### Global Premier CRDMO: Enabling Global Partners and Delivering Sustainable High Growth

Chris Chen, Ph.D. 2023 Investor Day Fengxian Shanghai





Stock Code: 2269.HK





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#### Use of Adjusted Financial Measures (Non-IFRS Measures)

We have provided adjusted net profit, adjusted net profit margin, adjusted EBITDA, adjusted EBITDA margin and adjusted diluted earnings per share for the corresponding periods, which excludes the share-based compensation expenses, listing expenses and foreign exchange gains or losses, and are not required by, or presented in accordance with, IFRS. We believe that the adjusted financial measures used in this presentation are useful for understanding and assessing underlying business performance and operating trends, and we believe that management and investors may benefit from referring to these adjusted financial measures in assessing our financial performance by eliminating the impact of certain unusual and non-recurring items that we do not consider indicative of the performance of our business. However, the presentation of these non-IFRS financial measures is not intended to be considered in isolation or as a substitute for the financial information prepared and presented in accordance with IFRS. You should not view adjusted results on a stand-alone basis or as a substitute for results under IFRS, or as being comparable to results reported or forecasted by other companies.

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Disposables as powerful as stainless technologies

**Success of Follow the Molecule Strategy** 

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#### **Pompe Disease Overview**



Pompe disease is a rare genetic disorder that causes progressive weakness to the heart and skeletal muscles.



Two types which are Late-onset Pompe disease (LOPD) and Infantileonset Pompe disease (IOPD) 5,000 – 10,000 patients globally.

Caused by mutations in a gene that makes an enzyme called acid alpha-glucosidase (GAA) Respiratory failure and heart failure are two of the most lethal manifestations of diseases.

Enzyme replacement therapy can treat Pompe disease.

Currently Nexviazyme from Sanofi are used on market, cost \$760k/year.

If newborn babies diagnosis as Pompe disease, they usually do not live to 1-2 years old.

#### How Drug Discovery Became a Personal Journey (1998-2010)?



John Crowley
Executive Chairman of
Amicus



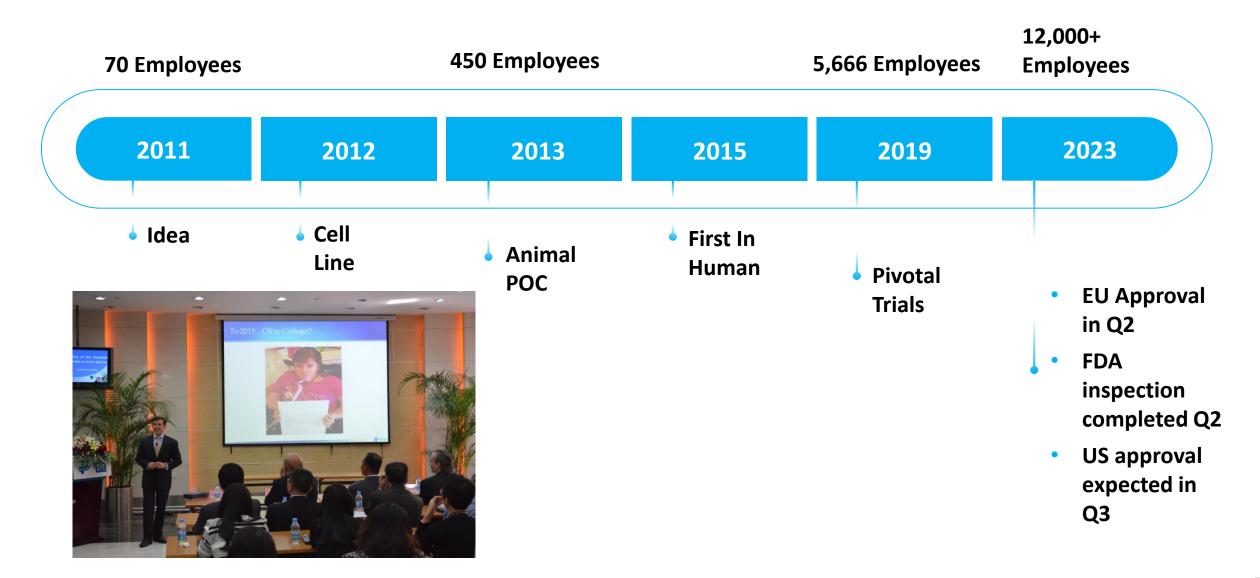
#### The Story was taken into the movie "Extraordinary Measures" in 2010





