The Rise of Chinese Biotechs and Increasing Competitiveness on a Global Scale

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Summary

China's status as one of the foremost economic powers is quite impressive given that China was playing economic catch-up with Western countries for much of the 20th century. The late arrival of industrialization in China was a major contributing factor, and it was not until Deng Xiaoping's sweeping economic reforms that the country finally began to open itself to global industry. Modern-day China has become a global powerhouse not just in its legacy industries in manufacturing, but also further up the value chain in IP origination and services — areas key to its future growth. While tech firms like Tencent and Alibaba have garnered the most international attention, Chinese biotech and pharmaceutical companies have made equally impressive strides. A deeper examination of the history of the domestic industry combined with a comparison between modern-day US and Chinese firms will reveal just how much more competitive Chinese firms have become in the last decade. Many of the leading Chinese biotech companies are Hong Kong or China A-Share, or Connect listed (without US listed ADRs). Without sophisticated mechanisms in place, such as on-shore accounts, local broker relationships, and regulatory compliance, it is very challenging to efficiently access these markets. Given the heightened interest in biotech investing globally, especially in a post-COVID environment, this White Paper aims to discuss why Chinese biotech innovation was inevitable from an economic standpoint, and how Chinese companies are beginning to level the playing field with established Western names by increasing their investment in research and development (R&D) to dominate not only the domestic market, but potentially foreign markets as well.

The Structure of Worldwide Biotechnology and Pharmaceutical Research and Development

Before we take a closer look at Chinese biotech, a key metric that will be discussed is the price-to-research ratio, which describes market capitalization as a multiple of R&D expense. Price-to-research essentially shows how much an investor pays per dollar of R&D, with a lower ratio implying that more investor money flows towards R&D, and thus towards the development of innovative products. While high R&D expense will not guarantee the discovery of commercial innovative products, it certainly provides an edge. We believe a significant portion of Chinese R&D is currently focused on the research segment (around 70%), whereas Western companies are the exact opposite, dedicating around 70% to development instead. As a result, their research and discovery capabilities may actually be quite similar. Table 1 shows the R&D capabilities of select Chinese biotech firms through their R&D spending, research personnel, and compounds under development. A detailed breakdown of select Western compared to Japanese and Chinese firms can be found in Table 2, which includes market capitalization, gross margin, gross profit margin, R&D expense, and price-to-research ratio.

Table 1

6/4/2021

Chinese Company Research Capacity

	Innovent Biologics (1801 HK)	Shanghai Junshi (1877 HK)	BeiGene (6160 HK)	Akeso (9926 HK)	Jacobio (1167 HK)	CStone (2616 HK)	InnoCare (9969 HK)
Cash & cash equivalents (USD, thousands)	1,249,380.00	528,905.94	1,381,950.00	419,452.97	223,502.50	472,585.63	2,300,881.00
R&D expenditures (USD, thousands)	(289,289.53)	(277,816.09)	(1,294,877.00)	(120,092.03)	(29,055.00)	(219,481.88)	(402,771.00)
Full-time employees	3,279	2,453	5,300	746	210	470	452
Research personnel	947	667	1,600	355	169	212	190
Compounds under clinical development	24	30	45	11	12	14	11
Commercialized compounds	4	2	7	0	0	2	1
Clinical-stage compounds	20	11	38	11	4	8	3
Pre-clinical	Not disclosed	17	Not disclosed	Not disclosed	8	4	7

Notes: Sourced from most recent 10-K filings on HKEX. Most information from MD&A, financial statements, and notes to financial statements. Converted to RMB at 6/4/21 conversion rate of 1:6.4

