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The dawn of China biopharma innovation

Chinese biopharma is making a mark on the global stage as the rapidly evolving regulatory landscape and maturing innovation ecosystem spur significant value creation.

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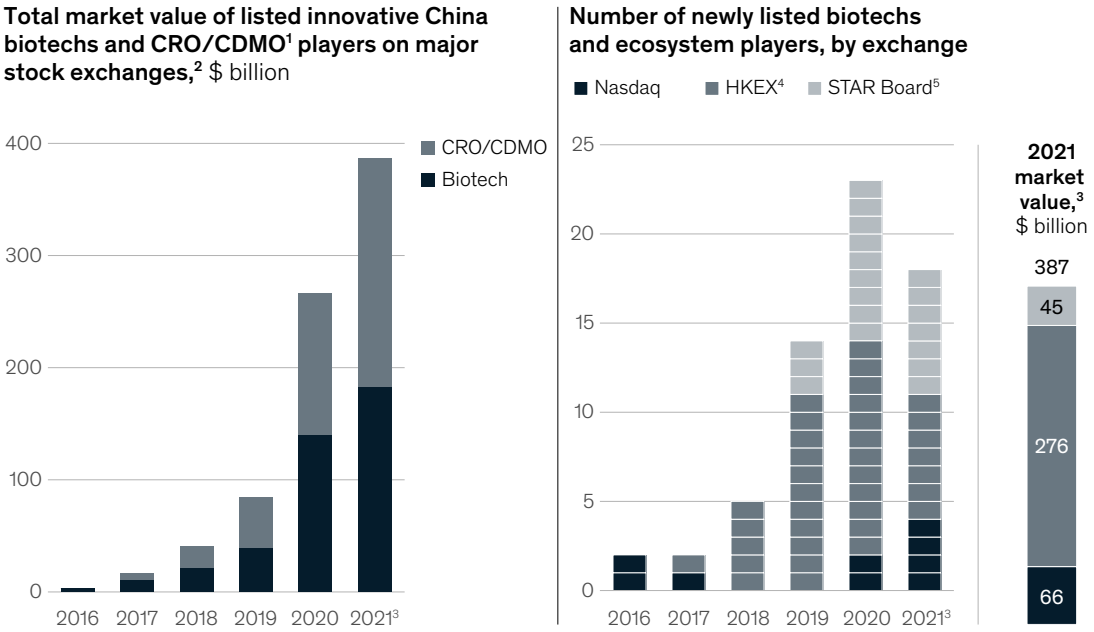
China's biopharmaceutical ecosystem is experiencing a momentous shift from a formerly generics-focused play into one that nurtures innovation, with profound implications for patients and industry peers. In this article, we take the pulse of China's vibrant innovation ecosystem, look at the key trends driving the biopharma industry, and share thoughts on how multinational pharmaceutical players can tap into innovation opportunities in the world's second-largest healthcare market.

Innovation in Chinese biopharma is fast becoming a notable story, underscored by significant value creation on global capital markets. The market value of publicly listed biopharma innovation players from China across the Nasdaq, Hong Kong Stock Exchange (HKEX), and Shanghai Stock Exchange Science and Technology Innovation Board (STAR) has surged from $3 billion in 2016 to more than $380 billion in July 2021. Biotechnology companies originating in China accounted for $180 billion of that total (Exhibit 1). Public debuts for Chinese players have also accelerated, with 23 IPOs in 2020 alone. Indeed, Chinese biotechs are leading on IPO fundraising—seven out of the world's top ten largest biopharma IPOs from 2018 to 2020 originated from China.

Exhibit 1

Chinese biopharma innovation players have spurred notable value creation since 2016.



[1]Contract research organization/contract development and manufacturing. [2]Biotechs and CRO/CDMOs focusing on innovative drug development. For companies listed in multiple stock markets, market cap value from the primary listing is used. [3]As of July 2021. [4]Hong Kong Stock Exchange. [5]Shanghai Stock Exchange Science and Technology Innovation Board.
Source: Capital IQ; McKinsey analysis

A rapid proliferation of new drug discoveries with the potential to address unmet needs in the domestic market and beyond has helped China increase its share of the global innovation pipeline to 13.9 percent in 2020 from 4.1 percent in 2015.[1]

