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China biopharma – Charting a path to value creation

Nov. 2023



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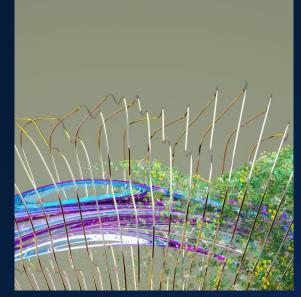
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Key questions







01-

What is the 5-10 years outlook for the China innovative biopharma market? What is the state of biopharma R&D innovation originating from China?

02

Can innovation be sustained under the current ecosystem conditions?

03

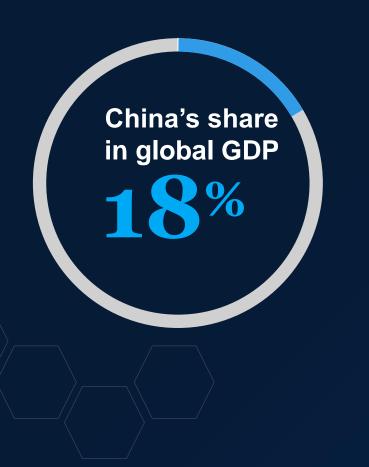


What could future success look like?

01

What is the 5-10 years outlook for the China innovative biopharma market?

China contributes 3% of the global innovative biopharma market, highlighting a significant opportunity for growth





Diverging performance of MNC biopharma in China, driven by portfolio mix and strategic stance

China revenue of MNC biopharma¹ As % of Range of China revenue growth 2022, Bn USD 2019-2022 CAGR global 13% Company A 5.7 Median 6% 9% Company B 5.2 Company C 3.3 7% 3.2 6% >1Company D 34% 1% 3.1 6% Company E **Bn USD** 2.3 9% Company F China revenue Company G 1.5 5% 0.9 15% Company H 0.8 15% Company I <1 -4% 6% 0.7 Company J 7% **Bn USD** Company K 0.6 5% China revenue 0.2 Company L 3%

Growth performance varies for MNCs with different China business scale

1. N=12, selected 12 companies from top 50 global biopharma that reported China pharmaceutical revenue in their annual report. The total China market revenue of the 12 companies is 27 Bn USD in 2022

Key performance drivers

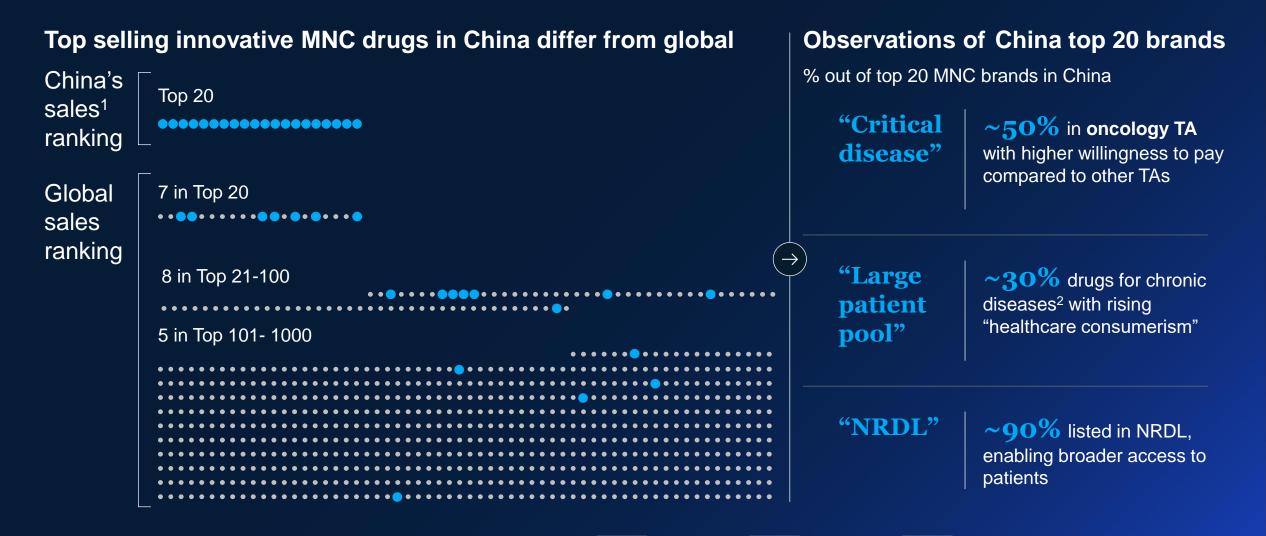
Top-down commitment from CEO downward

Portfolio mix and market relevance

Commercial scale, capability and investment

GTM innovation and ecosystem building

Top selling innovative MNC drugs in China differ from global, and are characterized by large patient pool and high disease severity



Top selling MNC Rx drugs in China launched since 2017, not including vaccine products
 Including metabolism, cardiovascular, dermatology and immunology

What could 2028 look like?

China inn	ovative drug ¹ ma	Key conditions for growth				
Bn USD	2022	2028	NDA approvals at a stable level of ~50 per year			
	20 bn	50 bn	Market access conditions steadily improve, with gradual shift of BMI funds towards innovative products			
MNCs Locals²	15 5	30 20	Continued investment in market shaping by both MNCs and locals			

1. Pre-LOE innovative Rx products, include both therapeutic drugs and vaccines; at ex-manufacturer price

2. Including both China-originated assets and license-in assets of China-originated biopharmas/biotechs

Local innovations expected to increase contributions to the China innovative biopharma market with continued momentum

Growth of local pipeline across modalities and TAs



23%

innovative INDs¹ initiated by Chinaoriginated biopharma² each year

Local innovations reaching commercial stage



Numbers of INDs consolidated at molecule level, including therapeutic drugs and vaccines 1.

China-originated biopharma defined as companies with HQ in China 2.

originated

China-originated assets only, not including licensed in assets 3.

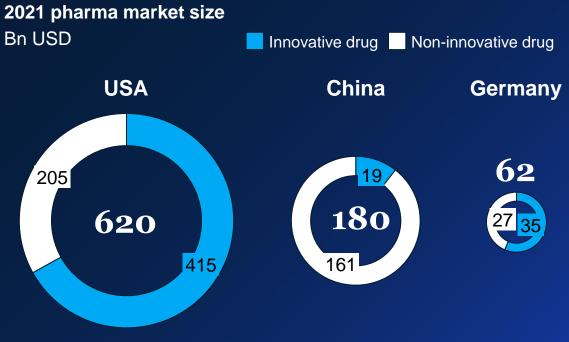
From 2018 to 2023Q3

Source: Press release; GBI; DXY; WIND; McKinsey analysis

Steady improvement of market access; ample room remains to improve access to innovative drugs



Room to further improve access for innovative drugs



1. Routine catalogue management, simple renewal and re-negotiation

02

What is the state of biopharma R&D innovation originating from China?

Four lenses to assess the state of China biopharma R&D innovation



-Patient

Early signs of expanding patient access (with more affordable innovations) and earlier access (accelerated by 1-2 years in the last 5 years) to global innovations

Gaps still exist as only 25% of FDA approved drugs in the last 5 years are approved in China



-Capital-

After a decade of rapid growth (100+ Bn USD market cap and 60 listed companies), China's biopharma innovation capital market is in reset mode (market cap of 2/3 biotechs' declined by 50%+ from peak)

PE/VC investments returning to pre-2020 levels



-Innovation

Continued momentum of China-originated innovation with 400+ INDs and 30+ NDAs over first 3 quarters in 2023

China-originated innovation increasingly seeking global value capture through out-licensing (~30 each year) and FDA/EMA registrations





Emergence of 4 leading biotech innovation clusters in China, hosting 8.5K+ biotechs

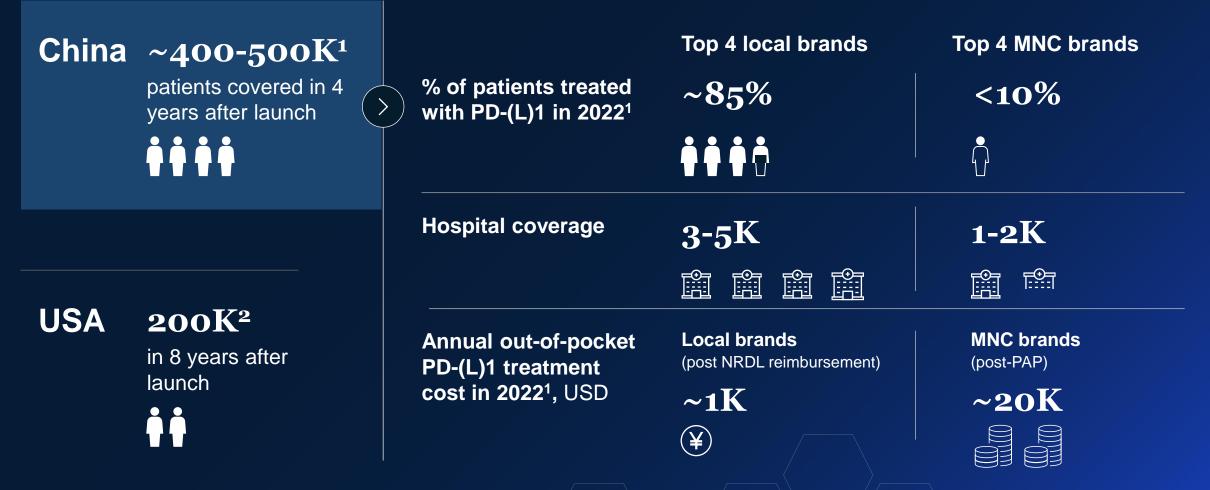
30K+ job opportunities added by top 10 listed biotechs

Biotechs' GDP impact remains limited, as most companies are not yet making profit or positive TSR¹

1. Total shareholder return generated by a stock, calculated using [(current price - purchase price) + dividends] / purchase price

Source: Company annual report; BCIQ; Preqin; WIND; Evaluate Pharma; FDA; CDE; PharmaDeals; GBI; DXY; McKinsey analysis

Patient: Expanded patient access with the emergence of "affordable innovations" – PD-(L)1 example



