

THE ALCIVAX

Alcimed questions whether we want to ride or bail on the COVID-19 induced biotech century innovation wave.

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Is COVID-19 starting the Biotech Century?

The Biotech Century, originally posited by Jeremy Rifkin in the late 90's never really come to fruition on its promises of faster cheaper development of new drugs with a higher success rate, and there are several theories as to why. One potential stumbling block, regulatory requirements for safety + non-inferiority may block disruptive technologies from using market forces to push products that do not improve off the market rather than rigid approval gateways.

The need to rapidly push COVID-19 vaccines & therapies to the market has removed many regulatory barriers to innovation, and when added to the current global collaborative spirit raises questions about whether the pandemic may finally usher in the "Biotech Century".

The State of Biotech Investment

Fast paced development would need to be met by investment for high burn rate biotechs. Under COVID-19, listed companies have fared well, with the Nasdaq Biotechnology Index and The S&P Healthcare Index just below their all-time highs. Funding cycles in the sector seem healthy with positive signals across all stages of funding. \$3.3 B was raised across 14 IPOs in Q1 2020. XILIO THERAPEUTICS, raised \$100 M during a series B round, led by TAKEDA with participation from MERCK and IPSEN. Others, like Shanghai based MABWELL biotech had a monster Series A round of \$278.5 M, while AKOUS (\$105m) or SPERO THERAPEUTICS (\$30m), have also taken part in this active funding landscape in March. In total, 28 biotech firms captured \$1 B of VC funds just in Boston alone.

But while funding is strong, questions remain as to what happens to Biotechs of all sizes that find themselves in the potentially deadly valley between funding rounds. Most US biotechs qualify as SMEs but have been denied access to Paycheck Protection Program (PPP) loans because of provisions in the law that small businesses funded by VC and Private Equity do not qualify for the PPP, as long as those VCs and PEs had multiple companies in their portfolio, pushing the employee count above the threshold fixed by the SBA. Moreover, under certain conditions, even a minority stake disqualifies the funded business. To solve the issue, the SBA gave the right to those companies to become eligible for PPP if the backer irrevocably waives its right to prevent a quorum or block any decision, waiving any control. This ultimately makes those investments riskier, requiring funds to choose between financial relief and control of their portfolios. How badly this will impact fledgling biotech survival or cause a rush for speedy funding rounds remains to be seen.

Public Assistance

There is still a good deal public-private partnership activity in the crisis, especially for contact tracing as part of reopening efforts. While healthcare facilities already have good partnerships with authorities for communicating active patients and the potentially exposed, standard tracing methods are ill suited for the size and scope of the current pandemic. The G20 has launched a program to fund much needed health tools and Germany has joined many other European nations in embracing the Decentralized Privacy-Preserving Proximity Tracing, proposed by the Google-Apple collaborative tracing app, after finding that the Pan-European Privacy-Preserving Proximity Tracing Bluetooth handshakes run in the foreground causing massive battery drain and preventing other phone use. This also means forgoing location data collection for only a list of potential contacts for people who test positive for COVID-19.



WFH: It's not Great

According to a recent Fortune poll, the vast majority of CIO's were not worried about the infrastructure requirements for moving business to Working From Home, but about whether or not their employees would communicate. Enter Zoom.

Globally, experts are suggesting that WFH is here to stay. More than a month into full WFH, the collected data show the overall advantage is the employers the average worker is putting in 3 extra hours per day in the US and 2 in Europe. The obliteration of work life balance, even for those maintaining a routine, is heightening stress levels made considerably worse by Zoom Fatigue.

Zoom fatigue, the exhaustion that comes from too much video conferencing, can be derived from Skype, Zoom, any video conferencing software. When overused zaps our energy and increases anxiety, as we are still searching but not finding any of the non-verbal communication cues. Gallery view actually makes this worse.

Thankfully, Psychology Today has some helpful tips on how to counteract Zoom fatigue.



Biotech Century Downsides

While the COVID pipeline shows the promise of a Biotech Century, other therapeutic areas have not been as lucky. The approval of Neurocrine, a new Parkinson's therapy, received US approval, the launch will be delayed due to the pandemic.

Similarly, more than 70 companies have reported delays in conducting clinical trials for non-COVID assets. About half of the stalled trails are Phase 1 and small biotech sponsors have been hit the hardest, suggesting that the pandemic is likely to derail innovation in other therapeutic by making it even harder for cash strapped biotechs to gather the data required to entice new investors.

Even the increased public coverage of the advancement of the COVID-19 pipeline has proved obstructive, as politicians over-hyping unproved therapies like chloroquine has damped enrollment for even COVID-related clinical trials.

