Biopharmaceutical manufacturers Pfizer/BioNTech and Moderna recently announced encouraging interim data for their COVID-19 vaccine candidates, with efficacy results exceeding expectations at above 90%.[1] In this investment note, portfolio manager Steven Slaughter looks at the short and long-term implications of the latest development, and how the base-case scenario of a Biden presidency and a split Congress might impact the pandemic and future healthcare reform.

Vaccine for COVID-19: Is the wait finally over?

The collective sighs of relief that greeted the announcements from Pfizer/BioNTech and Moderna were quickly followed by a flurry of questions over the efficacy, safety, and durability of the vaccines, as well as how quickly they might be made available and how widely.

Though it's certainly premature to start celebrating the end of the COVID-19 pandemic, the numbers are highly promising. At 95% effectiveness for the Pfizer/BioNTech vaccine and 94.5% effectiveness for the Moderna vaccine, both exceeded expectations and are consistent with existing approved vaccines, such as those for measles and mumps, which have been in use for decades.

It may be reasonable to assume that other COVID-19 vaccines currently in the latter stages of development (Oxford University/AstraZeneca, Johnson & Johnson, Sanofi, and Merck) may have similar effectiveness levels because they all target the same part of the virus – the now-infamous infectious spike protein. The datasets for these other vaccines are likely to be made available in the coming weeks.

Of course, it's too early at this stage to properly evaluate the safety profile, durability, and long-term effectiveness of the vaccines. The initial short-term safety profiles of each offer limited cause for concern. However, we won't have a proper understanding until the data is presented at an ACIP/FDA Advisory Committee meeting that will be held for each offering once Emergency Use Authorizations (EUAs) are submitted to the FDA.

Another important aspect we need to understand is the durability of these vaccines (duration of protection offered by the vaccine after receipt of all recommended doses). Both candidates are mRNA vaccines and, if approved, would be the first of their kind licensed for an infectious disease in humans. Rather than introduce small or inactivated doses of the entire infectious organism, mRNA vaccines induce the body to produce antibodies against a small portion of the viral spike protein genetic material, which then trigger an immune response. In the past, mRNA vaccines haven't precipitated a robust t-cell reaction, which may be the key to durability.

Additional COVID-19 vaccine considerations

The Pfizer/BioNTech and Moderna vaccines do come with an in-built challenge. As previously mentioned, they are a new type of vaccine called mRNA.

A challenge with mRNA vaccines is that they are relatively fragile and need to be stored at cold temperatures for transportation (-70 degrees Celsius for the Pfizer/BioNTech vaccine and -20 degrees Celsius for the Moderna vaccine). Logistics are being worked out from two giant cold-store

1. Bloomberg:"Moderna's Covid vaccine found 94.5% effective in early analysis", 16 November 2020. Financial Times: "Pfizer and BioNTech's Covid-19 vaccine found to be 90% effective", 12 November 2020.

centres – one in the US state of Michigan and the other in Belgium[2] – but outside of the developed world, cold-chain distribution may pose a significant challenge.

Both the Pfizer/BioNTech and Moderna vaccines require two doses. It is expected that up to 70 million shots will be produced this year (50 million from Pfizer/BioNTech and 20 million from Moderna), rising to a range of 1.8 billion to 2.3 billion in 2021 (1.1 billion from Pfizer/BioNTech and 500 million to 1 billion from Moderna). This equates to a potential 35 million people receiving either vaccine by year end and a possible 900 million to 1.15 billion people by the end of next year.

We would note, however, that scaling up mRNA manufacturing from small clinical quantities to large commercial quantities has never before been attempted. The early entrants here will need to successfully navigate uncharted waters to provide sufficient capacity to attain these distribution targets.

We look forward to seeing the full datasets at the upcoming advisory committee meetings and expect EUAs for both vaccine candidates by year end.

US healthcare reforms will likely take a back seat

Indeed, an incoming Biden administration in the US may likely prioritise the battle against COVID-19 to a greater degree than its predecessor.

Broadly, we can expect to see a Biden administration take a more federally focused approach to the pandemic. Measures could include national testing guidelines, mask mandates, and possibly directives over the control of vaccine distribution and allocation.

We do think that Operation Warp Speed is likely to continue in its current form, but perhaps with some incremental funding for things like PPE and emerging therapeutics. We may also see additional targeted financial support for hospitals, depending on the trajectory of COVID-19 cases.

Given the likely outcome of the recent US election (Democratic president, a narrow Republican senate and a narrow Democratic house) we expect legislative gridlock for at least the next two years. In our view this should prove to be a positive for healthcare investors given the diminished prospects for substantive healthcare legislation. More specifically, we believe that gridlock will lower the probability of drug-pricing reform, as well as substantive changes to the delivery/payment systems in the US. Also, gridlock reduces the likelihood of changes to the corporate tax code.

In short, 2021 is likely to see a new administration focus on the pandemic, to the detriment of any other sweeping changes to the US healthcare market. Downstream from there, we expect the Biden administration to push for expanded coverage and prop up the Affordable Care Act, both legislatively and through executive action.

Any substantive efforts at drug-pricing reform are probably going to be a post-2021 event. Both political parties seem cognizant of the fact that we will be reliant on biopharmaceutical companies' efforts around treatments and vaccines in order to move past this pandemic. Accordingly, we expect this circumstance will mitigate any pressures to enact sweeping changes to the industry.

Conclusion

The world has been waiting for this announcement, but it will have to be patient for a little longer until COVID-19 is brought under control. Clinically, the initial results are very positive for these candidates, as well as other vaccines in development, and the prospects for global distribution in the second half of next year look favourable.

While governments are busy battling the pandemic, healthcare reforms will likely take a back seat. We believe investors in US healthcare particularly should benefit from an incoming administration that looks inclined to place the near-term priority of pandemic crisis management above long-term policy goals until at least the second half of 2021.

[2] The Guardian: "Pfizer and BioNTech's vaccine poses global logistics challenge", 10 November 2020.

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