1. Factor in 6-month real world DoT based on mPFS data and clinical KOL inputs

2. Evaluate Pharma estimation

Source: Press release; NHSA; Evaluate Pharma; McKinsey analysis

Patient: Earlier access to global innovative drugs with shortened launch lag

Launch lag of imported drugs has been shortened (Distribution by launch lag time, 2018 vs. 2022¹⁾ Drugs launched within 2 years of global 1st launch benefited from MRCTs and conditional approvals # of drugs



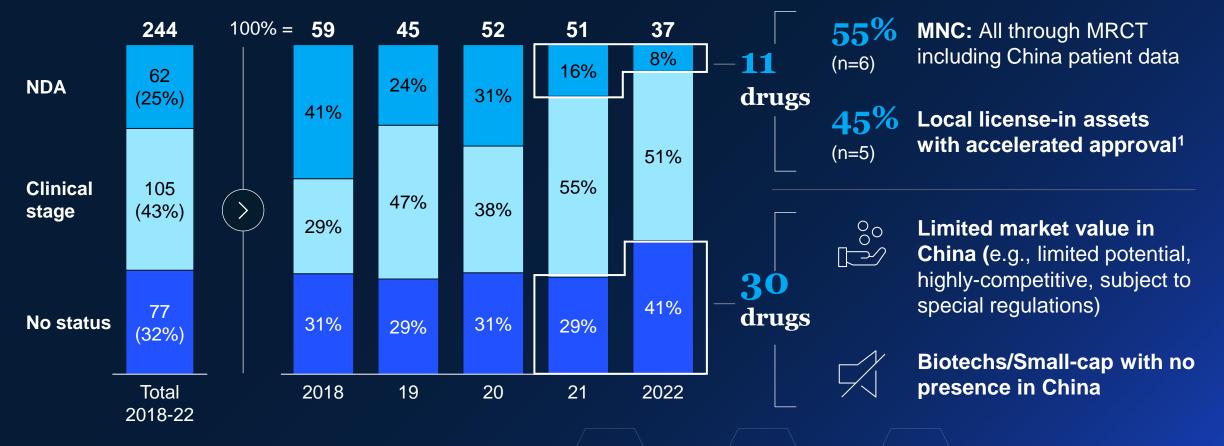
1. Launch lag of imported drugs (include both MNC and local license-in drugs) defined as the years between global first launch and China launch

2. Granted conditional approval to fulfill urgent clinical unmet needs (COVID, cholangiocarcinoma), incl. one using oversea Ph III trials for registrational approval, and the other one using oversea Ph II trial with local bridging Ph I + Ph II trials for approval

3. Granted conditional approval to fulfill clinical unmet needs (rare disease, ES-SCLC); both used overseas trial data for registrational approval

Patient: Gaps still exist as only 25% of FDA approved NMEs in the last 5 years have been launched in China

China regulatory status of NMEs approved by FDA # of NMEs, by FDA approval year



1. 2 conditional approvals, 2 bridging and MRCT, and 1 local PhIII trial

Source: FDA; DXY; GBI; Evaluate Pharma; McKinsey analysis

Capital: Following a decade of rapid development, China's biopharma innovation is experiencing a "reset" phase amidst a global downturn

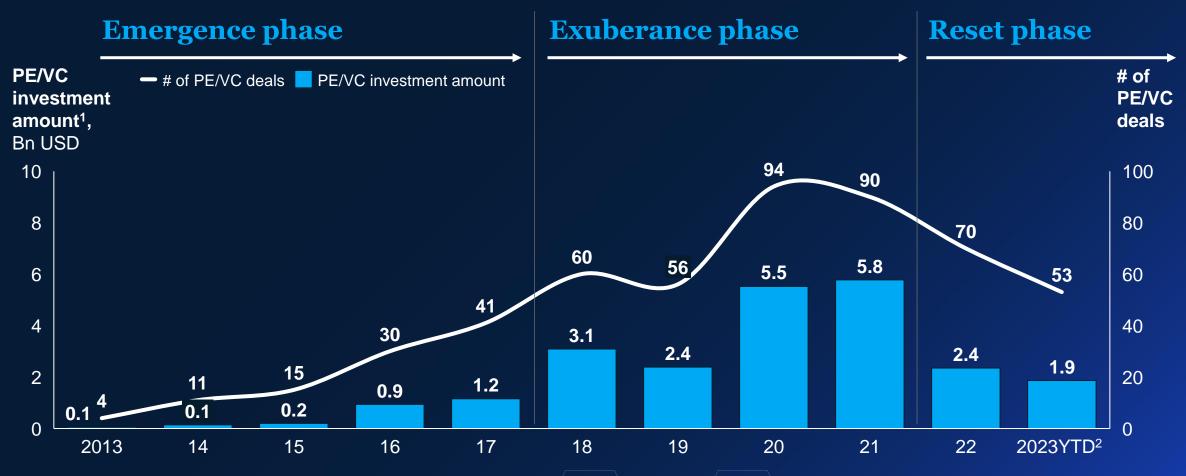
	Emergence phase Prior to 2017 1 st wave innovation accelerated with regulatory integration, sufficient funding and "returnee" talents					Exuberance phase 2018-2021 Catalyzed by flourishing funding (entrance of generalist investors) and new IPO channels (HKEX chapter 18A, SSE STAR)				Reset phase 2022 onward Drastic market correction mirroring global biotech trends		
Biote indus	1	Market cap	# of biotech list	ted								# of
	et cap ¹	-45%	Average mai	rket cap re	eduction ³	from 2021		•				biotechs
140		2/3	Biotechs ma	rket cap c	lropped by	more than	n half com	paring				120
120			to peak ⁴								-17%	
100		3/4	Biotechs are	trading b	elow IPO ⁵							80
80		80 Bn	USD market	cap erase	ed from th	e peak ⁶				50	60	
60				_			/	_	44	53		
40								30				40
20					2	7	13					
0				2	3							0
	2013	14	15	16	17	18	19	20	21	22	2023YTD ²	

Including 60 China-headquartered biotechs focusing on innovative drugs, and are listed in Nasdaq, HKEX Chapter 18A, and SSE STAR Market since 2013. Market cap prioritized Nasdaq if dual listed in Nasdaq and HKEX chapter 18A (BeiGene & ZaiLab) and if dual listed in HKEX chapter 18A and SEE STAR (RemeGen & TopAlliance) we took the cumulative value of both (share price * shares outstanding of that particular class) to arrive at the total market cap. Data used the closing market cap on the last day of each year. Excluded biotechs that focus on vaccine only

Source: Capital IQ; Nasdaq; McKinsey analysis

As of Oct 12, 2023 3. Included 44 companies with market cap data available from 2021 to 2023 4. Peak market cap in history since IPO market cap of biotechs (n=35) listed by June 2021 (the market cap peak month)
 Source Constrained Co

Capital: PE/VC investment has returned to pre-2020 levels

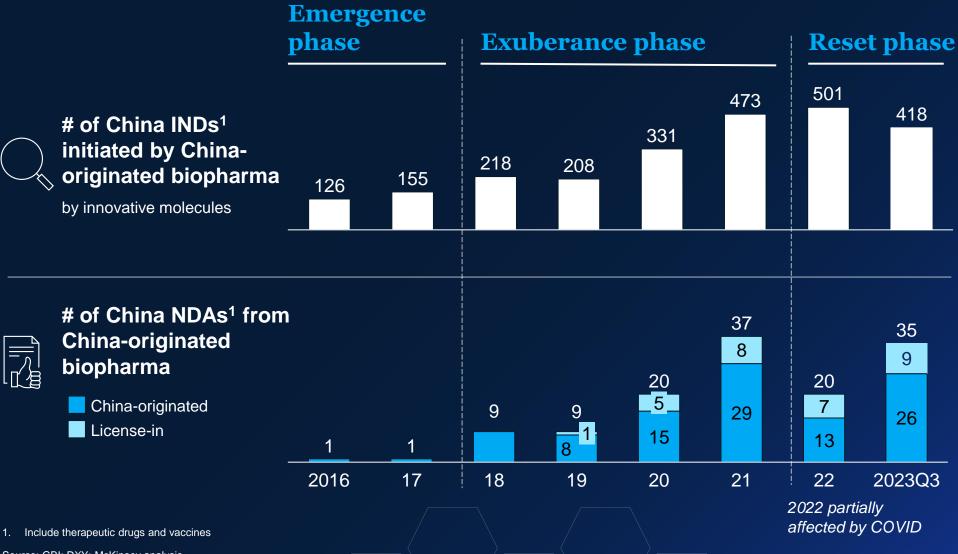


1. PE/VC fund investment in biopharma

2. As of Sep 14, 2023

j j

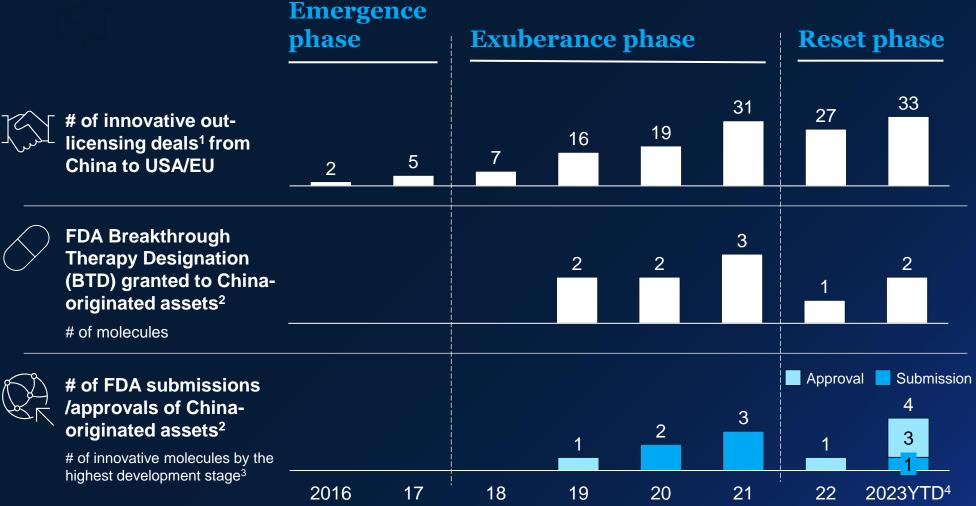
Innovation: Continued momentum of INDs and NDAs in China



