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

*Chris Chen PhD*

*40th Annual J.P. Morgan Healthcare Conference*

*(2269.HK)*

**January 2022**

WuXi Biologics

Global Solution Provider

# Agenda

01 Company Update

02 Explosive Growth of Commercial Manufacturing Projects

03 Disposable Manufacturing Proven as Disruptive Technologies

04 ESG as An Important Component of Business Strategy

05 Summary

01

# Company Update

# Evolution of Biologics Service Companies: WuXi Biologics as CRDMO

WuXi Biologics
Global Solution Provider

**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

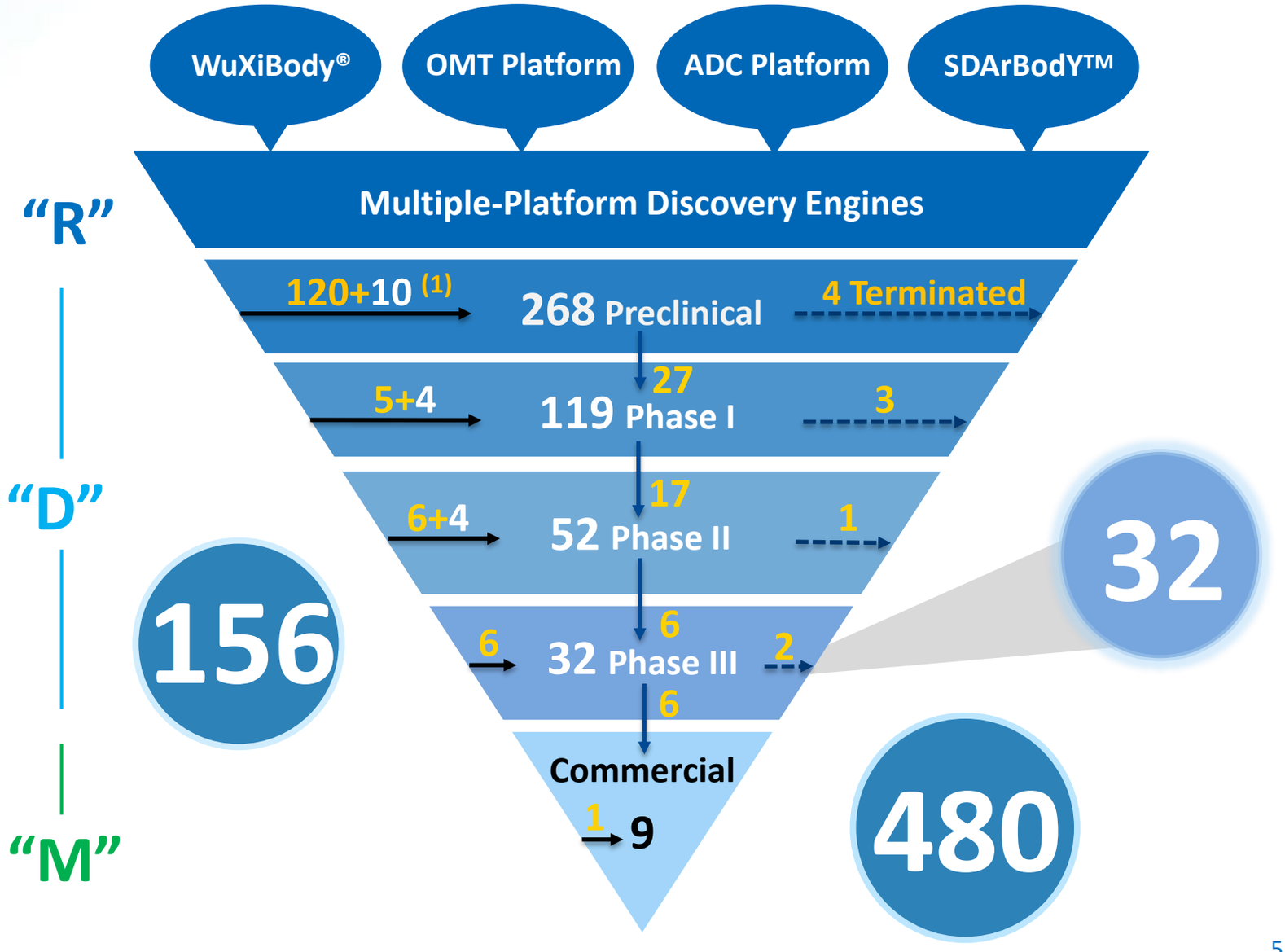
- **Business Rationale: small and medium-sized biotechs need end-to-end one-stop shop services and often require external technology for new modalities: ADCs or bispecifics**
- **Core expertise: development technology and large-scale manufacturing**

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

- **Business Rationale: innovation driven by small and medium-sized 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**

# Business Momentum Continues to Accelerate QoQ in 2021

- Business accelerates with newly-added projects reaching another record high
- 156 new integrated projects added as of Dec. 31, 2021: 138 organic and 18 acquired from CMAB
- 32 Phase III projects: drive near-term growth
- "Win-the-Molecule" Strategy continued: 18 external projects transferred into the pipeline
- Added 7 commercial projects in 2021 with more expected in the future



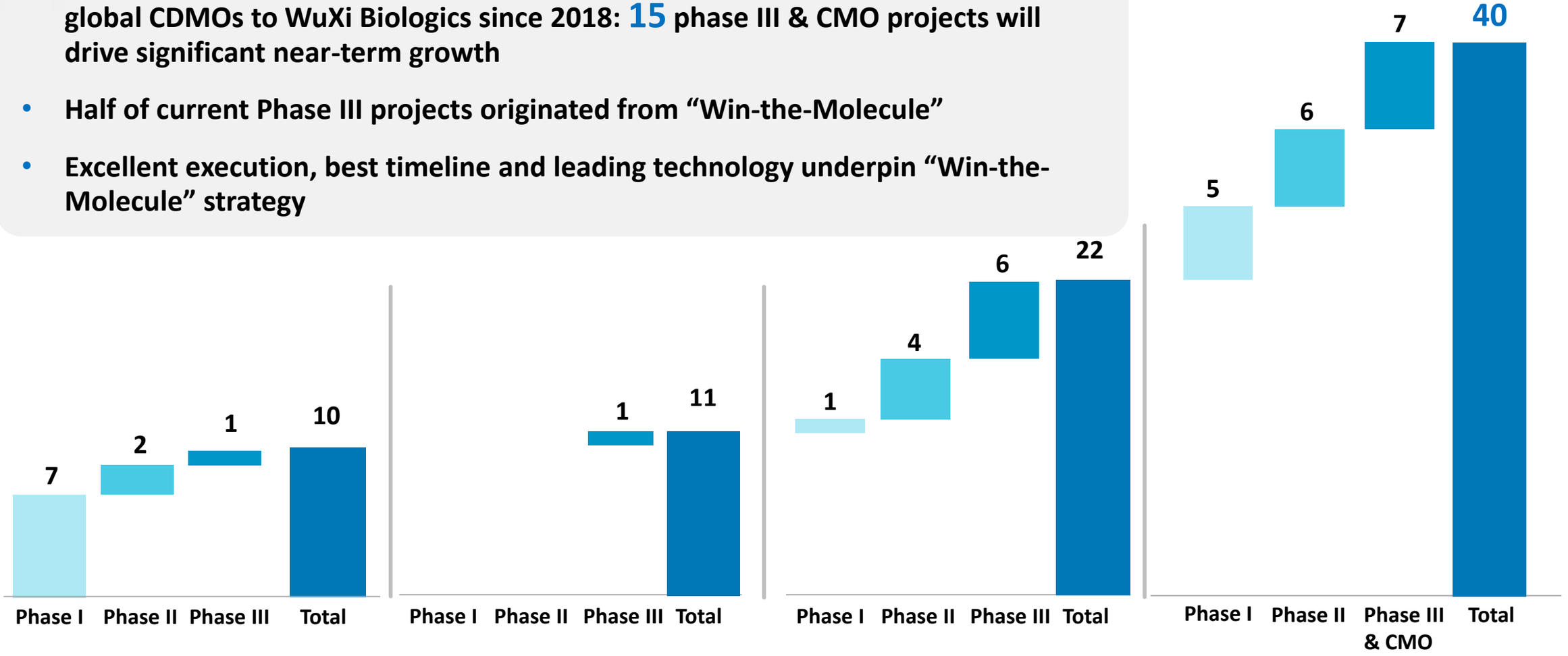

Notes:
1. As of Dec. 31, 2021
2. 10 Preclinical , 4 Phase I and 4 Phase II programs were from CMAB (total 18)
3. The arrows in black are the projects newly added from outside; the arrows in blue are the projects progressing from earlier stage; the dashed arrows are terminated projects

