# *Global Premier Biologics Platforms to Enable and Expedite Innovations*

*2021 Interim Results*
*(2269.HK)*

**August 2021**

WuXi Biologics
Global Solution Provider

# Forward-Looking Statements

This presentation may contain certain "forward-looking statements" which are not historical facts, but instead are predictions about future events based on our beliefs as well as assumptions made by and information currently available to our management. Although we believe that our predictions are reasonable, future events are inherently uncertain and our forward-looking statements may turn out to be incorrect. Our forward-looking statements are subject to risks relating to, among other things, the ability of our service offerings to compete effectively, our ability to meet timelines for the expansion of our service offerings, and our ability to protect our clients' intellectual property. Our forward-looking statements in this presentation speak only as of the date on which they are made, and we assume no obligation to update any forward-looking statements except as required by applicable law or listing rules. Accordingly, you are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. All forward-looking statements contained herein are qualified by reference to the cautionary statements set forth in this section.

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

To supplement the Group's consolidated financial statements which are presented in accordance with IFRS, the Company has provided adjusted net profit, adjusted net profit margin, adjusted net profit attributable to owners of the Company, adjusted EBITDA, adjusted EBITDA margin and adjusted basic and diluted earnings per share as additional financial measures, which are not required by, or presented in accordance with IFRS.

The Group believes that the adjusted financial measures are useful for understanding and assessing underlying business performance and operating trends, and that the Group's management and investors may benefit from referring to these adjusted financial measures in assessing the Group's financial performance by eliminating the impact of certain unusual, non-recurring, non-cash and/or non-operating items that the Group does not consider indicative of the performance of the Group's core business. These non-IFRS financial measures, as the management of the Group believes, is widely accepted and adopted in the industry in which the Group is operating in. 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. Shareholders of the Company and potential investors should not view the adjusted results on a stand-alone basis or as a substitute for results under IFRS. And these non-IFRS financial measures may not be comparable to the similarly-titled measures represented by other companies.

# Agenda

1 2021 Interim Results

2 Seven Keys for Future Success

3 Financial Overview

4 ESG

5 Summary

6 Appendix

01

# 2021 Interim Results

WuXi Biologics
Global Solution Provider

**286** $\xrightarrow{42.7\%}$ **408**
Integrated Projects YOY

**38** $\xrightarrow{107.9\%}$ **79**
New Projects YOY

**19** $\xrightarrow{68.4\%}$ **32**
Late Phase Projects YOY

**9.5** $\xrightarrow{31.7\%}$ **12.5**
Total Backlog (US$ Bn) YOY

**430K**
Capacity after 2024 (L)

**7,686/2,803**
Employees/Scientists


**1.94** $\xrightarrow{126.7\%}$ **4.41**
Revenue (RMB Bn) YOY

**0.67** $\xrightarrow{163.0\%}$ **1.77**
Adj Net Profit Attributable to Owners of the Company (RMB Bn) YoY

**40.5%→52.1%**
Gross Profit Margin YOY

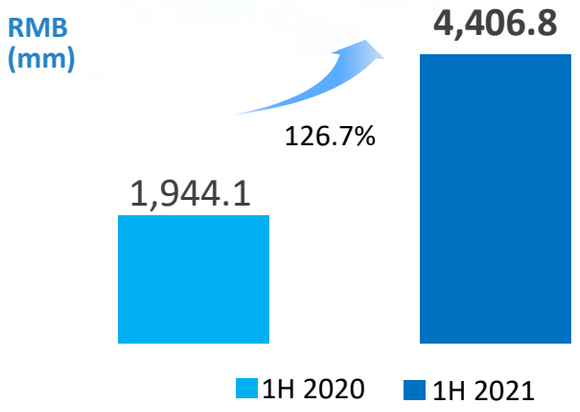
**37.6%→42.7%**
Net Profit Margin YOY

**48.4%→54.2%**
EBITDA Margin YOY

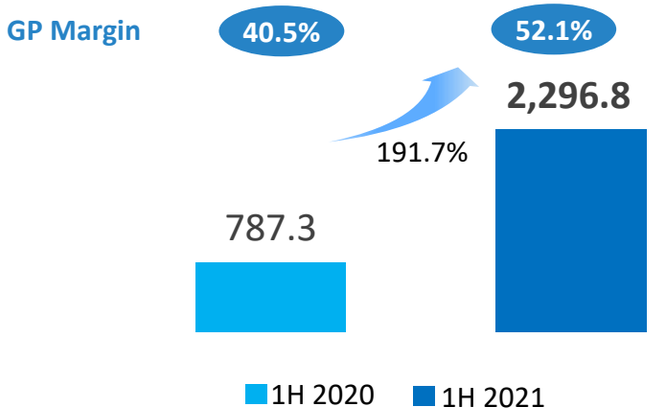
**0.18** $\xrightarrow{133.3\%}$ **0.42**
Diluted EPS (RMB) YoY

# Revenue, Profit and Margins Continued to Achieve Record-High

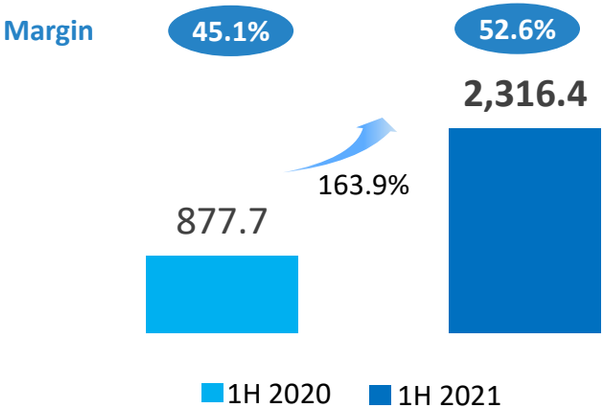
## Revenue



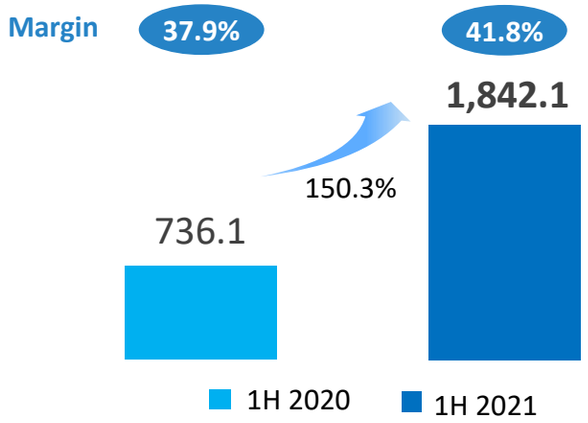

## Gross Profit



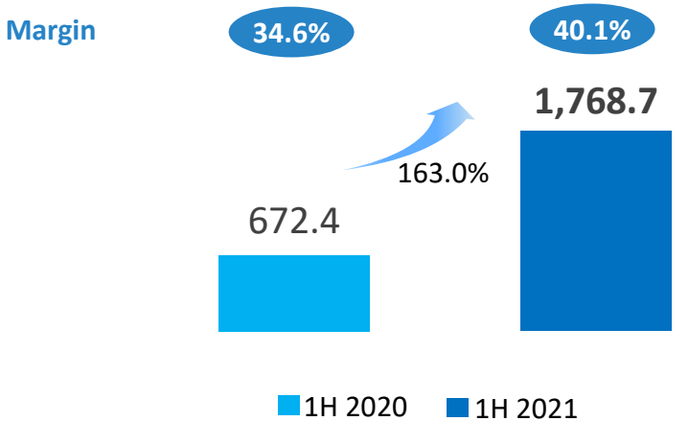

## Adj EBITDA



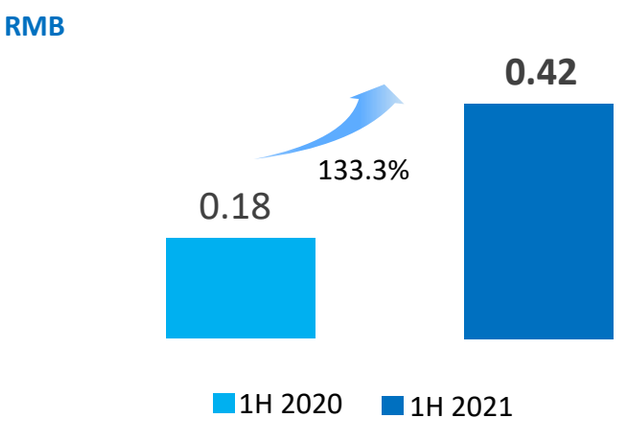

## Net Profit Attributable to Owners of the Company




## Adj Net Profit Attributable to Owners of the Company




## Diluted EPS

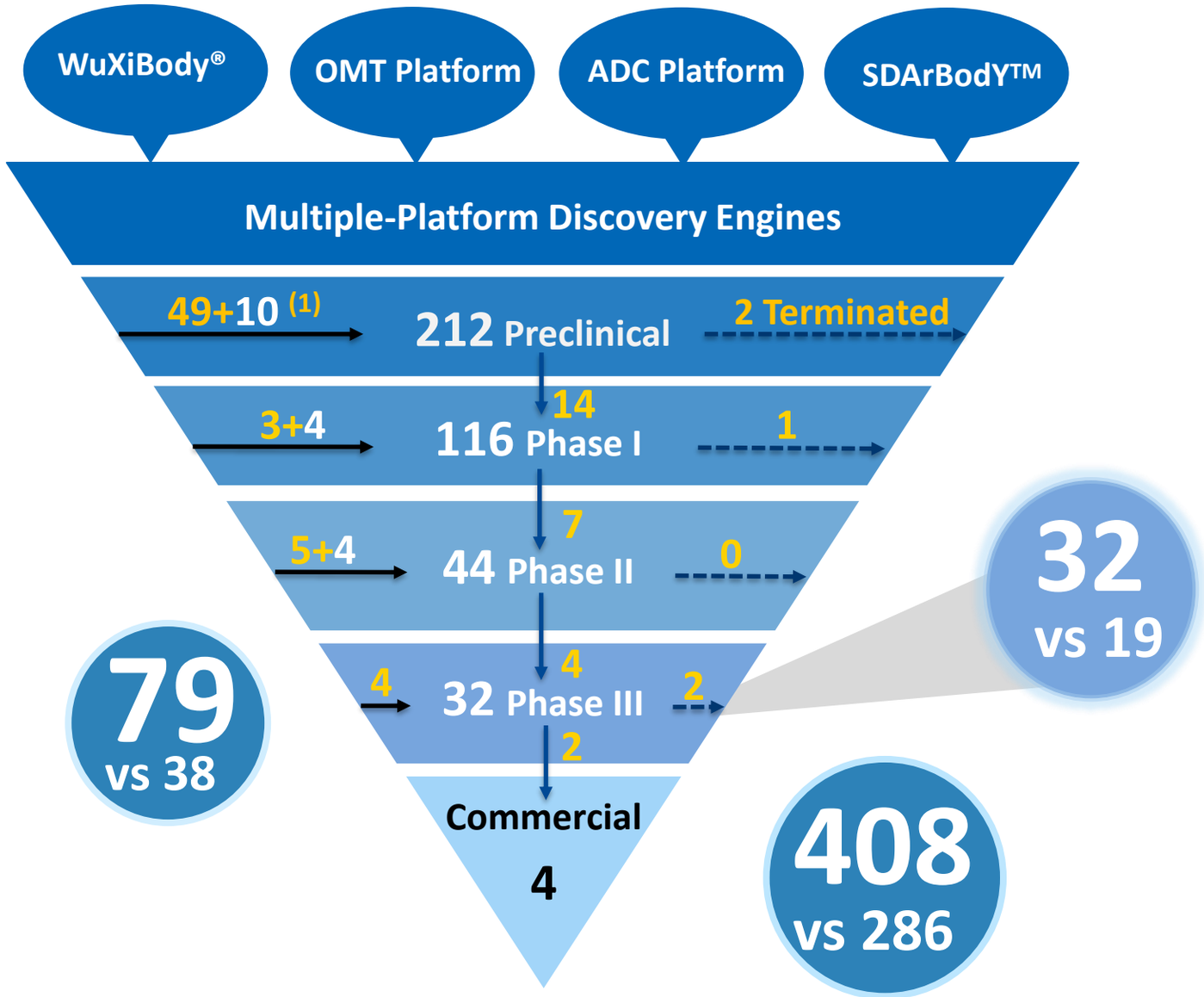


# Key Financials

| | |
|---|---|
| **AVAILABLE FUNDS** | • Available funds approx. RMB13.9 bn as at June 30, 2021<br>• US$1,692 million raised in Feb. 2021 to support DS/DP facility expansion, invest in microbial and viral platforms and technologies such as mRNA manufacturing and general corporate purpose |
| **LOAN** | • Approx. RMB3,235 million borrowings as at June 30, 2021<br>• Maintains bank credit facilities of around RMB2.4 bn for future cash needs<br>• Operating cash flow of RMB798 million, increased 85.2% YoY |
| **CAPEX** | • CAPEX spending amounted to RMB4.1 bn in 1H 2021<br>• 2021 CAPEX approximately RMB8 bn, mainly for capacity expansion |

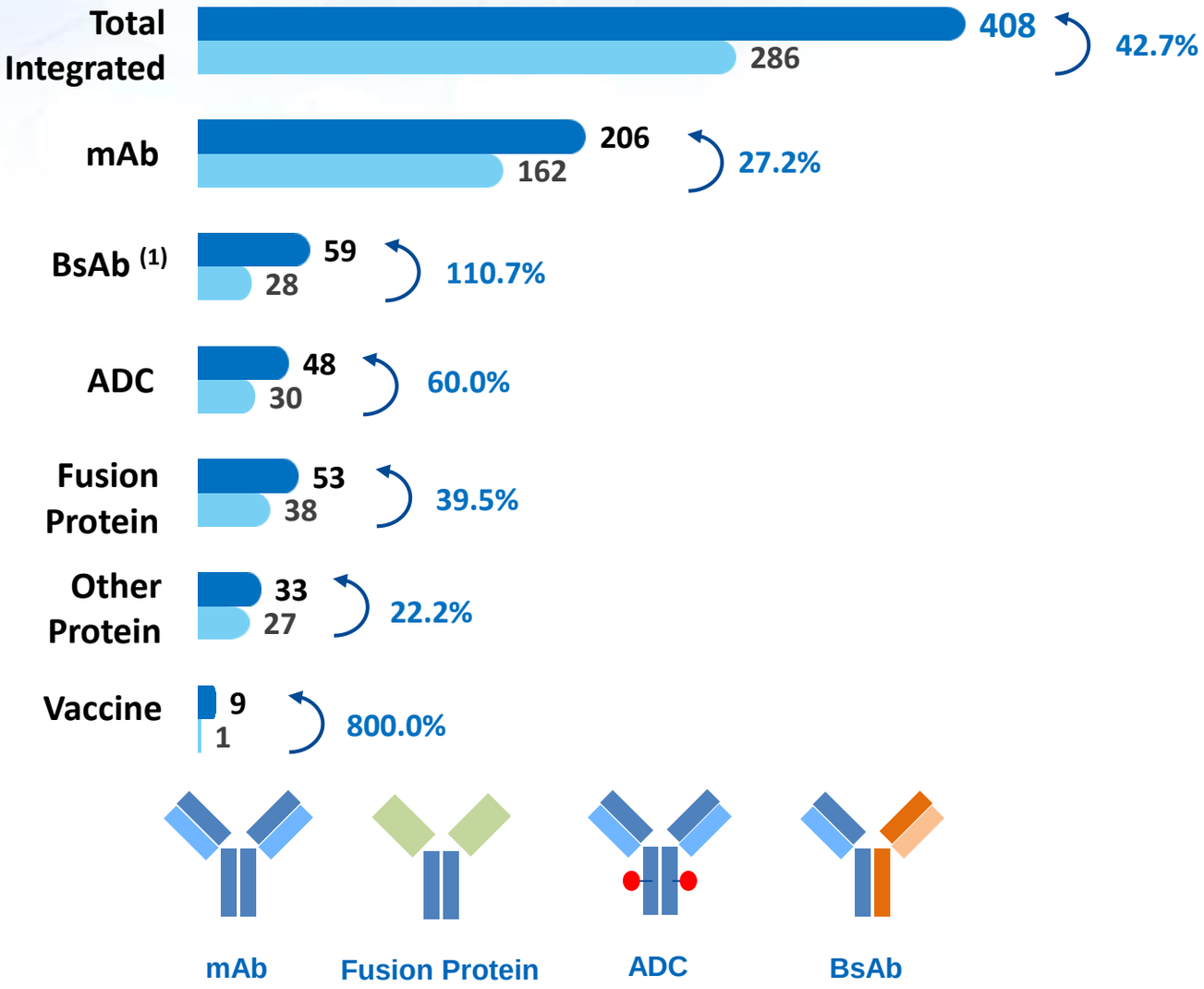
# Business Momentum Continues to Accelerate in 1H 2021

- 79 new integrated projects added in 1H, including 18 projects acquired from CMAB. Continues to gain more market share
- 32 Phase III projects: drives near-term growth
- "Win-the-Molecule" Strategy continued: 12 external projects transferred into the pipeline in 1H 2021
- Total 1,107 projects including 699 non-integrated CDO projects and 408 integrated projects
- Added 2 more commercial projects in 1H 2021
- Milestone revenue: US$24 mm in 1H 2021, uncertainty and timing choppy due to links to clinical milestones




Notes:
1. As of June 30, 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

# Rich Pipeline across All Biologics Modalities



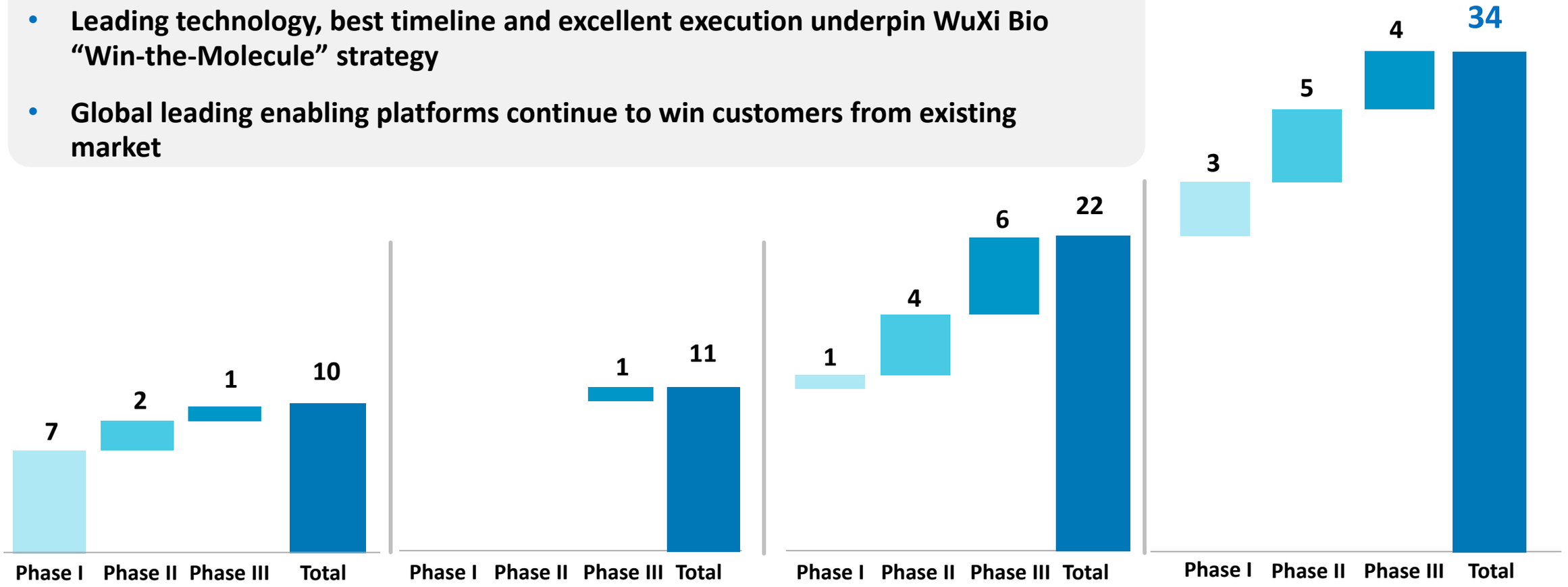

- **152** First-in-class programs
- Increase to **9** vaccine projects, including **6** non-COVID vaccines
- **5** CNS (Central Nervous System) programs from three global companies with exciting potential
- Expanding global leading technology platforms providing **mRNA-based vaccine** full CDMO services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

Notes:
1. As of June 30, 2021, compared with projects number as of June 30, 2020
2. Bispecific Antibody (BsAb) Included both WuXiBody® projects and non-WuXiBody ® projects