## Sequel of "Extraordinary Measures" (2011-2023): Finding a Next-generation Biologics – More Precise and Potent





#### **AT-GAA: Global Regulatory Status**



#### Anticipate regulatory approvals and launch into the three largest Pompe markets in Q3 2023



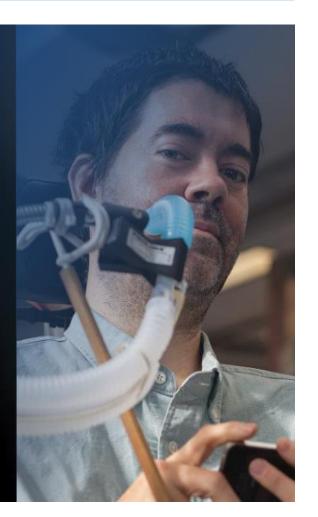
- Pombiliti™ (cipaglucosidase alfa) received a positive CHMP opinion in December 2022
- Miglustat CHMP opinion is expected in Q2 2023



- Pre-approval manufacturing inspection schedule for Q2
- Approval expected in Q3



 U.K. MAA submitted via recognition procedure based on CHMP opinion



#### Global Dual Sourcing Strategy to Enable the Client





Every batch can provide a full year supply for approx. 1% of global population!

#### D to M Conversion 100% Since 2018:





Concentrated Fed-batch process; China NDA approval as breakthrough in Aug 2021



Approved in US & EU; Continuously reporting positive data in new indication



China NDA approval in Dec 2021 & oversea BLA submission in Dec 2022

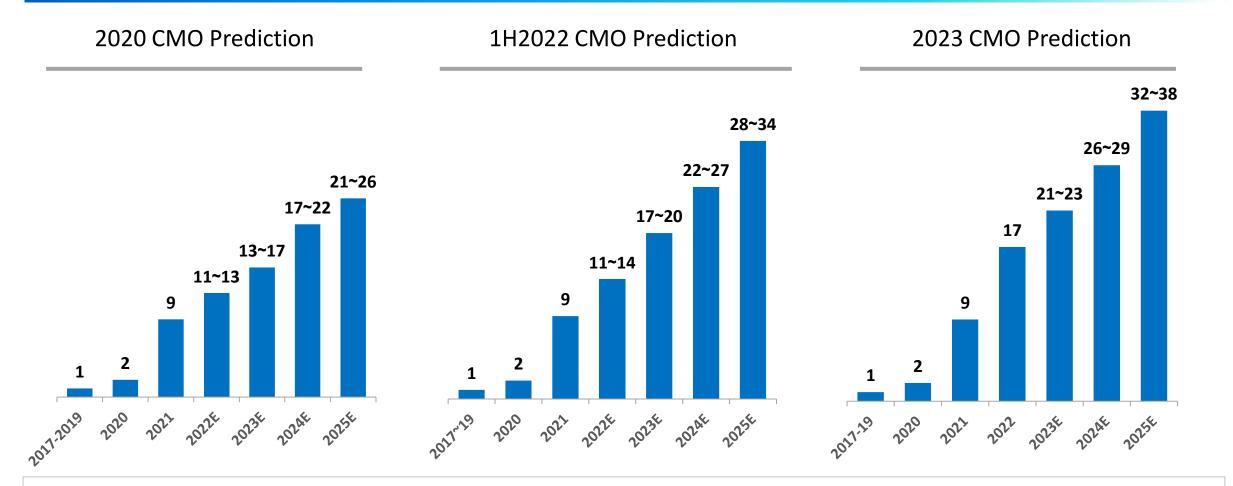


Challenging perfusion cell culture process; MAA approval in Mar 2023



## Commercial Manufacturing will Drive Strong Growth from 2021 and Beyond



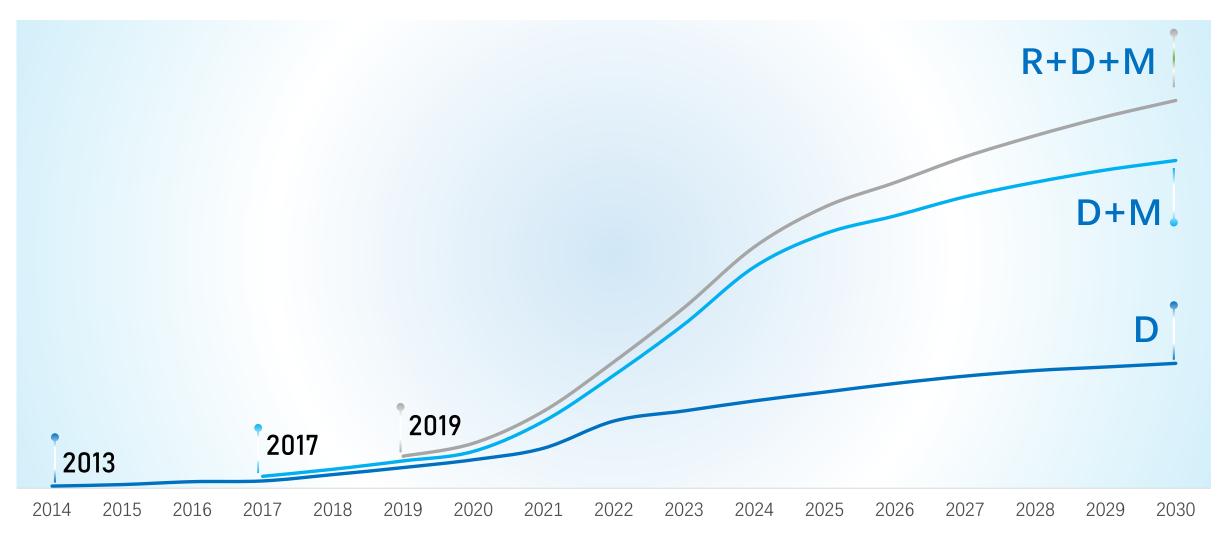


- CMO projects are expected to increase by implementing "Follow & Win the Molecule" strategies
- "Win-the-molecule" enables WuXi Bio to secure more potential CMO projects

## CRDMO: Three Growth Curves Drive Sustainable Long-term Growth



#### **Three Long-Term Growth Curves**



Transferring the Success to Ireland

02

## **Project Execution: Fastest Project Built to GMP in Ireland Despite COVID**









- 65.5 Acre greenfield site
- Construction started in early 2019 and completed 26 months later