# “Win-the-Molecule” Strategy: New Driver to Expand Pipeline and Drive Additional Near-term Growth

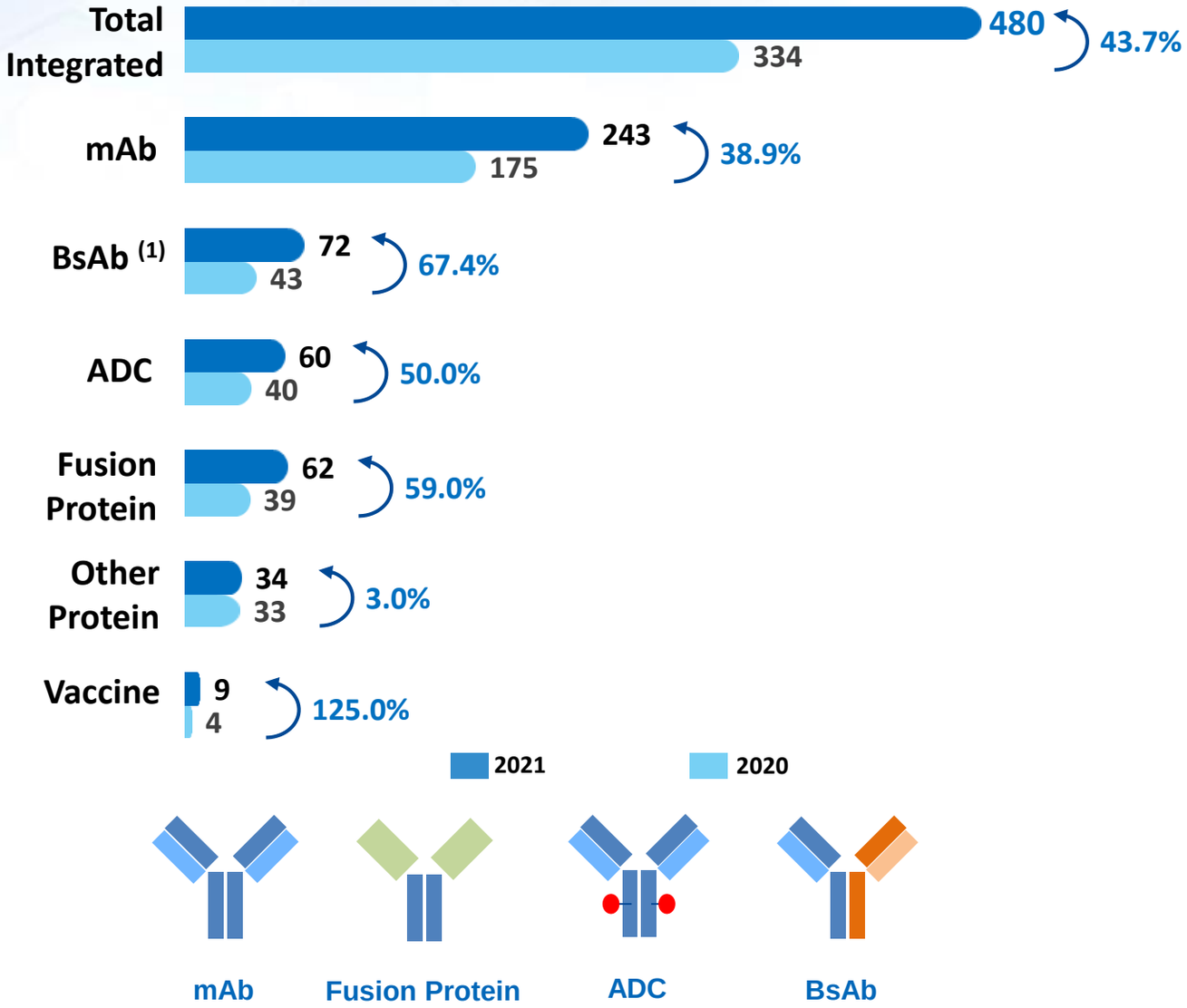
WuXi Biologics
Global Solution Provider

| 2018 | 2019 | 2020 | 2021 |
|---|---|---|---|

- Total 40 projects at different stages (Phase I, II and III + CMO) transferred from global CDMOs to WuXi Biologics since 2018: 15 phase III & CMO projects will drive significant near-term growth
- Half of current Phase III projects originated from “Win-the-Molecule”
- Excellent execution, best timeline and leading technology underpin “Win-the-Molecule” strategy



# Rich Pipeline across All Biologics Modalities

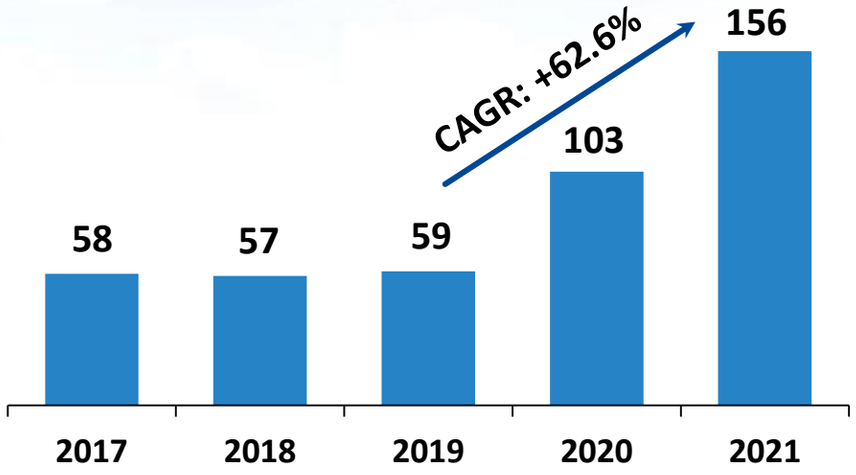



- **182** First-in-class programs
- **9** vaccine projects, including **6** non-COVID vaccines
- **8** CNS (Central Nervous System) programs from domestic and global companies with exciting potential
- Expanding global leading technology platforms providing **mRNA-based vaccine** full CDMO services **(DS+DP)**: **2** projects ongoing
- One of **the largest** portfolios of complex biologics, consisting of mAbs, bispecifics, multispecifics, ADCs, fusion proteins and vaccines, etc.

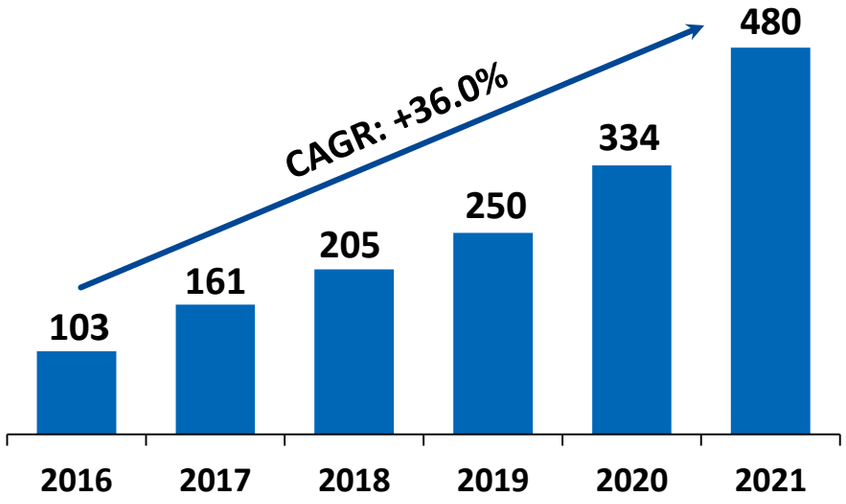
Notes:
1. As of Dec. 31, 2021, compared with projects number as of Dec. 31, 2020
2. Bispecific Antibody (BsAb) included both WuXiBody® projects and non-WuXiBody ® projects

# “Follow & Win the Molecule” Drives Robust Project Growth

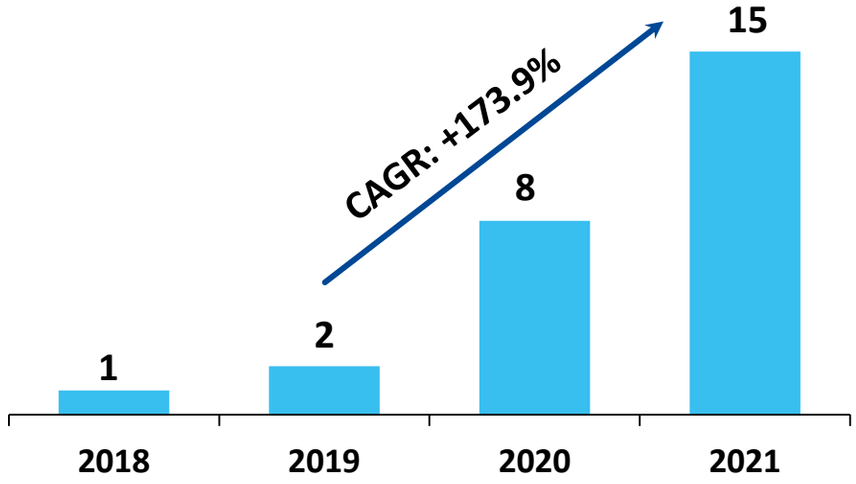
## No. of Newly Added Integrated Projects



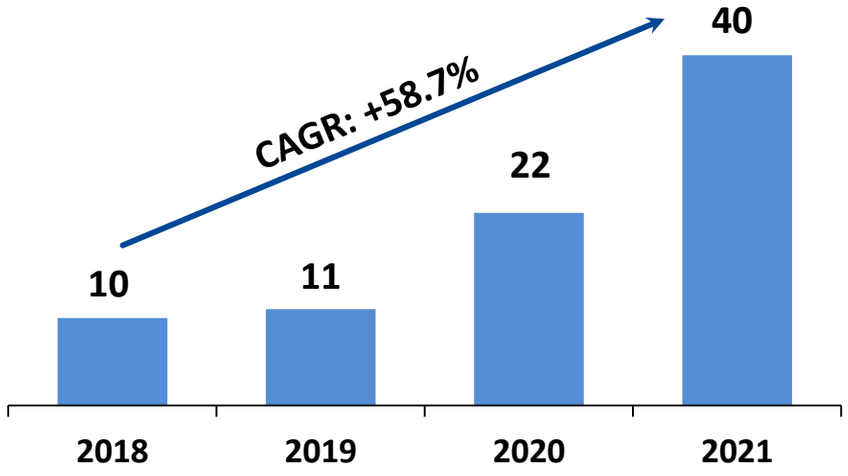

## No. of total Integrated Projects (1)




## No. of “Win-the-Molecule” Phase III & CMO Projects (2)




## No. of “Win-the-Molecule” Projects (2)




Notes:
1. Integrated projects are defined as projects requiring services for multiple stages during biologics development process
2. “Win-the-Molecule” projects are shown in accumulative number