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

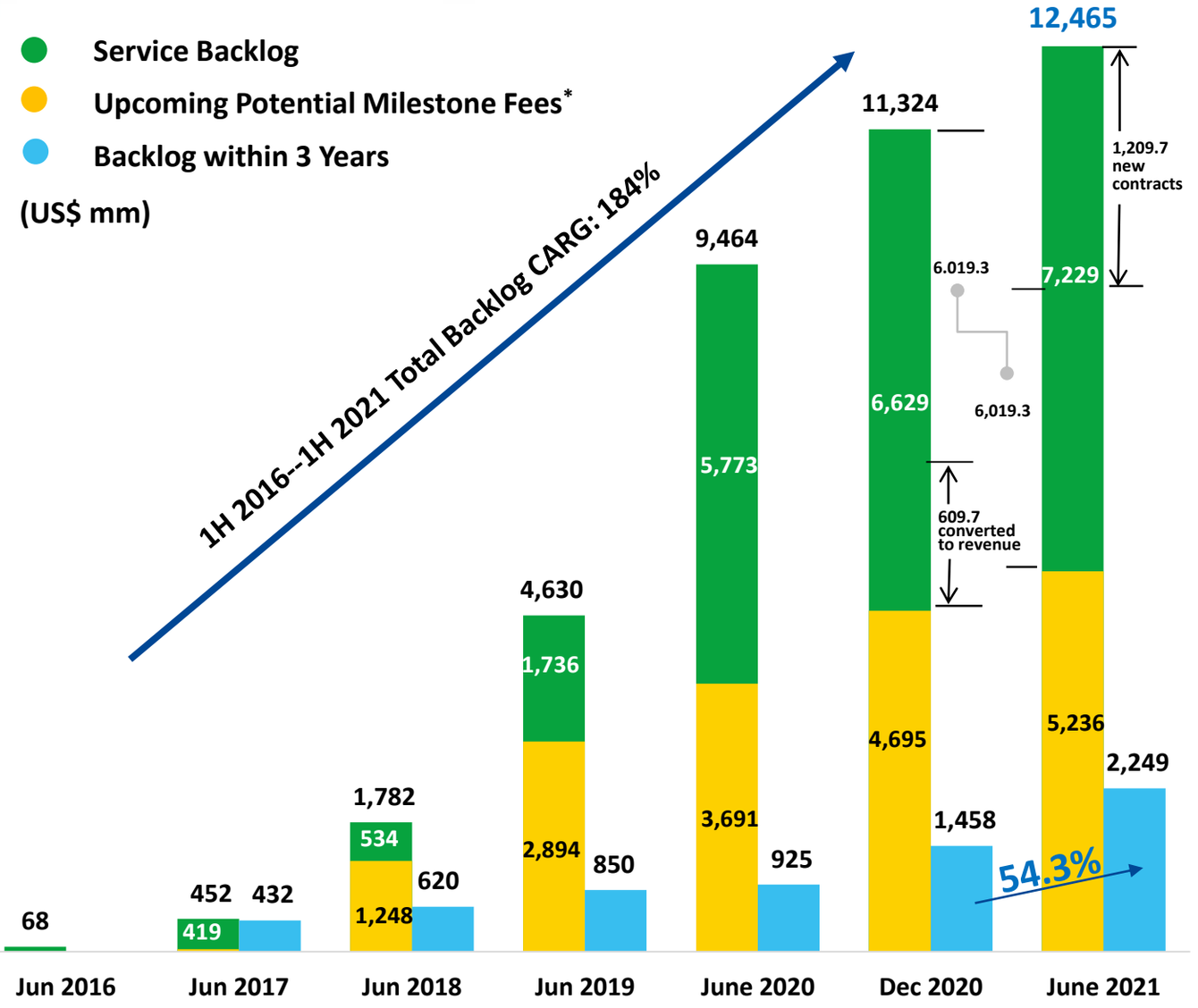
| 2018 | 2019 | 2020 | 2021.06.30 |
|---|---|---|---|

- Total 34 external projects at different R&D Stages (Phase I, II and III) have transferred to WuXi Bio since 2018
- Leading technology, best timeline and excellent execution underpin WuXi Bio “Win-the-Molecule” strategy
- Global leading enabling platforms continue to win customers from existing market



# Strong Backlog Growth Underpins Sustainable High Growth

- As of June 2021, total backlog grew to US$12.5 bn, strong momentum maintained despite COVID-19 impact
- Service backlog reached US$7.2 bn, mainly attributed to long-term vaccine CMO contract, growing COVID projects and more market share from non-COVID business
- Upcoming potential milestone fees (1) up to US$5.2 bn, will be the key to improve margin profile
- As of June 2021, backlog within 3 years increased 54.3% compared with the end of 2020, short-term high growth is secured
- ~82% total backlog is for year 3 and beyond while ~18% is for revenue within 3 years.
- 7.2 bn service backlog only included 4 long-term service projects while 28 remaining in the phase III are to be signed
- Strong backlog does not indicate lack of capacity for new projects. Any projects can be initiated within 4 weeks




Disclaimer:

1. The upcoming potential milestone fees take a longer term to charge at various development stages. The potential to realize these milestone fees is subject to the success rate of the projects and the project progress

# Updates on COVID-19 Programs: 2 Approvals and 3 Phase III

## Contribution to Fight against COVID-19

- 8 additional COVID-19 mAb programs initiated in 2021
- Enabled 15+ COVID-19 neutralizing mAbs with 25 IND globally and winning 80%+ global IND development projects for COVID-19 mAbs
- Timeline shortened to 3-5 months. IND enabling services: 100% success rate with world-class quality and high productivity of 4-8g/L
- GSK/Vir's antibody FDA EUA approval

## COVID Contracts and Backlog

- Total COVID-19 related contracts around US$1.3 bn for mAbs, vaccines and proteins with ~US$700 mm backlog
- 800kg+ neutralizing mAbs delivered (1~2 million patients)
- Expect to supply total ~1,500kg mAbs

## COVID Vaccines

- Supplying hundreds of million doses of COVID-19 vaccine DS and DP to a global TOP 10 Pharma
- Signed another 2 COVID-19 vaccines and initiated technology transfer, total COVID-19 vaccine contracts reached 3
- Negotiating significant mRNA vaccine contracts
- Total vaccine contracts of ~US$300 mm

## Revenue Impact

- Take-or-pay commitments minimize revenue uncertainty: still get paid for the slots if program fails.
- COVID-19 neutralizing mAbs and vaccines are expected to continue to contribute meaningful revenue in 2022
- If the program succeeds, potentially more revenue in 2022 and beyond

# WuXi Bio's Global Network to Enable Partners

Massachusetts
16,000L

Pennsylvania

New Jersey
6,000L

USA
22,000L



Dundalk, Ireland
54,000L

Germany
15,000L

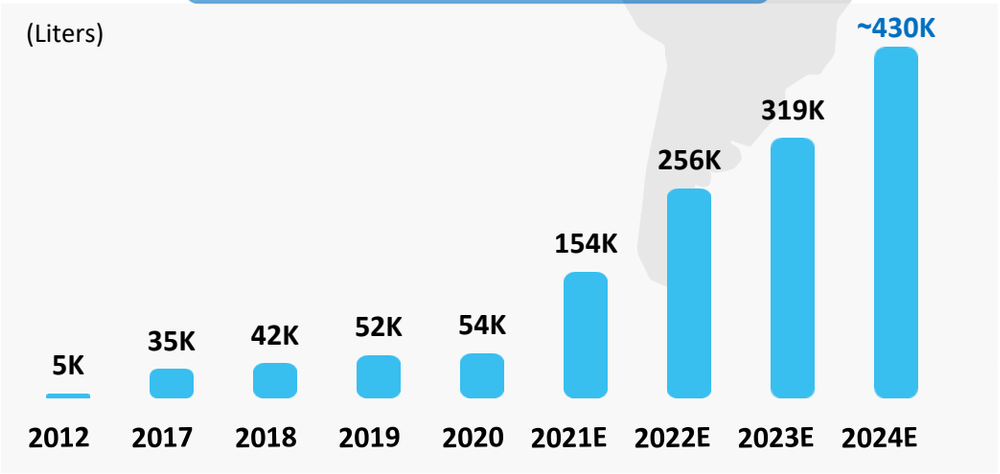
- Leverkusen DP
- Wuppertal DS

China
335,500L

- Shijiazhuang 48,000L
- Chengdu 48,000L
- Wuxi 203,500L
- Shanghai 16,700L
- Hangzhou 12,300L
- Suzhou 7,000L

Singapore
4,500L

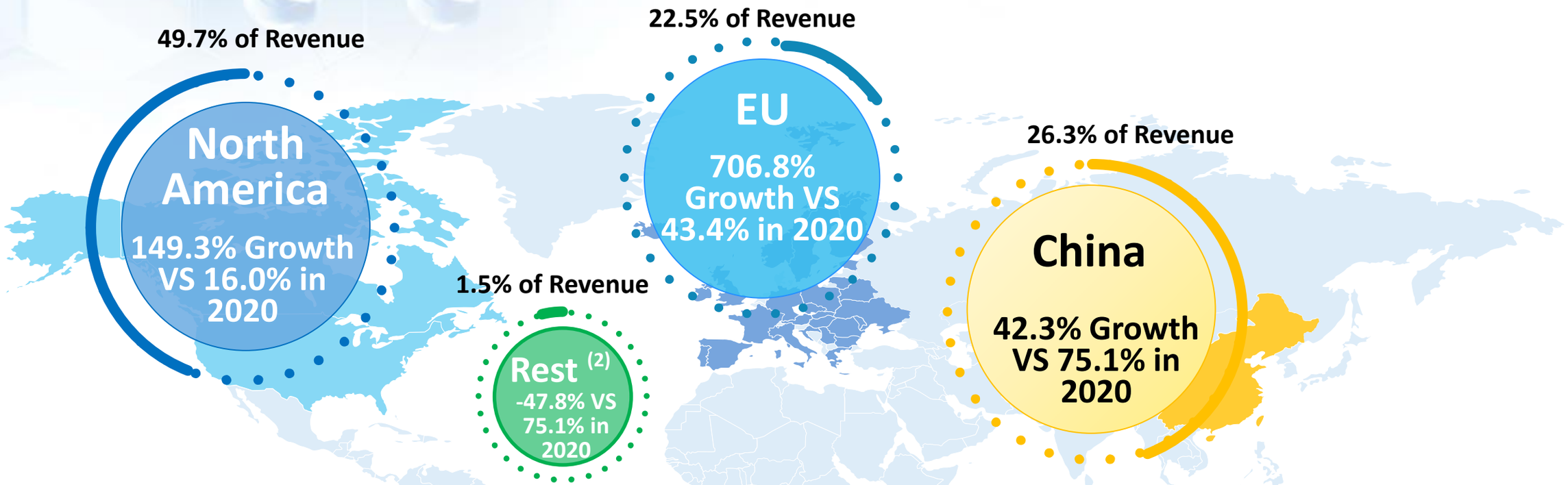
## Capacity in Progress (CIP) by Year




**Well-positioned for the era of innovative biologics. A robust global network with ~430,000 L [(1)] capacity in place to enable our partners over the world**

Note:
1. As of June 30, 2021

# Four Engines to Drive Sustainable High Growth



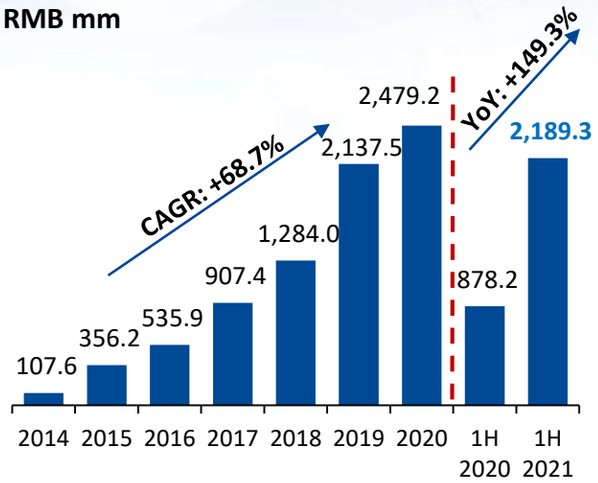

- North America: the largest market, with good performance in 1H 2021 mainly due to COVID recovery and strong innovation trend in the region, as well as the growth in commercial and late phase COVID and non-COVID projects.
- EU: 706.8% YoY growth attributable to commercial COVID projects and more market share
- China: sustainable 42.3% YoY growth benefiting from favorable macro-environment with surging R&D investments, expect continuous growth due to fast progress of late phase projects
- Rest of the world: decreased in 1H 2021 due to higher base in 1H 2020 from COVID projects which have not progressed, in discussions with significant number of projects include commercial manufacturing

Notes:
1. As of June 30, 2021
2. Rest market primarily includes Singapore, Japan, South Korea, Australia and Israel

# Overview on Geographic Markets [1]

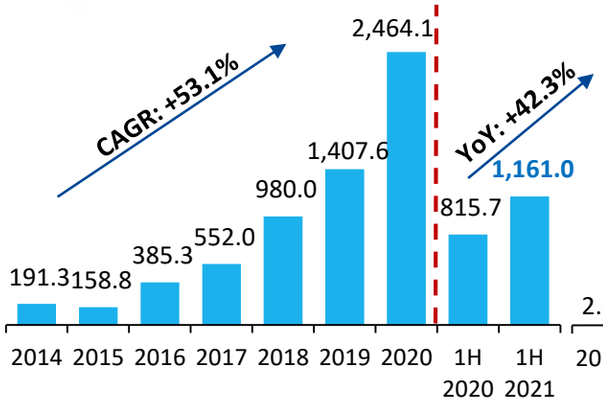
## North America

RMB mm



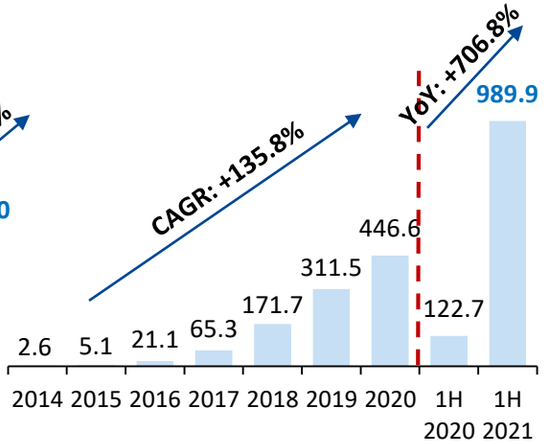

## PRC

RMB mm



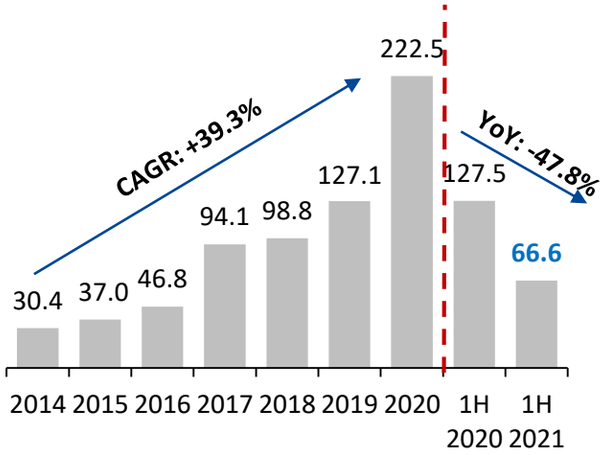

## Europe

RMB mm

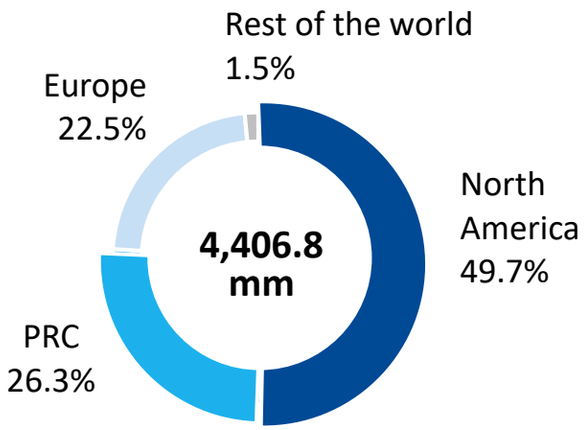



## Rest of the World [2]

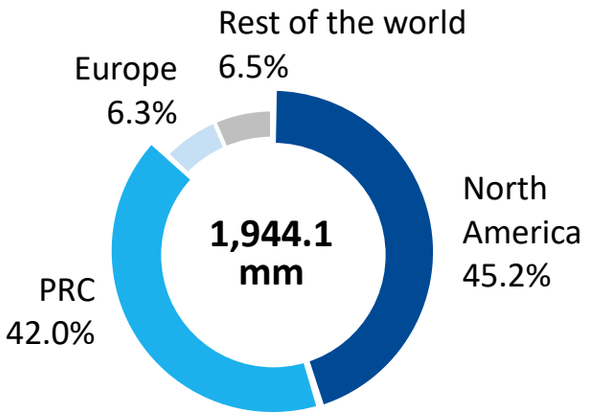
RMB mm




## 1H 2021 Revenue (RMB)




## 1H 2020 Revenue (RMB)

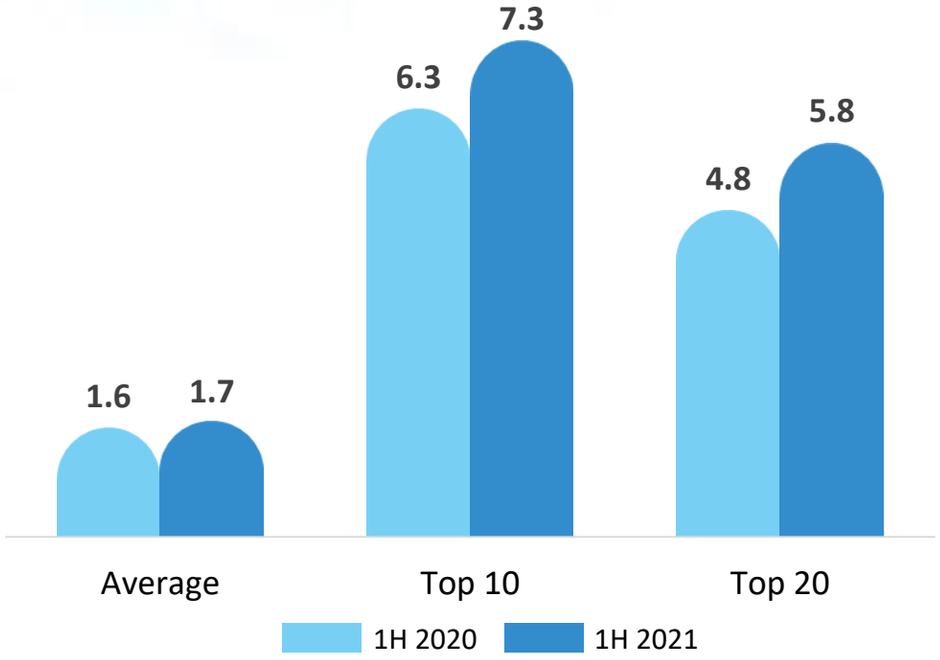



**Note:**

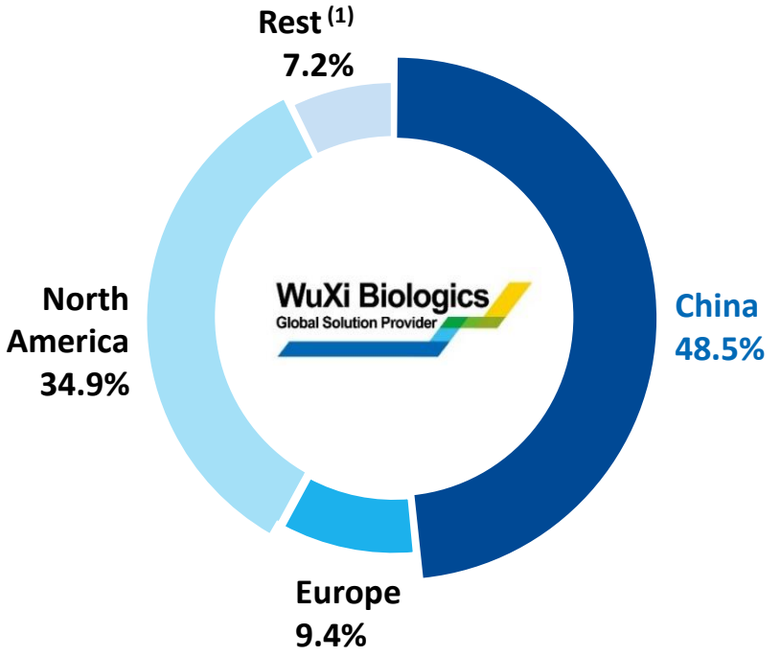
1. Customers are classified into different regions based on their headquarters
2. Rest of the world primarily includes Singapore, Japan, South Korea, Australia and Israel

# Balanced Customer Distribution Among Four Key Regions

## Integrated Projects Per Customer




## Customers No. By Region

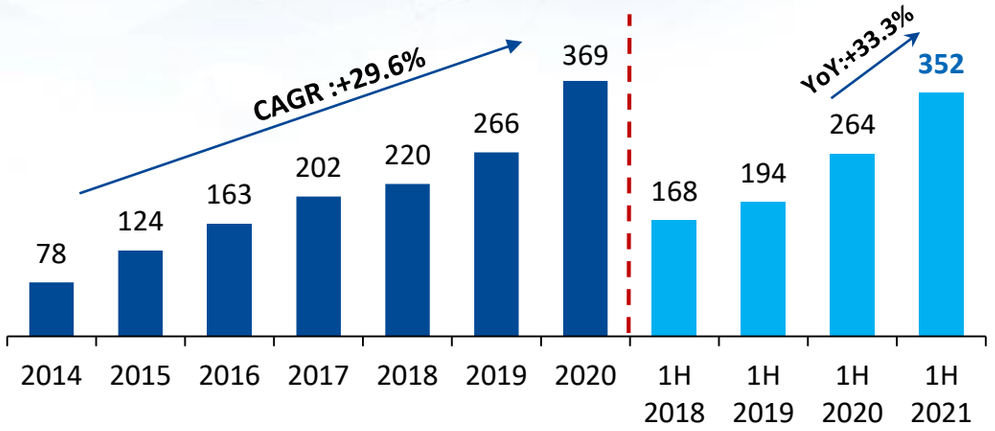



- **North America:** resilient growth despite COVID impacts; **China:** became the biggest customer base since 2020
- **Taking market share rapidly in EU** despite strong presence of global players, especially seized more opportunities from COVID
- **Trust from clients: 80%** existing clients will choose WuXi Bio again when they need CDMO
- **Leading platforms, best execution, track record and dedication to COVID-19 projects continue to enhance bonding with customers**

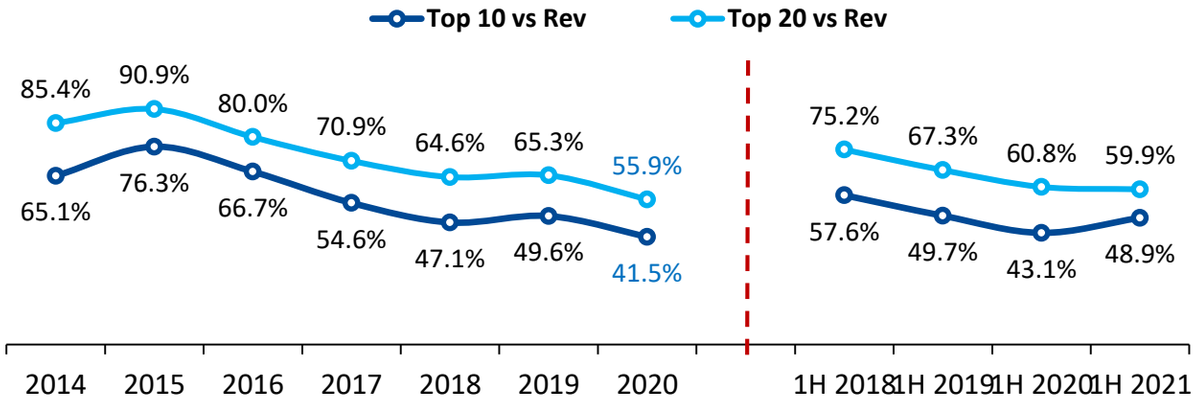
Note:
1. Rest market primarily includes Singapore, Japan, South Korea, Australia and Israel

