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SPECIAL REPORT

MELIOR INSIGHTS

INSIDE THIS ISSUE:

Melior
CAPITAL MANAGEMENT

Introduction to Melior Capital Management

MELIOR

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(from Latin)

BETTER, SOUNDER, SUPERIOR

Melior Capital Management is a Swiss domiciled company introducer and advisory firm focused exclusively on the global life science sector.

We specialise in finding funding for medtech, biotech and pharmaceutical companies by applying institutional quality service and process to raise capital.

Our investment approach is to find qualified innovative projects, with proven management teams, promising data, robust IP, strong corporate governance and a likely opportunity for significant commercial upside in a three to five-year horizon.

In the current environment, many existing companies seeking capital for medical trials have encountered a diminishing supply of funding from governments, private equity firms, investment banks and research foundations in favour of start-ups. At Melior, we combine the global reputation of our scientific, management and advisory members to select best in class investment opportunities with credible upside potential.

Our value proposition is attributable to our world class team and their proven track record in the life-science sector, plus the strong emphasis that we place upon due diligence and first-hand experience. Our goal is to offer attractive and diverse investments to both high net worth private clients and larger corporates through their professional advisers. For our business to be truly successful, we consider the needs of all parties, including our investees, investors and professional advisers at introduction and throughout the life of the investment. Our financial success depends on funds raised and the financial return of our investees as we share a common goal.

Melior does not accept enquiries from members of the general public, but we welcome enquiries from professional intermediaries.

Melior Capital Management

MELIOR CAPITAL MANAGEMENT

IS THERE A SOLUTION FOR COVID-19?

The view of a life science professional with 40+ years of experience

This article is authored by Dr Philip Lavin, PhD, FASA, FRAPS. With more than 40 years of expertise in clinical trials, regulatory affairs and product development planning, Dr Lavin has collaborated with world class investigators and sponsors since 1974. Phil is also one of the founding members of Melior Capital Management and chairs the Scientific Committee.

Each day the global media is reporting on the number of cases, death rate, potential treatments and the devastating effects that COVID-19 is having on human lives. The situation is very fluid as countries are having to choose between the risk of death and the healthcare burden, versus a severe recession and social isolation.

My position has brought me into the inner circle of COVID-19, which I wanted to share with our readership.

The situation is evolving quickly, and I see the following:

- 3-5 successful therapies will emerge this year with fast track approval putting these drugs on the market by the end of the year. There are multiple promising drugs, which are currently being tested.
- The new cases and death trajectories are flattening out to the degree that we are likely to see a 50% reduction in deaths within a month, 80% reduction in two months, and >90% in three months.
- There will similarly be decreases in the number of patients being hospitalized, on-ventilators or in ICU, so most health care systems should be able to manage the crisis.
- The expected drop in cases globally will make it difficult for pharmaceutical companies to test every suitable drug candidate if COVID-19 cases are already on the down swing.
- Only a second wave (from a more virulent strain or relaxed social isolation) will allow everything in the pharma pipeline to be properly tested, but more cases will justify further therapies to treat a returning virus.
- The race to develop a vaccine is up against the herd immunity effect and by the time a vaccine gets approved (>1 year), these vaccines will have limited value if COVID-19 continues to spread fast.
- The new drugs being developed will likely be faster to bring to market than the vaccines, especially if the drugs are approved and adopted in advance of the vaccines being ready….thus if new drugs can be shown to be safe and effective, then that will take the pressure off the need for a vaccine.
- There is also preliminary evidence that the virus strains are weakening over time and that the virus is sensitive to heat.
- We need, and now have multiple accurate COVID-19 diagnostic tests and antibody tests to determine who has and who has had the virus. This lets us determine the herd effect and the true hospitalization and death rates.
- periodic testing for COVID-19 infection will be key to managing social isolation, to permit rule relaxation and resume normal life. However, it will need to be frequent for those with a negative antibody test, since this test can assess who is safe to resume work and normal activities.

- Both forms of testing will need to be routinely implemented on a broader scale and more rapidly to get control of the pandemic. This will let the economy recover faster.
- Moving forward, we will be in a better position for future pandemics and potential bioterrorism, the former of which will very likely happen again.
- Financial markets will be fragile in the short term, until we can get a handle on testing and new treatments (anti-viral, anti-inflammatories, anti-immunologic cascades, anti-stroke, and organ protection). My sense is that there will be multiple successful drugs very shortly.

