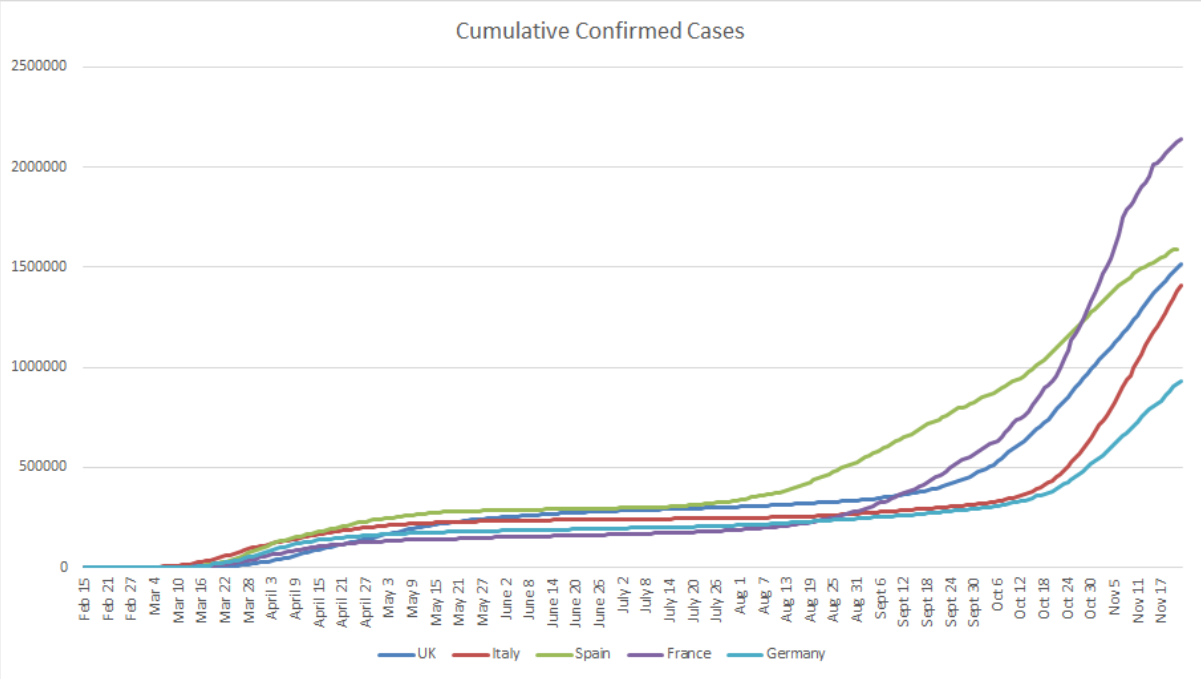
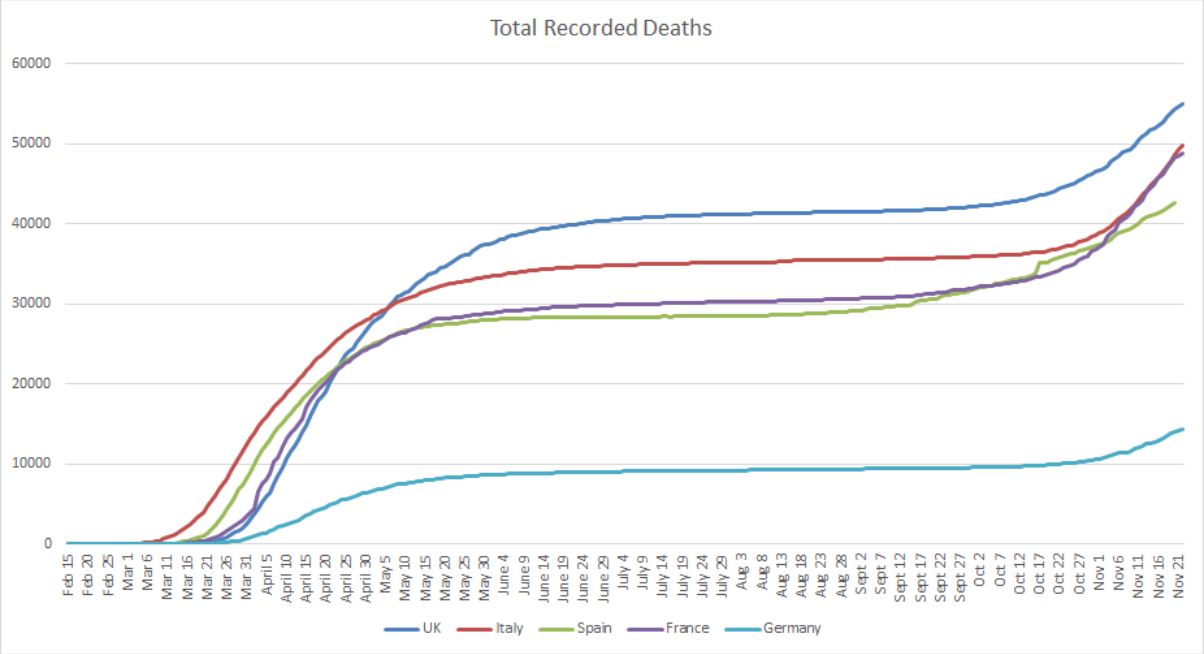
Health Matters

