**Premier Biologics Platforms to Enable Global Innovations** 

WuXi Biologics 2018 Interim Result

(Stock Ticker: 2269.HK)

**August 2018** 



## 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)**

We have provided adjusted net profit, net profit margin, EBITDA, EBITDA margin and diluted earnings per share for the first half of 2016 and 2017, which excludes the share-based compensation expenses, Listing expenses and a foreign exchange loss due to translation loss from the IPO proceeds, and are not required by, or presented in accordance with, IFRS. We believe that the adjusted financial measures used in this presentation are useful for understanding and assessing underlying business performance and operating trends, and we believe that management and investors may benefit from referring to these adjusted financial measures in assessing our financial performance by eliminating the impact of certain unusual and non-recurring items that we do not consider indicative of the performance of our business. However, the presentation of these non-IFRS financial measures is not intended to be considered in isolation or as a substitute for the financial information prepared and presented in accordance with IFRS. You should not view adjusted results on a stand-alone basis or as a substitute for results under IFRS, or as being comparable to results reported or forecasted by other companies.



### Agenda

- I. Result Highlights
- II. Technology Leadership and New Growth Areas
- **III.** Company Introduction
- **IV. Financial Overview**
- **Appendix Financial Summary**



## I. Result Highlights

### **Financial Highlights: Robust Revenue and Earning Growth**

- Robust revenue growth, increasing by 61.2% YoY, from RMB654.0 million to RMB1,054.4 million
- Gross profit rose 56.9% to RMB414.7 million. Gross profit margin was 39.3%, as compared to 40.4% of last year. Excluding foreign currency impact, it would have been approximately 41.4%
- Net profit was 270.7% of same period last year to RMB249.6 million, higher than 250.0% announced in Profit Alert. Adjusted net profit <sup>(1)</sup> increased by 94.2% to RMB296.7mm
- Net profit margin expanded 960 bps to 23.7%, adjusted net profit margin expanded 470 bps to 28.1%
- Diluted EPS was 211.1% of same period last year to RMB0.19 in 1H 2018 from RMB0.09 in 1H 2017, higher than 200.0% announced in Profit Alert. Adjusted diluted EPS increased 53.3% to RMB0.23 in 1H 2018 from RMB0.15 in 1H 2017



### **Other Key Financial Information**

- As of June 30, 2018, bank balances and cash, fixed deposits and financial assets amounted to RMB4,371.9 million in total
- No outstanding borrowings as of June 30, 2018
- 2018 CAPEX will be around RMB2,300 million, and RMB641 million has been incurred in 1H 2018
  - Rapid CAPEX increase for facility expansion globally to support our revenue growth
- R&D cost increased 54.4% YoY to invest significantly in new technology and new platforms which will result in further milestone and royalty payments and introduce more biologics projects into the "Follow-the-Molecule" model

RMB (million)	1H 2018	1H 2017	YOY Change
Revenue, reported	1,054.4	654.0	61.2%
(Increase)/Decrease due to FX			8.9%
Revenue Growth, Organic			70.1%



### **Business Highlights: Strong Operational Metrics**

- Phenomenal growth in total backlog including both service backlog and upcoming potential milestone fees. Our total backlog increased from US\$1,478.0 million as of Dec 31, 2017 to US\$1,782.0 million as of Jun 30, 2018
- Successful implementation of business development initiatives in the U.S., Europe and China
- Remarkable growth of our integrated projects from 134 in June 2017 to 187 in June 2018
- Substantial growth of our late-phase (Phase III) projects from six to ten as at June 30, 2018: late-phase projects involve more process development and large-scale manufacturing, resulting in a greater backlog

### **Operational Highlights**



- On March 6, 2018, the U.S. FDA granted approval for Ibalizumab (Trogarzo<sup>™</sup>), marking another major milestone for WuXi Biologics
  - First commercial manufacturing project showcasing success of "Follow-the-Molecule" strategy
  - First FDA-certified cGMP biologics DS and DP facilities in China
  - Fully validated our premier quality system as well as pioneering adaptation of singleuse disposable technology for commercial manufacturing
  - Commenced commercial production since April 2018

### Continuous improvement on project timeline generating a competitive edge

- Reduced IND enabling timeline to 15 to 18 months, and in certain circumstances as short as 9 months, creating a competitive advantage over our industry standards of approximately 18 to 24 months
- Received "CMO Leadership Award" from Life Science Leader Magazine and "Asia's CMO of 2017" at the BioPharma Industry Awards

### **Recent Achievements**



- 7,000L clinical manufacturing facility in Shanghai (MFG3): successful completion of the first cGMP run in July 2018
  - More than doubles existing clinical manufacturing capacity
  - One of the largest biologics clinical manufacturing facilities globally with 6 production lines which enable WuXi Biologics to complete 60 IND-enabling projects per year

