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WHITE PAPER

Go East: Trends Impacting Pharma Companies within the Chinese Market in 2021

China represents huge opportunities – and risks. In this roundtable discussion, Prescient's thought leaders discuss the approaches that Western pharma companies may consider as they explore a market unlike any other.

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Introduction

In every business, there is a gap between strategy and execution. For Western pharma companies looking at the Chinese market, the strategy looks obvious: it is a land of huge opportunity, with booming growth and a vast population that needs effective and well-tested treatments. Pushing forward into this territory has the potential to pay off, and no-one wants to be left behind.

However, before strategists can announce that their work is done, there is the small matter of actually seeing those grand schemes play out successfully, and this is where confusion can set in. China is unlike any other market, with challenges presented by reformed regulations, a healthcare system that includes the involvement of national and provincial government in the procurement process, policies such as 70:30 and competitors unique to the country, including the co-existence of traditional Chinese medicine. As a result, approaches that work well in other territories may not play out so effectively – if at all – in China.

Prescient Healthcare Group has had a presence in China for a number of years, providing valuable learning around an understanding of the market, competition, beliefs and physicians' perceptions of the various drugs being marketed by competitors. This experience has uncovered some of the most promising opportunities for Western companies wishing to make inroads into China, as well as some of the potential pitfalls that await the unwary. In a land that perhaps has more "unknown unknowns" than any other, Prescient's Ben Doran, Vice President, speaks to Dr. Aviral Maheshwari, Vice President, and Nishika Bhan, Associate Director, regarding what we do know about successfully conducting business in China.

Opportunity

Ben Doran:
China is the world's second-largest drug market, comprising 8.5% of global sales. We also know that there are many excellent drugs available in the West that have not been taken up in China. This points to a considerable unmet need that presents a case for businesses to seize an opportunity that will benefit the health of millions of people. Is this an opportunity for improving the Chinese nation's health that is simply too good to miss?

Nishika Bhan:
Yes, it is, but the Chinese pharma market is structurally very different from that of the US and any other developed pharma market, so businesses should not get the impression that the streets of Beijing are paved with gold. It is too easy to imagine that the market is like a monolith and will respond to the sort of marketing strategies that have been used in the US. China is a landscape that constantly changes in some areas yet remains fairly static in others. For example, in 2015 the number of pharma companies recording annual revenue greater than ¥10 billion was just 16; today that number is 27, as smaller companies have been consolidated and centralized.

The market depends on over-the-counter (OTC) products and generics, and traditional Chinese medicine (TCM) also accounts for a significant share; however, patented prescription drugs are now becoming increasingly popular and have garnered a market share of 25%. This is important, as it indicates that the momentum may just be shifting, and that is what makes China such a lucrative market. So, while there is more money in the system, the competition is much more fierce, and those numbers suggest the Chinese pharma ecosystem is evolving fast.

Looking at the top 100 pharma companies in China, we can see that 82 are domestically funded, which gives the impression that China has not been "hungry" for outside investment. This, I feel, will be one of the areas in which change will be slow: the government is paying attention to the market and is not going to let control slip out of its hands.

That said, global investment is also flowing in for Chinese companies. Having received $60 billion in foreign investment in 2018-2019, China is one of the most highly-funded countries globally, second only to the US.

Dr. Aviral Maheshwari:
You are right to sound a note of caution; China is not an open door, but it is looking at the West with the same mixture of excitement and apprehension as we look at it. Going into China, there is obviously the excitement of that potential for profit. Companies need to remember that we have something the Chinese want: research and development (R&D). While China is excellent at low-cost manufacturing, new ideas and products are not its strong suit.

As many of the big Chinese pharma companies, such as Livzon Pharmaceutical, Changchun High & New Technology Industry and Guangzhou Baiyunshan Pharmaceutical, look to expand their R&D budgets, they are likely to eye partnerships with global companies and research hubs for assets and technology. There is real enthusiasm from some about crossing borders and expanding into Western geographies.

The other advantage that we have in the West is marketing. So far, Chinese companies have not been investing in marketing or creating value for their medicines. We should expect this to change.

Ben Doran:
We should also be aware that, while R&D may not be China's strength, the Chinese have identified it as a weakness and are catching up fast. Research has been a strategy used by top players in China to boost their presence. The average R&D spending went up by 20% to RMB 550 million compared to a year prior.

