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EY Sees Potential for Uptick in M&A in 2023

(Source: An article by Joseph Haas for Scrip Intelligence)

Mergers and acquisitions (M&A) for 2022 proved to be lackluster in the life sciences sector, according to EY, whose team has been conducting an evaluation of the sector since 2014. Total deal volume suffered a 23% decline while total deal value for M&A was off by 39%.

Several factors contributed to less activity in 2022, but other factors incuding impending patent cliffs and an expected buyer's market (attributed to declines in the public market and special purpose acquisition company (SPAC) exits should lead to a more normal deal-making environment for both the life sciences sector and the biotech segment in 2023, according to the 2023 EY M&A Firepower Report.

Firepower – EY's term for capital that companies have available for business development activity (specifically M&A transactions), has been hovering in the US$1.2 trillion range since the initial 2014 report. EY's estimated firepower for the industry in 2023 is US$1.4 trillion. The combination of declining valuations and the need for additional pipeline assets due to patent cliffs will push companies to return to a normal or even higher than normal M&A level going forward.

Authors of the report, Arda Ural and Subin Bural, both conceded that a series of factors – including inflation, currency volatility, supply chain issues and uncertainty surrounding drug pricing impacts due to the U.S. Inflation Reduction Act (IRA) – constrained large-scale deals from happening in 2022. Going into 2023, companies with sizeable financial "war chests" paired with losses of exclusivity (LOEs) on the horizon will help drive demand for more M&A activity.

"There are also foundational, strategic issues that industry has to deal with, so that's why I say in 2022 'what got you here won't get you there,'" explained Ural, who is EY's industry market leader for life sciences and health. "During 2024-26, there is this massive patent cliff heading for the industry and it's around US$200 billion. Last time, the patent cliff from roughly 2010-14 was about US$100 billion, so this patent cliff is double what it was 10 years ago. It's incumbent on the industry to be more strategic in capital deployment and growth this time."

There is a level of expectation that companies will use their capital firepower to invest in new research breakthroughs that will position them to maneuver the next patent cliff, the report states. The focus will likely be on emerging therapeutic modalities such as cell and gene therapy as well as mRNA products. Novel digital technologies and data science will also likely figure into the mix when deciding where to invest.

"Among life science companies, the leaders will be those that set the pace of change," the report states, adding "The most important targets are not only the novel drugs and devices that offer immediate value, but also the innovative technologies emerging outside the [life sciences] sector, including breakthroughs in artificial intelligence (AI), big data, robotics, and others."

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In Brief...

- **McKesson** announced their Q3 2023 financial results, with total revenues of US$70.5 billion, an increase of 3% year-over-year. Adjusted earnings per diluted share was US$6.90, up 12% (excluding certain items an increase of 6%.) "McKesson delivered another solid quarter, driven by the dedication of our talented associates committed to advancing healthcare for all. Our performance was highlighted by execution across our scaled distribution businesses and differentiated capabilities in the oncology and biopharma services platforms," said CEO *Brian Tyler.*
- **Cardinal Health** reported Q2 2023 revenues of US$51.5 billion and increase of 13% year-over-year. Q2 GAAP operating loss was US$119 million due to a non-cash, pre-tax goodwill impairment of US$709 million related to the Medical segment. "Our second quarter results demonstrate continued momentum against our plans, led by better-than-expected performance in the pharmaceutical segment and medical results in-line with our prior commentary," said *Josh Hollar*, Cardinal's CEO.
- **The IQVIA Institute** has released its report *"Global Use of Medicines 2023: Outlook to 2027".* The report examines global spending on medicines and the drivers behind these trends in a post-pandemic world. The report quantifies the effects of dynamics such as innovation and losses of exclusivity in 2022 and looking forward to 2027. To download a copy, visit *https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicines-2023?utm_campaign=2023_GlobalUseofMedicinesOutlookto2027_Institute_TC&utm_medium=email&utm_source=Eloqua*. Separately, IQVIA has also inked a partnership deal with **Alibaba Cloud** (a unit of **Alibaba Group**) to leverage Salesforce in a first-of-its-kind deal

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Australian Wholesaler Association NPSA Joins IFPW

IFPW is pleased to announce that the National Pharmaceutical Services Association (NPSA), the leading industry body representing full-line pharmaceutical wholesalers in Australia, is the newest member of IFPW. Established in 1976, NPSA members include API, National Pharmacies, Sigma Healthcare and Symbion who have been supporting Australians for over 100 years with their primary focus on health logistics. They are a vital part of Australia's complex health infrastructure. NPSA members deliver their critical role through a 3,400 strong workforce in (34) distribution centers supported by a national transport network delivering to 5,800 community pharmacies and hospital pharmacies throughout Australia.

IFPW welcomes NPSA and looks forward to its participation, insight and perspectives on the global industry as an integral IFPW member!

EY Report (cont.)

According to Baral, EY's life sciences global deals leader, while the financial slowdown is causing biotech valuations to fall, greater scrutiny is being placed on the deal-making process so that buyers are more certain about what they are getting and why.