- 467,520sq.ft. of floor space across 18 distinct areas/buildings, 313,058sq.ft. GEP, 154,150sq.ft. GMP
- 500,000 tons of earth moved, 6,000 tons of structural steel, 39 miles of underground dry services, 6.2 million work hours, 1,400 average personnel on site
- Commissioning, Qualification and Validation (CQV) accounted for 70,000 files, 120,000 records and 9,500 material certs across over 140 equipment vendors and 4 mechanical contractors

#### **Project Successes**



- Over the course of the project nearly 75 archaeologists were empowered to dig and preserve the historical artifacts spread across the construction site
- Project was completed with a remarkable safety record of a 0.35
  recordable injury rate with the final 13 months of construction (3 million
  work hours) completed without a single recordable event
- Sustainability efforts include; heat recovery system, low emissivity glazing,
   PV solar, EV charging, 'wilding' of green spaces





#### **ISPE** Facility of the Year for 2023



- ISPE's (International Society for Professional Engineers) Facility of the Year Awards is an annual program that recognizes state-of-the-art projects unitizing new technologies to improve the quality of products, to reduce the cost of producing high-quality medicines, and demonstrate advances in project delivery
- Winners in the category of Operations exemplify the application of novel tools and approaches to delivering projects





#### Ireland will Deliver High Revenue & Profitability



Signed Commercial Contracts		MFG	Scale (FB)	Est. Batches/Yr.
	Pharma A	Perfusion	1K	30+
	Pharma B	Fed Batch	12K	10+
63	Pharma C	Fed Batch	16K	6+
	Pharma D	Fed Batch	8K	20+
	Pharma E	Fed Batch	12K	15+
	Pharma F	Fed Batch	12K	13+
	Pharma G	Fed Batch	12K	20+



