

Hong Kong

ADD (initiation)

Consensus ratings*: Buy 37 Hold 2 Sell 0

Current price:	HK\$46.25
Target price:	HK\$111.6
Previous target:	HK\$
Up/downside:	141.2%
CGI / Consensus:	6.4%
Reuters:	2269.HK
Bloomberg:	2269 HK
Market cap:	US\$25,152m
	HK\$197,441m
Average daily turnover:	US\$158.6m
	HK\$1,245m
Current shares o/s:	0.24m
Free float:	66.3%

*Source: Bloomberg

Key changes in this note

n.a.



Source: Bloomberg

Price performance	1M	3M	12M
Absolute (%)	-30.7	-40	-58.8
Relative (%)	-17.6	-19.7	-25.3

Major shareholders	% held
Ge LI	15.3
Ning Zhao	15.3

Analyst

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Wuxi Biologics

Expect fast revenues and EPS growth ahead

- WuXi is the second-largest global biologics outsourcing service provider with 10% market share in 2021 and expect it to gain market share further on capacity expansion.
- WuXi's robust service backlog and significant increase of commercial stage projects should secure its revenue growth outlook, in our view.
- We estimate WuXi to register strong revenue and EPS CAGR of 41% and 36% respectively, over FY21-24F.
- We initiate coverage on WuXi Biologics with an Add rating and DCF-based TP of HK\$111.6. It trades at undemanding valuation of 40x FY22F P/E.

Gaining market share from a fast growth industry

Frost & Sullivan forecasts a 21% and 30% CAGR over FY21-26F for the global and China biologics outsourcing market, respectively, driven by strong demand of the biologic drugs market. WuXi Biologics ("Wuxi") is the second-largest global biologics outsourcing service provider with a revenue-based market share of 10% globally in 2021 and we expect it to gain market further because of, a) its full spectrum of services, b) its global capacity expansion, and c) high entry barrier of the sector due to the complex nature of the biologics drugs.

Proven track record since FY16

WuXi provides a full spectrum of services and technologies for biologics discovery, development and manufacturing that many of its competitors are unable to provide. Given its competitive advantages, it recorded a fast CAGR of 164% for its revenues over FY16-21. Meanwhile, it also has diversified client base, which North America/China/Europe accounted for 54%/25%/18% of its revenue in 1H22, respectively.

Strong research capability and fast capacity expansion

Supported by its state-of-art technological platforms for bispecific antibody development, ADC development, and continuous bioprocessing, WuXi is able to provide high quality customizable service to its global clients with competitive costs thanks to rich talent pool and lower labor cost in China. WuXi is also expanding its manufacturing capacity aggressively worldwide to meet the increasing demands of biologic outsourcing service.

To see revenue/EPS CAGR of 41/36% over FY22-24F, respectively

Wuxi adopts two business strategies namely 1) follow the molecule (FtM), which high loyalty of its clients as the company has built relationship with them from the early stage of drug development, 2) win the molecule (WtM), which normally suggest that projects are transferred to WuXi from other service providers during the interim period of drug development. As increasing number of projects in commercial stage in the next few years, we expect Wuxi's revenues to experience fast growth. Specifically, we estimate its revenue CAGR of 41% over FY21-24F. Supported by relatively stable gross profit margin, we forecast its EPS CAGR of 36% during the same period.

Initiate with an Add rating and TP of HK\$111.5

We initiate coverage on WuXi Biologics with an ADD rating and DCF-based TP of HK\$111.6 (WACC: 9.3%, terminal growth rate: 4.0%) – suggesting 141% potential upside. It trades at attractive valuation of 40x FY22F P/E, well below its five-year average P/E of 151x. We believe its market leading position and strong profit growth outlook should deserve a higher valuation. Key catalysts include stronger than expected results due to strong US\$/Rmb and Wuxi has proposed a share back scheme (repurchase 10% of the total shares) while key risks are potential geopolitical conflicts among Chinese Government and western countries.

Financial Summary

	Dec-20A	Dec-21A	Dec-22F	Dec-23F	Dec-24F
Revenue (Rmbm)	5,612	10,290	15,179	21,223	28,865
Operating EBITDA (Rmbm)	2,032	3,885	6,076	8,358	11,180
Net Profit (Rmbm)	1,686	3,416	4,514	6,307	8,588
Normalised EPS (Rmb)	0.40	0.77	1.02	1.43	1.94
Normalised EPS Growth	(47.4%)	92.9%	32.1%	39.7%	36.2%
FD Normalised P/E (x)	64.98	50.20	39.02	27.93	20.51
DPS (Rmb)	-	-	-	-	-
Dividend Yield	0%	0%	0%	0%	0%
EV/EBITDA (x)	85.06	46.61	29.78	21.48	15.68
P/FCFE (x)	NA	NA	444.8	100.2	37.2
Net Gearing	(24.4%)	(18.2%)	(16.8%)	(17.9%)	(23.5%)
P/BV (x)	8.11	5.46	4.81	4.12	3.45
ROE	10.1%	12.9%	13.1%	15.9%	18.3%
% Change In Normalised EPS Estimates					
Normalised EPS/consensus EPS (x)			0.91	0.93	0.95

SOURCES: CGIS RESEARCH, COMPANY DATA, BLOOMBERG

Investment highlights

Strong profitability visible in the short-term

The foundation of WuXi Biologics' (the company's) profitability is the integrated project number. The total number of integrated projects increased by 30.9% from 408 at the same time last year to 534 as at Jun 30, 2022, including about 500 non-COVID-19 integrated projects. We expect the project number growth rate to be 31.1%, 29.1%, and 25.8% in 2022E, 2023E and 2024E, respectively. As at Jun 30, 2022, the total three-year backlog of the company increased from US\$2.2bn to US\$3.0bn, which also provided visibility for the company's short-term growth. In addition, since the banner year of commercial manufacturing projects in 2021, the company has maintained accelerated business momentum in late-stage and commercial manufacturing projects, contributing to significant revenue growth. This is another driver of strong revenue growth because typically, late-phase projects generate more revenue (US\$50–100m each). Therefore, we expect revenue to grow 47.5%, 39.8% and 36.0% in 2022E, 2023E and 2024E, respectively. We also expect the net profit margin will remain relatively steady and therefore forecast an EPS CAGR of 36% in 2022-2024F.

Expanding capacity ensures mid-term development

Owing to the complex nature of biologics R&D and manufacturing, the facilities typically need to be planned and constructed at least three years in advance. As at Jun 30, 2022, most of the company's manufacturing capacity was fully and efficiently utilized, thanks to a large number of integrate projects, including both COVID and non-COVID projects. The company has capacity-expanding plans globally, including Ireland, China, Germany, the US and Singapore. Capacity will reach 580,000L across five countries by 2026. Expanding overseas capacity will allow the company to better serve its overseas clients and reduce possible geopolitical risks.

Long-term development supported by biologic drug demand

The global aging population trend means an increasing need for medication. The pharmaceutical industry has seen a massive shift toward the use of biologic drugs from traditional small molecule drugs. Biologics offer higher specificity and better characterized mechanisms of action compared to small molecule drugs. Currently, most of the company's projects are monoclonal antibodies projects. But more complicated bispecific antibodies, ADC and other novel modalities are becoming increasingly more popular. The constant technology innovation will definitely generate more possibilities for biologic drugs. Owing to the complex nature of large molecules and living organisms, the R&D and manufacturing of biologics are more complicated, expensive and lengthy compared with that of small molecule drugs. Therefore, small- to medium-sized biotechnology companies with limited in-house resources tend to partner with biologics outsourcing services providers to expedite their development process and reduce costs. Partnering with biologics service provider allows large pharmaceutical companies to reserve their internal capabilities and capacity for their core pipeline. The biologics industry has high entry barriers and a strong Mathew effect. Therefore, in the long-term, the market favors leading companies, like WuXi Biologics.

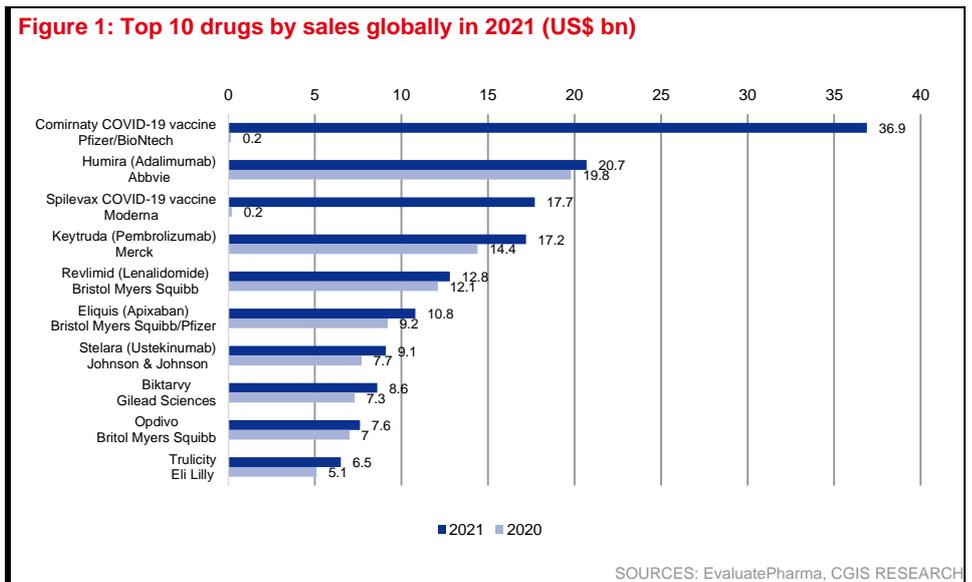
Industry Overview

Global and China biologics market

Biologics, or biopharmaceutical drugs, are a subset of pharmaceuticals. Unlike small-molecule drugs, which are chemically manufactured, biologics are derived from living organisms or contain components of living organisms. Biologics include a wide range of products, including monoclonal antibodies (mAbs), recombinant proteins, fusion proteins, vaccines, blood products, allergenics, cellular therapies, gene therapy, cytokines and insulin. Benefiting from ground-breaking developments in molecular biology and biochemistry over the past three decades, biologics are reforming disease treatments in many therapeutic areas. Advances in recombinant DNA technologies have ensured the large-scale manufacturing of biologics, and improvements in analytical technologies have improved the characterization of macromolecules.

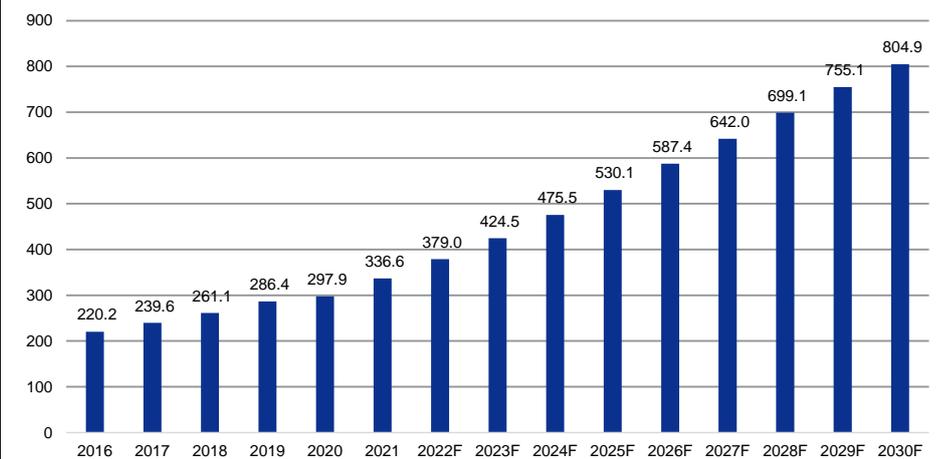
In the past three decades, the pharmaceutical industry experienced a massive shift towards the use of biologics. Biologics offer higher specificity and better characterized mechanisms of action (MoA) than small molecule drugs, and their use has revolutionized the treatment of a wide range of diseases and disorders. In 2021, six out of the top 10 best-selling drugs globally were biologics. These six biologics generated US\$109.2bn in sales in aggregate and consisted of two vaccines, and four mAbs. Global pharmaceutical and biotech companies are increasing their resources devoted to biologics R&D. Their focus areas include mAbs, bispecific antibodies (bsAbs), antibody-drug conjugates (ADCs) and vaccines.

Figure 1: Top 10 drugs by sales globally in 2021 (US\$ bn)



The biologics market is a subset of the global pharmaceutical market. In the past three decades, the biologics market has experienced robust growth, and the momentum continues to build. According to Frost & Sullivan, which is an independent global market research and consulting company, The global biologics market increased from US\$220.2bn in 2016 to US\$297.9bn in 2020, for a CAGR of 7.8%, and it is expected to reach US\$530.1bn in 2025F, for a CAGR of 12.2% from 2020 to 2025F, and US\$804.9bn in 2030F, for a CAGR of 8.7% from 2025F to 2030F.

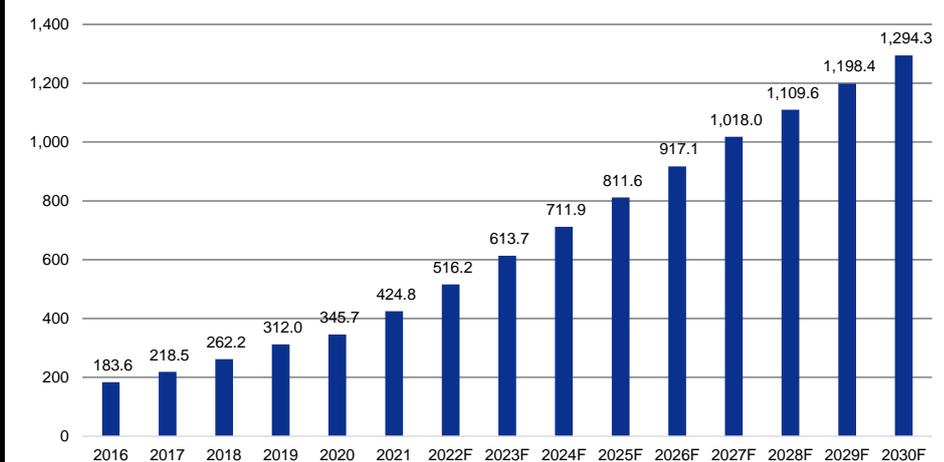
Figure 2: Global biologics market size, 2016–2030F (US\$ bn)



SOURCES: Frost & Sullivan, CGIS RESEARCH

Historically the biologics markets in North America and Europe have accounted for a majority of the global biologics market. In recent years, the biologics markets in emerging regions, such as China, have become increasingly active and have shown strong growth potential. China’s biologics market has a higher growth rate than global biologics market, increasing from Rmb183.6bn in 2016 to Rmb345.7bn in 2020, for a CAGR of 17.1%, and it is expected by Frost & Sullivan to reach Rmb811.6bn in 2025F, for a CAGR of 18.6% from 2020 to 2025F, and Rmb1,294.3bn in 2030F, for a CAGR of 9.8% from 2025F to 2030F. The rapid growth in the past few years of China’s biologics market was driven by increasing healthcare expenditure, increased research and development (R&D) capabilities, favourable government policies and expanded capital investment. China’s biologics market is expected to continue to grow significantly, driven by economic growth, expansion of medical reimbursement scope, and the emergence of more affordable biologics products, in our view.

Figure 3: China biologics market size, 2016–2030F (Rmb bn)



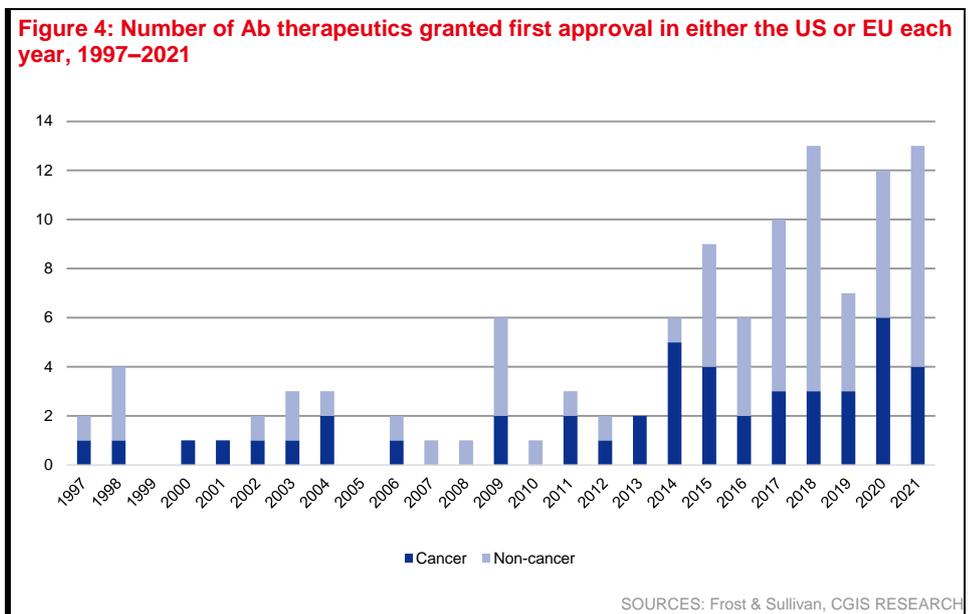
SOURCES: Frost & Sullivan, CGIS RESEARCH

Therapeutic Abs

The rapid growth of the biologics market is reflected by the increasing number of therapeutic Abs: mAbs, bsAbs and ADCs. In 2021, 13 therapeutic Abs were granted first approval in the US and EU, reaching the all-time high in 2018. In the past, most therapeutic Abs typically got their first global approval in the US or EU. However, an increasing number of first global approvals are being granted in other regions, most notably in China.

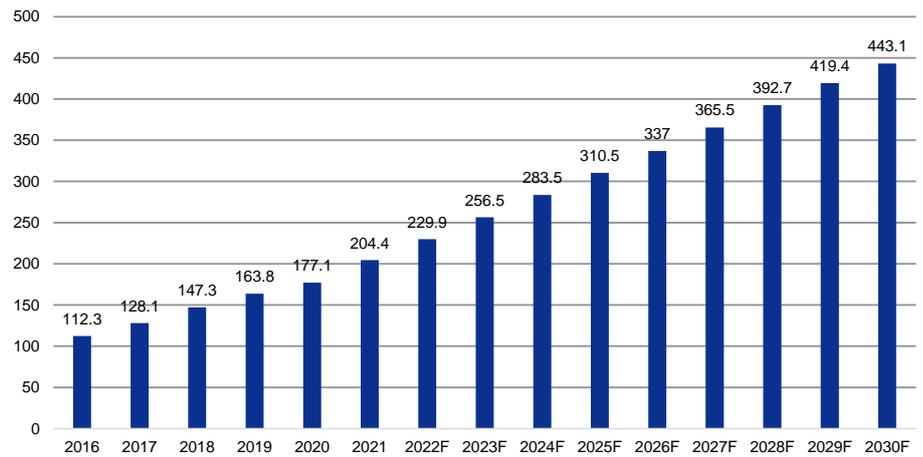
The biopharmaceutical companies have advanced many new therapeutic Abs into late-stage clinical trials in the past few years at a rapid pace. According to the “Antibody Society”, the number of commercial Abs in late-stage development (Phase II, Phase II/III and Phase III) grew by over 30% in the past few years. In addition, biopharmaceutical companies are continuing to apply for investigational new drugs (INDs) to regulatory agencies globally, especially in the US, EU, Japan, and China. So the long-term outlook for therapeutic Abs also seems promising, as in Nov 2021, there were over 800 early-stage projects in the commercial pipelines.

Figure 4: Number of Ab therapeutics granted first approval in either the US or EU each year, 1997–2021



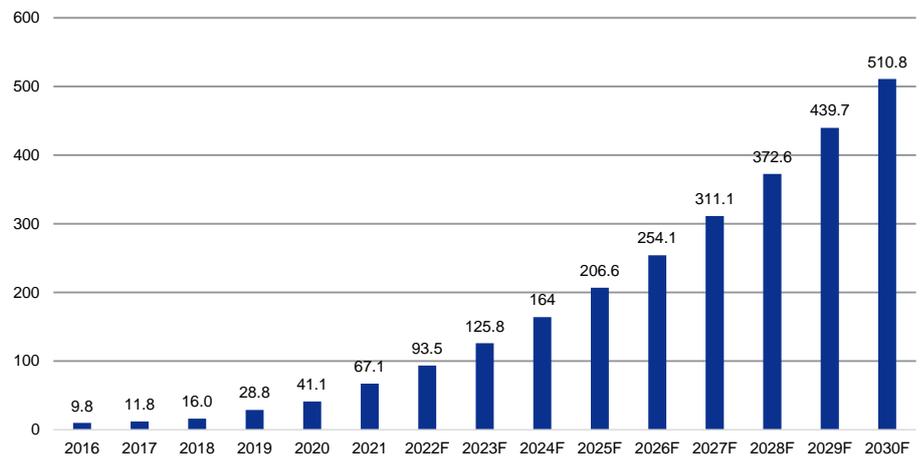
The global therapeutic Ab market is a subset of the global biologics market and grew from US\$112.3bn in 2016 to US\$117.1bn in 2020, representing a CAGR of 12.1%, according to Frost & Sullivan. The market is expected to grow at a CAGR of 9.6% from 2020 to 2030F, reaching US\$443.1bn in 2030F. China’s therapeutic Ab market grew from RMB9.8bn in 2016 to Rmb41.1bn in 2020, representing a CAGR of 43.2%. The market is expected to grow at a CAGR of 28.6% from 2020 to 2030F, reaching Rmb510.8bn in 2030F.

