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Lilly Saw Pandemic-Related Benefits In Q1, Expects Headwinds Long Term

by Joseph Haas

The pharma saw a \$250m revenue increase due to inventory stockpiling and early prescription renewals, but its therapies outside cancer and diabetes may suffer in the coming quarters due to COVID-19.

<u>Eli Lilly & Co.</u> chairman and CEO David Ricks kicked off the pharma's first quarter earnings call on 23 April with a lengthy discussion of the disruption the novel coronavirus pandemic has caused within and outside the world of biopharmaceuticals. The Indianapolis-based firm saw some revenue benefit from the pandemic during Q1, he said, but noted COVID-19 will take more of a toll on the company's business during the rest of the year.

Lilly brought in an estimated \$250m more in revenue during the first quarter due from purchases motivated by fear of supply chain disruptions, including wholesaler stockpiling of drugs and patient-level actions such as early renewals of prescriptions. The company attributed \$200m of this revenue to the US and \$50m to the rest of the world.

Chief financial officer Josh Smiley said uptake of insulin products in the US increased by \$70m-\$80m during the quarter due to pandemic-motivated decisions. Trulicity (dulaglutide) revenue increased \$30m-\$40m and Taltz (ixekizumab) was up \$20m-\$25m, he added. Both products have been recent growth drivers for Lilly. (Also see "*Lilly Calls It Quits On Pegilodecakin As Loxo Team Reorganizes Cancer R&D*" - Scrip, 30 Jan, 2020.)

"Despite that near-term benefit, the COVID-19 pandemic is likely to have negative impact on our business in the future," Ricks warned. "We expect headwinds later in 2020 and potentially beyond, such as destocking as supply chains normalize from the recent demand surge, decreases in new prescriptions as a result of fewer patients visiting physician's offices, potential changes in segment mix in the US due to rising unemployment, and pricing pressures resulting from the [increased dependence on] government health care systems around the world."

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Wolfe Research analyst Tim Anderson predicted in a 20 April note that Lilly would see little to no negative first quarter impact from the pandemic and possibly even a small upside – but warned that second quarter sales of non-critical or physician-administered products are vulnerable. "Revenue weakness in Q2 presumably recovers in 2H-2020, but will it be net-neutral on a full-year basis? This is not knowable at the moment," he said.

Like most of its publicly traded big pharma peers, Lilly's stock was up during the first quarter, nearly 5%, but analysts predicted its newer products like Emgality (galcanezumab), Verzenio (abemaciclib) and Taltz could be hurt by pandemic-related factors, including a greater reliance on virtual rather than in-person interactions with doctors. (Also see "*A Rocky First Quarter For Big Pharma Stocks*" - Scrip, 16 Apr, 2020.)

Smiley said Lilly saw little impact from reduced new therapy starts during the past quarter, but that is expected to be an increasing concern during the year. "In the US, we are starting to see an impact as IQVIA reported new-to-brand prescriptions across the industry declined by 42% for the week ending April 10 versus pre-COVID-19 averages," he told the call.

"For our portfolio, we anticipate this impact to be more pronounced for our immunology and pain products and less so for oncology and diabetes," the CFO added. "However, we expect this impact to be temporary and patients will return to seeing their doctors as social-distancing restrictions are lifted."

Lilly will also monitor expected increases in US unemployment due to the pandemic and how that could shift patients from commercial insurance to government-provided coverage or out of health coverage entirely, Smiley said. "While it could create headwinds in the near term, this effect should lessen when the global economy eventually strengthens," he said.

Supply Chain Unaffected, Clinical Trials Impacted Somewhat

Ricks noted that more than 40 million patients worldwide depend on Lilly drugs and said the company has taken steps to assure the continued availability of those products. "The majority of our supply chain is multi-sourced, and from the materials we supply from one source, we keep sufficient inventory on hand to avoid disruptions," he said.

