Investment views

A response to COVID-19 – Vaccines and diagnostics

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With the COVID-19 pandemic now into its second year, progress with vaccinations and testing raises the hope that lockdowns will lift and economic life will resume. Based on interviews with Bryan Dunn, investor relations officer at the US pharmaceutical company Pfizer, and Dr. Bruno Eschli, investor relations officer at the Swiss pharmaceutical company Roche, we bring you insights from the pharmaceutical industry about the latest vaccine developments and testing options in the fight against COVID-19.

Bryan Dunn
Investor Relations Officer, Pfizer

Interviewed by:

Guido Urban
Investment Insights

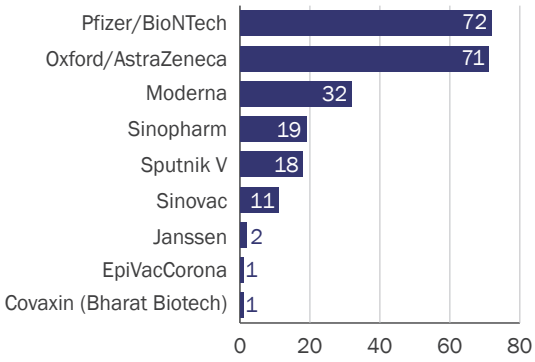
Christoph Wirtz
Equity Analyst

An interview with Pfizer

One of the greatest breakthroughs during the COVID-19 pandemic has been the development of vaccines. US pharma giant Pfizer and German biotechnology company BioNTech were the first to have their vaccine authorized for emergency use in the West. Since the start of vaccination programmes at the end of 2020, many countries across the developed world are seeing considerable traction in those citizens who have received at least one dose of a COVID-19 vaccine. Leading this race is the Pfizer/ BioNTech vaccine (see figure 1). In the following interview with Pfizer, we find out more about the world's first mass-produced mRNA vaccine.*

Figure 1: Which COVID-19 vaccine has greatest global reach?

Number of countries and territories using each vaccine



Source: Our World in Data, BBC.
Note: As at 15 March 2021. Only includes locations where data on doses administered is available.

Mr. Dunn, how successful has the delivery and administration of COVID-19 vaccine programmes been so far? What challenges do we continue to face?

It was obvious to us at Pfizer and BioNTech that the rollout of the first COVID-19 vaccine was going to be an enormous challenge, so we focused on anticipating and solving for these challenges very early in the process, including working to optimize our manufacturing processes to supply more doses sooner. Given the scale of this rollout and the urgent need for vaccines across the world, we engaged with governments early – even before we had a vaccine that we knew would work – in order to lock in supply timing and quantities so we could plan accordingly. While it is clear that demand still outpaces supply in most parts of the world, we should not lose sight of the fact that society has gained access to a vaccine in a matter of months rather than years. In this context, the discovery and rollout of multiple COVID-19 vaccines has been an enormous accomplishment both for Pfizer/BioNTech and the wider pharmaceutical industry.

What do we still have to learn about COVID-19?

We as a society still have much to learn about COVID-19. Currently, our focus at Pfizer is on how the virus mutates and how these mutations might impact the protection afforded from current vaccinations. We continue to test and monitor whether our current vaccine maintains its effectiveness against these new strains. One

“We expect to produce over 2 billion doses by the end of 2021, and potentially even more in 2022.”

Bryan Dunn | Investor relations officer, Pfizer

thing which is looking increasingly clear is that there will be further mutations, so as a society we must be prepared to deal with COVID-19 for longer than we previously anticipated or hoped, and potentially indefinitely.

A key question that is still unanswered is how long the vaccine protects people against the virus. Our current assumption is that people will need a vaccine booster at some point to maintain immunity against current strains and potentially to help increase protection against newer strains, and we are running studies to evaluate that. We still have to assess the level at which antibodies can no longer provide effective immunity, and these booster trials may also help to answer that question. In addition, we don’t know yet how the vaccine performs in younger children, and we recently initiated a study to test that as well. Finally, we are also still studying whether vaccinated people may have contracted asymptomatic infection – so there is still plenty of research to be done.

How could new COVID-19 variants impact broader vaccine distribution and overall supply chains?

