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The Healthcare & Life Sciences DealSCAPE

Executing Transactions in 2022

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The new DealSCAPE

A bold vision for the future is redefining corporate strategy for pharmaceutical and biotech companies, with new opportunities arising from disruption. Many large strategic players in pharma and biotech are increasingly shedding noncore business units, focusing instead on building specialty platforms. They are turning to M&A to supplement their R&D pipelines in areas where they have expertise and looking to leverage innovations in treatments at the frontier of science such as cell and gene therapy or next-generation therapeutics. Large pharma companies are using their strong cash positions and low cost of capital to look for innovation to fill their pipelines. At the same time, the traditional market is being buffeted by tech companies seeking to break into the healthcare market to grow their revenue. As part of Baker McKenzie's Life Sciences Business Evolution Series, and in collaboration with Informa Pharma Intelligence, we surveyed more than 300 global respondents across the Americas, Europe and Asia Pacific and explored how pharma, biotech, medical devices and medtech companies are responding to changes in demand, market saturation, regulatory regimes, R&D costs and other factors by evolving their business models to seek growth beyond traditional channels. In Part 2 of the series, 56% of global respondents said that growth through acquisition is the most popular route for pharma, biotech and medtech companies. In Asia Pacific, within the next one to two years, some pharma and biotech companies are looking to shift toward venture capital funding (62%), public offerings (58%) and private equity funding (58%) given the availability of dry powder in the region and a more buoyant economic outlook as compared to 2021.

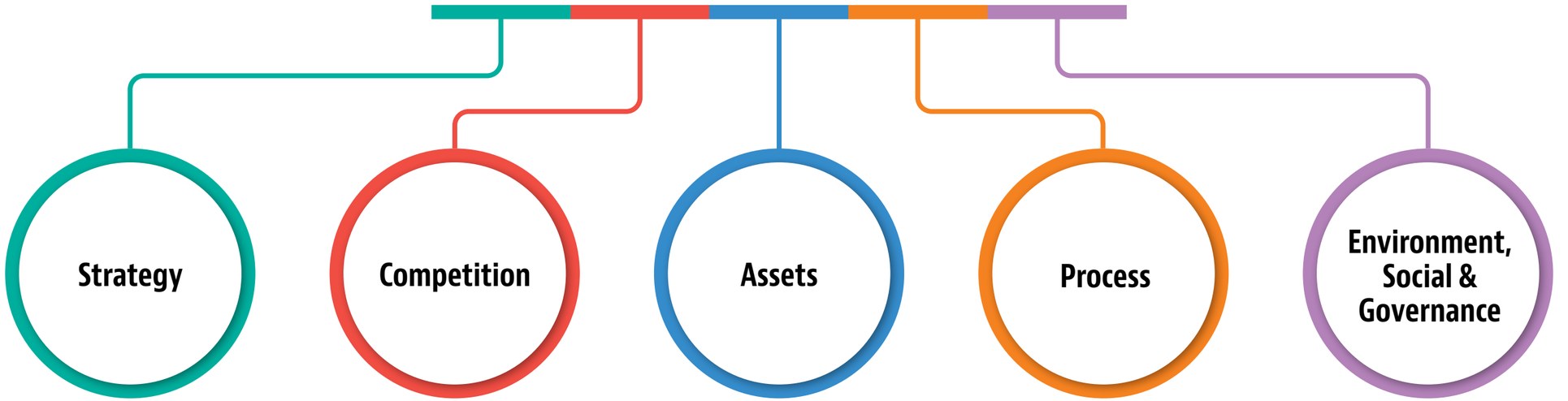
Pharma and biotech companies are also analyzing their businesses to identify gaps in their operations and engaging in transactions to resolve product, manufacturing or distribution gaps. Many companies are refocusing on innovation-led value creation and away from consumer-oriented businesses. Multinational companies from Europe and the US are designing tailor-made localized strategies to coordinate integration of regional operations with global operations. Large global players are investing in Asia Pacific to acquire skilled labor, economical production and high-quality infrastructure as well as to gain the benefits of shared services trending in Asia Pacific.

The acceleration of digital technologies, particularly amid the pandemic, has affected the entire ecosystem of the industry, from enterprise management to development of advanced precision therapeutics. Pharma and biotech companies are seeking acquisitions or partnerships to add to new technology capabilities they need to compete.

