COVID-19 PANDEMIC: THE PATH FORWARD

REGIONS ASSET MANAGEMENT

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Over the past 7 months, COVID-19 has changed the way the world functions. Since January 2020, the COVID-19 pandemic has resulted in extensive shut down of cities, regions and countries all over the world. This has resulted in an unprecedented slowdown in global economic activity. By mid-March 2020, most of the U.S. was under stay at home orders. As companies furloughed employees, jobless claims and the unemployment rate skyrocketed (Figures 1, 2). The National Bureau of Economic Research (NBER) announced that the U.S. has entered a recession since February 2020. The COVID-19 pandemic has ended the longest economic expansion in U.S history.

Figure 1: Continued Jobless Claims [1]

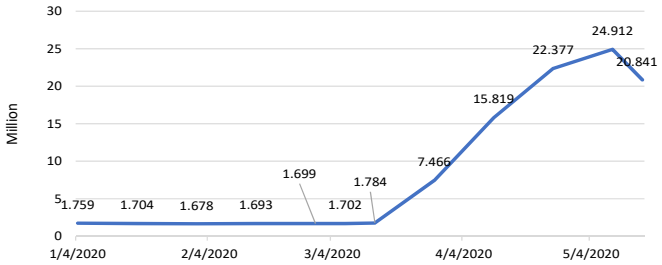
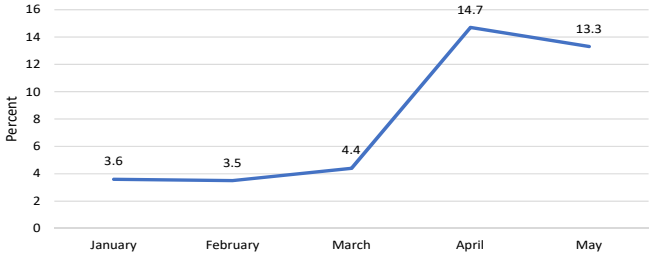


Figure 2: Unemployment Rate [2]



COVID-19

COVID-19 is the disease caused by a newly identified coronavirus, SARS-COV-2, in 2019. SARS-COV-2 virus belongs to the family of coronaviruses that cause upper respiratory illnesses. Coronaviruses are zoonotic viruses in that they have jumped from animals to humans. SARS-COV-2 virus appears to have jumped from bats to humans via an intermediary. There are 7 known coronaviruses that have infected humans. 4 of these cause minor illnesses like the common cold. Others have caused more serious infections like SARS and MERS. SARS-COV-2 appears to be the most virulent. It has spread around the world and has to date, infected 7.3 million people and caused over 417,000 deaths[5].

Several factors have resulted in COVID-19 becoming a global pandemic.

1. SARS-COV-2 virus spreads through droplets of saliva or mucus and can survive in the air for 4 hours and up to 2-3 days on plastic and stainless steel.
2. Most viruses have a short incubation time. For example, incubation time for the influenza virus is 3-4 days. SARS-COV-2 has an incubation period of 2-3 weeks. Most patients are asymptomatic during this period and can spread the virus. On average, one influenza patient spreads the disease to 1.3 other people, whereas the rate of spread for SARS-COV-2 is 2-2.3 people.
3. According to the World Health Organization (WHO), the SARS-COV-2 global death rate is 5-6%. This is significantly higher than that for influenza (0.1%).

INVESTMENT OPPORTUNITIES

Since the end of May, most states have relaxed their stay at home orders and allowed for partial reopening of businesses. Businesses are required to comply with social distancing and there is a limit to the number of people who can gather at a given place. Use of face masks is also recommended. Despite these precautions, new COVID-19 infections have started to increase. There is also a high probability of a resurgence of COVID-19 in Fall 2020.

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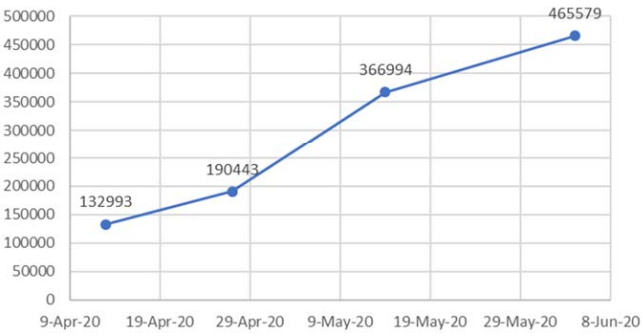
TESTING

Countries like South Korea and Singapore have been successful in controlling the spread of COVID-19. Comprehensive testing along with contact tracing has been the key. After a slow start, COVID-19 testing in the U.S. has increased. Daily testing volumes have increased from 133,000 per day in April 2020 to 465,500 in June 2020 (Figure 3). The Department of Health and Human Services (HHS) recently increased COVID-19 testing budget by $11 Billion (B). HHS expects testing volumes to be 40—50 million (MM) per month by September 2020. FDA has started issuing Emergency Use Authorizations (EUA) in order to get tests and treatments on the market. An EUA allows the FDA to grant fast approval using limited clinical data.

