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Credit Where It Is Due: Pfizer's COVID-19 Vaccine Smashes Launch Records As Expected

by *Jessica Merrill*

Pfizer said it expects to generate \$26bn in annual revenues from the COVID-19 vaccine BNT162b2 and is leveraging the platform to build out a durable business.

Pfizer Inc. launched the first COVID-19 vaccine BNT162b2, with partner *BioNTech SE*, and has succeeded in supplying the largest portion of the global market – and it is also reaping the financial rewards. Reporting first quarter sales and earnings 4 May that outperformed expectations overall, Pfizer raised its revenue forecast for BNT162b2 to \$26bn in 2021 from a prior estimate of \$15bn.

The raised forecast is likely still an underestimate, given the forecast accounts only for the 1.6 billion doses Pfizer has contracted through mid-April. The company said it believes it can manufacture 2.5 billion doses in 2021 and 3 billion doses in 2022. Bernstein research analyst Ronny Gal, for example, increased forecasts for the vaccine to \$33bn; Barclays analysts said the revenue could be as high as \$40bn if the pricing and economics hold for the outstanding supply.

"We also are in ongoing discussions with multiple countries around the world about their needs and we expect these discussions to lead to additional supply agreements," CEO Albert Bourla said on a same-day earnings call. "Based on what we have seen, we believe that the durable demand from our COVID-19 vaccine, similar to that of the flu vaccine, is a likely outcome."

The company is already in discussions with countries for vaccine contracts in 2022 as well, suggesting a prolonged business opportunity. Pfizer and BioNTech have shipped approximately 430 million doses of the vaccine to 91 countries, Bourla reported. But most of those doses have gone to the US and other wealthy nations. Pfizer books the majority of global sales of the vaccine, excluding Germany and Turkey, and shares profits equally with BioNTech.

At \$26bn, COVID-19 vaccine revenues would account for more than 36% of Pfizer's total forecasted sales in 2021. Pfizer raised its consolidated revenue forecast to the year from prior forecasts of \$59.4bn-\$61.4bn to \$70.5bn-\$72.5bn. In the first quarter, Pfizer reported revenues from the vaccine of \$3.5bn, far outpacing any of its blockbuster brands like Ibrance (palbociclib), Eliquis (apixaban) or Prevnar 13 (pneumococcal 13-valent conjugate vaccine).

A Launch Like No Other

The vaccine was expected to be a big financial windfall for Pfizer and BioNTech after BNT162b2 was authorized for use by the US Food and Drug Administration and European Medicines Agency late last year. (Also see "[Pfizer Rose To The COVID-19 Challenge And The Stars Aligned](#)" - Scrip, 11 Dec, 2020.)

But skeptics weren't sure how Pfizer would execute on the complicated launch of the first mRNA-based vaccine, a product that requires storage at ultra-cold temperatures and administration in two doses within a short time period, all as part of the first mass vaccination effort in decades. [Johnson & Johnson](#) and [AstraZeneca PLC](#)'s vaccines, based on an older adenovirus technology, were expected to eventually take up a more significant share of the market than they have yet. Perceived safety concerns slowed down those vaccines' launches, even though the blood clots at issue appear to be extremely rare.

Pfizer's revised vaccine forecast outpaces the forecast set by [Moderna, Inc.](#) for its vaccine in February. Moderna also successfully brought an mRNA-based vaccine to market and plans to update investors on its first quarter financial results on 6 May; the company may also raise its financial outlook. In February, Moderna forecast revenues of \$18.4bn in 2021 from the sale of its vaccine, despite the fact that the company had never launched a commercial product before. (Also see "[COVID-19 Vaccine Gives Moderna \\$18bn Launchpad Into HIV Vaccine, Cancer Therapies](#)" - Scrip, 26 Feb, 2021.)