### Commenced process validation in MFG2 July 2018

- Produced 7 batches at 6,000L/12,000L bioreactor scale for three projects, the largest scale cell culture operations in China at 100% success rate in MFG2, the largest biologics manufacturing facility globally leveraging single-use technology
- Process validation in MFG2 is a key milestone of the innovative "scale-out", instead of "scale-up" approach for large scale manufacturing
- After WuXi Biologics received U.S. FDA approval for commercial manufacturing, increasing number of external late-phase projects will be transferred
  - A development and manufacturing agreement for the production of Bertilimumab, Immune's first-in-class anti-eotaxin-1 monoclonal antibody

#### WuXi Biologics Global Solution Provider

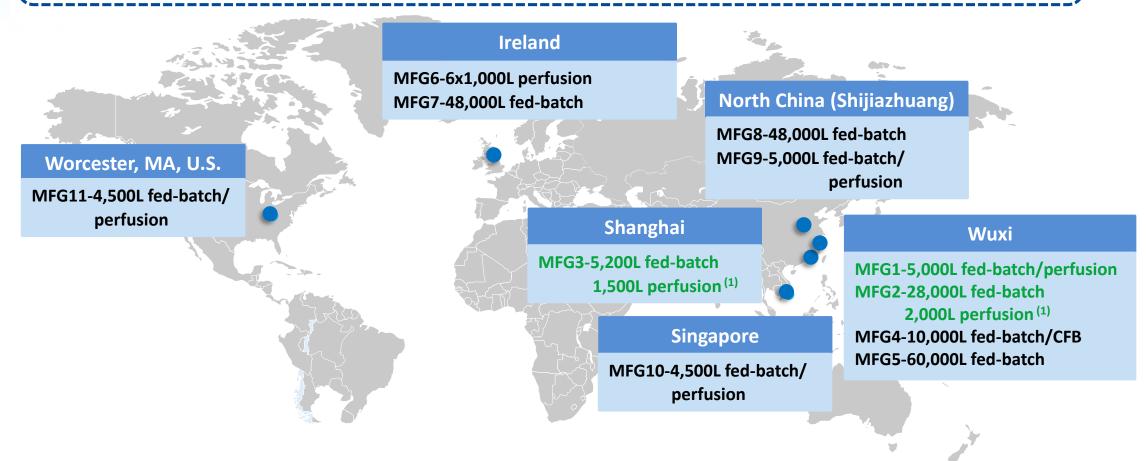
### **World-Class Talent Continues to be a Key Success Factor**

- Dr. Chiang Syin, former FDA Associate Country Director, joined as Chief Quality Officer in January 2018
  - 30+ years of experience in FDA regulatory review and GMP compliance of biological and biotech products
  - Formerly a Gates Project International Expert for the Center of Food & Drug Inspection (CFDI) of CFDA and an FDA Associate Country Director
- Dr. Gang Wang, former FDA inspector, joined as Vice President of Quality April 2018
  - Worked for FDA and CFDA for 13 years
  - A peer-review expert on cGMP and manufacturing of biologics.
- Rapid expansion of talent base to 3,059 employees as of June 30, 2018, vs 1,998 as of June 30, 2017
  - 287 employees possessing a Ph.D. or equivalent
- Expected to reach 4,000 employees by end of 2018 with one of the largest biologics development teams with 1,900 scientists expected by the end of 2018
- Employee attrition rate is high single digit, best in the industry in China

### **Premier Quality and Robust Global Network**



A GLOBAL company operating in many geographic regions to meet fast-growing global demands, leverage local talents, ensure global supply chain and mitigate geopolitical risks





# II. Technology Leadership and New Growth Areas

### **State-of-the-Art Technology Differentiates WuXi Biologics**

#### WuXiBody<sup>™</sup> 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

### **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 218 cell lines total for therapeutic protein purpose

#### 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

#### **5** Disposable Manufacturing Technology

- No cleaning and sterilization required for disposable bioreactors that use preradiated 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

#### Antibody Drug Conjugate Discoverv

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Integrate our in-house antibody discovery, toxin and linker to deliver the ideal lead ADC molecules

WuXi Biologics

- Greatly simplify ADC drug development by providing one-stop shop
- 17 ongoing projects with ADC discovery services with potential downstream service

### **6** Continuous Manufacturing Using Perfusion Technology

- Perfusion cell culture technology enables continuous manufacturing
- Reduces the costs of building a manufacturing facility, reduces manufacturing cost and improves product quality compared to traditional fed-batch manufacturing
- Titer reached 40+g/L equivalent which significantly reduced COGS for biomfg

### **Global Launch of WuXiBody™**



- Bispecific antibody leverages two antibodies to achieve 1+1>2 to treat diseases
- Assembly and manufacturing of bispecifics severely limited the potential of this category of therapeutics
- Proprietary WuXiBody Platform may expedite the field of bispecifics and tremendously reduce bispecific manufacturing cost