Figure 3: COVID 19Tests per Day[3]



There are two distinct methods to test for the virus. The first is to detect the actual virus. This is done by PCR testing which detects the genetic material of the virus. The advantage of PCR testing is that it can detect the virus in the very early stages of infection before development of any symptoms or an immune reaction. Early in the pandemic, PCR testing was done primarily in Point of Care (POC) locations like hospitals and physician clinics. Thermo Fisher Scientific (TMO) and Abbott Labs (ABT) were amongst the first to develop PCR tests. Sample collection has been a bottleneck due to supply constraints. Availability of testing supplies has now improved. Also, in May 2020, the FDA approved its first at home sample collection kit for COVID-19. Currently, there are five at home sample collection kits on the market. As testing volumes increase, analysts expect testing to shift from POC to centralized laboratories which can automate PCR testing for large samples. ABT and Hologix (HOLX) are some of the leading companies in this market. Also, HHS recently increased reimbursement rate for automated testing from $51 per test to $100 per test.

Table 3: COVID-19 Testing Opportunity[3]

Company	1Q2020 COVID-19 Revenue	Opportunity per Quarter (estimates)	Opportunity as Percent of 2019 Revenue
TMO	$84MM	$600MM	2.4%
ABT	$36MM	$600MM	1.9%
QDEL	$1MM	$174MM	33%
HOLX	$3.4MM	$45MM	1.4%
DHR	$90MM	$210MM	1.2%

The virus can also be detected using an antigen test. In this test, a monoclonal antibody is used to detect a viral protein. This test can be done either at POC or in a laboratory. Its advantage is that it is cheaper and faster than a PCR. However, it is not as accurate as a PCR test and can detect antigens only above a certain concentration. Quidel (QDEL) is the only company, so far, that has the EUA for this test.

The second method of testing is serology testing and is used to detect antibodies to the virus. Serology testing can be used to identify people who have been exposed to the virus. In general, antibodies to a given pathogen will protect the host from reinfection. Therefore, it may be possible for people with a positive COVID-19 antibody test to return to work or school. Some of the leading manufacturers are TMO, ABT and Danaher (DHR).

In the first quarter of 2020, COVID-19 testing has been a tailwind for companies developing both PCR and serology tests. This is expected to continue in the near future (Table 3).

TREATMENT

Drugs: So far, Remdesivir (Gilead, GILD) is the only drug that has been approved (EUA) for the treatment of COVID-19. The clinical data has shown that 5-day treatment of Remdesivir is effective in reducing hospitalization of severe patients by about 30%. GILD has pledged to donate 1.5MM doses which is expected to be reached by early summer. GILD has not yet priced Remdesivir and expects it to be a multiyear opportunity. The pricing decision should take into account that Remdesivir is administered in a hospital setting and has not shown a significant reduction in mortality rate. Also, approximately 15 existing anti-viral drugs are being tested for COVID-19. Analysts expect Remdesivir to start contributing to GILD's revenue from second half of 2020.

Neutralizing Antibodies (NAbs): Doctors have been successful in using plasma from recovered patients to treat some severe cases of COVID-19. However, convalescent plasma treatment is not scalable, as one donation can be used for only a few treatments. Pharmaceutical companies have started developing neutralizing antibodies for COVID-19. These humanized neutralizing antibodies confer passive immunity by binding to the virus and preventing it from infecting cells. NAbs can be used as treatment for COVID-19. They can also be used as short term prophylaxis (preventive) treatment for people in close contact with virus. Analysts estimate that the worldwide market for Nabs to be $2-$6B. Eli Lilly (LLY), Amgen (AMGN), Regeneron (RGEN) and VIR Biotechnology (VIR) are leading the development of Nabs. LLY has already started Phase I human trials. LLY, REGN and VIR expect possible FDA approval by year end 2020.

PREVENTION

Vaccines: All epidemiologists agree that a vaccine is essential for controlling the COVID-19 pandemic. Ideally, a vaccine needs to have high efficacy (>90%) to be effective. A high efficacy vaccine needs to protect against all strains of a pathogen and generate sufficient immune response to prevent future infections. Also, a vaccine should be safe and have a low number of adverse effects (AE). COVID-19 does not seem to have a high mutation rate. So far, there are only 14 known strains of the virus.