Weekly thoughts on the healthcare sector from finnCap's life sciences analysts: Mark Brewer and Arshad Ahad

Market	Last	-1D	-1M	-3M	-12M	YTD	Health	Last	-1D	-1M	-3M	-12M	YTD
MSCI World Index	1,914	0.0%	4.7%	5.8%	9.6%	6.4%	MSCI World Pharma/Biotech	218	0.0%	2.4%	-1.5%	6.8%	2.2%
FTSE All Share	3,591	0.0%	9.7%	7.0%	-11.4%	-14.5%	FTSE All Share Health	12,157	0.0%	4.2%	-2.7%	-2.4%	-5.6%
AIM All Share	1,034	0.0%	6.4%	7.7%	13.7%	7.6%	**AIM Health**	11,562	0.0%	0.5%	-0.7%	15.5%	11.5%
AIM 100	5,242	0.0%	6.4%	7.8%	12.7%	6.2%							




Total Recorded Deaths
60000
50000
40000
30000
20000
10000
0
Feb 15
Feb 20
Feb 25
Mar 1
Mar 6
Mar 11
Mar 16
Mar 21
Mar 26
Mar 31
April 5
April 10
April 15
April 20
April 25
April 30
May 5
May 10
May 15
May 20
May 25
May 30
June 4
June 9
June 14
June 19
June 24
June 29
July 4
July 9
July 14
July 19
July 24
July 29
Aug 3
Aug 8
Aug 13
Aug 18
Aug 23
Aug 28
Sept 2
Sept 7
Sept 12
Sept 17
Sept 22
Sept 27
Oct 2
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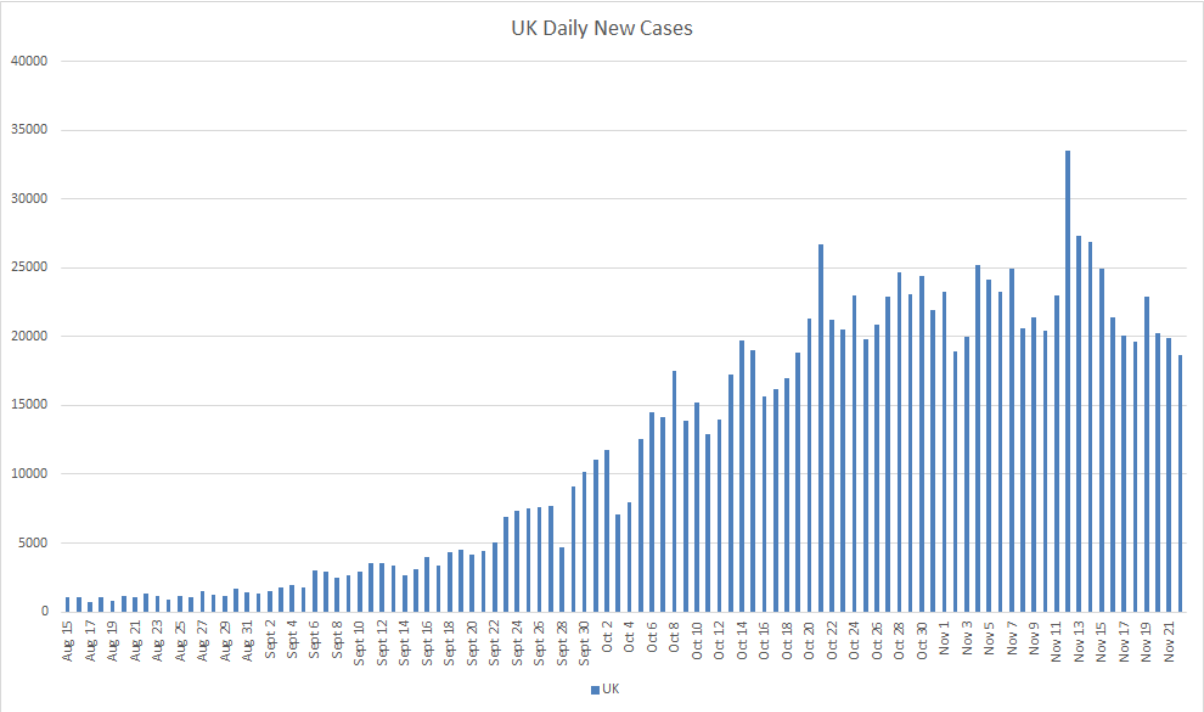
Oct 22
Oct 27
Nov 1
Nov 6
Nov 11
Nov 16
Nov 21
UK
Italy
Spain
France
Germany