As the waves of good news arrive from reduced incidence and deaths, as well as with new therapies following successful clinical studies, investors will soon awaken with the energy and enthusiasm to catch up for lost time. I believe that the life sciences will be a favoured investment since most of the good news will influence investing in the sector in general rather than just a few companies.

Success will also include diagnostic tests which are considered as medical devices. Other opportunities will emerge for home testing kits, as well as emergency drug packs for rapid treatment with doctors 'controlling passwords' to access emergency drugs. Remember that many of these test kits and drugs will be scalable to other viruses down the road.

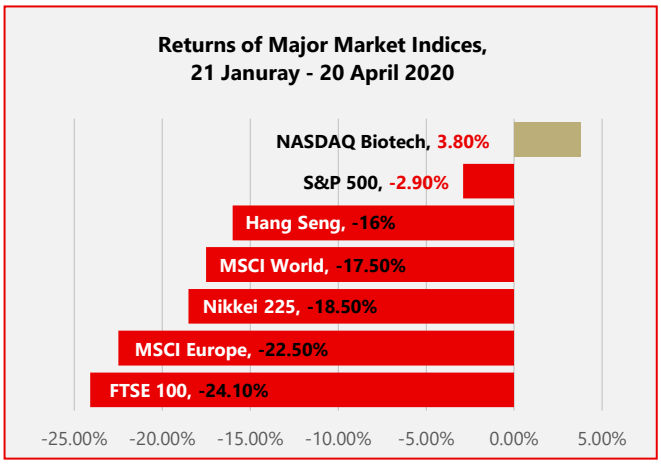
The companies that develop and produce drugs, reagents, distribute drugs, or coat surfaces will be in demand. Thus, I believe that the life science sector will benefit from such breakthroughs as good ideas abound and spill over to other clinical applications. This will encourage investment in the life sciences as the innovations extend beyond COVID-19.

LIFE SCIENCE MARKET FINANCIALS

What are the numbers telling us about the effects of COVID-19?

Life Science Public Markets

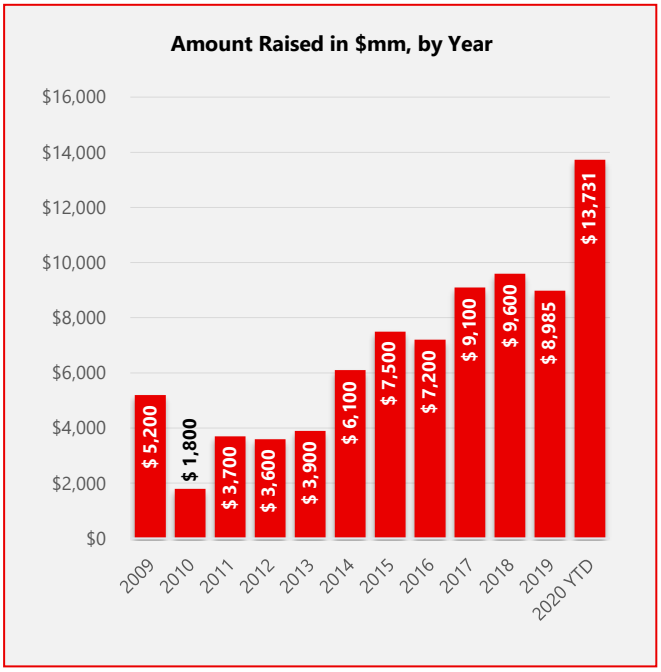
The future growth trend in the life science sector anticipated by Dr Phil Lavin can already be seen when looking at the evolution of the major market indices for the period of 21 January to 20 April 2020 – with most of the indices yielding negative returns. While NASDAQ Biotech showed a return of +3.8%, partially due to a number of COVID-19 driven stocks. The NASDAQ Biotech index actually fell 28% at its low between February and April of this year although, it has since recovered. The index includes 207 biotech companies, the major drivers of positive returns being 3 companies – Gilead, Moderna and Regeneron. All three companies are currently working on the development of potential COVID-19 therapies.



