Current Market News - Equity Research

Operation warp speed: Three contenders lead the pack

Jeffrey I Rogers, Senior Equity Research Analyst, BMO Wealth Management – U.S.

Michael P. Stritch, CFA, Chief Investment Officer, BMO Wealth Management - U.S.

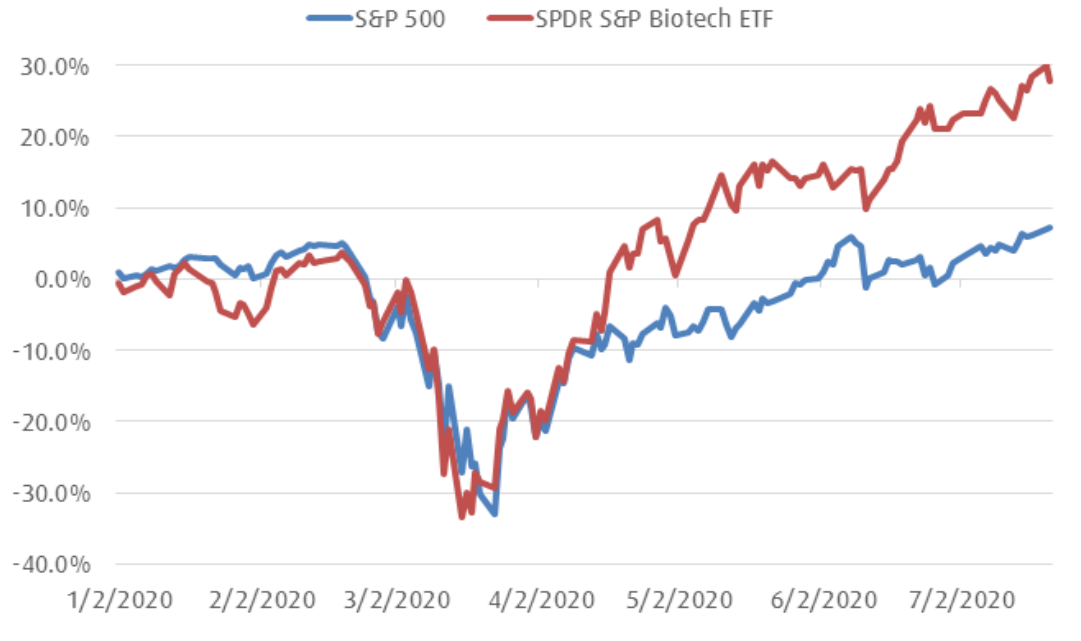
Thursday, July 23, 2020

The global race for a vaccine remains in full swing, and six primary technologies are being explored by clinical COVID vaccine programs. From a technical perspective, they include inactivated virus; DNA; Protein Subunit; Non-replicating viral Vector; RNA; and VLP (Virus Like Particles). At this stage two of these technologies (Non Replicating Viral Vector and RNA) and the three associated programs are furthest along in their research – AstraZeneca (AZN) / Oxford, Moderna (MRNA) and Pfizer (PFE) /BioNTech (BNTX).

Since the bottom of the equity markets in March, the biotech industry has been a top performer ***(Chart 1)***. This is not surprising given the intensive interest in health care businesses, most specifically those involved in combating the Coronavirus threat.

And thus far the investor sentiment seems justified from a scientific perspective, given the significance research advances made over the past several months. The most important recent news came from AstraZeneca/Oxford, when Phase I data published in The Lancet demonstrated a similar antibody response in vaccinated patients (after a month) to that seen in patients previously infected with the SARS-CoV-2 virus. A robust cellular response was noted, and neutralising activity to the live virus was seen in 95% of patients who received one vaccine dose (after one month) and 100% of patients who received a 2nd boost. The results were positive, but did fall short of the neutralising antibody levels seen in the Moderna and Pfizer/ BioNtech studies. However, it is important to note that there is currently limited consensus on what levels of neutralising antibodies are needed to achieve successful long-term clinical outcomes, as well as how critical cellular responses will be in generating durable immunity. Of course the AstraZeneca/Oxford study is only one of the trials currently underway. Two other candidates are also at the forefront.