# “Follow & Win the Molecule” Strategy Drives Customer Growth and Revenue Diversification

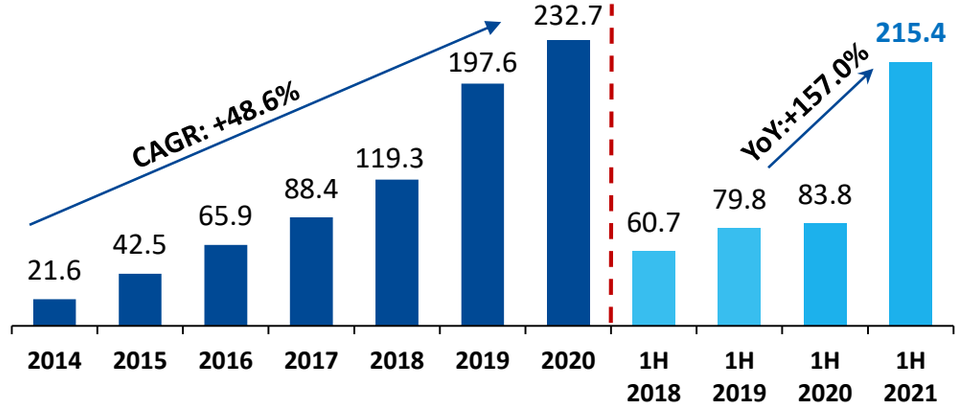
## Number of Large Customers [1] Serviced



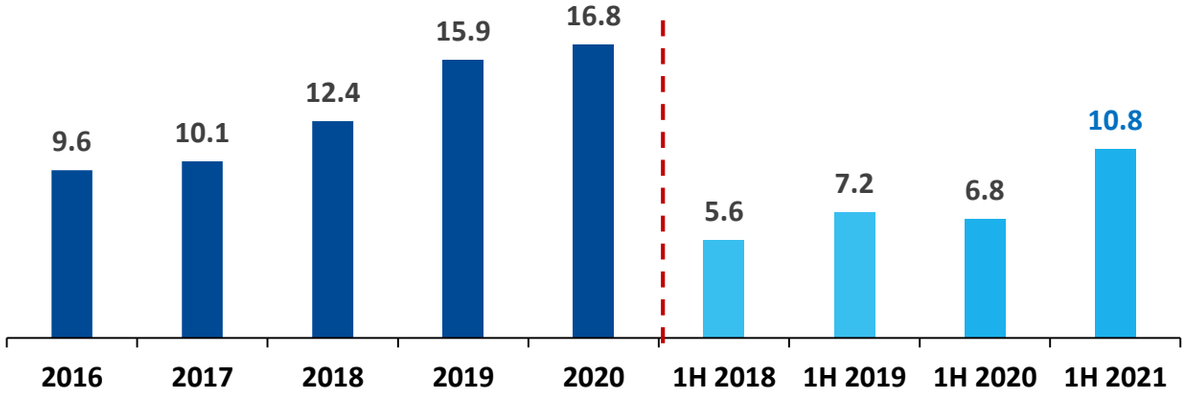

## Revenue % of the Top 20 and the Top 10 Customers




## Average Revenue per Customer among the Top 10 Customers in Each Period (RMB mm)




## Average Revenue per Project (RMB mm)




**The increase of Average Revenue per Customer (Top 10) & Average Revenue per Project showcases our pipeline is promptly progressing to late stage and more milestone payment received**

Note:

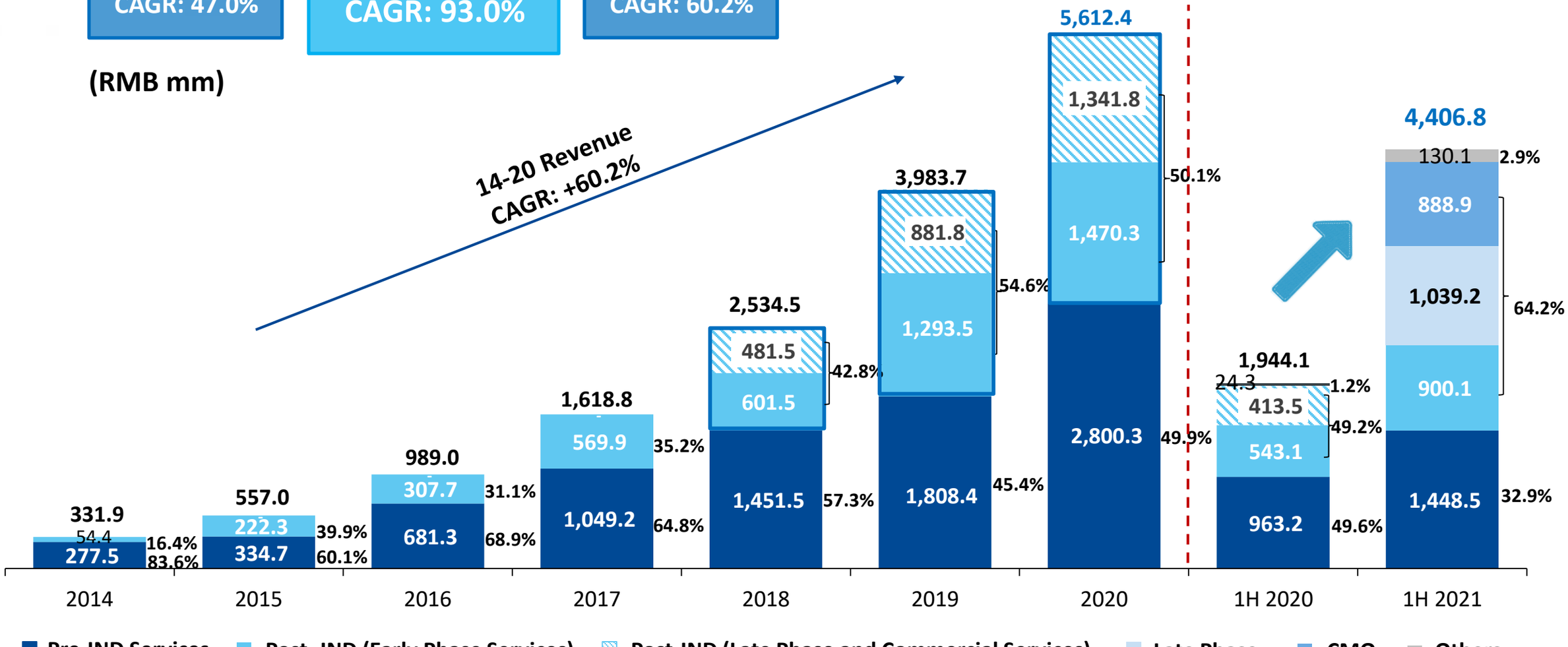
1. Customers refer to those clients who contributed revenue during the reporting period

# CDMO Model Validated as Post-IND Rev. Growing "Follow & Win the Molecule" in Full Play

| Pre-IND | Post-IND | Total Revenue |
|---|---|---|
| CAGR: 47.0% | CAGR: 93.0% | CAGR: 60.2% |

**366%+** growth in late phase and commercial revenue, **significant contribution from commercial**

(RMB mm)



# EXECUTION: Excellent Operational Metrics

## Track Record

- 215 INDs, 7 BLA/MAAs approved, 1 US EUA approved, 6 BLAs/MAAs/NDAs filed (1)
- 408 integrated biologics in development including 59 bispecific and 48 ADCs
- 31 on-going WuXiBody® bispecific antibody projects
- Total 15+ COVID-19 programs in progress and 25 INDs approved
- Capacity of 120 INDs and 7 BLA/MAAs enabled per year
- 1,107 projects including 408 integrated and other non-integrated CDO projects

## Operational Excellence

- 11 facilities with 150,000L DS capacity in 2021 expanding to ~430,000L after 2024
- 9 facilities for drug product filling, including 1 dedicated to bioconjugates in 2021
- 13 facilities will be online in 2021 including 6 from internal and 7 from M&A
- Building 13 facilities globally
- 1,100+ DS batches completed with 98% success rate
- 790+ DP batches completed with 99%+ success rate, 50+ media fills with 100% success rate
- 183 DS batches completed in MFG3 with 100% success since Apr. 2018
- ROI for MFG1 and MFG3 exceed 50%

Note:
1. As of June 30, 2021

02

# Seven Keys for Future Success

# SEVEN Keys for Future Success: Sustainable High Growth


精益奋进 势不可挡
To Benefit Patients Worldwide

# STRATEGY: Success of “Follow & Win the Molecule” Demonstrated

22 April 2021

## FDA grants accelerated approval for GSK’s JEMPERLI (dostarlimab-gxly) for women with recurrent or advanced dMMR endometrial cancer

### For media and investors only

Issued: London UK

- GARNET study represents the largest dataset of anti-PD-1 monotherapy treatment of women with endometrial cancer
- Study results showed an overall response rate of 42%
- 93% of responders had a duration of response of ≥6 months

GlaxoSmithKline plc today announced that the US Food and Drug Administration (FDA) has approved JEMPERLI (dostarlimab-gxly), a programmed death receptor-1 (PD-1) blocking antibody, based on the company’s Biologics License Application. Dostarlimab is indicated for the treatment of adult patients with mismatch repair-deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that have progressed on or following prior treatment with a platinum-containing regimen. This indication is approved under accelerated approval based on tumour response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

23 April 2021

## European Commission approves GSK’s JEMPERLI (dostarlimab), the first anti-PD-1 therapy approved for recurrent or advanced endometrial cancer

### For media and investors only

Issued: London UK

- **European Commission approves GSK’s JEMPERLI (dostarlimab), the first anti-PD-1 therapy approved for recurrent or advanced endometrial cancer**

GlaxoSmithKline (LSE/NYSE: GSK) plc today announced the European Commission has granted conditional marketing authorisation for JEMPERLI (dostarlimab), a programmed death receptor-1 (PD-1)-blocking antibody, for use in women with mismatch repair-deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer who have progressed on or following prior treatment with a platinum containing regimen. The approval makes dostarlimab the first anti-PD-1 therapy available for endometrial cancer in Europe.

# STRATEGY: Proactive Investments In New Platforms Proven Successful

WuXi Biologics
Global Solution Provider

## 2017

**WuXi Vaccines**

set up new vaccine CDMO business

**WuXiBody® platform launched to enable bispecific innovation**

## 2018

**WuXi Vaccines**

- signed a US$3 bn LOI

**WuXiBody®**

Signed 7 global clients

## 2019

**WuXiBody®**

6 projects in Preclinical stages

## 2020

**WuXi Vaccines**

- 4 vaccine deals signed
- 1 COVID vaccine CMO

**WuXiBody®**

- 1st IND filing
- 1st phase I
- More milestone payments

## 2021

**WuXi Vaccines**

- Total vaccine deals reached 9, including 3 COVID vaccine deals
- Expect ~US$300 mm revenue from COVID vaccine
- Full Capability for mRNA-based vaccines

**WuXiBody®**

- 1-2 IND filings
- More projects move to later stages

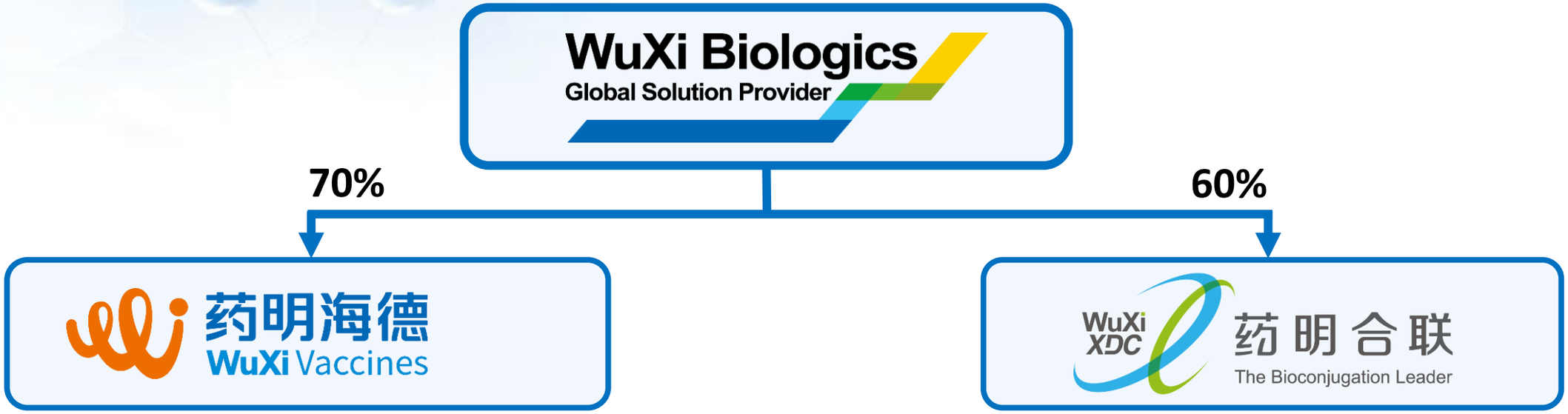
## 2022

## 2023……

**Continue to build new technology platforms and new modalities to enable global customers**

***With innovative technology platforms established ahead of the curve, WuXi Biologics continues to seize opportunities to enable global partners***

# STRATEGY: Expanding Capacities and Capabilities to Enhance Vaccine and Bioconjugate CDMO Services




- **WuXi Vaccines: the first and only global CDMO dedicated to vaccines. First CMO contract of US$3 bn for 20 years. 9 vaccine contracts have been signed and COVID vaccines contract reached ~US$300 mm**
- **WuXi XDC: first and only global leading one-stop CDMO dedicated to bioconjugates. 48 global projects with nearly 20% market share**
- **WuXi Vaccines and WuXi XDC are among global Top 20 CDMOs and Top 5 CDMOs in China by 2021 revenue ranking**

# PEOPLE: Talents Form the Prerequisite for Business Success

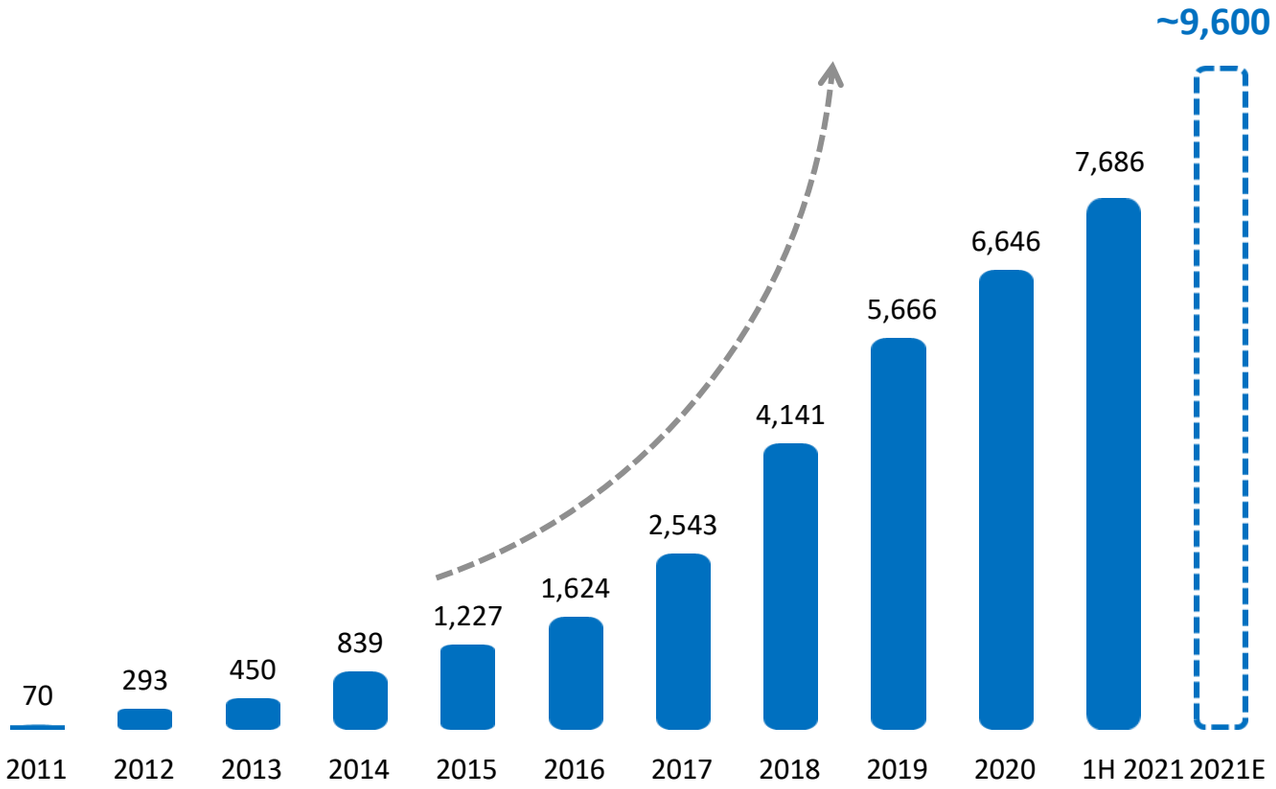
**7,686** Employees as of June 2021. Expected to reach 9,600 by the end of 2021

**500+** Employees work in US and EU

**552** Employees holding Ph.D. or equivalent

**2,803** One of the largest biologics development teams

## Rapid Expansion of Talent Pool




**1H 2021 Talent retention rate[(1)] >95%, Key talent >96%**

Note:
1. As of June 30, 2021, retention rate is calculated on voluntary staff turnover

# TECHNOLOGY: Globally Recognized Technology with 59 IP Applications

WuXia 13 patent applications
1 in-licensed patent

Proprietary High Titer Production CHO K1 Cell Line Development Platform

Antibody Drug Physic-chemical Structure and Biological Activity Analysis Platform

WuXiDAR4 7 patent applications

Comprehensive ADCs Development Platform

1 Proprietary Universal Bispecific Antibody Platform

WuXiBody Bispecific Antibody Technology Platform
25 patent applications

2 Proprietary Ultra-high Productivity Continuous Perfusion Cell Culture Platform

WuXiUP 14 patent applications

3

4 Antibody Drug Purification and Formulation Development Platform

5

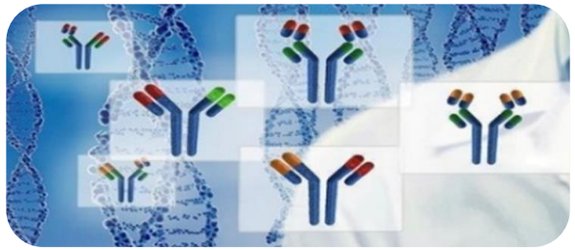
6 More……

Note:
1. as of June 30, 2021

# TECHNOLOGY: Bispecifics Will Be Key Next Wave - WuXiBody®

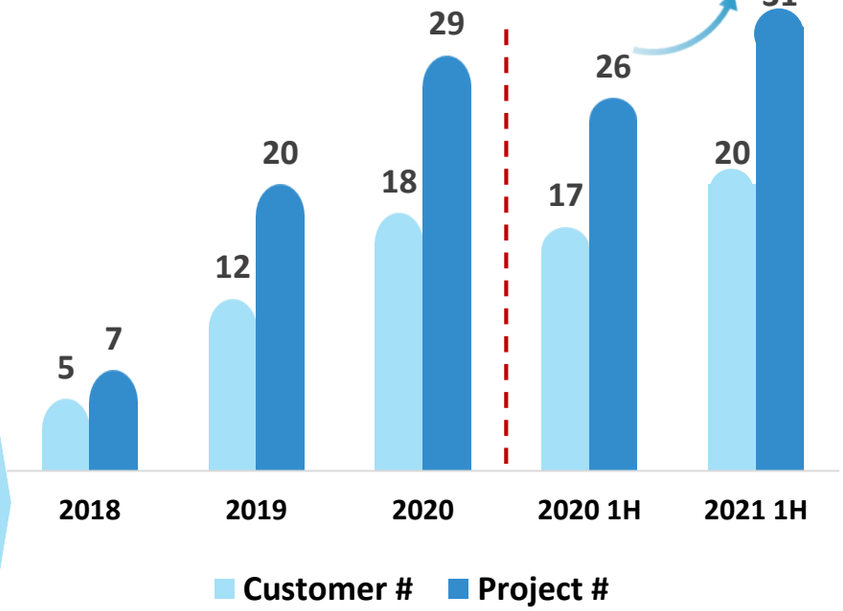
## Leading Edge Technology

**Empower to discover best or first-in-class molecules**

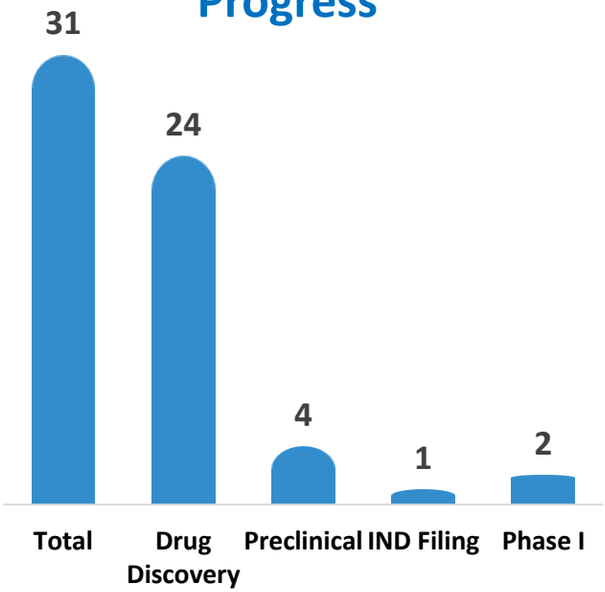


WuXiBody® Bispecific
Antibody Technology Platform

## Out-licensed Projects for WuXiBody®



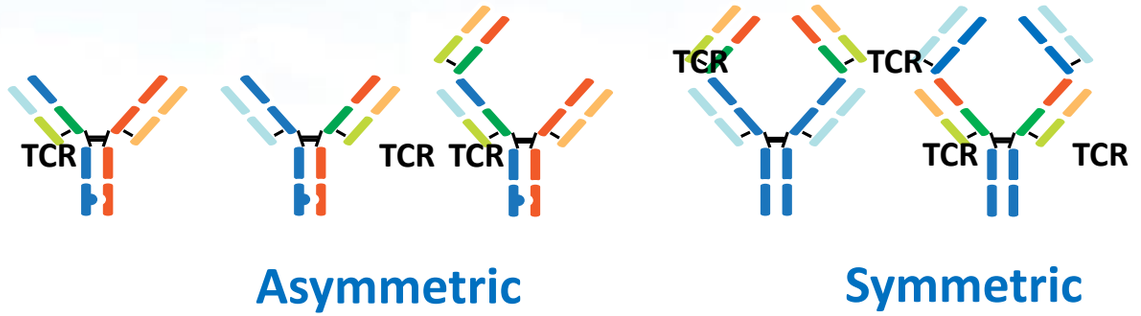

## WuXiBody® Development Progress




- WuXiBody® continues to gain worldwide recognition, 104% CAGR of out-licensed projects growth during 2018-2020
- 4 projects at preclinical, 2 project at Phase I, demonstrating state-of-the-art technology of WuXiBody®
- 1-2 WuXiBody® projects are expected to get IND approval in 2021

Note:
1. as of June 30, 2021

# TECHNOLOGY: Global Leader in Developing Bispecifics
# 11 Different Formats and 34 Papers Published




Asymmetric Symmetric

- 6 WuXiBody® projects in total, which adopt 5 different formats as shown above
- Titer: 3.0-4.9 g/L
- Overall yield: 42-55%


1.Wan Y, Wang Y, Zhang T, Zhang S, Wang Y, Li Y. Application of pH-salt dual gradient elution in purifying a WuXiBody-based bispecific antibody by MMC ImpRes mixed-mode chromatography. Protein Expr. Purif. 2021, 181: 105822.

