EY reports that 2021 saw an increase of around 64% in global initial public offerings (IPOs), with technology (c.26%), healthcare (c.16%), industrials (c.13%) and materials (c.13%) being the dominant sectors for this activity. If the views of US investment banks are to be believed, the outlook for global economic growth will remain robust for the next two years, which will provide a fertile environment for well-placed companies to look towards IPOs as the next natural evolution in their business life cycle.

On the other side of the ECM coin, with increasing inflation being one of the hottest topics at the start of 2022, reports from the likes of CNBC and the Financial Times point to an imminent move by the US Federal Reserve to raise interest rates. This same sentiment is echoed by the South African Reserve Bank, as the country, and the global environment, experience increasing inflationary pressures.

From a funding perspective, this rising inflation environment will make debt funding marginally more expensive in the near term, but that should in no way impede the desire by private equity firms to deploy their large capital reserves into value-accretive investments. We are already seeing evidence of this trend with KKR's \$40bn proposed offer for Telecom

Italia, Bain Capital and H&F's \$17bn acquisition of Athenahealth, and McAfee's \$14bn sale to an Advent-led investor consortium.

Depending on your point of view and your investment mandate, the year ahead looks to contain increased activity, both onto and off exchanges the world over.

Smith is a Corporate Finance Senior Associate | Nedbank CIB.



The role of mergers and acquisitions in the pharmaceutical industry





he pharmaceutical industry is dynamic - not just in current times, but also historically. It is not surprising that the industry is one of the frontrunners in the market space when it comes to M&A activity, the number of deals, deal value and innovative deal structuring. In this article, we will take a closer look at the role of M&A in the pharmaceutical industry, why M&A is central to such an industry, what the driving force is behind it, and what the future potentially holds for the pharmaceutical industry and the broader life sciences industry. We will also briefly consider M&A transactions from a South African perspective.

A brief history of how the pharmaceutical industry developed

The history of the top ten pharmaceutical companies is characterised by such companies continuously reinventing themselves. By way of an example, in 2018, only one of the top ten pharmaceutical companies, Gilead, had a history of less than 100 years, which speaks to the length of time many pharmaceuticals have been in the market.1 To further illustrate the evolution of pharmaceutical companies by way of M&A, consider that 60 of the pharmaceutical companies that existed in 1999 have been consolidated into

10 big pharmaceutical companies.² Moreover, 110 pharmaceutical companies have been consolidated into 30 in just the last three decades³. Interestingly, although one often thinks of M&A in the pharmaceutical space occurring on a multi-national scale by default, this was not always the case. As Davidoc points out, the trend of consolidations among pharmaceutical companies started out with companies converging within their home countries first, and thereafter moving on to global scale consolidations when internal consolidation opportunities were exhausted. The more recent trends are spin-offs, whereby the parts of companies' businesses with different business models, revenue streams and profit-growth opportunities are separated into smaller entities. The slow growth of specific products of a business, and competing generic products is, amongst others, one of the driving factors behind the spin-off transaction model. The demand for innovation within the industry which came about during the COVID-19 pandemic has also been a driving force behind a number of smaller, more innovative start-ups' growth, success and subsequent acquisition by larger companies. We will now consider other driving factors behind M&A activity in the pharmaceutical industry.

What drives M&A in the pharmaceutical industry?

As with any other business, profit-making is central to the business strategy and models of pharmaceutical companies. M&A enables companies to streamline their operations by optimising overlapping workstreams and reducing overhead costs, which can contribute to profit growth. Furthermore, M&A plays a significant role in the overall growth and expansion strategies of pharmaceutical companies. Deals focused on creating new growth platforms through consolidations are common, as they can provide companies with the capital required to fund new drug development by providing access to new revenue streams4.

The ever-increasing costs associated with new drug development, which many pharmaceutical companies can no longer afford, has pushed them to find innovative ways to access funds for research and development. For example, specialty pharmaceutical companies which are new to the market, and often funded by venture capital or private equity firms, are often acquired by larger pharmaceutical companies, thereby enabling these larger companies to access new generation technologies by outsourcing their research and development. The entire drug development cycle is also being reinvented through this approach, as companies increasingly outsource processes that are capital intense and provide lower returns, such as the manufacturing of commercial and clinical trial products, as well as the management of clinical trials. This trend has had a knock-on effect on the supply chain end of the drug development process, as consolidations and M&A activity amongst contract research organisations and contract development and manufacturing organisations follow suit⁵.

The nature of the challenges faced by pharmaceutical companies is a strong driver of M&A activity. In order to keep up with the rate of expansion of the critical size requirements of the pharmaceutical market segments, pharmaceutical companies were forced to consolidate in order to grow; as such, they could not have achieved this growth on their own. Furthermore, pharmaceutical companies continually need to keep up with

advances in medicine, as pharmaceutical drugs derive their value from solving a problem which could not previously be solved, or offering something better than what is currently available in the market, which requires cost-intensive research and development. There is also the challenge of competing with generic and biosimilar products and downward pricing pressure, as well as the challenge of reduced pipeline revenue streams due to the expiry of patents, and evolving regulatory requirements which lead to increased development costs, all of which drives cost-reduction mechanisms that can be achieved with M&A6.