There are several different platforms that can be used to develop a vaccine (Table 4). Some of the platforms have been used in the past. The live attenuated vaccine and the inactivated platforms are the basis for most childhood vaccines like the MMR, chicken pox and HepA. More recent vaccines like HepB and HPV have been developed using the newer recombinant subunit vaccine platform. The DNA/RNA vaccine and the viral particle vaccine are the newest platforms and are still in experimental stage.

Table 4: Vaccine Development Platforms[4]

Platform	
Live Attenuated Vaccine	Weak form of the virus, MMR, chicken pox vaccine
Inactivated Vaccine	Killed/ dead virus, HepA, Flu vaccine
Recombinant Subunit Vaccine	Subunits of virus in a vector, HepB, HPV
DNA/RNA Vaccine	Genetic material from virus, experimental
Recombinant viral vector Vaccine	Non-replicating virus vector, Ebola vaccine
Virus like particle Vaccine	Viral proteins to mimic virus, experimental

Due to the urgency of this global pandemic, many drug companies (pharmaceutical and biotech) are using multiple platforms to develop a COVID-19 vaccine. There are at least 50 distinct vaccine candidates in development. In order to accelerate development, the U.S. government has recently announced its private-public partnership program, Operation Warp Speed (OWS). OWS has identified five vaccine projects for additional government funding (Table 5). Each of these programs are using a different platform for vaccine development. Oxford University+ AstraZeneca (AZN), Johnson and Johnson (JNJ) and Merck (MRK) are using the recombinant viral vector platform with different viral vectors. Moderna (MRNA) and BioN Tech (BNTX)+ Pfizer (PFE) are using the experimental DNA/RNA platform. Moderna is the most advanced in its development. However, its platform is experimental and has not yet been used develop any vaccines. Oxford University+ AZN vaccine is only slightly behind Moderna timeline. Based on current data, none of these five pipeline vaccines have an ideal profile. Some do not have high efficacy (Oxford+AZN) and some have high AE (MRNA, JNJ).

Table 5: Vaccines in the Operation Warp Speed Program[4]

	MRNA	Oxford + AZN	JNJ	BXTN + PFE	MRK	
					Themis	IAVA
Platform	mRNA	Recombinant Subunit	Recombinant Subunit	mRNA	Recombinant Subunit	Recombinant Subunit
Development Stage	In Phase II Phase III in summer	I month behind MRNA	Phase I in September	I month behind MRNA	Phase I in June, Phase III in Fall 2020	Not announced
Manufacturing	Up to 1B doses in 2021	Up to 1B doses in 2021	Up to 1B doses in 2021	Up to 1B doses if positive results	Up to 1B doses	

In the past, vaccine development has taken, on average, between 10-11 years. Advances in science and in the understanding of the human immune system has reduced this time to 3-4 years. Due to the urgency for a COVID-19 vaccine, drug companies are trying to further reduce this time to one year by conducting clinical trials in parallel. They are conducting Phase II and Phase III trials before the conclusion of Phase I trials. Also, NIH has launched Accelerating COVID-19 Therapeutic Intervention and Vaccine Program (ACCTIV) to standardize efforts between different vaccine development platforms. NIH has indicated that it may be possible to use interim results from Phase I and II trials along with some preliminary efficacy

data from Phase III trials for EUA. For approval by year end 2020, phase III trials need to start at the latest by Fall 2020. Typically, commercial manufacturing of a vaccine is done after final FDA approval. As part of OWS, the U.S. government is making investments for manufacturing and distribution of 300 MM doses of potential vaccines by January 2021.

Using the influenza vaccine model ($12-$19/ shot) and assuming 70% compliance in adults, some analysts estimate a base case potential for the U.S. market to be $4.4B. The federal government is the most likely initial buyer of COVID-19 vaccine. Also, it is likely that the U.S. government will purchase an additional 20MM vaccine units for its strategic stockpile. Most countries are also likely purchasers of COVID-19 vaccines. Further expanding the market potential could be the need for booster shots to maintain long term immunity.

SUMMARY

The ongoing COVID-19 pandemic has changed the way of life in all countries and has had a devastating effect on the world economy. In the U.S., jobless claims and the unemployment rate has skyrocketed. As states start to relax their stay at home orders, infection rates have started to go up. Virus testing and contact tracing are essential to control this pandemic and to get back to a new normal. Drug companies are working on new treatments, some of which could be approved by end of 2020. An effective vaccine is essential for controlling this pandemic. Drug companies, in partnership with the U.S. government, are hoping to have an effective vaccine or treatment developed by the end of 2020.

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