### **Key Differentiation of WuXiBody™**



- Universal: almost any mAb sequence can be used to build bispecifics
- Eliminate CMC changes: no expression, aggregation or purification challenges
  Save 6-18 months of development time
  - Normal expression like a typical IgG (2.5 16 g/L)
  - Easy purification using Protein A
  - Stability: Tm = 57-64 °C; stable at 37 °C serum > 2 weeks
  - Solubility > 30 mg/ml
- Expected low immunogenicity: natural sequence without complicated engineering
- Typical in vivo half-life compared to mAbs, longer than typical bispecifics
- Flexibility: bi/tri/tetra valency based on biology
  - Available both asymmetric and symmetric formats
  - Different valency (2, 3 or 4 binding sites) upon project needs







- WuXia means "perfect"
- 60 cell lines per year, one of the largest capacities
- IP filed for 2<sup>nd</sup> generation Wuxia platform
- 20+ ongoing clinical projects in U.S., EU and China have proved the platform and more than 60 additional projects to be developed
- Fast-tracked Zika mab project to combat potential outbreak in Singapore & reduced 18-month IND timeline to 9 months

### **Best Technology Platforms Enable Consistent High Growth**

### ■ WuXiBody<sup>TM</sup> platform

- Up to 50 projects can be completed per year
- Each project may generate US\$50-100 mm milestone revenue and 3-8% royalties
- May lead to 30 development projects as a new entry point for "Follow-the-Molecule" strategy
- WuXia cell line platform
  - Up to 60 cell lines can be developed per year which leads to up to 60 integrated CMC projects with approx. US\$360 mm revenue

### Disposable manufacturing platform

- Enable fast build-out to support efficient capacity expansion to realize "Follow-the-Molecule" strategy
- Allow us to leapfrog global competitors by building facilities cheaper and standardizing our facilities to minimize technology transfer and startup risks.
- Industry leading WuXiBody<sup>™</sup> and WuXia platforms enable us to continue to gain market share and add 40-50 integrated projects per year

WuXi Bioloaics

### **Entering Global Vaccine Business to Support Future Growths**



- Recent vaccine quality incident in China may present opportunities for vaccine CDMO in China
  - Initiated dialogs with Chinese regulators to pilot vaccine CDMO
- Emerging field of cancer vaccines and patient specific vaccines may present future growth opportunities
- Joint venture with Shanghai Hile Bio-pharmaceutical (SH:603718) to leverage expertise in vaccines



## **III. Company Introduction**





### **Our Mission**

To accelerate and transform pharmaceutical discovery, development and manufacturing in the fast growing field of biologics to benefit patients worldwide

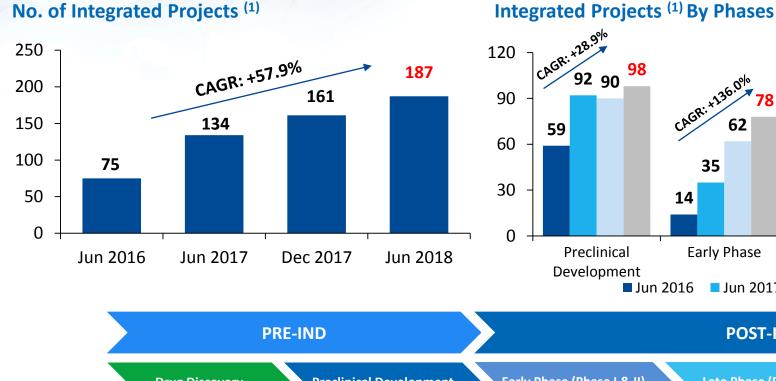


### **Our "Follow-the-Molecule" Integrated Solution Model**

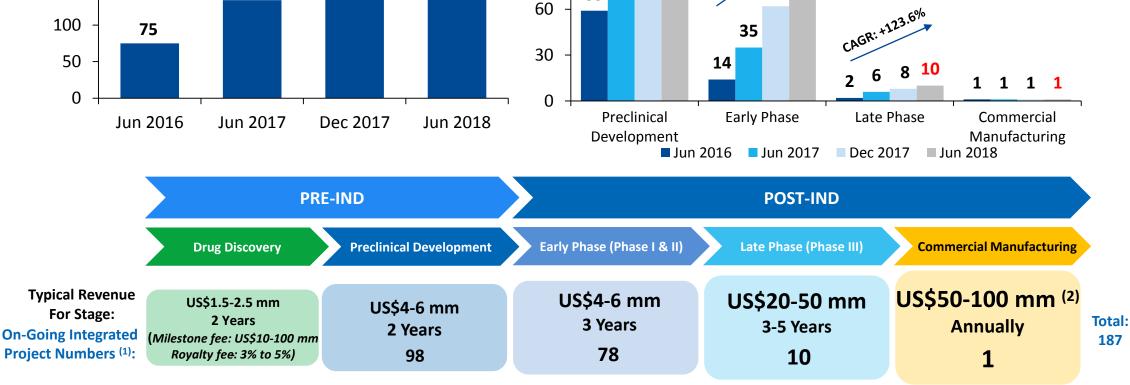
Our customers' demand for our services increases as their biologics advance through development and ultimately to commercialization, which allows our revenue from each project to grow geometrically as the project advances through the biologics development cycle