Dr. Aviral Maheshwari:
True, and that is about $85 million, so that compares with the average R&D spend in the rest of the world. That said, the impact of COVID-19 has been felt in R&D departments globally, so how this has been affected and how quickly it will come back up to speed remains to be seen.

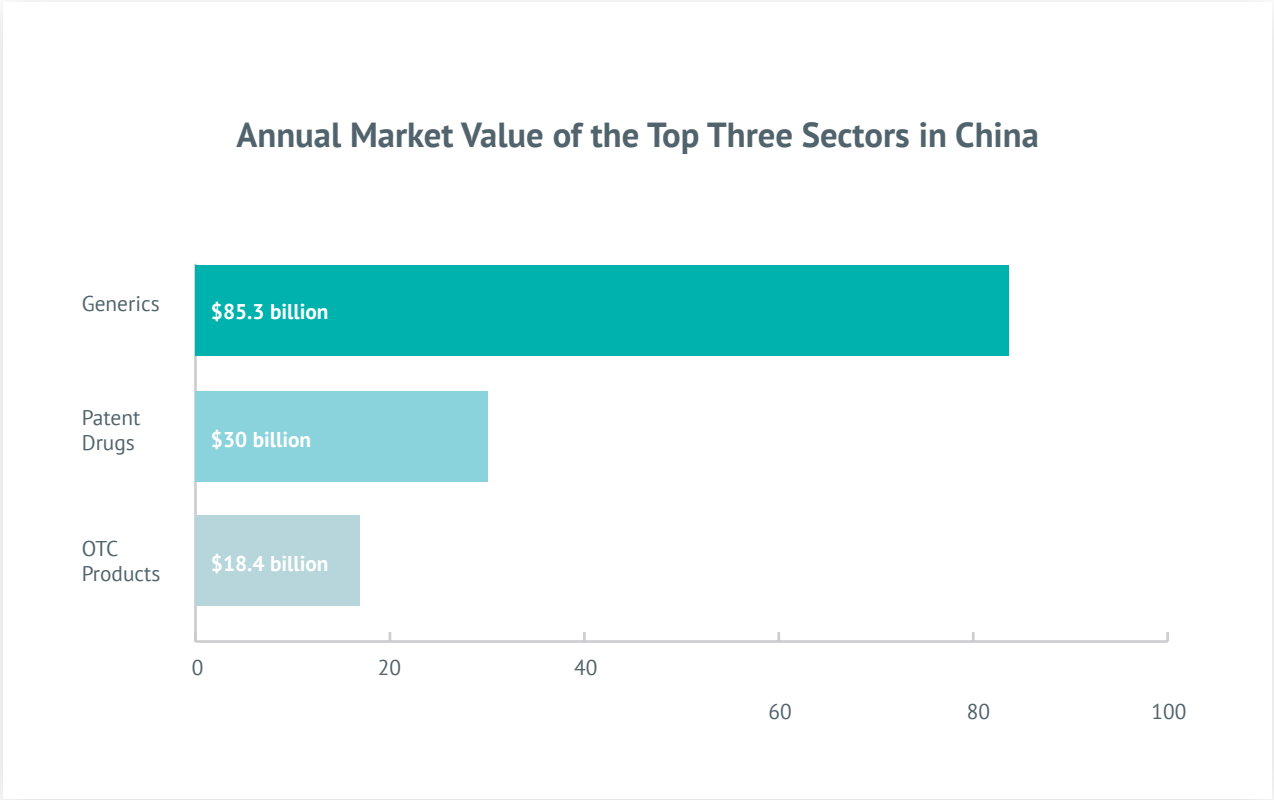
The impact of COVID-19 is now dissipating, but during the pandemic, the operations of many Chinese pharma companies were delayed, especially as there was a major impact on manufacturing and supply. Since the Chinese are traditionally manufacturing-focused, the intensity of R&D operations and investments may be reduced in order to recover from manufacturing- and supply-related losses. That said, China was able to control the spread of COVID-19 quickly and is now back to garnering revenue from commercialization.