The COVID-19 pandemic has further revolutionised the life sciences industry with the many challenges it has presented. With declining profits amidst the pandemic, executives have been aggressively expanding investments in digital transformation and customer engagement to generate prospects for longer term growth and value creation. The surge of digital health has been in the spotlight in

view that such M&A transactions in the pharmaceutical industry do not work optimally, due to the disruption caused by large-scale integrations across organisations, which negatively impacts on research and development productivity8. There is also the fact that despite the cost-saving which can be achieved with M&A transactions, the complexity involved in executing such large-scale transactions can be very costly. There are also various regulatory hurdles, especially in multi-jurisdictional M&A transactions, which need to be considered and overcome. One of the benefits that the COVID-19 pandemic has presented is the ramping up of digitisation, and regulatory timelines and approaches which have been forced to adapt, leading to renewed consideration of whether these changes should be permanent9.

Despite some of the setbacks that beset M&A transactions in the pharmaceutical industry, dealmakers have found innovative ways of

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the last two years, which has necessitated the need for the industry to invest and innovate as the demand for digital health services seems here to stay. The up-tick in venture capital funding of innovative start-ups has led to significant growth and success, resulting in an increase in strategic acquisitions. In 2021 alone, venture capital investment in the life sciences industry reached a staggering \$67,9bn worldwide, with almost 3,000 transactions. The upward rate of venture capital funding indicates that these strategic acquisitions are anticipated to continue7.

Despite the large volume of M&A activity that one sees in the pharmaceutical industry, there is a

optimising opportunities in order to ensure transactions are closed. While the use of debt to fund M&A transactions has declined, payment using a combination of cash and equities has gained popularity. In 2021, approximately 30 percent of global M&A value has been in shares. This upswing is likely due to steady rises in public equities' performance and size over the years.

The South African perspective

The pharmaceutical industry in South Africa is regulated by the South African Health Products Regulatory Authority (SAHPRA), which is the regulatory body that has replaced the Medicines Control Council, and is established by the

Medicines and Related Substances Act 101 of 1965. The Pharmacy Act 53 of 1974 also applies to pharmaceutical companies in South Africa.

As mentioned above, evolving regulatory requirements are often one of the major challenges faced by pharmaceutical companies, in terms of the cost and practical implications of complying with such regulations.

For example, marketing authorisations for products under South African law can take anywhere from 12 to 18 months to obtain from the SAHPRA. In most cases, for companies undergoing re-structuring transactions, there is a need to obtain such marketing authorisations sooner. Under these circumstances, various

structuring options are available to achieve the economic benefit derived from the transfer of a pharmaceutical business prior to having obtained the relevant marketing authorisations. For example, a seller and purchaser may conclude an interim licensing arrangement for the continued marketing, sale and distribution of products by the seller of the business which already holds the relevant marketing authorisations for such products, pending receipt of such market authorisations by the purchaser.

In such instances, parties closing transactions are able to minimise delays which may be caused due to long lead regulatory approvals. In a rapidly evolving industry such as the pharmaceutical industry, time savings such as these are crucial.

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Conclusion

Many factors drive M&A activity in the pharmaceutical space, as companies seek ways to grow and maximise profits. Despite the challenges faced by pharmaceutical companies, M&A transactions present opportunities for companies to find unique ways to adapt their business models in a manner that meets the market needs, whilst at the same time, optimising their operations. The ongoing pressure that COVID-19 has placed on pharmaceutical companies to innovate and provide solutions to long-standing issues in the industry provides additional impetus for dealmakers to make strategic investments. Indeed, if the South African market follows the international trend, we may be headed towards a record-breaking wave of M&A in the industry. There is no doubt, however, that in the years to come, the manner in which the COVID-19 pandemic has shaped the pharmaceutical industry will be a unique feature of its history.

Valayathum is a Director and Jansen van Vuuren a Candidate Attorney | Cliffe Dekker Hofmeyr.



KIETI LAW LLP, KENYA

Indemnities sailing into the sunset

n a contract for the sale of a business, the sale of shares or other assets, it is a standard commercial practice to include a clause setting out a list of warranties given by the seller to the acquirer. It is often a point of huge contention in negotiation as to whether the seller is also prepared to give a list of indemnities, including, in particular, a general indemnity against any loss that might be suffered by the purchaser as a result of a breach of any of the warranties, in addition to a list of specific indemnities for known liabilities. The question often arises: what is the difference between a warranty and an indemnity? In this

article, we tackle the sensitive issue of whether the indemnity is not redundant in such circumstances. Negotiations on warranties vs indemnities often lead to heated debates, and could be a stumbling block to concluding a transaction. We ourselves have been party to such debates, and question if it may be time to knock the wind from the sails of the heated exchanges on the topic.

During the course of negotiating a contract, a party will usually make a number of factual statements on which the other party will rely in deciding whether or not to enter into the

agreement. For example, in the sale of a business, the seller might state that the business has no outstanding tax liabilities. Without more, such a pre-contractual statement of fact is a mere representation, giving rise to remedies for misrepresentation if the statement proves to be false: (i) cancellation of the contract if the statement was material and induced the contract, and (ii) delictual damages if the statement was made fraudulently or negligently. The false representation will not give rise to a claim for contractual damages unless the representation was incorporated into the contract as a warranty.