In this briefing, we explore the defining characteristics of pharmaceutical and biotech transactions in 2022 and introduce a framework to understand legal complexity in a fast evolving sector at a uniquely opportune time.

Click on each of the DealSCAPE trends below to learn more about the Asia Pacific pharma and biotech transactional opportunities and the corresponding legal considerations.

DealSCAPE Trends



Use M&A to acquire expertise, R&D and innovative solutions

Pharma and biotech companies focused on building specialty platforms are using M&A to boost R&D pipelines and acquire access to frontiers of science in areas such as cell or gene therapy and therapeutics and digital revenue streams.

Secure supply chains to ensure growth and fend off big tech

Pharma and biotech are looking to secure supply chains and acquire tech firms to enhance their digital capabilities, while tech companies are breaking into healthcare.

Buy innovation to fill pipelines

Pharma has cash with a low cost of capital and is looking to use it to acquire innovative solutions that will fill their pipelines.

Invest to plug labor, production and other process gaps

Multinational firms are investing in Asia Pacific to acquire skilled labor, economical production, high-quality infrastructure and digital capabilities.

Improve ESG practices to meet regulatory, customer and investor requirements

Growing global demand for ESG accountability as well as increasing ESG regulatory requirements are driving pharma and biotech companies to improve ESG practices and to use data tools or advisory services to enhance their capabilities.

Fact file

- Asia Pacific saw **613 M&A deals in healthcare and life sciences** through the third quarter of 2021, according to S&P Global, up by 332% from 142 in 2020. Volumes rose by **201%** to **USD 31.6 billion**, and the outlook for 2022 is strong.
- Deals by Japan-based companies ranged from genomics to biofuels to medical devices, with five M&A deals totaling more than **USD 680 million**. China was second at more than **USD 600 million**, followed by South Korea, Australia, Hong Kong, Singapore and Taiwan.
- About **56%** **of total shareholder returns (TSR) from 2015 to 2020 in pharma and biotech were generated by revenue growth**. According to Bain, there is no discernable difference in the contribution to TSR between organic and acquisitive growth, so transaction volume will remain strong as companies seek top-line growth.
- Indian pharmaceutical companies hope to **insulate their supply chains from shocks** such as materials shortages from suppliers in China or other markets, which have been rampant in 2021, by becoming self-reliant, leading both to domestic pharmaceutical companies entering the active pharmaceutical ingredients (API) space and to global companies acquiring pharmaceutical companies in India.
- **Private Equity firm interest in Asia Pacific remains strong**, with recent acquisitions including a US-based private equity firm investing a 20% stake in an India-based pharmaceutical company, KKR acquiring a 54% stake in JB Chemicals & Pharmaceuticals, a US-based private equity firm picking up a 74% stake in an India-based pharma company focused on animal health and Advent acquiring a controlling stake in RA Pharmachem.
- Almost **60%** of respondents to a global survey said that the desire to **localize supply chains** because of regulatory concerns will be a key factor guiding their M&A decisions over the next 12 months.
- **Biotech IPOs in Hong Kong surged 85%** in the first seven months of 2021 compared to the previous year, continuing the trend of biotech IPOs in Hong Kong accounting for about a quarter of global biotech IPOs in recent years. According to Asia Legal Business, about 90% of the Chinese healthcare companies in the portfolio of a China-based healthcare-focused venture capital company indicated that they aim to go public in Hong Kong, bolstering the Hong Kong Exchange's goal of being the world's largest biotech stock market.
- **ESG scores used as indicators for measuring sustainability** have a positive and direct impact on company performance in the pharmaceuticals sector, according to research at the University of Malaga.
- **Licensing is rising in Asia Pacific**. Deals concluded in 2021 include Novartis paying USD 650 million in February for the US, European and Japanese rights to the immuno-oncology biologic product of a China-based biopharmaceutical company and Coherus BioSciences paying USD 150 million up-front with a further USD 380 million in potential milestones for Junshi Biosciences' PD-1 drug toripalimab. In 2020, Chinese firms accounted for a quarter of 2020's licensing deals for R&D-stage assets.