We continue to monitor emerging variants of SARS-CoV-2. We have seen no evidence to date that would suggest these newer variants result in a loss of meaningful protection provided by our original vaccine. However, in order to be prepared for any future strain changes, we recently announced that we will soon start a study of a variant-specific vaccine based on the B.1.351 variant, which was first identified in South Africa.

The mRNA technology used by BioNTech and Pfizer allows for the mRNA in the vaccine to be modified with relative ease, should it be required. We are coordinating with regulatory bodies on a potential pathway for a short timeframe (potentially 100 days from the moment a variant that escapes vaccine protection is identified) for development and clinical testing. This would of course require regulatory approval.

How did Pfizer decide who to sell the vaccine to? What was the sales process?

Pfizer and BioNTech engaged with governments around the world. Pfizer’s CEO has rightly said, *“in a pandemic you are only as safe as your neighbour”*. Pfizer and BioNTech pursued equitable distribution of the vaccine, engaging with both developed as well as emerging-market countries and the COVAX facility.

We followed a tiered pricing approach, based on countries’ ability to pay. Low income countries have received the vaccine at a not-for-profit price, while developed countries have paid more for their vaccines.

We expect to produce over 2 billion doses by the end of 2021, and potentially even more in 2022.

Given the recent success of mRNA vaccines in fighting COVID-19, can mRNA technology be used to fight other diseases? How much time for observation is needed to rule out any long-term vaccination side effects?

We were studying mRNA technology prior to the pandemic and we have another separate collaboration with BioNTech to develop a mRNA vaccine to prevent influenza. We believe mRNA is a well-suited technology, with the potential to fight many infectious diseases like flu, respiratory syncytial virus, cytomegalovirus and beyond.

Regarding long term safety, while the development and regulatory authorization process of the COVID-19 vaccine was relatively quick, Pfizer and BioNTech’s clinical study will be following trial participants for two years. The vaccine has been administered now to tens of millions of patients globally and we will continue to carefully monitor its efficacy and safety profile.

** Note: The Pfizer-BioNTech COVID-19 vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent COVID-19 for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheet at www.cvdvaccine.com*

An interview with Roche

Besides vaccinations, one component in the fight against COVID-19 is the widespread testing of citizens. In respect to diagnostics, Roche is a long-standing position in our portfolios and one of the leading pharmaceutical companies in the world. In summer 2020, we were fortunate to interview Roche (Investment views: A response to COVID-19) on its initial response to COVID-19. With the advent of the vaccine and rapid advances in testing, we bring you an update on how the world of diagnostics is responding to the fight against COVID-19.

Dr. Bruno Eschli
Investor Relations Officer, Roche

Interviewed by:

Guido Urban
Investment Insights

Christoph Wirtz
Equity Analyst

Dr. Eschli, how has the COVID-19 testing landscape changed since our last discussion in August 2020? In particular, how do new mutations affect existing government testing strategies?

The variety of tests available to individuals has expanded and can be complicated to understand (see boxout 'Testing for COVID-19'). What's important to understand is that the various tests give you different pieces of information. The PCR test is still the number one test on the market and the gold standard regarding sensitivity and accuracy. Based on a nasal/ throat swab, it detects viral RNA and you receive the result usually after 24 to 48 hours. We sell the test for around CHF15 to the laboratories, but patients will be charged up to CHF150 per test.

Demand significantly outstrips supply for PCR tests, such that Roche's supply is sold out every month. Roche currently produces 40 million tests per month and plans to further ramp up production to 70 million tests per month. The issue with increasing PCR test supply is that there still is a shortage of some key ingredients. For now, it remains unknown what the demand ceiling for PCR tests really is, but we anticipate that demand is likely to remain very high for the quarters to come.

Alongside the PCR test is the antigen test, which is cheaper and quicker – they give results in just 15 to 30 minutes and are sold at around CHF 7 per test to the wholesalers. However, they are also less accurate than a PCR test, with high-quality antigen tests providing > 95% sensitivity and specificity. Having said this, there are many tests on the market which we consider low quality. It's important to remember that a test offering less than 90% accuracy becomes problematic, as it provides users with a false sense of security.