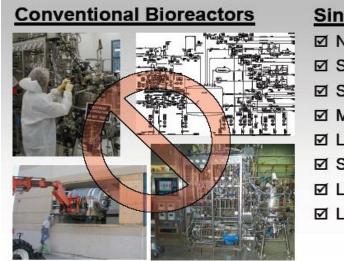
Significant commercial manufacturing from 2024 onwards, almost fully booked in 2025 30% projects transferred from China as global dual sourcing ie follow the molecule 70% win the molecule for all potential blockbuster biologics

Disposables achieved multiple ton scale with similar COGS

03

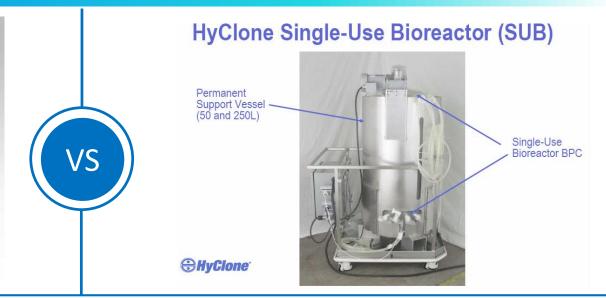
## TECHNOLOGY: Disposable Manufacturing Technology Proven Effective in Commercial Manufacturing





#### **Single-Use Bioreactors**

- ☑ No cleaning and sterilization
- ☑ Simple design & operation
- Saves time and resources
- Minimal utilities
- ☑ Less maintenance and repair
- ☑ Simple qualification & validation
- ☑ Low contamination risk
- ☑ Less capital investment



- Global leader and pioneer in using disposable manufacturing technology
- 4,000kg+ neutralizing mAbs delivered 12,000/16000L scale
- COGS reduced to <US\$80/g at 12,000L scale, comparable COGS with similar stainless steel</li>
- 1,500+ batches manufactured at ~98% success rate
- Less CAPEX, faster in building facilities (one year) and comparable COGS resulting in higher ROI (MFG1 10-year ROI 51% realized, MFG2 35%, MFG3 50% expected)

## Disposable Bioreactors CAN Deliver Lower COGS than Stainless Steel



Scale of Disposable Bioreactors	Scale of Stainless Steel Bioreactors	Cost Difference	Manufacturing Experience at WuXi Biologics
2,000L	12,000L	Disposable ~30% more expensive	MFG1 500+ batches
6 x 2,000L	12,000L	Disposable ~10% cheaper	MFG2 50+ batches
3 x 4,000L	12,000L	Disposable ~10% cheaper	MFG5 20+ batches
6 x 4,000L	12,000L	Disposable ~20% cheaper	MFG9
6 x 4,000L	25,000L	Disposable ~10% cheaper	MFG9
2,000L Wuxi UP™	2,000L	Disposable ~30% cheaper	MFG1/MFG2 50+ batches
2,000L WuXiUP™	12,000L	Disposable ~10% cheaper	MFG1/MFG2 50+ batches

- Through scale-out (multiple-pack of disposable bioreactors) and WuXiUP™, disposable bioreactors can achieve similar or lower COGS as any stainless steel bioreactors
- Supported with 100+ batches of data across 10+ projects at WuXi Biologics