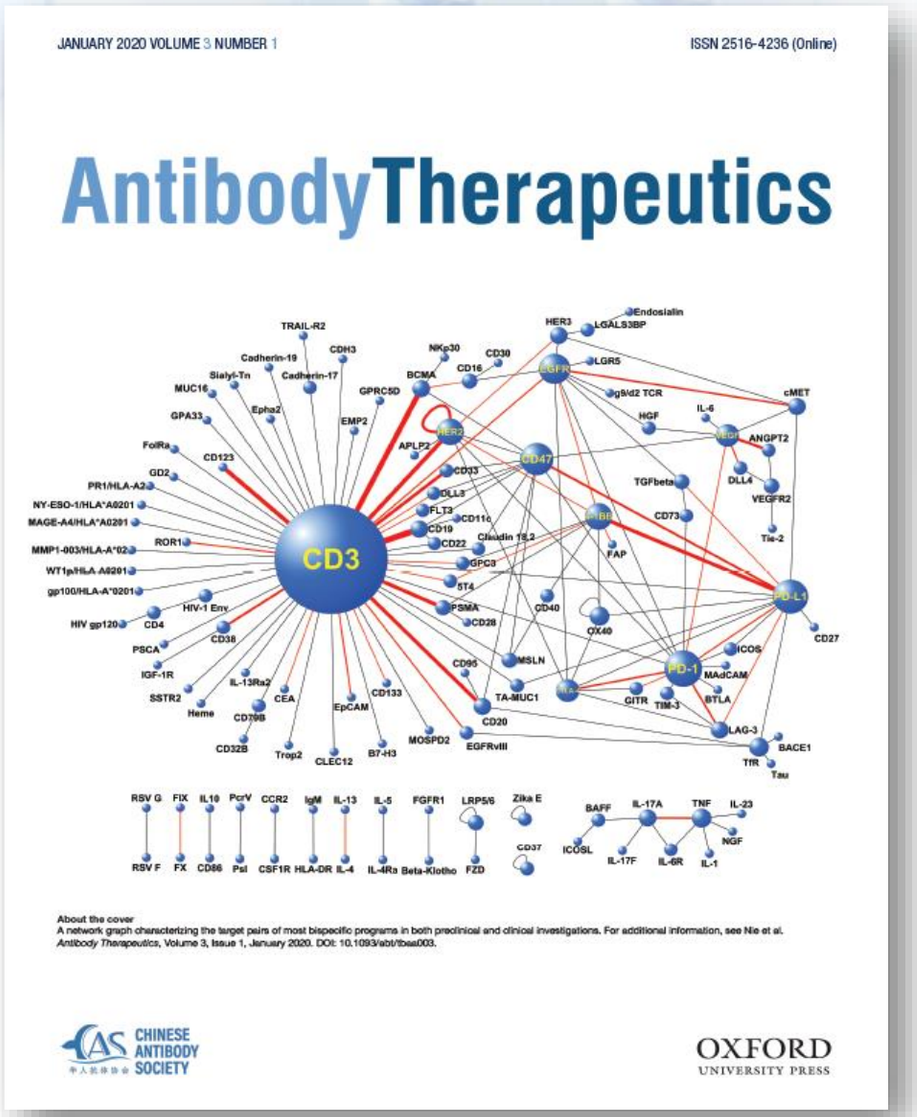
2.Wan Y, Zhang T, Wang Y, Wang Y, Li Y. Removing light chain-missing byproducts and aggregates by Capto MMC ImpRes mixed-mode chromatography during the purification of two WuXiBody-based bispecific antibodies. Protein Expr. Purif. 2020, 175: 105712.

3.Wang Y, Chen X, Wang Y, Li Y. Removing a difficult-to-separate byproduct by Capto L affinity chromatography during the purification of a WuXiBody-based bispecific antibody. Protein Expr. Purif. 2020, 175: 105713.

4.Guo G, Han J, Wang Y, Li Y. A potential downstream platform approach for WuXiBody-based IgG-like bispecific antibodies. Protein Expr. Purif. 2020, 173: 105647.


*One-Stop Bispecifics Technology Platform to Enable Global Partners*

# TECHNOLOGY: Well-recognized Peer-reviewed Paper Published




*Antibody Therapeutics, 2020, Vol. 3, No. 1 18–62*
*doi:10.1093/abt/tbaa003*
*Advance Access Publication on 17 February 2020*

Review Article

## Biology drives the discovery of bispecific antibodies as innovative therapeutics

**Siwei Nie[1,*], Zhuozhi Wang[1], Maria Moscoso-Castro[2], Paul D'Souza[2], Can Lei[2], Jianqing Xu[1] and Jijie Gu[1,*]**

[1]WuXi Biologics, 299 Fute Zhong Road, Waigaoqiao Free Trade Zone, Shanghai 200131, China and [2]Clarivate Analytics, Friars House, 160 Blackfriars Road, London SE1 8EZ, UK

Received: December 10, 2019; Revised: February 7, 2020; Accepted: Month 0, 2000

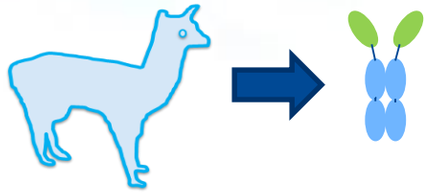
- **We proposed 3 principles and 6 criteria for discovery and development of biologic drugs**
- **We reviewed current bsAb formats and the bsAb drugs in clinical and preclinical development**
- **We also projected that "…NEXT DECADE will witness clinical success of bsAbs or multispecific antibodies employing some novel mechanisms of action..."**

**14,000+ reads and 6,700+ download**

# TECHNOLOGY: Multispecific/Multifunctional Proteins Enabled via SDArBodY™

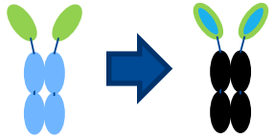
WuXi Biologics
Global Solution Provider

## 1 Naive & Immune Alpaca/llama VHH



- Naïve library constructed in house from 50+ alpaca donors. The library size is >$10^{11}$ transformants
- Immune library based on proprietary immunization protocol to achieve desired immune responses.
- Proprietary primer sets to achieve increased coverage of alpaca/llama VHH gene repertoire
- Delivered promising leads for more than 30+ targets with differentiation/superiority

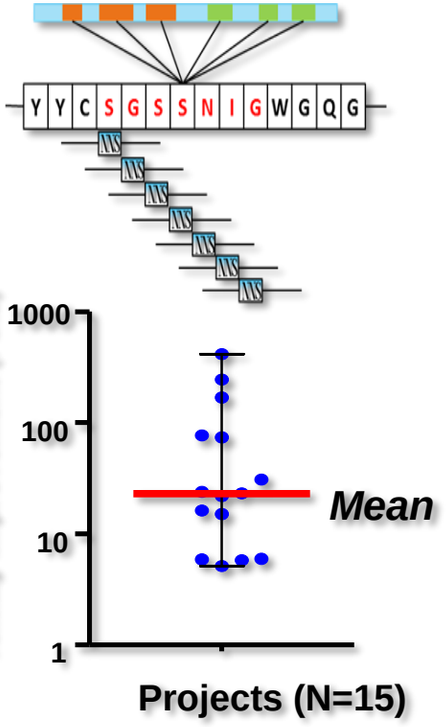
## 2 Humanization and PTM removal



**Proprietary VHH Humanization Method**

- Exhaustively humanized sequences
- PTM removed
- No affinity/function loss
- No developability compromise

## 3 Affinity Maturation




## 4 Features of Building Blocks

SDArBody™

- **High affinities**
  - Nano- to picomolar
- **Delicate molecular size**
  - Target difficult epitopes
  - Deep tissue penetration
- **Excellent developability**
  - Reduce production costs
  - Alternative routes of administration
- **Low immunogenicity risk**
- **Great flexibility**
  - Multivalency engineering
  - Enable multi-specific or functional molecules to meet various biology need

# TECHNOLOGY: 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**
- **WuXian Express pool and clone selection**
  - **Pool: ~3 month Gen1 IND**
  - **Clone: 6 month Gen2 IND**
- **8 mAbs and 1 vaccine for COVID-19 in CMC development in 2021**

Received: 24 March 2021 | Revised: 12 June 2021 | Accepted: 17 June 2021
DOI: 10.1002/btpr.3186

RESEARCH ARTICLE

BIOTECHNOLOGY PROGRESS

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

Zheng Zhang | Ji Chen | Junghao Wang | Qiao Gao | Zhujun Ma | Shurong Xu | Li Zhang | Jill Cai | Weichang Zhou

Waigaoqiao Free Trade Zone, WuXi Biologics, Shanghai, China

Correspondence
Weichang Zhou, CTO of WuXi Biologics, Shanghai 200131, China.
Email: weichang_zhou@wuxibiologics.com

**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

# TECHNOLOGY: WuXiUP™ to Dramatically Enhance Productivity and Reduce Cost of Goods – Universal Platform

WuXi Biologics
Global Solution Provider

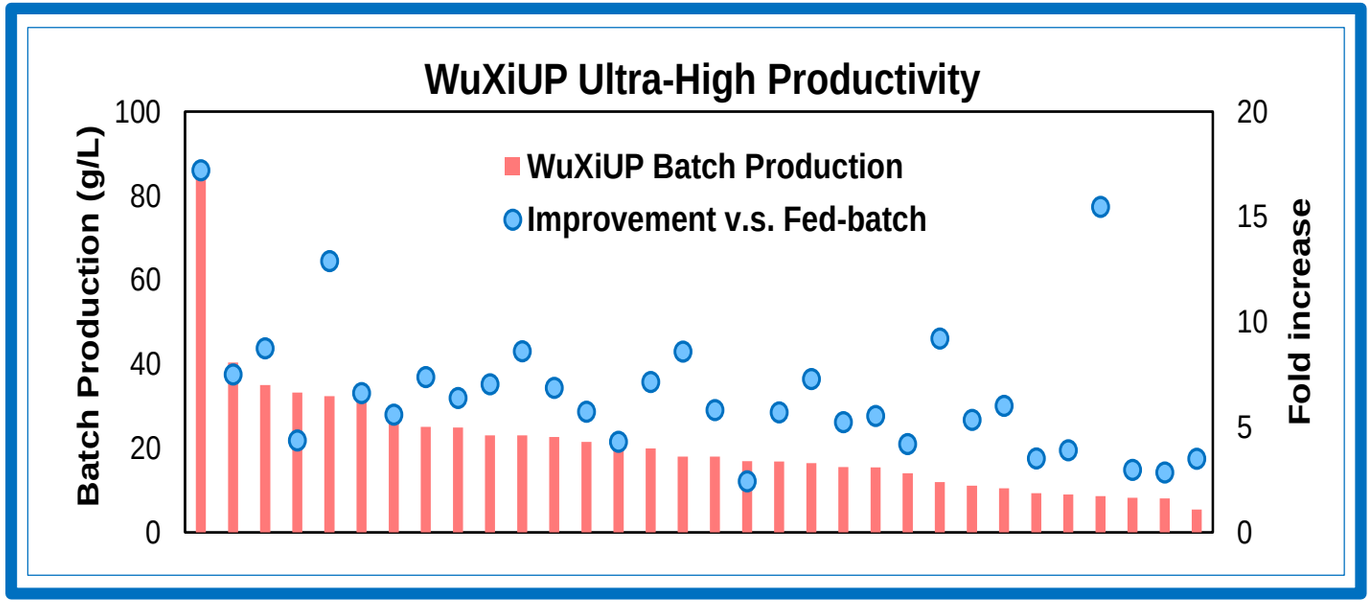
## WuXia™ Cell Line

- Robust cell line with proven track record
- Enabling 120 Integrated Projects Per Year

+

## WuXiUP™ Continuous Manufacturing Platform

- 20-85g/L for mAbs and BsAbs
- 2,000L disposable bioreactors to achieve comparable productivity as traditional 20,000L SS tanks




- 40+ WuXiUP™ projects: mAb, BsAb, Fusion Protein and enzyme
- Avg titer improvement: 6.6 folds; Avg daily productivity improvement: 4.2 folds
- 13 IND projects
- 5 BLAs targeted, 2 BLA approval in 2021

# TECHNOLOGY: WuXiUP™ Published in Premier Journals

BIOTECHNOLOGY and BIOENGINEERING

WuXi Biologics
Global Solution Provider

SSING Fermentation

TECHNOLOGY REVIEW

## Continuous Biomanufacturing Implementation

### Using an Intensified and Integrated Bioprocess Platform

Recent world events have demonstrated now more than ever the growing demand for pharmaceutical biologics that can be made rapidly and in high volumes yet somehow remain affordable. Hence, there is an urgent need to develop a next generation biologics manufacturing solution that provides high-yield, high-quality, is highly flexible and can be done cost-effectively. In this article we describe an intensified perfusion culture process, (the WuXi Biologics Ultra-High Productivity Platform or WuXiUP) that was developed to meet the aforementioned need. WuXiUP adopts process intensification strategies on to the traditional perfusion culture process, to boost the cell density and cell specific productivity. Additionally, the continuous harvest greatly reduces the residence time for the product within the bioreactor, leading to more desirable product quality, and facilitates integrated continuous bioprocessing.

WuXi Biologics
Global Solution Provider

Table 1: CAPTION

| Process | Culture Duration (Days) | Accumulated Harvest Pv (g/L) | Daily Productivity (g/L per day) |
|---|---|---|---|
| TFB | 14 | 2.82 | 0.20 |
| Perfusion | 40 | 31.63 | 0.79 |
| WuXiUP-1 | 21 | 52.14 | 2.48 |
| WuXiUP-2 | 27 | 85.86 | 3.18 |

***Weichang Zhou*** *is CTO and EVP, Biologics Development and Manufacturing, at WuXi Biologics; Weichang_zhou@wuxiapptec.com, 108 Meiliang Road. W, MaShan Binhu District, Wuxi 214092, China, www.wuxibiologics.com.* ***Hang Zhou*** *is vice president, Cell Culture Process Development, at WuXi Biologics.* ***Mingyue Fang*** *is Associate Director of Cell Culture Process Development, at WuXi Biologics.* ***Siyuan Tang*** *is Associate Director of Downstream Process Development, WuXi Biologics.*

Received: 23 October 2020 | Revised: 12 January 2021 | Accepted: 12 March 2021

DOI: 10.1002/bit.27768

COMMUNICATION TO THE EDITOR

BIOTECHNOLOGY BIOENGINEERING WILEY

## Improving an intensified and integrated continuous bioprocess platform for biologics manufacturing

Hang Zhou[1] | Mingyue Fang[1] | Xiang Zheng[1] | Weichang Zhou[2]

[1]Cell Culture Process Development, WuXi Biologics, Shanghai, China

[2]Biologics Development, WuXi Biologics, Shanghai, China

Correspondence
Hang Zhou, WuXi Biologics, Cell Culture Process Development, Shanghai 200131, China.
Email: zhou_hang@wuxibiologics.com

**Abstract**

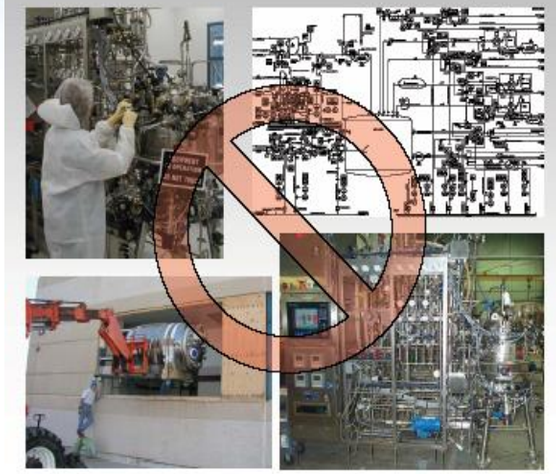
The WuXi Biologics' Ultra-high Productivity platform (WuXiUP) technology is an innovative and integrated platform of continuous biomanufacturing. Through process intensification, the platform enables continuous manufacturing of almost any type of biologics and delivers processes with ultra-high productivity. In this paper, a new case study producing a monoclonal antibody (mAb) via the WuXiUP process was further optimized. Key process parameters like culture temperature, basal media, and perfusion rate were evaluated to ensure an enhanced and robust process. To improve process efficiency for downstream processing, a continuous dual-pore size hollow fiber cell separation and product harvest system were also designed to complement the increased harvest volume from upstream production. In

**How to cite this article:** Zhou, H., Fang, M., Zheng, X., & Zhou, W. (2021). Improving an intensified and integrated continuous bioprocess platform for biologics manufacturing. *Biotechnology and Bioengineering*, 1–6. https://doi.org/10.1002/bit.27768

# TECHNOLOGY: Disposable Manufacturing Technology Proven Effective in Commercial Manufacturing

WuXi Biologics
Global Solution Provider

**Conventional Bioreactors**

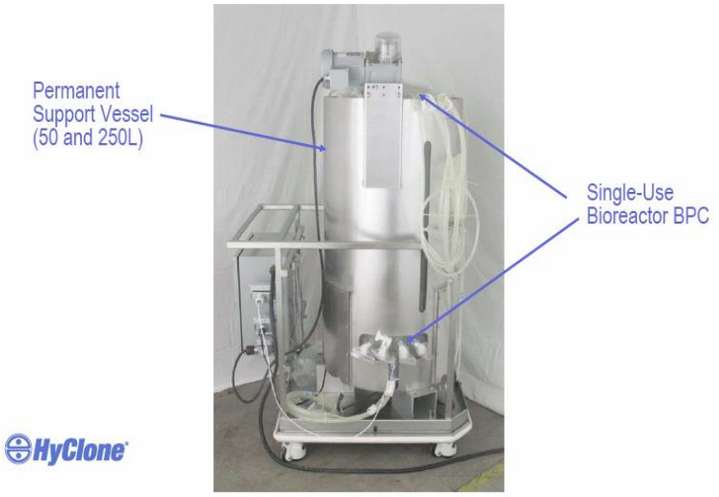


**Single-Use Bioreactors**

- ☑ 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)**



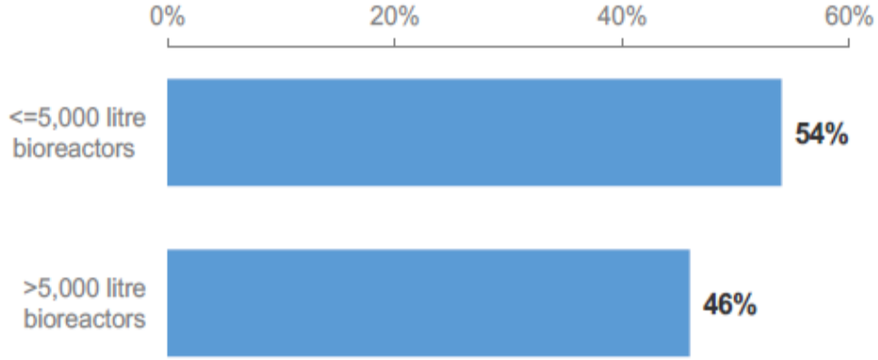

- Global leader and pioneer of using disposable manufacturing technology
- 800kg+ neutralizing mAbs delivered in 6 months at 2,000-12,000L scale
- COGS reduced to <US$80/g at 12,000L scale, comparable COGS with similar stainless steel
- CMO projects reached 4 in 1H 2021
- 1,100+ batches manufactured at around 98% success rate
- Less CAPEX, faster in building facilities and comparable COGS resulting in higher ROI (MFG1 10-year ROI 51% realized, MFG2 35%, MFG3 50% expected)

# TECHNOLOGY: Disruptive Single-Use Technology Pioneered by WuXi Biologics – 44% Market Share in New Capacity, 65-70% in R&D

## The Advantage of Single-Use Bioreactor

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

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



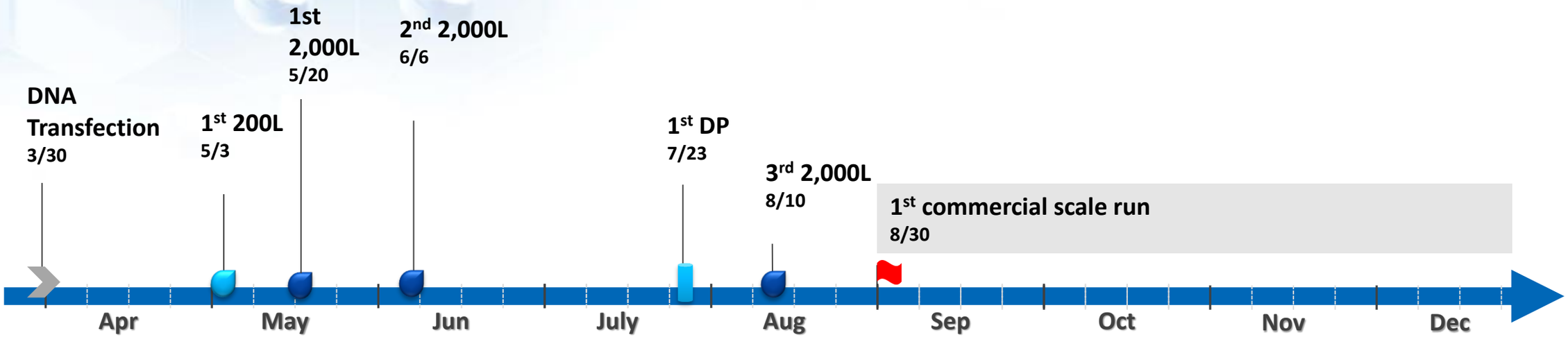

## Single-Use Bioreactor Capacity Expansion and its Penetration Rate


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


**Source:** Morgan Stanley report

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

WuXi Biologics
Global Solution Provider




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

# EXECUTION: DP7 – 12 Months from 1st Employee to Licensure
# WuXi Bio Speed and Quality first Demonstrated Globally

**Jan 2020**

Acquisition contract signed

**Jun 2020**

Take off! Site head arrived in Germany and local team started with 3 employees

**Mar 2021**

Completion of IOQ and PQ of Facilities, Utilities and Equipment

**May 2021**

Completion of media fill in campaign mode for 4 days filling time!