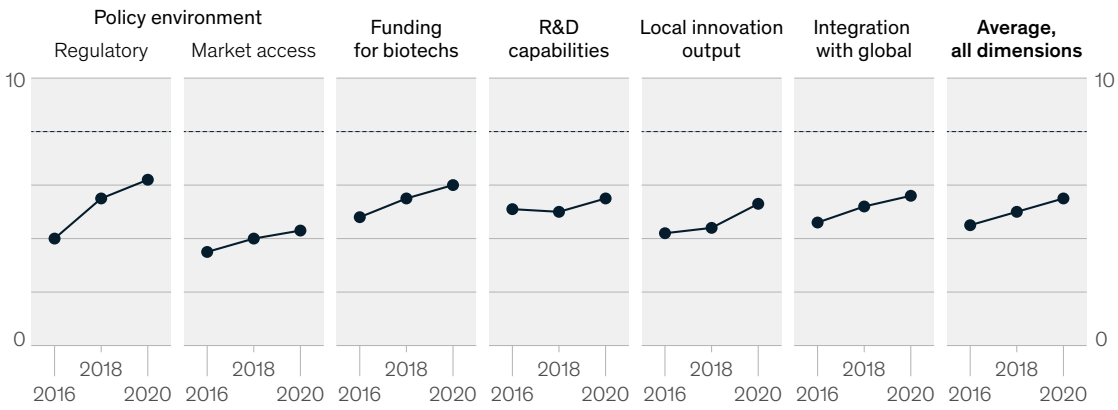
China's innovation ecosystem: A fast and slow evolution

Regulatory reforms, the emergence of bioclusters in areas such as the city of Suzhou, talent returning from overseas, and the opening of China's capital markets have all played a part in enabling Chinese biopharma to emerge on the global innovation stage.

To understand how China's biopharma innovation ecosystem is evolving and obtain a more nuanced understanding of the drivers behind its growth, McKinsey maintains the China Drug Innovation Index (CDII). First launched in 2016, the survey asks industry experts to gauge five dimensions that support healthy biopharma innovation: policy environment (split between regulatory reforms and market access policies), funding, research and development (R&D) capability, local innovation output, and integration with global markets. Participants rate China on a scale from 0 to 10, with 10 being the highest, and the United States serving as a benchmark with a score of 8 (Exhibit 2).

Exhibit 2

The China Drug Innovation Index shows the 'fast and slow' evolution of China's biopharma innovation ecosystem between 2016 and 2020.



Source: CDII Survey (2016, n = 65; 2018, n = 109; 2020, n = 129); McKinsey analysis

[1] *Building China's pharmaceutical innovation ecosystem—part one of the series research reports: 2015-2020 development review and future prospects*, jointly released by China Pharmaceutical Innovation and Research Development Association and the R&D-based Pharmaceutical Association Committee, April 2021, rdpac.org; includes all pipelines in preclinical, clinical, and preregistration stages; multinationals' pipeline is accounted for based on the location of the company headquarters.

We polled 129 industry experts for the 2020 edition of the CDII, two-thirds of whom are CEOs or senior executives, to establish the dimensions in which China has made the most progress and the areas that still require attention. Our research shows that industry sentiment is steadily improving, with the average rating across all criteria increasing from 4.5 to 5.5 between 2016 and 2020. Drilling down into each dimension reveals six key takeaways.

Rapid regulatory reform has supported faster development and approvals

The regulatory environment subdimension showed the largest improvement, with the score advancing from 4.0 in 2016 to 6.2 in 2020. The speed and scale of the reform is quite unprecedented in China's history; a 2015 overhaul with the goal to bring China's pharmaceutical regulations into line with international standards and by 2017 had facilitated accession to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. These steps enabled China's drug discovery and development ecosystem to integrate globally. Meanwhile, measures to accelerate new-drug reviews, including raising the number of staff at the Center for Drug Evaluation (CDE) from 150 in 2015 to 700-plus in 2018 (supplemented by over 600 external committee members), helped clear a backlog of 20,000 applications in two years, according to CDE data. Moreover, the CDE granted over 200 New Drug Applications (NDAs) from 2016 to 2020, according to data from GBI, a provider of intelligence and analytics for the Chinese pharmaceutical market.