Source: *S&P Capital IQ*

Life Science Private Markets

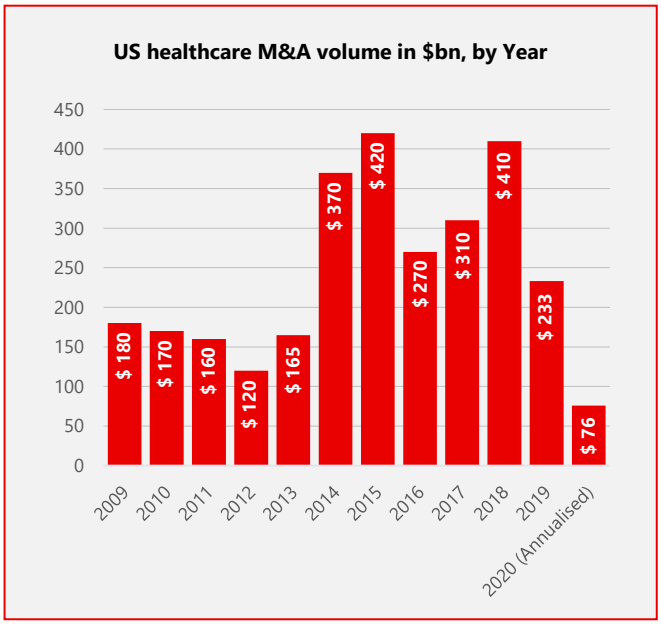
The private markets indicate much optimism from investors – the 2020 YTD figures already being a record considering the past 12 years, with investments approaching $1bn per week since the start of the year. Data also suggest that more and more investors previously unacquainted with life science, or that preferred public instruments, are finally venturing into life science VC investments.



Source: *S&P Capital IQ*

Life Science M&A Activity

The M&A activity has seen a drastic decrease globally, with the US figures indicating an annualised estimation of only $76bn for 2020 – the lowest in the last 20 years and a 67% decrease from the previous year. This is primarily driven by the reluctance of companies to invest in large deals, a risk management measure, but also a much more challenging task to achieve in market conditions of tightening credit. Q1 of 2020 was the second weakest quarter since 2014; however, experts expect the volumes to rebound and possibly exceed previous years.



Source: *Dealogic and CapitalIQ*

HOW ARE REGULATORY AGENCIES REACTING TO COVID-19?

The case study of the Food and Drug Administration

The COVID-19 pandemic has achieved global reach and created a new status quo for each and every industry. The various measures implemented by governments and businesses – e.g. social distancing, movement restrictions and lockdown, have reshaped the political, social and commercial processes and generated new challenges, as well as opportunities.

The importance of life sciences has grown even more in the current climate as they are essential in not only identifying a sustainable resolution for the COVID-19 pandemic (e.g. a vaccine), but also in diminishing the likelihood of such a pandemic recurring, as well as allowing the formulation of an improved and more comprehensive response from specialised government agencies and healthcare systems.

The FDA implemented a number of changes to ensure that the current situation is not displacing crucial elements of the life science industry and society in general. In the subsequent sub-sections, a number of key areas and the corresponding actions of the agency are reviewed. There is a particular focus on clinical trials as this domain is of highest importance to both current life science start-ups and big pharma alike, as well as the larger population due to new treatments.

Clinical Trials

The FDA has highlighted the importance of continuing clinical trials for various novel drugs and new treatments. However, it has stated that the safety of participants is paramount, which would lead to additional measures to be taken by sponsors, including potential modifications of studies.

Most protocol-specified visits are currently impossible, this is why sponsors need to identify alternative methods for safety assessment (e.g. virtual visit, phone contact, alternative location for assessments). Changes in study visit schedules, missed visits, or even patient discontinuations might lead to missing or distorted information. The FDA has released detailed guidance on how to resolve each of these issues. Hence, new processes might need to be implemented or modification of existing ones, to adapt to the specific local situation.

Creation of new policies and procedures is essential to adapt to the new circumstances. The development and application of contingency plans is also encouraged. Improved communication, better data collection, study monitoring, adverse event reporting, and changes in investigators/site staff and other measures should be considered as well.

In addition, the FDA provides some regulatory relief during this outbreak to help sponsors to cope better with the rising challenges of clinical trials and approval processes, as well as helping to expedite the availability of essential elements, like diagnostics and respirators.