Recent Developments

While Chinese pharmaceuticals are increasingly the product of novel IP and intensive R&D, many major Chinese players historically licensed drugs from more established Western firms. Even today, several large Chinese pharmaceutical companies continue to use licensing as their primary method of filling their pipeline. One notable recent example is Zai Lab (ZLAB), a US listed Chinese biotech with "unicorn" status, meaning a market capitalization of over $1 billion prior to IPO. Key commercial products like ZEJUNE, Optune, and QINLOCK are licensed from Western companies like Tesaro (acquired by GlaxoSmithKline), NovoCure, and Deciphera, respectively[1]. Across their pipeline, Zai Lab has 15 licensing agreements in place[2]. Licensing allows firms like Zai Lab to spend significantly less on R&D while having exclusive rights to commercialize novel compounds with IP protection in their designated markets. There is also lower risk associated with licensing, as compounds have oftentimes been clinically proven in a different market and can be deployed to market relatively quickly. What separates Zai Lab from other licensing-centric competitors is its focus on novel drugs with lengthy IP protection that target specific types of cancer. This makes it difficult for domestic competitors to replicate the drug, giving Zai Lab market dominance over the complete, albeit smaller, market. However, licensing agreements also come with the caveat of revenue sharing with the originator of the compound, which cuts into the licensee's profit margins. Zai Lab's 15 licenses all include flat upfront and milestone fees, as well as variable royalties if the company succeeds in commercialization of any licensed products[3]. While there is no clear breakdown of flat fees or royalties in their annual report, it does note that they are bundled into their cost of sales metric, which in total represented just over 34% of revenues. Additionally, of Zai Lab's approximately $223 million of R&D expenses in 2020, $108 million

[1] Zai Lab 2020 10-K
[2] Id.
[3] Id.

was attributed to both upfront and milestone licensing payments[4]. Due to its savings in overall R&D from the licensing model, Zai Lab carries a price-to-research ratio of 73.0, far above the average of 37.1 among the five selected Chinese biotech companies. However, its gross profit margin is only 65.8%, quite a bit lower than the average of 75.7%, which reflects the impact of the revenue sharing agreements it has in place with its partners (Table 2).

Table 2

6/15/2021

China v. Global Pharmaceutical Companies

United States Pharma	Ticker	Sales (Million USD)	Gross Profit (Million USD)	*GMP (%)*	Mkt. Cap. (Million USD)	R&D Expense (bn USD)	*Price-to-research (PRR)*
Merck	MRK US Equity	47,994	32,509	*67.7%*	191,044	13,558	*14.1*
Eli Lilly	LLY US Equity	24,540	19,057	*77.7%*	216,836	6,086	*35.6*
Pfizer	PFE US Equity	41,908	33,216	*79.3%*	221,837	9,405	*23.6*
BMS	BMY US Equity	42,518	30,745	*72.3%*	150,248	11,143	*13.5*
AbbVie	ABBV US Equity	45,804	30,417	*66.4%*	203,822	6,557	*31.1*
Average		40,553	29,189	*72.7%*	196,757	9,350	*23.6*
European Pharma	Ticker	Sales (Million USD)	Gross Profit (Million USD)	*GMP (%)*	Mkt. Cap. (Million USD)	R&D Expense (bn USD)	*Price-to-research (PRR)*
Sanofi	SNY US Equity	42,665	28,785	*67.5%*	136,795	6,313	*21.7*
Novartis	NVS US Equity	49,898	34,777	*69.7%*	230,892	8,980	*25.7*
Roche	RHHBY US Equit	62,197	44,945	*72.3%*	332,905	13,873	*24.0*
GSK	GSK US Equity	43,778	28,752	*65.7%*	101,863	6,545	*15.6*
AZN	AZN US Equity	26,617	21,318	*80.1%*	154,277	5,991	*25.8*
Average		45,031	31,715	*71.0%*	191,346	8,340	*22.5*
United States Biotech	Ticker	Sales (Million USD)	Gross Profit (Million USD)	*GMP (%)*	Mkt. Cap. (Million USD)	R&D Expense (bn USD)	*Price-to-research (PRR)*
Gilead	GILD US Equity	24,689	20,117	*81.5%*	85,472	5,039	*17.0*
Vertex	VRTX US Equity	6,206	5,469	*88.1%*	50,427	1,830	*27.6*
Amgen	AMGN US Equity	25,424	19,265	*75.8%*	138,577	4,207	*32.9*
Alexion	ALXN US Equity	6,070	5,516	*90.9%*	40,148	1,003	*40.0*
Average		15,597	12,592	*84.1%*	78,656	3,020	*26.0*
Japan Biotech	Ticker	Sales (Million USD)	Gross Profit (Million USD)	*GMP (%)*	Mkt. Cap. (Million USD)	R&D Expense (bn USD)	*Price-to-research (PRR)*
Astellas	4503 JT Equity	11,787	9,466	*80.3%*	32,347	2,118	*15.3*
Daiichi Sankyo	4568 JT Equity	9,080	5,888	*64.9%*	46,172	2,145	*21.5*
Takeda	4502 JT Equity	30,165	20,786	*68.9%*	53,612	4,300	*12.5*
Average		17,011	12,047	*71.4%*	44,043	2,854	*15.4*
China Pharma	Ticker	Sales (Million USD)	Gross Profit (Million USD)	*GMP (%)*	Mkt. Cap. (Million USD)	R&D Expense (bn USD)	*Price-to-research (PRR)*
Hengrui	600276 CH Equity	4,024	3,538	*87.9%*	72,945	724	*100.8*
Sino Biopharm	1177 HK Equity	3,431	2,679	*78.1%*	20,169	381	*52.9*
Simcere	2096 HK Equity	654	524	*80.0%*	4,241	166	*25.6*
CSPC	1093 HK Equity	3,619	2,711	*74.9%*	19,221	419	*45.8*
Hansoh	3692 HK Equity	1,261	1,144	*90.8%*	25,369	182	*139.6*
Betta	300558 CH Equity	271	251	*92.6%*	6,906	108	*64.1*
Average		2,210	1,808	*84.1%*	24,808	330	*75.2*
China Biotech	Ticker	Sales (Million USD)	Gross Profit (Million USD)	*GMP (%)*	Mkt. Cap. (Million USD)	R&D Expense (bn USD)	*Price-to-research (PRR)*
Junshi	1877 HK Equity	231	177	*76.6%*	11,117	258	*43.1*
Innovent	1801 HK Equity	558	501	*89.9%*	16,885	269	*62.9*
BeiGene	6160 HK Equity	309	238	*77.1%*	32,980	1,295	*25.5*
Henlius	2696 HK Equity	85	59	*69.0%*	2,769	130	*21.3*
Zai Lab	ZLAB US Equity	49	32	*65.8%*	16,134	223	*72.4*
Average		246	202	*75.7%*	15,977	435	*36.7*