"Even with increased demand and customer stocking, we have sufficient inventory and production capacity for all our products," Ricks continued. "This includes all forms of insulin, and we don't currently anticipate any issues meeting

Lilly Efforts On Treating COVID-19 Patients

patient needs through the remainder of the pandemic. Our manufacturing sites in the US, Europe and China have remained operational through this crisis."

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Lilly is among the numerous biopharma companies that previously reported that some ongoing and planned clinical trials are impacted by the pandemic. (Also see "*Lilly, Galapagos Put Some Trials On Hold Due To Coronavirus Concerns*" - Scrip, 23 Mar, 2020.) Ricks clarified during the earnings call that Lilly does not anticipate significant timeline changes for ongoing late-stage studies – such as for type 2 diabetes candidate tirzepatide – but did predict delays in producing data for IL-23 blocker mirikizumab in gastrointestinal indications.

Ricks said Lilly is prioritizing resources for its efforts to develop COVID-19 therapies *(see box)*. (Also see "*Deal Watch: Lilly, AbCellera Partner To Attempt Rapid COVID-19 Antibody Development*" - Scrip, 13 Mar, 2020.)

Solid Growth Quarter Driven By Increasing Volume

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In an alliance with the US National Institute for Allergy and Infectious Diseases, Lilly's JAK1/2 inhibitor for rheumatoid arthritis Olumiant (baracitinib) is being investigated for anti-inflammatory benefit in COVID-19 patients, with data expected in June

A Phase II trial of LY3127804, an antibody against angiopoietin 2, which is known to be elevated in patients with acute respiratory distress syndrome, is enrolling patients with COVID-19-associated pneumonia. Data are expected in June

Lilly is collaborating with AbCellera to assess therapeutic potential of antibodies in patients who recovered from the virus, with a goal of filing an investigational new drug (IND) application in May

Despite the company's warnings about the pandemic's impacts on future quarterly results, Lilly's stock price reached an all-time high on 23 April, closing up 2.1% at \$159.93 per share and rising to \$161 in after-hours trading based on the pharma's strong first quarter performance.

Lilly reported 15% year-over-year growth worldwide for its pharmaceutical sales; volume rose 22% but was squeezed 6% by pricing pressures and another 1% by foreign exchange. The products it calls its key growth drivers – including Trulicity, Taltz, Verzenio, Jardiance (empagliflozin), Emgality and Olumiant – yielded 19% aggregate growth year-over-year and accounted for 51% of the company's quarterly sales revenue.

US sales grew by 15% during the quarter, with volume up 19% driven mainly by Trulicity, Humalog (insulin lispro injection), Taltz, Alimta (pemetrexed), Verzenio, Emgality and Basaglar (insulin glargine injection), Smiley said, but noted there was a negative pricing impact of 4 points. In Europe, sales increased 18% on the strength of 24% volume growth, dragged down 3% by pricing adjustments. In China, volume growth soared 93%, but local restrictions on pricing offset that by 64% for total growth of 27%, the firm reported.

Morningstar analyst Damien Conover attributed the pandemic-related benefits to increasing Lilly revenue by about 4% but called the pharma "well positioned for growth with limited nearterm patent losses and solid late-stage pipeline," in a 23 April note.

Diabetes and cancer drugs, which comprise roughly 70% of Lilly's sales, should hold up well throughout the pandemic, he added, due to the severity of disease those patients face. Meanwhile, he predicted that Trulicity will maintain US market share despite new competition from *Novo Nordisk AS*'s oral GLP-1 agonist Rybelsus (semaglutide). (Also see "*Novo Nordisk's Oral Rybelsus Priced On Par With Injectable GLP-1s, But Big Discounts May Be Needed*" - Scrip, 23 Sep, 2019.) However, Taltz is more in danger of quick sales deceleration, the analyst said, thanks in part to competition from *AbbVie Inc.*'s Skyrizi (risankizumab).