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Multinational Pharma Companies Eye China as a CEO-level Priority

(Source: An Article by Fran Le Deu, Sr. Partner for McKinsey & Company, for Biopharma Dive)

At the International Pharma Forum this past spring, CEOs from seven of the most prominent pharmaceutical companies expressed their firm commitment to making China a priority in their global business strategy. The event, hosted by the R&D Based Pharmaceutical Association Committee (RDPAC) and the Pharmaceutical Research and Manufacturers of American (PhRMA) brought thoughtful insight regarding China from GSK, Eli Lilly, LEO Pharma, Merck KGaA, Pfizer, Sanofi and UCB. Several days before, CEOs from several other large multinationals attended the China Development Forum, an annual event hosted by China's State Council. Both events effectively demonstrated China's drawing power for some of the world's most influential pharmaceutical companies.

The implications of the current trend to prioritize China comes from four areas value creation (and related implications) which extend across industries for multinationals operating in country.

1. *Growth from millions to billions:* China is already a key contributor to the revenues and growth of multinational pharma companies. This is not unique to the pharma sector. However, the trend is made very clear in the quarterly earnings releases of most major pharmaceutical multinationals. Performance in China is frequently a highlight and one that companies are quick to showcase. Some companies even position China as a "key pillar of future growth." For some of these companies, China accounts for as much as 25% of global growth.

2. *Innovation:* China is an emerging source of product, portfolio and business model innovation. In a recent interview with China Daily, Novartis' head of global drug development and chief medical officer announced that the company is working on "having every pivotal drug development program include China from beginning by default." Companies are also tapping into China's innovation ecosystem. As an example, AstraZeneca opened the Commercial Innovation Center in the Wuxi region. Other companies that have opened innovation hubs across China include Merck KGaA, Johnson & Johnson, Roche, Novo Nordisk and Sanofi. While these facilities may vary in scope and operating models, they all center around innovation through partnerships with other players in the ecosystem.

3. *Global Supply Chain:* China is emerging as a more central player in biopharma. This is a new emerging trend for biopharma and can be explained by several factors, but most notably a concern around IP protection. It is expected that, over time, this will become increasingly manageable. Some companies, such as Boehringer Ingelheim, operate plants for contract manufacturing in mainland China, while others are announcing plans to follow a similar path.

4. *Capital and Talent:* China's role as a resource for the right individuals and venture capitalists (VCs) to fill gaps for in-demand skill sets. We have seen this trend play out clearly in the world of

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- **Pfizer** announced a US$500 million plan to ramp up its gene therapy manufacturing operations with a major expansion in Sanford, NC. "We're going to be a leading player in gene therapy," said Bob Smith, the SVP for global gene therapy at Pfizer. Building on to their operations in North Carolina gives the BD team an open highway to more deals as Pfizer continues to add to their existing gene therapy pipeline they already have built.
- **Biotin** announced that China-based **Harbin Gloria Pharmaceuticals** has terminated its deal for supply and distribution of Biotin's insulin products on the Chinese market. The deal was terminated due to changes on the Chinese pharmaceutical market. Harbin Gloria said that it was unable to meet the sales forecasts that were part of the terms of the deal, a situation that was reflected in the company's financial statements in 2018 and will likely be reflected in its 2019 results.
- Pharma manufacturer **Amgen**, scored a victory regarding its patent for the drug *Enbrel.* The U.S. District Court for the District of New Jersey ruled for Amgen in a patent fight against **Novartis' Sandoz** unit and its *Enbrel* biosimilar, *Erelzi*. Sandoz said that it will appeal the decision. *Enbrel* accounted for US$4.8 billion in sales for Amgen.
- In another change across its executive team, **GlaxoSmithKline** announced that its U.S. pharmaceutical president, *Jack Bailey* will step down at the end of the year. He will be succeeded by *Maya Martinez-Davis*, who currently serves as the president of Merck KGaA's Latin American pharmaceutical business. A number of leaders within GSK have left the company since the departure of CEO *Andrew Witty*, who was succeeded by *Emma Walmsley*.

(Sources: BioPharma Dive, FiercePharma, Reuters, and World Pharma News)

Pharmaceutical Showdowns to Watch

(Source: An article by Josh Nathan Kazis for Barron's)

The drug business can feel like a touch and go race, with big pharmaceutical giants and biotech startups knocking against each other as they scramble to be the first to market with the next big blockbuster. Several drug development races are on this summer. Companies are striving to be the first to market with next-generation therapies for diseases as common as rheumatoid arthritis, or as rare as spinal muscular atrophy.

Here are the big drug development showdowns to watch in the second half of 2019.

With AbbVie's mega-blockbuster *Humira* losing its patent protection in the U.S. in 2023, the company is looking for its next big anti-inflammatory drug. One with big potential is *upadacitinib.* The company has submitted *upadacitinib* for approval to the U.S. Food and Drug Administration as a treatment for rheumatoid arthritis. But there are hurdles since it won't be the only player

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China (cont.)...

biotech, with Chinese VCs being very active in global funding. In fact, in 2018, roughly 40% of biotech funding in the US came from Chinese sources. We also see Chinese pharma companies and investors—including Luye Pharma and Fosun—making larger and larger strategic investments outside of China, however it is still an early trend. On the talent side, several senior executives of leading pharma companies are China-based. For example, the current EVP of International for AstraZeneca and the head of the APMA region for Novartis are both of Chinese origin and based in Shanghai.