Continued momentum of INDs and NDAs from China-originated biopharma (exception in 2022 due to COVID)

Source: GBI; DXY; McKinsey analysis

Innovation: China-originated innovation is starting to show impact on the global stage



Stable outlicensing momentum with ~30 deals each year since 2021

A small set of assets have started pursuing FDA registration path to realize global potential

1. Innovative asset-based deals with licensor being China HQ companies and deal rights territory including USA/EU markets. Deals included 14 discontinued deals

Assets developed by China-originated biopharma
 For the 5 FDA NDAs: Brukinsa filed in 2019 and approved in 2019, Carvykti filed in 2020 and approved in 2022, Fruzaqla filed in 2023 and approved in 2023, Loqtorzi filed in 2021 and approved in 2023, Ryzneuta filed in 2021 and approved in 2023
 Source: GBI; Evaluate Pharma; Pharma projects; FDA; McKinsey analysis

Society: 4 Leading innovation clusters hosting 8.5K+ biotechs/biopharma and creating abundant job opportunities



1. Leading hubs in Bohai Rim cluster located in Beijing, Tianjin and Jinan; leading hubs in Yangtze River cluster located in Shanghai, Suzhou, Hangzhou, Wuxi; leading hubs in South China cluster located in Shenzhen, Guangzhou, Xiamen; leading hubs in Mid-west cluster located in Wuhan and Chengdu

2. Ranked by market cap as of Q3 2023

Source: Press release; WIND; Company annual report; McKinsey analysis

Society: Leading China-originated biopharma are establishing global footprints

Global footprints of top 10 China-originated biotechs¹

Out of the top 10 biotechs¹

- established overseas
 footprints in a total of 15+
 countries
- 3 set up full value chain footprints in USA and/or EU
- 6 set R&D centers in USA, EU and/or Australia
- Built manufacturer sites in USA and/or EU



R&D centers & offices in EMEA R&D centers, MFG sites, offices in Asia (incl. China) # of top 10 biotechs with footprints in the corresponding region

R&D centers, MFG sites, offices in USA



10

R&D centers & office in Australia

1. Ranked by market cap, data as of Oct. 2023

Improving patient access, innovation capability and outputs are among the top value creation drivers by the industry in the past 5 years

Over the past 5 years, which are the top-3 areas where China biopharma innovation has created the most impact/value? % of respondents, N = 33



Expanded patient access ranked at the top, followed by capability and innovation both in terms of input and output

Innovation

Capital

Patient

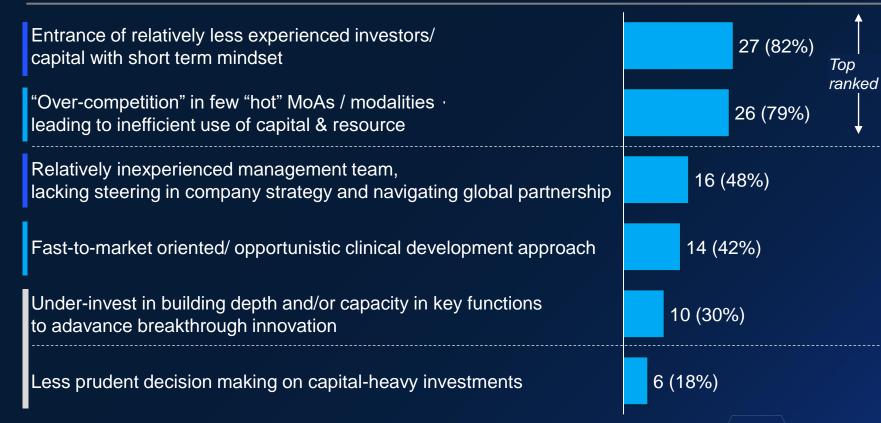
Globalized capability building and generating viable financial return remain challenging

"Growing pains" for China biopharma innovators to reflect and learn

Management team/Investor capability Clinical development direction/approach Internal Control

66 77

Reflecting on the past 5 years, which might be the top-3 areas that have stalled longterm value creation in the China biopharma ecosystem? (multiple choices) % of respondents, N = 33



From an investment perspectives, we are learning our lessons and staying away from herding/me-toos. We are looking at differentiation, the management team and capabilities.

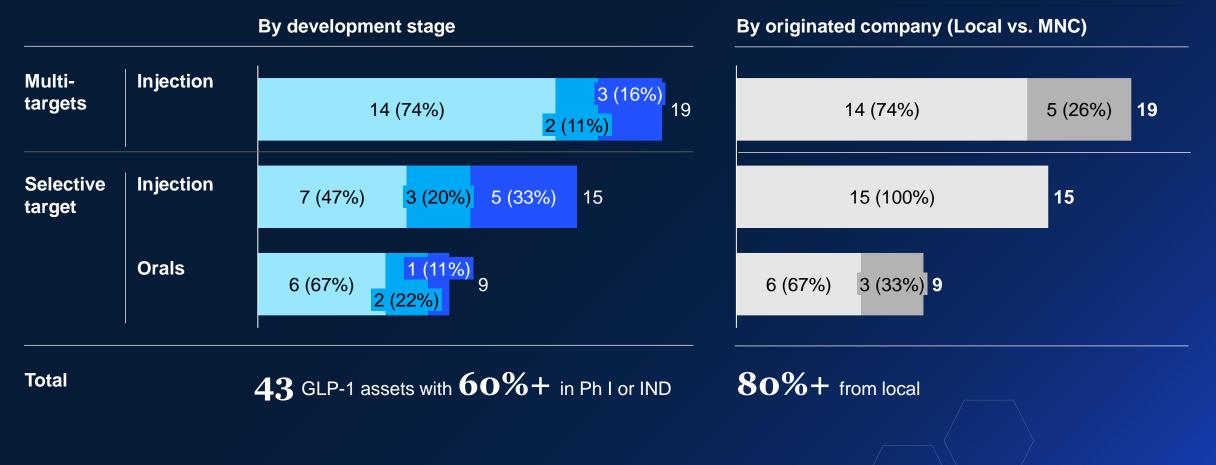
Investors that remain in biotech investment are more specialized and cautious, and we are getting back to the basics, which are science and team.

- Leading investors

Herding - Is the GLP-1 field at risk of becoming the next PD-1?

IND & Phase I 🗧 Phase II 🧧 Phase III & NDA 📃 Local 📕 MNC

of GLP-1 assets in China¹ (clinical stage or marketed stage assets)



1. As of Jun. 2023

Source: DXY; McKinsey analysis

03 Can innovation be sustained under the current ecosystem conditions?

3 lenses to assess the ecosystem sustainability and impact on global

A Enablers

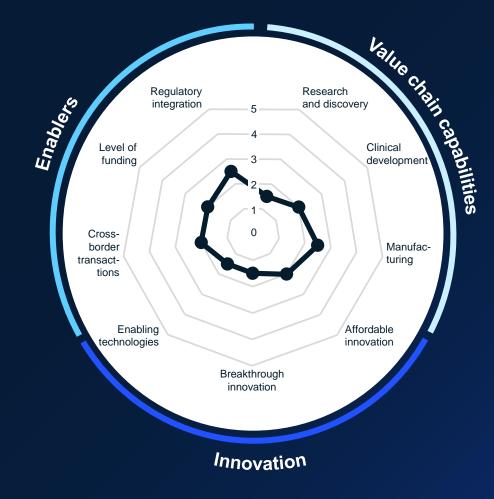
Regulatory integration – Continued progress on global regulatory alignment

Funding – Drastic decline in late-stage and public funding; earlystage funding level largely sustained

Cross-boarder

transactions – Vibrant cross-border asset-level transactions; M&A unlikely a meaningful funding source in the near term

Where China stood in 2021¹



B Value chain capability

Foundational capabilities in place across discovery, development and manufacturing; clear needs to further upgrade to drive global-caliber innovations

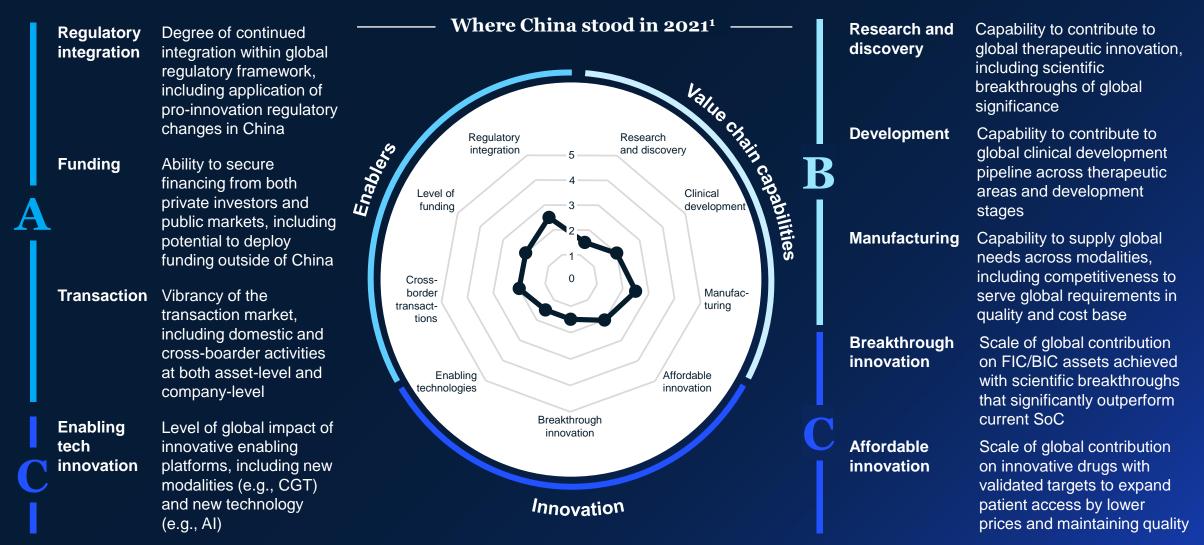
Globally-competitive CRO/CMO industry with quality and efficiency

C Innovation

"Going global" a clear pivot: despite early setbacks, innovation quality is improving evidenced by emergence of next-gen modality play and first-wave play