1 Strategy | Use M&A to acquire expertise, R&D and innovative solutions

Trend

Acquisitions in Asia Pacific continue to be driven by a focus on R&D and innovative solutions. This focus will drive an increase in licensing deals and partnerships. Companies will look to increase growth by acquiring targets that provide access to innovative treatments and products that enhance the customer experience or the ecosystem.

Opportunity

Pharma and biotech companies are turning to M&A to supplement their R&D pipelines. Traditional big pharma players have war chests for M&A and will look to acquire biotech firms at the frontiers of science, such as those involved in cell and gene therapy or next-generation therapeutics.

Chinese companies continue to look to jurisdictions such as Japan or South Korea for targets, while Japanese firms are leveraging M&A to acquire firms abroad that can transform business models and deliver new technologies.

Legal considerations

In planning a cross-border M&A in the heavily-regulated healthcare and life sciences sector, it is important to evaluate the viability and deal structure at an early stage. Key issues to consider include, whether the target/acquisition will be subject to foreign investment review or foreign investment restrictions (e.g., gene therapy and related businesses may be restricted for foreign investment in China). In certain situations, a change of control of a target will affect certain licenses or approvals possessed by the target business.

Compliance remains to be a key area in planning a cross-border M&A transaction, including whether the target business may have been exposed to certain anti-corruption risks, and whether the acquisition would subject the target business to additional compliance requirements. For example, an acquisition by a US investor of an Asia-based healthcare company would result in the target being subject to FCPA requirements.

In addition, regulators have been increasingly focused on merger control and national security review (i.e. foreign investment control review in certain jurisdictions) and enforcement, especially during the post-COVID era. If a transaction is caught by merger controls, the process will impact transaction timelines and/or feasibility. Merger control assessment can be complex, particularly for cross-border or multijurisdictional transactions, as the thresholds that trigger filings will vary. A cross-border transaction will also likely trigger filings in multiple jurisdictions. The prospect of clearing such regulatory procedures should be assessed at the outset.

Trend

Large strategic players will continue shedding noncore business units and focus instead on building specialty platforms.

Opportunity

Deal activity will include both the divestment of consumer-focused businesses and the acquisition of specialty pharma developers and R&D businesses. Transactions will also involve contract development and manufacturing. Innovation in treatments and a better customer experience are two key drivers of value, so the acquisition of capabilities in specialist areas such as gene therapy or mRNA will be crucial.

Large pharma and biotech players and private equity firms look set to invest more in China, while investors from China are more willing to take on greater risk in their investments.

Legal considerations

MNC players looking to carve-out their regional businesses for divestment or collaboration with third parties must review the regulatory issues that may arise from the restructuring. One key issue is whether the restructuring (e.g., change of supply chain, including producer of API or raw material) would affect the relevant market authorizations for the products. Pre-deal analysis should be conducted to ascertain whether a carve-out exercise could cause disruption to the business and require pre-closing planning (e.g., stocking up on inventory) and transition arrangements post-closing until all regulatory approvals are obtained to allow the transferee to independently run the business.

Chinese players (including large enterprises and biotech start-ups) are increasingly interested in offshore licensing transactions and acquisition opportunities. Private equity firms (especially China-based USD funds) often team up with Chinese investee companies to consummate transactions. Chinese investors will be subject to regulatory filings for any prospective contemplated offshore investment or acquisition, and regulators have broad discretion on whether to approve or disapprove such applications, depending on factors such as capital outflow controls, foreign exchange reserves, and other considerations around overseas investments.

2 Competition | Secure supply chains to ensure growth and fend off big tech

Trend

Life sciences companies are strategically buying tech companies to enhance their digital capabilities and boost their technical offerings, while tech companies are also seeking to break into the healthcare and life sciences market.

Opportunity

The ongoing adoption of digital technologies is affecting everything from patient-care delivery and practice management to the development of advanced therapeutics. Large pharma is refocusing to innovation-led value creation that can leverage digital technologies and shifting away from consumer-oriented businesses. Pharma and biotech companies are also using M&A to add new technology capabilities to their portfolios. In Baker McKenzie's 2021 Supply Chain Webinar Series for the healthcare and life sciences sector, respondents said that acquiring digitalization expertise (33%), data acquisition (29%) and creative collaborations with tech companies (29%) were the most attractive digital transformation deals.

Big tech is using expertise in software and AI to capture opportunities. A US-based multinational technology company is using its AI capabilities to make the drug discovery process more efficient, while others are using their technology to enhance areas such as clinical trial recruitment, patient monitoring, treatment optimization and reductions in development cost.

