

“Coronavirus is not an investment case in and of itself”



Dr. Daniel Koller
Head Investment Team

Attention has suddenly shifted to the biotechnology sector and the drugs and vaccines it is developing to contain and control the coronavirus outbreak. Amid the current pandemic, BB Biotech is adhering to its tried-and-tested investment strategy and continues to invest in innovative therapeutic solutions and long-term technology trends.

The Covid-19 pandemic is running rampant in a human population with no historical immunity to the novel coronavirus. Action to address and mitigate the serious health and economic consequences of the virus is being taken on multiple fronts. Rapid coronavirus diagnostic testing is being ramped up on a large scale so cases of infection can be quickly identified. Meanwhile scientists are racing to gain a better understanding of the Covid-19 viral disease and how it spreads while others are evaluating data on people who have developed an initial immunity to the virus. This is particularly important because containing pockets of infection more effectively and providing more efficient clinical care will be imperative to effectively manage the probable second wave of infections without having to resort to some form of social distancing or lockdowns again, thus hopefully avoiding the economic pain such measures entail.

Drug and vaccine developers – the prominent players

Researchers have also begun testing existing drugs to determine whether they can be repurposed to treat acute cases of Covid-19 and efforts to develop a prophylactic vaccine are already in high gear. Among the current antiviral programs, data on remdesivir, an investigational drug made by Gilead Sciences, is highly anticipated and should be available in the coming months. Rather than cure the disease outright, remdesivir could reduce viral load and thus mitigate the duration or severity of the disease. Data from two larger trials currently being conducted in China should be published very soon. In April or May at the latest, the clinical results from controlled trials in the USA should follow.

Passive immunization, i.e. the administration of recombinant antibodies that neutralize the virus, is an approach being pursued by Regeneron Pharma, Vir Therapeutics and other companies. These projects are still in pre-clinical stages of development and the earliest studies could commence would be in the summer.

Long-term protection against Covid-19 infection can only be achieved through active vaccination. Pharma companies Johnson & Johnson, GlaxoSmithKline and Sanofi are working on conventional recombinant vaccines. This classic development process is more complex and time-consuming. The earliest any such vaccines could be approved is in 12 to 18 months. Moderna is taking a different approach with its mRNA-based vaccine. In its studies mRNA is administered to healthy individuals where it instructs cells to make certain viral proteins which then elicit an immune response to these viral proteins. This would create longer-term protection against infection by SARS-CoV-2, or result in significantly milder symptoms. Vaccines based on mRNA technology are also being researched by other biotech companies such as CureVac, BioNTech and Translation Bio, but their programs are still in pre-clinical stages of development. Moderna's vaccine candidate is at the most advanced stage of development. The company began clinical trials in healthy volun-

teers in March and is now monitoring whether they make coronavirus antibodies. If successful, a larger efficacy study of the vaccine, which may be administered a second time, could be initiated in the summer. In order to shorten the timeline, the US FDA is likely to waive certain requirements, such as controlled clinical trials comparing groups of vaccinated individuals with unvaccinated individuals. Ideally, trial readouts in the fourth quarter of this year will set the stage for regulatory approval. Swift approval would mean vulnerable populations could already be vaccinated before a subsequent wave of infection. This scenario is only possible because Moderna's management decided to invest in production capacity at an early stage. Thanks to these investments, the company would be able to deliver 100 million doses of a vaccine, enough for 50 million people, within the next 6 to 12 months.

BB Biotech has been invested in Moderna since 2018 and it has a lot of confidence in the viability of Moderna's mRNA technology platform. Many other companies have announced Covid-19 programs but that has not prompted us to cast our net even wider. While some of the solutions under development could also prove to be worthwhile, we think the business models behind many of the specific products for Covid-19 will hardly be sustainable. Due to pressure from politicians and the general public, it appears likely that many of these companies will be selling these products at or near cost of manufacture, assuming they make it to the marketplace.

BB Biotech is banking on the key technologies of tomorrow

The investment company's focus is and has always been on emerging technologies that will shape the drug-development processes of tomorrow.