## Disruptive Single-Use Technology Pioneered by WuXi Bio ~44% Market Share in New Capacity, 65-70% in R&D



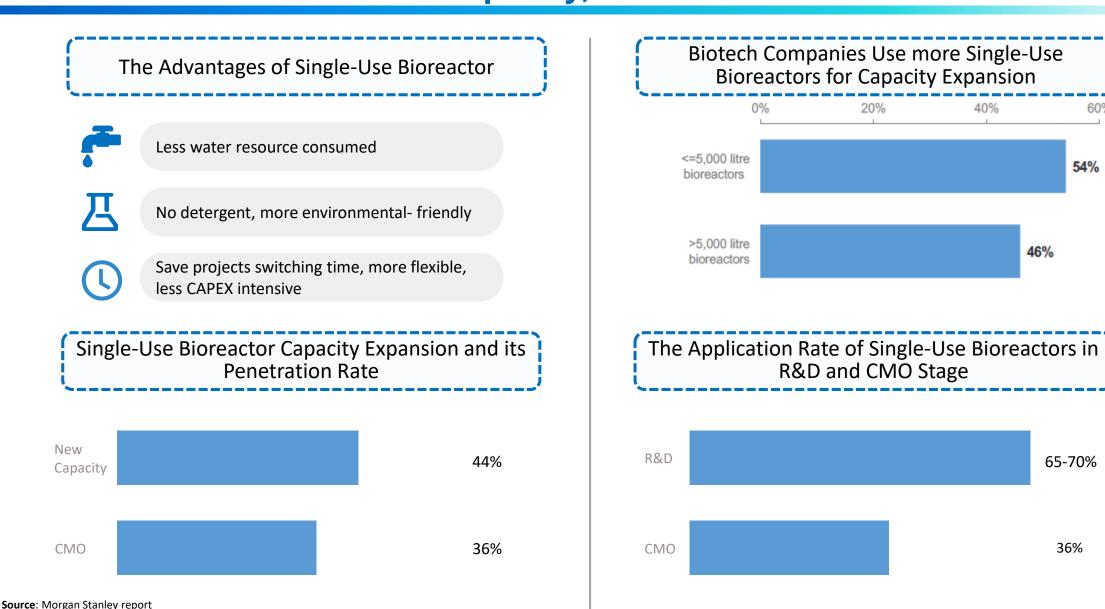
54%

46%

65-70%

36%

40%

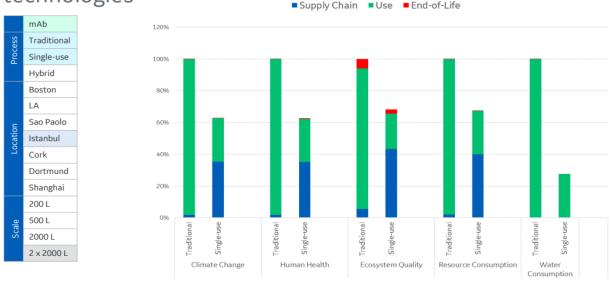


#### **Embracing ESG-friendly Disposable Technology** to Protect Environment



- Launched one of the world's largest cGMP biologics manufacturing facilities using disposable bioreactors in Wuxi
- Significantly reduced the impact on environment 70% water saving 33% energy saving 0 waste water generation
- Other advantages include:
  - Accelerate the R&D process
  - Improve product quality
  - Enhance production efficiency

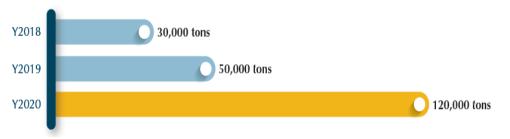
#### Impact comparison for traditional and single-use process technologies





Single-Use Technology and Sustainability | 2017 BPSA International Single-Use Summit

#### Annual water savings due to the adoption of SUT (estimated value)



**Source:** WuXi Bio's ESG Report 2020

#### R in CRDMO



#### **Enable our Clients to Develop First-in-Class & Best-in-Class Biological Drugs**

## Arcus Biosciences Expands Strategic Relationship with WuXi Biologics to Develop a Best-in-Class anti-CD39 Antibody for the Treatment of Cancer

- The parties will discover anti-CD39 antibodies using WuXi Bio's proprietary technology.
- This CD39 collaboration represents the fourth antibody development program on which the two companies have joined forces.
- Arcus was granted exclusive worldwide rights to anti-CD39 antibodies discovered under the collaboration and will be responsible for all further development and commercialization activities of such anti-CD39 antibodies.