Leading players have begun to realize commercial potential in China and capture global value

9 dimensions to assess China's impact on global biopharma



1. McKinsey & Co. Vision 2028: How China could impact the global biopharma industry

A. Do we have a viable enabling environment to support innovation post exuberance phase?

What could give people Confidence

- Continued progress in regulatory integration with global
- Level of early-stage investment sustained (for now)
- Innovators pivoting towards assets with global potential, making early progress evidenced by growing number of out-licensing deals to MNCs



What could give people Pause

- A prolonged "capital winter" pull back of late-stage and public funding, closed IPO window and limited feasibility of M&A
- Market access conditions (e.g., NRDL) showing insufficient momentum towards appropriate rewards for innovation

A. Early-stage VC/PE fundraising has sustained, but late-stage fundraising has declined most significantly in China

Early-stage funds Late-stage, growth, balanced, and general funds 🛛 🗙 % reduction in late-stage capital raised

Total amount of VC/PE capital raised in healthcare by region, 2018-2023YTD¹, Bn USD



1. As of Sep 26, 2023 Note: Selected fund with core industry in healthcare. Excluding funds that are smaller than 5 Mn USD

A. Late-stage investment in biopharma returned to pre-2020 levels, while momentum of early-stage investment is sustained

Early-stage rounds Eate-stage rounds

% reduction in late-stage investment

X

Total amount of VC/PE investment in biopharma by region, 2018-2023YTD¹, Bn USD



1. As of Sep 14, 2023

Note: Select investment organization type in biopharma. Early-stage rounds include seed financings and series A; late-stage rounds include series B and beyond. Not including venture (debt) and uncategorized equity rounds

A. M&A unlikely to become a major exit path for China biotech/ biopharma companies in the short/mid term

M&A is picking up momentum globally, but unlikely to be a major exit option for China-originated biotechs/biopharma



1. Target industry classification as biotechnology, transaction status as announced/effective/closed, by target geographic locations

2. As of Oct.10, 2023

3. Additional net debt capacity + cash capacity for biopharma companies. Top 10 Chinese biopharma selected from the listed pharmaceutical companies with largest # of innovative assets in the clinical stage

Rationale for global M&A

- Sufficient dry powder from top MNCs³ (~300 Bn USD)
- Hedge patent cliff: 70% revenue in 2022 are from products that will enter LOE by end of 2028

Conditions for China biotech M&A exit likely not mature

- Subpar innovation quality of the overall biotech portfolio (with many me-toos and limited value)
- Limited dry power from top China biopharma³ (~20 Bn USD) and mismatch given similar internal pipeline and commoditized capability in biotechs
- Uncertainty in cross-border transactions with geopolitical tension and M&A related regulations

Source: S&P Capital IQ (Oct. 2023) ; McKinsey analysis

A. IPOs slowed down significantly since late 2021; reopening of the IPO window is unlikely in the next 1-2 years



 1. As of Sep 14, 2023
 2. Selected organization type of biopharma for analysis
 3. Including 60 China-headquartered biotechs that focus on innovative drugs and are listed in Nasdaq, HKEX Chapter 18A, and SSE STAR

 Market since 2013. Excluded biotechs that focus on vaccine only
 4. Worsened liquidity in HKEX due to geopolitical tensions, US interest rate hikes, etc. Higher exit hurdles in STAR after new CSRC (China Securities Regulatory

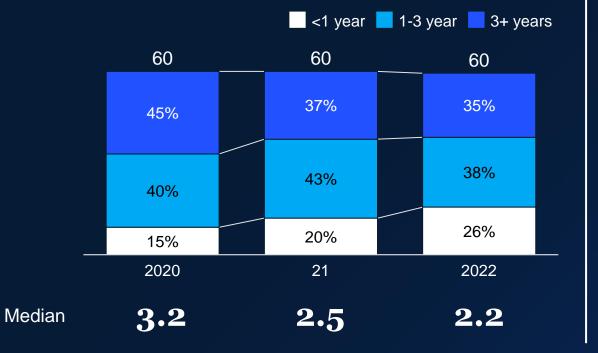
 Commission) shareholding reduction regulations
 9. Worsened liquidity in HKEX due to geopolitical tensions, US interest rate hikes, etc. Higher exit hurdles in STAR after new CSRC (China Securities Regulatory

Source: BCIQ (Sep 2023); Capital IQ; Nasdaq; WIND; McKinsey analysis

A. Challenging funding situation has led to rationalization of R&D investments

China-originated biotech funding situation has worsened since 2020

Year-end cash position¹/R&D expense of 60 listed biotechs²



Over 1/3 companies have scaled back R&D expenses

of biotechs² with decreased R&D expenses vs. previous year, as % of 60 listed biotechs²

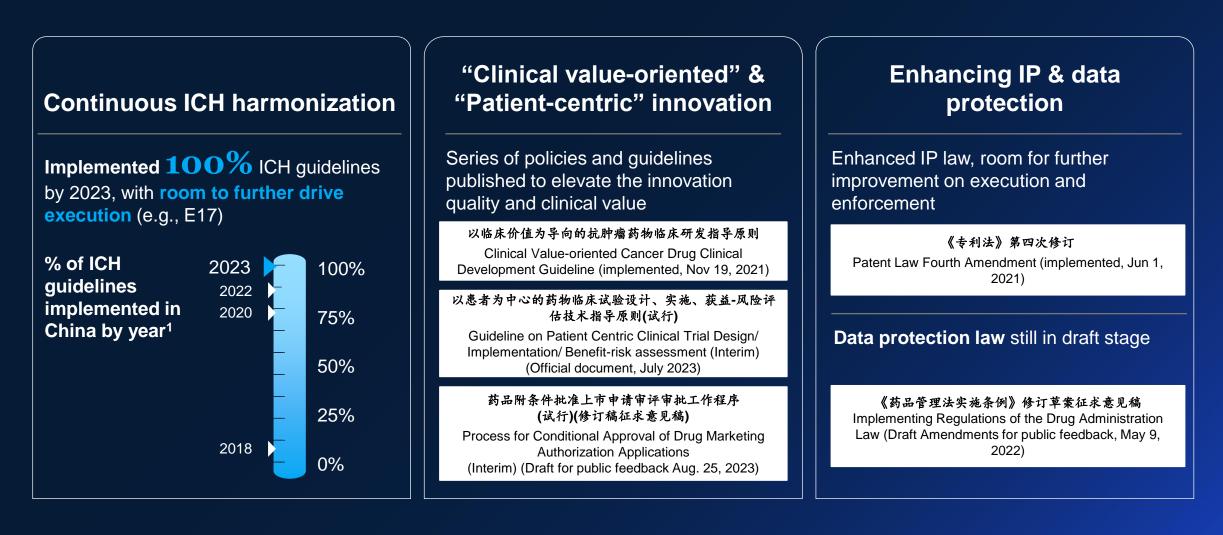


1. Cash position estimated by (total current assets – current liabilities - account receivables - inventory)/R&D expenses; cash positions may be underestimated if there are financial investments outside of current assets

2. Including 60 China-headquartered biotechs that focus on innovative drugs and are listed in Nasdaq, HKEX Chapter 18A, and SSE STAR Market since 2013. Excluded biotechs that focus on vaccine only

Source: Capital IQ; Nasdaq: WIND; McKinsey analysis

A. Continued progress expected on global regulatory integration with a few areas to further strengthen (e.g., clinical value)



1. NMPA announcement of the # of ICH guidelines implemented from 2018 to 2023 June

Source: Press release; ICH; McKinsey analysis

A. China market access environment calls for novel mechanism to better reward and sustain innovation



Industry experts interviewed expressed concerns over sustainability of the market access environment to support innovation



Suggested potential directions to consider:

Mechanism refinements

- Professionalize health benefit and economics assessment e.g., IQWiG¹ in Germany, HAS¹ in France, and Chuikyo¹ in Japan
- Fine-tune pricing negotiation process with HEOR inputs from various sources incl. professional organizations and biopharma

Bold moves

- **Risk sharing**: set capped cost agreements per drug between manufacturers & payers, e.g., risk-sharing arrangement (RSA) in Australia
- Setting reimbursement cap at MoA level: leaving the product pricing to manufacturers

^{1.} Institute for Quality and Efficiency in Health Care (IQWiG); National Health Service (HAS); Central Social Insurance Medical Council (Chuikyo)

^{2.} Based on McKinsey "momentum of China-originated biopharma innovation" executive interviews, 2023 (N=32)

A. Enablers: despite recent challenges, industry leaders retain a positive view on the 5-year outlook

Count of respondents by rating, N = 33• 2023 • 2028 Average Score score Key observations 2028 2 3 4 5 2023 1 2.8 3.6 No significant barrier Regulatory Global regulatory Full integration of integration integration stalls or for global regulatory China in global Regulatory integration goes in reverse regulatory ecosystem, outlook continues enabling Chinaoriginated innovation to to lead on the path access global patients of integrating with 0 6 3 23 9 3 19 2 0 global $\bullet \bullet \bullet \bullet$ $\overline{\bullet \bullet}$ $\bullet \bullet \bullet \bullet$ $\bullet \bullet \bullet \bullet$ $\bullet \bullet \bullet \bullet$ $\bullet \bullet \bullet \bullet$ $\bullet \bullet \bullet \bullet$ **Cross-border** transactions **HKEX** continues to Funding Funding mainly from HKEX continues to be 2.1 2.9 expected to grow China, stagnant growth viable, and remains as be viable, becoming in VC/PE investment a venue for Chinaa venue for global-Funding/IPO lags caliber biotech IPOs originated biotech IPOs and market cap among the 3 8 2 16 10 8 11 8 0 2 enabler $\bullet \bullet \bullet \bullet$ $\bullet \bullet$ $\bullet \bullet \bullet \bullet$ \bullet \bullet dimensions Transaction M&A happens mainly China-originated China-originated 2.2 3.3 within China biotechs increasingly biotechs acquire exattractive to global China originated **MNCs** biotechs 12 0 12 2 16 5 0 5 13 $\bullet \bullet \bullet \bullet$ $\bullet \bullet \bullet \bullet$ $\bullet \bullet \bullet \bullet$ $\bullet \bullet \bullet \bullet$ $\bullet \bullet \bullet \bullet$

How would you rate China's capability in regulatory integration, funding, and transaction today and by 2028?