Figure 5: Global therapeutic Ab market size, 2016–2030F (US\$ bn)



SOURCES: Frost & Sullivan, CGIS RESEARCH

Figure 6: China therapeutic Ab market size, 2016–2030F (Rmb bn)



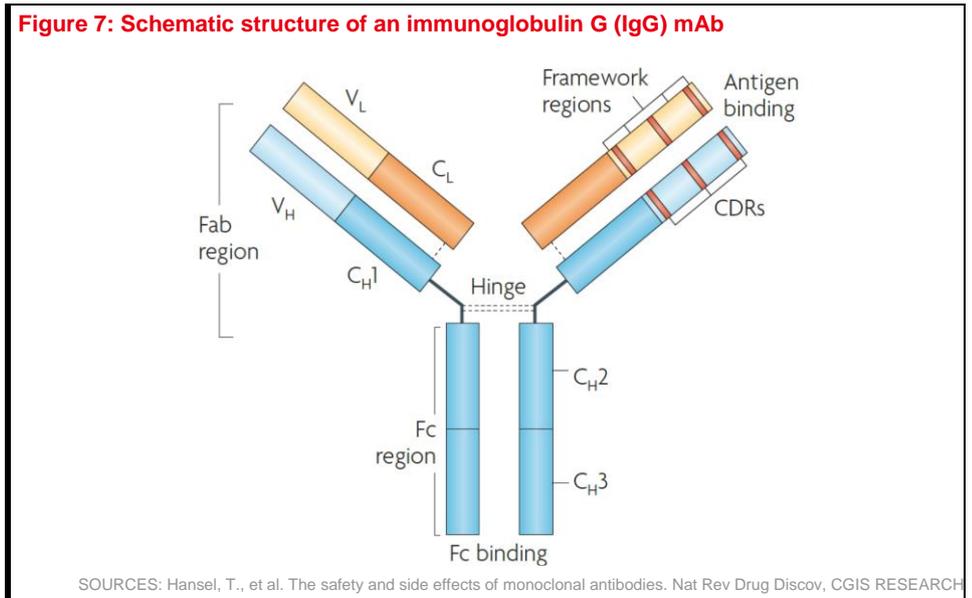
SOURCES: Frost & Sullivan, CGIS RESEARCH

mAb

mAbs are the main type of therapeutic Abs. mAbs are produced by B cells and can bind specific targets with high affinity and induce the immune response. Ab molecules have a Y-shaped structure and consist of two polypeptide chains: a heavy (H) chain and a light (L) chain. There are two regions on each chain, a constant region (C) and a variable region (V). Each Ab has two identical arms, and a fragment antigen-binding (Fab) region, binding to antigens. The VH and VL domains form the variable region of the Fab region, and the CH and CL domains form the constant region of the Fab region. In the variable Fab region, there are three hyper variable regions, complementarity-determining regions (CDRs), which are the most essential for diverse antigens recognition.

The Y structure's stem is called the fragment crystallisable region (Fc), which is a constant region. The Fc region determines the class of the Ab and its functions. There are five classes of Abs: immunoglobulin G (IgG), IgM, IgD, IgE and IgA. The Fc region can also interact with a variety of receptors. The interaction between the Fc region and immune system components initiate the effector functions of Abs, like Ab-dependent cell cytotoxicity (ADCC), Ab-dependent cellular phagocytosis (ADCP) or complement-dependent cytotoxicity (CDC).

Figure 7: Schematic structure of an immunoglobulin G (IgG) mAb



mAbs have been the most widely used biologics, accounting for a growing number of blockbuster drugs, and they are expected to maintain a dominant position in the biopharmaceutical market. mAbs have also played an important therapeutic role during the COVID-19 pandemic. Seven antibody therapeutics for the prevention and treatment of COVID-19 were granted approval or emergency use authorization (EUA) globally, including mAb products and combinations of mAbs. The substantial advances in the anti-COVID-19 Ab therapeutics in 2021 further increased the number of available mAbs.

bsAbs

During the past two decades, intensive progress has been made in the field of bsAbs. bsAbs and even multi-specific Abs (msAbs) have become increasingly of interest for diagnostic and therapeutic applications, representing a promising therapeutic area. Nine bsAb products have been approved globally, five of them this year. bsAbs have two binding regions that can recognize different antigens or two different epitopes of one antigen simultaneously. Since complex diseases generally involve multiple factors and mediators, bsAbs have demonstrated several therapeutic advantages compared to conventional Abs. Because bsAbs can bind two different antigens, the binding specificity is effectively enhanced, reducing the off-target side effects. In addition, the cost of bsAb treatment is lower than that of combination therapy of Abs. The quick development of bsAb is attributed to advanced biotechnologies and enhanced manufacturing processes.

bsAbs have many formats with variable binding moieties and can be roughly categorized into two groups: IgG-like and non-IgG-like. IgG-like bsAbs have a relatively large molecular weight, are easier to purify, have improved solubility and stability, and have an increased serum half-life. Non-IgG-like bsAbs do not have an Fc region, so they are easy to produce and have low immunogenicity. Because of the lack of an Fc region, bsAbs cannot initiate effector functions and have faster clearance from the body. mAbs consist of two identical H and two identical L chains. The manufacturing of mAbs always results in the correct assembly of H and L chains. bsAbs have two types of H chains and two types of L chains. The mismatch of chains produces a variety of side products. Ten chain combinations are possible, but only one is the properly assembled bsAb.

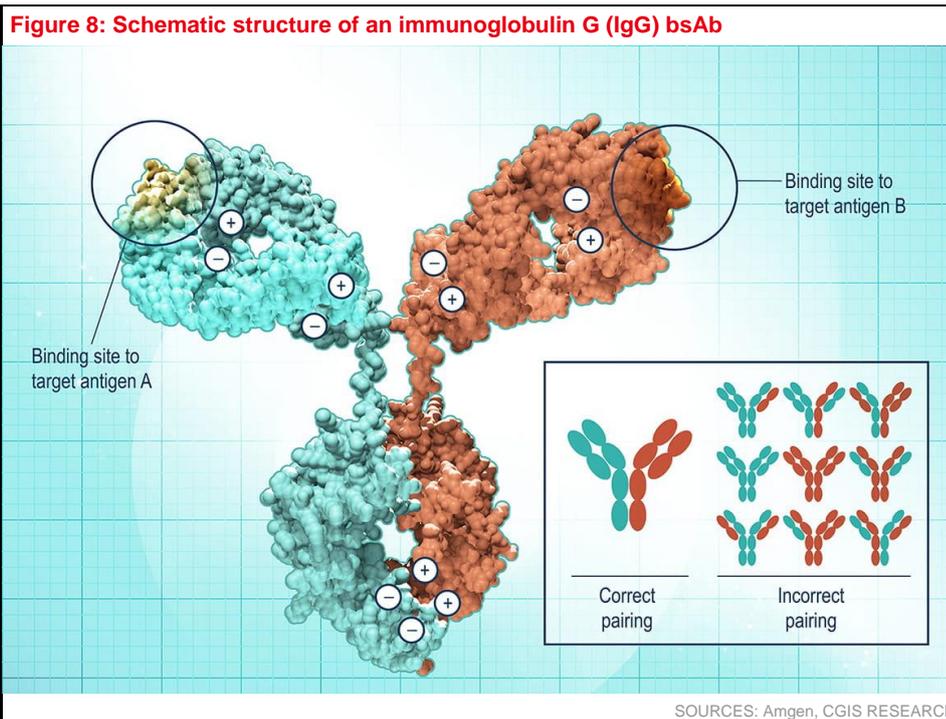


Figure 9: List of globally approved BsAb therapeutics

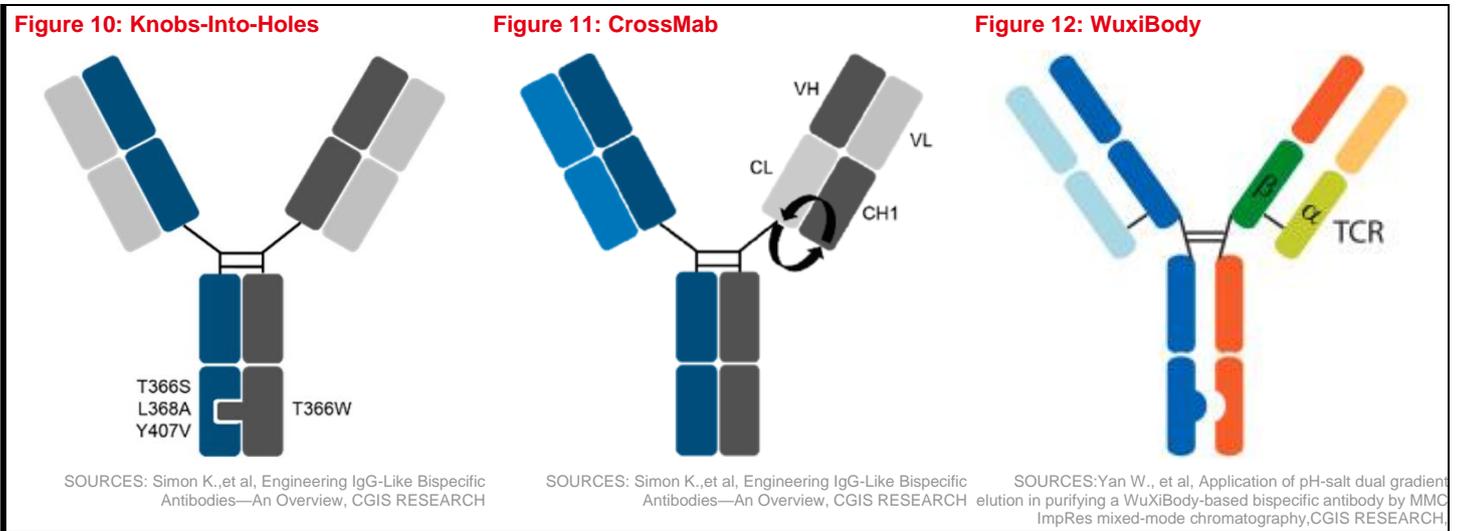
Drugs	Targets	Indications	Companies	Agencies	Time of Approval
Catumaxomab (Removab)	CD3/EpCAM	Malignant ascites	Trion Pharma	EMA	2009/04 (off market 2017)
Blinatumab (Blinicyto)	CD19/CD3	Acute Lymphoblastic Leukemia	Amgen	FDA EMA NMPA	2014/12 2015/11 2020/12
Emicizumab (Hemlibra)	Factor Ixa/Factor X	Hemophilia A	Roche/Genentech	FDA EMA NMPA	2017/11 2018/04 2018/12
Amivantamab (Rybrevant)	EGFR/c-MET	Non-small cell lung cancer (NSCLC)	Johnson & Johnson (J&J)	FDA	2021/05
Tebentafusp (Kimmtrak)	TCR/CD3	Metastatic uveal melanoma (mUM)	Immunocore	FDA	2022/01
Faricimab (Vabysmo)	CD20/CD3	Age related macular degeneration (AMD) diabetic macular edema (DME)	Roche/Genentech	FDA	2022/01
Mosunetuzumab (Lunsumio)	CD20/CD3	Non-Hodgkin's lymphoma (NHL)	Roche	EMA	2022/06
Cadonilimab	PD-1/CTLA-4	Relapsed or metastatic cervical cancer (r/r cc)	Akeso	NMPA	2022/06
Teclistamab (Tecvayli)	BCMA/CD3	Relapsed and refractory multiple myeloma (r/r mm)	J&J	EMA	2022/08

SOURCES: CGIS RESEARCH, COMPANY DATA

Dozens of technical platforms have been developed globally to reduce mismatching, including Knob-in-Hole (Roche), CrossMab (Roche), ART-Ig[®] (Roche), DVD-IgG, Azymetric[™] (Zymeworks), DuoBody[®] (Genmab), XmAb[®] (Xencor), Biclomis[®] (Merus), DART[®] (MacroGenics), Nanobody[®] (Ablynx), and TandAb[®] (Affimed). Several platforms for bsAb constructions have been developed in China, including YBODY[®] (YZY Biopharma), WuxiBody[™] (Wuxi Biologics), CRIB[™] (Alphamab Oncology), FiT-Ig[™] (EpimAb Biotherapeutics), and Tetrabody (Akeso).

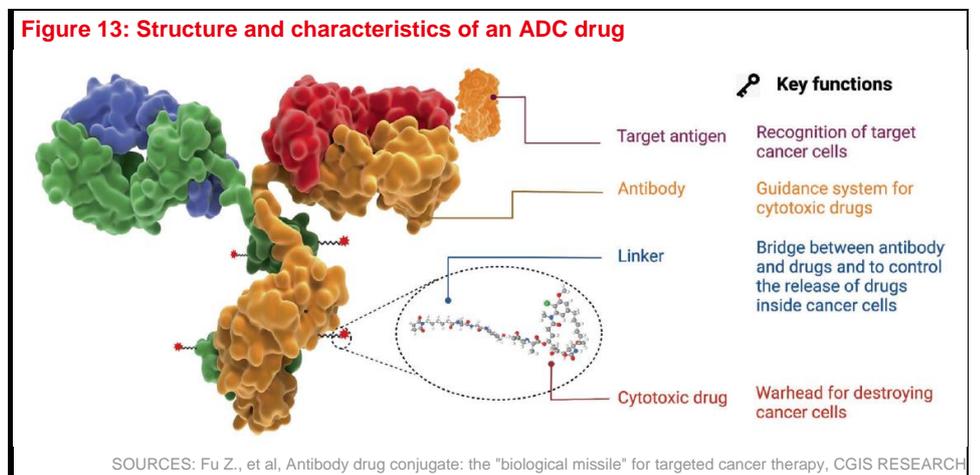
Knobs-Into-Holes (KiH) is a platform for constructing IgG-like bsAbs. A smaller amino acid is replaced with a larger amino acid in the CH3 region to form a “knob” structure, and a larger amino acid in the other chain is substituted with a smaller amino acid to form a “hole” structure. This modification drives assembly towards a heterodimer formation. KiH was discovered by Genentech, which was acquired by Roche in 1997. The patent of KiH has expired. Roche’s CrossMab platform is used for resolving the L chain mismatch. By swapping domains

between the H and L chain on one side, the bsAb's L chain can be assembled correctly, since only the L chain with swapped domains binds to the swapped H chain. WuXiBody is also used for resolving the bsAb L chain mismatch. WuXiBody replaces the CL and CH1 on one side with a constant region α and β of T cell receptors (TCRs). α and β are capable of forming a heterodimer to ensure the correct assembly of the light chain.



ADC

ADCs have become one of the most promising therapeutics for clinical oncology. ADCs comprise a mAb, which recognizes tumor-associated antigens, a cytotoxic payload and a chemical linker. In this way, ADCs exhibit the specific targeting feature of the Ab and the cell-killing feature of the payload, simultaneously. The off-target toxicities in patients are reduced by decreasing the exposure of normal tissues to an active cytotoxic component.

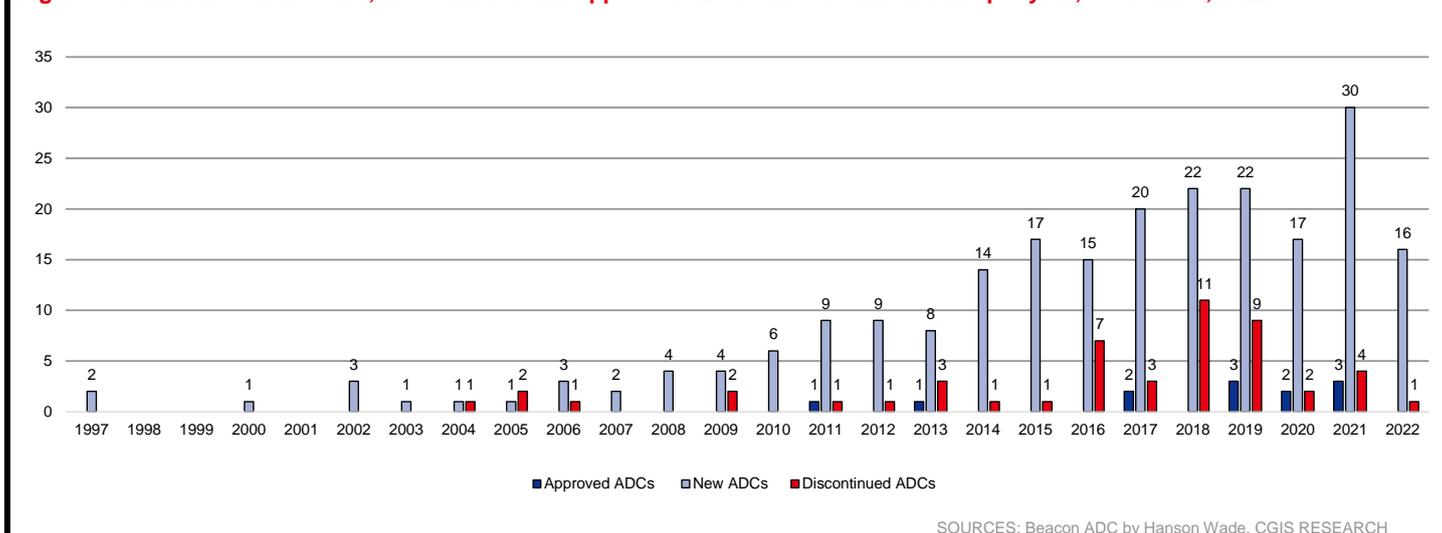


Technological advances, especially in the past 10 years, have affected Ab engineering, linker optimization and conjugation methods, which has promoted considerable progress in ADCs. Globally, 14 ADCs have approved for both haematological malignancies and solid tumours. In addition, a recent breakthrough was made in ADCs for the treatment of tumors. ADCs have become an exciting therapeutic modality and may have the potential to replace conventional chemotherapy in the future. The number of ADCs in clinical trials has increased continuously. Over 20 new ADCs have begun clinical trials every year for the past five years, except for 2020 because of the COVID-19 pandemic.

Figure 14: 14 ADCs approved globally

Name	Company	Target	Payload	Indication	Approved
Mylotarg	Pfizer	CD33	Calicheamicin	Acute myeloid leukemia (AML)	2000, 2017
Adcetris	Seattle Genetics	CD30	MMAE	Classic Hodgkin lymphoma (cHL), Systemic anaplastic large cell lymphomas (sALCL), Peripheral T cell lymphoma (PTCL)	2011
Kadcyla	Genentech	Her2	DM1	Her2+ breast cancer (BC)	2013
Besponsa	Pfizer	CD22	Calicheamicin	Acute lymphocytic leukemia (ALL)	2017
Lumoxiti	Astra zeneca	CD22	Pseudomona exotoxin A	Relapsed/refractory hairy cell leukemia (r/r HCL)	2018
Polivy	Genentech	CD79b	MMAE	Diffuse large B-cell lymphoma (DLBCL)	2019
Padcev	Astellas Seattle Genetics	Nectin 4	MMAE	Bladder cancer, Pt & PD-1/PD-L1	2019
Enhertu	AZ Daiichi Sankyo	Her2	Dxd	Her2+ BC	2019
Trodely	Immunomedics	Trop-2	Sn38	Metastatic triple-negative breast cancer (mTNBC)	2020/04
Blenrep	GSK	BCMA	MMAF	Multiple myeloma (MM)	2020/08
Akalux	Rakuten Aspyrian	EGFR	IRDye700DX	Head-and-neck cancer	2020/09
zynlonta	ADC Therapeutics	CD19	PBD	DLBCL	2021/04
Disitamab V edotin*	Remegen	Her2	MMAE	Gastric cancer	2021/06
Tivdak	Genmab/seagen	TF	MMAE	Cervical cancer	2021/09

*Approved by China NMPA
 SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 15: Number of new active, discontinued and approved ADCs entered clinical trials per year, as at Mar 1, 2022


Ideally, an ADC drug remains stable in blood circulation, reaches the target specifically, and then releases cytotoxic payloads. All components, including targets, Abs, payload, linker and the conjugation method, can affect the final safety and efficacy of ADCs, because they all define the biophysical and physiological properties of the molecule. However, there are still many challenges in the design, development and manufacturing of ADCs, due to their complexity in pharmacokinetic (PK) profiles, unavoidable side effects, insufficient tumor targeting and payload release, and drug resistance.