Legal considerations

Conducting a value-focused due diligence is important to ensure that a digital health target is a strategic fit for the acquirer (and vice versa). The due diligence should assess how the target's business or technology can enhance and integrate into the acquirer's business, including its existing technology, system and supply chain.

With the business or value proposition of many healthtech companies, especially start-ups, characterized by disruption and innovation, intellectual property, data protection, regulatory and compliance are often key areas of focus in the legal due diligence on a target.

Healthcare is a highly regulated industry, with active enforcement by regulators. An acquirer, and traditional tech companies investing in digital health, should consider not only the existing regulatory regime, but also future reforms and regulation to fully evaluate the value and risks associated with a target. Compliance is another key area. Acquirers, particularly traditional tech companies, should understand the nuances of the healthcare business, which should involve engagement with regulators and healthcare professionals, and a thorough review of the target's business model and related policies to assess regulatory and compliance risks.

Where issues or gaps are identified, investors and acquirers will likely seek appropriate protection in the transaction documents, whether by way of imposing remediation obligations on the target prior to closing or through warranties and indemnities.

Trend

Companies seeking to resolve gaps in their operations, to secure or diversify their supply chains or to localize supply chains because of product availability or regulatory concerns will continue to look for acquisition targets.

Opportunity

Changes in the regulatory climate such as domestic production requirements and export restrictions, as well as trade trends such as supply chain disruptions due to COVID-19 and concerns about component availability, will accelerate cross-border transactions. While regions such as ASEAN currently have a small share of global biopharmaceutical manufacturing, shifts in global supply chains are creating opportunities for ASEAN manufacturers to break into markets or expand their market share.

Indian and Southeast Asian biotech and pharma firms are also continuing to diversify supply chains to reduce their heavy reliance on imported ingredients from China. Factory closures due to COVID-19, regulatory enforcement, and other factors that led to shortage of materials as well as price rises are causing firms to seek to diversify supply chains by going beyond China to markets such as the US and Japan.

According to Part 1 of Baker McKenzie's Life Sciences Business Evolution Series, 34% of respondents cited supply chain as their top priority. This may reflect a focus on localization, which has spurred smart manufacturing practices such as the use of data analytics to manage inventories and drug distribution or the use of AI for quality control during production. Shifting regulatory and trade challenges also featured as concerns, as respondents named government actions and antitrust issues (both 31%) as focus areas for legal advice.

Legal considerations

Conducting a detailed review of the company's supply chain to assess the level of dependency on overseas suppliers for key raw materials (e.g., API), supply limitations (e.g., import controls) and availability of alternatives, and a target's role in addressing gaps, will be key to ensure that the target's supply chain remain resilient.

A company should review its supply chain arrangements, particularly its rights and obligations relating to force majeure, dispute resolution and termination. It will also be important to revisit the company's insurance policies to determine the extent of coverage and assess the suitability and sufficiency to guard against losses in case of stoppage or slowdown of business.

Companies operating in ASEAN should be prepared for the constantly evolving regulatory framework that may require more harmonized standards for the healthcare industry, such as in drug registration and medical device classification.

The pandemic also presents opportunities in digital transformation of the supply chain, from delivering healthcare remotely via telemedicine and telepharmacy to drug discovery involving online clinical trials and research. The regulatory framework for these activities will vary vastly between jurisdictions.

While data plays a positive role in digital transformation, companies should assess whether the acquisition and use of data may raise antitrust concerns. This analysis could arise in the context of merger control, depending on the structure of a transaction, or from the perspective of abuse of market power when companies use data as part of their competitive advantage.

3 Assets | Buy innovation to fill pipelines

Trend

Pharma and biotech companies are looking for innovation to fill their pipelines and have large war chests coupled with a low cost of capital.

Opportunity

The continued strong interest in innovations in fields such as cell and gene therapies, antibody treatments and genomics, will drive M&A.

Along with global firms acquiring expertise in the region, a China-based pharmaceutical and medical device company's purchase of a leading US-based pharmaceutical company's factory in western Switzerland exemplifies how Asian companies are pushing overseas to acquire products and distribution networks.