Source: McKinsey "momentum of China-originated biopharma innovation" executive survey (N=33), 2023

B. Can China develop globally competitive value chain capabilities to foster productive innovation? NOT EXHAUSTIVE What could give people

Confidence

Maturing value chain capabilities at scale as pipeline reaching critical mass with experiences across broader range of modalities and TAs

Speed and efficiency demonstrated in discovery (e.g., shorter cycle time to PCC) and clinical trial execution (e.g., accelerating global enrollment)

Manufacturing reaching scale and global quality standards across modalities

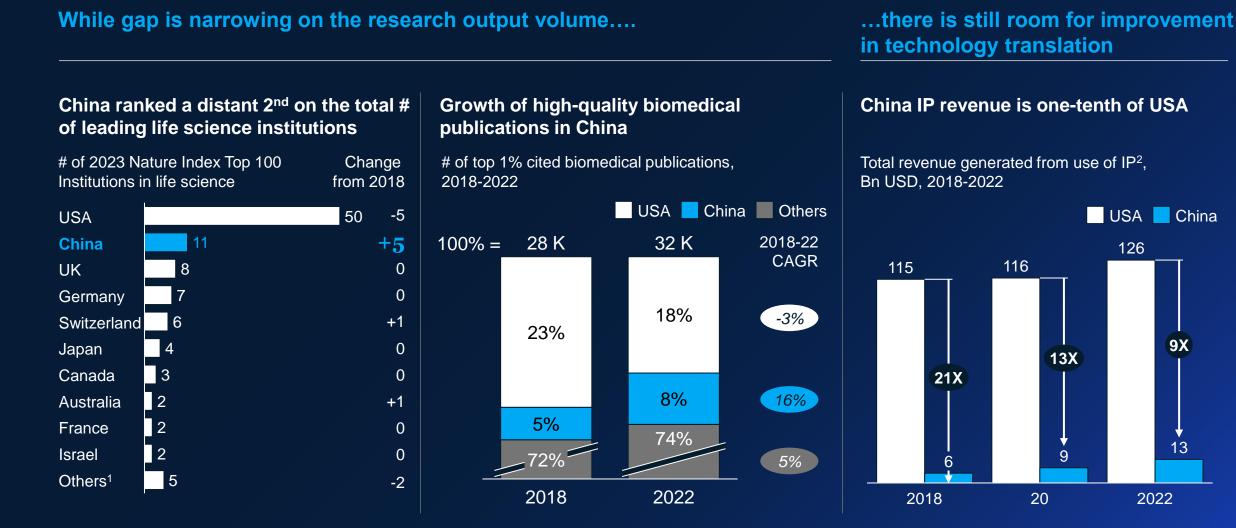
What could give people **Pause**

As many local innovators pivot towards globally competitive innovation, several capabilities need to be upgraded, e.g.,

- Scientific research in biology
- More effectively translating academic research to drugs
- More robust global clinical development & regulatory strategy; more thoughtful trial design

Uncertainty remains on how quickly China innovators can close these gaps

B. Rapid progress has been made in research; further strengthening of tech transfer will be essential

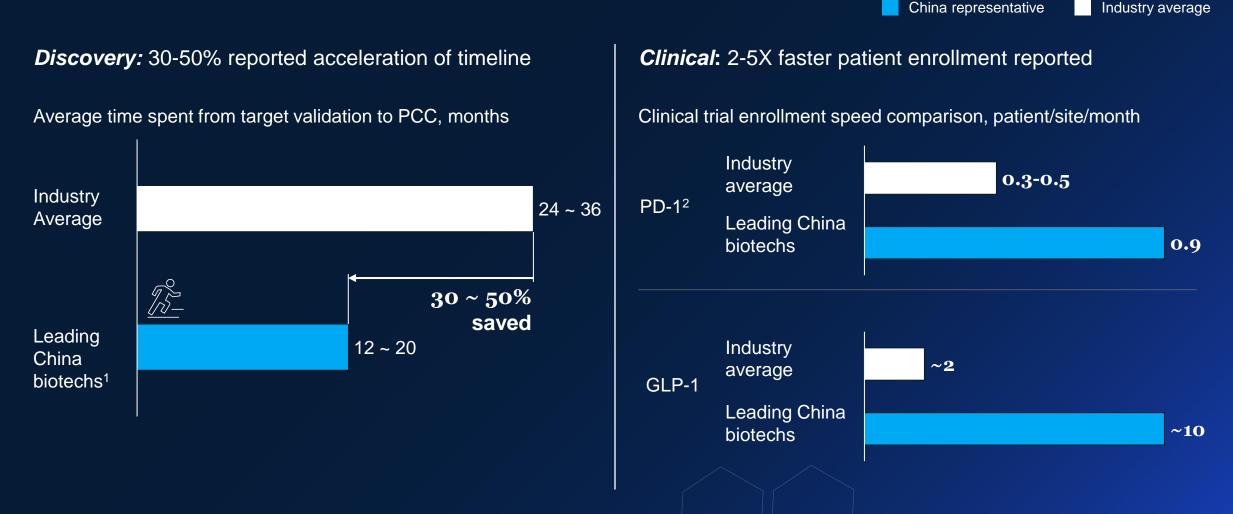


1. Including Denmark, Italy, Singapore, Spain, and Sweden

2. Total charges for use of IP across the industries. Share of biomedical patent among total patents in USA is 7%, and in China is 4%

Source: ESI; Web of Science; GBI; World Bank; McKinsey analysis;

B. Chinese companies have started to harness the discovery, trial execution efficiency and speed advantages of China



1. Self-reported time from 3 representative biotechs across different modalities, lead time from target validation to PCC/IND

2. 1L NSCLC studies

Source: Press release; McKinsey analysis

B. Improving clinical capabilities with more overseas trial experiences; still lagging in designing and leading global trials

China's innovation continues to accumulate overseas clinical trial experiences...

of Ph II & III trials initiated by top 5 China-originated biopharma in USA and EU¹



...and starts building the capabilities to lead global trials

12+ Chinese PIs led global Ph II or Ph III MRCT (incl. USA site)

focus on Oncology (lung,

unmet needs and patient base

liver, nasopharynx) given

since 2019

in China

85%+

Time and investment needed to further build global-caliber capabilities

- Invest and leverage the global talent pool and capability
- Improve site and PI capabilities through the collective efforts of MNCs and locals

1. Top 5 companies selected by number of total Ph II and Ph III oversea trials initiated in USA and EU, incl., both MRCT and standalone trials 2. As of September 2023

B. China has built a globally-competitive CRO/CDMO industry with global footprints, speed, and efficiency advantages

	2 out of	Company	Revenue in 2022, Bn USD	Global business rev. % in 2022	Global footprints (lab, manufacturing site, office, etc.)		etitive advantages na CRO/CDMO
	Top 10 ¹ global pre- clinical CRO	WuXi AppTec	5.6	81%	~ 9 countries in USA, Europe, Asia-pacific	\$	Cost-efficiency with economy of scale
	3 out of	WuXi Biologics	2.2	76%	~5 countries in USA, Europe, Asia-pacific		Reliable quality,
	Top 10 ¹ global CDMO/CMO…	Pharmaron	1.5	82%	~3 countries in USA, Europe, China	>	building on extensive
		Asymchem	1.4	85%	$\mathbf{\sim}3$ countries in USA, Europe, China		experiences serving MNC clients
	1 out of	Porton Pharma	1.0	N.A.	~ 6 countries in USA, Europe, China		Efficient & agile delivery enabled
are C compan	Top 10 ¹ global clinical CRO china-originated ies	Tigermed	1.0	49%²	20+ countries in Asia-pacific, Europe, North America, Latin America, Africa		by flexible teams and diverse talent pool to fulfill customized needs
1 Top 10 ranke	ed by revenue 2 Includes global clinica	I trial operation business		Global footprints	offer flexible sourcing options to		

Includes global clinical trial operation business anked by revenue from China biopharma customers Source: Company annual report; McKinsey analysis

address the rising needs in supply chain resilience McKinsey & Company

41

B. Value chain capability: continued momentum in capability build-up

Count of r	espondents Score	by rating, $N = 3$	33								Avera score		• 2023 • 2028
	1		2		3		4		5		2023	2028	Key observations
Basic research	therapeutic	tribution to global innovation, ISA/EU hubs			Innovation in s areas	selected			On par with leading inno		2.4	3.5	
	Subpar to O		11	4	16	10	1	17	0	2			
	••••			$\bullet \bullet \bullet \bullet$			•			••			Expectation of consistent
Drug	4	1	17	2	12	12	0	17	0	1	2.2	3.5	
discovery	••••	•		••						•			capability improvement across the
Clinical develop- ment	Activity larg	ely in China, wing global			On par with gl selected TAs, following in ot	closely			On par with global 2.3 3.5 development across TAs, and leading in selected areas		value chain in the next 5 years		
	5	1	12	4	16	7	0	19	0	2			the next o years
	••••	•		••••		•••				••			
Manufac- turing	Mostly supp market at lo					s (e.g., mature ith global quality			A global su across moo global qual competitive	dalities, with ity and	2.9	3.9	
	1	0	5	3	22	5	5	16	0	9			
	•		••••	•••		• • • •	••••						

How would you rate China's capability in basic research, drug discovery, clinical development and manufacturing today and by 2028? Count of respondents by rating. N = 33

Source: McKinsey "momentum of China-originated biopharma innovation" executive survey (N=33), 2023

C. Can at-scale breakthrough innovation emerge from China?

NOT EXHAUSTIVE

What could give people Confidence

- Leading local players adapting clinical development and registration strategy to meet USA & Europe requirements
- More deliberate focus on clinical differentiation and global first-wave; emerging edge in new modalities
- Leading players starting to realize ex-China commercial potential through partnership or in-house model
- Leading AI players demonstrating potential via MNC partnerships and advancing own pipeline

What could give people **Pause**

- Multiple rejected or delayed FDA/EMA registration reviews
- Wave of recent returns of outlicensed assets by MNCs due to company strategic redirection, lackluster clinical profile and/or changing competitive landscape
- No clear path yet to realize the commercial potential of affordable innovation at scale outside of China