*Source: Exome Asset Management, Bloomberg, Company

A different approach that eschews heavy R&D spending is generics manufacturing. Taking advantage of patent expiry, or in some cases, lax intellectual protection within China, firms like

[4] Id.

CSPC Pharmaceutical Group (1093 HK) and Jiangsu Hansoh Pharmaceutical (3692 HK) produce generics and undercut the market for key drugs. While Chinese generics have often been panned for poor quality control, improvements in regulatory standards and government reimbursement mechanisms could usher in noticeable improvements[5]. Hansoh alone has introduced more than 30 generics to the Chinese market since its inception in 1995, including versions of Novartis' Gleevec and Eli Lilly's Zyprexa; Hansoh beat out both originators to win public hospital supply contracts in a number of major Chinese cities in 2019[6]. Government procurement contracts like the ones won by Hansoh, which guarantee 60-70% market share for a year to the lowest generic bidder, can be a double-edged sword given the price cuts that are needed to win those contracts. Despite the fact that around 22 million tablets are to be delivered, Hansoh's drugs were discounted by about 25% to win the contracts, which is already less than the average discount of about 50% borne by other drugs added to the procurement program[7]. Nevertheless, Hansoh has shown that a generics manufacturer with a robust pipeline backed by strong quality control can be lucrative given the appropriate circumstances, with government pricing playing a major role. Hansoh's sky-high price-to-research ratio of 140.1 and gross profit margin of 90.8% reflect its incredibly low R&D spending for a product portfolio of its size[8]. Despite Hansoh's success, competitors like CSPC are attempting to move up-market towards origination and spending more on R&D for novel drugs, reflected in its far lower price-to-research ratio (45.2) and gross profit margin (74.9%)[9]. Pipeline renovation will be the main strategy for traditional generic pharmaceutical companies to retain competitiveness. Companies such as Hengrui (600276 CH) and Livzon (000513 CH) have built up their in-house development capabilities for novel targets and are catching up by taking advantage of their financial resources and well-established sales and marketing teams.