Legal considerations

IP due diligence is critical in the acquisition of a start-up biotech company. There is a need to evaluate if there is sufficient IP protection for pipeline products and if potential infringement risks exist. The prior employment of biotech firms' founders could raise the possibility of such risks. IP searches, such as the freedom to operate (FTO) search, should be conducted to ascertain if the pipeline products would infringe third parties' interests.

While biotech start-up firms are strong in R&D, they need to partner with traditional pharma or contract development and manufacturing companies to fill gaps in production facilities and marketing capability. Multinational companies have increasingly become interested in executing licensing transactions leveraging their on-the-ground promotion teams.

Trend

The growth of the pharma and biotech sectors in Asia Pacific and private equity appetite for bigger deals and broader investment opportunities in Asia Pacific are also driving M&A.

In recent years, PE/VC investors have shown great interest in growth deal opportunities in pharma and biotech. For example, private equity firm Hillhouse Capital has acquired stakes in I-MAB Biopharma and Joincare Pharmaceutical.

Opportunity

Japanese conglomerates are pursuing more aggressive growth through M&A to expand their platforms globally, transform business models and bring in new technologies. China's fast-growing biopharma and health technology businesses will also be key drivers of growth, as the search for innovation and new drugs fuels M&A activity. As examples, Viva Biotech agreed to acquire Zhejiang Langhua Pharmaceutical domestically in China and Pharmaron Beijing acquired a pharmaceutical company in the UK.

Legal considerations

Where USD fund investors look to invest in biotech startups in Asia Pacific, the target business needs to be pre-examined to ascertain that there is no business activity that might be restricted for foreign investment (e.g., a business related to CAR-T therapy should be closely scrutinized to ascertain whether foreign investment restrictions apply).

Financial investors that evaluate investment opportunities in biotech companies must assess as early as possible the prospect of a successful listing, particularly in China, especially when more biotech firms pursuing higher valuations on the Hong Kong Stock Exchange. It is important for investors to conduct careful due diligence, on key areas that will be covered by the listing requirements, during the deal process.

4 Process | Invest to plug labor, production and other process gaps

Trend	Opportunity	Legal considerations
Companies are carefully analyzing gaps in their operations, which will continue to trigger more cross-sector transactions.	Companies are investing in Asia Pacific to acquire skilled labor, economical production and high-quality infrastructure. Acquirers are also looking to gain the benefits of shared services, which is trending in Asia Pacific. Multinational companies from Europe and the US are designing tailor-made localized strategies to integrate their regional and global operations. Chinese biotechs, which accounted for more than a third of global biotech IPOs in 2020, look set to continue this strategy as they seek to acquire R&D expertise.	When establishing shared services in Asia Pacific, companies should consider the availability of investment incentives, whether tax or non-tax, in the particular country. The shared services arrangements should also be compliant with tax laws and regulations, particularly with respect to transfer pricing. How well the company is able to integrate the acquired business and operations will also determine the success of the acquisition. Oftentimes, this means that potential post-acquisition integration issues will need to be flagged — and a plan to address them formulated — during the due diligence well ahead of closing the transaction. The culture of the new workforce and how well it can integrate into the existing workforce against that of the acquirer will need to be assessed. Gaps will need to be filled in with robust policies and periodic training to ensure the workforce stays up-to-date.
While accelerated digitization during the pandemic has created sustained momentum in technological transformation, the rapid pace of change has resulted in a knowledge gap and a shortage of digital talent.	The ongoing adoption of digital technologies is affecting everything from business enterprise management and the development of advanced precision therapeutics to patient-care delivery. Facing a shortage of talent, firms are strategically buying tech companies to enhance their digital capabilities and boost their technical offering.	When acquiring a tech target, in particular a digital health or biotech company, the target's rights and obligations with respect to its intellectual property and compliance with personal data protection laws and regulations will also be key areas of investigation in the due diligence exercise. In cases where the real value of the particular tech company lies in the "brains" behind the operations, the acquirer will need to focus on retaining talent and technical expertise. The acquirer will need to ensure that these personnel are able to integrate seamlessly into the business and remain sufficiently incentivized to stay on with the business and contribute to the transformation.

