FOCUS

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South Korea - Key Drivers for Growth in the Next Decade

(Source: An article by Jung Won Shin for Scrip Intelligence)

Since the 1990s, the South Korean pharmaceutical industry has gone through several growth phases, with the initial development of new drugs.

From 2000-2010, there were structural changes, as the then generic-focused industry faced limitations in growth, due largely in part to continued drops in domestic prices. This brought about the need to focus not only on the home market, but to look for avenues that were more global in nature.

The period from 2010-2020 was concentrated on more innovative research and development, as well as large-scale global licensing deals that worked in parallel to biosimilar firms establishing a leading position in international markets where possible.

As the country looks forward to the next decade, Korean pharmaceutical companies may have to take one of two strategic positions – transform into fully-innovative developers or focus entirely on generics and functional health products. Although it would be ideal to enter the global marketplace through independent development and commercialization of new drugs, there is still a view that the South Korean industry should keep its licensing-focused model intact, at least for now, given the country's limited financing capabilities and sales as compared to global big pharma.

Economics remain a key consideration. Even if a firm reached a global licensing deal worth KRW1 trillion (US$896.2 million), it may receive an upfront portion of only about KRW40 billion (US$35.7 million). When divided over two to four years, this would translate into approximately KRW10 billion (US$8.9 million) to KRW20 billion (US$17.9 million) on an annualized basis requiring a reasonable investment for a single drug asset.

Companies that fully rely on a licensing model would need to bring in five to six large-scale deals per year to generate enough cash flow. Unfortunately, an R&D pipeline of that size is non-existent. Factor in the fact that five to seven out of ten assets licensed out eventually return to their originators and it becomes a very challenging situation, given the 70-80% success rate of clinical trials.

There is no doubt that achievements in global licensing have been made since 2015. However, the industry needs more successful cases of direct global market entry. South Korean manufacturer SK Biopharmaceuticals Co., Ltd. has proven that this approach is not impossible.

While many domestic companies lack the capital to make progress with late-phase trials overseas, finding the right partner may be the answer. If South Korean companies have successful Phase I and Phase II results, these can support partnerships with other firms to fund final overseas development. This would allow for financing of Phase III trials and marketing costs, while sharing profits of a successful product launch.

South Korean pharma giants Celltrion, Inc. and Samsung

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- The Biden Administration is proposing a sweeping strategy to boost domestic drug production. Under the plan, a public-private partnership to select 50-100 essential medicines are "to be the focus of an enhanced onshoring effort" according to the plan. Also, the U.S. government is committing approximately US$60 million to research new technologies that will boost domestic active pharmaceutical ingredient production.
- **Biogen** is ramping up its manufacturing in anticipation of full approval of its new Alzheimer disease drug *aducanumab*. The company will initially focus manufacturing in its U.S. facility in North Carolina and hopes to quickly bring its Swiss plant into the mix. The company anticipates enough capacity to adequately supply the drug to more than 1 million patients annually.
- China has issued an emergency use authorization for the COVID-19 vaccine *CoronaVac* (manufactured by Chinese firm **Sinovac**) for use in children 3-17 years of age. Sinovac has finished the Phase I and Phase II clinical research involving several hundred volunteers in this age group, and the results have proven safe and with good efficacy.
- An expert advisory panel in Japan granted formal emergency approval to two more COVD-19 vaccine candidates from **Moderna Inc./Takeda Pharmaceutical Co., Ltd.** and **AstraZeneca PLC/University of Oxford**. The vaccines were granted special approval by Japan's **Ministry of Health, Labour and Welfare**. The Japanese government hopes to ramp up inoculations to more than one million per day and will also administer vaccines in the workplace beginning June 21st. Separately the Japanese Ministry of Health has also approved the **Pfizer** COVID-19 vaccine for use in children 12-15 years of age.
- The COVID-19 vaccine candidate from **Novavax** has shown a 90.4% efficacy rate in prevention of the virus and

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Amazon's Pharmacy Tests Edge Closer to Generic Disruption

(Source: A report by Eric Percher of Nephron Research)

Amazon Pharmacy will begin offering 6-month fills starting at $6 and Walmart will add a drug discount card to Walmart+ membership. This is impactful Amazon news and shows the company continues to expand its testing of the pharmacy waters. It is noteworthy that Amazon's entry into pharmacy with Pill Pack and later collaboration with Cigna/Evernorth for the Prime Savings Benefit were incremental innovations and unlikely to prove disruptive on their own, Nephron views the 6-month fill program as potentially more impactful over time as the initial test focused on uninsured and under-insured could roil the usual and customary' PBM-Pharmacy contract model if expanded over time.

Reporting indicates Amazon will offer 6-month fills starting

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Korea (cont.)...

BioLogics may move in this direction in the next five to ten years. Biosimilar development and contract manufacturing are capital-intensive, making partnerships not just preferable but necessary so that they may successfully move forward. Other companies, such as Hamni Pharmaceutical Co., Ltd. and Yuhan Corporation are actively seeking open innovation alliances but need to have clearer strategies for business direction in the next five to ten years.