Vertex Pharmaceuticals is a good example of a company that has evolved over the years and become an undisputed leader in a particular therapeutic area. We made our first investment in Vertex in 2005. At the time the company was concentrating on developing treatments for hepatitis C. It has since shifted the focus of its attention. Today Vertex is the world's number one developer of cystic fibrosis medicines, having successfully launched four drugs to treat this severe hereditary lung disease. With these four products, especially its triple combination therapy, Vertex can now treat around 90% of all patients with this disease. Some experts expect peak sales of USD 10 bn from Vertex's cystic fibrosis franchise.

Vertex is using its sales revenues to broaden its research pipeline of mRNA drugs, cell-based therapies and gene editing. BB Biotech has opened positions in five biotech companies developing RNA-based medicines. Moderna is its most recent investment in this field. Gene therapy is another promising drug-development technology. The very first gene therapies were launched in recent years. Sangamo is one of our most recent investments in this area. Sangamo's most advanced candidate, a treatment for patients with hemophilia A, has just entered a pivotal study conducted by its pharma partner Pfizer. Sangamo also offers a gene editing technology platform that is used to develop gene therapies. Using this technology, gene defects can be corrected at DNA level by replacing a faulty sequence with the corrected DNA code. BB Biotech also holds shares of Crispr Therapeutics. Crispr could achieve a new milestone in the fourth quarter of 2020 when it presents pivotal clinical data from a trial in sickle-cell anemia and beta thalassemia, inherited blood disorders.

Sustainable portfolio performance

Steady and sound investment in groundbreaking biomedical technologies is a hallmark of BB Biotech's investment strategy. Its portfolio is well-positioned to weather financial market turbulence in the near- to mid-term future. Based on our conversations with portfolio company representatives, supply chains are still intact, ensuring patient access to key drugs.

Nevertheless, the operations of regulatory agencies and the companies active in the healthcare sector will be affected by the coronavirus outbreak. With respect to ongoing clinical trials, attention is focused on ensuring quality and their continued progress. Delays will be encountered in trials pending launch and in patient recruitment efforts. Regulatory agencies' evaluation of recently submitted applications will likewise be affected as regulators prioritize the processing and approval of diagnostic tests and treatments for Covid-19. There have also been fewer announcements of licensing agreements and M&A deals. We presume, however, that this activity will pick up again as soon as market volatility subsides. Another effect of the corona crisis: proposals for healthcare reform floated by White House contenders no longer capture the headlines.

Against this backdrop, we reiterate our portfolio strategy and will continue to identify long-term trends in therapeutic approaches at the earliest possible stage and invest in companies whose products and technologies have significant breakthrough potential. As before, our investments will be concentrated on small and mid-sized biotech companies. Several of the stocks in our portfolio could achieve major clinical breakthroughs during the course of this year. Examples are Exelixis with its cancer drug Cabometyx; Myokardia with Mavacamten for non-obstructive hypertrophic cardiomyopathy; Argenx with Efgartigimod for the treatment of rare autoimmune diseases; and Ionis Pharma with Tominersen for Huntington's disease. As for pending regulatory decisions, attention is focused on companies such as Intercept's application for obeticholic acid as a treatment of non-alcoholic fatty liver disease, for which there are currently no adequate treatment methods.

Covid-19 – a chance for biotech to shine

The companies in our portfolio were already inexpensively valued compared to historical valuation levels before the recent market sell-off. BB Biotech has no intention of changing its attractive dividend policy in the coming years. The coronavirus pandemic will not induce us to chase after any short-term market trends either. The current crisis is a chance for drug developers to change the public's perception of their business for the better. Through its actions, the biopharmaceutical industry can be viewed more widely as an indispensable partner offering viable and valuable solutions for challenging health issues.

Facts & Figures

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Management	Bellevue Asset Management
Legal structure	Incorporated company
Foundation	November 9, 1993
Share type	Registered shares
Nominal value	CHF 0.20
Share structure	55.4 mn shares
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