C. China-originated innovation experienced several regulatory setbacks and returns from partners

Recent setbacks of out-licensing deals and FDA registrations



Suggested reasons

- Data package not meeting FDA/EMA regulatory requirements (e.g., lack of representative global data)
- New MoAs with inherent R&D attritions
- Strategic or organizational change of the licensor

Potential path forward

- Ramp up the learning curve in adopting global mindset and standards (registration requirements, clinical plan and data, etc.)
- Proactive regulatory communication throughout the development processes
- Careful choice of partner
 with long term dedication
 and strategic alignment

1. As of Oct. 24th, 2023

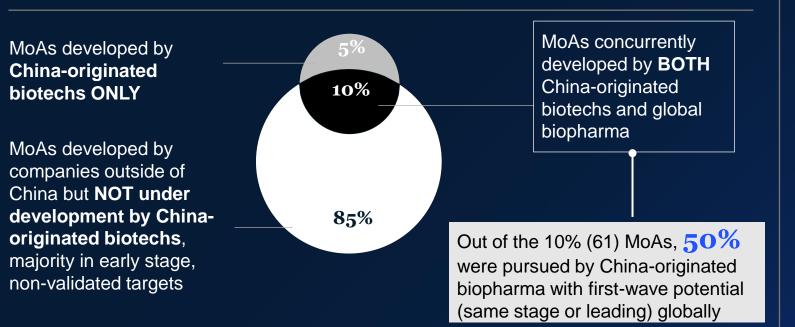
2. Clinical data related: lack of clinical evidence to support approval e.g., insufficient presentative global data; Procedure related: unable to conduct preapproval inspections in China due to COVID-related travel restrictions

C. China-originated fast-following assets have started to pursue differentiated profiles for globally-competitive value capture

Non-exclusive examples

China is fast-following with speed and differentiation

Breakdown of global clinical stage oncology MoAs¹ by company origin (2021)



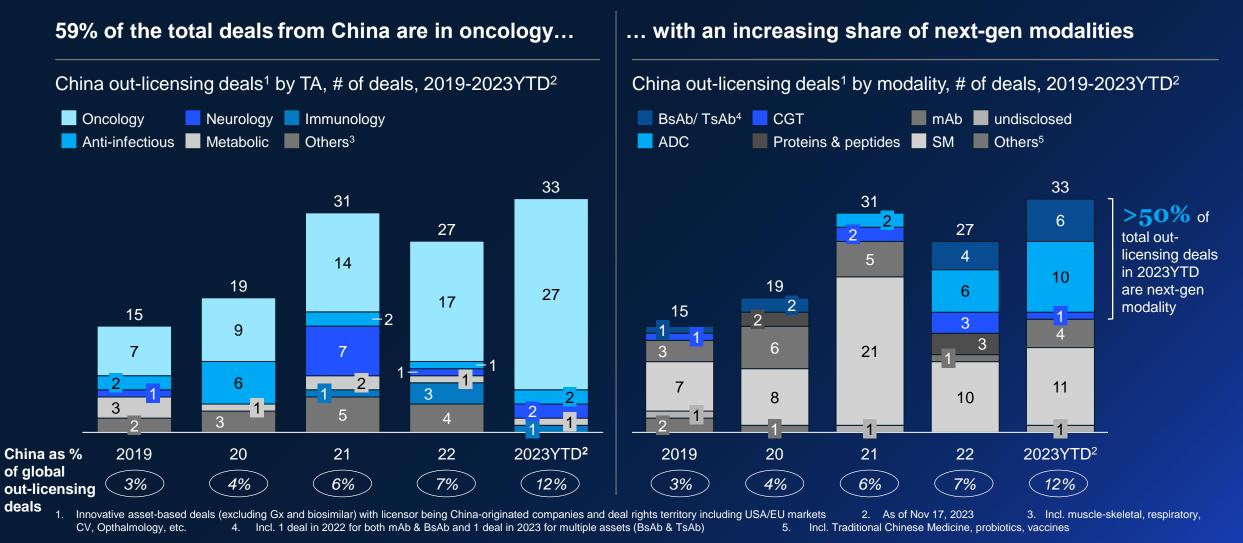
China-originated biopharma have started to pursue global head-to-head clinical trials with MNC assets to differentiate

2+ published results

5 + ongoing (initiated after 2021)

1. For small molecule, ADC, and mAbs, the MoAs are counted by the unique targets; for multivalent mAbs and CGT, the MoAs are counted by the target combinations Source: GBI; NEJM; 2023 ASCO; 2022 ESMO; McKinsey analysis

C. China has increased its contributions to global asset licensing activities, mostly in oncology, with an increasing mix of modalities

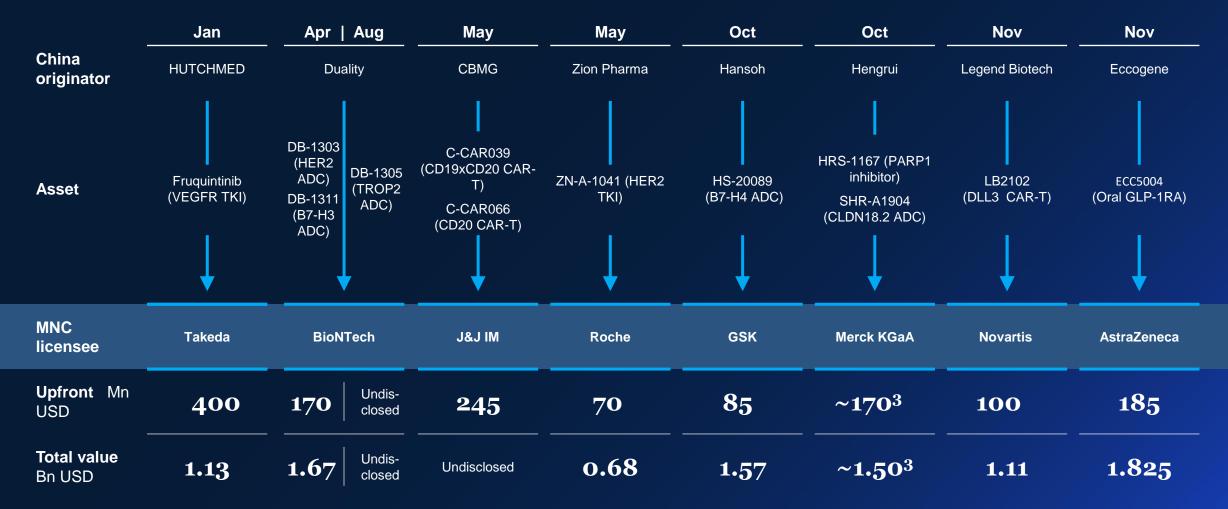


Source: Press release; PharmaDeals; McKinsey analysis

C. The steady flow of out-licensing deals from China to MNCs showcases China innovation potential

Top MNC out-licensing deals1 from China in 2023 YTD²

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1. Ranked by upfront payments 2. As of Nov 16, 2023

3. Exchanged rate: 1 EUR = 1.06 USD

Source: PharmaDeals; GBI; McKinsey analysis

C. China has built up competitive advantages in pursuing fastfollowing and modality/tech platform-based innovations

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ADC innovation as an example

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Decoding the advantages of China biopharma innovation (ADC as an example)



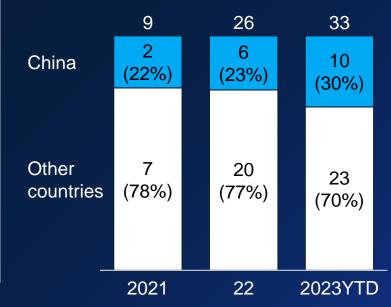
Strength in engineering-based innovation with rapid adoption of latest technology and fast iterations supported by the abundant high-quality STEM talents

)	"China speed" to generate fast clinical & Po
7	data with a resilient, efficiency-driven working
	model

"Multiple shots on goal" building on sizab
investment and scaled pipeline

1. ADC deals from China need to include USA/EU markets in deal territory, global ADC related deals exclude acquisitions 2. As of Oct 31, 2023

China increased its share of global ADC out-licensing deals¹ 2021-23YTD², %



Potential to extend the competitive edge to other "modality play" and MoAs, e.g., bispecific/multispecific antibody, CGT

C. In AIDD area, there has been significant investments and collaborations with global biopharma community

Companies with headquarters in Greater China

Companies with headquarters ex-Greater China

241

304

Deals with global biopharma

Global top 10 AIDD companies by pre-IPO funding¹, Mn USD 1,170 786 743 665 601 567 401 351

Relay Therapeut		alPi	Insitro	Recur- sion		Schro- ia dinger	Insilic Medi- cine	o Benevo- · IentAl	Owkin	Deep Geno- mics
USA	Cł	nina	USA	USA	UK	USA	China	UK	USA	Canada
	Global partner		Deal size		Global partner	Deal type		Deal size		
Deals with global	Lilly 2023.06	Small molecule discovery	Up to 250 USD	Mn	Exelixis 2023.09	Out-licensing of ISM3091	f	80 Mn USD	upfront by C	23 2023
biopharma		collabo- ration			Sanofi 2022.11	Research collal on new targets	l l	Jp to 1.2 Bn V ipfront)	U <mark>SD</mark> (21.5	Mn USD

Unique advantages of AIDD in China

NON-EXHAUSTIVE



Robust digital ecosystem and foundation, with digital native mindset of rapid iterations



Ample talent supply in computing, CADD², chemistry and biology areas



Fast clinical data generation to inform iterative design leveraging the CRO ecosystem and clinical resources