In parallel, China's National Medical Products Administration (NMPA) streamlined new-drug-approval procedures, beginning with the introduction of priority reviews in 2016. Based on NMPA data, the proportion of drugs under priority review increased from 14 percent in 2016 to 77 percent in 2019. In 2018, the NMPA added conditional approvals based on clinical trial data, and has since granted 34 conditional approvals, according to CDE data released at the 2021 Chinese Society of Clinical Oncology conference. In July 2020, Drug Registration Regulations introduced a new channel for breakthrough therapies, with over 70 drugs receiving the designation as of August 2021. These reforms helped energize a powerful innovation pipeline.

Market access is still slow to open up

This subdimension scored just 4.3, the lowest in our survey, and represents only minor improvement from 2016. Annual updates of the National Reimbursement Drug List (NRDL) since 2017 have helped broaden access for innovative drugs (previously, the list had not been updated for eight years). However, NRDL pricing pressures weighed in on the rating, according to 81 percent (105 out of 129) of the survey participants.

Ample access to capital for innovation

A score of 6.0 in 2020, the second-highest across the main index, reflects considerable confidence in the funding environment for Chinese biopharma. Fundraising and investment from venture capital and private equity is expected to remain the most accessible source of funds. Meanwhile, stock markets, and in particular the HKEX and Shanghai's technology-focused STAR board, have emerged as a vibrant financing channel, accounting for 21 of 23 Chinese biotech IPOs (two on the Nasdaq, 12 on HKEX, and nine on STAR) in 2020, led by Everest Medicine's $520 million debut on the HKEX.

Innovation value-chain capabilities are steadily improving

Overseas returnees with decades of drug-development expertise and the booming growth of contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs) helped lift the R&D score in 2020 to 5.5, a modest increase from 2016. The proliferation of CRO and CDMO infrastructure has helped to foster biotechnology innovation, allowing China to emerge as one of the leading providers of services in some subsegments. For example, WuXi AppTec and Pharmaron are now the world's largest providers of preclinical chemistry services. Our survey also highlights improvement in the clinical development and chemistry, manufacturing, and control (CMC) capabilities required to support ecosystem growth. That said, we still have gaps in academic research, drug discovery, and the infrastructure for technology transfer from academia to industry, according to the CDII.

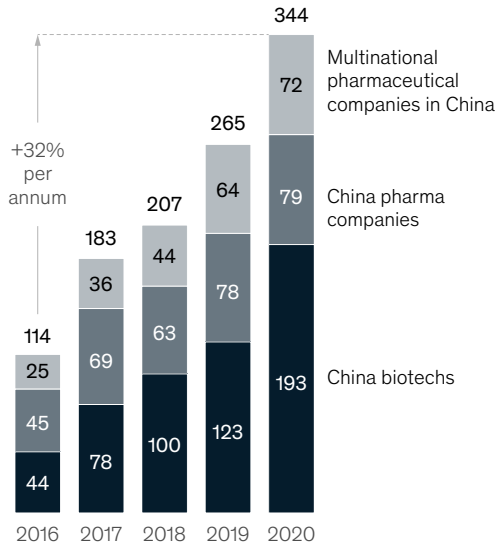
Local innovation takes center stage

The CDII suggests output from local innovators is Chinese biopharma's most improved primary dimension, achieving a score of 5.3 in 2020 versus 4.2 in 2016. This reflects strong growth in clinical-trial applications, which increased at an average of 32 percent each year from 2016 onward. Meanwhile, local biotechs have gradually improved their share of the innovative molecules under development in China to account for more than 50 percent of the total in 2020 (Exhibit 3). NDAs from local innovators have also grown from just 2 percent of the total in China in 2017 to over half in 2021 (23 of 43 NDAs as of the end of July). The novelty of these assets has also improved over time, progressing from "fast-follower" plays to a more differentiated approach.

Exhibit 3

China's innovation pipeline has grown steadily, with its biotechs submitting the most clinical trial applications in 2020.