### **Solid Business Progress – Integrated Projects**





#### No. of Integrated Projects (1)



#### Notes:

1. Integrated projects are projects that require us to provide services across different stages of the biologics development process

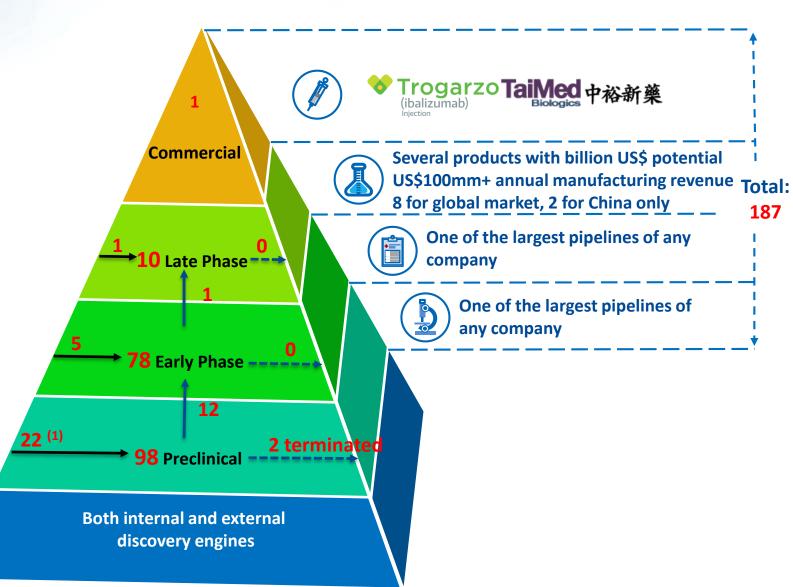
2. Estimated value when a biologic drug reaches peak sales. A biologic drug typically reaches peak sales after a ramp-up period

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### **First Half 2018 Pipeline Highlights**

- "Follow-the- Molecule" strategy in full motion
- Net added 26 molecules into the pipeline in 1H 2018
- 6 molecules transferred from competitors including
  1 late-phase
- Total 262.5% milestone revenue growth: From US\$4.8 million in June 2017 to US\$17.4 million in June 2018



#### Note:

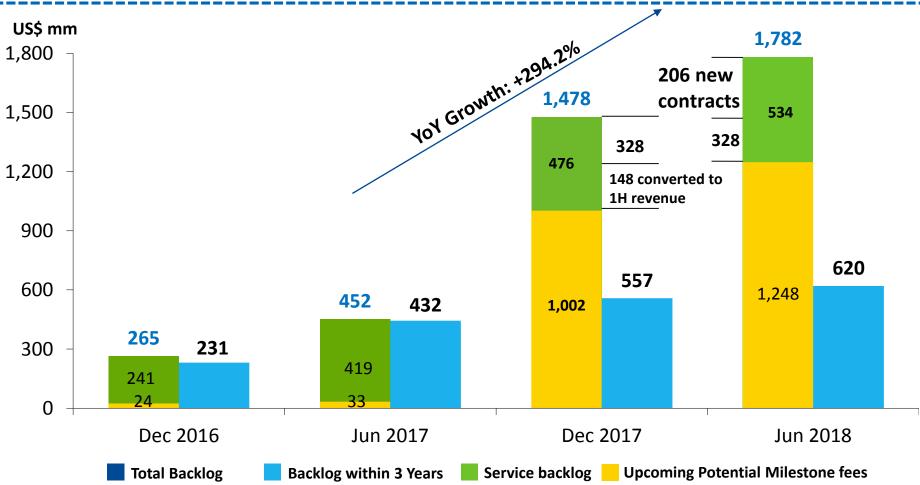
1. All of the project No. were compared to 2017 Q4

2. The arrows in black are the projects newly added from outside; the arrows in blue are the projects progressing from earlier stage thanks to our Follow-the-molecule strategy; the dashed arrows are terminated projects.