"There will always be some deals that will not work out in the scheme of things, but what we are experiencing is a higher threshold for getting strategic deals done," Baral said. "The bigger question is not the valuation – when biotech valuations have crumbled, we expected a flurry of deals to happen but it really didn't because [potential acquirers] wanted to see the quality and the strategic value of the assets, as opposed to doing a deal just because it's cheap."

According to Todd Skrinar of EY, "Sometimes the stars shine brightest on the darkest night, and right now there are more than a few very innovative biotechs that are trading under cash and/or have less than a year of cash runway. This may help close expectations gaps between buyers and sellers."

Concerns about the IRA have also added a challenge to the deal-making process. Companies are now trying to determine how the business case for a deal could be impacted by price negotiations for highly-prescribed drugs in 2026. Meanwhile, the unpredictability of the IRA has led some companies to do portfolio assessments, with some discontinuing development candidates that may not be as lucrative in light of the passage of the IRA.

"The focus will go more toward products like rare diseases, oncology, immunology, neurology," Baral said. "It's almost like the system is pushing you away from the blockbuster model to a more diversified portfolio model and then also pushing you towards more biologics than smaller molecules based on the number of years [of exclusivity] that you're getting on top."

EY concluded that the need for more well-thought out business development to position the companies for the future is necessary – all this in spite of headwinds. The combination of significant firepower, looming LOEs for blockbusters and declining valuations for biotechs should culminate in a busier year for M&A activity in 2023.

Antibiotics Shortages in Europe Continues to be a Concern

(Source: An article by Fraiser Kansteiner for FiercePharma)

As the increase in respiratory infections coincide with high inflation, an energy crisis and the war in Ukraine, officials in the European Union are making strategic moves to keep the supply of antibiotics intact.

Demand for antibiotics such as *amoxicillin*, especially in formulations for pediatric dosages is an ongoing public health concern several European agencies stated. Geopolitical events and trends have only exacerbated the situation, raising concerns at the highest government levels.

EU officials have asked drug suppliers to increase production capacity and have made recommendations, including encouraging EU states to allow the use of medicines that may not be authorized domestically.

The issue is also taking root in the U.S. where the U.S. Food and Drug Administration (FDA) in October warned that *amoxicillin* oral solution – the liquid form of the drug often given to children – was currently in short supply.

Manufacturing delays and production capacity issues have only served as further complications in Europe, fueling supply problems across a "majority" of EU member states, according to officials.

To help outmaneuver and get ahead of these supply shortages, a group called the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) has been monitoring Europe's antibiotic shortage since November of 2022. The group is working with partners in government and industry to boost capacity and resolve supply shortfalls.

The team has also put together measure behind temporary national solutions like unit dose dispensing and compounding.

Based on current information from companies and other stakeholders, MSSG and its partners believe the situation will improve in the coming months.

Europe's drug supply dilemma goes beyond just antibiotic supplies as well. In late September, Medicines for Europe wrote an open letter to the EU's energy and health ministers asking the block to lower energy costs for Europe's generic medicines sector. The trade group pointed to issues such as inflation, the war in Ukraine and historic pricing pressures as potential threats to the continent's generic drug industry.

"This threatens to undermine medicines supply and our industry's efforts to invest in manufacturing in Europe," the trade group said in September.

In Brief (cont.)

in mainland China. The collaboration is focused on providing customers an entry into the market by hosting clinical and commercial products on Alibaba's public cloud.

- **AmerisourceBergen** will serve as **Civica, Inc.'s** (a non-profit generics pharma company) exclusive distribution partner and provide suppy chain support for Civica's products and a best-in-class customer experience. AmerisourceBergen will work to ensure that Civica's products reach its members across the country efficiently, reliably, and securely. The partnership will be rolled out to Civica members throughout the first half of 2023 and aims to accelerate both organizations' mutual efforts to ensure the stability of the supply of generic medicines nationwide. The deal is expected to close in late 2023.
- **CVS Health** announced it is acquiring **Oak Street Health** for US$10.6 billion (US$39 per share in cash) as part of its goal to expand its primary care services. Oak Street runs care centers mostly for lower-to-middle income people with Medicare Advantage plans. Those are privately run versions of the federal government's program for individuals aged 65 and older. Separately, CVS posted Q4 revenues of US$83.8 billion, up 9.5% year-over-year.
- **Moderna's** RSV vaccine for older adults has received breakthrough designation from the **U.S. Food and Drug Administration (FDA)** as the three-way race with Pfizer and GSK nears the finish. The announcement comes two weeks after it posted competitive phase 3 data of the vaccine, *mRNA-1345*. The shot was found to be 83.7% effective against RSV-associated lower respiratory tract disease defined by two or more symptoms, with the majority of side effects rated as mild or moderate.

(Sources: Drug Store News, FiercePharma, Nephron Research, PharmaVoice, Press Releases, and Wall Street Journal)