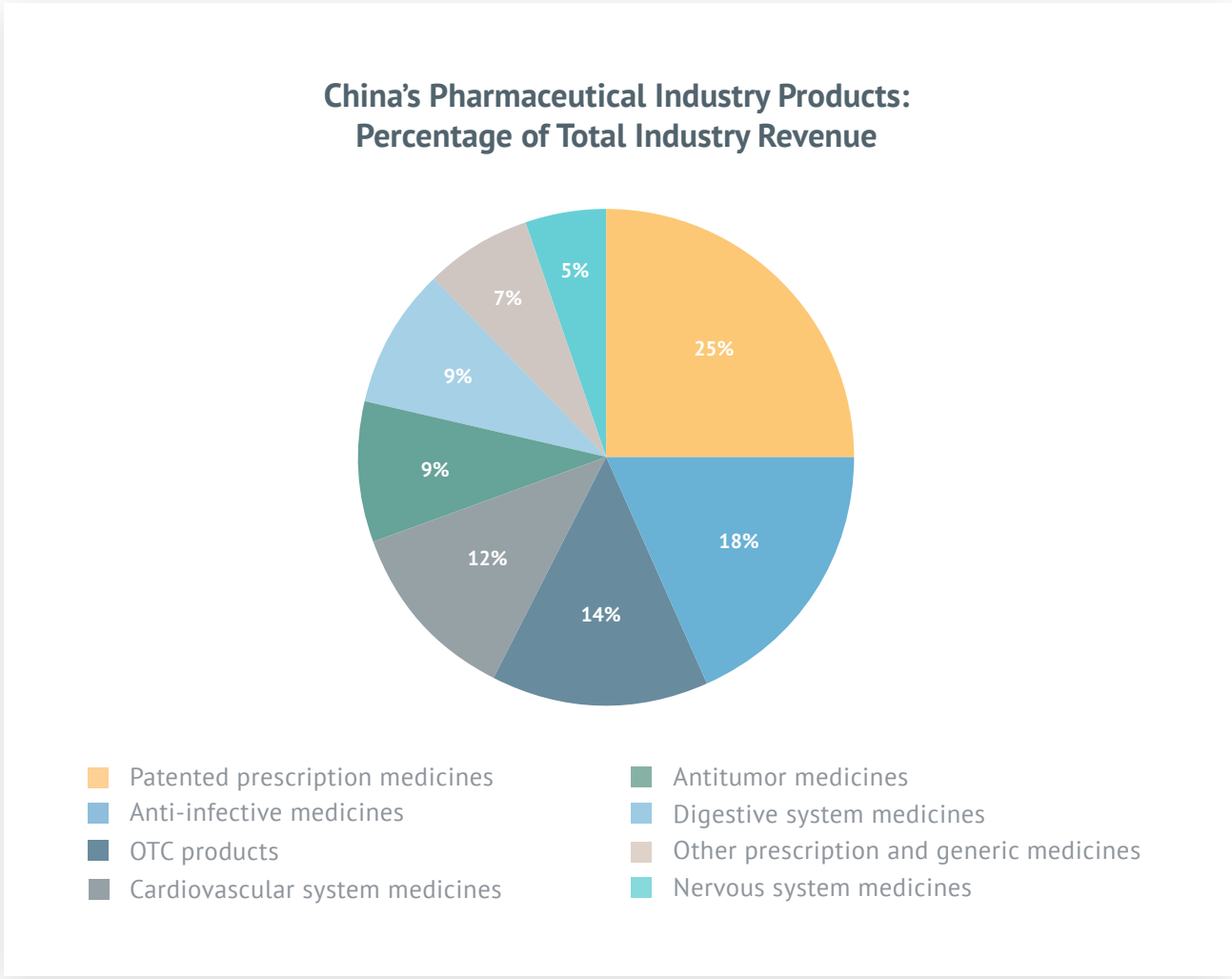
Ben Doran:
COVID-19 is likely to be a line in the sand for the global pharma industry, with governments investing in big data and AI for disease management, as well as how how the industry effectively communicates with major stakeholders (e.g., physicians and patients). In this respect, China's concerns will be much like those of the rest of the world, even if they play out differently.

Let's go back to one of the significant markers of difference, though. In the West, pharma businesses are built on the understanding that it is new products that drive profit. Is this not the case in China?

Nishika Bhan:
No, the breakdown is completely different in China. Their number one seller is generics, with patented medicines at number two and OTCs at number three. As Aviral mentioned earlier, the marketing and brand-building carried out by Western companies means OTC products present an excellent opportunity for those companies to pitch their products. When we widen our view of the country as a whole, projections are that 18% of the population will be 65 years or older by 2030; that is a population of about 245 million people. That percentage could double by 2050, not to mention the expanding middle class. Pharma is not the only booming industry in China, and the success of the economy continues to have a big impact on the quality of life (QoL) of millions of people. OTC products have huge potential in this space. This is the kind of market where, when given a choice between Western and Chinese brands, many will choose the former.