# Global Top 20 Large Pharmas Become Key Clients

- Traditionally “Follow & Win the Molecule” strategy pioneered by WuXi Biologics is a perfect match for small and medium-sized companies
- Global large pharmas became core clients and now contribute ~40% of total revenue in 2021 vs ~20% in 2020 due to growing recognition of WuXi Biologics, M&A of small and mid-sized companies and growth of outsourcing from large pharmas
- Large pharmas continue to work with WuXi Biologics for ~95% of M&A projects and award more projects to WuXi Biologics due to recognition of capabilities
- For two large pharmas, significant portion of their global portfolio being developed at WuXi Biologics. For another large pharma, significant approved products manufactured for US/EU markets at WuXi Biologics
- For two large pharmas, WuXi Biologics considered as an extension of their internal R&D with 100+ FTEs each

# Excellent Operational Metrics Win Client Approval

## Track Record

- 255 INDs, 8 BLA/MAAs approved, 8 BLAs/MAAs/NDAs filed
- 480 integrated biologics projects including 72 bispecifics and 60 ADCs (1)
- 31 on-going WuXiBody® bispecific antibody projects
- 20+ COVID-19 programs in progress and 29 INDs approved
- Capacity of 150 INDs and 12 BLA/MAAs enabled per year

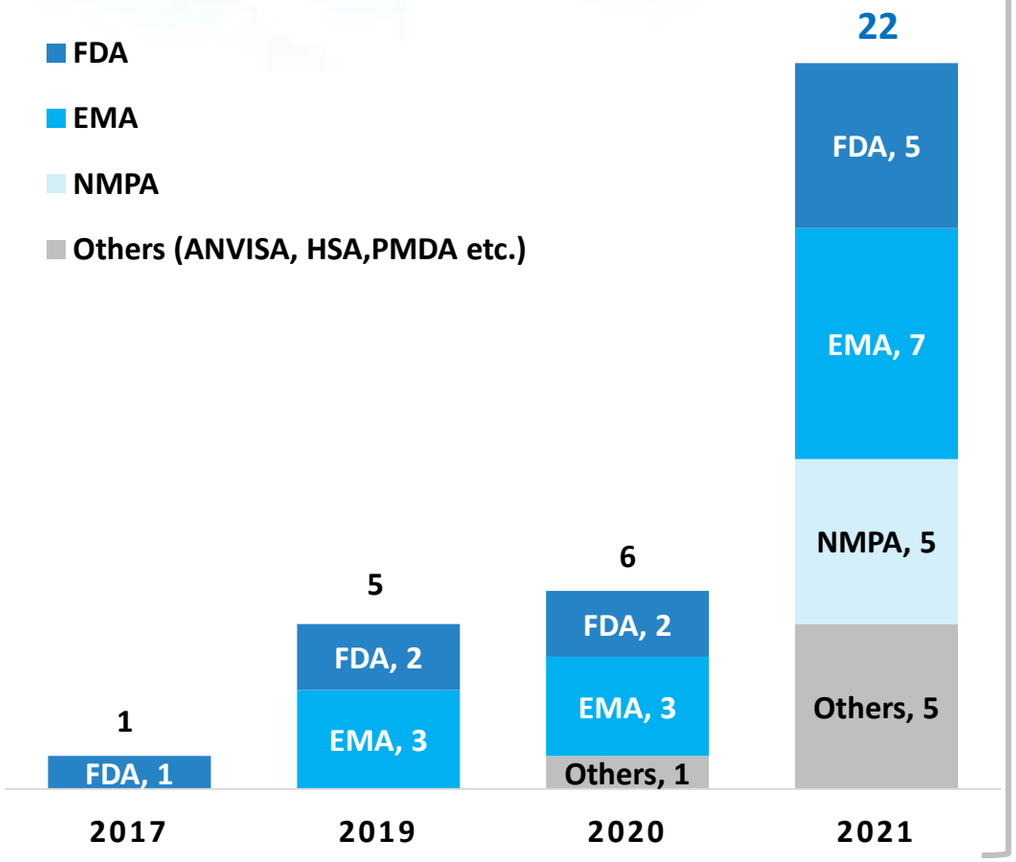
## Operational Excellence

- 15 facilities with 250,000L DS capacity in 2022 vs ~430,000L after 2024
- 13 facilities for drug product filling, including 1 bioconjugate DP in 2022
- Building 13 facilities globally
- 1,500+ DS batches completed with 98% success rate
- 1,300+ DP batches completed with 99%+ success rate, 100+ media fills with 100% success rate
- 247 DS batches completed in MFG3 with 100% success since Apr. 2018
- 208 DS batches completed in MFG1 with 100% success since Mar 2018

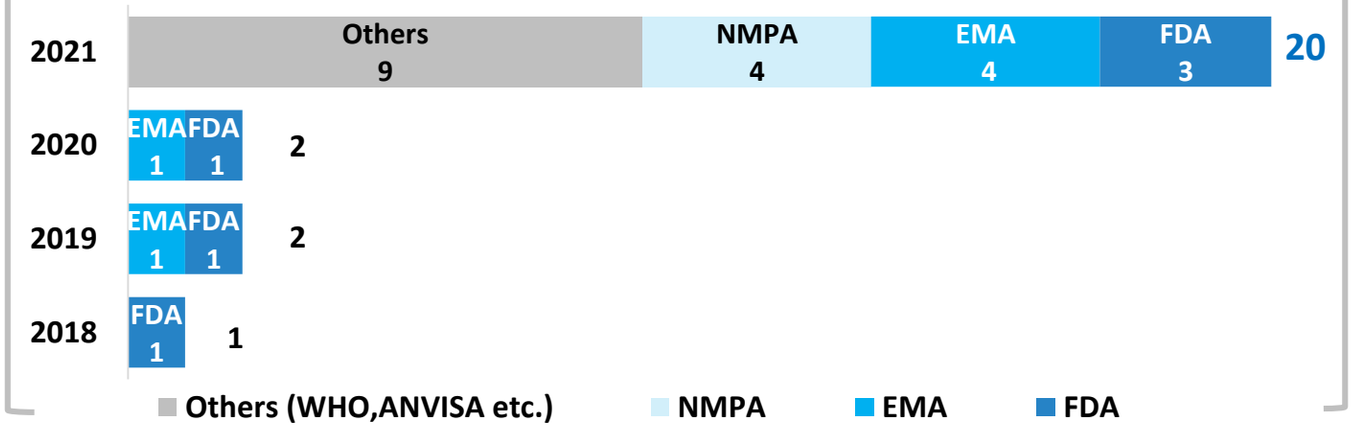
Note:
1. As of Dec. 31, 2021; Other numbers are shown as of Sept. 30, 2021

# QUALITY: Passed 22 Global Regulatory Inspections in 2021

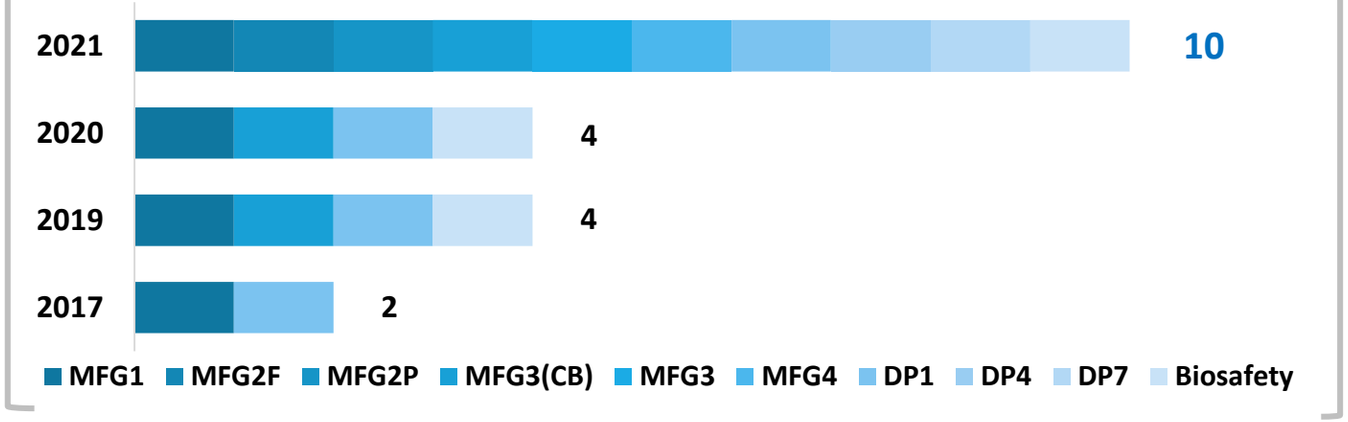
## Number of Regulatory Inspections




## Number of License Approval: 20




## Number of Certified Facilities: 10

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# Full Parallel Capabilities Established from DNA to BLA in US/EU in 2022

***One-stop fully integrated service within the US/EU network from process development to drug substance and drug product manufacturing***

**DNA** **IND** **BLA**

**"Follow & Win the Molecule" Starting from US**

- **MFG18 (Cranbury NJ): PD & 3x2,000L mfg**
- **DP12 (Cranbury NJ): Vanrx filling line**
- **KOP PA: PD lab**