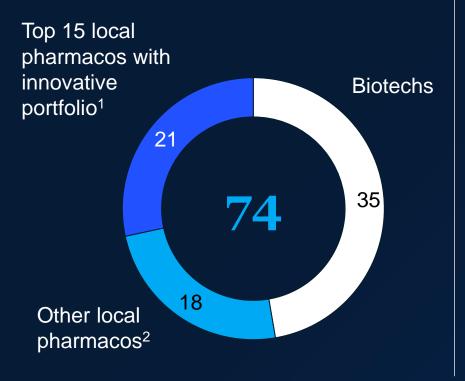
1. As of Sep 2023

2. Computer-Aided Drug Design

Source: Press release; Crunchbase; Pitchbook; McKinsey analysis

C. China-originated innovation has started entering commercial space, mostly with limited scale and global value capture to date

of China-originated innovative drugs approved in China between 2018-2022



 Top 10 China-originated innovative drugs launched between 2018-2022

 from biotechs

 China

 Overseas

Company	Molecule	Target	2022 Sales, Mn USD
BeiGene	Zanubrutinib	BTK	565
BeiGene	Tislelizumab	PD-1	425
Innovent	Sintilimab	PD-1	293
Legend	Ciltacabtagene Autoleucel ³	BCMA	134
Allist	Furmonertinib	EGFR	118
TopAlliance	Toripalimab	PD-1	109
HUTCHMED	Fruquintinib ⁴	VEGFR	94
Innocare	Orelabrutinib	BTK	84
Akeso	Cadonilimab	PD-1/CTLA4	81
Henlius	Serplulimab	PD-1	46

1. Top 15 large China pharmacos ranked by the number of innovative assets in clinical stage

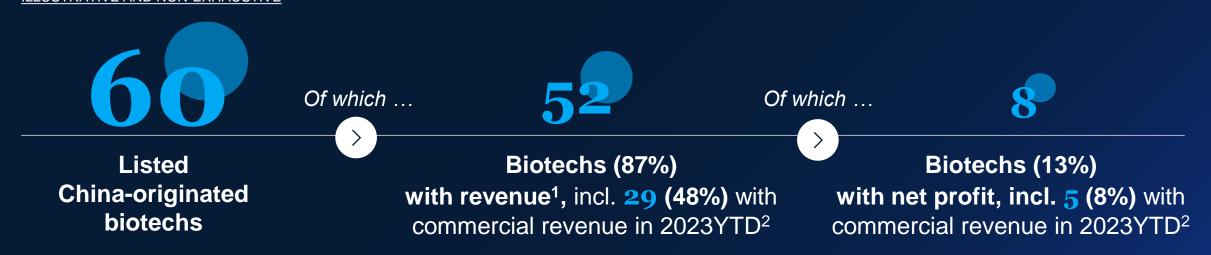
2. Other local pharmacos incl. local biotech/biopharma companies that beyond the top 15 local biopharma and the 60 listed biotechs

3. Ciltacabtagene Autoleucel approved in USA and EU

4. Recent FDA with global value capture potential

Source: Press release; GBI; DXY; WIND; McKinsey analysis

C. Profitability remains elusive for China-originated biotechs



Given a challenging funding environment, companies are becoming more vigilant in ROI assessment when making key investment decisions, for example:

- Reducing R&D burn rate: halt development of pipeline assets with questionable NPV (e.g., late to market in a crowded field with limited differentiation)
- More diverse commercialization approach: "in-house build" no longer the default choice for China launch. As first-time launcher, companies lacking sufficient portfolio scale could face sub-par productivity, and should proactively explore partnership as an alternative
- **Re-evaluating manufacturing investment:** critical to assess whether in-house manufacturing is justified with resized portfolio (i.e., overcapacity, learning curve to achieve cost competitiveness)

1. Revenue includes both product commercial revenue and partnership payment

^{2.} As of Oct. 30, 2023. Revenue and net profit data is based on the most recent company financial disclosure

C. *Innovation output:* optimism about the potential advancements across affordable & breakthrough innovations and technology

How would you rate where we are today and where we are heading in 5 years? Count of respondents by rating, N = 33

	Score	- 00				Average score	● 2023 ● 2028	
	1	2	3	4	5	2023 2028	Key observations	
Affordable innovation	Mostly in China		Expanded to selected developed countries (e.g., Japan) beyond emerging market		Enter USA/EU at scale	2.2 3.3		
	7 1	5	9 12	3 12	0 3			
							Similar level of	
Break- through innovation	No notable BIC/FIC from China to global market		Several scientifically differentiated innovation reaching global key markets with blockbuster potential		China establishes itself as a global innovation hub with steady flow of high- quality outputs	1.8 3.1		
N	10 1	18 8	5 13	0 10	0 1			
	••••				• • • • • • • • • • • • • • • • • • •		outputs	
Enabling tech innovation (e.g., Al)	Fast following global on technology (e.g., Al)		Lead global in certain technology areas		Leading in disruptive technologies changing drug R&D and delivery	1.9 2.9		
	111	137	9 19	0 5	0 1			
	• • • •				•			

Source: McKinsey "momentum of China-originated biopharma innovation" executive survey (N=33), 2023

● 2023 ● 2028

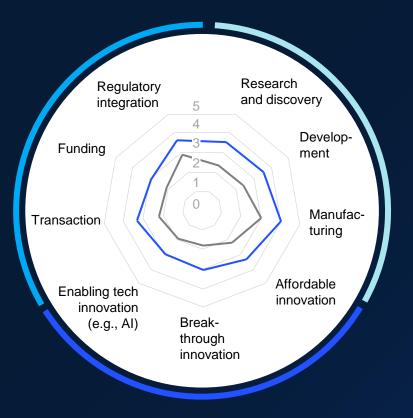
How will perspectives evolve from 2023 to 2028?

Value chain capability Enabler Output

How would you rate where we¹ are today and where we¹ are heading in 5 years?

Ratings from 1 to 5, N = 33

— 2023 ratings — 2028 ratings



1. China biopharma industry

Source : McKinsey "momentum of China-originated biopharma innovation" executive survey (N=33), 2023

By **2028**,

the Biopharma industry is expected to witness continued gradual improvement across dimensions, with regulatory integration and value-chain capabilities leading the way

9 dimensions to assess China's impact on global biopharma

Enabler Value chain capability Output

	Scoring criteria					
	1	3	5			
Funding	Funding mainly from China, stagnant growth in VC/PE investment and market cap	HKEX continues to be viable, and remains as a venue for China-originated biotech IPOs	HKEX continues to be viable, becoming a venue for global-caliber biotech IPOs			
Transaction	M&A happens mainly within China	China-originated biotechs increasingly attractive to global MNCs	China-originated biotechs acquire ex-China originated biotechs			
Regulatory integration	Global regulatory integration stalls or goes in reverse	No significant barrier for global regulatory integration	Full integration of China in global regulatory ecosystem, enabling China-originated innovation to access global patients			
Research and discovery	Limited contribution to global therapeutic innovation, subpar to USA/EU hubs	Innovation in selected areas	On par with global leading innovation hub			
Development	Activity largely in China, closely following global	On par with global in selected TAs, closely following in others	On par with global development across TAs, and leading in selected areas			
Manufacturing	Mostly supply to China market at lower cost	A global supply hub only in selected areas (e.g., mature modalities), with global quality and competitive cost base	A global supply hub across modalities, with global quality and competitive cost base			
Affordable innovation	Mostly in China	Expanded to selected developed countries (e.g., Japan) beyond emerging market	Enter USA/EU at scale			
Breakthrough innovation	No notable BIC/FIC from China to global market	Several scientifically differentiated innovation reaching global key markets with blockbuster potential	China establishes itself as a global innovation hub with steady flow of high quality outputs			
Enabling tech innovation (e.g., AI)	Fast following global on technology (e.g., Al)	Lead global in certain technology areas	Leading in disruptive technologies changing drug R&D and delivery			
Course: Makingov analysia			Makingay & Company E4			

04 What could future success look like?

What could be the success formula for local and MNC biopharma?

NON-EXHAUSTIVE



China-originated biopharma

Clear strategic bets (e.g., market and innovation focus, path to global value capture) combined with practical operational measures (e.g., funding management) and rapid upskilling of capabilities, to survive and thrive in the Reset Phase



MNC biopharma

Clear strategic stance choices, based on future aspiration and value at stake, a balanced and aligned view of risks and opportunities, combined with a reconfiguration of the approach to tap into value for China AND global

Three archetypes for China-originated biopharma innovators

ILLUSTRATIVE AND NON-EXHAUSTIVE

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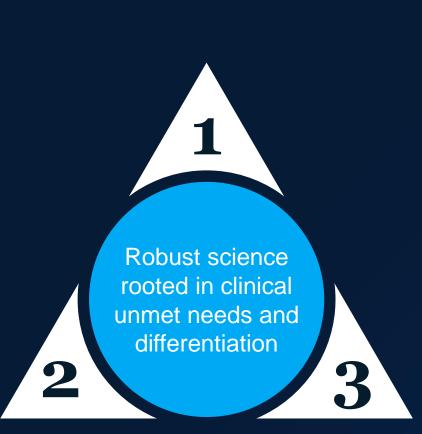
 \rightarrow Potential for companies to transition from one archetype to another

	Innovation focus	Archetype of leading future China-originated biopharma				
Global-oriented play	Globally competitive asset(s)/technology platforms with breakthrough potential	Global biotech with global caliber R&D and BD capabilities	Options to expand to global biopharma with innovation of sufficient scale	Global biopharma with global value chain capabilities, global culture, and robust funding capability		
		0		bal market-focused play		
China market- focused play	Me-too/Fast-following products		China's innovativ	e market and potentially rational efficiency and scale		

What could we expect on innovations from China?

3

NON-EXHAUSTIVE



Fast following with an edge in speed and differentiation

Reach first wave (global top 3) or demonstrate clinical differentiation (e.g., new indication, BIC potential) with fast iterations

2 Modality play powered by rapid engineering Rapidly adopt the latest modality technology and apply fast engineering iterations to drive innovation with differentiation potential (i.e., from "1 to 10")

TA bets based on disease knowledge and high unmet needs Select opportunities beyond crowded TA/DAs, by establishing deep disease and clinical insights, leveraging cost-efficiency and tapping into large patient population (e.g., CNS) 1. Fast-following with an edge: opportunities exist, but need to aim for top 3 and/or differentiated profile to capture meaningful value

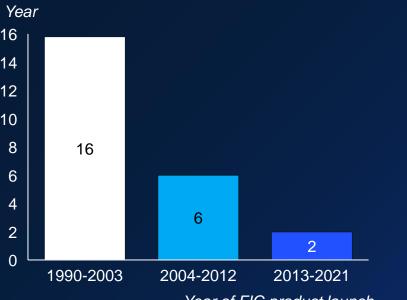
40-50% FDA-approved NDAs are not FIC assets

of FDA¹ approvals



Fast-following innovation has a much narrower window to compete effectively

Average time to have 3 products on market post launch of FIC product



Year of FIC product launch

90%

of VC investors interviewed are strengthening investment criteria and steering away from me-toos



We are no longer investing in me-too products; we will only invest if assets are
1) Globally top 3 by development status
2) Having clear differentiation potential

- Leading biotech investor in China

New approvals were tallied from CDER NDAs and BLAs and select CBER BLAs (only innovative vaccines, gene therapies, and cell therapies). First-in-class therapies were identified through publications up until 2011 and then through Evaluate pre-2011. All innovative CBER BLAs were assumed to be first in class.
 "Eint in class" approval is defined as the 1st drug approval is each MeA, not according to indications or clinical superior to the indication.