Vaccines

Another major category of biologics is vaccines. Vaccines are biological preparations used to safely stimulate the body's immunity against a particular disease to provide subsequent protection against the next exposure to the pathogen. Vaccination has already provided significant protection against dozens of diseases. A vaccine must contain antigens that are either derived from the pathogen or produced synthetically to represent the components of the pathogen. Traditionally, vaccines are categorized into live or non-live vaccines. Live vaccines contain attenuated strains of the pathogen, while non-live vaccines contain only components of the pathogen or the dead complete organism. Most of the available vaccines today are developed by either inactivated or live attenuated technologies. However, several other vaccine technologies have been developed over the past few decades, namely viral

vector, RNA and DNA vaccines, and virus-like particles. The COVID-19 pandemic has made the world's population familiar with mRNA vaccines.

There are still several important diseases for which new vaccines are needed to decrease morbidity and mortality in the world. If developed, those vaccines are likely to have a good market in both developing and developed countries. According to Frost & Sullivan, the global vaccine market increased from US\$27.6bn in 2015 to US\$39.9bn in 2020, representing a CAGR of 7.7%, and is expected to grow to US\$84.0bn in 2025F, for a CAGR of 16.1% from 2020 to 2025F, and to US\$129.2bn in 2030F, for a CAGR of 9.0% from 2025F to 2030F.

Figure 16: Global vaccine market by production value (LHS) and percentage of the global pharmaceutical market (RHS), 2015–2030F

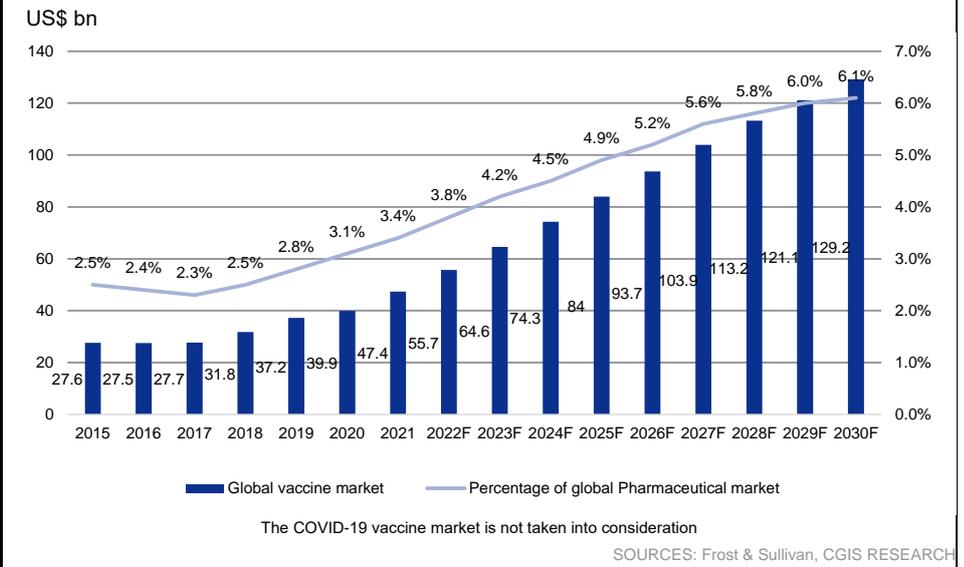
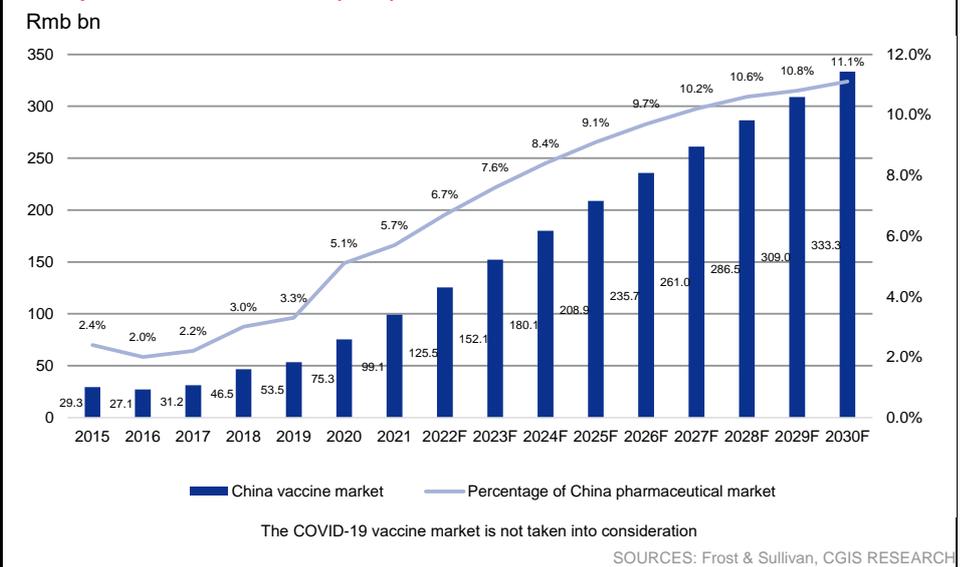


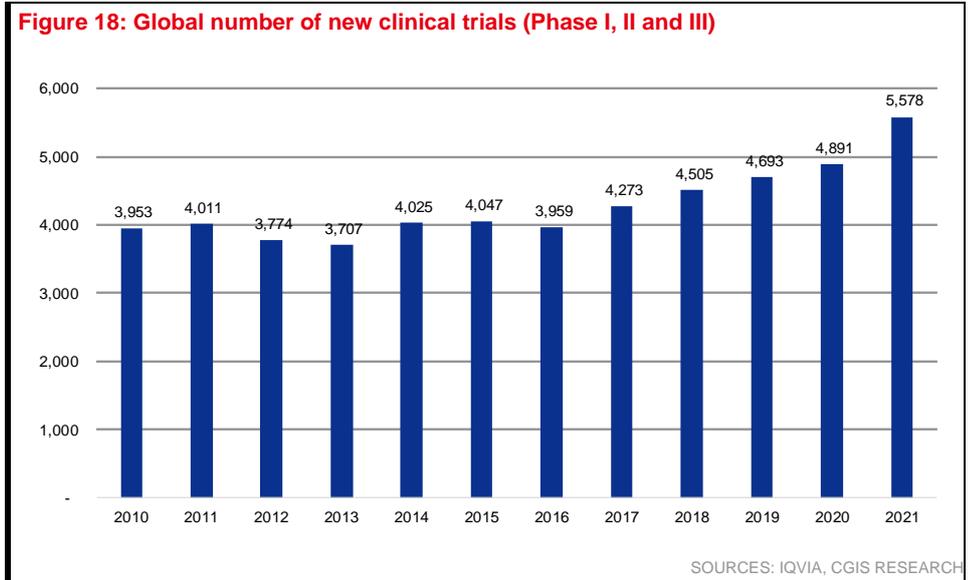
Figure 17: Vaccine market in China by production value (LHS) and percentage of the China pharmaceutical market (RHS), 2015–2030F



Biologics license applications (BLA) and Biosimilars

The incidence of chronic diseases around the world is growing, as is the aging population, indicating increasing demand for medications. Despite the COVID-19 outbreak in 2021, the number of new clinical candidates in the pipeline still increased by 14% in 2021, according to IQVIA, which is a global leading life science database provider. Most of the trials were treatments for cancer and rare diseases. Because of biologics’ targeted nature and high efficacy, they are taking on an increasingly important role in both common and serious diseases. Therefore, we expect the number of new clinical trials of biologic drugs to continue to increase.

Figure 18: Global number of new clinical trials (Phase I, II and III)



Besides the fast increase in the number of biologics in the pipeline, we think the biosimilar market will continue to exhibit significant growth since the patents and exclusive periods for blockbuster biologics have expired or will soon expire. The concept of biosimilars was established in the EU in the early 2000s, and subsequently, the regulatory framework for biosimilars was also established in the US, Japan, China, and other countries. A biosimilar product is highly comparable but not identical to an already licensed biologic product (reference product) in terms of quality, safety, and efficacy.

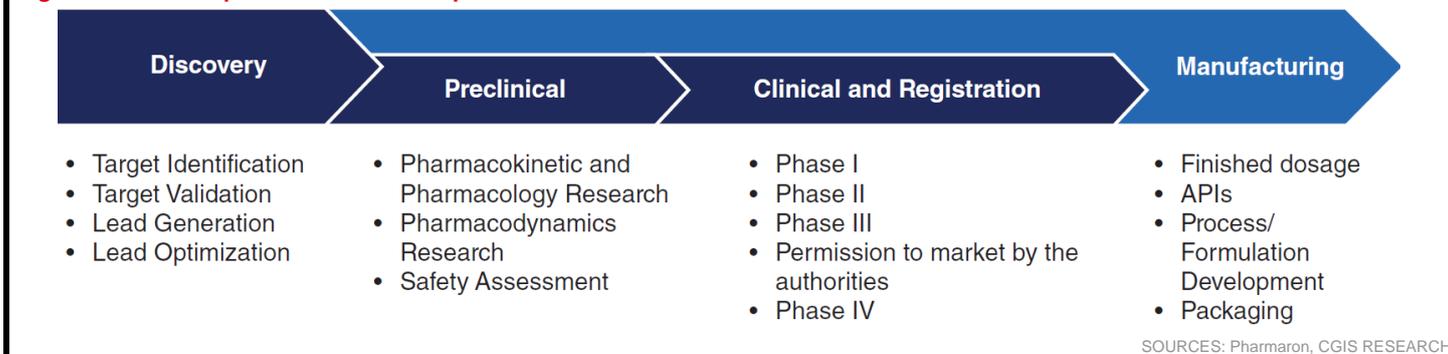
The concept of biosimilars was defined by National Medical Products Administration (NMPA) in China and the “Technical Guidelines for the Development and Evaluation of Biosimilars (Trial)” was released later. The first biosimilar licensed in China was the Rituximab biosimilar by Henlius in 2019. Since then, over 20 biosimilars have been approved in China, and more than 100 biosimilars are undergoing R&D. The main biosimilars launched in China are Bevacizumab, Adalimumab, Rituximab, Trastuzumab, Infliximab and Denosumab. The development of biosimilars is equally rapid in the US and EU. The Food and Drug Administration (FDA) approved the first biosimilar, Filgrastim-sndz (Zarxio), in 2015. As at end-Apr 2022, 35 biosimilars had been approved by the FDA. The European Medicines Agency (EMA) granted approval for the world’s first biosimilar, Somatropin (Omnitrope), in 2006. Since then, 68 biosimilars have been approved by the EMA.

Unlike generic drugs, biosimilars are unlikely to be exactly the same as the reference drugs, given their large molecular mass, complex structure, and undisclosed manufacturing process. But the characteristics, including the structure, and physicochemical and biological properties, of active pharmaceutical ingredients between a biosimilar and original drug must be very similar. Once the structural and functional similarities are demonstrated, biosimilars are often granted similar indications as the reference drugs. The introduction of biosimilars is an attractive way to reduce healthcare expenses through price competition with the reference product. Biologics provide higher specificity and better efficacy, but cost more. The medical cost burden on patients and society is another driver of biosimilar market growth.

Life cycle of biologics

Drug R&D is a multiple-step process, initiated because there is a unmet clinical need. The basic principles and general framework for biological drug discovery and development processes are the same as for small molecules. Typically, there are four stages in the biologic pharmaceutical R&D process: the discovery, preclinical, clinical and commercial stages.

Figure 19: General pharmaceutical R&D process



Discovery: from target to clinical candidate

Typically, after conceptualization (when a protein is identified to be linked to a disease), a biologics R&D project starts. Discovery is the process whereby a biologics drug candidate, in the form of mAb, bsAb or ADC, is identified and screened for activity against a chosen biological target (e.g. a receptor, enzyme, protein or gene) that is relevant to a disease. Generally, more than one molecule is generated in this step because many of them cannot go forward because of lack of potency or safety. The discovery process usually includes target identification target validation, lead generation lead optimization, and candidate selection. The goal of the discovery process is to deliver one or more drug-like candidate molecules with sufficient evidence of biologic activity and safety to progress to the preclinical stage.

Preclinical development: kinetics, disposition, safety and efficacy

The aim of preclinical testing is to obtain results that will enable the candidate molecule to be approved for human testing by the regulatory authorities. During the preclinical development phase, laboratory and animal studies are used to further evaluate the safety and biological activity of the candidates against the disease target. The range of potentially safe and tolerable doses of a molecule must be determined before human testing. During the preclinical stage, a small amount of the biologics is produced to be used in various studies.

Clinical development: testing on humans

Preclinical research answers basic questions about a drug's safety and potency, but it cannot show how the drug will interact with the human body. If satisfactory results are obtained from preclinical studies, an investigational new drug (IND) application is filed with the regulatory authorities for the initiation of clinical trials. Clinical research refers to studies that are done in people to examine the efficacy and safety of the biologics candidate and includes early-phase trials (Phase I and II) and late-phase trials (Phase III). After the IND application is approved, the biologic drug candidate proceeds to the early-phase clinical development stage, followed by the late-phase clinical development stage. During the clinical trials, a large quantity of the biologics candidate is manufactured. A successful clinical trial typically results in the filing of a BLA for marketing approval.

Commercialization: manufacturing and marketing

The manufacture, marketing and sale of the approved drug may commence after approvals are granted by the regulatory authorities. Commercial scale manufacturing typically requires larger quantities. The manufacturing process of biologics typically includes cell culture, harvest, purification, storage and shipping.

Biologics manufacturing

A key step in biologics manufacturing is the bioprocess, which is a specific process that uses living organisms or their components to generate the desired products. A bioprocess takes place in a bioreactor, which provides the optimum environment for the reaction to take place. It is generally divided into upstream and downstream processes. The upstream process includes cell line production and cell culture using a bioreactor. The downstream process comprises product purification from culture media, virus inactivation, and filling to get pharmaceutical substances (PSs).

Cell line development

Various cell lines are used in biologics production. The most frequently used cell lines are Chinese hamster ovary (CHO) cells, given their high productivity, glycosylation quality and safety.

Culture

The technology of bioprocessing has evolved in recent decades towards higher yield and lower cost. Improvements in bioreactor and bioprocess technologies have taken manufacturing from batch, to fed-batch, and on to perfusion.

The batch method was the first bioprocess adopted by in biologics manufacturing. Organisms are added to the culture media in the bioreactor, and the media remains the same, which means no supplementation, refill or exchange during the entire process. All nutrients are supplied at the beginning of the cultivation, and products are removed at the end. There is less chance of contamination of batch method since the nutrients are added only once at the beginning. But the production time is shorter owing the depletion of nutrients.

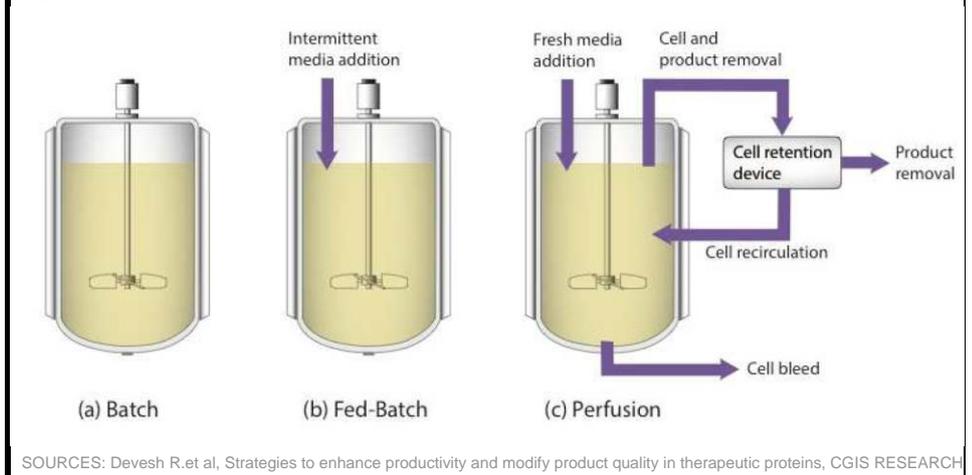
The fed-batch method has been the dominant bioprocessing method for decades. In the fed-batch bioprocess, initially, the bioreactor is filled with a base amount of media to support initial growth, and then extra media is added sequentially once they are depleted. The cells and their products remain in the bioreactor until the end of the run.

Continuous bioprocessing, or perfusion technology, is one of the newest cell culture methods. In the continuous bioprocess, fresh medium is continuously supplied, and the old culture medium is continuously taken out at the same rate. In this way, the cells have continuous access to fresh medium, which increases the culture's productive duration and productivity. At the same time, products are continuously removed for downstream processing, so small-scale downstream purification is sufficient. Because of the low concentration of waste products due to the constant removal of waste, the lifetime of the cells is increased. In addition, perfusion bioreactors are smaller, so they require less space, infrastructure, utilities, and labour. Therefore, continuous production makes the generation of large quantities of culture in small facilities possible. Owing to all these advantages, perfusion has become the leading technology and is adopted more in bioprocessing. Perfusion technique is very flexible, it can be used for a variety of cell types, and it can be adapted to produce various products, including vaccines, Abs and cell therapies. Naturally, perfusion bioprocessing is more complex from a technical and a regulatory point of view than fed-batch since it requires more process knowledge, equipment and technology.

Purification

Downstream processing can be complex, expensive, and time-consuming. To purify and recover biologics efficiently and gently, a variety of methods for recovery, separation, and purification have been developed. One of the most efficient purification processes is affinity chromatography, which removes most of the impurities and provides the desired concentration factor. Subsequent purification steps are used to remove traces of remaining process- and product-related impurities. The commonly used affinity chromatography is protein A resin-based. Protein A contains five regions that bind to the Fc region of IgG.

Figure 20: Three different modes of operation in bio-manufacturing



Biologics outsourcing services

Biologics outsourcing services specifically target the biologics market and cover all the stages in the biologics development process, from drug discovery to commercial manufacturing. The market for biologics outsourcing services is expected to expand, along with the increase in the biologics market, in our view. The vigorous growth of the biopharmaceuticals market has boosted demand for biopharmaceutical contract manufacturing services.

In addition, the capital intensive, complex and highly technical nature of the biologics development process, in particular at the commercialization stage, has prompted an increasing number of pharmaceutical and biotechnology companies to turn to outsourcing. The development of biologics is more complicated than that of small-molecule drugs. The active pharmaceutical ingredients (API) structure of a small-molecule drug is well-defined, but that of a biological drug is not always well-defined and may not even have a static structure. In addition, the production process of biologics, as described above, is more complex and is more costly than that of small molecule drugs. Therefore, developing biologics requires state-of-the-art facilities and an array of technical and operational expertise. The complexity of biologics development and manufacture has driven pharmaceutical and biotechnology companies to outsource a broad spectrum of services, from the early drug development stage to manufacturing. Using the outsourcing services, the buyer can gain access to novel technologies and regulatory expertise to expedite R&D, thereby shortening the time to market and minimizing risks at a competitive cost.

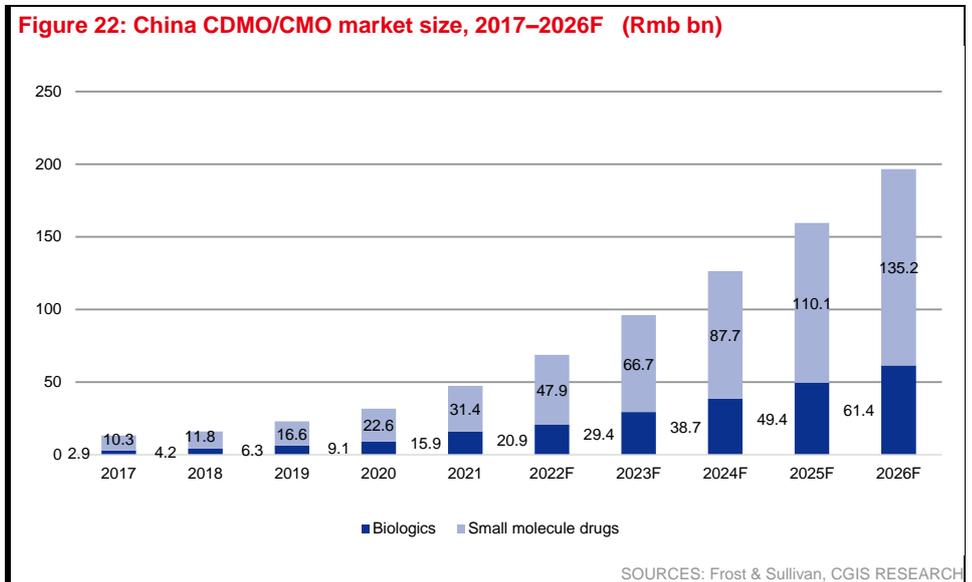
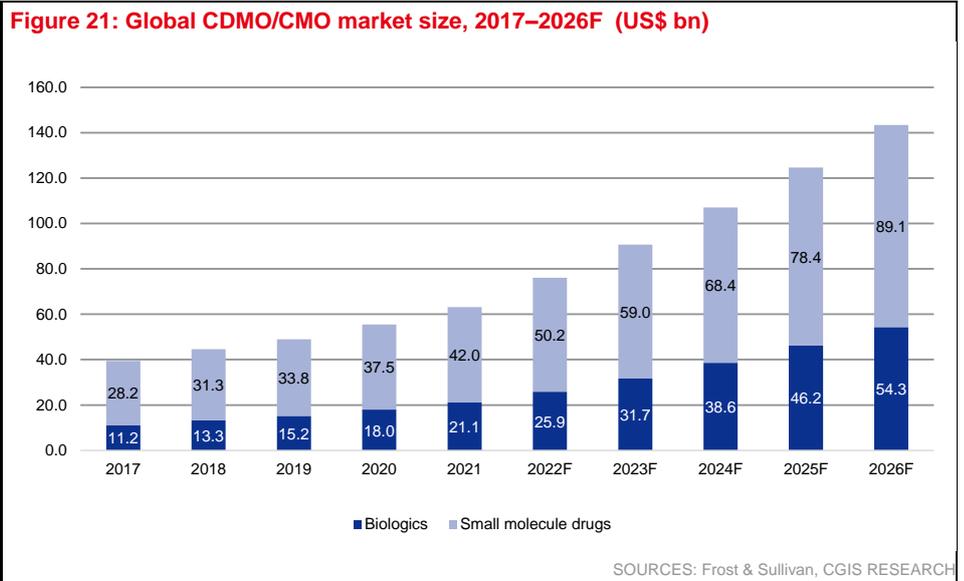
Especially with more biologics, including biosimilars, entering the market, competition will become fierce. To stand out from the competition, biopharmaceutical makers need to reduce manufacturing cost, improve process efficiency, ensure high quality and efficacy, and shorten the time to market. Especially for a biosimilar developer, shortening the time to market is very critical.

