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Modern Digital Solutions for the Pharma Industry

(Source: An article by Sergey Avdeychik, Director of Healthcare Technologies at Andersen, for Forbes)

According to data by Statista, the revenue of the worldwide pharmaceutical market at the end of 2020 was US$1.27 trillion. This market growth is largely associated with information technologies, as more and more pharmaceutical companies are entrusting their manufacturing and logistics processes to outsourcing companies to reduce costs and increase overall efficiency. It is important to understand how pharmaceutical manufacturers apply technologies throughout drug discovery and development and what opportunities this brings for technology companies.

According to *Journal Biostatistics*, only 13%-14% of more than 20,000 drug candidates from all disease areas entering the development process from the year 2000 to 2015 will ultimately be approved. In oncology, the success rate dropped to a devastating 3.4%. AI/ML technologies can help select several of the most promising compounds out of tens of thousands of candidates for the role of a drug. This selection process is carried out in silico, entirely by computer with no lab tests or human participation, and can accelerate drug discovery from 4-5 years to several months, driving down the costs. A growing trend of digital health is cooperation between AI companies and big pharma. An example of AI's potential in drug discovery is the identification of *baricitinib* as a potentially effective drug against coronavirus in just a few days, and now, this medication has been approved by the FDA for emergency use against COVID-19.

For state-funded scientific institutions, an area of interest is in silico drug discovery. In this area, the ATOM Modeling PipeLine stands out. This open-source modular and extensible software pipeline exists to build and share models which help advance silico drug discovery. The National Cancer Institute in the United States oversees this project as part of the Cancer Moonshot initiative.

Another area of interest for the IT business in the pharma industry is the development and implementation of clinical trial management systems (CTMS). These solutions make it possible to find trial subjects, including remote enrollment capabilities, manage their data, streamline data transfer, achieve greater transparency of the trial conduction, improve research documentation, and make trial audits clearer. Applications that

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In Brief...

- **AmerisourceBergen (ABC)** released its *2021 Global Sustainability Report and Environmental, Social and Governance (ESG) Reporting Index*, detailing the impact of its robust sustainability and community efforts. The report and ESG Reporting Index highlight ABC's commitment to corporate responsibility and global sustainability. For the fourth year in a row, selected information within the 2021 report was assured by *ERM Certification and Verification Services*. The Corporate Responsibility and Global Sustainability strategy focuses on key priorities that align with the services and beliefs at ABC and details several notable milestones, including initiatives led by **Alliance Healthcare**, a leading pharmaceutical wholesaler in Europe which ABC acquired in 2021. Separately, ABC announced the appointment of *Ann Anaya* as the organization's SVP and Chief Diversity Equity and Inclusion Officer. Anaya will lead the Office of Diversity, Equity and Inclusion (DEI) and be responsible for driving ABC's global DEI strategy to enable a more inclusive culture, foster more engaging environments and deliver more favorable customer and patient outcomes.
- **Cardinal Health** announced its Q2FY2022 financials, with revenues totalling US$45.5 billion, an increase of 9% year-over-year. GAAP operating losses totalled US$950 million, which the company attributed to a non-cash, pre-tax goodwill impairment of US$1.3 billion related to the medical segment. Second-quarter revenues for the pharmaceutical segment increased 11% to US$41.4 billion, attributable to branded pharmaceutical sales growth from large pharmaceutical distribution and specialty customers.
- **IQVIA** released its *Global Trends in R&D: Overview through 2021*, which assesses the trends in new drug approvals

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Pharma Consolidation in China by 2025

(Source: An article by Dexter Yan for Scrip Intelligence)

China's new five-year plan for the pharma sector calls for closer collaboration between large and small domestic pharma companies, not only for products and technologies but also capital. However, it remains to be seen which specific measures government agencies will take to achieve the broader goals.

The Chinese government has laid out a blueprint to drive closer collaboration between large and small Chinese pharma companies by 2025, with M&A being a major route. In the 14th Five-Year plan (2021-2025) for Development of the Pharma Industry (released on 30 January) the Ministry of Industry and Information Technology (MIIT), together with eight other departments, stated that they aim to nurture a pharma industry ecosystem in which large and smaller-sized companies

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automate the process of data exchange between an electronic health record (EHR) and electronic data capture (EDC) and solve the current interoperability problem are also worth devoting attention.