**Jun 2021**

Completion of local authorities' GMP inspection


**Jul 2021**

Obtained GMP licensing and started the first overseas commercial manufacturing

# EXECUTION: Completed 98% of Ireland Sites Construction in <2 Years Demonstrating WuXi Bio Speed and Quality in Ireland

April 2019

November 2019

December 2019

May 2020

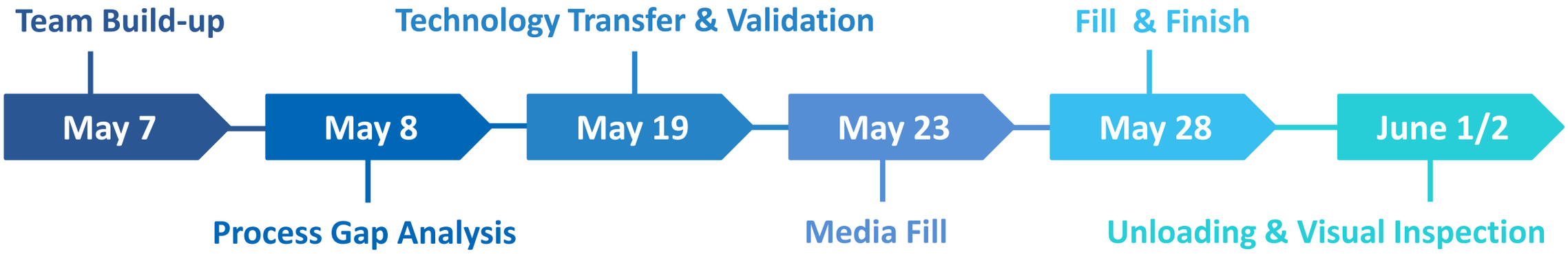
February 2021

May 2021

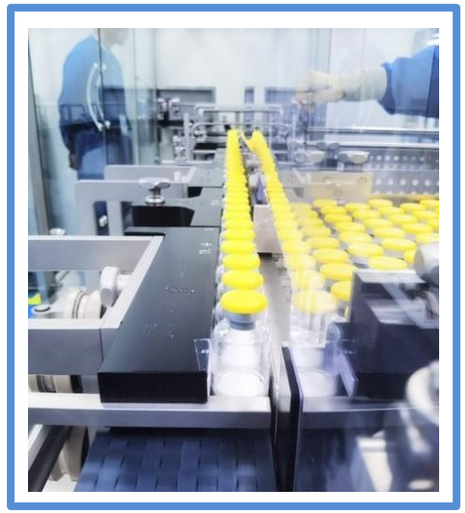
# EXECUTION: WuXi Bio Speed – Only 33 Days! Completed the First Batch of DP Manufacturing in former Pfizer DP Facility

WuXi Biologics
Global Solution Provider

**WuXi Bio Speed with more flexibility and consistent quality standard**
**bridge the process gap from single-project manufacturing to multiple-project manufacturing**







# EXECUTION: WuXi Bio Speed – Only 47 Days! Completed the Manufacturing for First WuXi Bio's Project in Former CMAB DS Facility

**MFG21 collaborated with multi functions (MFG3, WXPD, SHQC, WXQC, SCM, QA, RA, CB etc.) to successfully complete first tech-transfer of DS Manufacturing with 0 deviation in 47 days.**

**Day 0: Project Kick-off** — May 13

May 21 — **Day 8: Materials Supply Process bridging Completed**

**Day 17: Materials arrived at MFG21&Tech transfer Completed** — May 30

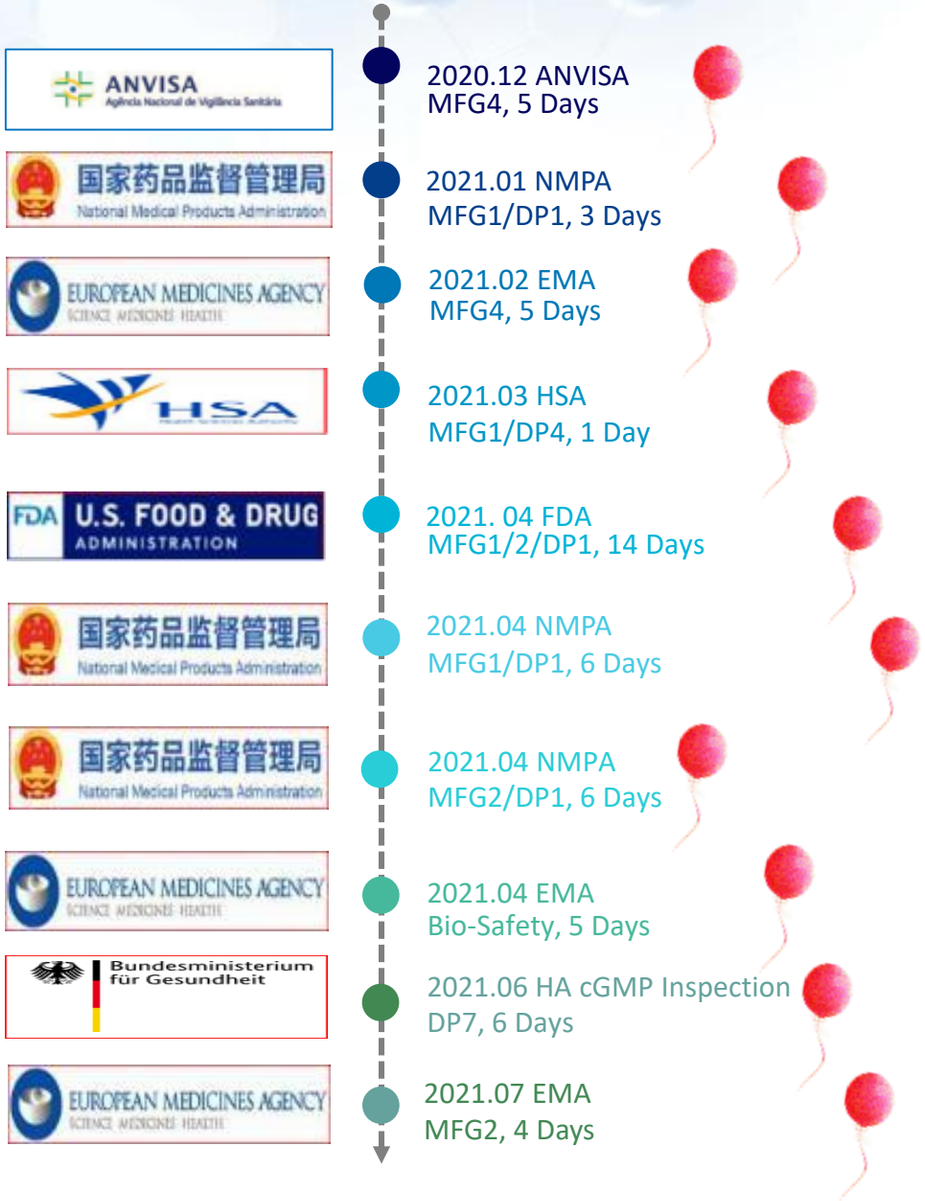
May 31 — **Day 18: Vial Thaw**

**Day 42: Harvest & MFG3 WXPD On-site Support& SHQC Started Real Time Support** — June 24

June 29 — **Day 47: Bulk Fill Completed**




# QUALITY: Tried-and-True Quality Systems




**15** Regulatory Inspections
(**9** regulatory GMP inspections in first 7 months of 2021)

**8** Approvals for **4** Commercial Products from US/EU/Brazil/WHO

**7** Facilities Certified (MFG1/2/3/4, DP1/4/7)
(**5** GMP certificates from the EMA)

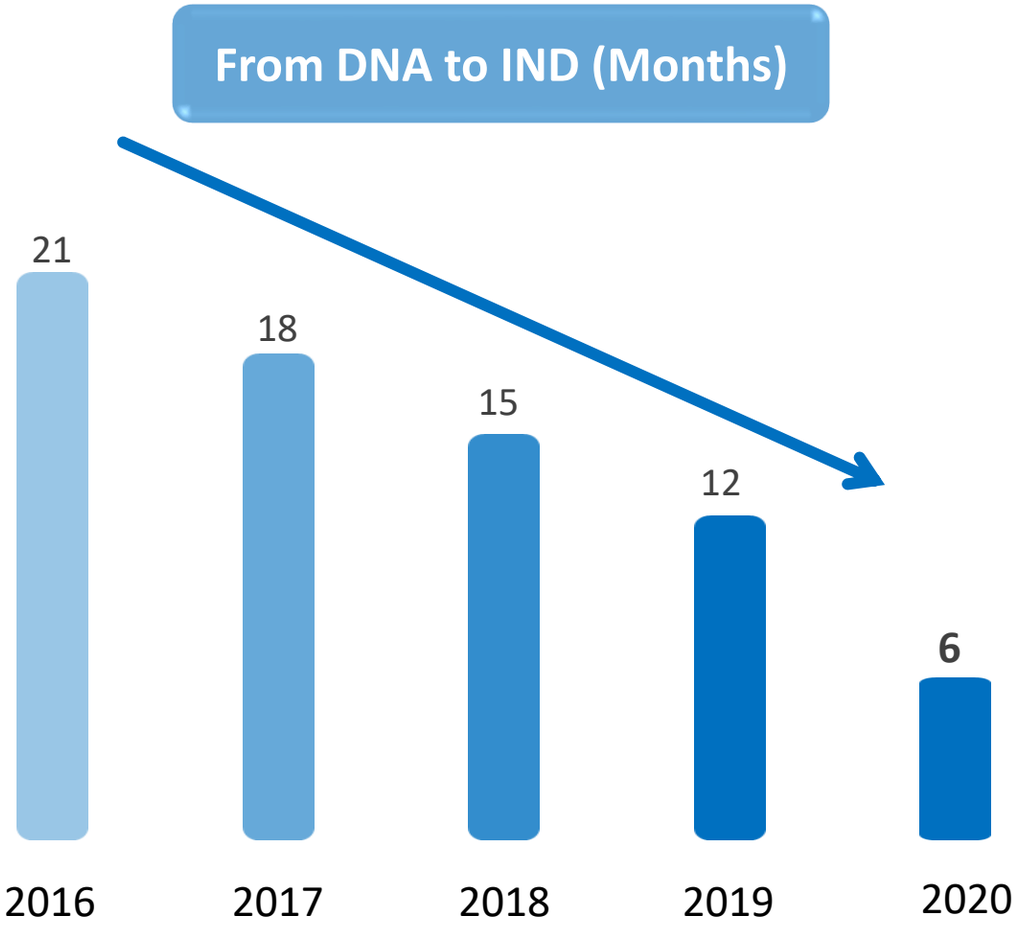
**6** Different Regulatory Agencies

**0** Major observations in EMA PAI

# SPEED: WuXi Bio's Record Speed for IND – 6 Months!

**Rewriting the shortest timeline for all IND-enabling CMC activities by implementing more advanced technology platforms**

- Standard timeline shortened to **6** months
- For public health emergencies:
  - D-to-D (DNA to IND) Recorded **2.5** months
  - A-to-A (DNA to EUA) targeting **15** months



# FLEXIBILITY: Industry Awards & Recognition from Global Clients


"The best team I ever worked with in my 40 years of development. I know with so many programs ongoing. It is exceptional and rare. "

----Customer A

"The WuXi Bio team has been tremendous in their diligence, thoughtfulness, organization, preparation, and follow-through."

----Customer B


"Other industrial friends asked me how is WuXi Biologics. I said that it is very hard to compete with a company that always says YES."

----Customer C


"Far exceeded our expectation. Money pays for services but can't buy commitment and collaboration from an excellent team who made this happen in a difficult year like 2020."

----Customer D


"Having worked with a dozen CMOs in the past five years, your quality and adherence to the agreed timeline really stand out. Your team was flexible and made extra effort to meet the timeline demand."

----Customer E

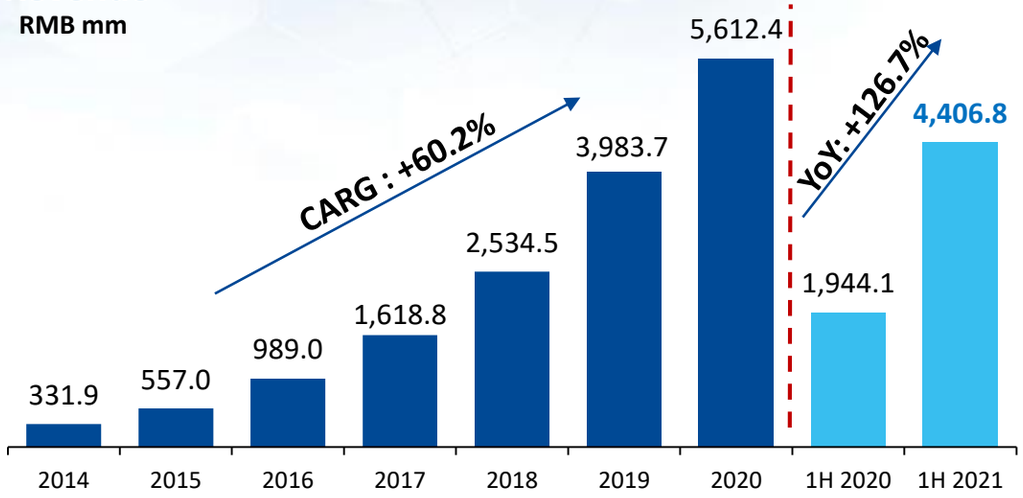
Winner in all **6** Life Science Leader CMO awards categories **each year** since 2019

# 03 Financial Overview

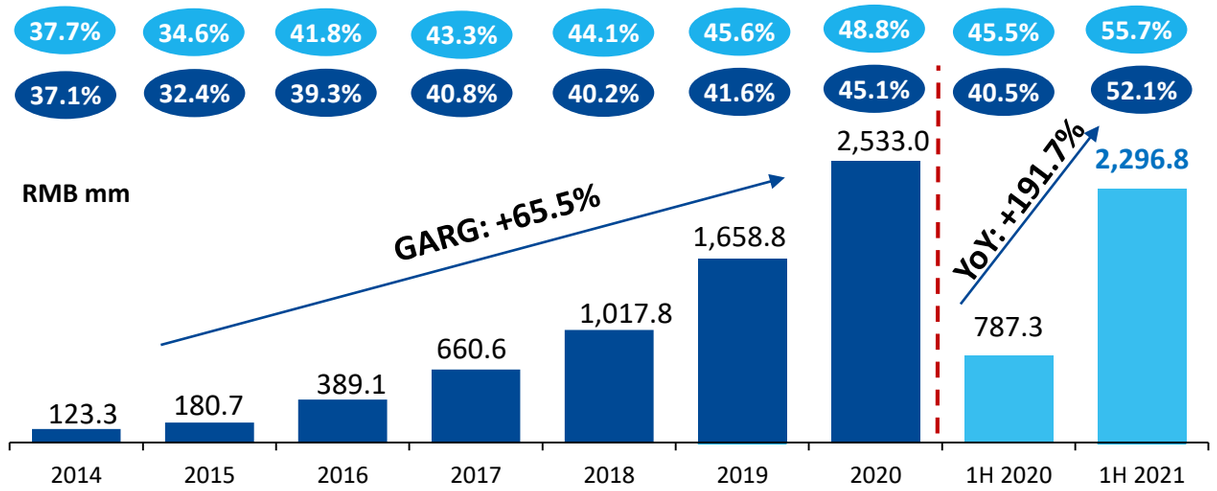
# Profitability Hit Another High

## Revenue

RMB mm

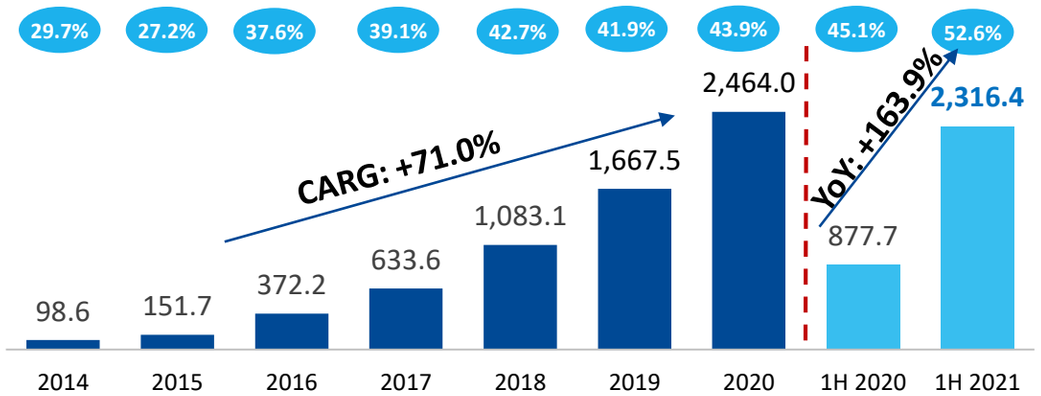



## Gross Profit

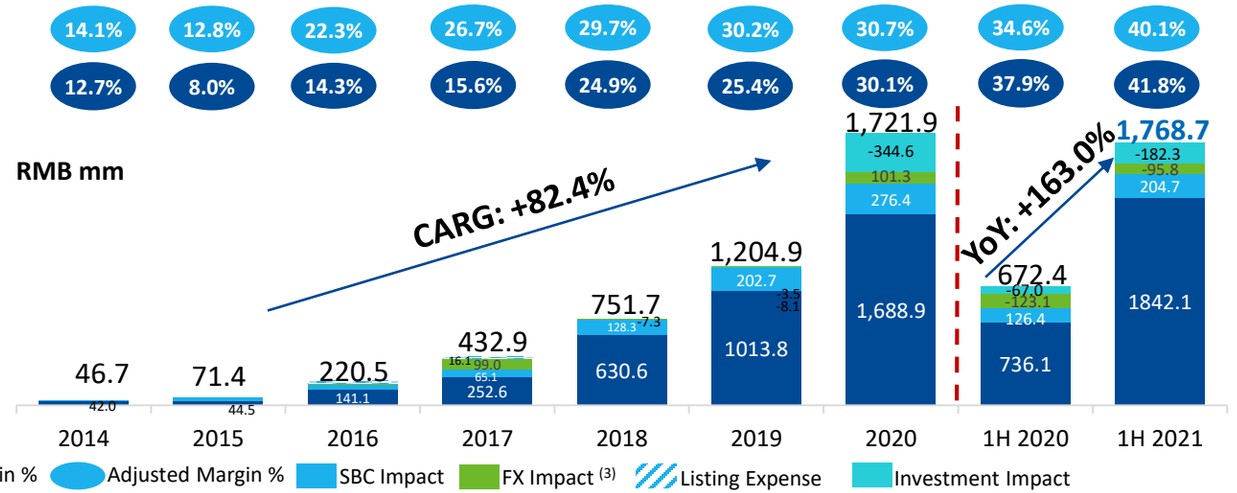



## Adjusted EBITDA (1)

RMB mm




## Adjusted Net Profit Attributable to Owners of the Company (2)

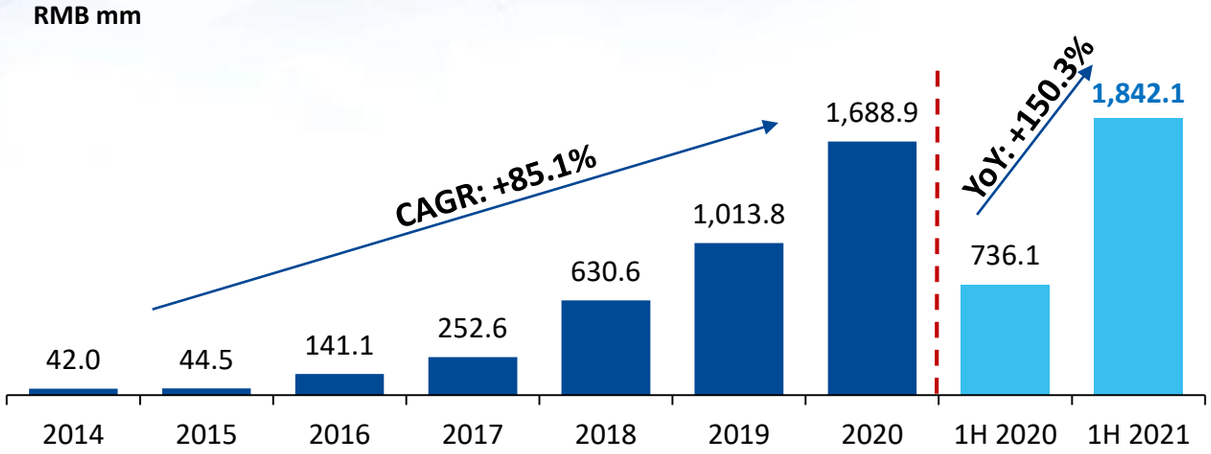



Notes:

