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Q3 Headwinds For Pharma Could Dampen A Continued Rally

by Jessica Merrill

COVID-19 disruptions, less favorable currency and the shadow of drug price reform could mean more headwinds for pharma during this S&E period after a strong Q2.

Pharma would like the financial rally experienced in the second quarter to persist through the end of the year but macro pressures, including the continued impacts of the COVID-19 pandemic, currency fluctuations and the looming threat of US drug price reform could dampen the momentum when the sector reports third quarter financials over the next few weeks.

Johnson & Johnson and *Roche Holding AG* will begin third quarter reporting with sales and earnings results on 19 October and 20 October, respectively, and could foreshadow what might be in store for the sector more broadly.

The second quarter marked something of a turnaround for the industry after navigating a disrupted health care market for 18 months because of the global pandemic. Big pharma turned in strong Q2 financial results, fueled by normalizing doctor visit and prescription trends. They also benefited from easy comparisons against the year-ago period, when uncertainty around the global pandemic was at a peak, as well as a favorable currency impacts for pharmaceutical manufacturers on international revenue versus the US dollar.

Second quarter revenues increased by double-digits on a reported basis versus the year-ago period across most of the sector among big biopharma players.*GlaxoSmithKline plc*, *Amgen, Inc.*, *Sanofi* and Roche Holding AG were among the outliers but still generated single-digit top-line growth.

Among the leading growth companies, *AbbVie Inc.*'s second quarter revenues increased 33.9%, Johnson & Johnson increased 27%, *AstraZeneca PLC*'s increased 25% and *Eli Lilly and Company*;s increased 23%. *Pfizer Inc.*, with its mega-sized commercial COVID-19 vaccine success, and

Regeneron Pharmaceuticals, Inc. with its COVID-19 therapeutic antibody, experienced exceptional growth of 86% and 163%, respectively, although those results are not the kind likely to be repeated.

Now, the question is if that strong growth trajectory continued in the third quarter and will persist through the full second half of this year. Some analysts expect it is unlikely given some of the headwinds, such as the persistent impact of COVID-19 in many regions of the world, including parts of the US, driven by the Delta variant. Less favorable currency trends also could blunt Q3 growth.

Delta Delivers Prolonged Impact

Cancer, vaccines, lung disease, HIV and multiple sclerosis have been among the disease areas most heavily impacted by the pandemic and challenges continue when it comes to diagnosing new patients and switching patients already on medication to new therapies. Oncology, for example, has continued to face pressure as many patients skipped regular screening visits during the pandemic, within a therapy area that can take a long time to diagnose patients. (Also see "*Stock Watch: Oncology After The Pandemic*" - Scrip, 23 Aug, 2021.)

As another example of the challenging commercial dynamics, in an interview with *Scrip*, *Novartis AG* pharmaceuticals president Marie-France Tschudin highlighted multiple sclerosis as an area that has experienced a substantial decline in the dynamic market of patients new to treatment or switching therapies. The dynamic market remains at about 75%-80% of what it was before the pandemic, she said. (Also see "*Novartis's Tschudin On Launches, Drug Pricing And Lasting COVID Impacts*" - Scrip, 22 Sep, 2021.)

"Our pre-earnings analysis points to weak volume trends and potential earnings and revenue misses across our large-cap coverage universe," SVB Leerink analyst Geoffrey Porges said in a 12 October research note. "Many of the companies in our coverage have broad exposure to therapeutic areas most impacted by COVID, including vaccines, HIV/HCV and oncology, which will be a headwind for Q3 results.

A broad rally among large-cap pharma players is unlikely, he added, and the trend could continue into the fourth quarter given the overhang of US drug pricing reform, which is expected to loom as a headwind for the sector through the end of the year.

Currency is another factor that could weigh on third quarter financials, particularly for companies with a large commercial presence outside the US, as the benefit versus the US dollar will be less favorable.

"The point is rather straightforward, but its impact on earnings shouldn't be overlooked," Bernstein analyst Ronny Gal said in a 5 October note. The one country where currency is still a

tailwind is China, so sales figures in that region may be strong, Gal added.