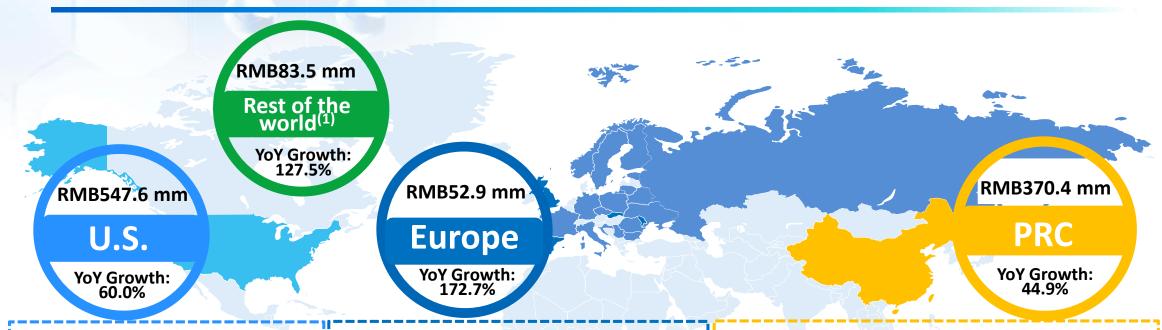
### **Solid Business Progress – Backlog**

- Strong backlog growth, total backlog grew from US\$1.478 billion as of Dec 31, 2017 to US\$1.782 billion as of Jun 30, 2018
- Current service backlog is sufficient to support substantial revenue growth near term. As we continue to gain market share and add early stage projects and more projects progress to late stage, we expect significant growth of service backlog as well
- Strong backlog continue to reinforce sustainable high growth





### **Rapid Business Progress Across Geographic Markets**



### U.S.

Notes:

- The largest single regional market
- Accounted for 51.9% of total revenue in 1H 2018
- Significant branding effect
- Seven new clients with potentially 15 projects
- Three pipeline deals broadened

### Europe

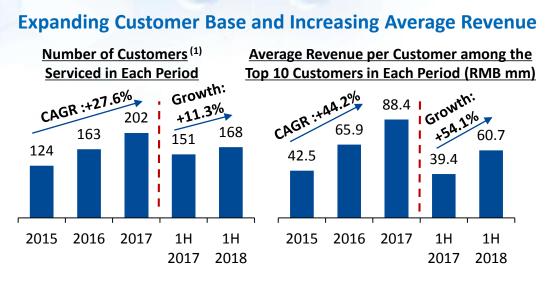
- Second largest biologics market globally
  - Accounted for 5.0% of total revenue with tremendous growth potential
- Two new clients and six projects signed in 1H 2018 with potential to move to the late stage
- Three pipeline deals established with one more in negotiation

### PRC

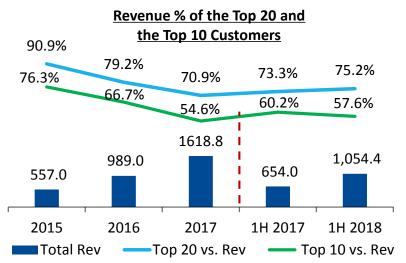
- Dominant leader with 63.5% market share
- Accounted for 35.1% of total revenue
- Clients increasingly focusing on global market
- Significant milestone and royalty fees expected
- Huge opportunities for MAH: 40+ potential projects commercial manufacturing not reflected in the backlog
- Most projects from China currently are in early stages, as they will move into later phases in the future, their revenue will grow strongly in PRC

#### WuXi Biologics Global Solution Provider

### **Proven Track Record with Growing Customer Base**



#### **Diverse and Strong Customer Base**





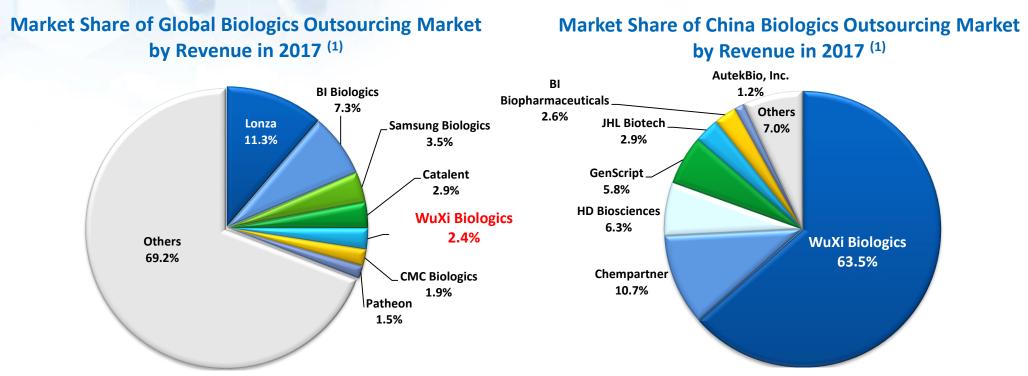
#### 1. Number of customers refer to those who incurred revenue during the reporting period.