UK Daily New Cases
40000
35000
30000
25000
20000
15000
10000
5000
0
Aug 15
Aug 17
Aug 19
Aug 21
Aug 23
Aug 25
Aug 27
Aug 29
Aug 31
Sept 2
Sept 4
Sept 6
Sept 8
Sept 10
Sept 12
Sept 14
Sept 16
Sept 18
Sept 20
Sept 22
Sept 24
Sept 26
Sept 28
Sept 30
Oct 2
Oct 4
Oct 6
Oct 8
Oct 10
Oct 12
Oct 14
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Oct 20
Oct 22
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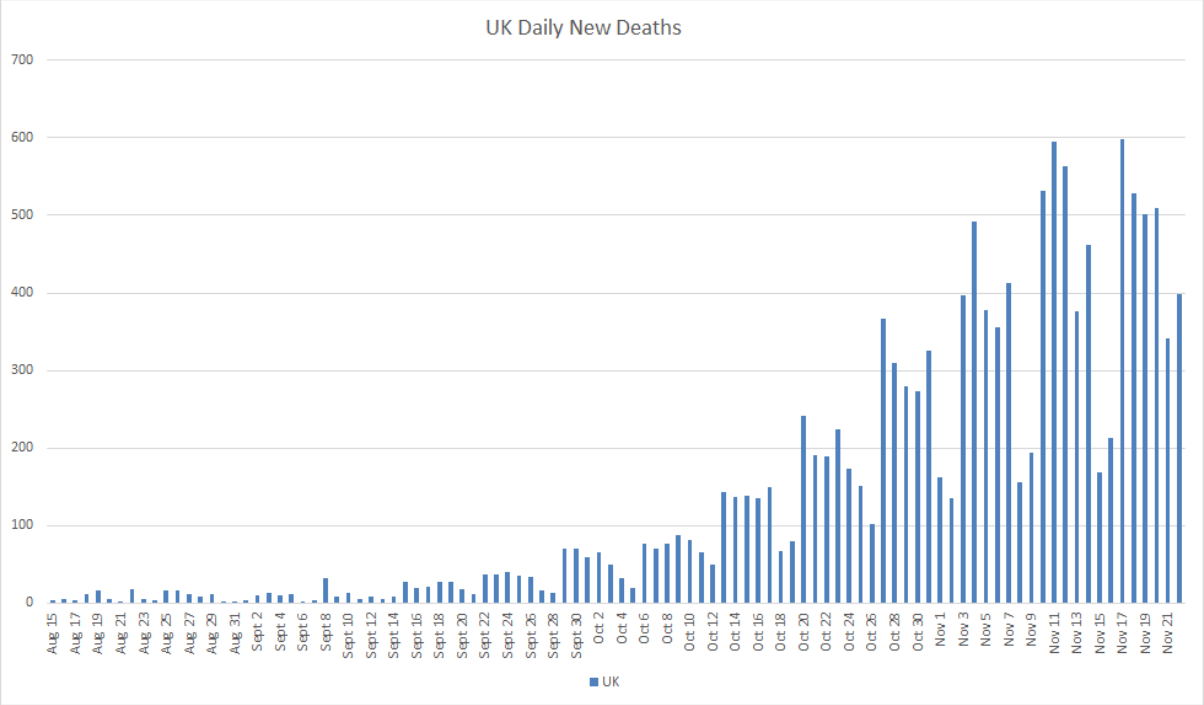
Nov 17
Nov 19
Nov 21
UK



