipped with latest technology**

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

Warehouse

# **Analytical & CMC Global Capabilities**



#### **QC Lab**

# **Global Testing Platform**

- Analytical Method Validation & Transfer
- Global Stability Center & Reference Standard Management Center



# PD Lab

## Large Molecule Development Platform

- Cell Line & Process Development
- Media Development, Proprietary Media
- Formulation Development



# СМС

### **End-to-End CMC Strategies & Management**

- Fast to IND, BLA strategies
- Internal & External Programs Management

Growing Quality Track Records with Approved Internal & Partnered Assets and Manufacturing Authorizations



**Global Quality Systems** 

**30+** Approvals & Inspections in **5+** years

Critical Observations

(US FDA, EMA, China NMPA, ANVISA, TGA, MFDS +)



**17** Approved Products

**30+** Clinical & Commercial Assets

**40+** Phase 3 or potentially registration enabling trials

- Globalized Quality System enables the quick and efficient biologics CMC development
- Phase-Appropriate Strategy which meets international GMP regulatory requirements

# Molecule to IND and beyond



- Proprietary afucosylated CHO & Media
- Industry-leading productivity: 8-10g/L for mAbs, 5-8g/L for complex molecules
- Media, Buffer & Excipient Screening
- Assay Development & Characterization Study

# **Global BeOne Network**

Experienced BeOne's global team to support collaborations



**40** offices, **11,000+** colleagues globally on **6** continents with **1,500+** Global Tech Ops Team



~**20** industry collaborations





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