Note:



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### **Top 5 Player Globally and Dominant Share in China**



#### WuXi Biologics is the Only Player Providing the Full Spectrum of Biologics Outsourcing Services<sup>(2)</sup>

	Novel mAb Discovery	Discovery Biology/Drug Screening	Cell Line Engineering/ Construction	Bio-analytical Testing	Research Manufacturing	Assay/ Formulation/ Process Development	Cell Banking/ Cell Line Characterization	Viral Clearance Validation	cGMP Manufacturing	Lot Release/ Stability Testing
	<b>444</b>	<b>V V V</b>	<b>~~~~~</b>	<b>444</b>	<b>~~~~~</b>	<b>~ ~ ~</b>	<b>444</b>	<b>~ ~ ~</b>	<b>√</b> √	<b>√</b> √
Lonza			✓	✓	<b>√</b> √	44	<b>√</b> √	<b>4 4</b>	<b>4 4 4</b>	<b>4 4 4</b>
Boehringer Ingelheim			✓	✓	<b>4 4</b>		√√	✓	<b>~ ~ ~</b>	<b>~ ~ ~</b>
Patheon			✓	<b>√</b> √	✓	✓	✓	✓	✓	✓
Catalent			✓	✓	✓	✓	✓	<b>4 4</b>	✓	✓
СМС				✓	✓	✓	✓		44	44
Samsung Biologics				✓	1	✓	√		<b>1</b> 1	<b>√</b> √
Source: Contract Pharma							Discove	ry Preclinica	l/Development	Clinical/Commercial

1. Source: Contract Pharma

2. Source: Frost & Sullivan

### **Global Leading Technology Platforms with WuXi IP**



**Biologics Discovery Platform (IP)** 

**CHO Stable Cell Line Platform (IP)** 

**High Density Cell Culture Platform (IP)** 

**Protein Analytics Platform (IP)** 

**Protein Purification/Formulation Platform (IP)** 

**Disposable Manufacturing Platform (Know-how)** 

WuXi Biologics

Global Leading State-of-the-art Biologics Platform with superb capabilities and unlimited capacities

### >220,000L MFG Capacity in Global Regions to Ensure Robust Supply Chain



	DS Capacity	GMP Ready	Location	Comments
MFG1	5,000L fed-batch/perfusion	2012	Wuxi	Commercial
MFG2	28,000 L fed-batch 2,000 L perfusion	2017	Wuxi	Commercial
MFG3	5,200 L fed-batch 1,500 L perfusion	2018	Shanghai	Clinical
MFG4	10,000 L fed-batch/CFB	2019	Wuxi	Clinical/Commercial
MFG5	60,000 L fed-batch	2020	Wuxi	Commercial
MFG6	6 x 1,000 L perfusion	2021	Ireland	Commercial
MFG7	48,000 L fed-batch	2021	Ireland	Commercial
MFG8	48,000 L fed-batch	2021	Shijiazhuang	Commercial
MFG9	5,000 L fed-batch/perfusion	2022	Shijiazhuang	Clinical/Commercial
MFG10	4,500 L fed-batch/perfusion	2021	Singapore	Clinical/Commercial
MFG11	4,500 L fed-batch/perfusion	2022	Worcester, U.S.	Clinical/Commercial



## **IV. Financial Overview**



43.3%

39.3%

414.7

1H2018

28.1%

23.7%

296.7

52.1

249.6

1H2018

Listing Expense

43.2%

40.4%

264.3

1H2017

23.4%

14.1 %

152.8

16.1

30.