**Global Dual Sourcing within WuXi Biologics**

- **MFG6/7: Dundalk, Ireland (54,000L)**
- **MFG19: Wuppertal, Germany (10,000L)**
- **DP7: Leverkusen, Germany (EU approved)**

- ***2022: Total cumulative CAPEX of ~US$1.5 bn in US/EU to support ~US$1 bn revenue***
- ***2025: Total cumulative CAPEX of ~US$3 bn in US/EU/Singapore to support ~US$2 bn revenue***
- ***2022: All cumulative CAPEX in China ~US$0.9 bn***

# WuXi Biologics Making Significant Contributions to Combat COVID-19

- GSK/Vir's antibody FDA EUA approval
- Brii NMPA approval and FDA EUA pending
- Another COVID mAb phase III successful pending EUA

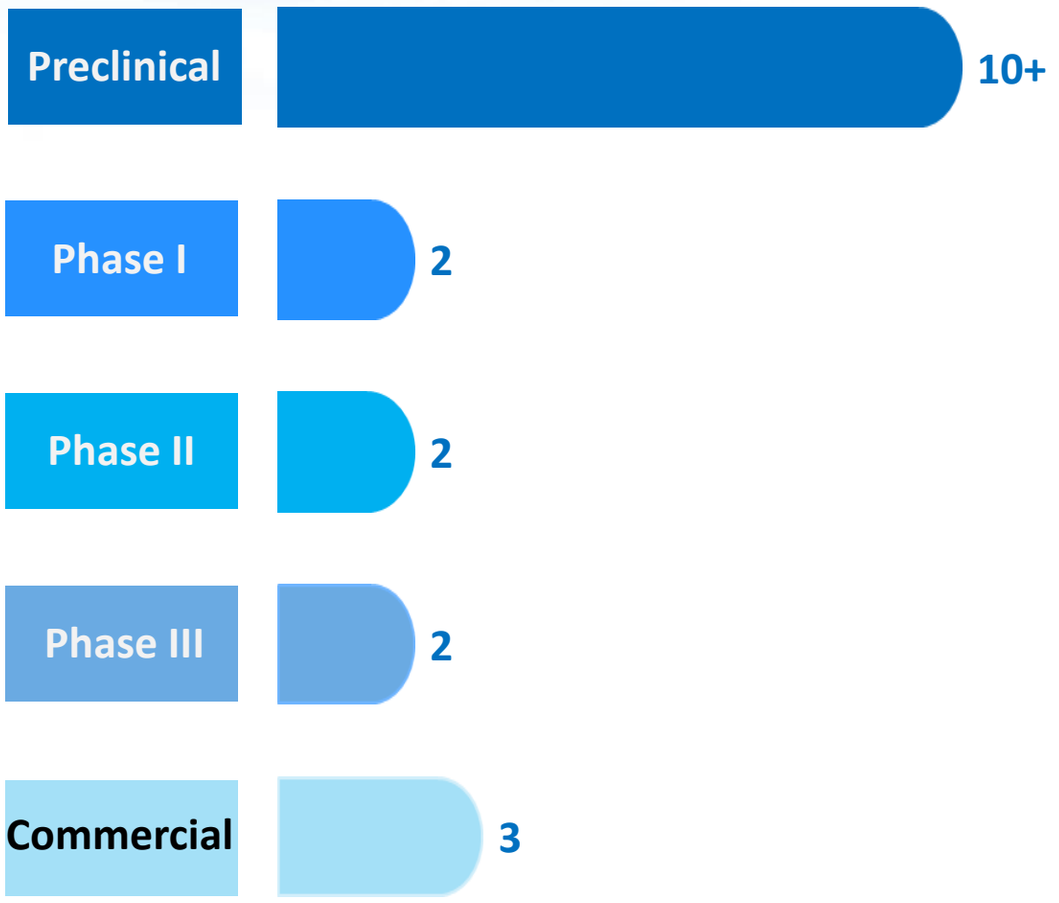
20+ COVID-19 related contracts for mAbs, vaccines and proteins:

- ~US$460 mm expected in 2021
- ~US$300 mm contracted in 2022, revenue expected to increase due to Omicron

Take-or-pay commitments minimize revenue uncertainty: no downside for COVID-19 CMO projects regardless of commercial success of these programs

Note:
1. As of Sept. 30, 2021

# Enabling mAb and Vaccine Portfolio to Combat COVID-19 Globally




## COVID-19 mAbs

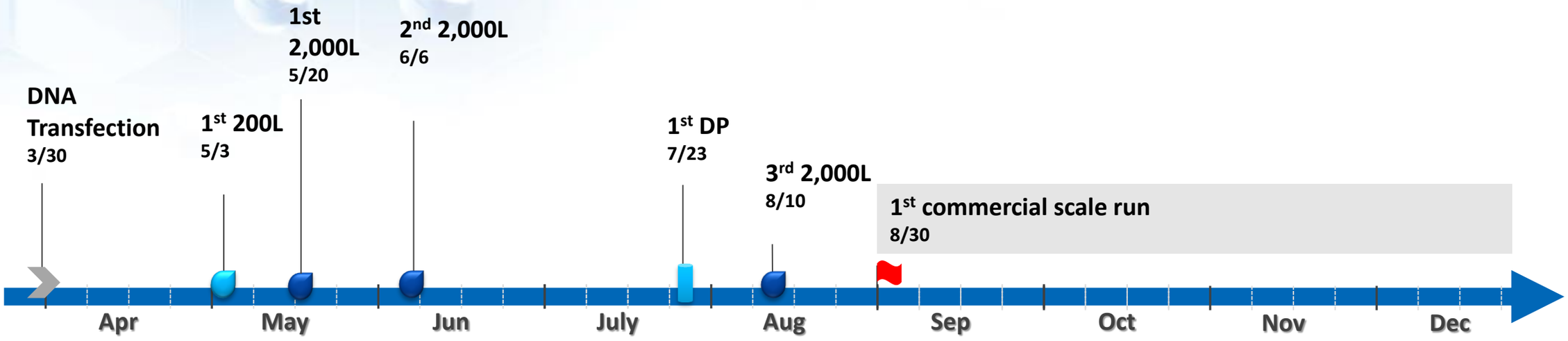
- Commercial: 3 mAbs (1,000Kg+)
- 10+ Active programs
- 10+ Clients

## Develop and manufacture three modalities of COVID-19 Vaccines

- Viral vaccine (hundred million doses of DS delivered)
- Protein and mRNA vaccines being developed and manufactured

# COVID-19 Neutralization mAb Development at the Speed of Light – 14 months from DNA to EUA

WuXi Biologics
Global Solution Provider




- Reduced DNA to IND from conventional 12-18 months to 4.5 months
- DNA to Commercial Inventory: 5 months

# Technologies and Approaches that Enabled COVID-19 mAb Speed Shared with Global Community

WuXi Biologics
Global Solution Provider

- **WuXi Codon**
  - Average titer: 5.9g/L for mAbs
  - 80% projects >5g/L
- **HT NGS of plasmids and clones**
  - No sequence variants
  - Accelerated biosafety testing
- **IND timeline vs traditional 12-18 months**
  - Pool: ~3 month Gen1 IND
  - Clone: 5-6 month Gen2 IND

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RESEARCH ARTICLE

BIOTECHNOLOGY PROGRESS

## Reshaping cell line development and CMC strategy for fast responses to pandemic outbreak

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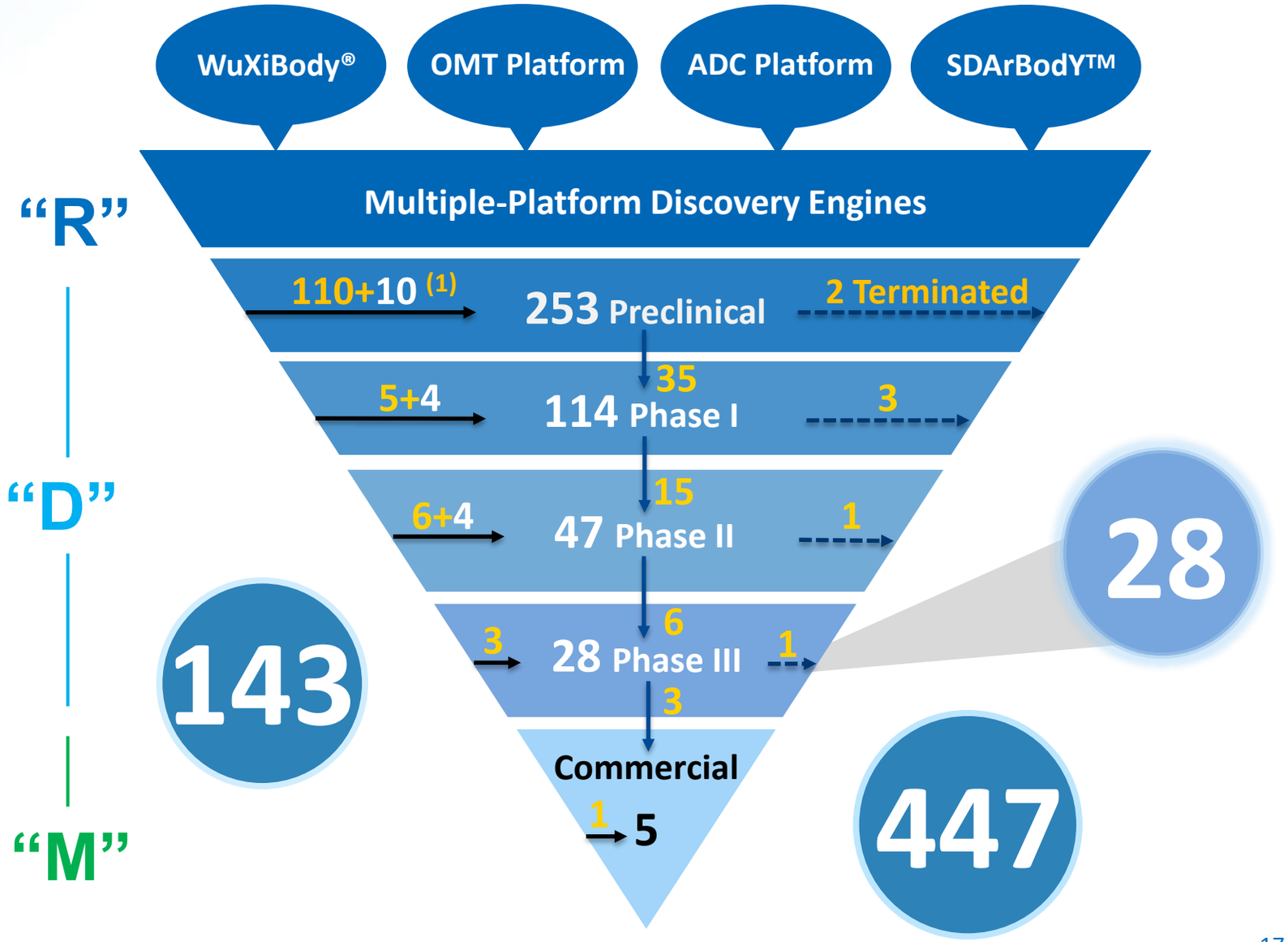
**Abstract**