We also need to understand the healthcare spending differences between the West and China. China has a per capita healthcare spend of just $501.60, whereas developed markets, such as the US and UK, have per capita spends of $10,623.85 and $4,315.40, respectively. Historically, innovative products have done well in markets where out-of-pocket (OOP) costs are low; however, in China, these can be as high as 35% compared to the 10.8% and 16.7% of the US and the UK, respectively. Since China's OOPs are considerably lower than those of its Asian counterparts like India, with a gross national income (GNI) per capita income of just $16,760, affordability can be an issue.





Ben Doran:
If it is difficult for Western companies to go it alone in China, what is the potential for partnerships between Chinese and Western companies?

Nishika Bhan:
Partnerships have a good track record of bringing the best of both sides together. Chinese companies will bring their market knowledge while Western companies will bring their brands, and when those brands say quality, it is very powerful. In fact, even the local regulations are designed to favor and motivate international companies to partner with local companies. In 2020-2021, 271 cross-border licensing cooperation agreements were recorded between global and Chinese pharma companies in the areas of clinical trials, drug development and commercialization.

There are some great examples of how partnerships have given Western companies a foothold in China, and likewise have provided Chinese companies opportunities in the West; Raziel Therapeutics, for example, recently announced a China market license agreement with Fosun Pharma for its medical aesthetics drug, RZL102. Similarly, Novartis and BeiGene entered into a global alliance to bring a China-developed PD-1 inhibitor to the rest of the world.

Limiting Factors

Ben Doran:
I want to look a little more closely at some of the factors that can trip up companies going into China. Is having a presence on the ground really that important?

Nishika Bhan:
I would say that having a presence on the ground is the number one factor that will mark success or failure. If you think about meeting a former boss from another country, you might say hello in your school-learned Spanish or French, and they will respond in somewhat better English, and the two of you will exchange pleasantries. In China, unless you are lucky enough to be genuinely bilingual, your attempts at Mandarin simply will not cut it. They are also very unlikely to try speaking to you in your own language.

This embedded approach is essential because of the way that information is guarded, valued and traded. In the US, for example, there is a single point of truth: the FDA. No such organization exists in China. Information is much more dispersed, much less centralized, and it is much harder to get a full picture.

Dr. Aviral Maheshwari:
I think there is a danger of real disconnect between the cultures. Without up-to-date intelligence, it is really easy to fall back on assumptions, and at the pace of change we are seeing, these assumptions are quickly becoming obsolete. For example, the idea that a Chinese manufacturer provides low-cost, high-volume and low-quality products was certainly true some years ago, but this is a situation the Chinese are aggressively tackling across the industries.

Furthermore, diversity in the region also calls for a local presence. A pharma presence in China varies from its eastern to western borders. It is also estimated that there are about 200 dialects in China emerging from 56 ethnic minorities.

And then there is the global perception that having a local presence increases your regulatory compliance substantially in China; this is also reflected in the approach taken by global pharma companies when entering China. In an independent survey of global pharma companies, the preferred mode of entry into the Chinese market remains either licensing to a local company

or agreeing a joint venture with a local partner for all approved, late-stage and early-stage products, rather than owning a commercial entity.

Ben Doran:
Do you believe the Chinese government is committed to making this kind of change?

Dr. Aviral Maheshwari:
Without a doubt. Recently, the legislation changed dramatically, which is often the case in China. This is another good reason for having native Mandarin speakers on the ground. Consider the approval process for a new drug. In the West, it is a fairly well-understood process with established timelines allowing companies to plan their intended strategy with some accuracy. This is not the case in China. The rules have only recently changed; before 2015, for example, receiving approval for a Phase I clinical trial of a new drug could take 20 months or longer. This was due to the shortage of China Food and Drug Administration staff, who were unable to process approvals as quickly as new drugs were being presented. This situation created a backlog of cases that was bad enough in itself, but when the CFDA had discretion over which drugs it would consider next, it prioritized domestic generic manufacturers over foreign and novel drugs. Things had to change, and the agency did so by increasing the number of technical review committee members from 150 to over 1,000.

Comment:
In 2018, the CFDA became the National Medicinal Products Administration (NMPA).

Nishika Bhan:
Furthermore, the Chinese government realizes its importance in the global pharma ecosystem. For a long time, global pharma companies have been trying to access Asia's volume-based markets. Due to multiple factors, such as geopolitical differences, unfavorable trade regulations and price sensitivities in these markets, access has been limited over the years. Most of the developed markets have manufacturing and access connections.