Another test is the antibody test, which measures whether an antibody immune response to the virus has been triggered. A positive result can show up as early as a few days post the initial infection. Depending on the magnitude of the response, antibody tests can detect infections which took place six to nine months ago and which have been cleared in the meantime. The effectiveness of these tests varies, but high-quality antibody tests have an accuracy level of around 99%. In contrast to PCR tests, there is an oversupply of antibody tests. Roche could produce up to 100 million tests per month, but currently we sell only around 10 million per month. The tests are relatively cheap and cost only CHF1 per test. We had expected to see an uptick in antibody testing alongside countries' vaccination programmes, but so far this has not materialised.

Testing for COVID-19

	PCR (molecular)	Antigen	Antibody
What does the test do?	Identifies people currently infected with COVID-19	Identifies people currently infected with COVID-19	Identifies people who have previously had COVID-19 (post infection)
Who performs the test?	Skilled and trained doctors and nurses	Self-test	Self-test
How is it executed?	Nose and throat swab	Nose or throat swab	Blood test – finger prick
Time until result?	24–48 hours	15–30 minutes	A few minutes
Sensitivity?	Close to 100%	>95%	>95%

"Roche currently produces 40 million PCR tests per month and plans to ramp up production to 70 million tests per month."

Dr. Bruno Eschli | Investor relations officer, Roche

“Self-testing and on-the-spot rapid testing are becoming more common to access services like flights or public events.”

Dr. Bruno Eschli | Investor relations officer, Roche

What is your outlook for self-testing, and do you think governments should deploy more antigen or antibody testing?

Self-testing and on-the-spot rapid testing are becoming more common to access services like flights or public events. Frequent use of PCR tests – for example, twice per week – is unrealistic considering the timeframe, costs and laboratory capacity required. PCR tests will still be used in hospital settings for confirmation, where it is taken by professionals and sent to the laboratory. In comparison to PCR tests, antigen tests are much quicker and will be widely used in cases where, for example, you want to visit your vulnerable family relatives. In this case, an antigen test is practical and quick, even if it is not quite as accurate.

With vaccination campaigns under way, what is your longer-term outlook for antibody testing, and the role of mutations?

Roche originally anticipated more antibody testing, but we haven’t seen it so far. As vaccines are rolled out, we are keeping a close eye on countries leading the way, like Israel (see *Investment views: Israeli Diaries*). Currently antibody tests still get used in screening studies to determine how far a population has progressed towards a potential herd immunity, but they have not been used as a routine follow up after a vaccination.

Regarding mutations: I consider every vaccination to be better than no vaccination and I believe even if mutations emerge and people are reinfected for a second time they are probably on average better protected than before. This is partly due to the fact that vaccines not only trigger antibody immune responses, but also T cell responses. What is important is that vaccinations will hopefully ensure that hospitalizations and the current mortality rates fall significantly. This is critical for re-opening societies. However, nobody knows exactly when we will reach this point as the virus keeps evolving. Vaccines will put evolutionary pressure on the virus to escape via mutation until the virus reaches a point when it can no longer do so.

Riding the waves

In 1889, the last great pandemic of the 19th century struck Europe. The Russian Flu (which is conjectured to have been from the coronavirus family) swept across the world that year, with recurring waves in the spring of 1891, winter of 1891–92 and winter of 1893–94.

Source: Wikipedia

What is the outlook on COVID-19 testing volumes for 2021?

We believe 2021 will see overall strong testing as the vaccination programs, especially throughout Europe, have been slower than what we anticipated at the beginning of the year. On the basis that the vaccination programmes are successful (which also depends on what mutations will come up over time), we could expect peak testing sometime in H2 21. However, if there is another harsh winter season in 2021/22, we are likely to see another spike in testing. Therefore, Roche will keep increasing its PCR testing capacity, while for now there is no need to ramp up antigen or antibody testing.

Looking ahead, I could imagine two key scenarios playing out mid-term. Either the virus will be cornered within the next 12 months and it can no longer mutate much beyond its current state, or it could be a battle over several years where the virus continues to evade immunization by evolving with new aggressive variants. Historic pandemics (see ‘Riding the waves’) usually lasted somewhere between two to five years. Given the multiple vaccination breakthroughs of the last six months and the easy adaptability of mRNA vaccines to tackle new variants, I am optimistic, however, that we can start to see the back of the pandemic in the second half of 2021.

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Produced by: Guido Urban
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