For a latecomer country like South Korea to have global competitiveness in new drug development, it is more appropriate to seek first-in-class rather than best-in-class assets, because the latter requires more of the capital that South Korean firms lack. Companies in the country still need such assets, which accounted for only 5% of all programs funded by the Korean Drug Development Fund. Given the attrition rate between preclinical and clinical stages, the number of pipeline projects generated through state-level R&D has to increase several times. There will also need to be support for medical complexes and active pursuit of overseas licensing deals in the medium- to longer-term.

In recent years, universities and research institutes in South Korea have been urged by the government to meet the industry's demand for new pipeline assets. While this may be useful in solving the problem short-term, it could lower the innovativeness and novelty of R&D programs in the long run. The government needs to create an environment that fosters cooperation between large pharma firms to pursue co-marketing and joint clinical development alliances while larger, more established bioventures could pursue late-phase trials and market in regional markets such as Asia or South America bridging the difficulty of entering major global markets.

Amazon (cont.)...

at $6, expanding on Walmart's US$4 generic program (covering 300-400 meds with 30-day prices of US$4 to US$15 and 90-day prices of US$10-US$38) but stopping short of Ro Pharmacy's recent launch of a 3-6-12 month fill offering (perhaps 500-1,000 meds including both low and mid-priced generics). It is expected that the program will initially focus on the uninsured and under-insured cash pay market and curate the selection of meds so as not to reduce generic profits within Amazon Pharmacy's existing commercial business. Amazon Pharmacy's cost to fill likely remains above industry levels, a disadvantage that will diminish over time and is here offset by the six-month fills.

Is a cash price generic model down the road? It remains Nephron's view that if Amazon wants to truly disrupt the pharma supply chain and aggregate significant share, it will eventually launch a broad-based low-cost generic offering, sacrificing the profitability of the company's existing commercial generic book governed by 'usual & customary' contracts in return for a massive share gain opportunity. Such a move would truly change competitive dynamics within the retail and mail pharmacy marketplace while reducing costs for consumers. This requires bold action from Amazon and is unlikely to happen until the company can reduce its cost to fill to support an influx in volume.

Walmart+ pharmacy addition is a natural evolution. Expansion of Walmart+ to include a pharmacy savings card for discounts at Walmart's 4,000 physical pharmacy locations seems to be a natural expansion of Walmart+ membership benefits and very much in line with historical retail pharmacy membership discount programs. Nephron sees limited impact for CVS and WBA.

Incremental action results in only an incremental impact. Unlike recent reporting on the potential for Amazon to enter physical pharmacy, Nephron does not expect the reports of a 6-month generic program will materially weigh on pharmacies and distributors. Generally, given the long-term nature of Amazon's many pharmacy tests, we view headline related weakness as a buying opportunity for AmerisourceBergen (Amazon's distributor), McKesson and Cardinal Health but are more conservative with respect to pharmacies CVS Health and Walgreens Boots Alliance. We also see a significant opportunity for Cigna/Evernorth if Amazon is succssful in building a discount card competitor to GoodRx and as success for Amazon if mail is likely to drive incremental margin for Evernorth in specialty.

IQVIA Institute Issues New Report on the Use of Medicines in the U.S.

(Source: Company Press Release)

According to a new report from the IQVIA Institute for Human Data Science, "The Use of Medicines in the U.S." the U.S. health system demonstrated resilience and flexibility during 2020, recovering toward its pre-pandemic levels of activity and progressing into 2021, even as the backlog of missed or delayed activity remains substantial.

Medicine supply was largely maintained and spending on medicines increased by less than 1% on a net price basis. Other key findings in the report include: health services utilization index during COVID-19; medicine use; medicine spending; patient out-of-pocket costs and affordability; and, an outlook on 2025.

To download the please visit *https://www.iqvia.com/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends-outlook-to-2025*.

Also, join us on June 22nd at 9 a.m. EDT for a webinar featuring Doug Long and Per Troein of IQVIA as they give their latest insights and information in the pharma industry. To register for this timely and informative webinar, please visit *https://bit.ly/3cNVYHm*

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a 100% protection against moderate and severe cases of the disease. A study that included nearly 21,000 participants across 119 sites in the U.S. and Mexico evaluated efficacy, safety and immunogenicity with a representative population across demographic groups most impacted by the disease.

- French pharma manufacturer **Sanofi** will manufacture its COVID-19 vaccine in Japan in partnership with **UNIGEN**, headquartered in Gifu prefecture. The company said that it is in the process of building a global manufacturing network for its vaccine. Its vaccine is based on its recombinant-DNA-based antigen and **GSK's** adjuvant. Approval in the U.S. and Europe is expected by the end of the year.

Sources: Drug Store News, Fierce Pharma, Japan Today, Pharma Japan, and World Pharma News