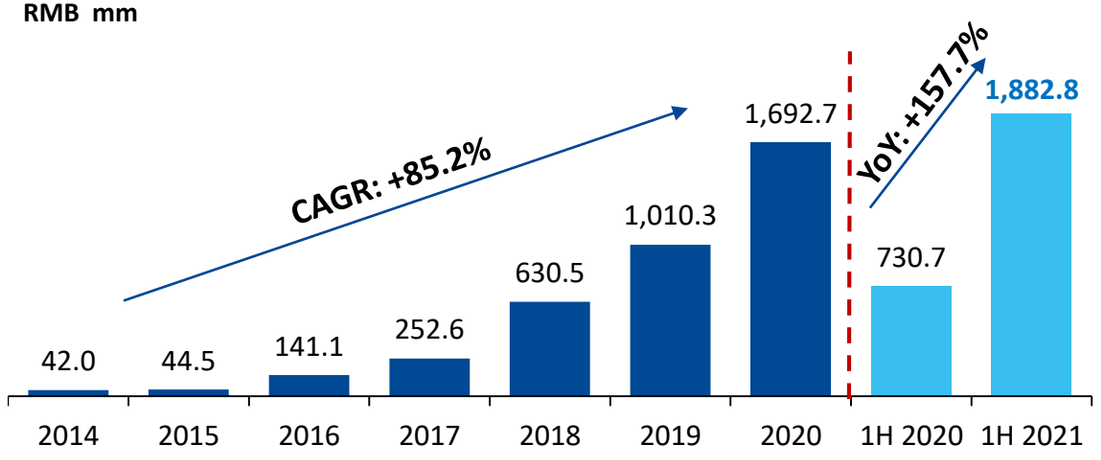
1. Adjusted EBITDA represents net profit before (i) interest expenses, income tax expenses, listing expenses (ii) certain non-cash expenses, consisting of share-based compensation, amortization and depreciation and (iii) foreign exchange (gains)/losses and (iv) fair value gains on investment portfolios
2. Adjusted net profit excludes the share-based compensation expenses, investment (gains), foreign exchange (gains)/losses and listing expenses
3. Refers to foreign exchange (gains)/losses
4. Adjusted EBITDA and adjusted net profit of 2019 have been restated to further exclude the fair value gains on the Group's investment portfolios

# WuXi Bio Financial Performance: Sustained High Growth

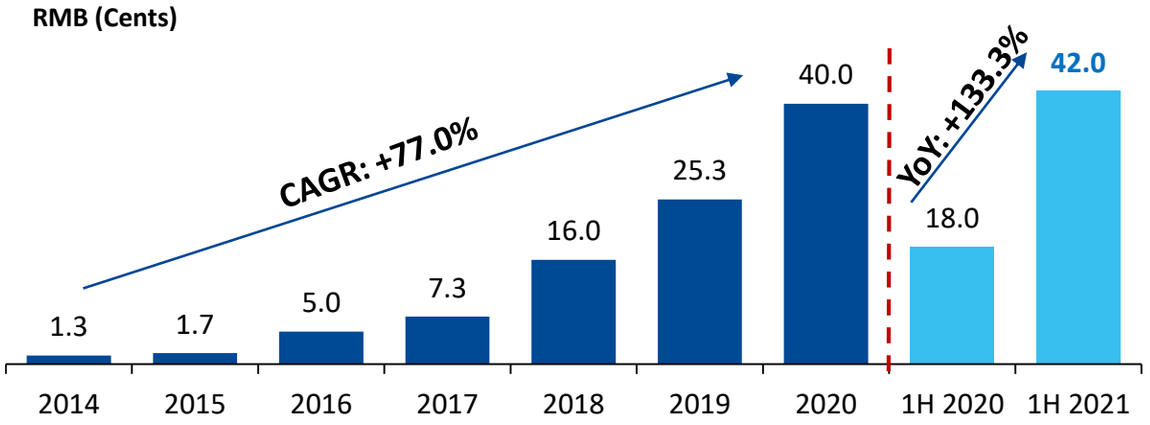
## Net Profit Attributable to Owners of the Company



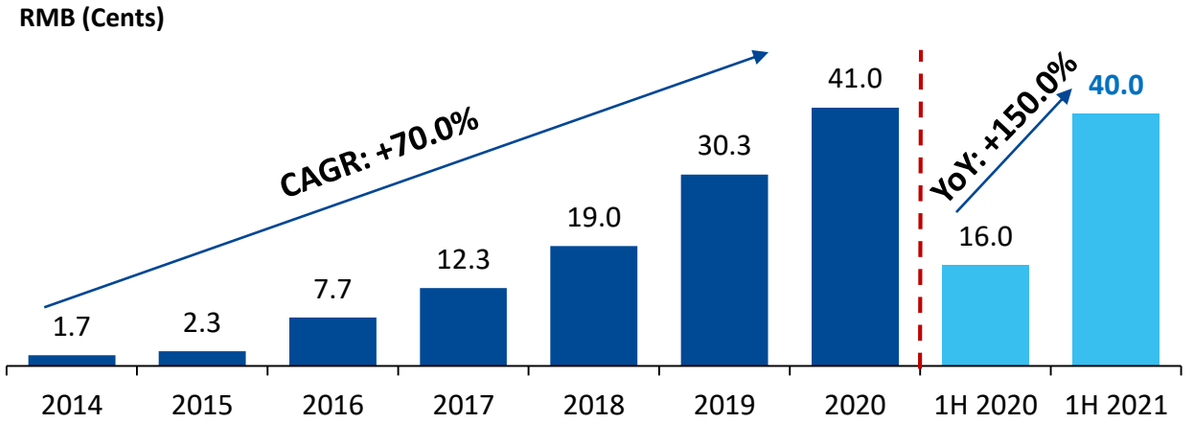

## Net Profit




## Diluted EPS [1]



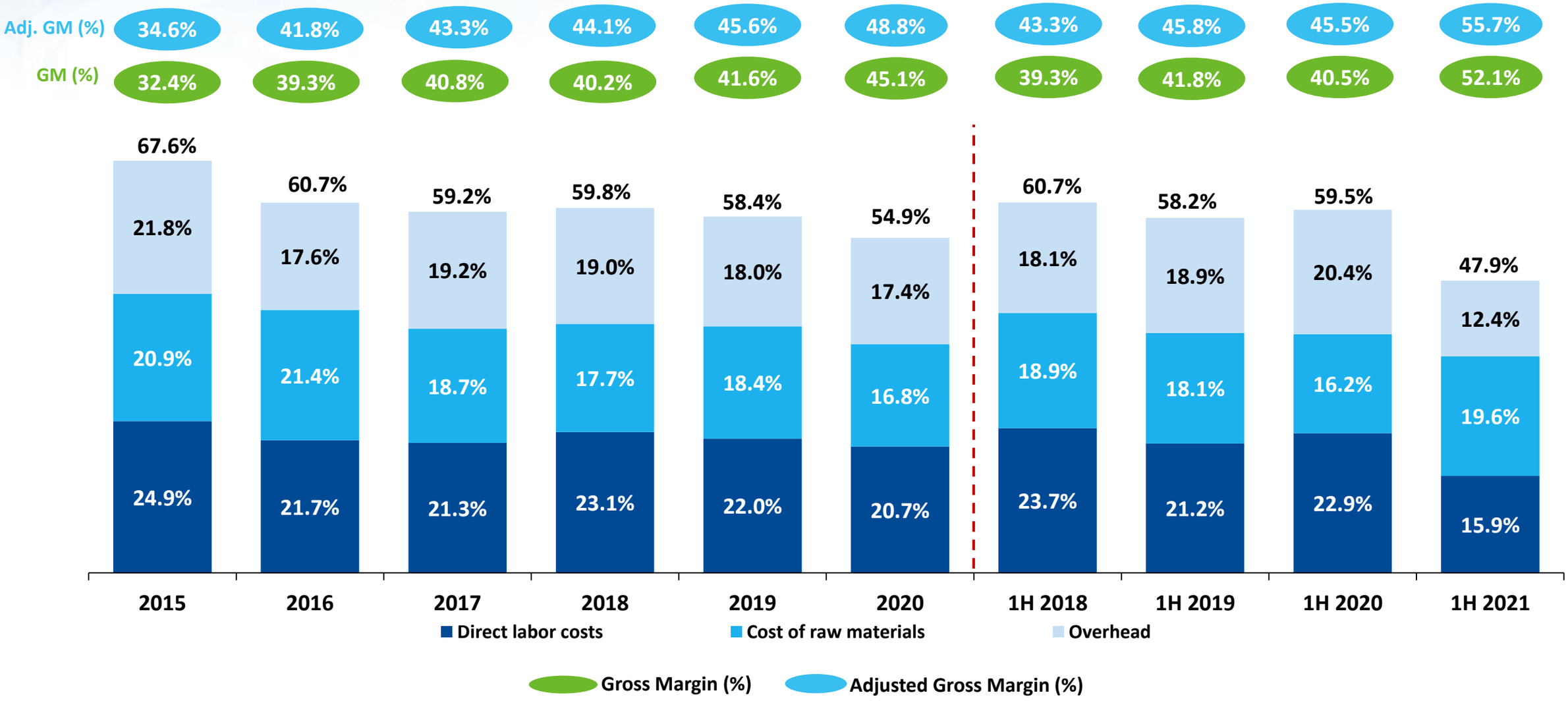

## Adjusted Diluted EPS [1]




Note:
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

# Gross Margin Snapshot

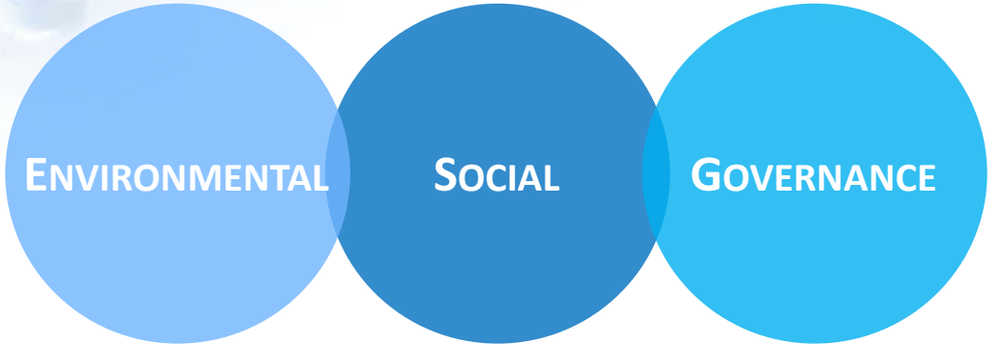
## Cost of Services as % of Revenue




Notes:
1. Adjusted gross margin excludes the share-based compensation expenses

# 04 ESG

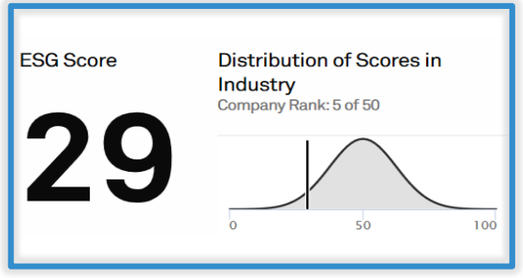
# Well Recognized by Global ESG Rating Agencies




- ESG Committee at the board led by CEO
- Strictly comply with the Environmental Protection Law and other EHS regulations
- 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 Russel


MSCI
ESG Research


Institutional Investor




Dow Jones Sustainability Indexes


FTSE Russell

# Corporate Social Responsibilities in Fighting Against COVID-19
# Enabling COVID Projects at the Speed of Light

WuXi Biologics
Global Solution Provider

- Scientists Working on COVID
- COVID Vaccines Delivered
- Neutralizing Antibody Delivered




**25** | **INDs filed globally for COVID antibody projects.**

**14** | **months from DNA to EUA, enabling Vir/GSK neutralizing antibody at the speed of light!**

**5** | **months from DNA to IND for neutralizing antibodies. Best technology & execution shortened the IND timeline**

**4** | **US, EU, WHO and Brazil GMP approvals (COVID vaccines and mAbs)**

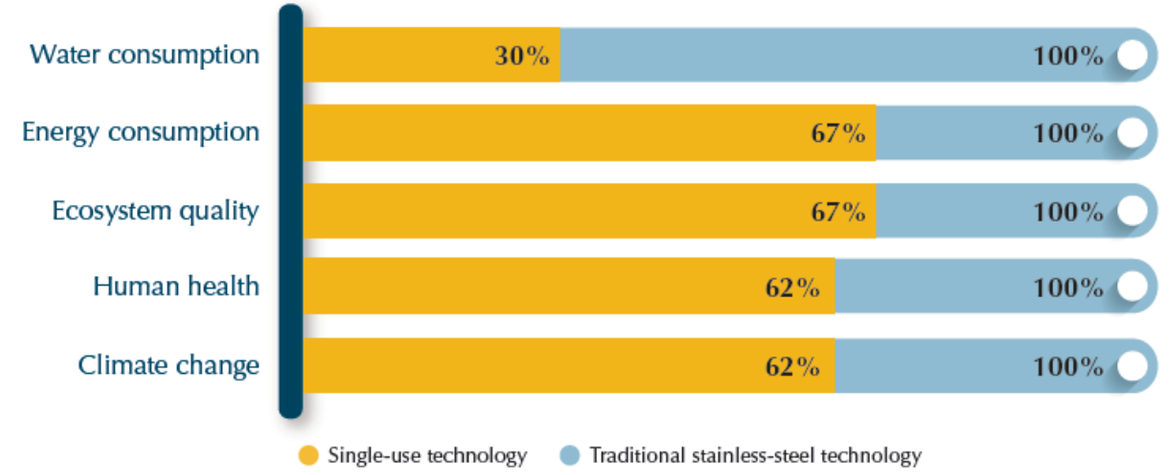
***As a global corporate citizen, WuXi Biologics is enabling and working with global partners to fight against the pandemic***

# Disposable Technology: Significant ESG Improvement

Various studies showed disposable or single-use generally has less impact on the **ENVIRONMENT** than traditional stainless-steel technology

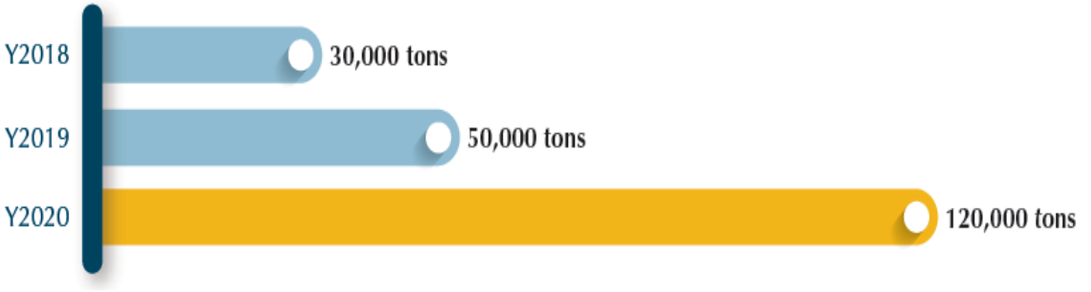
Especially in **WATER** consumption, SUT is **29%** of that of traditional stainless-steel technology (according to internal calculation)

Environmental impact of the two technologies*




*Source: Single-use technology and sustainability-quantifying the environmental impact. GE Healthcare (2017)

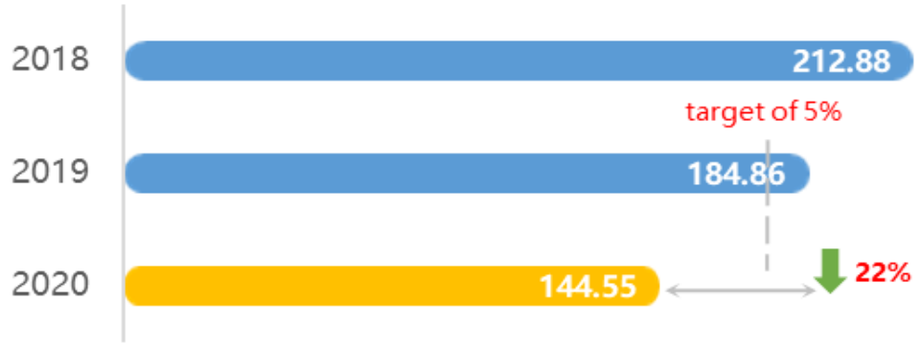
Annual water savings due to the adoption of SUT (estimated value)



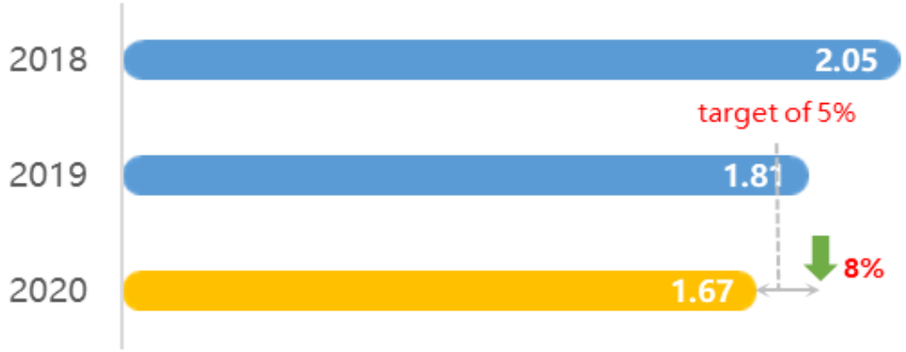
# Effectively Reduced Energy Consumption & Emission
# Set Annual and Mid to Long-Term Energy Consumption & Emission Reduction Target

**WuXi Biologics has made relentless efforts to reduce its impact on the surrounding environment and advocated for the low-carbon operation and sustainable development**

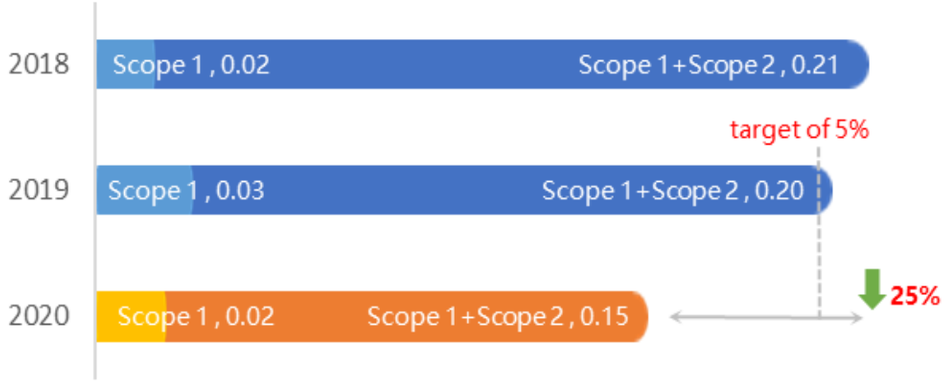
## Intensity of electricity consumption( kWh/RMB0'000)



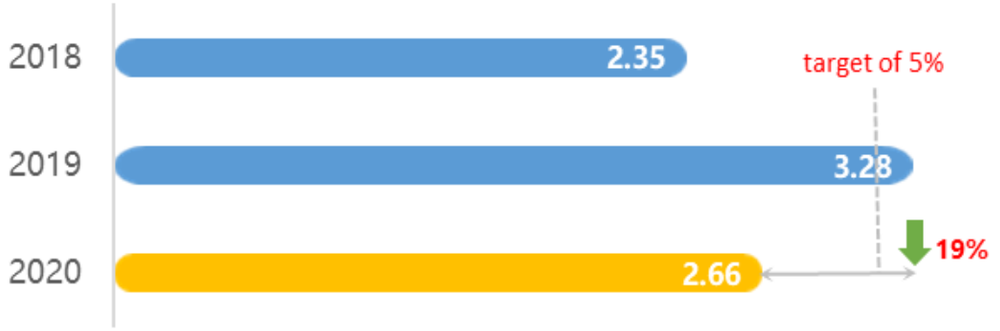

## Intensity of water consumption (tonnes/RMB0'000)




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




## Total Nitrogen Oxide emission (tonnes)



# Supported Henan Province Timely with RMB10 mm Donation


药我以心 明你之爱 | 药明生物捐赠1000万元驰援河南

愿洪水早日退去。药我以心，明你之爱，和你在一起度过难关！

- The torrential rains in Henan Province have brought significant impact and 1.5 mm people have been affected and relocated to safe places
- The Company Management and CSR Foundation responded to donate RMB 10mm for Henan disaster-relief efforts

## Donation Efforts

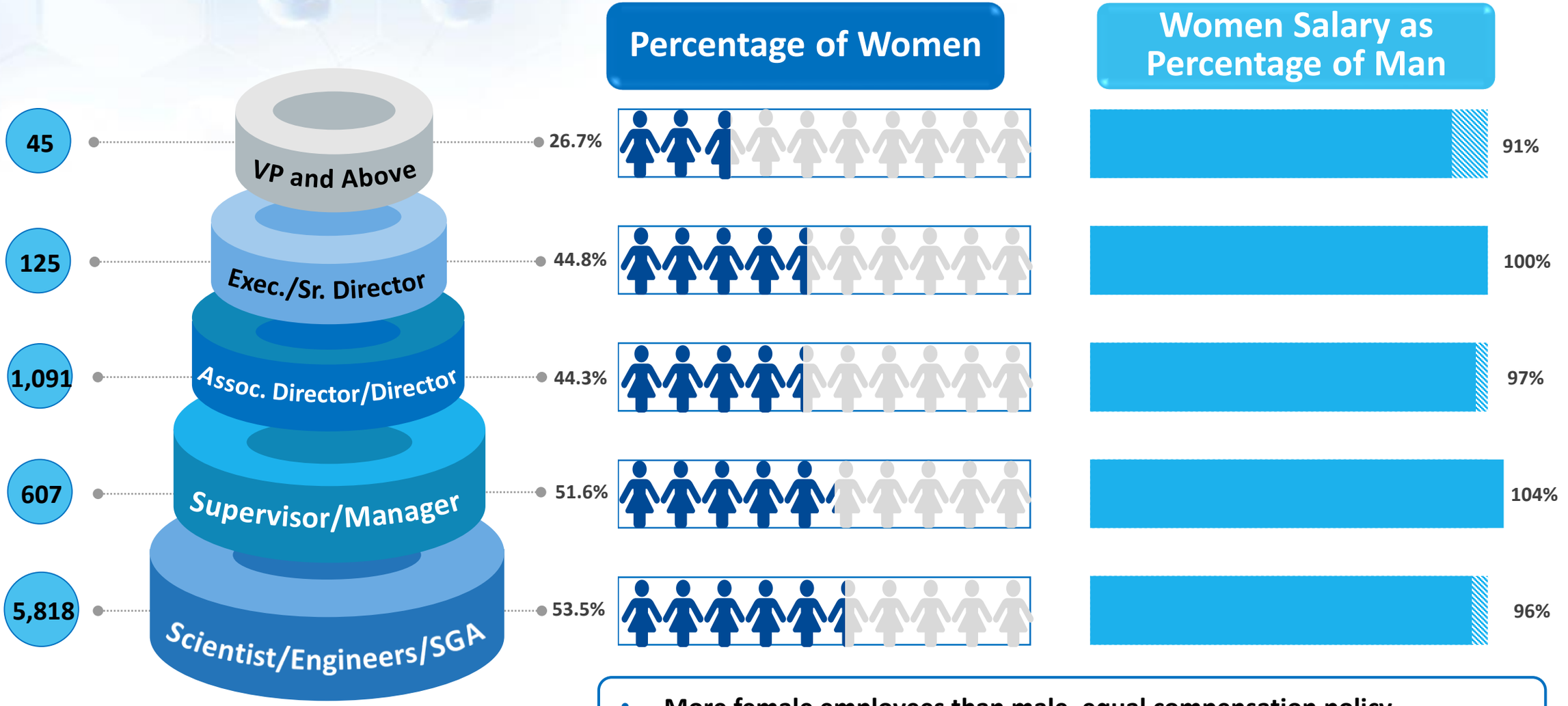
**Respond timely to support Henan:**

- 25 July: Completed purchasing first batch of supplies
- 26-29 July: Supplies shipment to disaster area