2. "First in class" approval is defined as the 1st drug approved in each MoA, not considering the indication or clinical superiority

Source: FDA CDER New drug approvals review ; FDA CBER Biological license application approvals; McKinsey analysis

3. Opportunity for China to tackle TAs of high unmet needs and large patient populations that are underrepresented in global pipeline?

Not exhaustive of all TAs

In USA, a clear shift toward developing drugs for smaller patient populations with high per patient value

of novel drug approvals in the last 5 years are orphan indications

90%

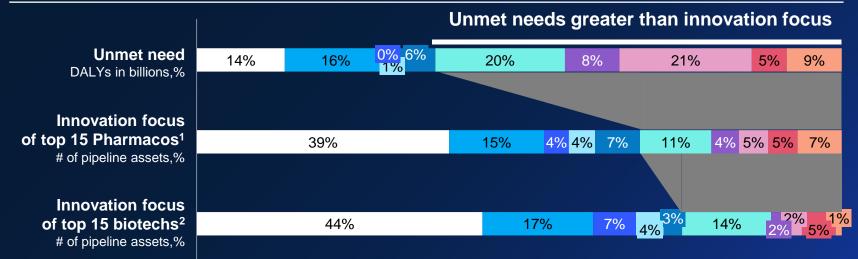
drop in the number of USA patients treated by top 10 drugs in the last 10 years

 Endocrine
 Cardiovascular
 Central nervous system
 Hematology
 Anti-infectives (incl. vaccines)

 Respiratory
 Musculoskeletal
 Gastrointenstinal
 Immune system
 Oncology

There are large disease areas presenting substantial unmet needs, creating opportunities for China and the industry as a whole

Innovation efforts do not fully align with global patient needs





Does China have the potential to tackle the TAs that are underrepresented in global pipeline leveraging the large patient base, cost efficiency and speed advantages, and increasing regulatory openness?

1. Top 15 Pharmacos ranked by November 2022 market cap and classified as pharmaceutical companies by S&P Global Market Intelligence

2. Top 15 biotechs defined by November 2022 market cap and classified as biotech companies by S&P Global Market Intelligence with a market cap less than 85 Bn USD

Source: WHO; McKinsey & Co. <u>Helix: Rewiring the DNA for the next wave of impact in biopharma</u>; EvaluatePharma November 2022, IHME database as of October 2022; S&P Global Market Intelligence as of November 2022; McKinsey analysis

Potential strategic bets to "survive and thrive" for future globaloriented innovators

NON-EXHAUSTIVE

¥ Y	A	Prudent funding management	More cautious cash flow management and capital deployment with clear linkage to value creation
	B	Portfolio innovation	Place a few bets on portfolio innovation with clear unmet needs and differentiation potential
E		Creating strategic distance	Along the value chain, make clear choices of what to build in- house vs. leveraging partners
		strategic distance	Build distinctive capabilities to compete globally (e.g., deep biology insights, clinical science in priority TA/DAs)
	D	Global value	Plan globalization roadmap that best matches company development stage and capability
		capture	Build the "right culture" (e.g., org and team) and management approach to enable a high performing global company

priorities to enable value creationBusiness strategy Operation Looking ahead, which would be the top-3 priorities for China innovative biopharma

Industry leaders and investors are largely aligned on the top set of

CEOs to maximize value creation in the next 5-10 years? (multiple choices) % of respondents, N = 33



Globalization mindset and global value capture ranked at the top

On top of managing funding, industry executives highlighted the necessity for companies to upgrade company strategy (e.g., more rigorous portfolio decisions)

D. Common pitfalls to look out for to fully realize global market value

NON-EXHAUSTIVE

Common pitfalls

- Insufficient understanding of regulatory requirements in the US/EU
- Late and reactive engagement with global expert network
- Internal-orientation, insufficient communication/data exchange and networking with potential biopharma partners
- Underestimation of the complexity of global clinical operation, often overly relying on CROs
- Lack of understanding of commercialization barriers by geography

Potential mitigation tactics



- Proactively and regularly communicate with regulatory authorities, and seek early input to shape clinical development plan and registration pathway
- Intentionally **tap into global expert network** (e.g., scientific advisors, KOLs/PIs, regulatory expert, etc.) to formulate clinical development strategy
- Exchange early data through global forums
- **Proactively engage** potential MNC biopharma partners, and consistently invest efforts across companies to build trust
- Build Pl/site network and take systematic approach to drive trial execution excellence (e.g., predictive model to optimize site selection, submission excellence)
- Carefully assess commercialization approach (partnering vs. self-build), taking into account competition intensity, investment required, etc.

In this era of resilience, a clear strategic posture will be critical for MNCs

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Four primary courses of action for biopharma MNCs in China¹

Accelerate selectively Ramp up selectively in segments with a structural advantage	Renew commitments Stay heavily vested in China and double-down capital investments as necessary		
Reduce stake Limit stake in China through local partnership, or exit	Diversify Refocus presence or streamline China operations by reallocating resources across BUs and brands		
Low to Moderate	High to Critical		
	Ramp up selectively in segments with a structural advantage		

Review of current value at stake and future right to win should be conducted at both corporate and business segment levels, for biopharma MNCs to define their strategic posture

Amid current macroenvironment in China, MNCs more than ever need to reconfigure for their opportunities and risks in China

Current value at stake in China

incl. China revenue/profit/growth to global, MNC's value chain in China, etc.

1. McKinsey & Co. <u>The China imperative for multinational companies</u>

Source: McKinsey analysis

A balanced view is necessary to assess both opportunity and risk in China

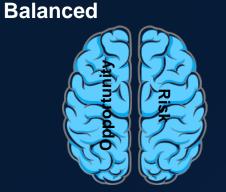
ILLUSTRATIVE AND NON-EXHAUSTIVE

Three mindsets observed when reconfiguring for opportunity and risk

Opportunity-driven



Opportunity focused - considering China LT upside exceeded downside and justified bold bets, with limited attention given to risks



Taking a balanced view on opportunity and risk, realistically assessing and managing both sides

Before COVID, many MNCs skewed towards "opportunity-driven"

Post COVID, more MNCs shifting towards "risk-centric"

A proper strategy should be based on a balanced posture

Difficult equilibrium to find given dynamics

1. McKinsey & Co. <u>The China imperative for multinational companies</u>

Source: McKinsey analysis

Risk-driven



Driven by risk avoidance, overlooking potential opportunities and ways to de-risk. Short term focused on opportunity assessment

MNCs can swing from one main mindset to another as a result of geopolitical and China sectorial dynamics

Lately, risk-driven mindsets *are more prevalent*, in the USA in particular

Landing on a balanced view requires anchoring into a common source of truth, and developing scenarios that can be aligned at HQ level, and between HQ and local operations

Future-proof recipe for MNC biopharma in China

NON-EXHAUSTIVE

Top-down CEO commitment and full alignment

across senior management team behind a well-defined China strategy

China for China

- Market-relevant portfolio addressing differentiated unmet needs with synergy and continuous launch momentum
- Upgraded GTM model to drive profitable growth and hedge against increasing operational cost (e.g., rethink of coverage and channels, digital and omni-channel engagement, and innovative patient solutions)
- Integration into the fabrics of local innovation and digital ecosystem to pioneer and capture unique opportunities (e.g., health consumerism, digital/AI)

China for global

- Accelerating global development for both pivotal and early clinical stages
- Enriching global portfolio with local innovative assets/technology platforms
- Innovating global business model with China as a testing ground
- Empowering global talent pool with globalcaliber diverse talent resources and capabilities

Raised importance of effective partnership in full range from asset licensing, value chain capability leverage, and broader ecosystem partnership to maximize value capture

龠鳥

Locally empowered governance model with an upgraded risk management mechanism to remain "in control at arm's length"

China for China and China for global can both create significant value, and be the primary axis of the strategy

Key takeaways

China innovative pharma market is still a growth story with room to grow into 2.5x the size of today

China biopharma went through a Cambrian phase before 2021, with many companies created and fund raised, formation of the innovation ecosystem, and value chain capability build-up with scaled fast-following innovations

A significant correction took place globally in 22-23, and is more severe in China, challenging the fundamentals of value creation and revealing major ecosystem gaps

However, China biopharma innovation ecosystem is showing signs of resilience (e.g., flow of ex-China deals, shifting toward globally-competitive innovation) and we have seen enough green shoots to recover overtime towards more sustainable value creation

Locals could accelerate a steep and tough journey towards capturing global potential to "survive and thrive"

MNCs could consider reconfiguring their business and the risk/opportunity equation to preserve their rights to win in China, while more actively leveraging China for global

For more on China life sciences and healthcare...



McKinsey China Life Sciences Practice leadership team



www.mckinseychina.com



2022 China biotech executive roundtable on global BD&L partnership



McKinsey 2022 China Launch Roundtable



China Local Pharma Roundtable

Acknowledgements

We would like to thank the global biopharma BD executives, industry experts, leading China biotech executives and investors that participated in our interviews and survey



In-depth interviews with 30+ global and China biopharma leaders and investors



Focused C suite and investor survey (N=33)

Consolidated inputs from 54 experts worldwide



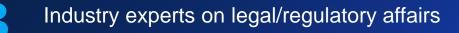
CEOs and executives from Chinaoriginated biotechs/biopharma



Investors and equity researchers from leading PE/VC and investment banks



Senior BD executives from global biopharma



McKinsey & Company