92.2

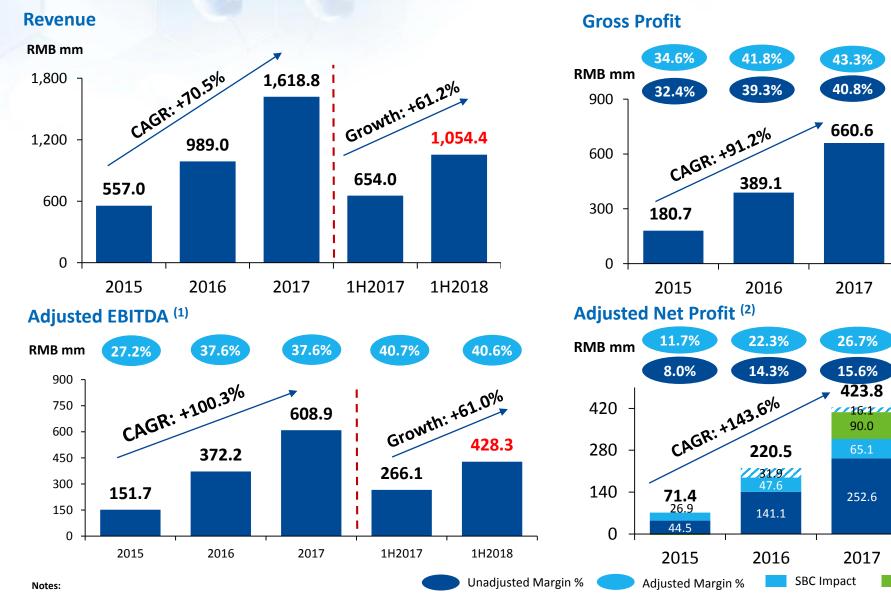
1H2017

FX Impact <sup>(3)</sup>

Growth: +94.2%

Growth: +56.9%

### **Phenomenal Financial Performance**

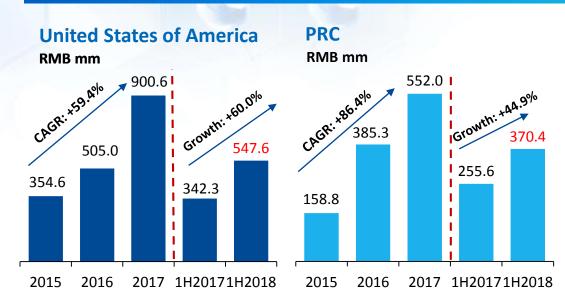


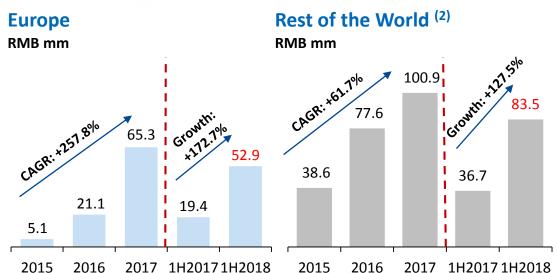
1. Adjusted EBITDA represents net profit before (i) interest expenses, income tax expenses, listing expenses and (ii) certain non-cash expenses, consisting of share-based compensation, amortization and depreciation and (iii) foreign exchange (gains)/losses

2. Adjusted net profit excludes the share-based compensation expenses, Listing expenses and foreign exchange (gains)/losses

3. Refers to foreign exchange (gains)/losses

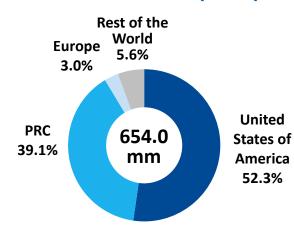
### **Robust Growth Across All Geographic Markets**<sup>(1)</sup>



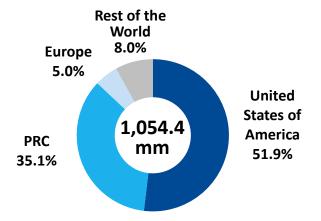


WuXi Biologics

1H2017 Revenue (RMB)



#### 1H2018 Revenue (RMB)



#### Notes:

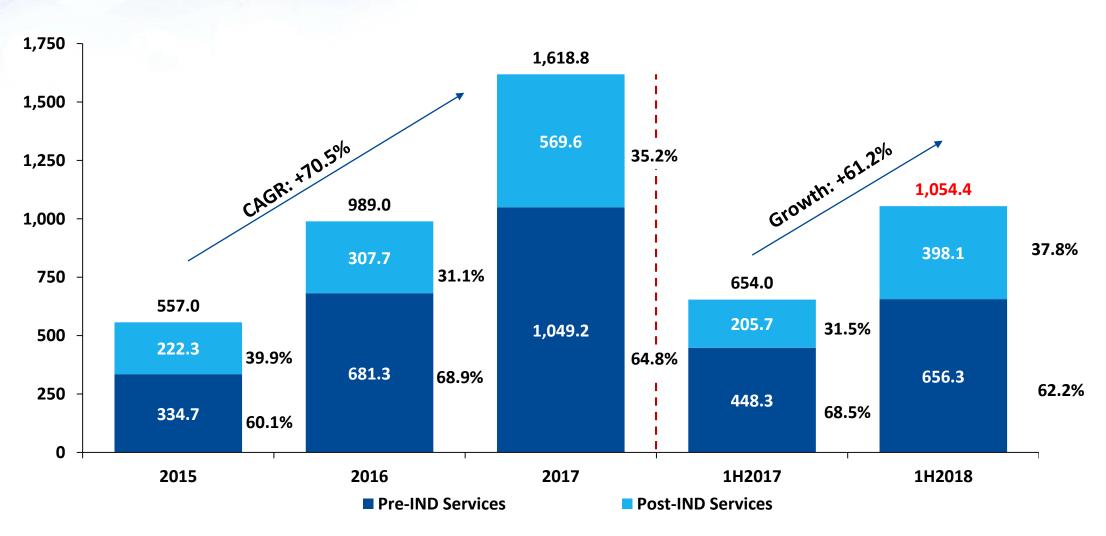
1. Geographic breakdown by client headquarters