## Employee Donation

**Both domestic employees and overseas employees proactively participate in donation to aid the people in need**


# Focus on Diversity and Inclusion: Women Playing Critical Roles




- More female employees than male, equal compensation policy
- Female management members increased to 45%
- Added a female board member in June 2021

Note:
1. as of June 30, 2021

# 05 Summary

# Robust Momentum Continues in 2021
# FIVE Key Milestones Achieved in 1H 2021

WuXi Biologics
Global Solution Provider

**1**

- #3 CMO project: GSK/ Tesaro's PD-1 to treat endometrial cancer
- #4 CMO project: GSK/ Vir's Neutralizing Antibody for COVID
- Fully validate WuXi Bio business model and capabilities to enable customers from DNA to BLA

**2**

- 3 M&A deals close announced within 1 week (Pfizer/Bayer /CMAB)
- New capacities acquired including DS + DP were GPM ready in 1H 2021 to increase short-term capacities

**3**

- WuXi Bio and WuXi AppTec established WuXi XDC to become a dedicated global leading one-stop CDMO services for bioconjugates
- ADC projects increased to 48

**4**

- WuXi Vaccines on fast track: 9 projects signed as of June 30, 2021, including 3 COVID vaccines
- End-to-end mRNA technology enabling platform with 100 mm doses capacity in 2021 and more in 2022

**5**

- More new modality platforms (SDArBodY™ enabled multispecifics) to empower Biologics and Vaccines development

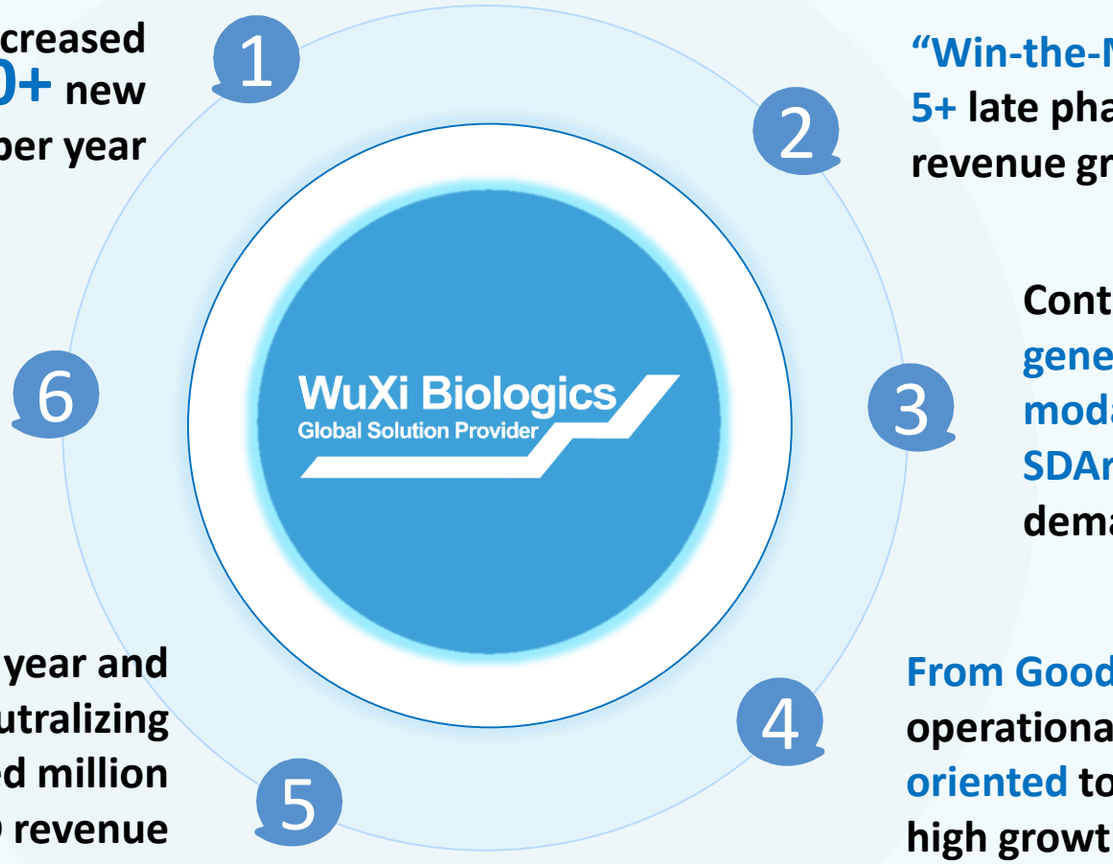
***Driving Sustainable High Growth***

# WuXi Bio's Pioneered Global Trends Consistent with Industry Report

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

# Higher Revenue and Profit in 1H 2021 and Beyond: SUSTAINABLE HIGH GROWTH

**In 2H 2021, WuXi Bio will continue its efforts on technology innovation, capacity expansion and operation excellence to achieve outstanding performance**




1. Expanded capacity to **120** INDs per year and increased the target to **100+** new integrated projects per year

2. **"Win-the-Molecule"** strategy: add **5+** late phase projects to boost revenue growth

3. Continue to invest in **next-generation technologies and new modalities (such as mRNA and SDArBodY™)** to meet unmet demands for patients

4. **From Good to Great:** operational excellence, **ESG-oriented** to deliver sustainable high growth

5. To launch **4** products this year and manufacture **~1,500kg** neutralizing mAbs and several hundred million doses of vaccines, COVID revenue contribution in 2022 likely significant

6. **6** in-house facilities on line **(peak revenue US$700 mm)**

   **7** purchased facilities on line **(peak revenue US$500 mm)**

# 2021 Key Milestones and Catalysts

## Q1

- MFG5 4K line operation
- MFG4 EMA remote inspection completed

## Q2

- DP7 operation
- MFG4 EMA approved
- GSK's PD-1 approved
- Vir's neutralizing mAb EUA
- CStone, Gloria PLI completed

## Q3

- Amicus BLA filing
- Pfizer/CMAB facilities contributing revenue
- MFG18 operation

## Q4

- 1-2 projects get BLAs approval in China
- MFG19 operation



06

# Appendix

# A. Financial Summary

# 1H 2021 Financial Summary

| (RMB million) | 1H 2021 | 1H 2020 | *Change* |
|---|---|---|---|
| **Revenue** | **4,406.8** | **1,944.1** | ***126.7%*** |
| **Cost of Sales and Services** | (2,109.9) | (1,156.8) | |
| **Gross Profit** | **2,296.8** | **787.3** | ***191.7%*** |
| **Other Income** | 127.3 | 148.4 | |
| **Impairment Losses under ECL model, Net of Reversal** | (133.2) | (56.6) | |
| **Other Gains and Losses** | 311.5 | 225.7 | |
| **Selling and Marketing Expenses** | (60.4) | (48.5) | |
| **Administrative Expenses** | (347.6) | (203.4) | |
| **Research and Development Expenses** | (115.4) | (124.4) | |
| **Share of Loss of an Associate** | - | (1.1) | |
| **Financial Costs** | (20.9) | (22.4) | |
| **Profit before Tax** | **2,058.2** | **705.1** | |
| **Income Tax (Expense) Credit** | (175.5) | 25.6 | |
| **Profit for the Period** | **1,882.8** | **730.7** | ***157.7%*** |
| **Earnings per Share – Basic (RMB)** | 0.44 | 0.19 | |
| **Earnings per Share – Diluted (RMB)** | 0.42 | 0.18 | |

**Notes:**
1. **Results may not foot due to rounding**
2. **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.**

# Reconciliation for Adjusted Net Profit Attributable to Owners of the Company and Adjusted EBITDA

| (RMB million) | 1H 2021 | 1H 2020 | *Change* |
|---|---|---|---|
| **Adjusted Net Profit Attributable to Owners of the Company Reconciliation** | | | |
| **Net Profit Attributable to Owners of the Company** | **1,842.1** | **736.1** | |
| **Add: Share-based Compensation** | 204.7 | 126.4 | |
| **Less: Foreign Exchange Gain** | (95.8) | (123.1) | |
| **Less: Fair Value Gain on Equity Investments at FVTPL** | (182.3) | (67.0) | |
| **Adjusted Net Profit Attributable to Owners of the Company** | **1,768.7** | **672.4** | ***163.0%*** |
| | | | |
| **Adjusted EBITDA Reconciliation** | | | |
| **EBITDA** | **2,387.1** | **941.4** | |
| **Add: Share-based Compensation** | 204.7 | 126.4 | |
| **Less: Foreign Exchange Gain** | (93.1) | (123.1) | |
| **Less: Fair Value Gain on Equity Investments at FVTPL** | (182.3) | (67.0) | |
| **Adjusted EBITDA** | **2,316.4** | **877.7** | ***163.9%*** |

Notes:
1. Results may not foot due to rounding
2. Adjusted EBITDA and adjusted net profit of 2019 have been restated to further exclude the fair value gains on the Group's investment portfolios

# B. WuXi Bio's Company Introduction

# "Follow & Win the Molecule" Integrated Solution Business Model

## Mission

***To accelerate and transform the discovery, development and manufacturing of biologics through a comprehensive open-access platform, enabling our global healthcare partners and benefiting patients worldwide***

## "Follow & Win the Molecule" Integrated Solution Model

***Our customers' demand for our services increases as their biologics advance through development and ultimately to commercialization, which allows our revenue from each project to grow geometrically as the project advances through the biologics development cycle***

## Revenue from Each Project Increases as the Program Progresses

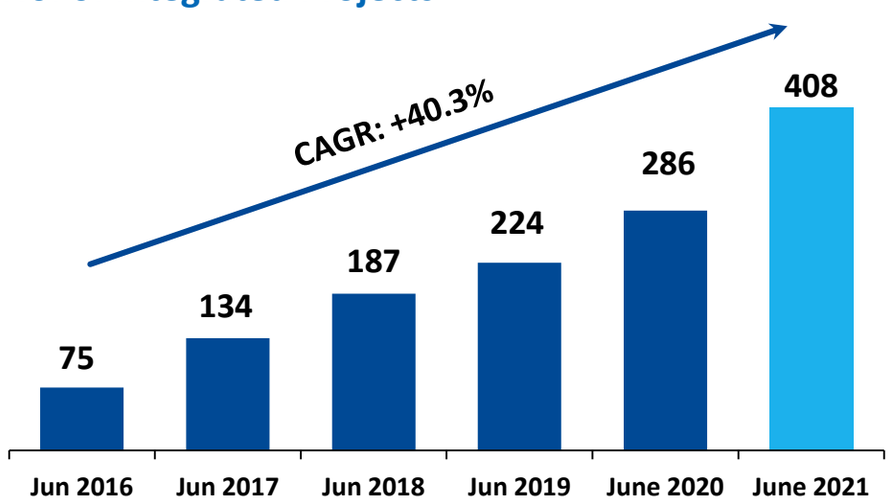
| Biologics Development Process | Typical Duration | Typical Revenue |
|---|---|---|
| **Prior to Clinical Trials** | | |
| Drug Discovery Services | 2 Years | US$1.5-2.5 mm<br>(Milestone fee ranges from US$ 10-100 mm<br>Royalty fee ranges from 3% to 5%) |
| IND-enabling CMC Development | 1-2 Years | US$5-8 mm |
| **Post Clinical Trials** | | |
| Early-Phase (Phases I & II)<br>Clinical Manufacturing | 3 Years | US$4-6 mm |
| Late-Phase (Phase III)<br>Clinical Manufacturing and PPQ | 3-5 Years | US$20-50 mm |
| Commercial Manufacturing | 20-30 Years | US$50-100 mm annually |

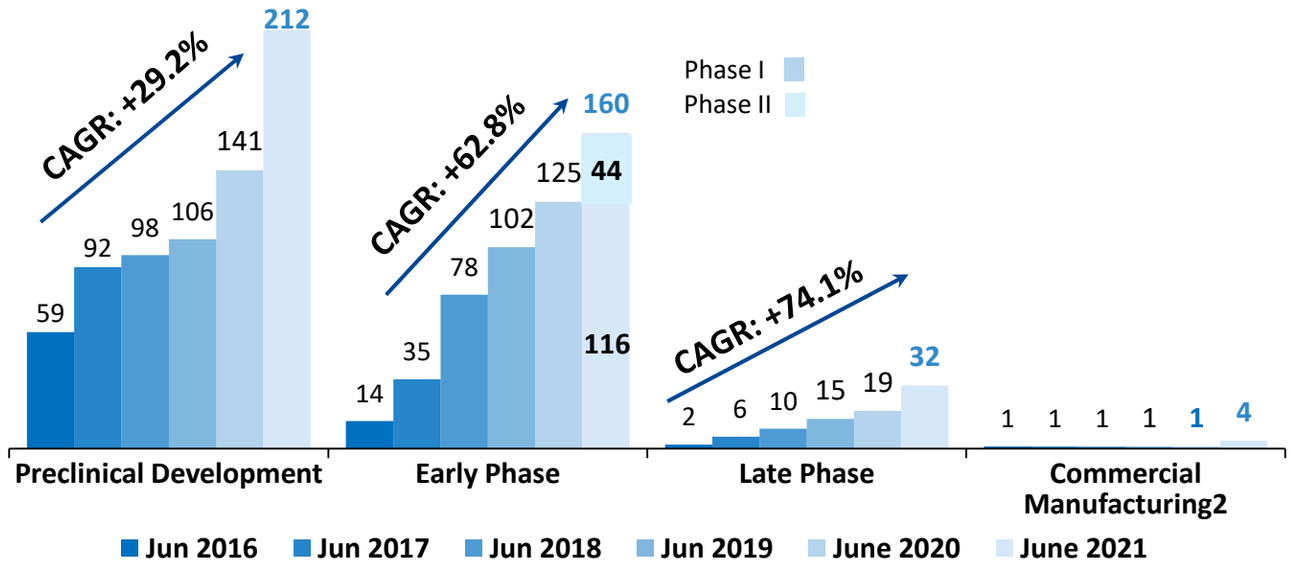
# Solid Business Progress – Integrated Projects

| | PRE-IND | | POST-IND | | |
|---|---|---|---|---|---|
| | Drug Discovery | IND-enabling CMC Development | Early Phase (Phase I & II) | Late Phase (Phase III) | Commercial Manufacturing |
| Typical Revenue For Stage: | US$1.5-2.5 mm<br>2 Years<br>*(Milestone fee: US$10-100 mm*<br>*Royalty fee: 3% to 5%)* | US$5-8 mm<br>1-2 Years | US$4-6 mm<br>3 Years | US$20-50 mm<br>3-5 Years | US$50-100 mm (2)<br>Annually |
| On-Going Integrated Project Numbers (1): | | 212 | 116 (I) 44 (II) | 32 | 4 |

Total: 408

## No. of Integrated Projects (1)




Notes:
1. Integrated projects are defined as projects requiring services for multiple stages during biologics development process
2. Estimated CMO revenue when a biologic drug reaches its peak sales. A biologic drug typically reaches peak sales after a ramp-up period

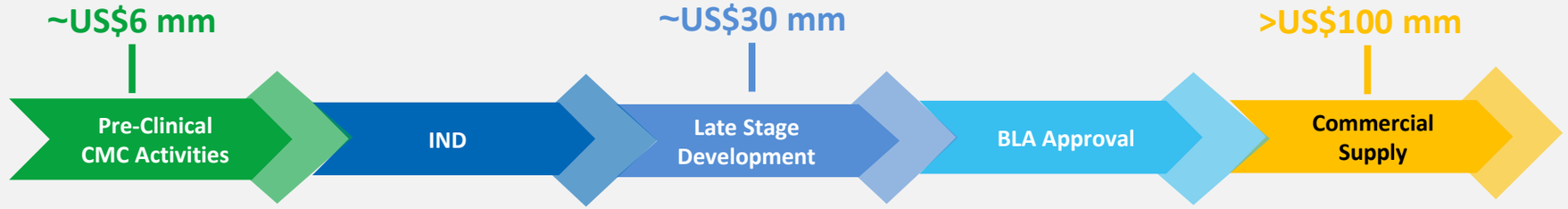
# Diversified Revenue Model: Service fee + Milestone + Royalties

WuXi Biologics
Global Solution Provider

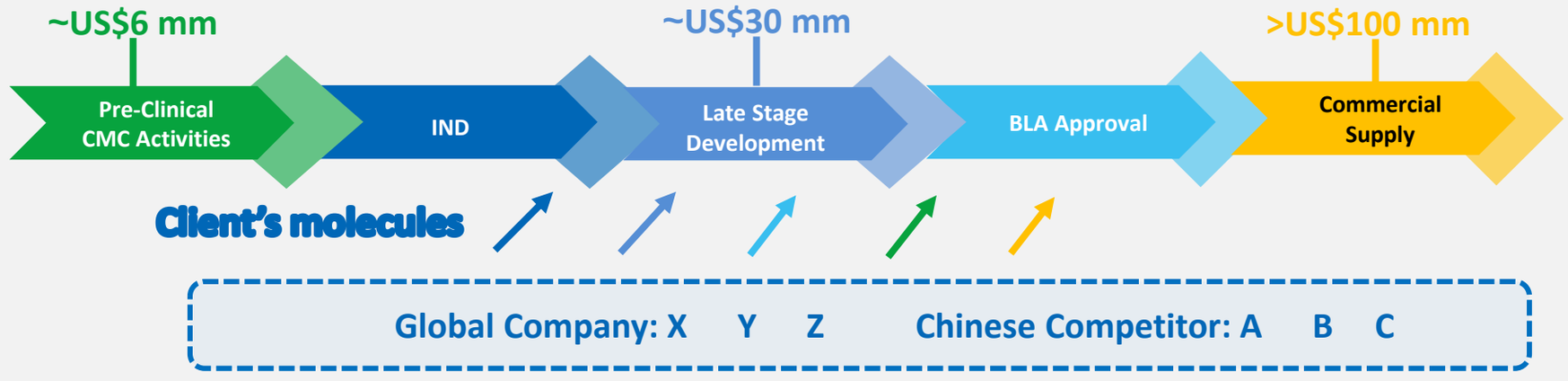
| | PRE-IND | | POST-IND | | | |
|---|---|---|---|---|---|---|
| | Drug Discovery | IND-enabling CMC Development | Early Phase (Phase I & II) | Late Phase (Phase III) | Commercial Manufacturing | |
| Typical Service Revenue | US$1.5-2.5 mm 2 Years | US$5-8 mm 1-2 Years | US$4-6 mm 3 Years | US$20-50 mm 3-5 Years | US$50-100 mm Annually | Contract to revenue conversion >95% |
| Typical Milestone Payment for global programs, if any | US$1-4 mm of preclinical milestone | US$2-6 mm of preclinical milestone | US$4-10 mm of clinical milestone | US$20-50 mm of clinical milestone | US$30-50 mm of Commercial Milestones | Typical ~US$100 mm per global program<br>High margin<br>Pay only if success |
| Typical Milestone Payment for Chinese programs, if any | US$1-2 mm of preclinical milestone | US$1-3 mm of preclinical milestone | US$2-4 mm of clinical milestone | US$4-10 mm of clinical milestone | US$6-10 mm of Commercial Milestones | Typical ~US$20 mm per Chinese program<br>High margin<br>Pay only if success |
| Typical Royalty Payment | | | | Royalty starts as typical 5% as high as 10% of annual product sales for 10-15 years | | Pay only if the product is launched |

# “Win-the-Molecule” Strategy Reinforces the Pipeline Growth

**The strategy of following the molecule from concept to commercialization: molecule lifecycle at WuXi Bio**




**“Win-the-Molecule” Strategy: client transfers molecules from other peers to WuXi Bio during development cycle as a direct result of WuXi Bio’s better technical capability, services and capacities**



# Global Partners Continue to Expand

**450+** global partners including **18** of the 20 largest pharmaceutical companies in the world and **36** of the 50 largest pharmaceutical companies in China