Chart 1: S&P 500 vs. S&P Biotech ETF (Cumulative Total Returns)



Source: Bloomberg, BMO Wealth Management Strategies

For more insights and information, follow - BMO Wealth Management - U.S. on LinkedIn.

Moderna's RNA Vaccine (mRNA-1273)

- Moderna was the first company to enter clinical development in the U.S., with its Phase 1 trial initiated in March, followed by Phase 2 in May.
- In May, they announced positive interim Phase 1 data, though it contained limited information.
- Phase 2 enrollments and the finalization of the Phase 3 trial protocol was announced in mid-July, based on FDA feedback.
- Phase 3 trials are scheduled to start on July 27, 2020, enrolling 30,000 subjects in the U.S., and Moderna has communicated that they expect emergency use authorization to be available in the fall of 2020.

Pfizer/BioNtech

- Pfizer is developing its mRNA vaccine with BioNTech (BNTX) of Germany. While Moderna is testing a single vaccine candidate, Pfizer has brought four separate versions of its vaccine into clinical trials. Phase 1 interim results from the lead program (BNT162b1 RBD modRNA) were announced in early July.
- On July 13, the FDA has granted fast track designations to the two lead vaccine programs (BNT162b1 and BNT162b2) out of the four total vaccines.
- The next step in the trial is to identify a lead candidate following further data, and also finalize the dose level for a global Phase 2b/3 safety and efficacy study. If all goes well, that study may begin as early as later this month, pending regulatory approval.
- Most recently, on July 22, an agreement with the U.S. Government was announced for up to 600M doses. The government will pay the companies $1.95B when the first 100M doses are received, following FDA authorization or approval, with an option for up to an additional 500M doses thereafter. If the ongoing studies are successful, PFE/BNTX plans to seek accelerated approval as early as October 2020.

Vaccine Timelines

With governments, businesses and academic institutions around the world acutely focused on vaccine development, standard drug study timelines are being significantly condensed. The clinical development process for a typical novel preventive vaccine would take years, while many have suggested current efforts could lead to a drug being produced in as little as 9-12 months (i.e. sometime in the fall of 2020).

While the progress made to date is another testament to human ingenuity, it is important to view any projected approval timelines with some amount of skepticism. Unlike most medications, which are given to ill patients, vaccines are received by healthy individuals, thus the margin of safety needs to be very high. There is reason to be hopeful - particularly as so many programs have been fast-tracked by the FDA – but the reality of the availability, effectiveness, and utility may fall short of an immediate, universal cure. That said, we are optimistic on the future, and do believe the initial vaccines should be broadly available to the public sometime in the first half of 2021. Though it is important to note that whichever comes to market first is unlikely to be the last, or ultimately the best.

Disclosure

CFA® and Chartered Financial Analyst® are registered trademarks owned by CFA Institute.

This report contains our opinion as of the date of the report. It is for general information purposes only and is not intended to predict or guarantee the future performance of any investment, investment manager, market sector, or the markets generally. We will not update this report or advise you if there is any change in this report or our opinion. The information, ratings, and opinions in this report are based on numerous sources believed to be reliable, such as investment managers, custodians, mutual fund companies, and third-party data and service providers. We do not represent or warrant that the report is accurate or complete.

To the extent this report contains information about specific companies or securities, including whether they are profitable or not, it is being provided as a means of illustrating the investment manager's investment thesis. The investment manager may or may not have invested in these securities at the time this report was prepared or is accessed by the reader. References to specific companies or securities are not a complete list of securities selected and not all securities selected in the referenced timeframe were profitable.

Other Bank of Montreal affiliates, and their agents and employees, may provide oral or written market commentary or trading strategies to clients that reflect opinions that are contrary to the opinions expressed in this report. These same persons and affiliates may make investment decisions that are inconsistent with the recommendations or views expressed in this report. We and our affiliates, directors, officers, employees and members of their households, will from time to time have long or short positions in, act as principal in, and buy or sell, the securities referred to in this report. We and our affiliates, directors, officers, employees and members of their households, may have positions in the securities mentioned that are inconsistent with the views expressed by this report.