Moderna said in April that it successfully delivered 132 million doses of its vaccine globally, the vast majority to the US, and was on track to deliver another 100 million doses to the US by the end of May and another 100 million doses by the end of July. The company has said it aims to manufacture 1 billion doses in 2021.

Both Pfizer's and Moderna's current forecasts walloped any other drug launch in history. (Also see "[10 Triumphant Drug Launches Of The Decade](#)" - Scrip, 6 Jan, 2020.) The only similar comparison is [Gilead Sciences, Inc.](#)'s launches of Sovaldi (sofosbuvir) and Harvoni (sofosbuvir/ledipasvir) in 2013 and 2014, respectively, for hepatitis C – a similar model in that there was a substantial bolus of patients waiting treatment and as patients were treated and essentially cured, the market collapsed. Sovaldi and Harvoni generated \$12.41bn in 2014 after the first launch of Sovaldi in 2013. Harvoni generated just over \$1bn in 2018, however, as the market peaked and sunset early.

What's not clear is how long the COVID-19 tail could run. Pfizer is bullish the business will be a durable one given the global market dynamics, the rise of new variants and what will likely be a need to administer booster shots on a regular basis for some time.

"It is our hope that the Pfizer/BioNTech vaccine will continue to have a global impact by helping to get the devastating pandemic under control and helping economies around the world not only open – but stay open – creating a scenario in which Pfizer can continue to be both a leader and a beneficiary," Bourla said.

Vaccine Expansion

Pfizer is preparing to submit a biologics license application (BLA) to the FDA later in May seeking a full approval for the vaccine for individuals 16 and older. It is currently administered under an emergency use authorization.

The vaccine is also on track to be the first administered to children under the age of 16. The company has filed to expand the current EUA to children 12-15 in the US and FDA authorization is expected to come shortly; Phase III data showed 100% efficacy and good tolerability in adolescents. (Also see "[Adolescent Results Put Pfizer/BioNTech Ahead Of COVID Vaccine Pack, For Now](#)" - Scrip, 31 Mar, 2021.) A trial in children ages six months to 11 years is ongoing with data from two cohorts – children two to five years of age and five to 11 years of age – expected in September.

Pfizer is also studying the safety and immunogenicity of a third dose of the existing vaccine as a booster shot against SARS-CoV-2 variants, as well as an updated variant version encoding the spike protein of the B.1.351 SARS-CoV-2 variant, which includes the E484K mutation, identified in South Africa.

"This study is designed to establish a regulatory pathway to update the current vaccine to address any future variant of potential concern in approximately 100 days if needed," Bourla said. Immunogenicity data from both studies are expected in July, he added.

The company is also continuing to evaluate the vaccine in additional populations, including pregnant women and is exploring coadministration of the vaccine in combination with its investigational 20-valent pneumococcal conjugate vaccine for adults.

What is clear is that COVID-19 and the vaccine are poised to change Pfizer over the long-term – no matter the durability of the COVID-19 business specifically. The company will have unexpected resources to invest in R&D, manufacturing and business development – and is looking to build out a broader portfolio of vaccines and therapeutics based on the mRNA platform.

Pfizer is rapidly progressing a potential flu vaccine, expected to enter the clinic in the third quarter, and is exploring other infectious disease areas. The company increased its 2021 R&D guidance to \$9.8bn-\$10.3bn from \$9.2bn-\$9.7bn, which Bourla said reflects the company's expanded investment in mRNA.

Bourla also admitted that the intensity of the initiative to combat COVID-19 has taken a toll on some employees in certain parts of the company. "There is a very intense, let's say, disruption that happened in part of the organization, not the entire organization," he said. But, he said, "that has been offset by an incredible sense of pride that those people are taking because of what has been achieved."

Outside of the COVID-19 effort, Pfizer reported a solid quarter in the base business despite what has been a challenging quarter for some of the company's peers. Excluding the impact of the COVID-19 vaccine, Pfizer said revenues grew 8% operationally, including a 5% negative impact from price.

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