It is common for small- to medium-sized biotechnology companies to partner with biologics outsourcing services providers. In this way, companies can dedicate their scarce resources to their core strengths. By accessing various technology platforms and experts from outsourcing services providers, they also can expedite their development process. There is also an increasing industry trend for large pharmaceutical companies to use outsourcing services providers to reserve their internal capabilities and capacity for the core products in their pipeline. Partnering with outsourcing services providers can also help them gain entry to emerging markets like China more easily.

Outsourcing services providers are called “contract research organizations” (CROs), “contract development manufacturing organizations” (CDMOs), “contract manufacturing organizations” (CMOs), or “contract research, development, and manufacturing organizations” (CRDMOs), depending on the scope of the services they provide. We use the term CXO to generally refer all

kinds of outsourcing services providers, including CRO, CMO, CDMO, and CRDMO.

CROs provide R&D solutions covering mainly the discovery, preclinical and clinical stages. CDMOs focus mainly on providing chemistry, manufacturing and controls (CMC) services. According to Frost & Sullivan, The market size of the global biopharmaceutical CDMO/CMO industry increased from US\$11.2bn in 2017 to US\$21.1bn in 2021, representing a CAGR of 17.2%, and it is expected to grow to US\$ 54.3bn in 2026, for a CAGR of 20.8%. The market size of China’s biopharmaceutical CDMO/CMO industry increased from Rmb2.9bn in 2017 to Rmb15.9bn in 2021, for a CAGR of 52.7%, and it is expected to grow to Rmb61.4bn in 2026F, for a CAGR of 31.0%.



The growth drivers of the global CXO services market are a) increasing R&D spending on biologics in big pharmaceutical companies and small- to mid-sized biotech companies; b) cost and time saving benefits, which means by using CXO services, companies can save large amount of investment in establishing biologics development capabilities and facilities, and expedite the discovery, development and commercialization of their biologic products; c) better supply chain and capacity management, which means pharmaceutical and biotech companies can ensure robust supply chain secure manufacturing capacity by appointing a CXO as a secondary manufacturer; and d) gaining access to outside technologies because CXOs are constantly updating their discovery, development and manufacturing technologies, have proprietary technologies,

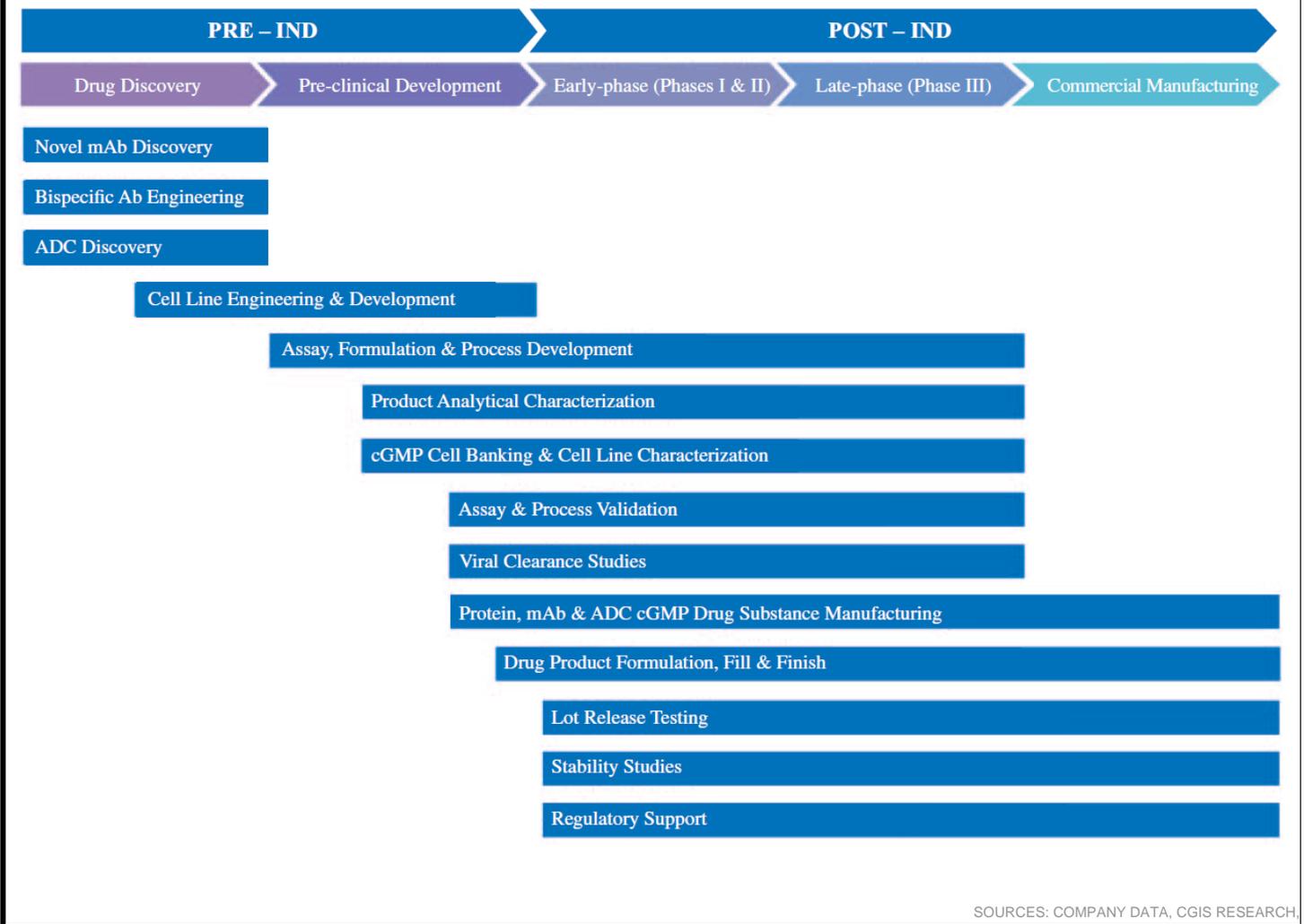
and have institutionalized expertise that pharmaceutical and biotech companies may not have.

China's biologics outsourcing services market has the fastest growth rate in the world and is expected to maintain a robust growth rate in the future, in our view. The rapid development of CXO services in China is driven by the robust growth of China's biologics market. This robust growth demands strong discovery, development and manufacturing capabilities that may not available in-house and need to be outsourced. In addition, the enhanced capabilities and increased capacity of Chinese CXOs are more and more recognized by overseas pharmaceutical and biotech companies. Overseas clients account for a large portion of Chinese CXO clients. There is a trend for overseas pharmaceutical companies and biotech companies to use Chinese CXOs since they can access experts at a lower cost. Furthermore, the Chinese government has published many regulations and policies to support the development of CXOs. The Marketing Authorization Holder (MAH) program was first piloted in China in 2015 and officially implemented in 2019. It allows MAHs to entrust manufacturing activities to third-party CXOs.

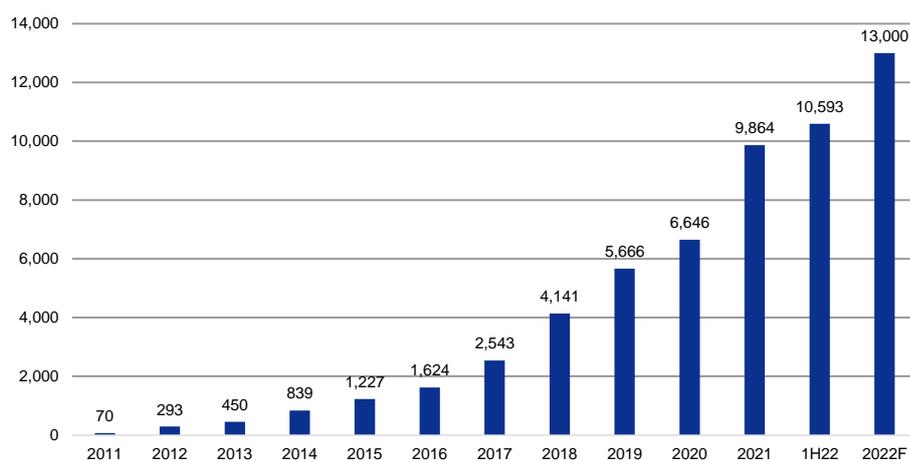
Company introduction

WuXi Biologics (the company) is a CRDMO and provides a comprehensive, integrated, highly customized range of services for the discovery, development, and manufacturing of biologics to pharmaceutical and biotechnology companies, supported by the company’s team of scientists, proprietary technology platforms, state-of-the-art laboratories, and current Good Manufacturing Practice (cGMP)-compliant manufacturing facilities. The one-stop, full-spectrum services provided by the company cover the whole range of biologic R&D and manufacturing processes that few competitors can rival. The company’s client base includes leading global pharmaceutical companies, as well as start-up companies and small to mid-sized biotechnology companies. As at Jun 30, 2022, the company had worked with all of the top 20 pharmaceutical companies in the world and 43 out of the 50 largest pharmaceutical companies in China.

Figure 23: Main services of WuXi Biologics



As at Jun 20, 2022, the company had 10,593 employees working in the US, EU and Asia-Pacific (APAC), and the company estimates the employee number will to reach about 13,000 at the end of 2022 due to capacity expansion. All members of the senior management team have worked at the forefront of biologics industry and have average working experience of over 20 years each in their respective fields of expertise.

Figure 24: Employee number


SOURCES: COMPANY DATA, CGIS RESEARCH

Figure 25: Management profile

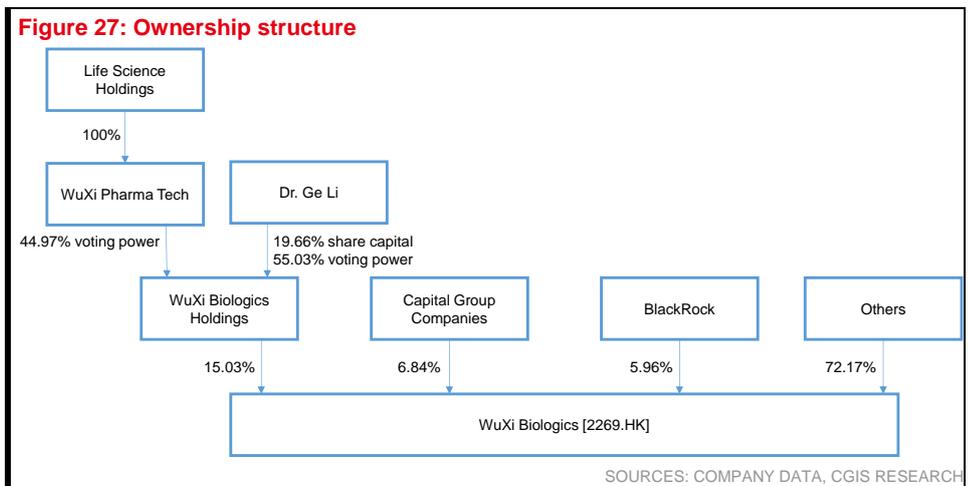
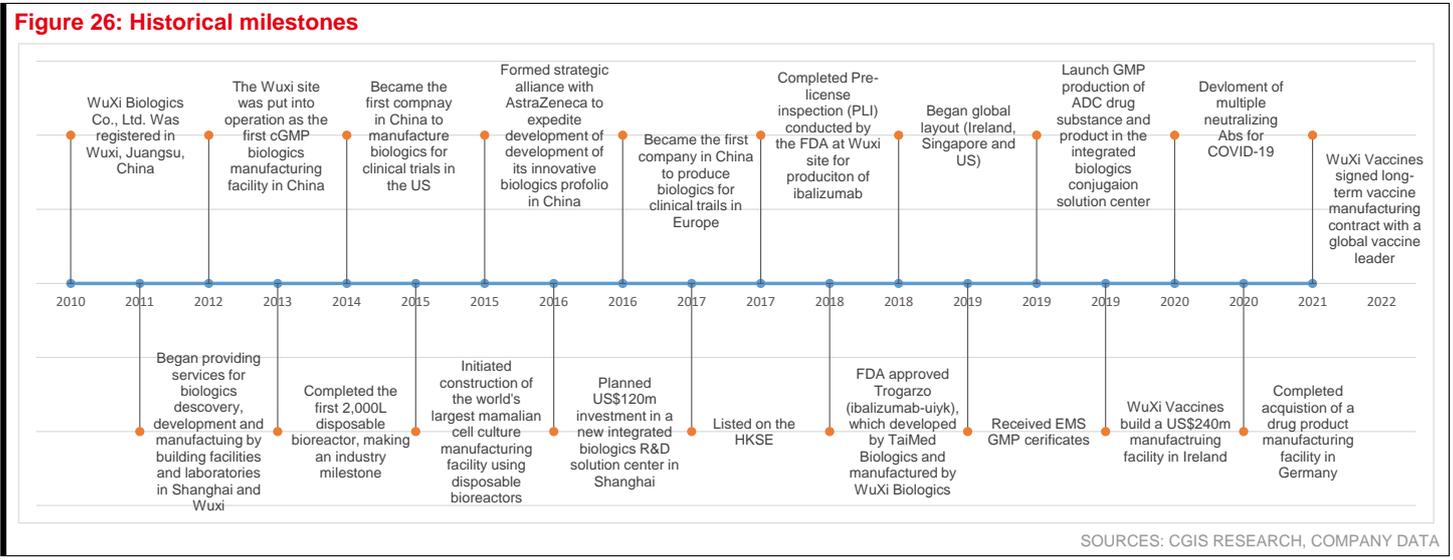
Name	Title	Experience
Chris Chen, Ph.D.	CEO of WuXi Biologics Chairman of WuXi Vaccines and WuXi XDC	<ul style="list-style-type: none"> • More than 20 years' experience in therapeutic proteins and vaccines industry • Celgen, Eli Lilly, and Merck
Weichang Zhou, Ph.D.	Chief Technology Officer	<ul style="list-style-type: none"> • More than 25 years pharmaceutical industry experience • Genzyme, PDL, and Merck.
Ming Tu, MBA	Chief Financial Officer	<ul style="list-style-type: none"> • More than 26 years' experience in financial management, global operations and strategic planning • CFO of General Electrics (GE) China, CFO of GE Healthcare China
Jijie Gu, Ph.D.	Chief Scientific Officer	<ul style="list-style-type: none"> • 20+ years' experience in biologics R&D • AbbVie, Abbott, Harvard University
Xuejian (Jerry) Xu, Ph.D.	Chief Quality Officer	<ul style="list-style-type: none"> • 25+ years' experience • FDA, Genzyme, Wyeth (Pfizer), Fleecon
He (Daniel) Wang	Chief Compliance Officer	<ul style="list-style-type: none"> • 17 years' experience in legal, compliance and corporate risk management • Geely Auto, Lotus Cars, DLA Piper, Kirkland & Ellis
Jian Dong, MBA	Chief Executive Officer of WuXi Vaccines Head of Global Engineering, WuXi Biologics	<ul style="list-style-type: none"> • 30+ years' experience • Unilab Bioscience, Eli Lilly, Shenzhen Kangtai
Jincai (Jimmy) Li, Ph.D.	Chief Executive Officer of WuXi XDC Senior Vice President of WuXi Biologics	<ul style="list-style-type: none"> • 8+ years' biologics process development, scale-up & GMP manufacturing experience • Genentech, Tanox, Diversa
Keqiang (Peter) Shen	Head of Asia-Pacific Manufacturing	<ul style="list-style-type: none"> • 25+ years' experience • Laurate Biopharm, DuPont Pharma, J&J, BMS
William (Bill) Aitchison, Ph.D.	Head of Global Manufacturing	<ul style="list-style-type: none"> • 30+ years' development and manufacturing experience from global pharmaceutical companies across multiple technology platforms (vaccines, MAbs, proteins and small molecules) • GSK (TESARO), Genzyme, Sanofi Pasteur, Wyeth, Diamond Animal Health, Biostar
Cong (Connie) Ding, J.D.	Head of Legal Department	<ul style="list-style-type: none"> • 20+ year's experience in legal at Baker Donelson, in clinical at Beijing Xiyuan Hospital, and in cancer research at St. Jude Children's Research Hospital.
Gang Huang, Ph.D.	Analytical Sciences and Shanghai QC Head of Fengxian Site	<ul style="list-style-type: none"> • 20+ years' experience • Amgen, Sigma-Aldrich
Shaogui (Sharon) Tang, MBA	Head of Global Communications and Operatio	<ul style="list-style-type: none"> • 25+ years' experience in corporate communications and public affairs from a wide range of industries including high-tech, chemical, pharma and FMCG • Thought leadership in corporate reputation management and CSR
Angus Turner, MBA	Head of Global BD and Alliance Management	<ul style="list-style-type: none"> • 20+ years' experience • Lonza, Bayer, AppTec
Li (Lily) Xiong	Head of Global Human Resources	<ul style="list-style-type: none"> • 19 years' working experience in wide range of industries including healthcare, high-tech and industrial software • GE, Siemens, Honeywell

SOURCES: CGIS RESEARCH, COMPANY DATA

History

Originally, the biologics business of WuXi Biologics was one of the five distinct business units of WuXi PharmaTech, along with with small molecules, cell and gene therapies, medical devices and genomics. The founders, Dr. Ge Li, Dr. Ning Zhao, Mr. Xiaozhong Liu and Mr. Zhaohui Zhang, and other independent third parties founded WuXi PharmaTech (currently known as WuXi Apptec [2259.HK]) in the PRC in Dec 2000.

Wuxi PharmaTech was incorporated in March 2007 as an offshore holding company of WuXi Apptec. In Jan 2008, Wuxi PharmaTech acquired AppTec Laboratory Services, a company engaged in biopharmaceutical and medical device testing and biologics-based manufacturing and related services. Subsequently, WuXi PharmaTech was renamed WuXi AppTec and expanded its services into biologics-related discovery, development and manufacturing services by establishing WuXi Biopharma in May 2010 in Wuxi, Jiangsu. WuXi PharmaTech's shares were listed on the NYSE on Aug 9, 2007 and were delisted from the NYSE on Dec 10, 2015. Following the delisting, a reorganization was carried out, along with, and as part of, a strategic restructuring to realign Wuxi PharmaTech's businesses through three primary business units: WuXi Biologics, WuXi AppTec and Nextcode. Prior to Feb 2016, WuXi Biologics was wholly owned by WuXi PharmaTech.



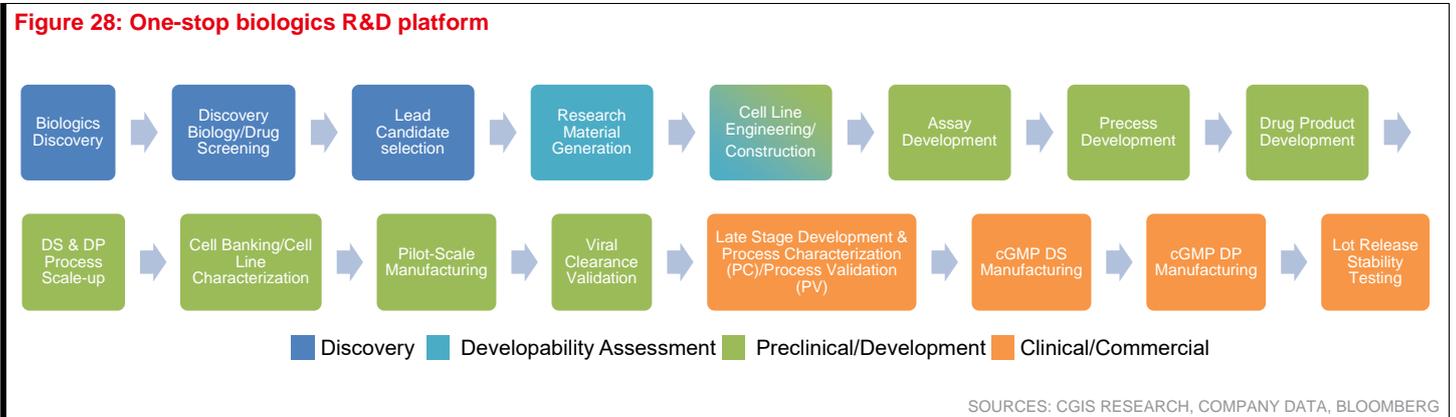
After a series of restructuring steps, Biologics Holdings became a substantial shareholder of WuXi Biologics. As at the end of 2021, Biologics Holdings had a 15.03% stake in WuXi Biologics, and Dr. Ge Li controlled 19.66% of the issued share capital of Biologics Holdings and 55.03% of the voting power at its general meetings. In addition, Life Science Holdings wholly owned Life Science Limited,

which wholly owned WuXi PharmaTech, which in turn, controlled 44.97% of the voting power at general meetings of Biologics Holdings.