Also of note, McKinsey has estimated that, in terms of investment volume, supply chain management and manufacturing is the second-largest sector after marketing and sales, reaching US $88.9 billion globally. The manufacturing stage of drug development requires processes to be organized in accordance with the industry standards, such as good manufacturing processes (GMP) and process analytical technology (PAT) framework. Pharmaceutical manufacturers must comply with the requirements for the procurement of raw materials, organization of pharmaceutical production, supply chain and pharma distribution management, as well as disposal of waste and unclaimed products. Dedicated software – including enterprise resource planning, batch management software and more – can be used for procurement management, production, and quality control.

Intelligent tools make supply chains faster and cheaper, improve end-to-end supply chain visibility, adjust needed inventory levels on time and accurately, optimize predictive maintenance, protect the integrity of the supply chain, and help monitor compliance with the transportation technical standards.

A technology that is gaining momentum is blockchain, which can be used to track the path of raw materials, ingredients, and components. An example of such a solution is a temperature-monitoring system developed to maintain the required temperature regime during the transportation and storage of shots.

Blockchain is likely to be part of the future of supply chain management. There are also signs pointing to the onset of pharma Industry 4.0, which is characterized by the integration of connectivity, AI and robotics to enable systems that operate with little or no human involvement for an efficient, safe and cost-effective pharma business.

It is evident that the tightening of standards for control over pharmaceutical products at the level of state regulators increases the demand for solutions to detect, assess, report, understand and prevent adverse effects of medicines.

The partnership between IT businesses and pharmaceutical companies contributes to the effective organization of processes at all levels of drug discovery — from identifying drug candidates to managing production and supply chain. The advantages of integrating software solutions, blockchain tools, cloud technologies and AI/ML in the pharmaceutical industry include automated production and distribution cycles, lower production and logistics costs, increased efficiency and quality of production and management processes, and enhanced data security.

Pharma Consolidation (cont.)...

can develop by leveraging synergies generated by deeper collaborations across products, technologies, the market, and capital.

The roadmap calls for larger drug makers to achieve "a higher degree of market competitiveness" and more global reach, while smaller companies will focus on niche and innovative products as an emerging force in the sector, according to the MIIT. The strategic aim is a higher aggregate market share by 2025. In 2020, these firms generated more than 30% of total revenues in the industry.

Although mega deals involving large companies taking over smaller biotechs are rare in China, smaller transactions have taken place in recent years. In April 2021, for instance, Shenzhen-listed Huadong Medicine Co., Ltd. acquired a 75% stake in privately held Doer Biologics, an antibody specialist, for US$76.6 million.

The five-year plan also calls for domestic pharma companies to increase their R&D expenditure over the 2021-2025 period, by an average of more than 10% annually. Comparatively, the five-year period that ended in 2020 saw a growth rate of 8%.

The issue at hand is that the planned spending growth looks set to come against the backdrop of an outlook for slower profit and revenue increases. From 2021-2025, Chinese pharma companies' revenue and gross profit growth targets are seen in the plan as increasing approximately 8% on average, down from 9.9% and 13.8%, respectively, over the 2016-2020 period.

While many of the specifics on how the new targets will be practically achieved remain sparse, as part of incentives for the manufacturing sector's increased capital spending on R&D, the plan reiterates that pharma companies in China can access double tax deductions for every effective dollar spent on innovation from 2021-2025. However, MIIT has yet to set out more details on other specific policies that Chinese pharmas could take advantage of for future business activities, such as M&A.

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and launches, overall pipeline activity in terms of actively researched medicines, and the number of initiated clinical trials. It also profiles the state of R&D funding and the activity of companies of different types, and the results of research are compared to the input effort in a Clinical Development Productivity Index. To access the report, visit the link ***Global Trends in R&D 2022 - IQVIA***.

- For the sixth consecutive year, **McKesson** received approval from **The Centers for Medicare & Medicaid Services (CMS)** to participate in the Merit-based Incentive Payment System (MIPS) as a *Qualified Clinical Data Registry (QCDR)*. The designation enables *iKnowMed*™ electronic health record (EHR) users to efficiently submit data directly to CMS without engaging a separate registry vendor, streamlining data submission and minimizing administrative burden. Along with *The US Oncology Network*, McKesson also supports oncology practices through its Onmark group purchasing organization (GPO), and the QCDR measure approvals reflect the organization's insight into the entire landscape of oncology care.

- **Eli Lilly** announced that **The U.S. Food and Drug Administration (FDA)** has issued an Emergency Use Authorization (EUA) for *bebtelovimab*, an antibody that demonstrates neutralization against the Omicron variant. *Bebtelovimab* can now be used for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

(Sources: Business Wire, Company Press Releases, Drug Store News, FiercePharma, FierceBiotech, and World Pharma News)