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Life sciences M&A

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Q&A:

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THE PANELLISTS

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Dr Mathias Schulze Steinen boasts 20-plus years advising strategic and financial investors on domestic and cross-border deals, emphasising corporate, M&A, joint ventures, private equity, venture capital, corporate finance and restructuring in the life sciences sector. Clients value his entrepreneurial mindset, negotiation prowess, solution-focused advice, and unwavering support throughout transactions, regardless of scale.

FW: How would you describe the current appetite of companies in the life sciences sector for dealmaking? To what extent can M&A assist companies looking to bolster product pipelines, improve efficiencies and tap into new markets?

Gilbert: Dealmaking remains a core component of most life sciences companies' business models. For example, biotechnology companies' goals are to license or sell their assets or company to large pharma at an appropriate stage of development and pharma companies are constantly looking to enhance their pipelines of new therapeutics or enter new markets. The current market has not altered those objectives. However, there are significant factors that have impacted the volume of transactions. Higher interest rates and regulatory and legislative developments in the US have created a pause in the M&A market. The larger acquisitive companies are still digesting assets acquired over the last few years and are less likely to part with cash in this environment for less than ideal targets. That said, depressed market caps for many biotechnology companies, even those with positive clinical data and a regulatory approval pathway, should present buying opportunities. European and Asian companies remain very interested in acquiring US companies or licensing US assets to establish commercial capabilities in the US market.

Li: The lack of liquidity in the domestic China life sciences market is palpable. While the US to date does not explicitly restrict US investment in Chinese life sciences companies – unlike Chinese artificial intelligence (AI), quantum computing and advanced semiconductor companies where US investment is now heavily restricted – US funds and US dollar limited partners have dramatically curtailed their investment allocations to China owing to a host of reasons, including geopolitics. China's own institutional investors are still absorbing and digesting the market downturn and weighing their next moves – while large amounts of state and non-state funding continue to pour into infrastructure and semiconductor sectors. Multinational corporations (MNCs) – and US MNCs in particular – will see some of their Chinese start-up competitors wobble, leading to interesting, albeit opportunistic, consolidation driven by MNCs. In the meantime, Chinese public companies in the life sciences space, especially medical technology companies, remain cash rich to attempt cross-border acquisitions to improve their product and intellectual property (IP) portfolios. Many of them will become increasingly interested in setting up research and development (R&D) platforms in the US and in other developed markets; to that end, they are keenly aware of the regulatory and trade barriers, especially those of the US. The good news is the Committee on Foreign Investment in the United States (CFIUS) has approved a number of Chinese investments in and acquisitions of US life sciences companies even while US-China competition remains intense.

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> DLA Piper

Steinen: The appetite of companies is still big and there is lots of M&A activity in the European life sciences sector. Market players constantly want to improve their portfolio efficiency to adapt, for instance, to new forms of treatments, regulatory changes or the latest technical developments such as AI. Recently, big M&A tickets dropped slightly due to higher interest rates in the market. Also, the transactional approach has changed as market players have become more risk averse. This has resulted in a rise in partnerships and other forms of collaborations, instead of full acquisitions.

FW: To what extent are regulatory changes or pressures influencing M&A strategies?

de Kondserovsky: The life sciences sector is increasingly regulated in the European Union (EU) – at both local and EU levels. Such regulatory changes have not undermined the appetite for M&A transactions in the sector, which have continued to boom, but have created numerous complexities which impact deal process deadlines. By way of illustration, in France, recent legislative changes have included investment in biotechnologies within the scope of the foreign investment regulations requiring the prior authorisation of the Ministry of Finance. Although there are no known precedents of refusals, the ministry has sometimes conditioned its approval to commitments taken by the foreign purchaser, such as maintaining manufacturing facilities in France. Another example is the European Medical Device Regulation (EU MDR) which introduced major changes regarding pre-market conformity requirements, its implementation has turned out to be very challenging for companies. The European Commission (EC) has thus reacted to companies' concerns by delaying the EU MDR implementation by four years.

Gilbert: In the US, the Inflation Reduction Act, CFIUS and anti-merger sentiment within the US administration has presented challenges for dealmaking for larger deals. Such regulatory headwinds, however, have not had a significant impact in the middle market and acquisitive companies can acquire assets or companies without meaningful concerns of US governmental intervention. Transactions, whether large or small, may likely take longer as the deals

are reviewed for competitive issues, but they will most likely be consummated.

FW: Have any recent life sciences deals caught your eye? What market insights can we draw from these deals?