If this is the beginning of the Biotech Century, it is certainly off to a very bumpy start.

The Search for Therapies

Positive news this week comes for severe COVID patients with distressed immune systems, with [emergency approval of two blood-filtering devices](#). The ALung Technologies' Hemolung system removes excess carbon dioxide from the bloodstream. Baxter's Oxiris filter set to remove excessive inflammatory cytokines and provide needed renal replacement therapy.

The immune cleansing support is welcome after disappointing news [Regeneron and Sanofi's Kevzara fails](#) to decrease inflammation in COVID patients. Roche's Actemra seems to potentially be effective at reducing ventilator use and mortality, suggesting Kevzara dosing may need adjusting.

Studies in France on whether [nicotine lowers susceptibility](#) to COVID infection are also underway.

The Remdesivir's Rough Tide

It was a rough week for Gilead. [Clinical data from Remdesivir trials in China were leaked suggesting no benefit to the treatment](#). However, the study which was not completed due to halted enrollment as the pandemic receded in China seemed to dash hopes of a treatment in the near future.

This conflicts with the benefits observed during compassionate use and the [positive results officially released from placebo controlled trials run by the NIH](#) in the US which suggest that remdesivir speeds recovery by 31% and may be most efficacious when used early. In further good news for Gilead, [remdesivir is close to approval for use in Japan](#).

The Hunt for Immunity

To help you keep track of all the COVID vaccines in trial, the WHO has created a [draft landscape of the coronavirus candidate vaccines](#), including 7 vaccine candidates in clinical evaluation and 82 candidates in preclinical evaluation. Additionally, a visual guide to the 8 vaccine strategies and their mechanisms of actions are explained in a [visual guide in the journal Nature](#) this week.

A Chinese biotechnology company, [Sinovac, reports that their COVID-19 vaccine protects monkeys from new coronavirus](#). The company gave two different vaccine doses to a total of eight rhesus macaque monkeys. Three weeks later, the group introduced SARS-CoV-2, the virus that causes COVID-19, into the monkeys' lungs through tubes down their tracheas, and none developed a full-blown infection.

India is also making a big vaccine push. Half a dozen Indian firms are developing vaccines against the virus that causes COVID-19. Serum Institute of India has partnered with Codagenix, an American biotech company, to develop a "live attenuated" vaccine.

With Q1 financial results, also came [Merck's announcement to pursue both antivirals and vaccines for COVID-19](#). Three potential vaccine collaborations are being considered, but no official announcements have been made for now.

The debate over COVID immunity continues with the WHO warns that ["there is currently no evidence that people who have recovered from COVID-19 and have antibodies are protected from a second infection"](#). Some [scientists fear that it may be impossible to produce an effective coronavirus vaccine](#), based on how quickly immunity wanes in other coronavirus strains. Despite this, calls for [human challenge models](#) to speed vaccine production continue. Nations are trying to out compete other countries for [1st access to a vaccine allowing a vaccine nationalism to emerge](#) as purchase agreements are negotiated.

What we know

Several months now into the COVID-19 pandemic there is a good deal that we know about COVID pathogenesis and yet there is a lot we are still learning. Here's a recap of this weeks new findings:

The US CDC has updated its list of symptoms for COVID-19 adding [six new possible symptoms](#) chills, repeated shaking with chills, muscle pain, headache, sore throat and new loss of taste or smell as possible symptoms of COVID-19.

In younger people in their 20-30s [frostbite tools and other peculiar rashes](#) may present.

Perhaps most concerning is analysis [showing that mild patients in their 30-40s are susceptible to large vessel strokes](#) once infected with COVID-19.

The [risk of dying from COVID-19 is 3X in cancer patients](#) than the general population, patients with lung and blood malignancies are the most at risk.

Aerodynamic analysis of SARS-CoV-2 in two Wuhan hospitals found that hospital toilets can be a hotspot for airborne viral RNA.

A study conducted by the Yale School of Public Health found that [saliva is more sensitive for SARS-CoV-2 detection in COVID-19 patients than nasopharyngeal swabs](#), which is good news for testing shortages.



All Joking Aside



[Bobby Bandito](#) played by Matthew McConaughey has put together PSAs to encourage mask wearing.

Enterprising distillers are converted unsold stale beer into [pandemic whiskey](#) to be bottled and sold to recoup what would otherwise have been poured down the drain.

Earth Day 2020 saw [less pollution](#) than prior years. Celebrations were [sadly muted](#) this year.



Credit: Joe Heller

The week in Pandemic Cartoons

Too much Zoom



Credit: Peter Kuper

The Human Zoo



Credit: Gary Varvel

Sunday in the Coronapark



Credit: Peter Kuper

Need Gas?



Credit: Steve Kelley