The global pandemic outbreak COVID-19 (SARS-COV-2), has prompted many pharmaceutical companies to develop vaccines and therapeutic biologics for its prevention and treatment. Most of the therapeutic biologics are common human IgG antibodies, which were identified by next-generation sequencing (NGS) with the B cells from the convalescent patients. To fight against pandemic outbreaks like COVID-19, biologics development strategies need to be optimized to speed up the timeline. Since the advent of therapeutic biologics, strategies of transfection and cell line selection have been continuously improved for greater productivity and efficiency. NGS has also been implemented for accelerated cell bank testing. These recent advances enable us to rethink and reshape the chemistry, manufacturing, and controls (CMC) strategy in order to start supplying Good Manufacturing Practices (GMP) materials for clinical trials as soon as possible. We elucidated an accelerated CMC workflow for biologics, including using GMP-compliant pool materials for phase I clinical trials, selecting the final clone with product quality similar to that of phase I materials for late-stage development and commercial production.

KEYWORDS
CMC for biologics, COVID-19, mammalian cell line development, next-generation sequencing

# Business Momentum Remains Strong without COVID-19 Contributions

- Non-COVID project addition speeded up and hit another record high
- 143 new non-COVID integrated projects added as of Dec. 31, 2021, including 18 projects acquired from CMAB
- 28 non-COVID Phase III projects and total 447 integrated projects
- Added 4 non-COVID commercial projects in 2021
- Long-term business growth momentum still remains strong driven by non-COVID projects

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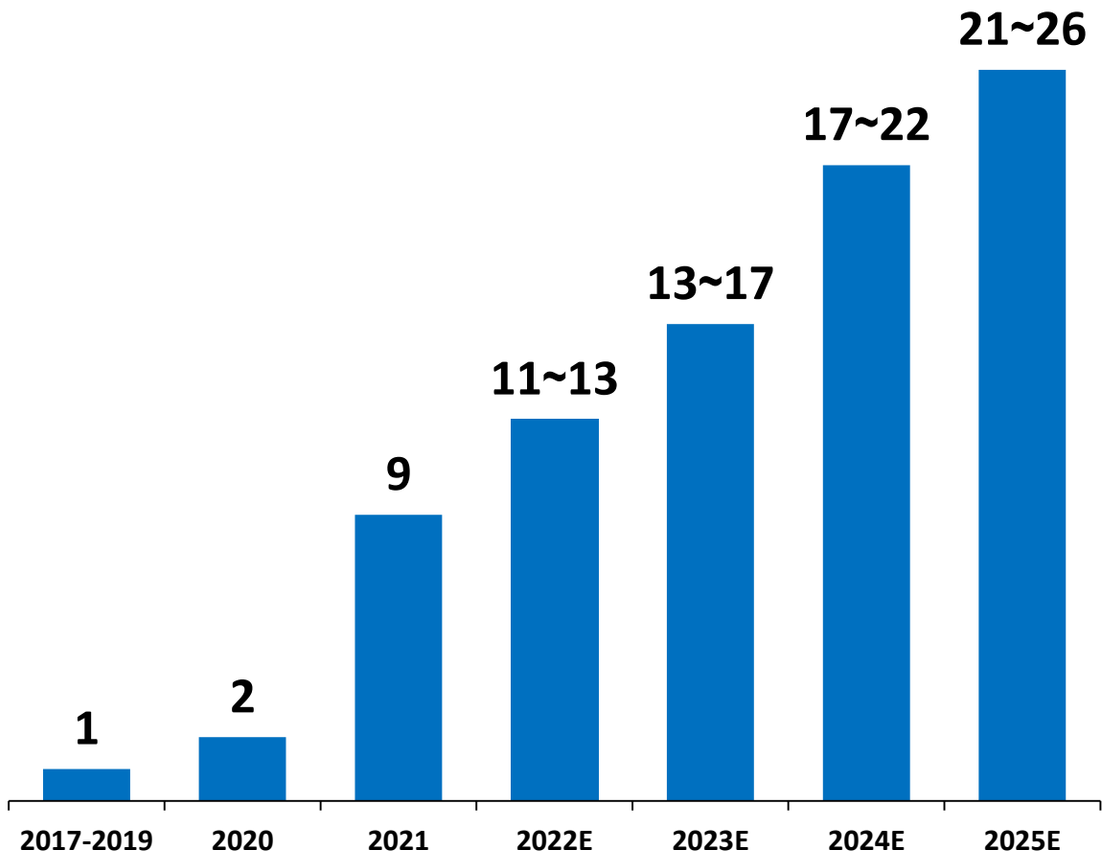
02

# Explosive Growth of Commercial Manufacturing Projects

# Banner Year for Commercial Manufacturing: from 2021 and Beyond

- Added 7 commercial manufacturing projects in 2021
- Total 9 commercial projects by end of 2021, including one via “Win-the-Molecule” strategy
- 4 COVID commercial projects and 5 non-COVID commercial projects, diversified CMO pipeline
- Expecting 2-4 in 2022-2023 and 4-6 in 2024-2025, respectively
- 20+ commercial manufacturing expected in 2025

## Explosive CMO Revenue Growth Expected



# Explosive Growth of Non-COVID Commercial Projects in the Near Term

WuXi Biologics
Global Solution Provider

**Manufacturing projects that could potentially generate US$200 mm+ peak revenue per year**

- Cancer bispecific A
- FcRn mAb
- CD47 mAb
- TIGIT mAb
- Cancer ADC Z

**Manufacturing projects that could potentially generate US$100-200 mm peak revenue per year**

- Pompe ERT
- Cancer bispecific B
- Cancer bispecific C
- Non-COVID Vaccine
- Global biosimilar 1
- Global biosimilar 2
- Infectious disease mAb1

**Manufacturing projects that could potentially generate US$50-100 mm peak revenue per year**

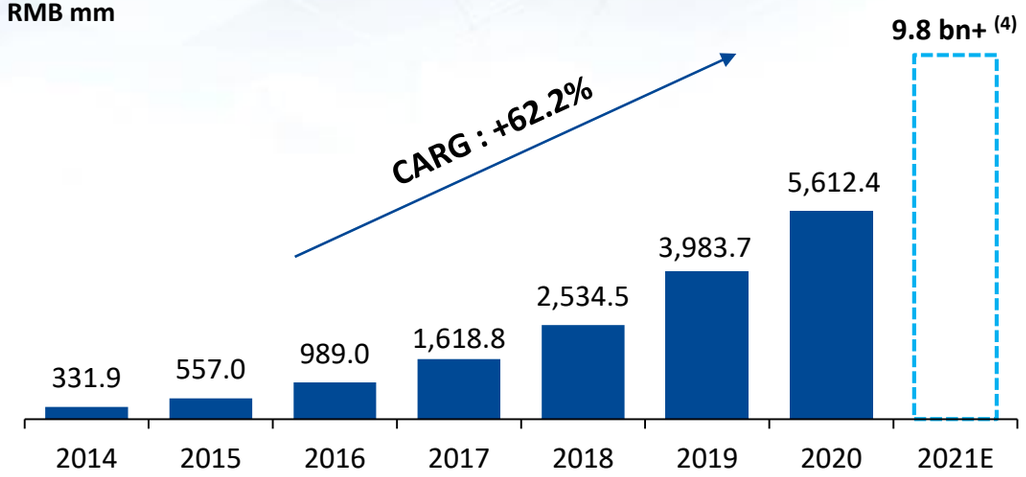
- Cancer bispecific D
- Cancer ADC Y
- CD38 mAb
- DR5 mAb
- Global biosimilar 3
- Cancer ADC X
- Gaucher's disease ERT
- Infectious disease mAb 2

- Multiple programs and higher POS for exciting targets
- Inventory-built for biologics can start 2-3 years before approval due to complexity of manufacturing and long supply chain
- CMO revenue from these projects expected to be US$2 bn+