Origination is proving to be an attractive area, demonstrated by projections for Shanghai Junshi (1877 HK), an innovator in the biotech space. TUOYI, their commercialized PD-1 inhibitor, boasts a product gross profit margin of nearly 90%[10], and while the margins are strong, efforts to spread adoption are often gatekept by the Chinese National Reimbursement Drug List (NRDL), an annually updated list that demands heavy price cuts for drugs to be included. However, past data on 17 drugs showed an average of over 600% volume growth one year after NRDL inclusion. In most cases, the growth in volume sufficiently offsets the decline in profit margin. A clear example would be Innovent's (1801 HK) TYVYT, which was included in the NRDL in late Q1 2020 with a 63.7% price cut. Later in the year, Innovent's *gross profit* grew rapidly and had a fourfold increase compared to FY2019. Moreover, some of that *margin reduction* can be made up for in other areas, such as expansion overseas to new markets. Products like Junshi's TUOYI (toripalimab), which received the US FDA's Breakthrough Therapy Designation (BTD), and Akeso's (9926 HK) AK105 (penpulimab), which was granted the US FDA's Real-Time Oncology Review (RTOR), could compete to be the first Chinese PD-1 products to be commercialized in the US, where they can be sold at higher prices while still being distinctively cheaper than other approved PD-1 products in the US. The road to commercialization in the US is still long, especially because of the impact of COVID on FDA operations and production facilities. Nonetheless, these

[5] https://www.westpharma.com/en/blog/2020/April/generic-drugs-in-china#
[6] https://www.fiercepharma.com/pharma-asia/a-hong-kong-ipo-to-make-one-world-s-richest-biopharma-families
[7] Id.
[8] See Table 2
[9] Id.
[10] Junshi FY2021 Estimates

designations bring tangible benefits that increase the chances of approval and could play a key role in bringing novel Chinese compounds to different markets. Additionally, BeiGene's (6160 HK) tislelizumab, Innovent's sintilimab, and CStone's (2616 HK) sugemalimab (PD-L1) are all queued up for US FDA approval.

Western biotech has dominated the global market in the past several decades, with advanced innovation and origination. This gave rise to some of the largest and most well-known companies in the world, such as Novartis (NVS), Roche (RHHBY), GlaxoSmithKline (GSK), Amgen (AMGN), etc. More recently, however, competition has risen in developing markets, especially in China, where a number of government policies and general interest in the space has ushered in an era of novel innovation as opposed to licensing or generics manufacturing[11]. The move towards in-house innovation has yielded dividends for several Chinese biotechs, including Junshi, BeiGene, and Innovent, all of which have obtained unicorn status. All founded within the last decade, these relative newcomers to the biotech scene have developed an impressive array of products, both independently and in partnership with others. Junshi's immense investment in R&D has yielded 30 compounds in its development pipeline (28 novel compounds), resulting in a price-to-research ratio of 45.8 and gross profit margin of 76.7% roundly comparable with notable US biotech companies, which have an average of a price-to-research ratio of 26.0 and a gross profit margin of 84.1%[12]. Similarly, BeiGene, with 45 compounds in clinical development and 1,600 research personnel, boasts a 25.3 price-to-research ratio and a 77.1% gross profit margin[13]. Innovent, with 24 compounds in the clinical stage, is somewhat of an outlier in this set due to its 62.3 price-to-research ratio and a 89.9% gross profit margin, which may be partially attributed to the impact of commercialized biosimilars remaining in their business.

The impact of investments in R&D can be seen from licensing deals that the firms have made with major Western players. Innovent reached a $1 billion deal with Eli Lilly for TYVYT, a co-developed innovative anti-PD-1 antibody, and another deal with Coherus for BYVASDA, an innovative anti-VEGF antibody. Junshi signed over North American rights to TUOYI (China's first homegrown PD-1 inhibitor) to Coherus (CHRS) for $150 million upfront. At the same time, Junshi entered a co-development partnership with Eli Lilly (LLY) and granted the firm ex-China rights to JS016, a COVID-19 antibody that when combined with Eli Lilly's own CoV555 decreases hospitalization and death by 70%[14]. The ex-China rights to BeiGene's PD-1 inhibitor tislelizumab, previously licensed to Celgene (CELG, acquired by BMY), were acquired by Novartis in a blockbuster deal with $650 million upfront and another $1.55 billion in milestones[15]. Similar out-licensing agreements for novel compounds can be found in a number of Chinese biotechs, including I-Mab's (IMAB) nearly $2 billion deal with Abbvie (ABBV) for TJC4 (anti-CD47 antibody), Legend Biotech (LEGN) and J&J's (JNJ) deal for LCAR-B38M, and CStone's deal with EQRx (private) for sugemalimab. The development timeline of Chinese biotech firms has been quite impressive, going from licensees and generics manufacturing to becoming licensers to Western firms in the span of two decades or less. Even further growth is expected given the size