Diagnostics

During this pandemic, the FDA has worked with more than 220 test developers who are planning to submit emergency use authorization (EUA) requests. To date, 55 such EUA have already been issued for diagnostic tests.

PPE and medical devices

The FDA issued a number of guidance documents regarding the production, import and use of Personal Protective Equipment (PPE), ventilators and other medical devices, both used directly in the combat of the pandemic and those used indirectly as required by the current circumstances. Certain regulations were eased to facilitate the fight against the pandemic.

Supply Chain

The FDA published guidance for the manufacturers of drugs and biological products to coordinate their inventory with the agency and to announce their needs in a timely manner. The FDA has assumed the role of monitoring the supply chains in order to prevent and mitigate shortages.

Chemical compounds

The FDA highlighted the risks of using various compounds for treating COVID-19, which had not been specifically tested and approved for such purposes. One such drug is chloroquine phosphate, which is used to treat disease in aquarium fish, was allegedly used to treat COVID-19 and has caused the death of at least two people.

Consumer Update

The agency has issued a communication with regards to Food Safety and Availability during the Coronavirus Pandemic. It described the measures taken by the FDA to ensure that the necessary quantity and quality of food required during this time is available and well distributed.

The FDA continues to closely monitor the situation and to intervene with actions to maintain a good regulatory environment, supply chains and enforcement of rules for the life science industry. Similar measures are taken by the European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA) and other national agencies.

Source: *FDA, Regulatory Focus, Target Health, Melior Insights Team*

THE LIFE SCIENCE INDUSTRY IN THE COVID-19 EPOCH

Critical questions for companies and investors

Every business sector is looking for ways to stay relevant under the current circumstances and companies are seeking solutions to continue operating; this is the only way to avoid potential catastrophic consequences. Rethinking business strategy, re-evaluating resources, adjusting processes, improving communication and other actions are essential not only for the survival of businesses, but to flourish in times of crisis.

The life science industry is one of the few industries that sees extra opportunities in the short and medium term, as in addition to its significant societal role, it is essential in minimising the effects of, and ultimately eradicating the pandemic. There will be benefits in the long term too for the life science industry as it will adapt to the new status quo for R&D, regulatory, distribution, marketing, financing and acquisition issues.

Pharma and medtech companies are looking for ways to capitalise on their capabilities. Lab testing companies are developing new molecular tests to rapidly and accurately diagnose COVID-19. Pharma companies started clinical trials to test existing anti-viral medicines for their relevance and efficacy in treating COVID-19, as well as seeking new treatments. Significant work has been conducted to develop vaccines, with one company developing a COVID-19 prototype vaccine in just 42 days (which will still require at least 12-18 months for FDA approval).

In the larger context of the pandemic, there are three areas that are very critical to life science companies:

1. Supply chains

International transportation and logistics are disrupted - how can the supply of diagnostic kits, medical supplies, equipment and drugs be sustained in the face of significant global logistical disruptions?

2. Research & Development

Many locations and subjects of research are affected - how to ensure good continuation of R&D processes, including planned and ongoing clinical trials as the challenges of conducting them increases drastically?

3. Taking care of patients

Non-COVID-19 diseases are ongoing and continue to be diagnosed and treated - how to continue catering to the various categories of clients and to manage operations under these difficult circumstances?

Supply Chains

The situation generated by the COVID-19 pandemic puts enormous pressure on global supply chains, affecting each sector that is reliant on international sourcing and logistics. Life science is no exception – the US is sourcing 80% of its active pharmaceutical ingredients (APIs) globally, including generics from China and India. There are more than 600 FDA-registered facilities in China alone, producing more than 1,000 APIs for the US.

Medtech is equally affected by the current circumstances, with Asia producing 50% of N95 masks, and a significant percentage of isolation gowns. Heightened demand and stockpiling from consumers might lead to a shortage of these products for medical professionals who are the most exposed. Several European and Asian countries have already instituted export controls for protective apparel (masks, gowns, drapes and gloves).