2. Rest of the world primarily includes Canada, Israel, Japan, India, South Korea

### **Revenue Breakdown by Development Stages**

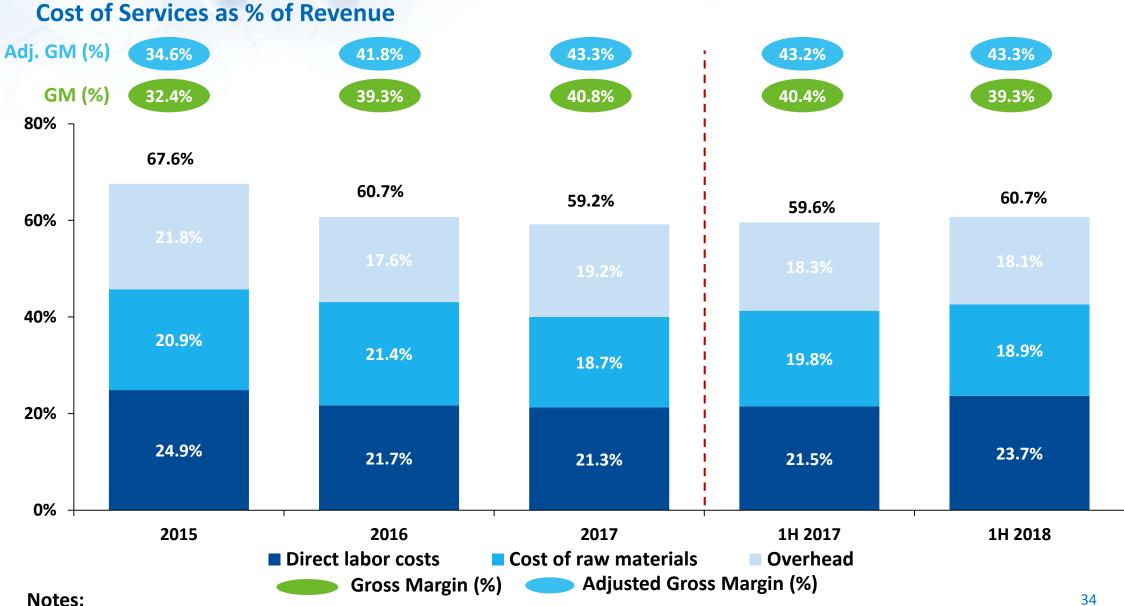


RMB mm





### **Gross Margin Snapshot**



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

### Six Unbreachable "MOATS" of WuXi Biologics



**Excellent IP protection (vs China and India competitors)** 

2

5

6

FDA accepted quality system: only company in China, top 10 among global CDMOs

World-class talent: 300+ senior scientists, 1,000+ entry-level scientists per year

Superb execution won trust from global clients

Strong financials: around US\$661 mm in the bank, no debt

State-of-art technology platform: comparable to large pharma



# Appendix – Financial Summary



### First Half 2018 Financial Summary

(RMB million)	1H 2018	1H 2017	Change
Revenue	1,054.4	654.0	61.2%
Cost of Services	(639.7)	(389.8)	
Gross Profit	414.7	264.3	56.9%
Other Income	40.8	16.1	
Including Interest Income	26.3	0.7	
Other Gains and Losses	12.3	(11.9)	
Impairment losses, net of reversal	(19.6)	(4.0)	
Selling and Marketing Expenses	(19.9)	(13.3)	
Administrative Expenses	(87.1)	(51.1)	
Research and Development Expenses	(56.2)	(36.4)	
Other Expenses	-	(16.1)	
Financial Cost	-	(31.3)	
Profit before Tax	285.1	116.2	145.4%
Income Tax Expenses	(35.5)	(24.0)	
Total comprehensive income for the period attributed to the owners of the Company	249.5	92.2	170.7%
Earnings per share – Basic (RMB)	0.21	0.09	133.3%
Earnings per share – Diluted (RMB)	0.19	0.09	111.1%

### **Reconciliation for Adjusted Net Profit and Adjusted EBITDA**



(RMB million)	1H 2018	1H 2017	Change
Adjusted net profit Reconciliation			
Net Profit	249.6	92.2	170.7%
Share-based Compensation	52.1	30.7	69.7%
Listing Expenses	-	16.1	(-100)%
Foreign Exchange Loss/(Gain)	(5.0)	13.8	(-136.2)%
Adjusted Net Profit	296.7	152.8	94.2%

Adjusted EBITDA Reconciliation			
EBITDA	381.1	205.5	85.5%
Share-based Compensation	52.1	30.7	69.7%
Listing Expenses	-	16.1	(-100)%
Foreign Exchange Loss/(Gain)	(5.0)	13.8	(-136.2)%
Adjusted EBITDA	428.3	266.1	61.0%

## THANK YOU!

Contact: Wang\_yue0502@wuxiapptec.com Website: http://www.wuxibiologics.com



## WuXi Biologics

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