When taking these four value creation areas, what does it all mean? Here are a few implications, and predictions:

Up and up: China's importance in many pharma companies' global agendas will continue to rise, with an increasing number of companies managing China as a region, rather than as a country within Asia-Pacific. As a result, many companies may decide to have China report more directly to the CEO or to a direct report to the CEO.

Beware of the spotlight: The top-line contribution of China to revenues and growth will become a hot topic, given the visibility of these metrics to global investors. We are reaching the point at which performance in China can "move a stock." The challenge, however, is predicting China's future growth with accuracy. Companies will need to manage expectations.

Expect peer pressure: As more and more companies communicate to investors about their China performance and strategy, more discreet companies could be asked by financial analysts to clarify their strategic stance towards the market.

Be wary of tensions emerging with proponents of the status quo: As China takes its rightful position at the global boardroom table, internal tensions with traditional developed markets could increase. Committing to China requires more allocation of resources—particularly capital and talent—and will inevitably lead to difficult budgetary discussions as companies aim to maximize ROI on a global basis.

Mind the gap in supply chain: Demand in China is on a scale not seen elsewhere in the world. In the last few years, we have witnessed some supply chain disruption due to the sudden uptake of demand post-reimbursement, for example. Going forward, allocation of supply to China could become a complex strategic decision that considers the significant upside in volume and, in some cases, will need to be weighed against the lower price point of drugs required to secure national reimbursement in China

Count on the talent market to heat up: The rapid growth of the market is creating an exceptional environment for talented executives at both multinational pharma and local Chinese biotech companies to pursue a range of attractive career opportunities. To stay competitive in this new market for talent, companies will need to fundamentally rethink their value proposition to the talent they hope to hire—and retain in China. Just adapting a global recipe for talent management may not be enough to sustain differentiation.

Plan for "fast and slow" integration with global R&D: Integration with global R&D remains a work-in-progress. The strategic intent is relatively clear. But the ability to execute the strategy remains a challenge in the context of what is still a developing innovation ecosystem.

Expect the unexpected: China will not fail to surprise us. and some bumps in the road should be expected. Ultimately, China remains a "high risk, high reward" market.

Drug Showdown (cont.)...

in the game.

Gilead Sciences (GILD) has its own anti-inflammatory called *filgotinib* that it hopes to have on the market as a rheumatoid arthritis treatment soon after AbbVie's entry. In July, the company said it was planning to file an application for the drug with the FDA this year. It is expected to be available by the start of 2020, setting up a commercial showdown between AbbVie and Gilead that will play out over the next few years. AbbVie has an advantage, given its current dominance of the anti-inflammatory market, but Gilead is a strong player and could threaten AbbVie's market share.

Another area of competition involves Duchenne muscular dystrophy, an inherited genetic disorder that leads to muscle degeneration, and significantly shortens life expectancy. Companies are developing gene therapies that could dramatically improve the conditions of people suffering from the disease.

Three players are in the race for the first DMD gene therapy: Pfizer (PFE), an 800-pound gorilla of drug development, and two smaller companies, Sarepta Therapeutics (SRPT) and Solid Biosciences (SLDB).

Sarepta already has one available treatment for DMD called *Exondys 51*, which the FDA approved in 2016, though questions linger about the drug's effectiveness. A functional gene therapy would be a major development for people suffering from the disease.

In July, Pfizer released initial data from a Phase 1b study of its gene therapy for DMD. It showed that two of the six participants in the study had been hospitalized following their treatments. Pfizer said it had stopped giving patients the drug until it had implemented new safety monitoring. Sarepta is now considered the leader in the DMD gene therapy contest, on the strength of data the company released last year. This month, Sarepta announced a new timeline for trials of its gene therapy which faces delays when the company submits its application to the FDA, narrowing its lead over Pfizer.

Spinal Muscular Atrophy, another rare genetic neuromuscular disorder, is also shaping up to be a major competition among drug developers. Some new SMA drugs are already on the market, and the competition is starting to heat up.

Back in 2016, Biogen (BIIB) received regulatory approval for *Spinraza*, the first SMA treatment available in the U.S. This year, Novartis (NVS) received approval for *Zolgensma*, a US$2.1 million gene therapy. Also, Roche is currently testing a drug called *Risdiplam* and is expected to submit the drug for FDA approval late this year.

All three companies face significant challenges from the FDA, so it remains to be seen who will dominate that market.

Today, people suffering from Hemophilia A can receive regular injections of Roche's *Hemlibra* to manage their symptoms. A gene therapy could cure the disease with a single treatment. Three experimental drugs have been leading this race: BioMarin Pharmaceutical's (BMRN) *Valrox*, Sangamo Therapeutics' *(SGMO) SB-525*, and Spark Therapeutics' *(ONCE) SPK-8011*.

Sangano's entry, on which it is collaborating with Pfizer Inc., has been shown to have promising early stage results. New data is expected from Spark on its latest drug, but BioMarin may be even further along in the development race. The company said in July that it would file for regulatory approval of its drug in the U.S. and the European Union sometime in the fourth quarter of this year.

If the regulators bite, this contest could have a clear and decisive winner by the middle of next year.