5 Environment, Social & Governance | Leverage ESG scores and audits to reduce pollution and contamination

Trend

Asian pharma and biotech companies are laggards in ESG globally, according to research by Moody's unit Vigeo Eiris. However, a combination of more intense ESG scrutiny by regulators, pressure from global product distributors for suppliers to improve their ESG practices, and investor pressure driving for higher returns from companies with better ESG standards have increased the push for companies to proactively implement ESG solutions to reduce environmental pollution, improve worker safety and increase workplace diversity.

Opportunity

Transparency, thorough due diligence and compliance with ESG standards are critical in M&A. Companies are using third-party analytics tools such as Novata to support internal ESG reviews, leveraging the Sustainability Accounting Standards Board (SASB) for standardized data, and obtaining advice from experts to enhance their internal practices or capabilities. A leading Japan-headquartered pharmaceutical company, for instance, touts achieving carbon neutrality in its value chain, plans to eliminate greenhouse gases from company-wide operations by 2040, and is pushing for gender equality.

A China-headquartered company that provides R&D and manufacturing services to pharma, biotech and medical device companies, increased its MSCI ESG rating to AA after enhancing practices including corporate governance, product safety, HR development and environmental protection.

Legal considerations

Pharma and biotech companies looking to secure investment, or sellers looking to divest, can expect a heightened focus on ESG issues from investors and purchasers. Investors and purchasers are applying increased scrutiny to the policies of a target, board materials and other documents to consider the extent to which ESG topics and concerns are considered and addressed in a target's business model and whether there are appropriate governance frameworks in place.

Where ESG risks are identified, investors and purchasers will likely seek contractual protections in the transaction documents to mitigate such risks. Where ESG risks are significant, such matters have the potential to be "deal critical."

There is increasing regulatory requirements relating to disclosures of ESG matters, with climate change arguably more advanced than other ESG themes. While compliance and implementation of ESG policies are important, there may be laws that prohibit "greenwashing," either directly or through general prohibitions on misleading and deceptive conduct.

Finally, while the focus of ESG has concentrated on climate change and modern slavery and human rights, the issue of waste for the pharmaceutical industry is likely to emerge as a key area of focus for regulators and the public in coming years.

Trend	Opportunity	Legal considerations
Pharma companies in Asia Pacific that outsource, collaborate or use third parties for functions including R&D, manufacturing, distribution and data management need to manage contractors effectively to ensure regulatory compliance, receive financing from banks that incorporate ESG practices and meet customer ESG requirements and standards.	Transparency and control over ESG practices across the entire production cycle, including internal practices as well as supply chain and outsourced services, are critical. Companies increasingly need to ensure a careful approach to ESG due diligence and supply chain governance, both internally and when they are considering an acquisition or partnership.	We are seeing enhanced due diligence on supply chains from an ESG perspective, with parties reviewing disclosures made in a counterparty's environmental or compliance reports, annual reports, sustainability reports, information memoranda or prospectuses or other voluntary disclosure documents before contracting with that counterparty. Transaction documents are increasingly requiring positive obligations on parties to comply with ESG related policies. We are also seeing an increasing trend in which parent companies are held liable for ESG-related breaches of subsidiaries, and in some cases, of contractors. This has occurred not only through litigation but also through proposed regulations.
There has been a recent surge in big pharmaceuticals committing to long-term solar and wind power purchase agreements (PPAs), which require minimal investment and help companies achieve their decarbonization goals.	Wind and solar electricity generated from renewable energy projects aim to tackle a company's carbon footprint and can be equivalent to removing tens of thousands of vehicles from the road. While PPAs can be complex, the long-term benefits can outweigh the substantial commitment, so pharma or biotech firms are looking at leveraging expert advice to structure the deals effectively.	There are various PPA structures available, and the optimum structure for a business will depend on the objectives of the business. It is important to define these objectives at the outset and consider carefully, with the assistance of expert advice, which structure best suits its needs. If a business wants to use a PPA to meet emission reduction commitments, the deal will involve the purchase of green products/ large-scale generation certificates that can then be voluntarily surrendered to meet those goals. PPAs also provide other opportunities to support a business' ESG credentials. For example, if the PPA is with a renewable energy project that is not yet constructed, the business may be able to claim that it has "underpinned" development of the project because the PPA allows the seller to obtain greener financing for its development. Businesses can also impose other conditions on the PPA seller as part of its contractual requirements, such as provisions relating to best practice local community engagement, to maximize the positive social impact of the PPA.

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