LATAM supports the US market and we have Eastern Europe in the EU; however, there is nothing in Asia. China has favorable trade relations, such as Free Trade Agreements (FTAs) and Most-Favored Nation Treatment (MFN), with most Asian countries, ensuring low-cost production and high tech compliance. Global companies may need to find a similar connection if they are allowed to enter China.

"There are also many provincial contracts that are open for all. Winning one of the big bids is lucrative, but it does not mean the pressure is completely off."

This realization by the Chinese may be what is leading to the opening of its borders. Opening China to global pharma will not only mean access to innovative drugs, but it will also divert a lot of other global pharma business to China, making it the epicenter of pharmaceutical activity in Asia. This will further consolidate China's dominance in the active pharmaceutical ingredient (API) market.

Ben Doran:
Even so, I understand that the approval process remains unpredictable and unstandardized; while the approval process for generics in China is expected to take between 180 and 210 days, the review process can still be extended to up to 15 months in some cases.

Dr. Aviral Maheshwari:
This is correct. Uncertainty remains a significant hurdle for Western companies that want to launch or market in China.

Nishika Bhan
Beyond the approval process, China's volume-based procurement (VBP) scheme has turned many market opportunities into an "all-or-nothing" proposition. This is a fairly new development. In 2018, China piloted what became known as the 4+7 reform, named after the 11 cities in the trial process. It selected a list of 31 generic categories and invited drug manufacturers to bid for a contract for all public hospitals in Beijing, Shanghai, Chongqing and Tianjin, as well as seven cities in other provinces. Foreign companies did not fare well, with only AstraZeneca and BMS winning tenders against their Chinese counterparts. Winning the contracts came at a high price, with estimated discounts of 50% being reported in the region.

Ben Doran
Clearly this approach suited the government, as it expanded the scheme to an additional 25 provinces and regions in 2019. How did the pilot and this expanded program differ?

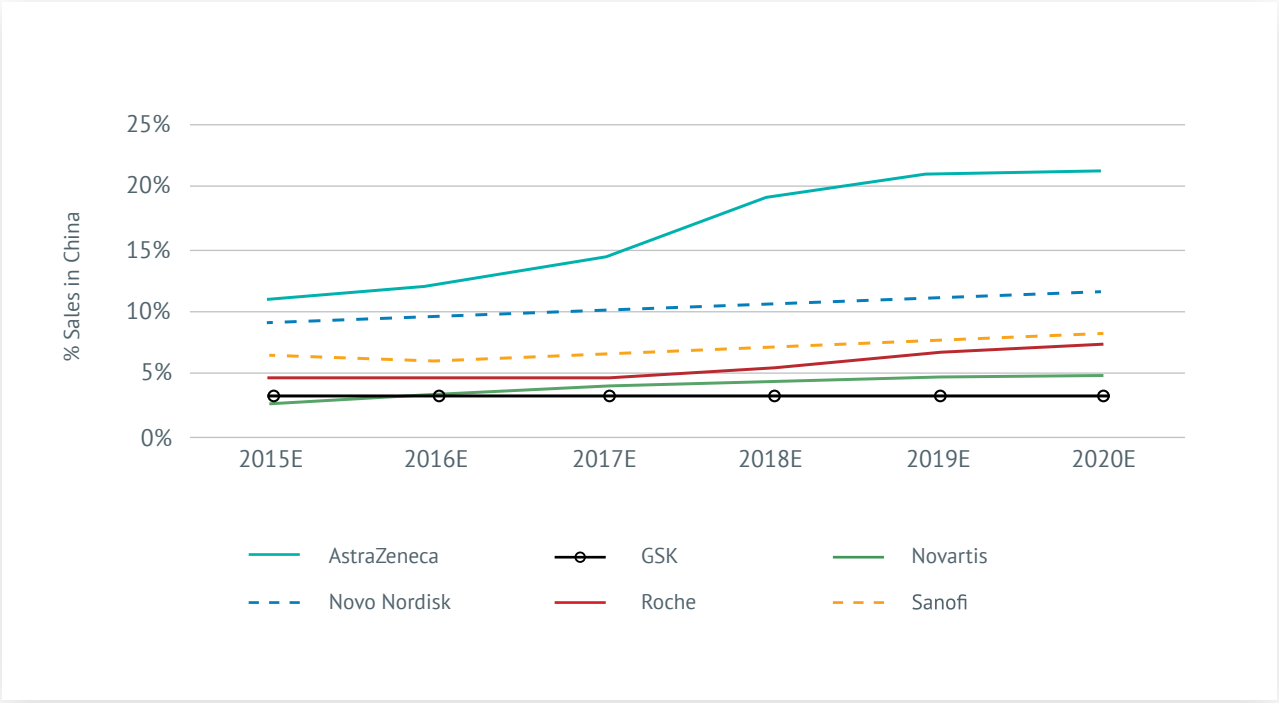
Nishika Bhan:
It still paid to win the bid, as successful companies could secure as much as a 70% share of the government's purchase volumes and a 50% share of all purchase volumes in China. But clearly there is room for unsuccessful bidders to do business, as this system is only for national tender. There are also many provincial contracts that are open for all. Winning one of the big bids is lucrative, but it does not mean the pressure is completely off.