This report is not intended to be a client-specific suitability analysis or recommendation, an offer to participate in any investment, a recommendation to buy, hold or sell securities, or a recommendation of any investment manager or investment strategy. Do not use this report as the sole basis for your investment decisions. Do not select an asset class, investment product, or investment manager based on performance alone. Consider all relevant information, including your existing portfolio, investment objectives, risk tolerance, liquidity needs and investment time horizon.

Any forward-looking statements in this report involve known and unknown risks, uncertainties and other factors that may cause the actual performance of future markets to differ materially from the projections depicted in the report. Past performance is not indicative of future results and current performance may be higher or lower than that shown in the report. There can be no certainty as to the extent or depth of any market downturn, nor any assurance regarding the nature, extent or timing of markets rebounding. When evaluating the report, you are cautioned not to place undue reliance on these forward-looking statements, which reflect judgments only as of the date of the report. Investment returns fluctuate, and investments when redeemed, may be worth more or less than the original investment.

Standardized performance returns include reinvestment of dividends, other income and capital gains, which depict performance without adjusting for the effects of taxation or the timing of purchases and sales. Performance data is presented without deducting the investment advisory fees and other charges that may be applicable. The deduction of such fees and other charges (and the compounding effect thereof over time) will reduce portfolio return.

Unless otherwise indicated, traditional investment performance data generally represents a composite or representative portfolio return and is shown gross of the investment manager's advisory fees. Unless otherwise indicated, alternative investment performance data is shown as net of fund expenses, management fees, and incentive fees. Index performance data is shown as total return. You cannot invest directly in an index. Due to a system conversion, the ability to manipulate or restate client specific performance data prior to December 31, 2007, may be limited.

Any discussions of specific securities, investment managers, or strategies are for informational purposes only and should not be considered investment advice. The report does not constitute an offer to sell or a solicitation to buy any security or investment product. Any offer to sell or solicitation to buy an interest in any private security, investment product or fund may only be made by receiving a confidential private offering memorandum, prospectus, investment advisory agreement or similar documents from the investment manager, which describes the material terms and various considerations and risks relating to such security, investment product or fund.

Alternative investments, such as private equity and hedge funds, contain risks that are amplified when compared with other asset classes, such as illiquidity, stock or sector concentration, financial leverage, difficulties in valuation, and short selling. Alternative investment vehicles have minimal regulatory oversight and alternative managers have the latitude to employ numerous investment strategies with varying degrees of risk.

We are not licensed or registered with any financial services regulatory authority outside of the United States. Non-U.S. residents who maintain U.S.-based financial services accounts with us may not be afforded certain protections conferred by legislation and regulations in their country of residence with respect to any investments, investment solicitations, investment transactions or communications made with us.

You may not copy this report or distribute or disclose the information contained in the report to any third party, except with our express written consent or as required by law or any regulatory authority.

"BMO Wealth Management" is a brand name that refers to BMO Harris Bank, N.A., BMO Family Office, LLC, BMO Harris Financial Advisers, Inc., BMO Delaware Trust Company, and certain affiliates that provide certain investment, investment advisory, trust, banking, securities, insurance and brokerage products and services. "BMO Family Office" is a brand name that refers to BMO Harris Bank, N.A., BMO Family Office, LLC, and BMO Delaware Trust Company. The BMO Family Office brand provides family office, investment advisory, investment management, trust, banking, deposit and loan products and services. These entities are all affiliates and owned by BMO Financial Corp., a wholly-owned subsidiary of the Bank of Montreal. Capital Advisory Services are offered by a division of BMO Harris Bank, N.A. Member FDIC.

NMLS #401052 EQUAL HOUSING LENDER

Securities, investment advisory services and insurance products are offered through BMO Harris Financial Advisors, Inc. Member FINRA/SIPC. SEC-registered investment adviser. BMO Harris Financial Advisors, Inc. and BMO Harris Bank N.A. are affiliated companies. Securities and insurance products offered are: **NOT FDIC INSURED – NOT BANK GUARANTEED – NOT A DEPOSIT – MAY LOSE VALUE.**

Not all products and services are available in every state or location or through all entities within BMO or BMO Family Office.