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Pharma Is Poised For A COVID-19 Recovery; Will Q2 Deliver?

by Jessica Merrill

The second quarter could mark a financial turning point for big pharma as demand rebounds from the pandemic, but variability remains across portfolios and therapeutic areas.

Second quarter financial results are expected to mark a financial inflection point for big pharmaceutical manufacturers after nearly 18 months of navigating the uncertain commercial market for drugs amidst the COVID-19 pandemic. Revenues across the sector are expected to rebound in the quarter following a challenging first quarter, when drug makers posted mixed financial results and offered investors cautiously optimistic forecasts for the second half of the year.

As the industry hits the midpoint of 2021 and makes progress in its slow pandemic recovery, strong second quarter financial results could give some drug makers confidence to increase their financial outlook for the year. Comparisons against the second quarter of 2020 – when the pandemic was at its peak in many regions of the world, including the US and Europe – should also be markedly easier for drug makers to beat.

There is still uncertainty, however, and it remains to be seen if the rebound will deliver as investors are hoping.

SVB Leerink analyst Geoffrey Porges predicted a positive second quarter growth story for pharma, driven by a strong recovery in demand, positive currency impact for US-based companies on ex-US sales and a tailwind from year-over-year comparisons versus the second quarter of 2020, the trough of the pandemic in terms of stay at home orders and lockdowns.

"We are increasing our revenue and [earnings per share (EPS)] estimates across the board," he said in a 9 July research note.



"Management teams that were very cautious in their initial guidance for the year are likely to increase their guidance for the year, based on a more positive outlook in the US and selected international markets," he said.

The first companies to report are <u>Johnson & Johnson</u> and <u>Novartis AG</u> on 21 July, which could reveal clues for the sector. J&J has already forecast solid revenue growth of 9.7%-10.9% in 2021 after a relatively strong first quarter performance when top-line revenue increased 7.9% driven by pharmaceuticals and a rebound in the medical device segment. Novartis had a harder first quarter and has forecast low to mid-single digit growth after posting a 2% net sales decline in the first quarter, which it attributed to tough comparisons to first quarter 2020, when purchasing was higher ahead of the pandemic. (Also see "<u>Novartis Big Earners Beat Q1 Forecasts</u>" - Scrip, 27 Apr, 2021.)

Variability A Factor

J&J and Novartis will offer some foreshadowing for the sector but there remains significant variability in the recovery, depending on each company's product portfolio and how disease diagnosis rates and prescription trends are normalizing across therapeutic areas after more than a year of patients putting regular doctor visits and health care screenings on hold.

Areas like immunology and diabetes, for example, appear to be normalizing faster than oncology, since cancer can take longer to diagnose and begin treatment.

"Looking at script trends across markets, we noted a wide disparity in the degree of recovery back to pre-COVID trends," Bernstein analyst Ronny Gal said in a 30 June research note. "Oral oncology scripts like CDKs or BTKs, for example, are still well below pre-COVID levels." The speculation is that while patients already taking oral cancer treatments when the pandemic hit didn't discontinue their medications, missed well visits and cancer screenings have impacted new diagnoses and patient starts.

"Thus, the impact on oncology-like markets was moderate early on in the pandemic but deepened over time and the recovery for these markets is likely to be slower," Gal speculated. In markets that are not driven by well visits – therapeutic areas like diabetes, for example – he said volumes are recovering faster.

Data from IQVIA released earlier this year suggested that 111 million, or 3.8%, of total US prescriptions would be lost through the first half of 2021 due to missed diagnosis visits. IQVIA forecast that diagnosis visits would be down 8.8% in the US in the first half of 2021 versus a pre-COVID baseline. Oncology, gastroenterology and dermatology were among the most heavily impacted therapeutic categories, according to IQVIA. (Also see "*Pandemic Perspectives: COVID-19 Upended Drug Launches In Ways That Will Stick*" - Scrip, 24 Mar, 2021.)



Questions For Vaccines

Another area that has been heavily impacted in 2020 and the first half of 2021 is vaccines for adults and adolescents, like <u>Merck & Co., Inc.</u>.'s cervical cancer vaccine Gardasil and <u>GlaxoSmithKline plc</u>'s shingles vaccine Shingrix. Such vaccines have faced challenging commercial dynamics given the mass COVID-19 vaccination effort and hesitancy to administer other vaccines in close proximity to SARS-CoV-2 vaccines on top of reduced doctor visits.