[11] https://www.fiercepharma.com/special-report/10-biotechs-to-know-china
[12] See Table 2
[13] Id.
[14] Junshi 2020 Annual Report
[15] https://www.fiercepharma.com/marketing/novartis-takes-celgene-s-baton-licensing-beigene-s-tislelizumab-as-own-pd-1-fails-to

of the Chinese market and the emphasis the Chinese government has put on homegrown development. Programs to encourage "hai gui," or highly educated Chinese who studied abroad, to migrate back to China to innovate have been quite successful, with significant returnee representation on the executive level of Chinese healthcare discovery companies — particularly those designated as unicorns (Table 3). Partly due to their ability bring back and implement foreign expertise and knowledge, many of these returnees have been on the forefront of Chinese innovation in the space.

Table 3

Key Metrics for Selected Healthcare Discovery Company "Unicorns"

Name	Ticker	Price (USD)	Market Cap (mil USD)	Revenues (mil USD)	Operating Income (Loss) (mil USD)	Non-cash Charges (mil USD)	R&D Spending (mil USD)	Cash & Cash Equivalent (mil USD)	Total Debt (mil USD)	Net Cash (mil USD)	Operating Cash Flow (mil USD)	Headcounts
Hengrui	600276 CH Equity	12.89	68,701	4,023.76	940.69	89.56	723.80	1,918.42	16.31	1,902.10	1030.24	24,431
Wuxi Biologics	2269 HK Equity	15.41	65,005	814.25	288.64	32.05	44.07	1,282.03	510.48	771.56	320.69	5,666
Beigene	BGNE US Equity	344.44	31,692	308.87	(1657.68)	18.62	1294.88	1,901.82	561.96	1,339.86	(1639.07)	3,500
Hansoh Pharma	3692 HK Equity	4.30	25,454	1,260.79	416.77	29.18	181.68	232.02	14.21	217.82	445.95	9,178
CanSino Biologics	6185 HK Equity	44.46	18,218	2.69	(62.80)	-	62.17	681.31	21.84	659.47	(62.80)	402
Innovent	1801 HK Equity	11.50	16,739	557.66	(57.56)	12.51	268.61	165.54	184.85	(19.31)	(45.05)	2,000
Zai Lab	ZLAB US Equity	171.28	16,256	48.96	(301.80)	3.77	222.71	442.12	18.60	423.52	(298.04)	111
Shanghai Junshi	1877 HK Equity	10.12	11,814	231.39	(238.64)	8.66	257.96	518.60	130.34	388.26	(229.97)	1,421
Genscript	1548 HK Equity	4.02	7,889	390.85	(276.46)	20.64	263.40	629.06	55.00	574.06	(255.82)	3,738
Remegen	9995 HK Equity	14.31	7,007	-	(93.30)	-	67.58	424.15	30.29	393.86	(93.30)	998
Akeso	9926 HK Equity	8.02	6,550	-	(132.41)	2.39	111.51	411.28	30.49	380.79	(130.03)	109
InnoCare	9969 HK Equity	3.07	4,600	0.20	(97.20)	1.31	58.43	608.17	179.79	428.38	(95.89)	214
Henlius	2696 HK Equity	5.54	3,008	85.25	(130.21)	11.94	129.72	170.72	280.92	(110.20)	(118.26)	1,172
Burning Rock Biotec	BNR US Equity	28.54	2,984	62.37	(24.48)	4.54	22.72	318.21	9.69	308.52	(19.94)	705
Suzhou Zelgen	688266 CH Equity	12.19	2,926	4.01	(51.26)	4.78	45.58	176.15	7.97	168.18	(46.48)	241
Kintor	9939 HK Equity	7.25	2,810	-	(57.26)	0.68	23.68	163.25	33.97	129.29	(56.59)	145
Everest Medicine	1952 HK Equity	9.00	2,670	-	(99.74)	-	54.76	686.53	11.93	674.60	(99.74)	110
Alphamab	9966 HK Equity	2.55	2,388	-	(87.45)	1.70	48.06	28.39	34.13	(5.74)	(85.74)	220
Jacobio	1167 HK Equity	2.75	2,123	70.55	29.36	-	26.98	249.33	1.57	247.76	29.36	110
C-Stone	2616 HK Equity	1.66	1,964	150.71	(180.46)	1.68	203.79	518.36	12.85	505.51	(178.78)	157
HitGen	688222 CH Equity	4.52	1,810	35.34	9.10	1.92	14.49	65.67	16.21	49.45	11.03	397
Ascentage	6855 HK Equity	5.74	1,451	1.81	(92.73)	3.83	81.91	156.94	81.15	75.79	(88.90)	410
Antengene	6996 HK Equity	2.04	1,367	-	(426.55)	-	50.44	476.44	1.67	474.77	(426.55)	90