Steinen: Some large transactions in the first half of 2023, including the acquisitions of Prometheus Biosciences by Merck and of Seagen by Pfizer, indicate that big pharma might try to compensate the expiration of 'blockbuster' patents by major buy-ins. Another noticeable trend can be seen in the acquisition of orphan drugs that have increasingly become the target of M&A activities. The acquisition of Chinook Therapeutics by Novartis is a prominent example. Due to high profit margin in a market with less competition, the market for treatment of rare diseases sees higher growth rates. Recent M&A activities in life sciences tend to focus on genetic medicine. The acquisition of Polyplus by Satorius is a good example here. It is also worth noting in this context that the three largest financing rounds in the biotechnology sector in the US were secured by companies that are all involved in gene and cell therapy.

Rhodes: The £4.46bn EQT takeover of Dechra – which is still awaiting various regulatory approvals – is a great success story for an innovative company in the veterinary space achieving a multiple of 25.9 percent earnings before interest, taxes, depreciation and amortisation (EBITDA) and a premium of around 44 percent on its share price. While it will be a blow to the London markets for it to delist and reflects current market conditions in the capital markets, it is an exciting development for the company and shows that there are deals to be done for high quality companies.

FW: What advice can you offer to companies in terms of scoping deals and identifying opportunities across the life sciences sector?

Li: In the many markets with a general shortage of liquidity in the current high interest rate climate, including China and

many of the more developed markets, start-up companies may be starving for funding. Many large local institutional investors that ordinarily fund later stage start-ups are now looking to invest in earlier stage start-ups; this, in turn, is driving up the valuation of earlier stage start-ups while leaving behind a bigger vacuum for later stage financing or exits. While this phenomenon operates to depress the market, strategic or private equity (PE) investors that do have access to cash can leverage the phenomenon to find opportunities – especially cross-border opportunities, such as Middle East investors investing in China, or Chinese investors investing in developed markets – to invest in or acquire synergistic start-up businesses or technologies at a bargain price.

Gilbert: Buyers in markets with a general shortage of liquidity have a distinct advantage in many cases due to the lack of or reduction in bid competition for many assets compared to prior years. As capital markets have been largely shut for biotechnology companies and venture capital has become much more selective, many such targets are cash poor and need to transact in order to advance the lead programmes and extract value for their stakeholders. Potential buyers are scrutinising assets at a much higher level than in prior years. Potential sellers need to plan for longer and tougher due diligence processes. Understanding the realities and dynamics of the current market and each party's resulting leverage or lack thereof is an important aspect of transacting more than ever.

Rhodes: Current market conditions are fostering a more buyer-friendly environment than we have seen in recent years, which sellers should be prepared for. The price of debt is also swaying in favour of corporate buyers, who can sometimes take slightly longer to transact but can have an advantage in not having to leverage the transaction. Considering the regulatory position at the very start of the deal is now critical, especially in the life sciences sector as we see increased antitrust and regulatory

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> DLA Piper

regimes across jurisdictions impacting on deals in this sector.

FW: To what extent have you seen foreign direct investment regulations impacting on deal terms and timetables? Do you anticipate a similar picture in the next 12-18 months?

Gilbert: The life sciences industry generally has long embraced a global approach and utilised foreign direct investment (FDI) to facilitate R&D and to enter new markets. Companies and funds investing internationally generally looked to jurisdictions that had demonstrated robust R&D capabilities, capable workforces, stable governments and growing economies, as well as a regulatory environment that was receptive to investment and novel therapeutics and vaccines. The recent developments in FDI regulation in virtually all countries and regions has only had a modest impact on investment activity to date, but we expect to see more scrutiny of more transactions as regulators continue to expand the scope of technologies covered by the regimes. Regardless, transactions which require mandatory filings and agency review will take longer, resulting in deal uncertainty. As a result, this may limit the deployment of needed international capital into the sector and reduce competition for transactions.

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> DLA Piper

Li: China has for some years adopted a 'negative list' approach to foreign market access. While China's bureaucracy is known to be burdensome on administration, where the proposed market access does not – as is the case for most life sciences projects – fall into an industry on the negative list, it now takes minimal government approval to complete a transaction, either an M&A or a greenfield project. China does have a national security review regime for inbound M&A transactions, but the regime has been invoked on very few occasions – given that foreign market access is already subject to plenty of government scrutiny in any event – so few that there are hardly any reported cases and most foreign investors, and their counsels, see FDI review as a much lesser risk than that related to China's merger control clearance.

Steinen: There has recently been an increase in the application of FDI regulations in various European countries. The life sciences sector is also affected and receives more attention from lawmakers and regulators, such as when the companies involved are active in the development of mass products such as vaccines and antibiotics. The wider application of FDI regulation has an impact on deal terms, such as the allocation of risks related to the outcome of the approval process, or the time until completion of a transaction, which can take up to several months. We expect this trend to intensify.

FW: When pursuing a transaction, how important is it for life sciences companies to undertake thorough due diligence alongside other steps to manage transactional risk?