# Expanding Global Capacity to ~430,000L after 2024

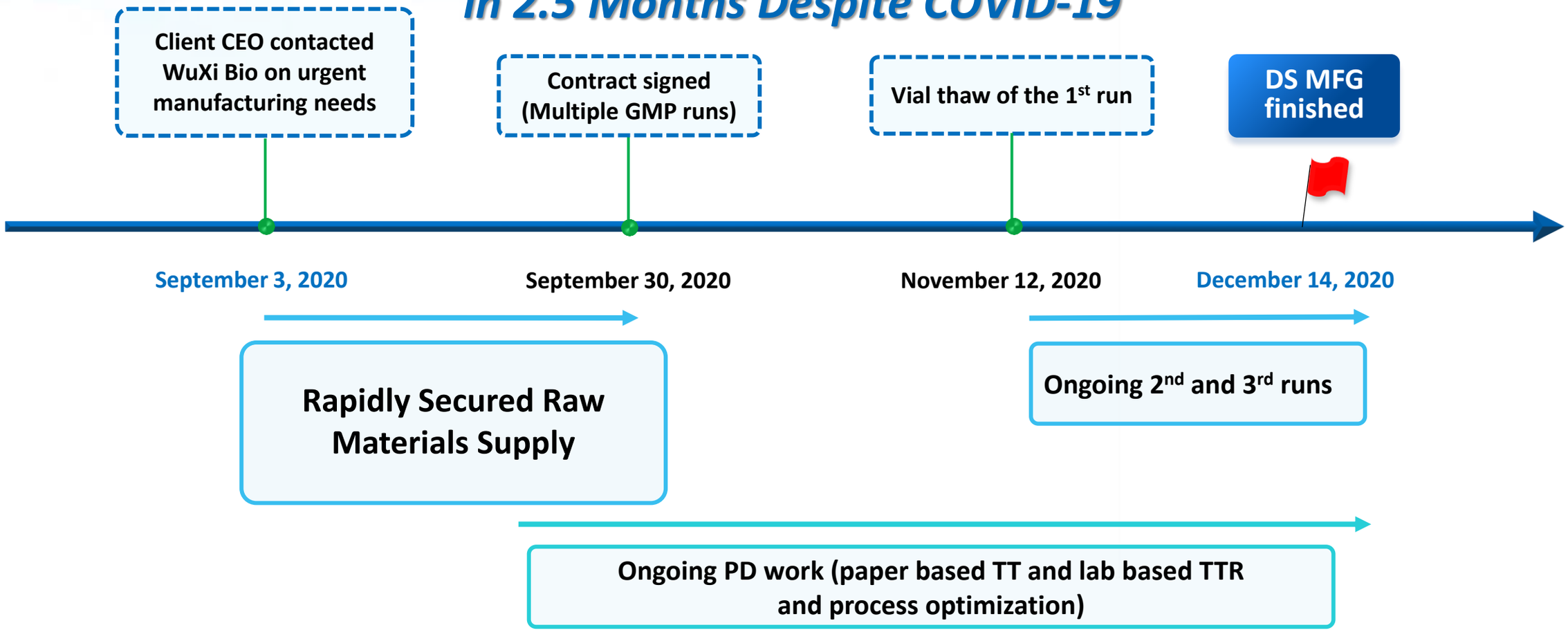
| Site # | DS Capacity | GMP Ready | Location | Comments |
|---|---|---|---|---|
| MFG1 | 7,500L fed-batch/perfusion | 2012 | Wuxi | Commercial |
| MFG2 | 28,000L fed-batch/2,000L perfusion | 2017 | Wuxi | Commercial |
| MFG3 | 5,200L fed-batch/1,500L perfusion | 2018 | Shanghai | Clinical |
| MFG4 | 10,000L fed-batch/CFB | 2019 | Wuxi | Commercial |
| MFG5 | 60,000L fed-batch | 2021 | Wuxi | Commercial |
| MFG6 | 6,000L (6 x 1,000L) perfusion | 2022 | Ireland | Commercial |
| MFG7 | 48,000L fed-batch | 2023 | Ireland | Commercial |
| MFG8 | 48,000L fed-batch | 2022 | Shijiazhuang | Commercial |
| MFG9 | 96,000L fed-batch | 2024 | Wuxi | Commercial |
| MFG10 | 4,000L fed-batch/500L perfusion | 2023 | Singapore | Clinical/Commercial |
| MFG11 | 16,000L fed-batch | 2024 | Worcester, MA | Clinical/Commercial |
| MFG12 | 48,000L (12 x 4,000L) fed-batch | 2023 | Chengdu | Clinical/Commercial |
| MFG13 | 2,000L (2 x 1,000L) viral manufacturing | 2021 | Hangzhou | Clinical/Commercial |
| MFG14 | 2,300L (300L/2,000L) microbial | 2021 | Hangzhou | Clinical/Commercial |
| MFG17 | 10,000L fed-batch | 2023 | Shanghai | Clinical |
| MFG18 | 6,000L fed-batch | 2021 | Cranbury, NJ | Clinical |
| MFG19 | 12,000L fed-batch/3,000L perfusion | 2021 | Wuppertal, Germany | Commercial |
| MFG20 | 8,000L (4 x 2,000L) fed-batch | 2021 | Hangzhou | Commercial |
| MFG21 | 7,000L fed-batch | 2021 | Suzhou | Clinical |

Note:
1. As of June 30, 2021

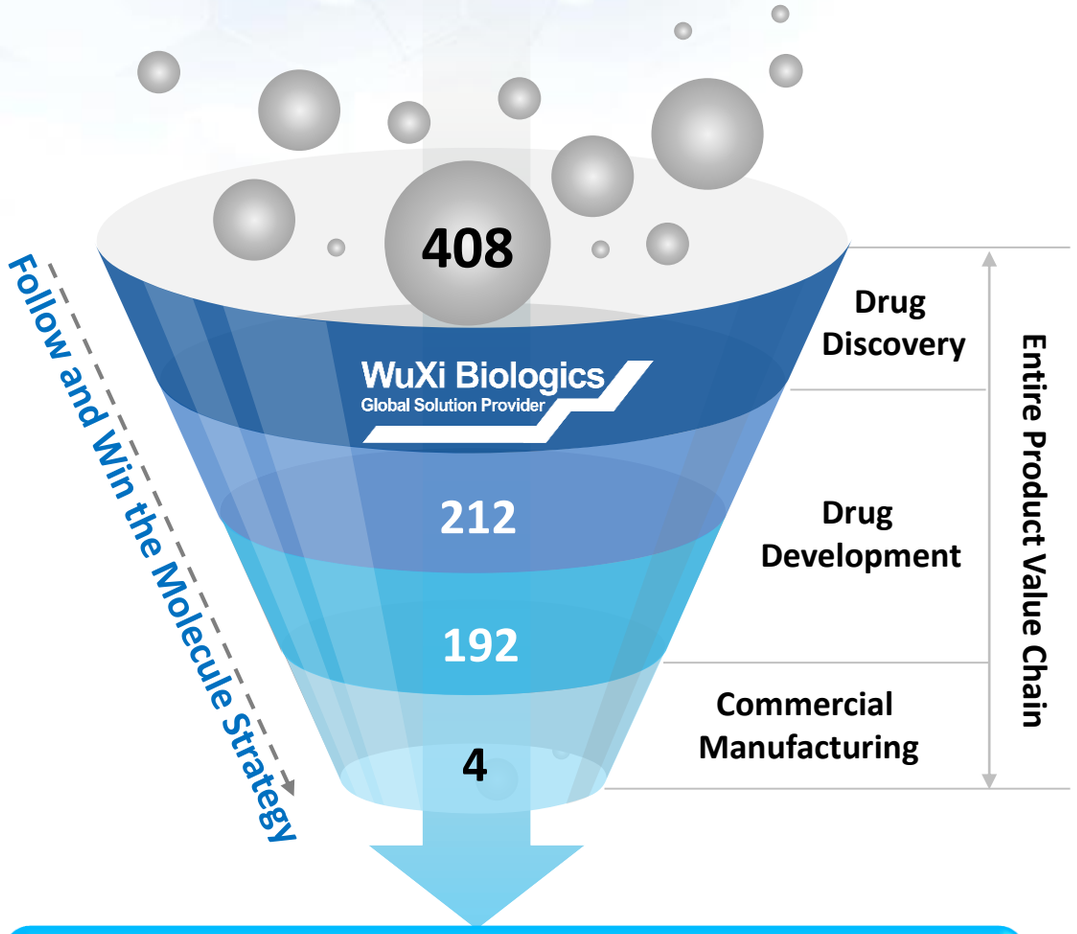
# SPEED: Mission Impossible Technology Transfer During COVID-19 Cut 6-12 Months to 2.5 Months

WuXi Biologics
Global Solution Provider

## *Tech Transfer/Manufacturing Resupply in 2.5 Months Despite COVID-19*



# Global Dual Sourcing within WuXi Bio: Robust Supply Chain




- World-class capabilities, expanding capacities, excellent track record and superb execution securing more projects globally than other players
- Biologics projects are sticky, securing early stage projects to ensure high likelihood of continuing to commercialization
- Our "on-demand global capacity planning" and "global dual sourcing within WuXi Bio" fulfill our global customers' rapid growing demand
- "Follow & Win the Molecule" strategy to increase late stage projects
- Multiple CMO programs starting from 2021

# High-Impact Innovation to Enable Customer Success

## WuXiBody® Bispecific Platform

- Universal
- 6-18 months of time-saving
- Minimal CMC issue
- More strategic partnerships with customers

WuXiBody® Bispecific Antibody Technology Platform

+

## WuXia™ Cell Line

- Robust cell line with proven track record
- Enabling 120 Integrated Projects Per Year
- 100+ ongoing clinical projects in U.S., EU and China

WuXia 无瑕™

+

## WuXiUP™ Continuous Manufacturing Platform

- 30-90g/L titer, 10+x
- Achieving ultra-high productivity
- Enabling 2,000L disposable bioreactors to comparable productivity as 20,000L traditional SS tank

WuXiUP 无上™

Discovery → Development → Manufacturing

Innovation of next growth cycle in biologics

# QUALITY: WuXi Bio's Cornerstone for Sustained Growth
## A World-Class Quality System

1. WuXi Bio: the first and only biologics company in China passed FDA , EMA and ANVISA inspections

2. Total 15 inspections conducted by FDA, EMA, NMPA and ANVISA since 2017.  9 inspections in first 7 months of 2021

3. Quality system in compliance with global regulatory requirements, enables the Company to outperform in global competition

# Multiple Engines to Sustainable High Growth

**2019**

WuXiBody® Bispecifics (Target 10-20 projects every year)

**2020**

"Win-the-Molecule" bringing in more CMO projects. Promote ADC integrated capabilities

**2021**

Considerable CMO revenue growth by "Win-the-Molecule" and COVID projects. Expect to 1st royalty revenue

**2022**

Global capacities promptly expanding. Full-spectrum services for mRNA-based vaccine to enable customers.

# SIX Pillars Underpins WuXi Biologics Sustainable High Growth

1. Excellent IP protection (vs China and India competitors)
2. FDA and EMA accepted quality system: only company in China, among Top 5 global CDMOs
3. State-of-art technology platform: comparable to large pharma
4. Superb execution won trust from global clients
5. World-class talent: 500+ senior scientists, 1,000+ young scientists per year
6. Strong financials: around US$2.2 bn cash

# Continuing to Gain Market Share for Sustainable High Growth

**Cutting Edge Technology**

- WuXiBody® bispecific (universal, 6-18 months of time-saving, minimal CMC issue)
- ADC (greatly enhanced DAR4, dedicated MFG sites, 15+ IND filings)
- WuXia™ cell line (robust cell line with proven track record)
- WuXiUP™ continuous manufacturing platform (30-90g/L titer, 10+x)

**Best Timeline**

IND Filing Timeline

- Industry average: 18-24 months
- WuXi Bio target: 15 reduced to 6-9 months now!
- WuXi Bio record: 7 months, <3 months for coronavirus related projects

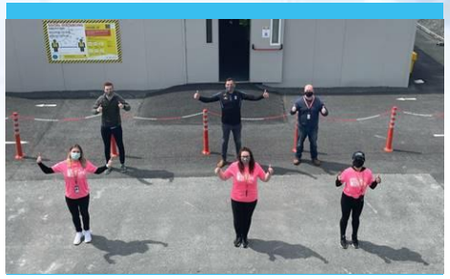
**Excellent Track Record**

- 100% projects delivered
- Outstanding customer satisfaction and high recognition
- Excellent execution on COVID-19 projects

**Unparalleled Capacity**

- Capacity for IND enabling projects increased from 60 per year to 120
- Late phase capacity increased from 5 BLAs to 7 per year
- One of the largest scientist team: 2,800+
- Largest capacity using single-use bioreactor: ~430,000L after 2024

# Sustainable Corporate Social Responsibility (CSR) Efforts
# Doing Good and Good Business




- Fundraising campaign to support Breast Cancer Ireland
- Enable Employee Volunteerism and giving back to community at our global sites
- Focused on public health, educational and charity programs to support those under-privileged
- Setting up dedicated *WuXi Bio CSR Foundation*

- Established company-wide and sites level volunteers' associations to support volunteer activities systemically and sustainably
- Joint efforts with site contractor and his baby son Sean Óg for employee donation for Crumlin Children's Hospital in Ireland

- Under extensive collaboration *with China Population Welfare Foundation*, donated RMB 500,000 to purchase first-aid kits to needed families in Jiangxi province
- Working with NGOs e.g. *The Illness Challenge Foundation, provides* education grants to over 30 students suffering from rare diseases

# C. Leading Industry Trends Favoring WuXi Biologics

# State-of-the-Art Technology Differentiates WuXi Bio

## 1 WuXiBody® Bispecific Platform

- Combine any two antibodies and assemble into bispecifics
- Easy to express, no aggregation or mispairing, can be developed 6-18 months faster and much lower COGS than competitor platforms
- Support 50+ projects per year which attracts downstream services

## 2 Transgenic Animal For mAbs Discovery

- Access to OMT's state-of-the-art transgenic animal technology to develop fully human antibodies with high quality, specificity, expression, solubility and stability
- Proven technology platform used by 20+ other global companies
- Support 50+ projects per year with potential downstream services

## 3 Antibody Drug Conjugate Discovery

- Integrate our in-house antibody discovery, toxin and linker to deliver the ideal lead ADC molecules
- Greatly simplify ADC drug development by providing a one-stop shop
- 48 ongoing projects with ADC discovery services with potential downstream service

## 4 WuXia™ Cell Line Platform

- Our own proprietary cell line paired with our own proprietary algorithm is more cost-effective, more efficient and yields better results
- License know-how generated during cell line engineering and development process to the customer in exchange for a license fee and future royalty payments
- Developed 530+ CHO-K1 cell lines total for therapeutic protein purpose

## 5 Disposable Manufacturing Technology

- No cleaning and sterilization required for disposable bioreactors that use pre-radiated plastic bags as the production vessel in a stainless holder
- A facility using disposable bioreactors can be built 12 to 18 months faster with 30% to 50% less investment, and can produce 5% to 15% more batches of products with a higher success rate compared to traditional stainless steel bioreactors

## 6 WuXiUP™ Continuous Manufacturing Platform

- The next generation biologic manufacturing solution to accelerate biologics development and manufacturing as well as to improve the affordability of biologics
- 30-90g/L titer, 10+x
- Enabling 2,000L disposable bioreactors to comparable productivity as traditional SS tank through WuXiUP™

# Leading Edge Technology of WuXiBody®

## DIFFERENTIATION

- **Universal:** almost any mAb sequence can be used to build bispecifics
- **Flexibility:** bi/tri/tetra valency based on biology

## SPEED

Minimal CMC challenges: no expression, aggregation or purification challenges – Save 6-18 months of development time

## QUALITY

- Expected low immunogenicity: natural sequence without complicated engineering
- Typical in vivo half-life, longer than typical bispecifics

WuXiBody® Bispecific Antibody Technology Platform

ablbio medicine for a better life

AC Immune

正大天晴 CHIATAI TIANQING

基石药业 CSTONE PHARMACEUTICALS

天境生物 I-MAB BIOPHARMA

OXFORD BioTherapeutics

Brii

aravive BIOLOGICS

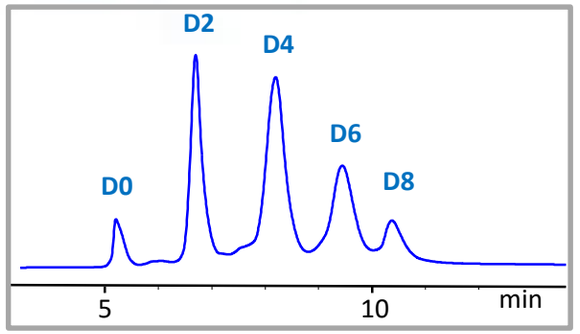
OncoC4

More…

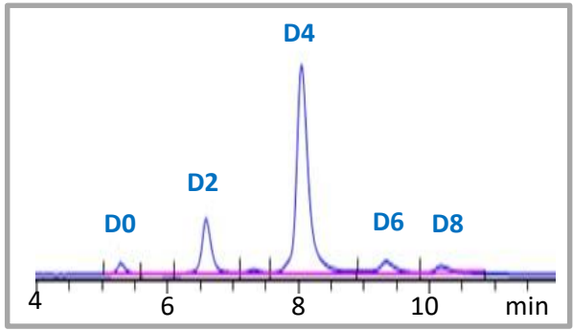
# WuXi Bio's Patented ADC Conjugation Technologies - Greatly Enhanced DAR4, Significantly Improved Therapeutic Windows

WuXi Biologics
Global Solution Provider

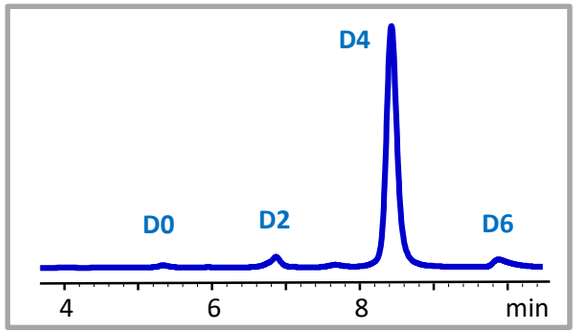
**ADC produced with conventional method, natural DAR distribution**



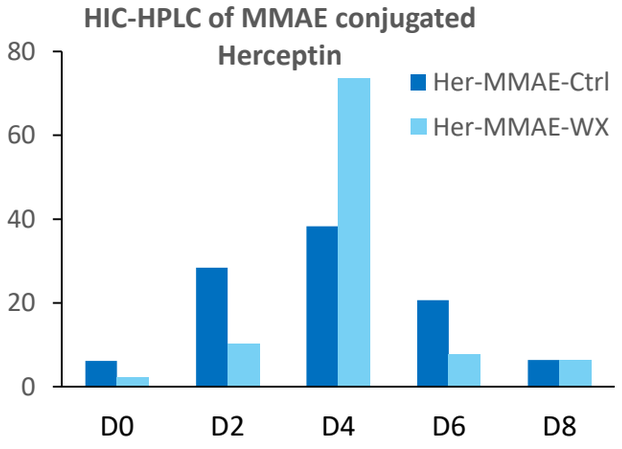

**ADC produced with WuXi Biologics' IP for native IgG1**



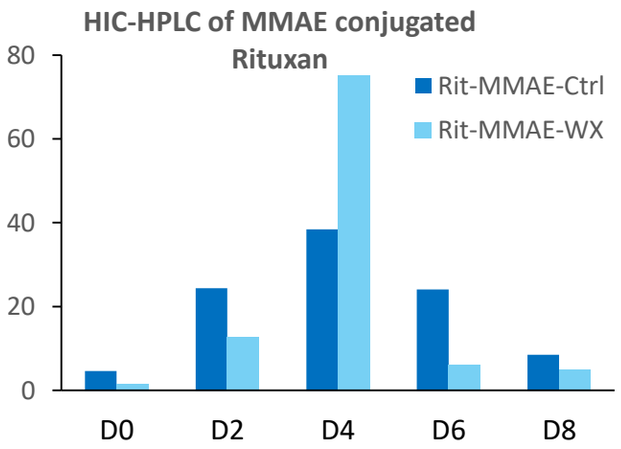

**ADC produced with WuXi Biologics' IP for engineered IgG1/4**




## mAb in clinic: Trastuzumab

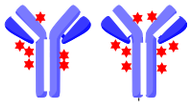



## Rituximab




**Drug-Antibody Ratio (DAR) Greatly Affects Efficacy And Safety of ADC**

Insufficient drug load leads to low efficacy (D0)

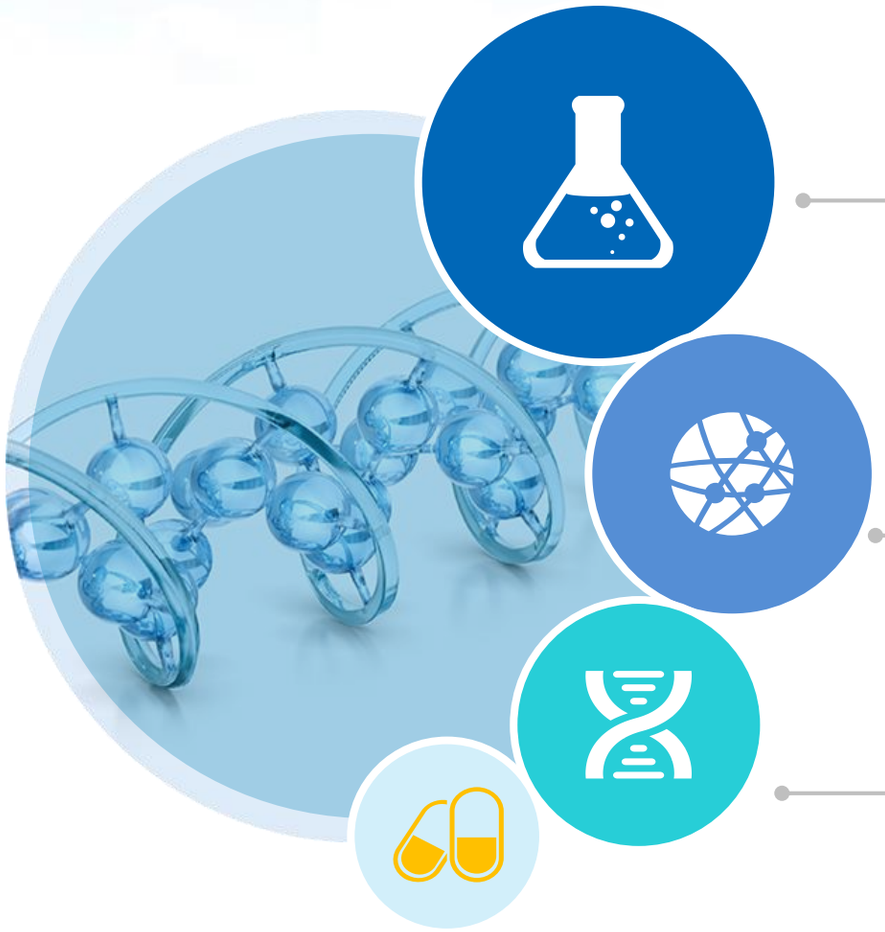


Too high drug load causes toxicity (D6, D8)

Appropriate drug load enhance safety and efficacy (D4)

*Clinical Cancer Research. 10, 7063–7070 (2004)*
*Bioconjugate Chem. 25, 656−664 (2014)*

# WuXiUP™ to Expedite Product Launch and Reduce Manufacturing Cost



## Comparable to Traditional bioreactors

Enable 2,000L disposable bioreactors to achieve comparable productivity as traditional 20,000L stainless bioreactors, significantly reduce the manufacturing cost

## High Purification Yield

Achieve ultra-high productivity while enabling similar purification yield of the traditional purification process

## Scale-up to GMP

The technology is being scaled up to GMP production and will be deployed throughout our global manufacturing network

# WuXi Bio's 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.**