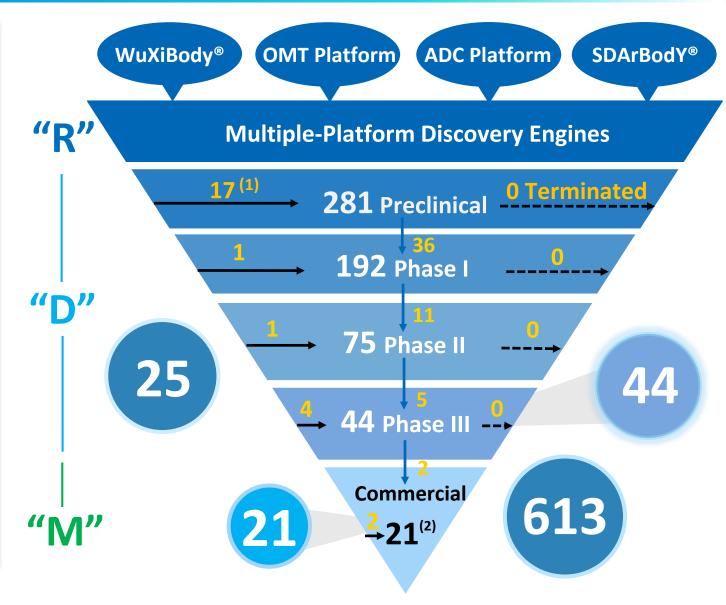
## WuXi Biologics and GSK Enter into License Agreement on Multiple Novel Bi- & Multi-specific T Cell Engagers

- WuXi Biologics will provide an exclusive license to GSK for 1 preclinical bispecific T cell engaging (TCE) antibody and 3 additional bi-/multi-specific TCE antibodies developed using WuXi Biologics' proprietary technology platforms
- WuXi Biologics will receive an upfront payment of US\$40 million, up to ~US\$1.4 billion at key milestones and tiered royalties on net sales

## Soft Growth in Pre-clinical balanced with Strong Growth in Phase III & CMO Drive 2X industry growth



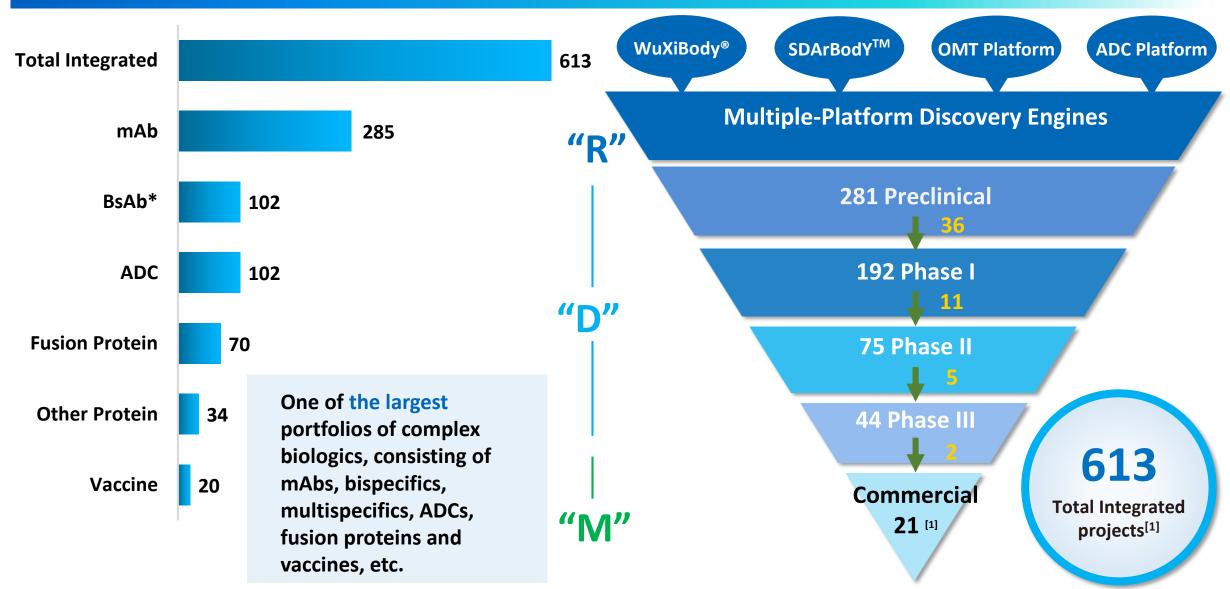
- Biotech funding slowdown especially in China resulted in softer growth in preclinical stage. Only observed 6Q into the cycle still highlighted our leadership position.
- Anticipate similar market share as the acceptance rate for WuXi is similar.
   Sales cycle extension is the reason for the lower No. of projects
- Q4 2022 drive to sign record numbers of projects also pulled up H1 2023 demands
- "Win-the-Molecule" strategy continued to excel: 8 external projects transferred into the pipeline as of May 31, 2023, including 4 phase III projects and 2 CMO for blockbuster products
- 21 CMO projects: superb growth