Teens and adults potentially missed over 26 million doses of recommended vaccines in 2020, including 8.8 million missed adolescent vaccine doses and 17.2 million missed adult vaccine doses, according to a study commissioned by GSK and released in July.

The recovery of these businesses is critical to several players, but perhaps most notably GSK, which has a lot riding on Shingrix, a key near-term growth driver. The shingles vaccine generated £1.99bn in 2020 sales despite the impact of the pandemic, but revenues took a dive in the first quarter, down 47% year-over-year to £327m in large part due to recommendations by health authorities in the US and other key markets to hold off on taking non-COVID-19 vaccines close to a SARS-CoV-2 vaccination. (Also see "GSK Sees Light At End Of Shingrix Tunnel As COVID-19 Eases" - Scrip, 28 Apr, 2021.)

The company has guided investors to expect that headwind to resolve as the year progresses. During a recent investor day, GSK positioned Shingrix as a cornerstone of its vaccines growth strategy and guided for sales of the vaccine to double in five years. (Also see "GSK Has Big Ambitions In Vaccines, With An Eye On Blockbuster Opportunities" - Scrip, 23 Jun, 2021.)

GSK experienced a challenging first quarter with revenues down 18% to £7.42bn and operating profit down 16% to £1.69bn. Investors are getting anxious to see a recovery begin to take shape. GSK has forecast a challenging year in 2021, including expected adjusted EPS to decline by midto high-single digit percentage at constant exchange rates, but management has vowed that sales and adjusted operating profit will increase at a compound annual growth rate of more than 5% and 10%, respectively, off the 2021 base.

Uncertain Upside

While COVID-19 has been challenging for pharmaceutical manufacturers, it has also brought a windfall for those that were able to deliver solutions to treat the virus and hopefully end the pandemic. *Pfizer Inc./BioNTech SE* and *Moderna, Inc.* – developers of the two mRNA vaccines that are being widely used – are the clear winners in that regard. But others, including vaccine developers J&J and *AstraZeneca PLC*, monoclonal antibody treatment developers *Regeneron Pharmaceuticals, Inc.* and *Eli Lilly and Company.*, and *Gilead Sciences, Inc.*, the developer of the antiviral Veklury (remdesivir), could benefit from upside from those products in the second quarter.



How much vaccines and therapeutics for COVID-19 will pad the top line is uncertain, however. (Also see "*The Extraordinary But Uncertain Growth Of The COVID-19 Market*" - Scrip, 26 May, 2021.) More clarity on the long-term outlook for these products may also be forthcoming in the upcoming second quarter calls.

Pfizer forecast it will generate a stunning \$26bn from sales of the COVID-19 vaccine BNT162b2 this year, a figure that was largely viewed as an underestimate given that it only accounted for the 1.6 billion doses of the vaccine Pfizer had already contracted through mid-April. (Also see "Credit Where It Is Due: Pfizer's COVID-19 Vaccine Smashes Launch Records As Expected" - Scrip, 4 May, 2021.) Pfizer reported \$3.5bn in revenue from the vaccine in the first quarter and analysts are forecasting notably higher revenue from the vaccine in the second quarter.

The unprecedented launch led Pfizer to raise its consolidated revenue forecast for the year from \$59.4bn-\$61.4bn to \$70.5bn-\$72.5bn and it remains to be seen if that forecast might be raised even higher.

"The BNT162 number will blow away consensus (again)," Bernstein's Gal predicted. Bernstein forecasts \$7.3bn in COVID-19 vaccine revenue in the second quarter, versus consensus estimates of around \$6bn.

Regeneron's second quarter revenues are expected to see a big bump coming from the antibody cocktail REGEN-COV2 (casirivimab/imdevimab). The company recorded \$262m in revenue from the product in the first quarter, driving a 38% increase in total revenues. (Also see "<u>S&E Briefs: The Good and The Bad Of COVID-19 On Biotech's Top Line</u>" - Scrip, 6 May, 2021.)

But analysts expect revenue to be significantly steeper in the second quarter as Regeneron has ramped up its supply and delivered on its US supply contracts targeted for 30 June. Analyst consensus estimates model \$1.64bn in revenue from the product, but SVB Leerink forecasts significantly more, \$2.98bn, and Bernstein forecasts \$2.35bn.

Regeneron's cocktail, along with GSK/<u>Vir Biotechnology</u>, <u>Inc.</u>'s sotrovimab, are now the dominant antibody treatments after distribution of Lilly's antibody combination, bamlanivimab and etesevimab, was paused in June over concerns about reduced efficacy against new variants.