The increase in demand, caused companies to boost their production of drugs and medical devices used for treating viral and respiratory illnesses (IV fluids, IV pumps, IV catheters, respiratory disposables and ventilators). To further improve their supply chains, companies must implement advanced analytics and scenario modelling to identify and mitigate risks. A few critical questions should be addressed:

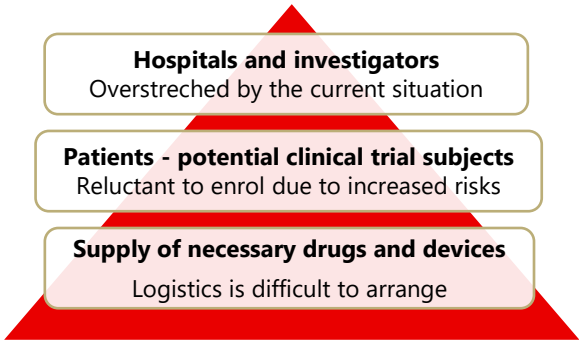
- What products might be affected by possible shutdowns – directly (at supplier) or indirectly (suppliers' supplier or due to logistical issues)?
- What are the inventory levels and the new consumption rates – how can they be better optimised?
- How resilient are the supply chains especially in worst-case scenarios, such as a second wave of infections?
- How can production be readjusted geographically or new suppliers be used?
- How to improve and prioritise the use of products with a low inventory?
- How can suppliers of critical APIs, ingredients, raw materials and components be diversified, including reaching potential technical transfers and regulatory approvals?

It is uncertain what will happen to the global life science supply chains; however, it is very likely and strongly recommended that companies invest heavily in improving supply chains, as well as creating contingency plans.

Research & Development

The responsive reaction of the life science industry to develop a remedy for the COVID-19 pandemic is very laudable; however, it is important that companies balance well their resources and priorities in order to also remain focused on other R&D areas, which would return as top priorities once COVID-19 is contained.

The pandemic created a number of challenges for the R&D processes of life science companies:



Companies should carefully address these issues, assess how the current situation influences the ongoing trials, identify measures that can mitigate risks and optimise trial time and chances of success. The following vital questions should be considered:

- Which trials can be affected by possible shutdowns or logistics issues?
- What issue can COVID-19 generate and how to include the impact tracking into trial management plans?
- How to best communicate with investigators and understand what problems might be caused at their sites (e.g. local lab testing capacity, patient retention, serious adverse event risks)?
- What alternative location and timing can be identified and how to best prioritise these new implementations?

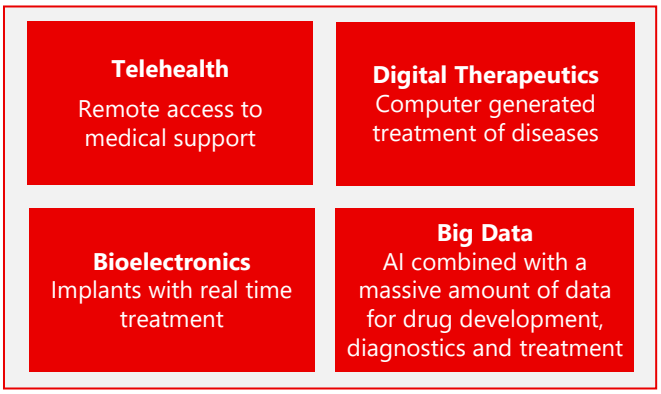
- How to ensure that strong patient communication plans are put in place?
- How to best organise the internal regulatory perspective to guide the communication with institutional review boards and investigators?
- How to better manage the enhanced event risk in currently enrolled patients and potential new enrolees, as well as cooperating with regulators on these aspects?

Taking care of patients

Experts are predicting significant social and economic changes originating from the COVID-19 pandemic; however, it will take some time to properly assess the scale of these changes. It is already clear though that the trends of digitization of healthcare are accelerating.

Beyond supplying products for prevention, diagnosis and treatment of COVID-19, the life science industry is able to assist customers in novel ways, telehealth, digital therapeutics, bioelectronics and big data innovations. These approaches will allow a shift from traditional face-to-face engagements and implement other measures in order to offer a personalised care approach and a better patient experience.

Working with stakeholders like the healthcare and insurance industries, as well as government, focusing on the needs of patients and seeking creative solutions for the new circumstances would generate numerous innovative sustainable solutions that would materialise in new products and revenue streams.



Source: *BCG, Melior Insights Team*

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MELIOR CAPITAL MANAGEMENT:
PIONEERING LIFE SCIENCE INVESTMENT

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