Number of innovative molecules[1] for clinical trial applications in China by company type



Note: Biotechs defined as companies focusing on innovative drugs; China pharma companies defined as companies with a portfolio including both generics and innovative drugs. Figures may not sum, because of rounding.
[1]New molecular entities (both chemical and biological) in China.
Source: GBI; McKinsey analysis

Cross-border deals underpin global market integration

Chinese innovations are also making an impression on the world market, supporting a global integration rating of 5.5, a solid improvement over 2016. Over the past 12 months, Chinese biotechs have signed a record 12 major out-licensing deals for innovative drugs with multinational pharmaceutical companies (MNCs), carrying a median deal value of more than $900 million (Exhibit 4). The deals exemplify strength in oncology, particularly around well-established PD-1 assets. They also show how far local biotechs have come: I-Mab Biopharma's anti-CD47 monoclonal antibody (mAb) for hematologic malignancies such as leukemia is a potential best-in-class treatment currently undergoing Phase II clinical trials, following in the footsteps of the front-runner from Gilead Sciences, which is in Phase III.

In parallel, Chinese biopharmas continue to source innovations from the global market, striking more than 60 in-licensing partnerships in 2020, based on GBI data. We are observing more creative deal structures, including strategic partnerships inclusive of equity investment, and tie-ups between MNCs and China-based venture-capital funds to foster innovation, among other models.

Mapping the future of Chinese innovation: Three trends to watch

China's biopharma ecosystem is advancing in the right direction across the CDII, showing incremental improvements in most of the areas necessary to foster innovation. These advances are ushering China's biopharma industry into a new phase characterized by three major trends: faster drug development, deeper differentiation, and the ambition to make an impact on the global innovation landscape. Below, we take a look at what these trends mean for the future of biopharma innovation in China and beyond.

1. Chinese players will continue to accelerate drug development

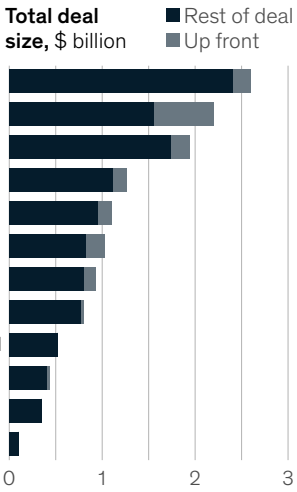
China-based biopharmas have historically pursued a fast-follower strategy, developing a risk-balanced portfolio heavily weighted in favor of clinically

Exhibit 4

Chinese biotechs have struck a dozen major out-licensing deals with global biopharma companies in the past year.

Notable out-licensing deals from Chinese biotechs to multinational pharmaceutical companies, July 2020–July 2021

Chinese biotech	Global licensee	Asset	Modality	Stage at deal
RemeGen	Seagen	disitamab, vedotin	ADC[1]	Approved
BeiGene	Novartis	BGB-A317	mAb[2]	Approved
I-Mab	AbbVie	TJC4	mAb	Phase 1b
CStone	EQRx	sugemalimab, CS1001	mAb	Phase 3
Junshi Biosciences	Coherus	toripalimab	mAb	Approved
Innovent	Eli Lilly	Tyvyt	mAb	Approved
InnoCare	Biogen	ICP-022[3]	Small molecule	Phase 2
Allist	ArriVent	AST2818	Small molecule	Approved
Tide Pharmaceutical	Graviton	TDI01	Small molecule	IND[4] approved
Fosun Pharma	Eli Lilly	FCN-338	Small molecule	Phase 1
TransThera	LG Chem	TT-01025	Small molecule	Preclinical
Hansoh	EQRx	HS-10296	Small molecule	Approved



[1]Antibody-drug conjugates. [2]Monoclonal antibodies. [3]InnoCare licensed the related autoimmune indication to Biogen and kept the oncology-related indication.
[4]Investigational New Drug application.
Source: GBI; McKinsey analysis

validated targets pioneered overseas. More recently, many players are shortening the time lag with global leaders targeting the same mechanism of action (MoA) while turning toward early-stage, nonclinically validated MoA.

The lag between the launch of new drugs to the US market and the appearance of a Chinese follower is shortening. Whereas it took eight years from the 2003 first-in-class (FIC) launch of AstraZeneca's epidermal growth factor receptor inhibitor Iressa to the appearance of Betta Pharmaceuticals' Conmana in China, just four years elapsed between the 2014 debut of Merck's PD-1 anticancer treatment Keytruda and the release of Tuoyi from Top Alliance (also known as Shanghai Junshi Biosciences) to the China market.

