SCRIP
CITELINE COMMERCIAL

04 Aug 2022 | **Analysis**

The COVID-19 Market: Keeping Up With The Changing Landscape

by Alaric DeArment

Some products are still going strong, while others that once generated blockbuster revenues have faded away, as companies develop next-generation antivirals and vaccines.

The variety of sales figures and pipeline updates for antiviral drugs and vaccines for SARS-CoV-2 coming out in various drug makers' second-quarter earnings illustrate just how much the COVID-19 treatment landscape has changed over the past year, with some drugs once viewed as promising now pulled from shelves while next-generation products that could treat newer strains inch toward the market.

To be sure, some of the products that have been around for a while are still going strong. *Pfizer Inc.*/*BioNTech SE*'s vaccine Comirnaty raked in sales of more than $8bn during the quarter, while sales of *Moderna, Inc.*'s Spikevax came in at more than half of that. Sales of the two marketed oral drugs, Pfizer's Paxlovid (nirmatrelvir and ritonavir) and *Merck & Co., Inc.*/*Ridgeback Biotherapeutics LP*'s Lagevrio (molnupiravir), have also stayed well within blockbuster range. (Also see "*Merck's Solid Quarter Doesn't Soothe Seagen M&A Watchers*" - Scrip, 28 Jul, 2022.). *Gilead Sciences, Inc.*'s antiviral Veklury (remdesivir) saw a significant decline in sales, mainly due to fewer hospitalizations; the drug continues to see use among well over half of those COVID-19 patients who are hospitalized. (Also see "*Gilead Oncology Sales Take Off As Veklury's Come Down To Earth*" - Scrip, 2 Aug, 2022.)

Pfizer is the undisputed leader in the COVID-19 market by revenue, guiding sales of $32bn for Comirnaty and $22bn for Paxlovid this year. (Also see "*Pfizer Strengthens Foundation For A Long-Term COVID Commercial Business*" - Scrip, 28 Jul, 2022.) At the time of the company's first quarter earnings report, when sales were $1.47bn, executives said the drug had "a long way to go," but it has certainly come a long way since then. (Also see "*Pfizer On Paxlovid: "There's Still A Long Way To Go"*" - Scrip, 3 May, 2022.) (*Story continues below table.*)

SCRIP
CITELINE COMMERCIAL

Click here to explore this interactive content online

But as the SARS-CoV-2 virus has mutated far beyond the original, wild-type strain, with the BA.4 and BA.5 subtypes of the Omicron variant now dominant in the US and elsewhere, the product mix is starting to shift and industry is once again looking for new tricks.

BA.4 and BA.5 are managing to infect even people who have received three shots of Comirnaty or Spikevax, while Omicron and its subvariants have already rendered multiple leading monoclonal antibodies for COVID-19 – notably *Regeneron Pharmaceuticals, Inc.*'s REGEN-COV/Ronapreve (casarivimab/imdevimab), *Eli Lilly and Company*'s bamlanivimab and etesevimab and *GSK plc*/*Vir Biotechnology, Inc.*'s Xevudy (sotrovimab) – essentially useless, leading the US Food and Drug Administration to withdraw its emergency use authorizations (EUA) for those products. (Also see "*Regeneron's Oncology Strategy Gets Warmer With Early Prostate Data*" - Scrip, 3 Aug, 2022.)

Among next-generation products, Lilly's bebtelovimab has the leading position, garnering an EUA shortly after the FDA pulled the EUAs for bamlanivimab and etesevimab. (Also see "*US FDA Lowers Bar for Latest COVID Monoclonal Antibody Authorization*" - Pink Sheet, 22 Feb, 2022.) The drug remains in its infancy on the market, and the company pooled its revenues together with the other two antibodies, with the total actually declining by 13% from the second quarter of 2021.

But that may soon pick up, as Lilly said on 29 July that it would supply 150,000 doses to the US government for about $275m. During the firm's 4 August earnings call, it announced that it will begin commercial sales. "In collaboration with the US government, we intend to begin making bebtelovimab available for purchase by states, hospitals and certain other providers through a sole distributor agreement," CEO David Ricks said, starting later this month and before the anticipated depletion of the US government supply. (Also see "*As Lilly's Realized Sales Prices Drop, Ricks Reiterates Criticism Of US Drug Price Plan*" - Scrip, 4 Aug, 2022.)

Other drugs in the pipeline are considerably less advanced in their development, and it remains to be seen how much of a role they might ultimately play as existing therapies become dominant. Gilead, which called off a development program for an inhaled form of remdesivir, has an oral prodrug, GS-5245, in Phase I development. Regeneron also has a collection of monoclonal antibodies against SARS-CoV-2 in Phase I.

Next-generation vaccines are moving ahead as well. On 27 July, Pfizer and BioNTech said they had started a randomized Phase II trial of BNT162b5, a bivalent vaccine consisting of RNAs encoding advanced prefusion spike proteins for the wild-type strain of SARS-CoV-2 and an Omicron variant. Moderna said in its second quarter earnings that it had already filed for authorization for its bivalent vaccine containing the BA.1 subvariant of Omicron, mRNA-

1273.214, in the EU, Switzerland, UK, Canada and Australia, while per FDA guidance it would seek authorization in the US for mRNA-1273.222, a bivalent vaccine based on the BA.4 and BA.5 subvariants. (*See table below.*)

Click here to explore this interactive content online