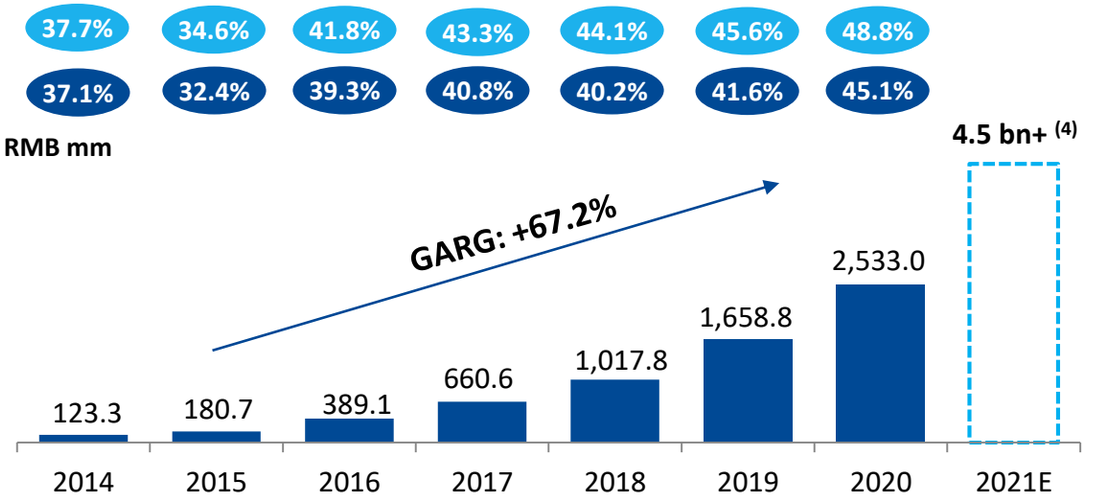
# Consistent and Robust Financial Performance in the Last Eight Years
## Bloomberg Consensus 75% YOY growth in 2021

### Revenue

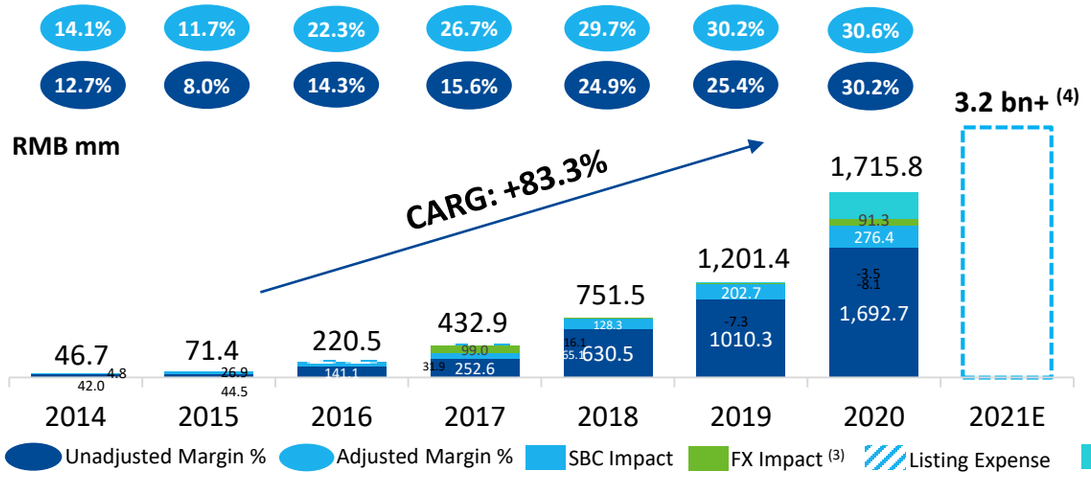
RMB mm




### Gross Profit

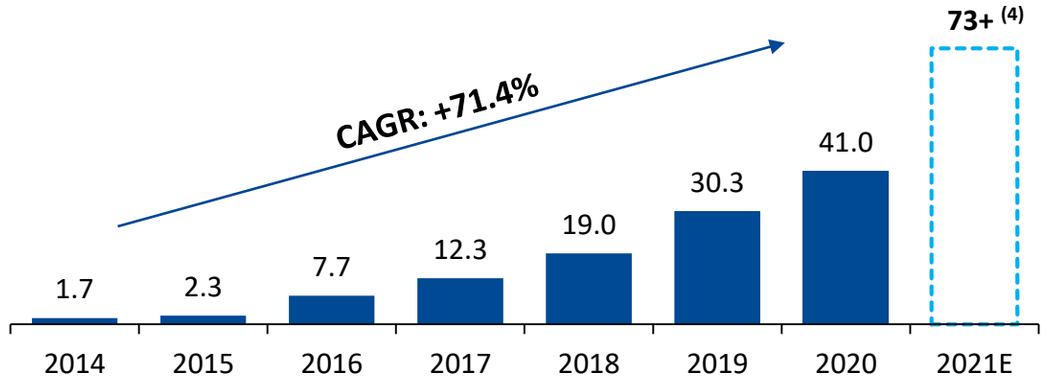



### Adjusted Net Profit (2)




### Adjusted Diluted EPS (1)

RMB (Cents)



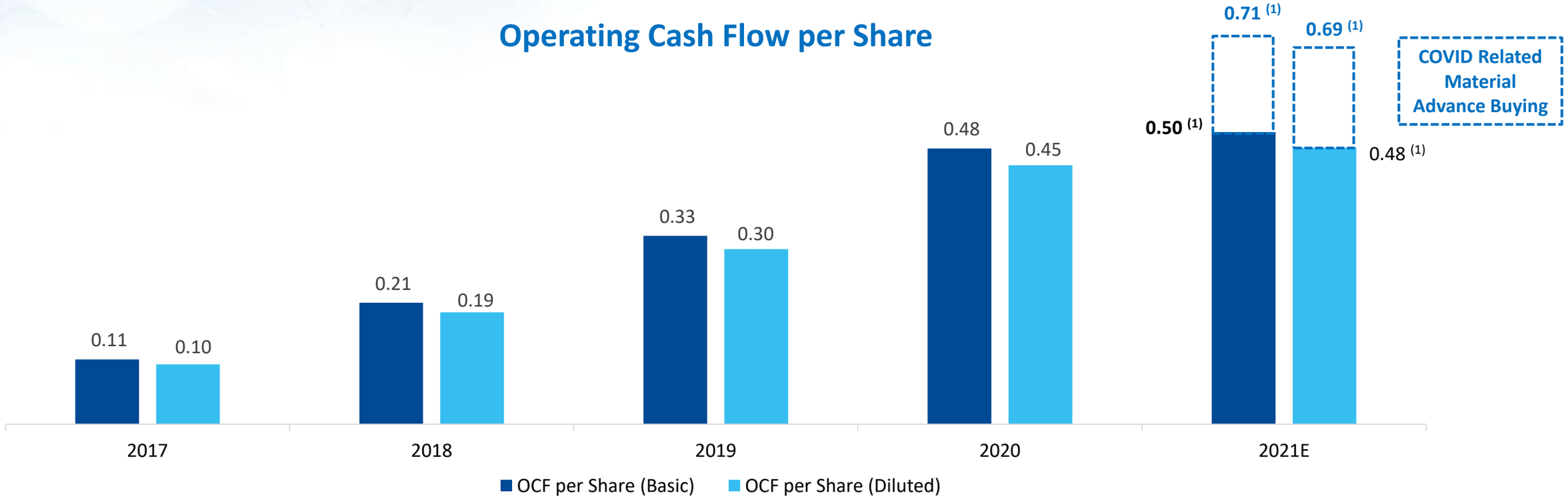

Unadjusted Margin % | Adjusted Margin % | SBC Impact | FX Impact (3) | Listing Expense | Investment Impact

**Notes:**

1. The authorized and issued shares of the Company were subdivided on the basis that every one (1) issued share is subdivided into three (3) subdivided shares (the "Share Subdivision"), which became effective on November 16, 2020. Basic and diluted earnings per share were stated after taking into account the effect of the Share Subdivision. Comparative figures have also been restated on the assumption that the Share Subdivision had been effective in the prior year
2. Adjusted net profit excludes the share-based compensation expenses, investment (gains), foreign exchange (gains)/losses and listing expenses
3. Refer to foreign exchange (gains)/losses
4. 2021 estimates are sourced from Bloomberg Best Mean Consensus, and the actual numbers are subject to 2021 annual results announcement

# Strong Operating Cash Flow Supports Future Capacity Expansion with Own Funding

## Operating Cash Flow per Share




- **Operating cash flow improved year by year, target free operating cash flow positive in 2022**
- **Operating cash flow generated in 2023 and beyond will support significant capacity expansion (300,000L capacity in China or 100,000L capacity outside of China per year)**

**Note:**
**1. 2021 estimates are sourced from Bloomberg Consensus and public research reports, and the actual numbers are subject to 2021 annual results announcement**