Rhodes: The Theranos case has highlighted the importance of undergoing appropriate due diligence in life sciences transactions. While diligence is important in all M&A transactions, for life sciences companies the additional regulatory regimes which can apply, alongside the need to examine valuable IP rights and the potential for sensitive personal data to be processed, means that there are some areas of diligence which may be fundamental, depending on the asset or business being acquired. The potential for risks which arise in a life sciences transaction to be significant if not identified means that early and strategic consideration of the diligence scope is critical to ensuring that the greatest focus is on the real value items and risk areas. This also helps to ensure that diligence which adds value to the M&A process is undertaken on an economic basis.

Li: International, and especially US investors, tend to hold themselves to higher operational standards in China and Chinese regulators tend to scrutinise them on the basis of such higher standards, whether in relation to labour practices, permitting requirements, anti-commercial-bribery –

especially in light of China's crackdown on corruption in public hospitals this past summer – anti-financial fraud, data privacy or in relation to other operational aspects. These investors would be well advised to conduct thorough diligence on their M&A targets and sign the acquisition agreement with their eyes open.

FW: How important is it for companies in this sector to pay careful attention to intellectual property and related licences when drafting transaction documents?

de Kondserovsky: IP rights are often the key assets of any M&A transaction in the life sciences sector. Thus, thorough due diligence and specific representations and warranties that IP rights are properly transferred and protected is critical. The scope of the due diligence and warranties should include ownership, valid registration and the absence of infringements or encumbrances. For biotechnology transactions in particular, special attention should be paid to third-party licences existing or needed to protect the business, such as with universities.

Li: While China lags behind the US in its portfolio of foundational technologies in life sciences, it remains one of the world's largest markets to commercialise new technologies. Allocation of IP rights among key market participants and stakeholders is no less critical in China transactions than in US transactions.

FW: What general steps should companies take in the pre- and post-deal phases to help deliver the intended benefits of a transaction and optimise long-term value?

Rhodes: It is critical that all internal stakeholders are aligned on what the strategic value of a transaction is and that this is communicated to all the advisory team. This can impact on how diligence is approached, the appetite for risk in certain areas and the drafting of the transaction documents. Failure to communicate where the value lies could lead to a suboptimal process and, ultimately, failure to realise the value which is sought. It is equally critical to ensure that this messaging is passed to the post-deal integration team. It is still the case that integration is often left to those not involved in the deal and then the value which was hoped to be achieved may be missed. Being really clear on this pre-deal, during the transaction as issues arise and terms are negotiated, and then post deal in a consistent way, gives the best chance of realising value from the transaction.

de Kondserovsky: Special attention to retention of key employees should be sought through an adequate compensation package and the proper definition of such employees' position and status. In particular, specific attention should be paid to employees possessing the know-how in companies where R&D or manufacturing is key.

FW: How do you envisage M&A in the life sciences sector developing over the coming months? Are there any trends you expect to see?

Gilbert: In the coming months, M&A deal volume will largely be driven by developments in capital markets. If the initial public offering (IPO) market for later stage biotechnology companies does not rebound, those venture capital-backed companies with promising pipelines will need to pursue an acquisition to continue to advance their programmes. We are starting to see signs of life in the IPO market with a few deals, but it is too early to determine whether it will be sustained. Additionally, many of the smaller publicly traded biotechnology companies have market cap challenges, making follow-on offerings more challenging, and as a result such companies will also become likely targets. On the buy-side, despite the multitude of potential targets, many strategic pharmaceutical companies are likely to remain relatively inactive due to pressures in their core commercial businesses and need for cash preservation. We would expect the larger pharmaceutical companies to be more focused on commercial targets rather than development stage companies. PE firms with sufficient capital to acquire

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> DLA Piper

targets and fund the ongoing business without utilising debt, which has become more expensive and less available, will have an advantage in this market.

Rhodes: We expect that large pharmaceutical companies will try to offset declining revenues due to patent expirations by acquiring innovative later stage biotechnology companies. The increasing need for AI that can help to reduce cost and time to develop drugs or medical products also looks likely to result in an increase of M&A activities, as many life sciences companies are likely to choose to buy-in and integrate the relevant technological expertise and products from the outside rather than developing these organically.

de Kondserovsky: Due to increased interest rates, PE funds will have more difficulty raising capital, and asset valuations should thus ultimately decrease. This will provide opportunities for cash-rich industrial groups to acquire a variety of biotech and medical technology companies.

Steinen: I envisage not so much of a development as a continuation. I anticipate seeing even more AI-focused deals in the life sciences sector by both medical device and biotech companies and also in the pharmaceutical sector. Given the recent interest in the sector from the EC and the Federal Trade Commission (FTC), it seems likely that caution may be applied to some of the larger transactions, but we will still continue to see deals where they are of strategic value and importance.

Li: China outbound M&A in life sciences will continue, especially in medical technology. The US and the EU will be prime destinations. Middle Eastern investors will potentially fill the void left by US investors for funding Chinese life sciences start-ups which will continue to seek IPOs in the US or in Hong Kong. ■