We expect Chinese players to continue closing the gap on global FIC assets. For example, BeiGene's drug targeting the TIM-3 immune checkpoint receptor is in Phase II clinical trials, compared with the FIC competitor in Phase III. Abbisko Therapeutics' drug targeting FGFR4 is in Phase I clinical trials, while the FIC competitor from Blueprint Medicines (in-licensed by CStone Pharmaceuticals) is conducting Phase II trials targeting FGFR4-driven, locally advanced or metastatic hepatocellular carcinoma (HCC).

2. Chinese biotechs are moving toward differentiated therapies and platforms

Investment by Chinese biotechs in innovation and differentiation is bearing fruit. For instance, Junshi Biosciences is developing an anti-BTLA mAb with

FIC potential, while I-Mab's anti-CD47 mAb has best-in-class potential due to an elevated safety profile that lowers red blood cell binding, according to the deal news release.

Chinese players are also building up platform technology and investing in new modalities. Notably, Akeso Biopharma and EpimAb Biotherapeutics are building up proprietary bispecific technology platforms. For example, Gracell Biotechnologies' FasTCAR aims to tackle challenges with autologous therapies, including lengthy manufacturing times, suboptimal manufacturing quality, high therapy cost, and poor T-cell fitness, according to their latest news release. RemeGen, meanwhile, is developing an antibody-drug conjugate platform based on its lead asset disitamab vedotin (RC48), which launched conditionally in China for gastric cancer and obtained US Food and Drug Administration (FDA) breakthrough therapy status for the treatment of urothelial cancer. RemeGen has entered a $2.6 billion licensing and co-development deal for RC48 with Seagen (Exhibit 5).

3. Chinese innovations are entering the global marketplace

Chinese biopharmas are exploring options to go global and secure the full value of their innovations. As a result, one could expect more international partnerships that encompass overseas clinical trials and aim to develop and commercialize innovative drugs discovered in China for patients in US and European markets. As a corollary, Chinese biopharma innovations are gaining regulatory recognition worldwide. In the past two years, FDA designations for China-originated therapies have proliferated, including fast track—the pathway for drugs filling unmet medical needs—and breakthrough therapy for those that may improve existing treatments (Exhibit 6).

Exhibit 5

Chinese biotechs are moving toward differentiation.

Selected examples of local innovations, nonexhaustive

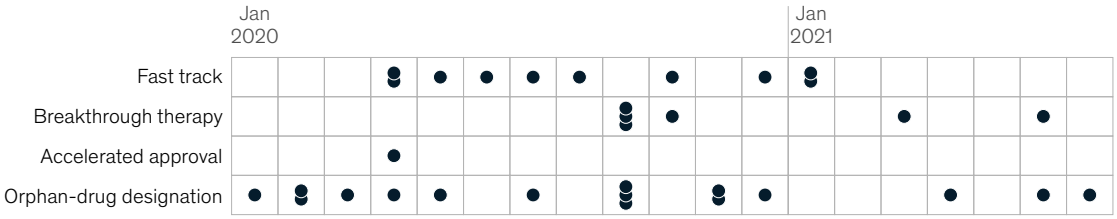
Potential first/best-in-class		Proprietary technology platform			
		Bispecific		ADC[6]	CAR-T
Junshi Biosciences	**I-Mab**	**Akeso**	**EpimAb**	**RemeGen**	**Gracell**
JS004, self-developed by Junshi, is the first BTLA[1] mAb,[2] and received IND[3] from both FDA[4] and NMPA[5]	TJC4, a potential best-in-class anti-CD47 mAb, recognizes a unique epitope on CD47 and exhibits minimal binding to red blood cells	Tetrabody platform for the design and production of innovative tetravalent bispecific antibodies	FIT-Ig (fabs-in-tandem) technology allows rapid bispecific lead generation from mAbs without mutations or linkers	ADC platform for end-to-end R&D and manufacturing of ADC drugs	FasTCAR solution, cutting CAR-T cell preparation time to 24 hours

[1]B and T lymphocyte attenuator. [2]Monoclonal antibody. [3]Investigational New Drug application. [4]US Food and Drug Administration. [5]China National Medical Products Administration. [6]Antibody-drug conjugates.

Exhibit 6

Chinese biotechs are going global and obtaining US Food and Drug Administration designations.