Services and technologies

The services provided by the company can be generally categorized into three phases: research (R), development (D) and manufacturing (M). The different stages have specific technological requirements.

Figure 28: One-stop biologics R&D platform



The “R” of CRDMO

The company’s discovery organization has approximately 400 scientists as of Apr, 2022, offering a full spectrum of discovery services and technologies for the generation, characterization, engineering, optimization and selection of drug candidates to transform concepts into IND, and seamlessly transitioning to CMC. Several platforms are accessible to clients to support the biologics discovery process, including WuXiBody, hybridoma systems, phage display, VHH immune libraries, and the OminiAb and Allogy Therapeutics transgenic technologies.

- WuXiBody® : bsAb drug development

WuXiBody is a proprietary technology platform developed by WuXi Biologics for bsAb development. The platform can speed up the drug development process by 6–18 months and significantly reduce production costs. The WuXiBody platform enables almost any mAb sequence pair to be assembled in the bsAb form.

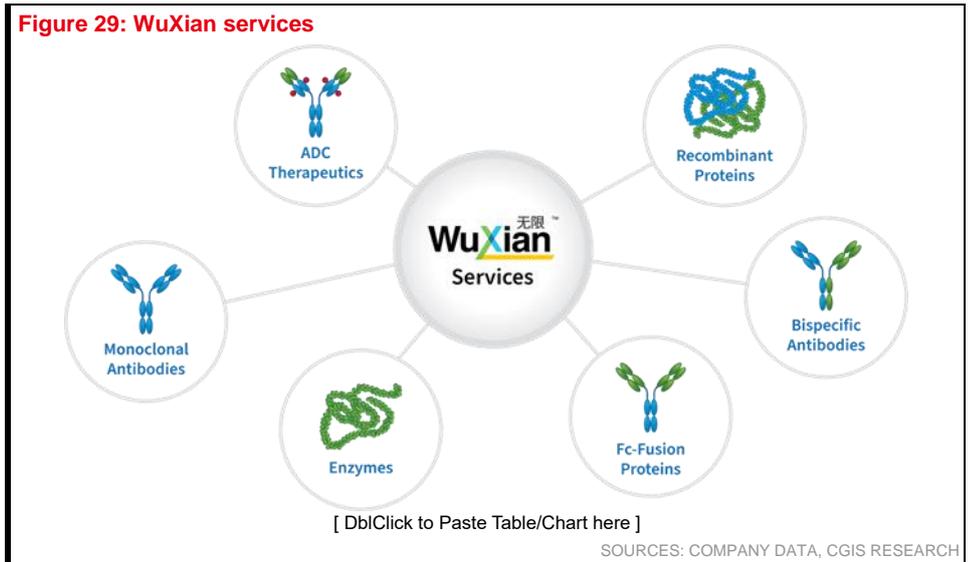
The “D” of CRDMO

WuXi Biologics constructed the WuXian, WuXia, WuXiUP and WuXiDAR4 platforms to facilitate the biologics development process. At the preclinical development stage, it provides services like cell line engineering and development, assay, formulation and process development, product analytical characterization, cGMP cell banking and cell line characterization, assay and process validation, and viral clearance validation. At the clinical development stage, it provides mAb/recombinant protein/ADC cGMP drug substance manufacturing, lot release and stability testing, fill & finish, and regulatory support services.

- WuXian™: custom protein generation services

WuXian protein generation services can generate a wide variety of proteins from mammalian, microbial and insect protein expression systems. The company has an industry-leading team of cell culture, purification and analytical experts to deliver high-quality proteins on-time to customers.

Figure 29: WuXian services



- WuXia™: cell line development

The WuXia cell line development system is ideal for a wide variety of biologics. The WuXia platform can deliver high-yield, well characterized, and stable single clones starting with a DNA or protein sequence from the client and enables 150 intergraded CMC projects per year.

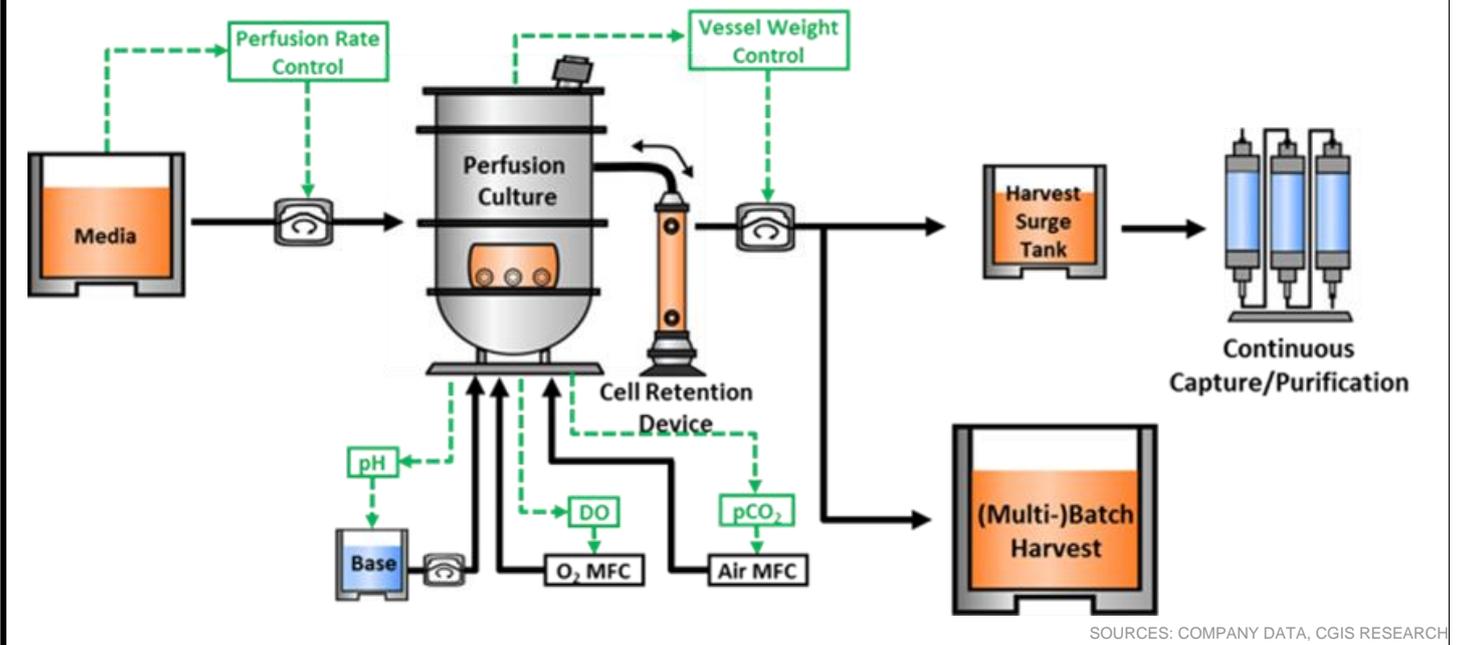
Figure 30: WuXia services



- WuXiUP™: ultra-high productivity continuous processing

WuXiUP is an intensified perfusion culture process that enables the manufacture of a variety of proteins with higher productivity than using fed-batch or traditional perfusion culture. WuXiUP also reduces resin usage, which requires a smaller facility footprint, leading to significant cost savings.

Figure 31: WuXiUP process



- WuXiDAR4™: antibody ratio technology platform

The patented WuXiDAR4 drug antibody ratio (DAR) platform enhances the DAR4 percentage in the final ADC product. DAR4 means four payload molecules per mAb in the final ADC product. A major challenge for the ADC industry is precisely controlling DAR. By using WuXiDAR4, the homogeneity of the ADC product is tightly controlled, which allows more precise quality control and more accurate assessment of ADC clinical efficacy.

The “M” of CRDMO

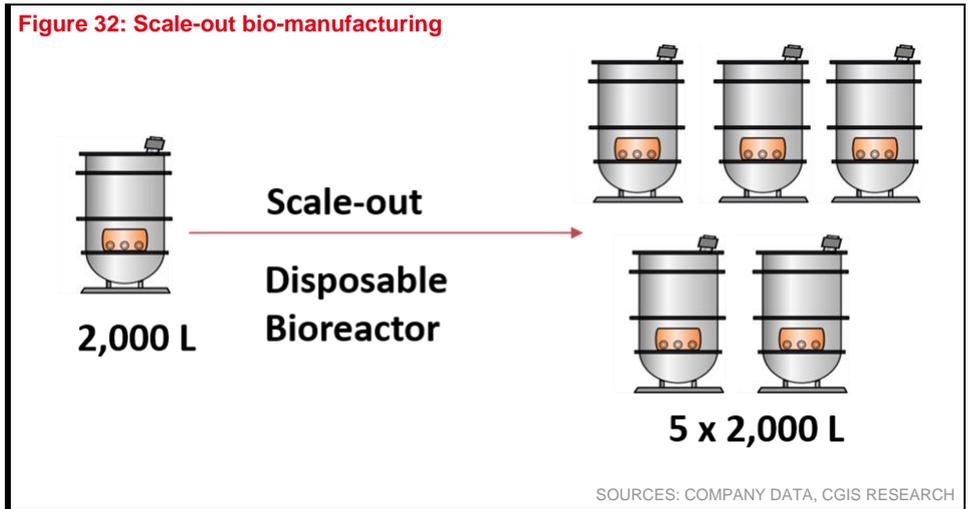
WuXi Biologics also provides commercial manufacturing services supported by its single-use bioreactors, scale-out biomanufacturing, continuous manufacturing, and robotic aseptic filling technologies.

- Disposable single use bioreactor

Ten to 20 years ago, the main focus of the biologics CDMO industry was the mass production of blockbuster drugs, so stainless steel bioreactors were used. But with the development of new modalities and the increased demand for producing products in specific quantities, single-use bioreactors became more popular. Plastic disposable equipment has higher flexibility and wider variety. In addition, because each lot use new disposable equipment, no cleaning or validation is required. Therefore, the production can be started faster than using stainless steel bioreactors, and it is more cost effective. It also lowers the risk of contamination. WuXi Biologics operates several of the world’s largest biologics cGMP manufacturing facilities that exclusively use single-use bioreactors at a scale ranging from 200L to 4,000L.

- Scale-out biomanufacturing for drug substances

WuXi Biologics uses a scale-out instead of a scale-up strategy to achieve higher volume production scale. Scale-out manufacturing utilizes multiple bioreactors run in parallel to produce late stage clinical materials or commercial stage products that require large volume, using the same size bioreactor used in the early clinical trial stages. Since the same size bioreactor is used through the whole development and commercial stages, there is less quality and process risk when volume increases. In addition, an adverse event in a single bioreactor does not mean the whole production lot is lost.



Follow the molecule and Win the molecule strategies

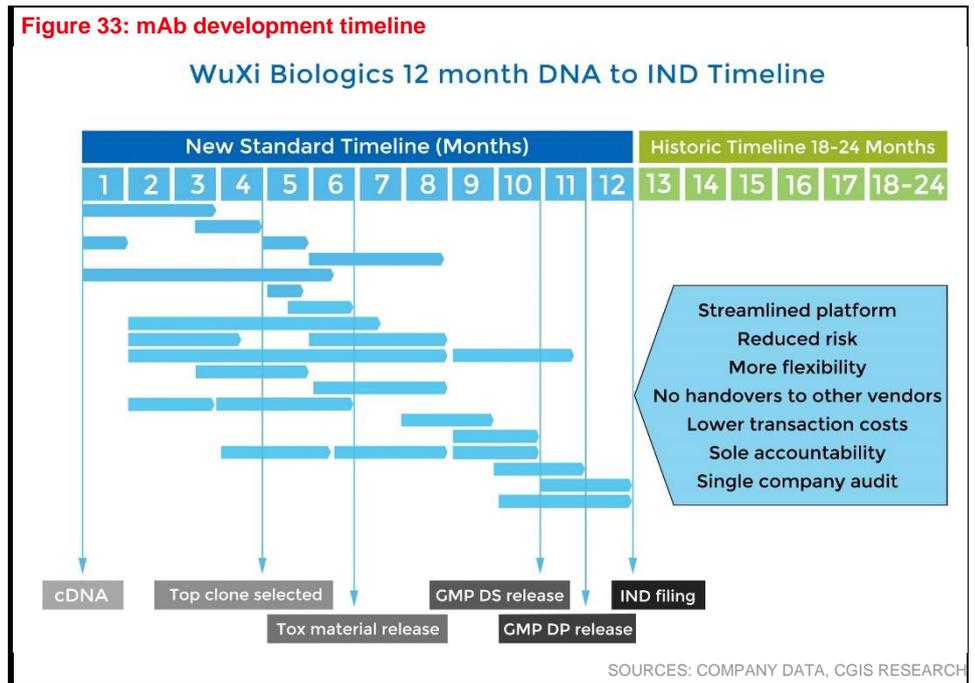
The company’s business is built on follow the molecule (FtM) and win the molecule (WtM) strategies. Typically, client demand for the company’s services increases as their biologics advance through the drug development process and ultimately to commercial manufacturing. Also, revenue from each integrated project typically increases as the project advances. The company is entitled to share the upside of its clients’ projects through milestone and royalty fees in certain projects. Its clients tend to use the company’s integrated services from the beginning of a project and do not change to other services providers, because of regulatory requirements and the lengthy and costly technology transfer process. The FtM strategy can give more visibility on clients’ future demand, which helps the company plan its business expansion in advance. In addition, as WuXi Biologics can provide a full spectrum of services during the biologics development and manufacturing process, it can also bring external projects into its pipeline from other CDMOs. Its clients can initiate a project with WuXi Biologics at any stage in the drug development process. In 2021, 18 external projects were transferred to WuXi Biologics.

DNA to IND: 12-month Ab therapeutic development timeline

The company stepped up its efforts to enable the development of multiple anti-COVID-19 neutralizing Abs (nAbs). The company took prompt action to accelerate the development of nAbs, from DNA to IND, in four to six months. Traditional, it takes 12 to 18 months. It took only 14 months for the company to get EUA approval for anti-COVID-19 nAb Sotrovimab of Vir Biotechnology/GSK from DNA.

A proven track record of expediting 12-month DNA to its IND timeline gives WuXi Biologics an advantage over its competitors. It can help its clients expedite their candidates to the clinical stage, which gives it a competitive advantage over competing products, reduces development costs and the internal burn rate, and simplifies project execution by choosing single end-to-end service provider rather than multiple vendors.

Figure 33: mAb development timeline



DS and DP Manufacturing Capacity

Over 260,000L of bioreactor capacity will be available by the close of 2022 for both clinical trials and commercial drug substance (DS) supply, and its capacity will increase to 580,000L in five countries by 2026, including the newly announced Singapore CRDMO center. As at Jun 30, 2022, most of the company’s manufacturing capacity was fully and efficiently utilized, thanks to a large number of integrated projects, including both COVID and non-COVID projects. As at Jun 30, 2022, the company’s operational DS manufacturing capacity and designed DS manufacturing capacity is listed in Figure 32. The company has continued to increase its capacity domestically and internationally in alignment with the industry’s rapid growth to meet demand for a rapid increase in the company’s global late-stage and commercial projects, through new construction and global acquisitions.

Figure 34: WuXi Biologics’ global network in 2026F

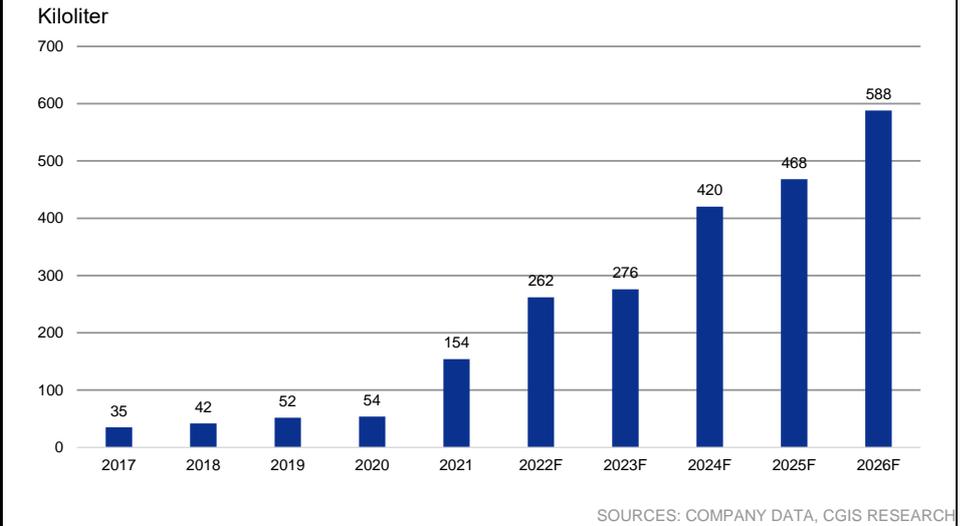


Figure 35: DS manufacturing in use and in design, as of Jun, 2022

Facility	Highlights	Location	Current Capacity	Designed Capacity	Designed Usage
MFG1	<ul style="list-style-type: none"> WuXi Biologics' first biologics manufacturing facility in China and approved by the U.S. FDA, the EU EMA, France HAS and China NMP Only utilize single-use bioreactors 	Wuxi	12,500L Fed-batch/Perfusion		
MFG2	<ul style="list-style-type: none"> Offer a highly flexible manufacturing facility through combination of multiple 2,000L and 1,000L disposable bioreactors Received GMP accreditation from various regulatory agencies, including but not limited to China NMPA, U.S. FDA, Japan PMDA and Italy AIFA and completed a remote GMP inspection by South Korea's MFDS Fully utilized by two commercial products and one post-process performance qualification (PPQ) product, producing substantial amount of neutralized antibody for COVID-19 during the Report Period 	Wuxi	28,000L Fed-batch, 4,000L Perfusion		
MFG3	<ul style="list-style-type: none"> With MFG3, Shanghai site offers complete one-stop biologics development and manufacturing services in one central location 	Shanghai			
MFG4	<ul style="list-style-type: none"> The first GMP facility in China to use the industry's largest disposable bioreactor (4,000L) Successful DS PPQ production of COVID-19 vaccine in supporting WHO inspection 	Wuxi	10,000L Fed-batch		
MFG5	<ul style="list-style-type: none"> One of the world's largest single-use bioreactor-based cGMP biologics facility 	Wuxi	60,000L Fed-batch, 4,000L Perfusion		
MFG6	<ul style="list-style-type: none"> GMP Manufacturing available in 2022 	Dundalk, Ireland		6,000L perfusion	Commercial
MFG7	<ul style="list-style-type: none"> When completed, this facility will represent one of the world's largest facilities using single-use bioreactors. 		48,000L fed-batch	Commercial	
MFG8	<ul style="list-style-type: none"> GMP manufacturing available in 2022 Will be built to meet cGMP standards of the US, the EU and China 	Shijiazhuang		48,000L fed-batch	Commercial
MFG9	<ul style="list-style-type: none"> GMP ready in 2024 	Wuxi		120,000L fed-batch	Commercial
MFG10	<ul style="list-style-type: none"> GMP Available in 2023 Will be the company's first overseas site in Asia. 	Singapore		120,000L fed-batch	Commercial
MFG11	<ul style="list-style-type: none"> GMP Available in 2024 	Worcester, MA		24,000L fed-batch	Clinical/Commercial
MFG12	<ul style="list-style-type: none"> GMP Available in 2023 Will include integrated drug development, clinical and commercial manufacturing facilities 	Chengdu		48,000L fed-batch	Clinical/Commercial
MFG13	<ul style="list-style-type: none"> Part of the Group's microbial and viral platform (MVP) business unit Support the integrated CMC development and GMP manufacturing of viral vector based products like gene therapy vectors, oncolytic virus and vaccines 	Hangzhou	2,000L		
MFG14	<ul style="list-style-type: none"> Part of the Group's MVP business unit in Hangzhou Offers services of integrated CMC package based on E. coli and yeast host systems As of 1H22, MFG14 had been working on more than 20 projects for various modalities spanning recombinant protein, virus like particle, enzyme, plasmid DNA, etc. 	Hangzhou	2,300L		
MFG17	<ul style="list-style-type: none"> Acquired from Bayer in december 2020 Global Dual Source network for supply of vaccines and other biologics. Together with DP7 in Leverkusen the DS facility will be used for commercial manufacturing. 	Shanghai		10,000L fed-batch	Clinical
MFG18	<ul style="list-style-type: none"> GMP Available in H2 2021 The first operational bioprocessing site in North America for WuXi Biologics Will contain both upstream and downstream process development laboratories and two suites of single-use bioreactors for clinical trial drug substance production. 	Cranbury, NJ		6,000L fed-batch	Clinical
MFG19	<ul style="list-style-type: none"> GMP Available H2 2021 Acquired from Bayer in December 2020 	Wuppertal, Germany		15,000L fed-batch/perfusion	Commercial
MFG20	<ul style="list-style-type: none"> Acquired from Pfizer China in Hangzhou, designed 8,000L, designed 8,000L capacity with further expansion plan GMP released in 2021 	Wuppertal	8,000L Fed-batch		
MFG21	<ul style="list-style-type: none"> GMP certificated facility acquired in 2021 Applies single-use technology with four upstream production lines with flexible capacities and two downstream purification lines 	Suzhou	7,000L Fed-Batch		