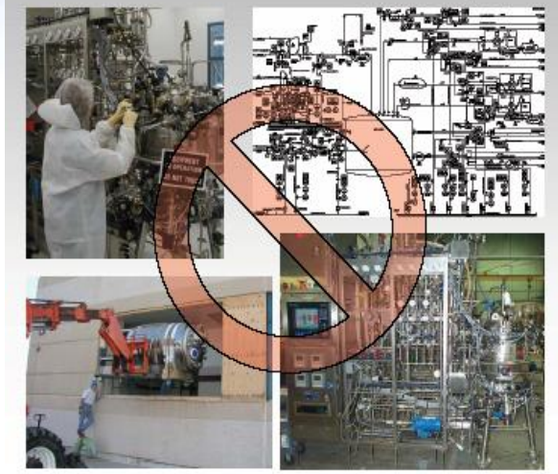
03

# Disposable Manufacturing Proven as Disruptive Technologies

# TECHNOLOGY: Disposable Manufacturing Technology Proven Effective in Commercial Manufacturing

WuXi Biologics
Global Solution Provider

**Conventional Bioreactors**

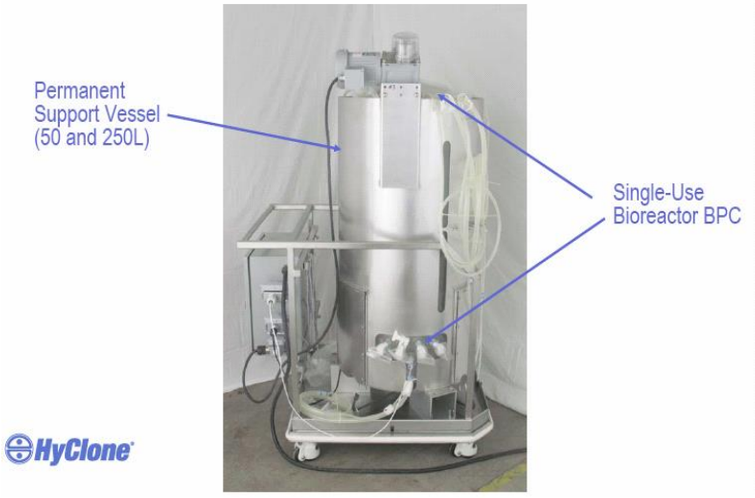


**Single-Use Bioreactors**

- ☑ 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

VS

**HyClone Single-Use Bioreactor (SUB)**




- **Global leader and pioneer in using disposable manufacturing technology**
- **1,000kg+ neutralizing mAbs delivered in 6 months at 2,000-12,000L scale**
- **COGS reduced to <US$80/g at 12,000L scale, comparable COGS with similar stainless steel**
- **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 WuXiUP™ | 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

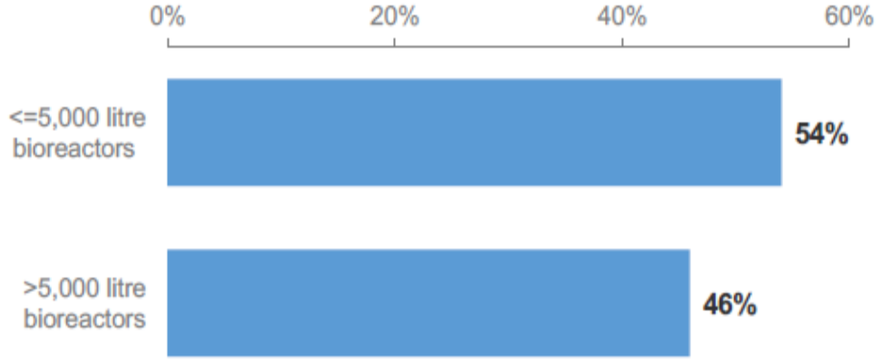
# Disruptive Single-Use Technology Pioneered by WuXi Bio

## ~44% Market Share in New Capacity, 65-70% in R&D

### The Advantages of Single-Use Bioreactor

- Less water resource consumed
- No detergent, more environmental- friendly
- Save projects switching time, more flexible, less CAPEX intensive

### Biotech Companies Use more Single-Use Bioreactors for Capacity Expansion




### Single-Use Bioreactor Capacity Expansion and its Penetration Rate


### The Application Rate of Single-Use Bioreactors in R&D and CMO Stage

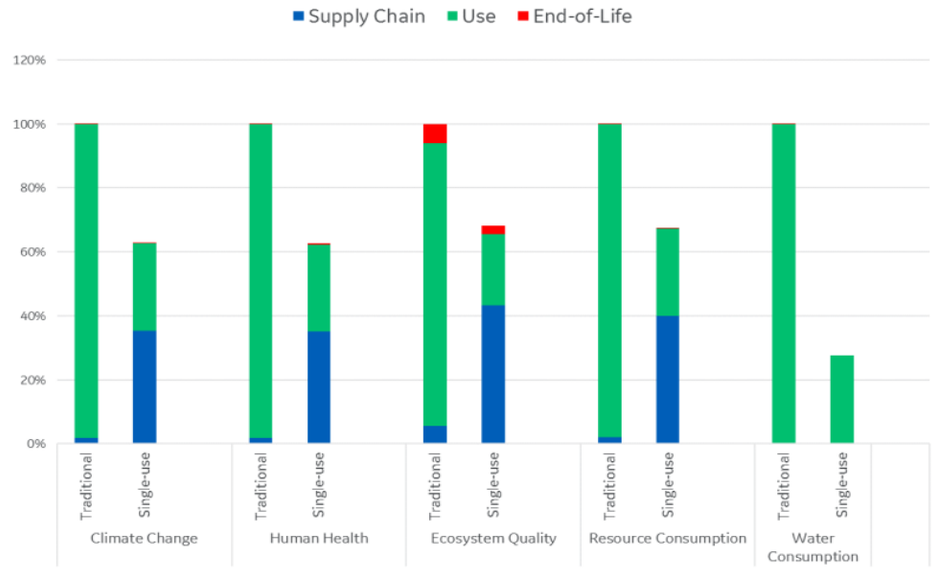

Source: Morgan Stanley report

# 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**

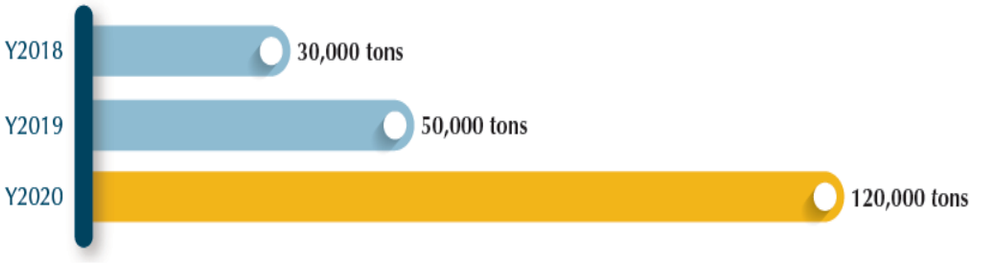
## Impact comparison for traditional and single-use process technologies

| | |
|---|---|
| | mAb |
| Process | Traditional |
| | Single-use |
| | Hybrid |
| Location | Boston |
| | LA |
| | Sao Paolo |
| | Istanbul |
| | Cork |
| | Dortmund |
| | Shanghai |
| Scale | 200 L |
| | 500 L |
| | 2000 L |
| | 2 x 2000 L |




Single-Use Technology and Sustainability | 2017 BPSA International Single-Use Summit 13 July 2017 20

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

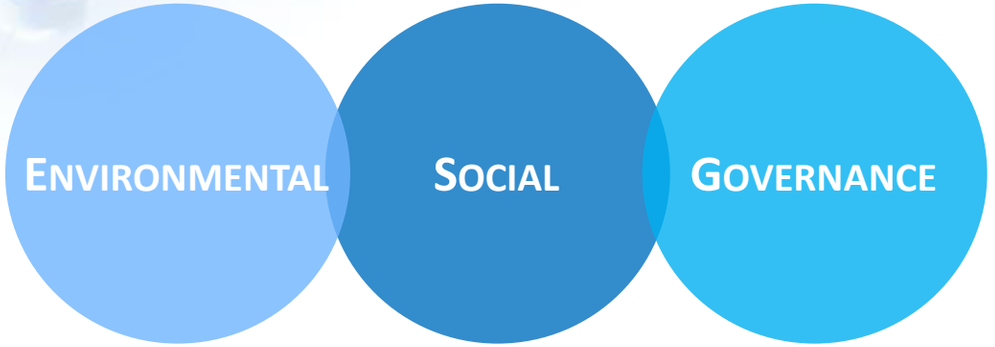



Source: WuXi Bio's ESG Report 2020

# 04

# ESG as an Important Component of Business Strategy

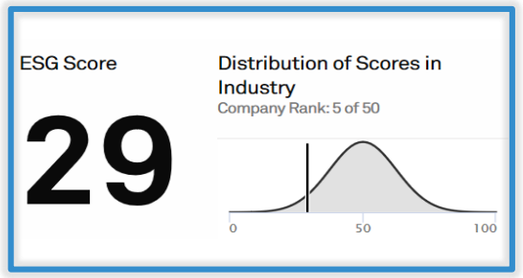
# Well Recognized by Global ESG Rating Agencies




- ESG Committee at the board level led by CEO
- Advocate low-carbon and sustainable development, set mid-to-long term emission reduction target, reduce greenhouse gas (Scope 1+2) emission density by 50% by 2030
- Disposable bioreactors consume 90% less water and energy and eliminate 100% detergent during cGMP production
- Least resources consumed, lower emissions and less waste produced
- WuXi Biologics has been well recognized for its good ESG performance by: MSCI, DJSI, FTSE Russell