*Source: Exome Asset Management, Bloomberg, WIND, Company

In the biotech space, the consistent shift towards innovation has been reflected in the R&D spending of Chinese companies. As such, we believe that Chinese R&D spending will eventually equal that of Western firms. This view is now being substantiated by the price-to-research ratio of several high profile Chinese and US biotech firms. The average price-to-research ratio for selected Chinese biotech firms is now 37.1, while selected US biotech averages around 26.0[16]. R&D expenditure aside, a look at a different metric, price-per-compound, presents another argument for the case that Chinese biotechs remain undervalued. Price-per-compound breaks down how much investors are paying per compound in the development pipeline. BeiGene, for example, has 45 compounds in clinical development, meaning that each compound is worth approximately $728 million. Amgen similarly has around 60 products in its pipeline, but its price-per-compound is about $2.3 billion, meaning that each compound that Amgen tests in its pipeline costs investors just over three times more. We expect Chinese and Western averages for both price-to-research and price-per-compound to converge further as China continues to develop its nascent market, and Chinese firms begin to enter more out-licensing agreements to bring their unique capabilities and compounds to the global market.

[16] See Table 2

The rise of truly innovative Chinese biotech firms has begun to put them on equal footing with legacy Western firms. Over a dozen Chinese biotech firms have become unicorns, and that does not even include unicorns in other healthcare subsectors, truly demonstrating how far Chinese firms have come in the space[17]. Biotech in China is still a relatively young industry, and continues to lag behind Western firms in some areas, like development of novel drug targets. However, we are seeing gradual improvements in many of those areas, with firms like Innovent beginning to innovate with IBI322, an anti-CD47 bispecific antibody that is potentially first-in-class. Not only are Chinese firms now spending proportionally comparable amounts on R&D, Western firms are beginning to take increased notice of their cutting-edge innovation and paying to partner with them. Amgen, for example, acquired a 20.5% stake in BeiGene for $2.7 billions at a 25% premium in late 2019 to enlist BeiGene's R&D capabilities for the development of 20 Amgen compounds for use in the Chinese market and to evaluate global clinical feasibility[18]. At the same time, BeiGene's established commercial infrastructure and local relationships for oncological products in the Chinese market proved to be extremely attractive to Amgen, who determined that cooperative sales at a 50/50 split with BeiGene would ultimately be more beneficial than relying on and developing their own sales pipeline in China. While raw sales and gross profit cannot yet be put side-to-side in a direct comparison, the numbers show comparable gross profit margins and price-to-research ratios in biotech. With such a large Total Addressable Market, Chinese biotechs are poised to take the next step to compete with the dominant Western firms, especially as they continue to innovate and bring products to market. With the fast-tracking of drugs like TUOYI and AK105 to approval in the US, and the beginnings of out-licensing to Western firms, Chinese biotech has shown its ability to innovate at the highest level and compete on product quality alone with some of the best in the business.

[17] See Table 3

[18] https://www.fiercebiotech.com/biotech/amgen-pays-2-7b-to-enlist-beigene-as-chinese-r-d-partner

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