#### Notes:

#### Rich Pipeline across All Biologics Modalities: ADC and BsAb





#### Notes:

<sup>\*</sup> Bispecific Antibody (BsAb) Included both WuXiBody® projects and non-WuXiBody® projects

#### **QUALITY: Global Regulatory Inspections**



#### **Number of License Approvals: 42 Number of Regulatory Inspections:30** Q1, 3 WBP23XX Q1, 1 WBP21XX WBP23XX WBP1XX 30 I EMA 2023 **■** FDA \_ . \_ . \_ . \_ . **■** EMA 27 Q2, 1 FDA **EMA** 37 2022 **MNPA** FDA, 7 Others(ANVISA, HAS, PMDA etc.) 2021 20 FDA, 6 22 2020 EI ■ EMA ■ FDA FDA, 5 2019 EMA. 8 EMA, 8 2018 EMA, 7 Q1 **Number of Certified Facilities: 14** NMPA. NMPA, 5 MFG1 MFG2F MFG2I MFG3(CB) MFG3 MFG4 DP1 DP4 DP7 Biosafety Vaccine DP2 MFG5 MFG6/7 2023 14 MFG1 MFG2F MFG2I MFG3(CB) MFG3 MFG4 DP1 DP4 DP7 Biosafety Vaccine DP2 MFG5 MFG6/7 6 NMPA, 5 14 Q1, 2022 5 FDA, 2 MFG1 MFG2F MFG2I MFG3(CB) MFG3 MFG4 DP1 DP4 DP7 Biosafety 10 2021 FDA, 2 Others, 8 EMA, 3 Others, ! MFG1 MFG3(CB MFG4 DP1 Biosafety 5 2020 EMA. 3 FDA, 1 MFG1 MFG2F ■ MFG2P ■ MFG3(CB) 2019 FG1 MFG3(CB) DP1 Biosafety 4 MFG3 MFG4 M DP1 ■ DP4 2021 2022 2023 2017 2019 2020 M DP7 ■ Biosafety ≥ Vaccine M DP2 DP1 **2** MMFG5 MFG6/7 Ministry of Food and 角 国家药品监督管理局 **Y**HSA Health

#### **ESG** Highlights



- 1. 53% of employee are women; 47% of managerial positions and 30% of executive management are female
- 2. 100% renewable energy combined with disposable manufacturing technologies make Irish manufacturing site "greenest" biologics manufacturing globally
- 3. Committed to Science Based Targets Initiative (SBTi)
- 4. 21% YoY reduction in GHG emissions intensity (Scope 1/2)





#### **WBS: Continuous Improvement**



#### **CEO Kaizen**

#### 70million

Cost saving on materials for clinical drug substance manufacturing

#### 15million

AS/QC cost saving on testing reagents and consumables

#### 4batches

MFG5 capacity increase by buffer preparation method improvement

#### 30%

XDP1 capacity increase by reducing change over time

#### 70%

QC CoA approval lead time reduction to speed up product release and improve customer satisfaction Inventory control strategy optimization to significantly reduce Inventory and material impairment Risk-based material management process optimization to enable more flexibility and agility in material selection and reduce material cost

Target to improve 300 bps GPM in 2023



## **Evolution of Biologics Service Companies: WuXi Biologics Leading the Industry as CRDMO**



## CMO: Contract Manufacturing 1990s – 2000s

- Business rationale: mostly 2nd supplier for large pharmas to ensure robust supply chain
- Core expertise: large-scale manufacturing