"The current trends could impact companies with larger OUS exposure – Merck (Keytruda, animal health), Pfizer (Eliquis, Ibrance, hospital products) and Bristol (Eliquis, Revlimid, Opdivo," he said. "Companies with less OUS exposure (Gilead, Regeneron, Jazz), should be relatively less exposed here."

On the issue of US drug price reform, the options for legislative changes that could put substantially more pressure on the industry are still being debated. The industry is pushing back hard on one proposal in particular that would allow the US government to negotiate drug prices directly with manufacturers and put a 95% tax on those that don't comply. (Also see "*Pharma On Its Back Foot As US Drug Price Reform Advances*" - Scrip, 8 Sep, 2021.)

The latest outlook for US drug price reform and the potential impact on individual drug makers will certainly be a theme across the third quarter conference calls. US corporate tax reform is yet another possibility that could impact industry's long term financial outlook as Congress weighs raising the corporate tax rate to help pay for President Joe Biden's sweeping social expenditures in the Build Back Better Act. (Also see "*Under The Shadow Of Drug Price Reform, US Tax Policies Still Challenge Pharma*" - Scrip, 12 Oct, 2021.)

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While the sector faces macro pressures, financial performance comes down to individual company portfolios and dynamics. Drug makers like Pfizer, *Gilead Sciences, Inc.*, Regeneron and *Moderna, Inc.* are expected to continue benefiting from the pandemic through the sale of vaccines and medicines against COVID-19. Will Pfizer/*BioNTech SE* and Moderna revise their unprecedented revenue expectations for their COVID-19 vaccines upwards yet again?

Merck may have more to say as well about the financial outlook for its antiviral pill molnupiravir now that it appears poised to reach the market. The company released positive Phase III data showing the pill cut the risk of hospitalization or death by half in a Phase III trial in people with mild to moderate COVID-19, presenting a potential new tool to treat the virus and a new commercial opportunity for Merck. (Also see "*Merck's Molnupiravir Set To Lead Forecast $6bn COVID-19 Oral Antiviral Market*" - Scrip, 6 Oct, 2021.)

Across the sector, there will be plenty of other individual corporate updates to keep tabs on. Top of mind is J&J's plans for a smooth leadership transition now that CEO Alex Gorsky and chief scientific officer Paul Stoffels have both announced plans to step down from the company at the end of the year. J&J veteran and vice chairman Joaquin Duato has been appointed to succeed Gorsky but no successor was appointed to take over the top R&D role at J&J. (Also see "*J&J's Longtime R&D Head Stoffels To Retire, Raising The Leadership Transition Stakes*" - Scrip, 12 Oct, 2021.)

New drug launches are always interesting to monitor and this quarter *Biogen, Inc.* investors – and the general public – will be paying close attention to the company's launch of Aduhelm (aducanumab) for Alzheimer's disease, arguably the most controversial drug launch in recent memory. Management has already warned that the launch has gotten off to an even slower than expected start for what already was projected to be a challenging commercial entry. (Also see "*Biogen Says Physician Debate About Aduhelm More 'Pervasive' Than Anticipated*" - Scrip, 9 Sep, 2021.) A third quarter update could reveal more clues about how much Biogen will need to invest to get a successful launch off the ground and how long that might take.

Also in Alzheimer's disease, Roche has so far held off on confirming whether or not it will file its beta-amyloid antibody gantenerumab for accelerated regulatory review with the US Food and Drug Administration. The company said it is discussing its options with the FDA and weighing whether or not to file for an accelerated approval based on surrogate endpoints or wait for the full Phase III data to read out, anticipated in 2022. (Also see "*Roche Deals With Huge Gantenerumab Curiosity At H1 Update*" - Scrip, 23 Jul, 2021.) However, Roche's Genentech subsidiary announced on 8 October that the FDA granted a breakthrough therapy designation for gantenerumab, which could speed up the agency's review of an application whether it is submitted for accelerated or standard review.