This expanded scheme saw multinational companies doing marginally better, winning seven out of 25 tenders. Price reductions were also less extreme, with average discounts being closer to the 25% mark. At present, these heavy markdowns seem to be the principal means of keeping business in this aggressive procurement environment. If you take the view that these are perhaps the early stages of building a long-term relationship, companies prepared to do what it takes to win contracts clearly think it is a price worth paying.

Conclusion

Ben Doran:
We have seen how companies benefit from intelligence gathered on the ground from native sources. We have also seen how multinational companies have won tenders in the face of competition from Chinese manufacturers. It is a long way from dominating the market, but it is showing signs of improvement.

Those winning bids in the expanded VBP scheme were placed by Sandoz, Sanofi, AstraZeneca, BMS, MSD and Eli Lilly. AstraZeneca seems to be the one to watch, appearing to be the most successful multinational player in the Chinese market by quite a margin; with double the proportion of sales of its nearest competitor, the company also owns the most lucrative single asset, cancer drug Tagrisso.



Dr. Aviral Maheshwari:
This shows that AstraZeneca has managed to execute a well-planned strategy to achieve success. The company will be looking to replicate this while others seek opportunities to adopt a similar approach.

Ben Doran:
Last question to you both: what would be the number one thing you would encourage Western pharma companies to do if they want to succeed in China?

Dr. Aviral Maheshwari:
Unsurprisingly, it is always going to be about working from the best data possible. If your strategy is not based on intelligence from on-the-ground sources in China, I would question how achievable or realistic it is. Circumstances will change very quickly in some areas, while seeing any change at all will seem impossible in others. Good intelligence will help you work out which side your project falls on.

I would like to make another observation here: China does seem insular, but it also wants to be part of a global community. Failure to contain outbreaks of SARS and COVID-19 have caused political tensions to rise. Given that the Chinese have the infrastructure and technology to tackle such outbreaks more effectively in the future opens up the possibility of "good neighbor" partnerships.

Nishika Bhan:
I would say that, if you are looking to establish a partnership, you need confidence in your own insights and data for the market and competition, and you need to see the world through China's eyes. Figure out what it is that you can bring to the table, and what the Chinese company wants from you. This will put you in a stronger bargaining position and allow both sides to see the true value of the partnership.

About the Authors

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Ben is a Vice President at Prescient, supporting both our East and West Coast clients in the US. He holds a BSc in biomedical sciences and an MSc in biomedical engineering, and prior to joining Prescient in 2010, he had eight years' experience in biotech. Ben has held progressively more senior roles at Prescient, which has given him a deep understanding of what is needed to build and motivate teams to deliver results with a high degree of client satisfaction. Ben has also been closely involved in managing projects across multiple therapeutic areas, including oncology, immunology and biosimilars.

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Aviral is a Vice President at Prescient. He completed his MBBS and MS degrees at Jawaharlal Nehru Medical College, India, and his MBA at IESE Business School, Spain. Aviral has developed a strategic understanding of both the clinical and commercial sides of the life sciences industry from working as a physician and holding strategic consultancy roles at GSK and Grail Research. Since joining Prescient in 2010, Aviral has examined all aspects of the product life cycle for companies developing biologics, biosimilars and generics, OTC medicines, vaccines and medical devices within various disease areas.

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Nishika has over five years of healthcare consulting experience spanning diverse functions such as market research, strategy consulting and competitive intelligence in various therapeutic areas, including immunology, rare diseases and infectious diseases. She holds an MSc in Microbial Technology. Prior to joining Prescient, she worked as a project manager at SmartAnalyst India Private Limited, where her role was to lead end-to-end consulting projects for Fortune 100 pharmaceutical clients.

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