SOURCES: COMPANY DATA, CGIS RESEARCH

Figure 36: WuXi Biologics's historical and designed DS capacity by year



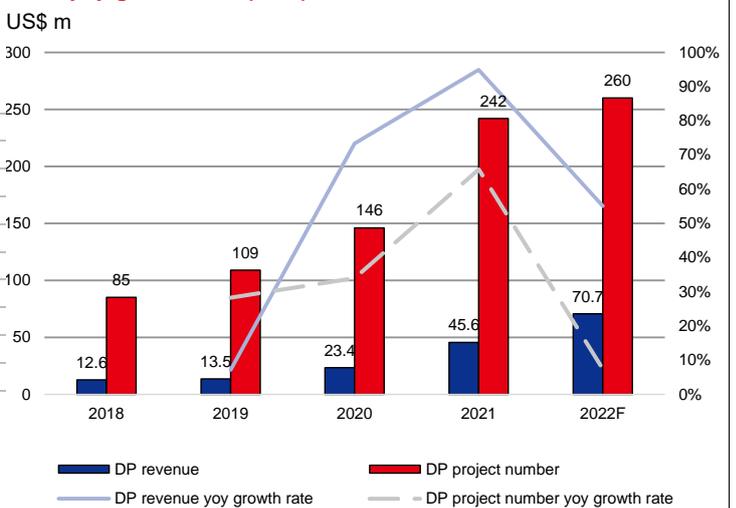
While the DS capability and capacity of the company is well known, WuXi Biologics also expanded its drug product (DP) development in the past decade. It established one-stop comprehensive DP services for biologics, vaccines, and small molecule parenteral covering all clinical and commercial drug formulations and processes. The company's capabilities include the development of liquid frozen, lyophilized dosage forms, and multiple container closure systems (CCS), including vials and combination products such as pre-filled syringes (PFS), PFS with needle safety devices (NSD), and autoinjectors (AI). As at Jun 30, 2022, the company had witnessed rapid growth in the number of DP projects.

Figure 37: DP manufacturing facilities of WuXi Biologics, as of Jun, 2022

Facility	GMP Ready	Location	Usage
DP1	2013	Wuxi	Clinical/Commercial Reg. Agency Certified
DP2	2021	Wuxi	Clinical/Commercial
DP3	2019	Wuxi	Clinical
DP4	2019	Wuxi	Clinical/Commercial Reg. Agency Certified
DP5	2022	Wuxi	Commercial
DP6	2020	Germany	Clinical/Commercial Reg. Agency Certified
DP7	2021	Hangzhou	Commercial Reg. Agency Certified
DP9	2021	Hangzhou	Commercial
DP10	2021	Hangzhou	Clinical/Commercial
DP11	2021	Suzhou	Clinical
DP12	2022	Cranbury, NJ	Clinical

SOURCES: COMPANY DATA, CGIS RESEARCH,

Figure 38: DP project number and DP revenue (LHS) as well as their yoy growth rate (RHS)



New modalities

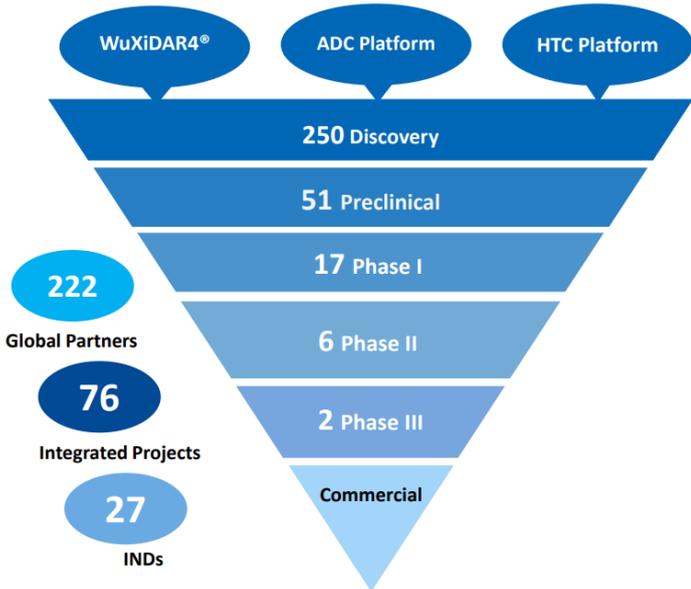
WuXi XDC – Bioconjugation

WuXi XDC is a WuXi Biologics subsidiary and a joint venture between WuXi Biologics and WuXi AppTec subsidiary WuXi STA. Owing to the complex structure of XDC molecules, the joint venture greatly expedited XDC drug development by leveraging technologies from WuXi Biologics and WuXi AppTec. WuXi XDC can provide one-stop service for the development and commercial manufacturing of bioconjugate drugs in one centralized geographic region. As at Jun 30, 2022, it had completed over 130 projects, from preclinical to commercial scale.

WuXi Vaccines

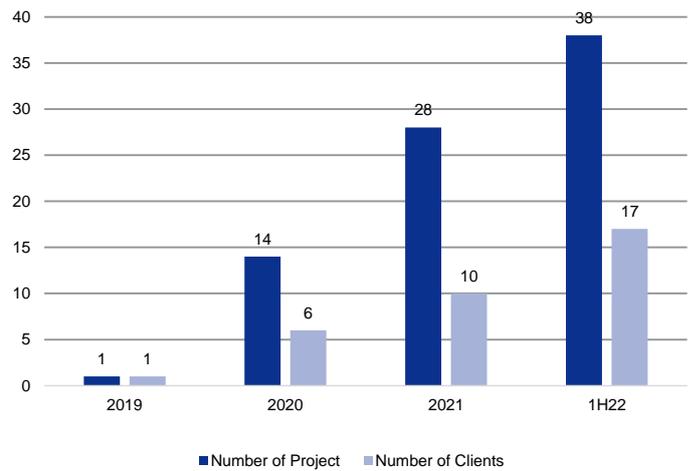
WuXi Vaccines was established in 2018 as a joint venture between WuXi Biologics and Shanghai Hile BioTechnology. The first contract of WuXi Vaccines was signed in 2019 for a 20-year supply of innovative viral vaccines. In 2020, it signed its first COVID-19 project. As at June 30, 2022, over 500m doses of COVID-19 vaccines had been delivered, and WuXi Vaccines had served for 17 clients on 38 projects. Platforms with vaccine contracts signed including CHO, adenoviral vectored, microbial, mRNA and attenuated live viral. In order to meet the demands of vaccine projects, WuXi Vaccines has planned new capacity in Germany, China and Singapore.

Figure 39: Cumulative number of projects of WuXi XDC, as at Jun 30, 2022



SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 40: Historical cumulative number of projects and clients of WuXi Vaccines



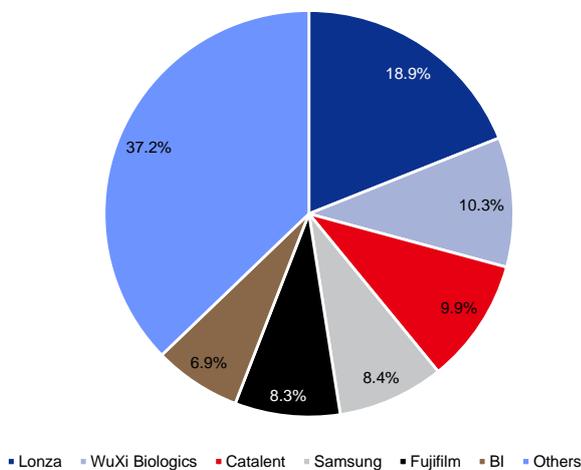
SOURCES: CGIS RESEARCH, COMPANY DATA

Competitive landscape

The global biologics outsourcing services market is highly fragmented among the top six players. WuXi Biologics was the second-largest player in 2021 in the biologic outsourcing industry and accounted for 10.3% of biologics outsourcing market share by revenue. While, Swiss-headquartered company, Lonza was the largest biologic outsourcing service provider and accounted for 18.9% of biologics outsourcing market share in 2021.

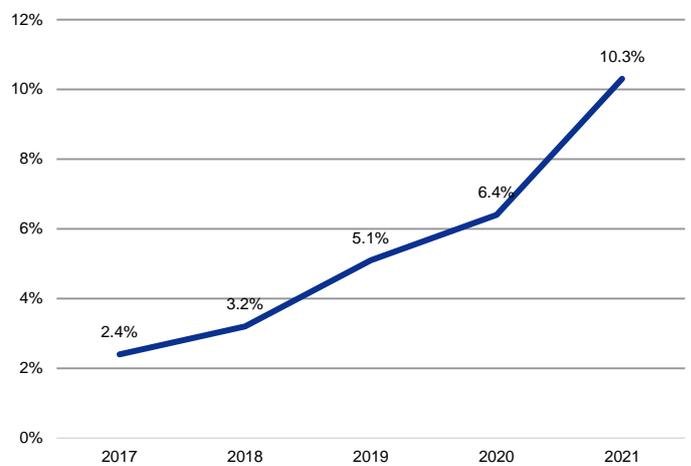
Other top players are Catalent, Samsung Biologics, Fujifilm, and Boehringer Ingelheim (BI). In 2017, WuXi Biologics accounted for only 2.4% of the global biologics outsourcing market, but it expanded very fast during the past five years and was able to compete with strong competitors like Lonza, Samsung Biologics and BI.

Figure 41: Market share of global biologic outsourcing by revenue in 2021



SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 42: Global biologics outsourcing market share by revenue of WuXi Biologics from 2017 to 2021



SOURCES: CGIS RESEARCH, COMPANY DATA

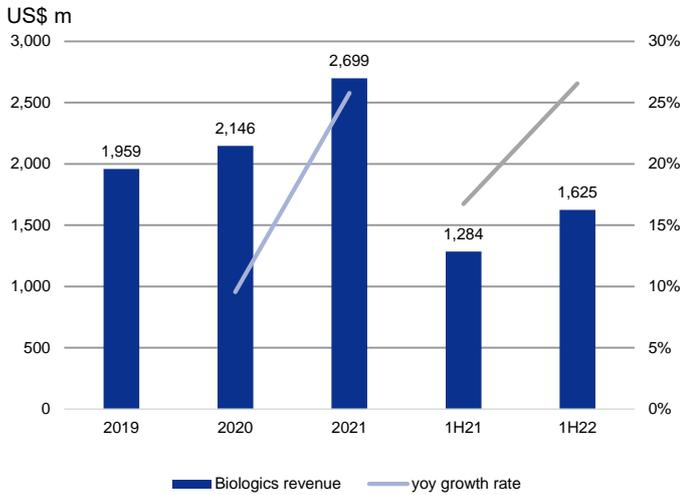
Lonza, the leading player in the biologics outsourcing industry, was founded in 1897 in Switzerland. With operations across five continents and 17,000 employees, Lonza is also the largest CDMO company by market capitalization. Currently, Lonza offers services in four categories: biologics, small molecules, cell & gene, and capsules & health ingredients. Its biologics division provides services from preclinical to commercialization for drug products. In 2021, Lonza's biologics division had revenue of US\$2.7bn, representing a yoy sales growth rate of 26%, and US\$1.6bn in 1H22 for a yoy sales growth rate of 27%. As at the end of 2021, Lonza had manufacturing capacity of about 303,000L for biologics and continued to invest in new capacity in Portsmouth (US), Viso (Switzerland) and Guangzhou (China).

Samsung Biologics currently has the largest biologics manufacturing capacity. Samsung Biologics was established in 2011. It had revenue of US\$1,370.1m in 2021, representing 34.6% yoy growth; 92% of its total revenue came from its CMO business. Its 2021 gross margin was 46.3%. Samsung Biologics is also widening the scope of its business to CDO services. Currently, Samsung has production capacity of 364,000L. After completing Plant 4, which will be GMP ready in 2023F, Samsung Biologics will have a total biomanufacturing capacity of 620,000L, according to Samsung Biologics' FY21 financial report.

The CMO business of (BI) achieved net sales of €917m (US\$1.08bn) in 2021, representing a growth rate of 9.5%. As at the end of 2022, BI CMO had manufacturing capacity of 275,000L. New Jersey headquartered CDMO Catalent also reported strong 2021 revenue of US\$1.93bn, representing an 89% yoy growth rate in its biologics segment. Cell and gene therapies are also included in Catalent's biologics division. Catalent has global expansion plans, and US-based Fujifilm is aggressively expanding capacity. As at the end of 2021, three companies had global biologics production capacity of about 300,000L:

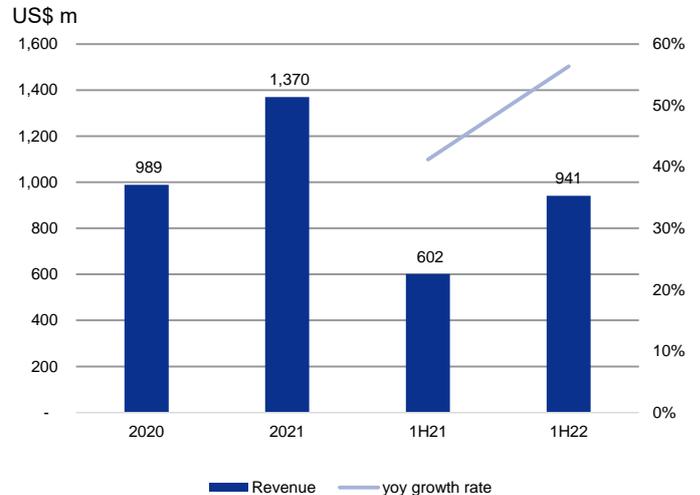
Samsung Biologics, Lonza and BI. According to WuXi Biologics' capacity expansion plan, its DS capacity will reach 262,000L at the end of 2022. Therefore, most of the leading players had capacity expansion plans to meet the increasing market demands.

Figure 43: Lonza's biologics business historical revenue (LHS) and yoy growth rate (RHS)



SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 44: Samsung Biologics historical revenue (LHS) and yoy growth rate (RHS)



SOURCES: CGIS RESEARCH, COMPANY DATA

In a nutshell, the market of biologic outsourcing is dominated by a few players with large-scale manufacturing facilities. Among them, WuXi Biologics has been one of the fastest-growing CDMOs in the past five years. WuXi Biologics' market share increased from 2.4% in 2017 to 10.3% in 2021. Since WuXi Biologics has partnered with large global pharmaceutical companies, and there has been a significant increase in the number of late-phase projects, we estimate that WuXi Biologics still has potential to increase its market share of biologics outsourcing business. Other domestic CXO companies are listed in Figure 45. The 2021 performance of some companies were analyzed in our previous report, "China CXO sector (Link)".

Figure 45: Peer comparison

Company name	Bloomberg Ticker	Rating	Target price	Last price	Market cap	P/E (x)			3yrs EPS CAGR	P/BV (x)			EV/EBITDA (x)			ROE (%)			Dividend Yield (%)		
						(local curr)	(local curr)	(US\$, m)		2022F	2023F	2024F	2022F	2023F	2024F	2022F	2023F	2024F	2022F	2023F	2024F
China's CRO companies																					
Hangzhou Tigermed Consulti-H	3347 HK	NR	na	53.80	9,014	14.9	12.2	10.3	na	2.1	1.7	1.5	26.6	20.3	17.2	14.0	15.3	15.7	1.3	1.9	2.0
Pharmaron Beijing Co Ltd-H	3759 HK	NR	na	31.95	7,593	17.6	12.7	9.4	30%	3.0	2.6	1.9	20.8	15.2	11.8	16.3	18.8	20.6	1.1	1.5	2.2
Joinn Laboratories China C-H	6127.HK	NR	na	26.55	3,651	17.8	13.8	10.8	28%	1.7	1.5	1.3	31.0	21.7	16.8	10.3	11.8	13.4	1.4	1.8	2.0
Chempartner Pharmatech Co-A	300149 CH	NR	na	9.01	626	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
Boji Medical & Technologic-A	300404 CH	NR	na	6.92	355	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
Shanghai Medicilon Inc-A	688202 CH	NR	na	200.69	2,427	35.9	23.4	16.1	57%	9.6	6.9	4.8	28.4	19.7	13.8	27.4	30.7	32.0	na	na	na
China's CDMO companies																					
Genscript Biotech Corp	1548 HK	NR	na	14.46	3,895	na	na	153.5	-141%	5.7	7.1	6.1	na	na	29.9	-39.6	-44.9	-5.1	na	na	na
Wuxi Apptec Co Ltd-H	2359 HK	NR	na	60.40	27,519	19.9	16.8	13.5	33%	3.5	3.0	2.6	17.7	14.6	11.7	19.8	19.8	20.7	1.2	1.4	1.9
Asymchem Laboratories Tian-H	6821 HK	NR	na	85.25	6,451	10.2	10.7	9.5	na	1.8	1.6	1.4	12.1	12.1	10.7	19.9	16.2	14.6	2.4	1.3	1.1
Shenzhen Hepalink Pharmace-H	9989 HK	NR	na	4.97	2,647	6.2	5.0	4.3	86%	na	na	na	13.9	12.4	10.8	9.9	11.9	12.9	2.4	3.1	3.5
Porton Pharma Solutions L-A	300363 CH	NR	na	43.09	3,262	13.2	13.4	11.5	57%	4.1	3.2	2.6	11.0	12.1	9.4	31.9	24.5	22.6	1.3	1.4	1.6
Zhejiang Jiuzhou Pharmaceu-A	603456 CH	NR	na	37.33	4,333	34.1	25.2	19.0	37%	5.8	4.9	4.0	21.2	16.4	13.1	17.4	19.6	21.1	1.1	1.4	2.0
Overseas CRO companies																					
Cmic Holdings Co Ltd	2309 JP	NR	na	1622.00	211	6.4	11.0	9.7	14%	na	na	na	3.5	4.8	4.5	15.9	8.9	9.5	4.7	2.7	3.1
Icon Plc	ICLR US	NR	na	183.98	14,999	15.7	14.2	12.3	87%	1.8	1.7	1.5	13.5	12.2	11.1	11.5	11.2	12.9	0.0	0.0	0.0
Iqvia Holdings Inc	IQV US	NR	na	175.91	32,809	17.5	15.4	13.3	38%	5.7	5.1	4.5	13.2	12.0	10.8	31.3	32.5	33.0	0.0	0.0	0.0
Laboratory Crp Of Amer Hldgs	LH US	NR	na	205.71	18,596	10.2	11.5	10.5	-7%	1.8	1.6	1.5	7.5	8.4	7.8	18.0	14.7	15.0	1.1	1.2	1.1
Medpace Holdings Inc	MEDP US	NR	na	158.60	4,916	25.7	24.1	22.2	12%	10.8	7.7	5.9	18.9	18.2	16.6	36.5	41.4	34.7	na	na	na
Syneos Health Inc	SYNH US	NR	na	47.22	4,847	9.5	9.0	8.2	37%	1.4	1.2	1.1	9.1	8.5	7.8	14.0	14.4	15.0	0.0	0.0	0.0
Overseas CDMO companies																					
Samsung Biologics Co Ltd	207940 KS	NR	na	801000.00	39,734	97.2	82.1	71.1	24%	8.0	6.9	5.6	59.6	44.4	38.0	10.3	9.7	9.0	0.0	0.0	na
Catalent Inc	CTLT US	NR	na	74.98	13,489	19.7	19.8	16.8	16%	2.8	2.5	2.3	13.4	12.7	11.1	14.7	13.0	13.3	na	na	na
Lonza Group Ag-Reg	LONN SW	NR	na	485.80	36,134	32.4	27.5	23.4	-19%	3.5	3.2	3.0	18.7	16.2	13.9	10.4	11.5	12.3	0.7	0.7	0.8
Thermo Fisher Scientific Inc	TMO US	NR	na	510.84	200,141	22.2	21.0	18.6	12%	4.4	4.2	3.8	19.2	18.5	16.6	20.6	20.6	21.6	0.2	0.2	0.3
Average						22.4	19.4	23.2	38%	4.3	3.7	3.1	18.9	15.8	14.2	18.4	18.2	18.4	1.6	1.5	1.8
Wuxi Biologics Cayman Inc	2269 HK	ADD	111.6	45.80	24,907	39.6	28.3	20.8	36%	4.9	4.2	3.5	30.2	21.8	15.9	13.1	15.9	18.3	0.0	0.0	0.0

Closing price as of 10 Oct 2022

SOURCES: CGIS RESEARCH ESTIMATES, COMPANY DATA, BLOOMBERG

Note: Estimates for Not rated companies are based on Bloomberg consensus estimates

Investment risks

Two sites of WuXi Biologics added to the US government UVL

In Feb 2022, the Wuxi and Shanghai sites of the company were added to the US government's unverified list (UVL). The details of this and its impact were discussed in our previous report, "US government adds 33 Chinese companies to the unverified list (Link)." Basically, the impact of being included in the UVL is that US suppliers cannot ship certain bioreactor hardware and special filters to the Wuxi and Shanghai sites. Except for these two sites included in the UVL, everything the company needs can be purchased legally from global vendors, including the US. However, the WuXi and Shanghai sites do not need to purchase more bioreactors. The company also has enough filters in stock, and it can purchase filters from European and Japanese suppliers. Therefore, there had been no meaningful impact on its global clients. In addition, the company has made significant progress to resolve this problem. In Oct, 2022, the Wuxi site of the company had been removed from the US government UVL list after an onsite inspection of the Wuxi site. The company is also working closely with relevant government authorities to schedule the on-site end-use check of the Shanghai site to be also removed from the UVL list. We believe the general impact of the UVL on WuXi Biologics' business has been limited, and as the COVID-19 pandemic eases, the company's Shanghai site is also moving actively towards being removed from the UVL.