MSCI ESG Research


Institutional Investor




Dow Jones Sustainability Indexes

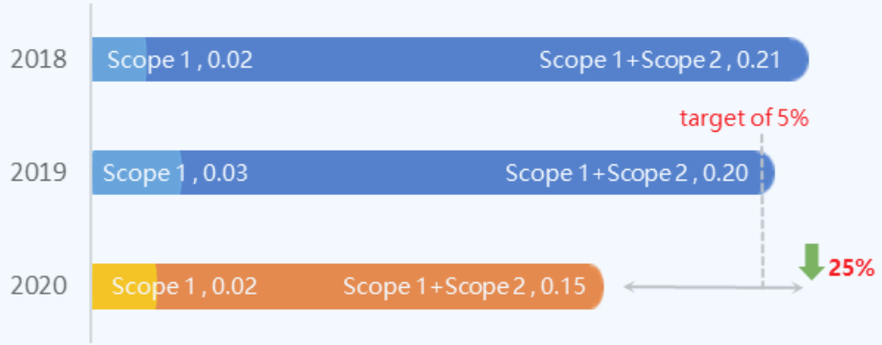

FTSE Russell

# Effectively Reduce Energy Consumption and Emissions

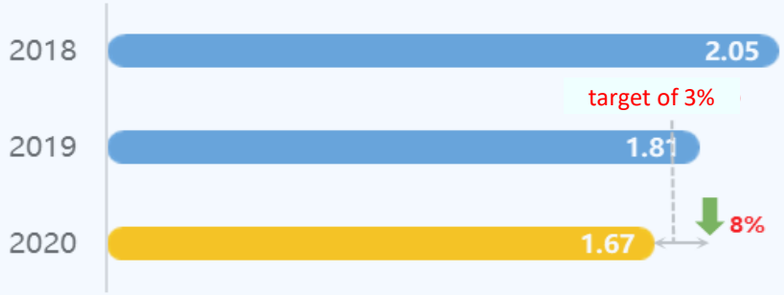
**In response to climate change, target minimum reduction of 5% per year for GHG emission intensity**

**Improve resource efficiency, target minimum reduction of 3% per year for water consumption intensity**

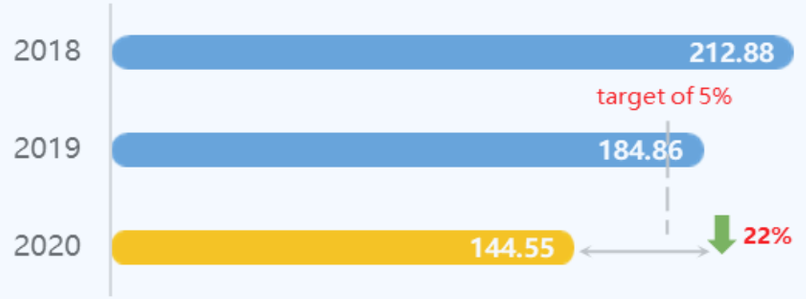
## Intensity of greenhouse gas emission (tonnes/RMB0'000)



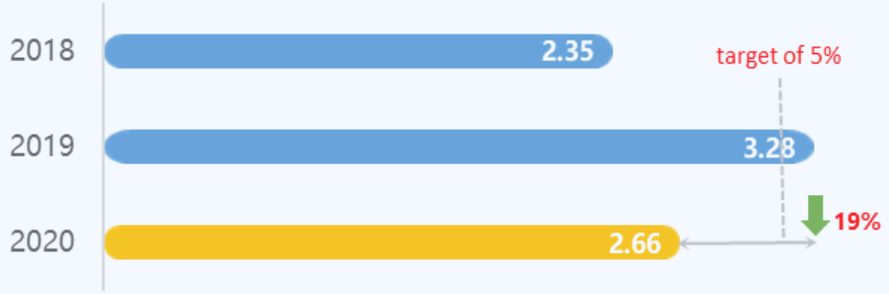

## Intensity of water consumption (tonnes/RMB0'000)




## Intensity of electricity consumption( kWh/RMB0'000)




## Total Nitrogen Oxide emission (tonnes)

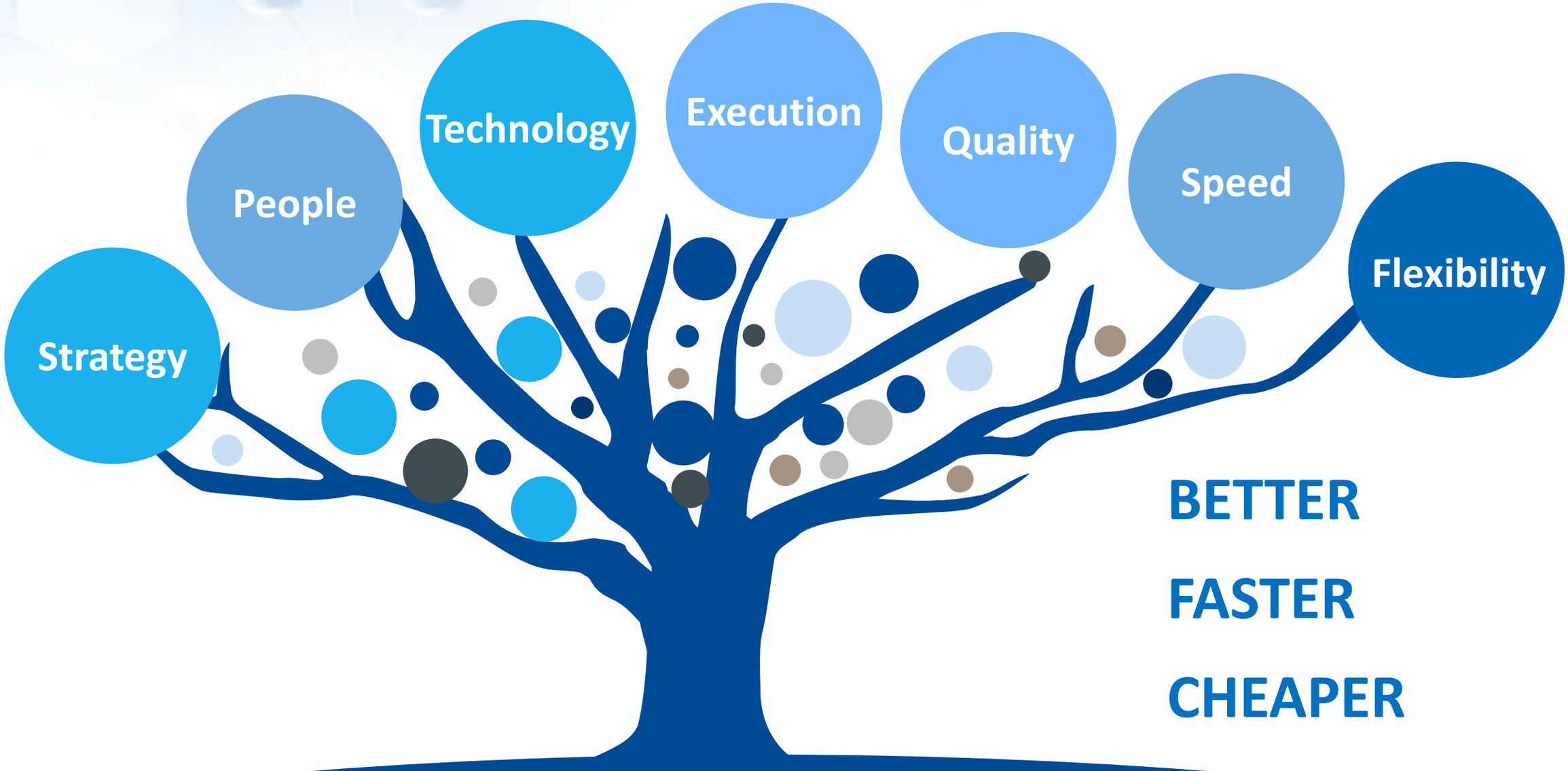


# 05 Summary

# WuXi Biologics Pioneered Global Trends that are Adopted by the Industry

1. **Follow the Molecule from Concept to Commercial: CRDMO vs CMO**
2. **Fully Integrated Services: from A to Z**
3. **Disposable Manufacturing: world leader and KOL**
4. **Scale-OUT vs Scale-UP**
5. **Continuous Processing: state-of-the-art**

# SEVEN Keys for Future Success: Sustainable High Growth



# Global Premier CRDMO with Sustainable High Growth

## WuXi Biologics as a Global CRDMO, not a Chinese Biotech

- 70%+ of 2021 revenue generated from global clients
- US Cranbury site ready for DNA to IND and Ireland/Germany IND-BLA : global network
- US$3 bn investment and ~30% of development and manufacturing capacity in US, EU and Singapore

## Sustainable High Growth for WuXi Biologics

- Innovation from global biotech
- Large pharmas continue to increase outsourcing
- Tremendous growth and needs in China
- Huge unmet needs in developing countries
- Uncharted territory on vaccines

# Global Premier CRDMO: Enable Global Partners and Deliver Sustainable High Growth

1. Despite sentiment changes of biotech investment and trade tensions, WuXi Biologics continues to see huge demand of services in US, EU, China and ROW: 138 organic growth projects including 18 projects won from competitors (7 phase III & CMO) in 2021

2. Strong drivers for sustainable high growth : explosive growth of commercial manufacturing (M), strong growth of early and late phase projects (D) and milestone and royalty bearing discovery projects (R). 2022 outlook continues to be exciting

3. Besides traditional small and medium-sized companies, large pharmas became core clients and now contribute ~40% of total revenue

4. Combatting COVID-19: manufacturing of THREE Omicron-effective mAbs and THREE modalities of COVID-19 vaccines

5. In 2022 and beyond non-COVID programs will make up the revenue from decreasing COVID-19 projects and continue to deliver consistent high growth

# Global Premier CRDMO: Enable Global Partners and Deliver Sustainable High Growth

6 Execution track record proven to satisfy and retain every client: BETTER, FASTER AND CHEAPER

7 Disruptive disposable technology with comparable or even lower cost compared with SS tank

8 ESG continues to be at the core of our sustainability strategies

9 All operations and capacity expansion on track: did not miss any revenue due to supply chain constraints or electricity curtailment in China, not impacted by recent CDE policy on cancer drugs

10 Strong financial position to grow the business: as of Dec. 31 2021 ~US$1.65 bn of cash, ~US$0.4 bn of loan, strong cash flow in 2023 supports 300,000L DS capacity in China or 100,000L capacity in outside of China

# Vision of WuXi Biologics

**“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**