Instances of FDA designations for innovative therapies by Chinese biopharmas and biotechs, Jan 2020–July 2021



Source: Company websites; press releases; US Food and Drug Administration; McKinsey analysis

On the commercial front, Chinese companies are striking significant partnerships with MNCs, seeking to leverage their established development and commercial capabilities for US and European markets. A few Chinese players are also building their commercial presence outside of China. For example, BeiGene has split its headquarters across Beijing and Cambridge, Massachusetts. HutchMed is ramping up its R&D and commercial footprint across China, Europe, and the United States, having initiated US NDA proceedings for its new molecule, surufatinib. It remains to be seen whether such commercial expansions will help these companies capture more value from China-originated innovations and establish a global biopharma with significant US and China footprints. For example, limited experience in the reimbursement complexities in the US pharma market could pose significant challenges.

Accessing the innovation opportunity: Three strategies for multinational involvement

Clearly, China's emergence as a new actor in the global biopharma innovation ecosystem has important implications for the industry. A few MNCs are consequently moving to tap into China's pipelines of innovative assets, with their actions revolving around three primary models.

— *Sourcing assets from China for local and global markets.* AbbVie has been actively sourcing assets from China. In addition to licensing I-Mab's TJC4, AbbVie has partnered with Jacobio Pharmaceuticals to tap its SHP2 assets, a potential first-wave anticancer monotherapy. Legend Biotech's deal with Johnson & Johnson on CAR-T therapy, and a handful of deals by other MNCs to exploit China-sourced PD-1 assets globally, also illustrate a trend of outward-facing deals.

Regarding inbound activity, MNCs are looking to acquire new products as off-patent originator drugs enter volume-based procurement and no longer command significant price premiums. Bayer's 2020 move to in-license dorzagliatin, a dual-acting glucokinase activator, is indicative of such activity and will enrich Bayer's antidiabetic portfolio.

— *Striking multifaceted strategic partnerships.* Strategic partnerships with Chinese counterparts can provide access to local development and commercialization capabilities. Such deals also offer the opportunity to tap robust capital markets: as of August 2021, the value of Amgen's 2019 acquisition of a 20.5 percent stake in BeiGene was up by approximately $1.5 billion, representing a solid gain on a purchase initially worth about $2.7 billion. On the strategic front, the deal supports Amgen in developing and commercializing its oncology portfolio in China. Elsewhere, Pfizer invested $200 million in CStone, and got access to CStone's late-stage oncology asset sugemalimab in mainland China.

— *Fostering innovation on the ground in China.* Various models have emerged as MNCs seek to capture and catalyze innovation in China, including the following:

- *Partnering or launching local investment funds.* Sanofi in 2020 invested in Cathay Innovation to support healthcare entrepreneurs, following on the heels of AstraZeneca's launch of a $1 billion fund with China International Capital Corporation to invest in China's healthcare sector.

- *Establishing incubators to foster early-stage innovation.* Launched in 2021, Roche Accelerator, the Swiss company's first global accelerator, aims to attract entrepreneurial talent in pharmaceuticals, diagnostics, and personalized healthcare, including AI and digital solutions. Johnson & Johnson's Shanghai branch of its JLABS incubator network is the largest in the world and aims to serve both China and Asia–Pacific.

- *Opening technology platforms to Chinese innovators.* In 2020, Innovent secured access to Roche's universal CAR-T platform and to technologies that enable the discovery and development of specific 2:1 T-cell bispecific antibodies. While Innovent will develop, manufacture, and commercialize the products, Roche retains an option to license them for ex-China development and commercialization.

These strategies and trends represent early-stage attempts to capture a share of China's rapidly growing pipeline of biopharma innovations. They will likely gather momentum as Chinese players continue to evolve and augment the global innovation marketplace. As a case in point, China's investment in AI is opening the door to new drug discovery and delivery models for healthcare, deepening the pool of opportunity for both local and international partners.

Global ambition, significant funding, the scale and pace of reforms, the talent supply, and the healthcare opportunity are galvanizing a new era of biopharma innovation in China. The CDII suggests that challenges remain with regard to nurturing a productive policy environment and securing a sufficient supply of talent. Industry participants should also seek to effectively hedge the risk of participating in such a dynamic and nascent innovation market. But overall, China's emergence as a potential new source of differentiated innovation is positive news for a global biopharmaceutical industry facing intense competition and pressure on R&D productivity. Determining a strategy to capture the rising value of China-related innovation would increasingly be featured on many global biopharma players' agendas.

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