US advances its National Biotechnology and Biomanufacturing Initiative

In Sep 2022, the US announced new investments and resources to promote the domestic development of biotechnology and biomanufacturing. The aim of the National Biotechnology and Biomanufacturing Initiative is to promote the biomanufacturing of drugs and bio-based materials for the defence supply chain, such as fuels, fire-resistant composites, polymers and resins. The pharmaceutical industry is not the only industry that relies on biomanufacturing. Biomanufacturing, or synthetic biology, is a future manufacturing trend, as it can be used to manufacture bio-fuels, plastics, etc. The aim of the initiative is not to ban Chinese CXO services, but to encourage US domestic biomanufacturing. China also emphasized the development of synthetic biology in 14th Five Year Plan for biologics development.

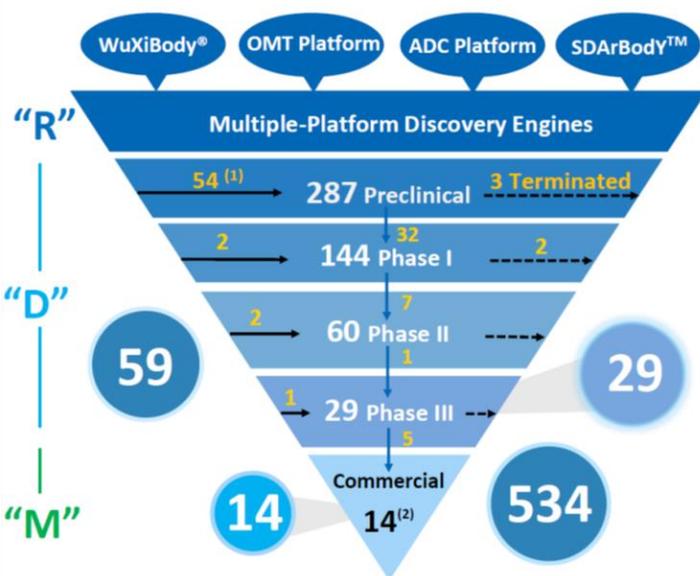
Biomanufacturing is heavily CAPEX-dependent. It takes several years to build factories and infrastructure. More time is required, especially given the US inflation rate. Therefore, in our opinion, in practice, from a short-term point of view, the impact on China's CXO companies is limited. In the long term, the overseas capacity plan of WuXi Biologics will not conflict with the initiative from a long-term perspective. In addition, large pharmaceutical companies and biotech companies have development and manufacturing costs to consider. They use CXO services to achieve cost effectiveness, because they do not need to establish in-house capacity and capability, which are CAPEX dependent and time consuming.

Financial Analysis and Forecasts

Sustainable integrated project number growth

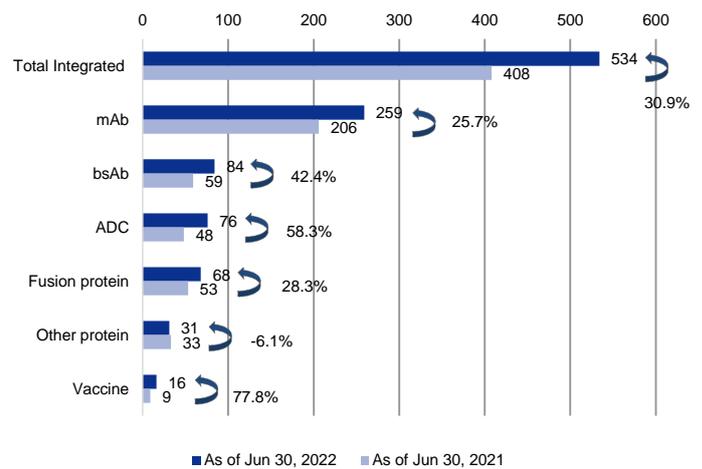
Given the implementation of the FtM and WtM strategies, the company has seen significant growth in the number of integrated projects. Integrated projects are projects that require multiple services from different departments of the company, and across various stages of the biologics development process. The total number of integrated projects increased by 30.9%, from 408 as at Jun 30, 2021 to 534 as at Jun 30, 2022, including about 500 non-COVID-19 integrated projects. The company added 59 new integrated projects to its pipeline in 2H21 and 1H22. In 2021, there were 148 new projects for a total of 482 projects, representing a growth rate of 44.3%. Of these 482 projects, 448 were non-COVID-19-related. The company has maintained sustainable growth in the number of integrated projects in the past three years even without COVID-19 projects. Most of the integrated projects are mAb candidates or products. However, there has been a large increase in the number of ADC projects. bsAb projects have also shown a high growth rate. ADC and bsAb projects have higher technical requirements and demand more in-depth expertise than mAb.

Figure 46: Number of integrated projects of WuXi Biologics as at Jun 30, 2022



SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 47: Number of integrated projects across all biologics modalities



SOURCES: CGIS RESEARCH, COMPANY DATA

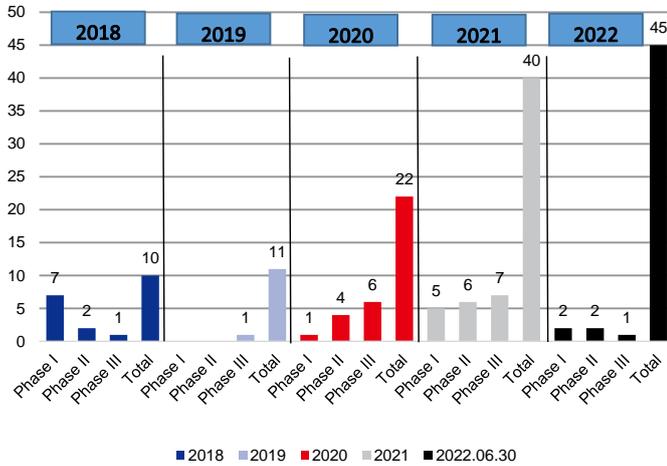
Regarding the growth in the number of projects of different phases, the total number of pre-clinical projects increased by 35.4%, from 212 as at Jun 30, 2021 to 287 as at Jun 30, 2022. The total number of early-phase (Phase I and II) projects increased by 27.5%, from 160 as at Jun 30, 2021 to 204 (144 in Phase I and 60 in Phase II) as at June 30, 2022. The number of late-phase (Phase III) projects and commercial manufacturing projects increased by 19.4%, from 36 as at Jun 30, 2021 to 43 as at Jun 30, 2022.

In 1H22, 32 projects progressed from the pre-IND stage to post-IND, which was a good demonstration of the company's FtM strategy. Five external projects were brought into the company's pipeline which was a good demonstration of the company's WtM strategy. Its WtM strategy has been a new driver to expand the company's pipeline in the past several years. In 2021, 40 external projects were added to the company's pipeline.

Basically, the fee income of the company is charged on a fee-for-service basis for the services provided. The fee level for each discovery, development or manufacturing step is determined based on the scope of the services required and the amount of time allocated. Typically, the revenue from a project increases as the project advances. Besides service fees, milestone fees are

paid at different R&D stages, and royalty fees are charged once the new drug is launched in the market for 5–10 years or until the patent expires. Therefore, the significant increase in the number of commercial project is a revenue growth driver.

Figure 48: External projects in the pipeline



SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 49: Typical revenue contribution from projects at different stages of development

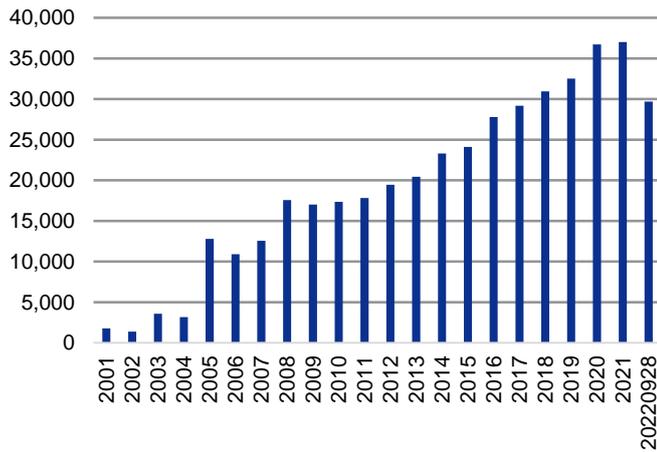
Biologics Development Process Stage	Typical duration	Typical Revenue
Pre-IND		
Drug discovery	2 years	US\$1.5-2.5m
Pre-clinical development	1-2 years	US\$5-8m
Post-IND		
Early-phase (phase I&II) clinical development	3 years	US\$4-6m
Late-phase (phase III) clinical development	3-5 years	US\$20-50m
Commercial manufacturing	Annually	US\$50-100m

SOURCES: CGIS RESEARCH, COMPANY DATA

The momentum of sustainable project number growth is expected to continue

With the easing of the COVID-19 pandemic globally, the impact on clinical trials has been gradually lifted. In 2021, there were 37,020 new registered clinical studies, which was similar to the number in 2020. A recovery is evident, since as at Sep 28, there were 29,687 new registered clinical studies. The increasing R&D pipeline will create more business opportunities for Wuxi Biologics. In addition, in combating COVID-19, Wuxi Biologics has further demonstrated its capability of biologics R&D to the world. It was able to transfer DNA to the EUA in 14 months for Vir/GSK’s Sotrovimab, an anti-COVID-mAb, which was several months faster than traditional mAb development. Because of the complex nature of biologic R&D and manufacturing, pharmaceutical companies are quite cautious when choosing outsourcing partners. Some important aspects to consider include quality assurance, time from DNA to EUA or BLA, development flexibility, and manufacturing cost. Wuxi Biologics’ full spectrum service landscape, and good track record of successfully developed biologics will help attract new clients. Therefore, we believe the number of projects of the company will continue to grow sustainably.

Figure 50: Number of newly registered clinical studies



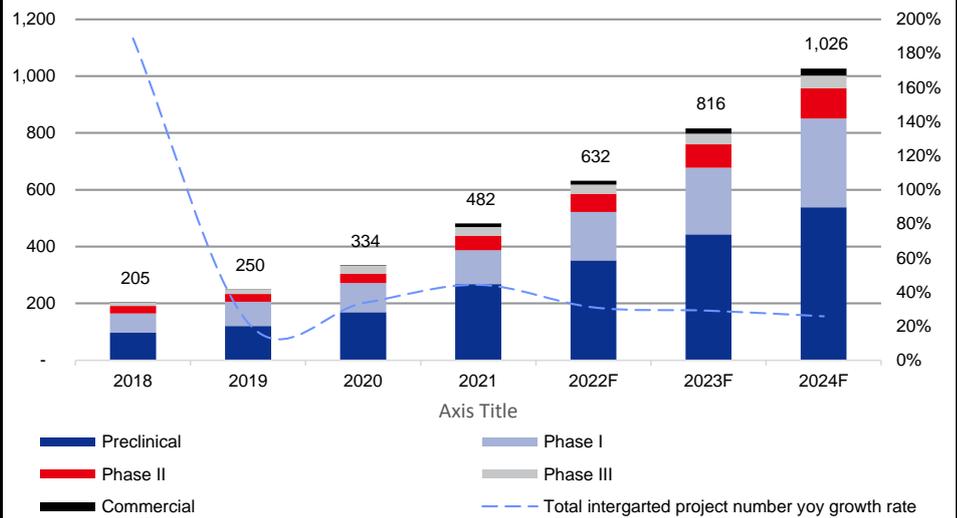
SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 51: Challenges for biologics development & manufacturing



SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 52: Historical and forecast integrated project number breakdown by business (LHS), and overall project number yoy growth rate (RHS)

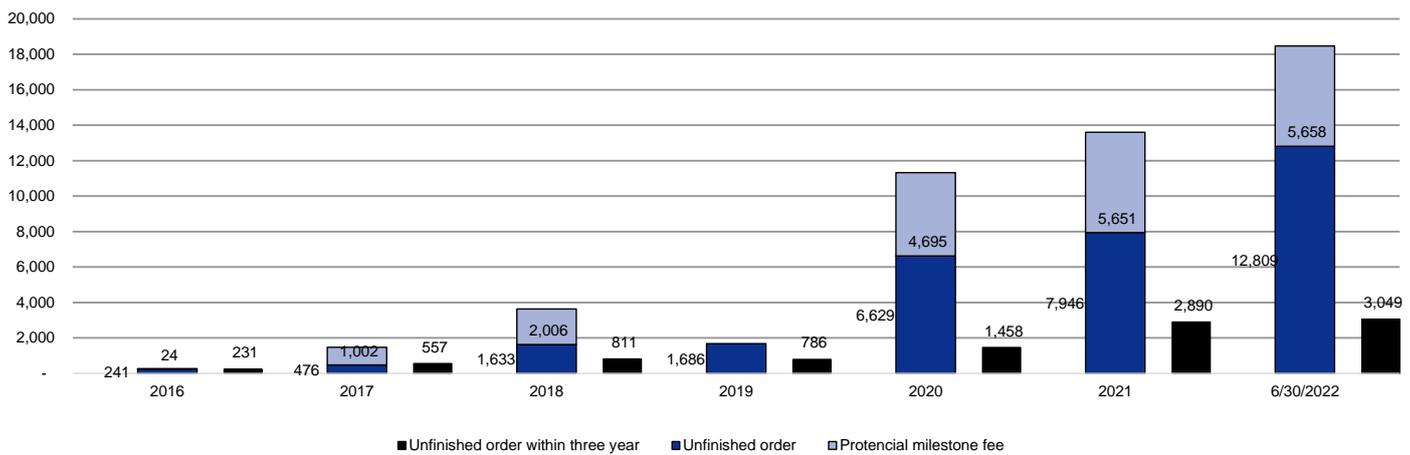


SOURCES: CGIS RESEARCH ESTIMATES, COMPANY DATA

Strong revenue growth

WuXi Biologics has a track record of strong revenue growth. Its revenue in 2021 rose to Rmb10.29bn, representing a growth rate of 83.3% yoy. Its revenue in 1H22 increased by 63.5% yoy to Rmb7.21bn, driven mainly by a substantial increase in project numbers, especially late-phase projects. When forecasting revenue, one powerful reference is the company's backlog, since its clients tend to engage with it at the pre-IND phase and continue to work with it throughout the biologics development process. Therefore, the total backlog includes the service backlog, representing the revenue the company has contracted but has yet to perform, and upcoming potential milestone fees, which the company has contracted but has not yet performed or received. The company's total backlog, including the service backlog and the upcoming potential milestone fees backlog, increased from US\$12.5bn as at Jun 30, 2021 to US\$18.5bn as at Jun 30, 2022. Of this, the service backlog increased from US\$7.2bn to US\$12.8m and the upcoming potential milestone fee backlog increased from US\$5.2bn to US\$5.7m. As at Jun 30, 2022, the total three-year backlog increased from US\$2.2bn to US\$3.0bn, which provides visibility for the company's short-term growth.

Figure 53: Total backlog (US\$ m)

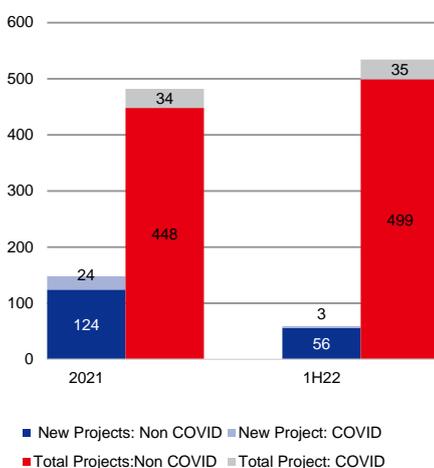


SOURCES: CGIS RESEARCH, COMPANY DATA

Non-COVID projects, especially late-phase projects expected to lead revenue growth in the long term

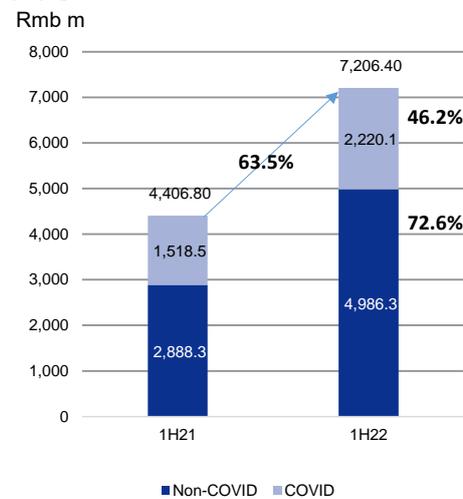
Since 2020, WuXi Biologics has helped its clients and partners combat COVID-19 worldwide by enabling more than 30 global INDs for COVID-19-related projects, supplying hundreds of millions of doses of COVID-19 vaccines, and manufacturing over 2,000kg of COVID-19 nAbs. COVID-19 projects contributed substantial revenues. The company’s expedited development of COVID-19 projects has demonstrated the power of its technology platforms and strong execution. Along with the additional contribution from COVID-19 projects, the number of non-COVID projects showed strong growth. As at Jun 30, 2022, 499 out of 534 total integrated projects were non-COVID projects and 8 out of 14 commercial projects were non-COVID projects. In addition, 124 out of 148 new projects in 2021 were non-COVID projects, and 56 out of 59 new projects in 1H22 were non-COVID projects. In 1H22, the revenue contribution derived from non-COVID projects increased more significantly than that for COVID projects. In addition, in 2022, non-COVID revenue growth has been stronger than total revenue growth. The inflow of the non-COVID revenue is a better indicator of the company’s mid- to long-term development.

Figure 54: Number of COVID and non-COVID projects



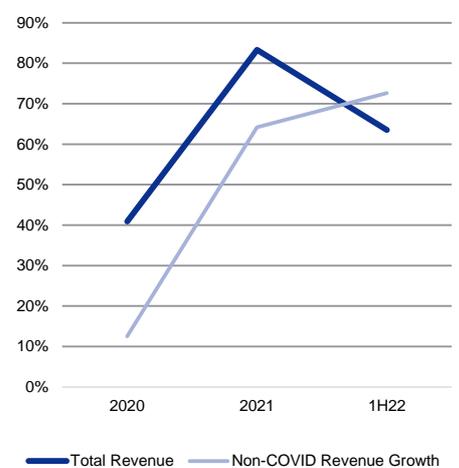
SOURCES: COMPANY DATA, CGIS RESEARCH

Figure 55: Revenue breakdown (LHS) and yoy growth rate



SOURCES: COMPANY DATA, CGIS RESEARCH

Figure 56: Growth rate of total revenue and non-COVID revenue

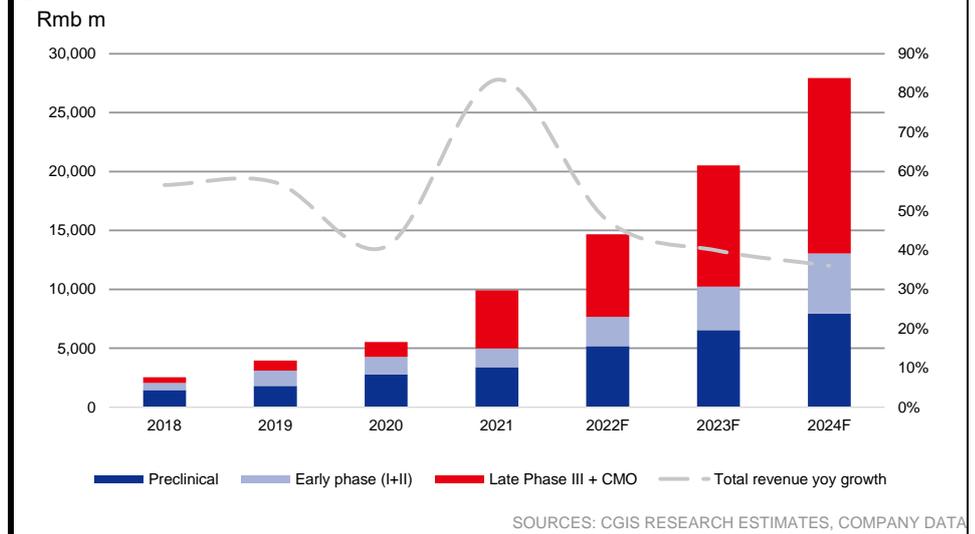


SOURCES: COMPANY DATA, CGIS RESEARCH

2021 was a banner year for WuXi Biologics’ CMO business. At the end of 2021, it had nine CMO projects compared to only two CMO projects at the end of 2020. The company has maintained accelerating business momentum in late-stage

and commercial manufacturing projects, contributing to significant revenue growth. As at Jun 30, 2022, it had 14 CMO projects, six of which were COVID-19 related and eight non-COVID-19 related. Because of the company's FtM strategy, more projects will advance to the commercial phase. In addition, with the implementation of its global capacity expansion, the company will have the capability and capacity to attract more late-phase projects. Based on our project number projection, and high revenue income per late-phase project, we forecast that the company's yoy revenue growth will be 48%, 40% and 36% in 2022F, 2023F and 2024F, respectively.