## CDMO: Contract Development and Manufacturing 2000s – 2015s

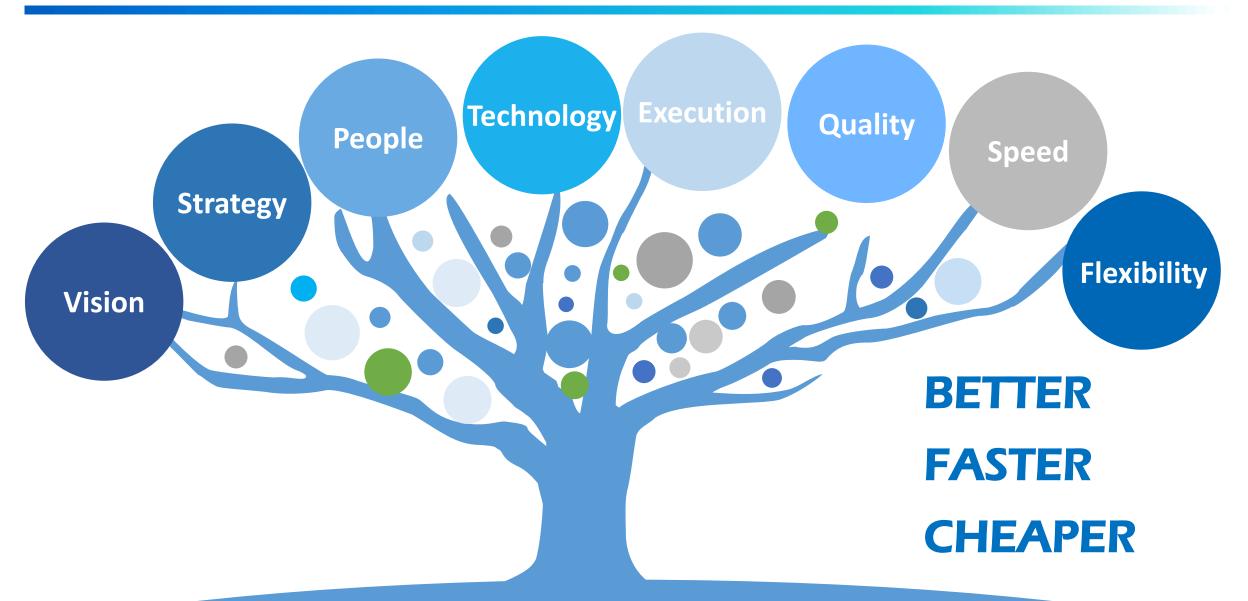
- Business Rationale: small and medium-sized biotechs need end-toend one-stop shop services and often require external technology for new modalities: ADCs or bispecifics
- Core expertise: development technology and large-scale manufacturing

# CRDMO: Contract Research Development and Manufacturing 2015s - present

- Business Rationale: innovation driven by small and mediumsized companies requires end-to-end services from ideas to commercial manufacturing
- Core expertise: discovery/development platforms and manufacturing
- Newest trend of service companies: sticky business model which engages with partners 5-10 years earlier than traditional CMOs







#### Global Premier CRDMO Enable Global Partners and Deliver Sustainable High Growth Despite Recent Challenges



- 2X industry growth achievable due to success of both Follow and Win the Molecule strategies.

  1 H witnessed slower growth of follow the molecule, however win the molecule for phase III and blockbuster commercial drugs accelerated
- Ireland site almost fully booked for 2025 demonstrated great success of strategy and execution: 30% projects transferred from China as global dual sourcing ie follow the molecule and 70% win the molecule for all blockbuster biologics
- 3 Disposable manufacturing proven to deliver multi-ton of mAbs at similar COGS as stainless steel. Flexibility of Disposable technologies: from 100Kg to 10+ tons
- Digitalization have been effectively used in discovery, development and manufacturing for 3+ years. Digital empowered WuXi Biologics will continue to enable faster, better and cheaper services for biologics discovery, development and manufacturing
- Due to high base in 1H 2022 and shutdown for maintenance after three years of bullet train speed, 1H 2023 will see slower revenue growth. Despite all challenges, maintain the full year guidance

### **WuXi Bio Vision**

"Every drug can be made and every disease can be treated" by building an open-access platform with the most comprehensive capabilities and technologies in the global biologics industry