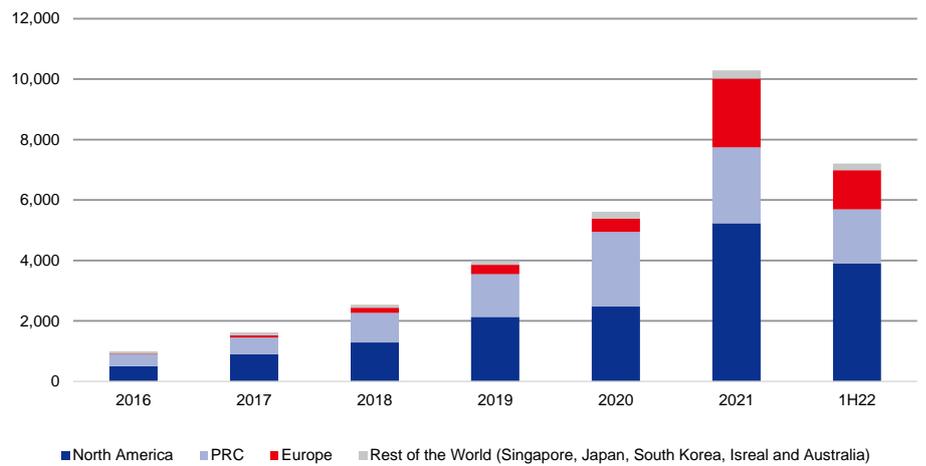
Figure 57: Historical and forecast revenue breakdown by project stage (LHS) and yoy growth rate of total revenue (RHS)



Overseas clients contribute more to total revenue

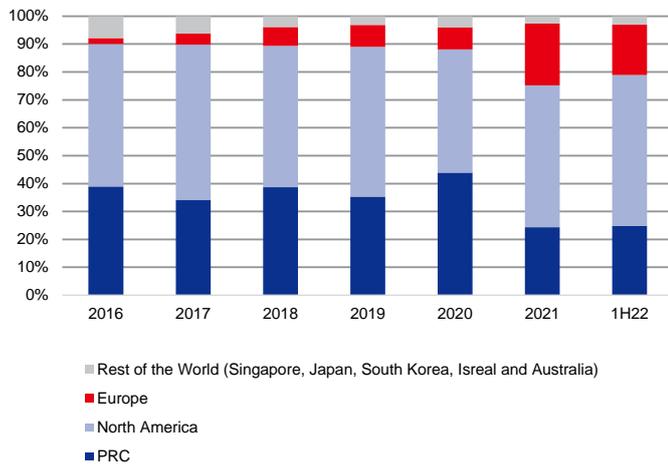
North America has always been the biggest market for the company. Despite the high base, North American revenue still had robust growth in 1H22, with a yoy growth rate of 78.0%. In 1H22, over 50 new projects and 32 new clients were added from North America. Given the uncertainty regarding China policies and the healthcare funding slowdown, China revenue in 2021 was at a similar level to that in 2020. But exciting growth resumed in 2022, with 24.9% yoy revenue growth in 1H22. Because of the significant revenue contribution from COVID projects, the EU market had a 409.7% yoy growth rate in 2021. Despite the high base in 1H21, the EU market still maintained solid growth of 31.0% in 1H22, with increased collaboration with top global pharmaceutical companies. Given the implementation of capacity expansion in Ireland, Germany and Singapore, we think there are further revenue growth potential in overseas markets. WuXi Biologics' global capacity expansion plan will also help mitigate possible geopolitical risks, in our view.

Figure 58: Historical revenue breakdown by global region (Rmb m)



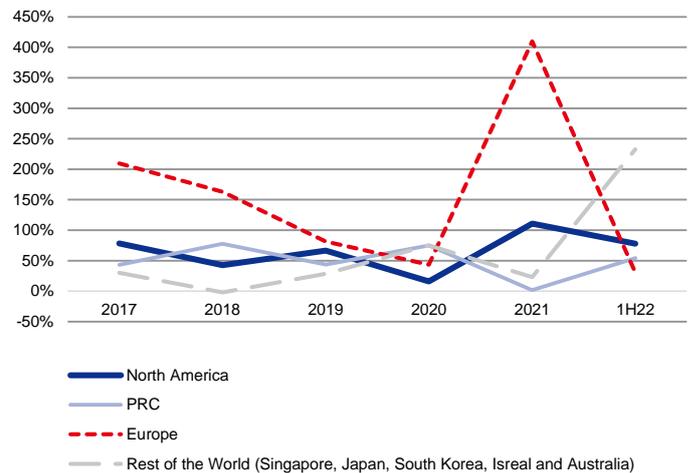
SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 59: Historical percentage of revenue by region



SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 60: Historical growth rate by region

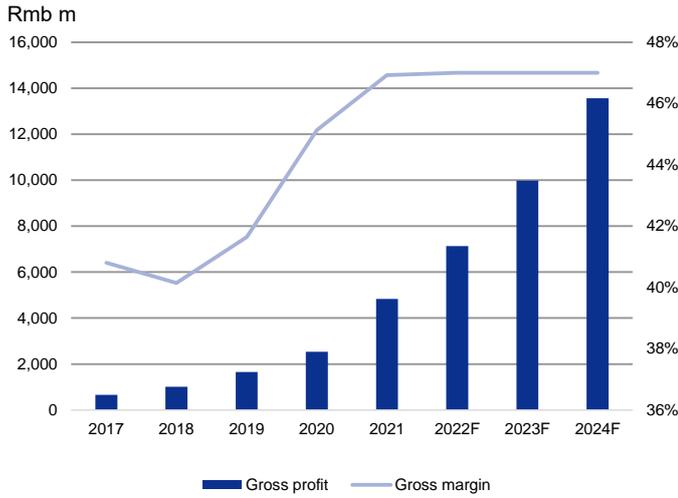


SOURCES: CGIS RESEARCH, COMPANY DATA

Net profit expected to grow along with revenue growth

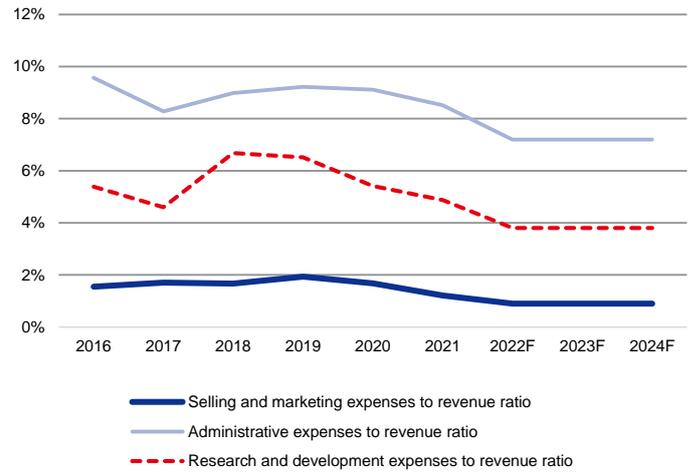
We expect the company's gross margin to remain steady in the coming years. The SG&A to revenue ratio was dropped in 1H22 thanks to the economy of scale and we expected the SG&A expenses to remain steady in the near future. Therefore net profit is estimated to grow along with revenue growth. We expect a net profit to shareholder yoy growth rate of 32%, 40% and 36%, respectively, in 2022E, 2023E and 2024E.

Figure 61: Historical and forecast gross profit (LHS) and margin (RHS)



SOURCES: CGIS RESEARCH ESTIMATES, COMPANY DATA

Figure 62: Historical and forecast SG&A to revenue ratio



SOURCES: CGIS RESEARCH ESTIMATES, COMPANY DATA

Valuation

We use the DCF method to value WuXi Biologics, given the current substantial backlog and strong profitability going forward. We derived our TP of HK\$111.6 based on a 10-year DCF model (WACC: 9.3%, terminal growth rate: 4%). We assume a 4% terminal growth rate because of the globally fast-growing biologics industry and surging demand for biological CRDMO services. The corresponding P/E is 39.6x, 28.3x and 20.8x in 2022F, 2023F, 2024F, respectively, which are far lower than WuXi Biologics' five-year historical P/E (151.2x). We believe its market leading position and strong profit growth outlook should deserve a higher valuation.

Given its leading position in biologics outsourcing industry and strong growth visibility, we don't think there is a direct comparable peer domestically. Internationally, Lonza and Samsung Biologics are other two leading biologics outsourcing provider. However the service scope provided by Lonza (NR, last close price: CHF485.8) and Samsung Biologics (NR, last close price: KRW801,000.0] are not exactly as the same as WuXi Biologics, since WuXi Biologics provided a full spectrum of service covering the whole process of Biologics discovery, development and manufacturing which few companies provide. According to Bloomberg consensus estimation, Lonza is trading at 32.4x 2022F P/E, with -19% EPS CAGR in 2022-2024F and Samsung Biologics is trading at 97.2x 2022F P/E, with 24% EPS CAGR in 2022-2024F. While WuXi Biologics is trading at 39.0x 2022F P/E, with 36% EPS CAGR in 2022-2024F, which makes it more attractive than its international peers, in our view.

Figure 63: DCF valuation

Rmb m	2022F	2023F	2024F	2025F	2026F	2027F	2028F	2029F	2030F	2031F
EBIT adjusted	5,309.8	7,431.3	10,113.5	13,150.8	16,903.5	21,073.8	26,199.3	32,549.1	39,161.0	47,017.0
EBIT(1-t)	4,665.5	6,529.5	8,886.3	11,555.1	14,852.4	18,516.7	23,020.2	28,599.5	34,409.1	41,311.9
Add: D&A	765.7	926.4	1,066.5	1,166.8	1,228.6	1,288.6	1,346.6	1,402.8	1,457.3	1,509.9
Less: Capex	(5,000.0)	(5,000.0)	(5,000.0)	(3,000.0)	(3,000.0)	(3,000.0)	(3,000.0)	(3,000.0)	(3,000.0)	(3,000.0)
Less: Working capital	(45.8)	(725.4)	(272.9)	(723.0)	(640.5)	(693.5)	(1,158.2)	(1,155.5)	(767.6)	(1,965.0)
FCF	385.4	1,730.6	4,679.9	8,998.8	12,440.6	16,111.7	20,208.7	25,846.9	32,098.8	37,856.8
Terminal value										745,390.9
PV of FCF	385.4	1,583.6	3,918.7	6,895.1	8,722.6	10,337.1	11,864.4	13,885.8	15,779.8	352,341.5
Corporate value		425,714.0		Assumptions						
Debt & preferred stock		4,295.3		Risk free rate	3.0%					
Cash		10,150.9		Company Beta	1.28					
Minority interest		427.6		Equity Risk premium	6.3%					
NPV to equity share holders		431,142.1		Cost of equity	11.1%					
Divided by: # of shares outstanding		4,173.7		Pre-tax Cost of debt	2.5%					
NPV per share to equity shareholders RMB		103.3		Tax rate	12.1%					
CNY/HKD		1.1		After-tax cost of debt	2.2%					
NPV per share to equity shareholders HKD		111.6		Total Debt/equity	20%					
				WACC	9.3%					
				Terminal growth	4.0%					

SOURCES: CGIS RESEARCH ESTIMATES, COMPANY DATA, BLOOMBERG

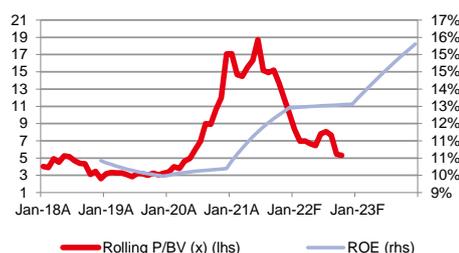
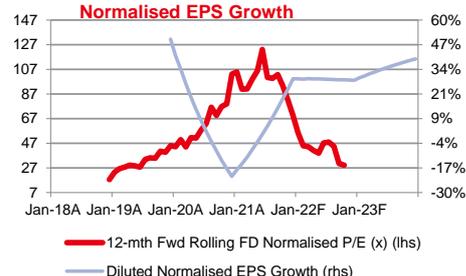
Figure 64: Sensitivity test

		Terminal growth rate				
		3.0%	3.5%	4.0%	4.5%	5.0%
Wacc	8.4%	117.7	127.6	139.8	155.2	175.2
	8.8%	106.5	114.6	124.3	136.3	151.4
	9.3%	97.1	103.7	111.6	121.2	132.9
	9.7%	89.0	94.5	101.0	108.7	118.1
	10.2%	82.0	86.6	92.0	98.4	105.9

SOURCES: CGIS RESEARCH, COMPANY DATA

Figure 65: Historical five-year P/E (x)



BY THE NUMBERS
P/BV vs ROE

12-mth Fwd FD Normalised P/E vs FD Normalised EPS Growth

Profit & Loss

(Rmbm)	Dec-20A	Dec-21A	Dec-22F	Dec-23F	Dec-24F
Total Net Revenues	5,612	10,290	15,179	21,223	28,865
Gross Profit	2,533	4,829	7,134	9,975	13,567
Operating EBITDA	2,032	3,885	6,076	8,358	11,180
Depreciation And Amortisation	(391)	(576)	(766)	(926)	(1,066)
Operating EBIT	1,642	3,309	5,310	7,431	10,114
Financial Income/(Expense)	38	19	(17)	(35)	(44)
Pretax Income/(Loss) from Assoc.	3	0	0	0	0
Non-Operating Income/(Expense)	283	666	0	0	0
Profit Before Tax (pre-EI)	1,966	3,993	5,293	7,396	10,070
Exceptional Items					
Pre-tax Profit	1,966	3,993	5,293	7,396	10,070
Taxation	(273)	(485)	(642)	(897)	(1,222)
Exceptional Income - post-tax					
Profit After Tax	1,693	3,509	4,650	6,499	8,848
Minority Interests	(7)	(93)	(137)	(191)	(260)
Preferred Dividends					
FX Gain/(Loss) - post tax					
Other Adjustments - post-tax					
Preference Dividends (Australia)					
Net Profit	1,686	3,416	4,514	6,307	8,588
Normalised Net Profit	1,693	3,509	4,650	6,499	8,848
Fully Diluted Normalised Profit	1,686	3,416	4,514	6,307	8,588

Cash Flow

(Rmbm)	Dec-20A	Dec-21A	Dec-22F	Dec-23F	Dec-24F
EBITDA	2,032	3,885	6,076	8,358	11,180
Cash Flow from Invt. & Assoc.					
Change In Working Capital	(367)	(963)	(46)	(725)	(273)
(Incr)/Decr in Total Provisions					
Other Non-Cash (Income)/Expense	276	532	0	0	0
Other Operating Cashflow	270	516	0	0	0
Net Interest (Paid)/Received	(57)	(54)	(55)	(55)	(55)
Tax Paid	(273)	(485)	(642)	(897)	(1,222)
Cashflow From Operations	1,881	3,431	5,332	6,680	9,630
Capex	(6,124)	(6,494)	(5,000)	(5,000)	(5,000)
Disposals Of FAs/subsidiaries					
Acq. Of Subsidiaries/Investments	0	(2,162)	0	0	0
Other Investing Cashflow	(1,092)	(946)	64	77	109
Cash Flow From Investing	(7,216)	(9,602)	(4,936)	(4,923)	(4,891)
Debt Raised/(repaid)	703	158	0	0	0
Proceeds From Issue Of Shares	10,978	5,585	0	0	0
Shares Repurchased					
Dividends Paid					
Preferred Dividends					
Other Financing Cashflow	(5,115)	2,467	0	0	0
Cash Flow From Financing	6,566	8,209	0	0	0
Total Cash Generated	1,231	2,039	396	1,757	4,739
Free Cashflow To Equity	(4,632)	(6,013)	396	1,757	4,739
Free Cashflow To Firm	(5,278)	(6,117)	451	1,812	4,794

SOURCES: CGIS RESEARCH, COMPANY DATA, BLOOMBERG

BY THE NUMBERS... cont'd
Balance Sheet

(Rmbm)	Dec-20A	Dec-21A	Dec-22F	Dec-23F	Dec-24F
Total Cash And Equivalents	8,368	10,151	11,113	13,522	19,042
Total Debtors	3,242	4,857	7,090	9,614	13,105
Inventories	1,084	1,687	2,396	3,313	4,451
Total Other Current Assets	1,510	2,834	2,834	2,834	2,834
Total Current Assets	14,204	19,530	23,433	29,283	39,431
Fixed Assets	11,996	18,065	22,355	26,481	30,461
Total Investments	0	0	0	0	0
Intangible Assets	577	2,131	2,076	2,023	1,976
Total Other Non-Current Assets	2,186	4,307	4,307	4,307	4,307
Total Non-current Assets	14,759	24,503	28,737	32,811	36,744
Short-term Debt	767	2,122	2,122	2,122	2,122
Current Portion of Long-Term Debt					
Total Creditors	2,789	3,801	5,922	7,681	10,826
Other Current Liabilities	942	2,332	3,156	4,175	5,462
Total Current Liabilities	4,498	8,256	11,200	13,977	18,410
Total Long-term Debt	1,838	641	641	641	641
Hybrid Debt - Debt Component					
Total Other Non-Current Liabilities	1,728	2,430	3,109	3,949	5,010
Total Non-current Liabilities	3,566	3,071	3,750	4,589	5,651
Total Provisions	0	0	0	0	0
Total Liabilities	8,064	11,326	14,950	18,567	24,060
Shareholders' Equity	20,564	32,279	36,656	42,772	51,100
Minority Interests	335	428	564	755	1,015
Total Equity	20,899	32,706	37,220	43,527	52,115

Key Ratios

	Dec-20A	Dec-21A	Dec-22F	Dec-23F	Dec-24F
Revenue Growth	40.9%	83.3%	47.5%	39.8%	36.0%
Operating EBITDA Growth	48.9%	91.1%	56.4%	37.6%	33.8%
Operating EBITDA Margin	36.2%	37.8%	40.0%	39.4%	38.7%
Net Cash Per Share (Rmb)	1.29	1.43	1.50	1.87	2.94
BVPS (Rmb)	5.20	7.73	8.78	10.25	12.24
Gross Interest Cover	21.03	35.40	39.32	44.53	48.82
Effective Tax Rate	13.9%	12.1%	12.1%	12.1%	12.1%
Net Dividend Payout Ratio	NA	NA	NA	NA	NA
Accounts Receivables Days	162.3	143.6	143.6	143.6	144.0
Inventory Days	88.16	92.62	92.62	92.62	92.87
Accounts Payables Days	271.7	214.8	214.8	214.8	215.3
ROIC (%)	18.2%	19.6%	19.1%	23.2%	27.5%
ROCE (%)	10.2%	13.2%	13.6%	16.4%	18.9%
Return On Average Assets	7.1%	9.6%	9.7%	11.4%	12.9%

Key Drivers

	Dec-20A	Dec-21A	Dec-22F	Dec-23F	Dec-24F
Pre-IND services %	54.8%	21.1%	52.6%	26.2%	21.5%
Early-phase services %	13.7%	9.0%	55.5%	48.3%	38.5%
Late-phase services %	46.1%	293.0%	42.0%	46.8%	44.8%

SOURCES: CGIS RESEARCH, COMPANY DATA, BLOOMBERG

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Add	68.4%	0.8%
Hold	24.6%	0.0%
Reduce	7.0%	0.2%

Spitzer Chart for stock being researched (2 year data)

Wuxi Biologics (2269 HK)

RECOMMENDATION FRAMEWORK

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