COVID-19 News Alert

Implications of AstraZeneca-Oxford University's Early Vaccine Data

Oxford University and AstraZeneca announced the first interim analysis from the Phase III study of its COVID-19 vaccine candidate, which was found to be 70% effective in preventing COVID-19. This follows similar announcements from Moderna, and Pfizer/BioNTech in the previous two weeks, and the caveats we mentioned at the time remain the same. While all of these results have been highly encouraging, we reiterate that they do not diminish the urgent need for COVID-19 treatments and testing, which will be required for years to come. We consider Synairgen, Avacta, genedrive, Omega Diagnostics and Open Orphan to offer good buying opportunities.

-News. AstraZeneca and Oxford University announced the first interim analysis from its Phase III COVID-19 vaccine, AZD1222, which was found to be 70% effective in preventing COVID-19. This figure is a combination of results from two different dosing regimens, one which showed an efficacy of 90% when the vaccine was given as a half dose, followed by a full dose at least one month later (n=2,741) and another which showed 62% efficacy when given as two full doses at least one month apart (n=8,895). Combined analysis from both regimens (n=11,636) resulted in an average efficacy of 70%. There were a total of 131 COVID-19 cases in the interim analysis, with 101 cases in the placebo group, and 30 cases in the vaccine group. All results were statistically significant ($p<0.0001$). No serious safety concerns have been observed thus far, and AZD1222 was well tolerated across both dosing regimens. AstraZeneca is now preparing regulatory submission to authorities around the world. The UK Government has pre-ordered 100m doses (enough for 50m people), of which 4m are ready immediately. It is not clear why there is a difference between the two regimens, but if the company is able to roll out the higher efficacy regimen, then it will have more doses to distribute.

-Comparisons. AZD1222 is a genetically modified common cold virus that causes infection in chimpanzees, and has been modified to contain the genetic material of the SARS-CoV-2 spike protein. It differs to the ground-breaking mRNA technology used in Pfizer and Moderna's candidates, and while the average efficacy is lower than the 95% reported by those companies, AZD1222 has some advantages. A full course of AZD1222 is expected to cost £6, compared with £30 and £38-45 for Pfizer and Moderna's candidates, respectively. AZD1222 can be stored, transported and handled at normal refrigerated conditions for at least six months. The lower cost and logistical burden will be critical for ensuring vaccine roll-out in developing countries. In addition, Astrazeneca aims to produce up to 3bn doses in 2021, which is more than the number available for the Pfizer and Moderna vaccine combined.

-Unknowns. Full results have not been released or peer-reviewed. Last week, findings from an AstraZeneca Phase II trial found that AZD1222 generated similar immune response across all age groups, but that data (560 participants of which 240 were aged 70 or over) uses a relatively small sample size and may not be representative of the oldest generation as a whole, as few in its elderly groups had underlying health conditions. In today's Phase III interim analysis, there were lower levels of asymptomatic infection in the group which showed 90% efficacy. However, there is not enough data yet to say whether the vaccine will prevent asymptomatic infection, and therefore have an effect on community transmission. No hospitalisations or severe cases were observed in the AZD1222 group. However, AstraZeneca has not disclosed how many hospitalisations or severe cases, if any, were in the placebo group. Duration of protection is also unknown. As a result, it is likely that recommendations will remain in place for people to get tested when they develop symptoms, even if they have been vaccinated for COVID-19. Finally, it is too early to know whether there are any long-term safety implications.

-Challenges. Vaccine manufacturing is complex, and every batch has to be quality assured before release. This vaccine requires two doses, one month apart before it can be effective. A roll-out campaign is likely to be slow, and may take many months to cover a significant proportion of the population. Even once available, anti-vaccination movements, and general public concerns over the rapid speed of COVID-19 vaccine development also pose challenges for mass-scale vaccine uptake.

-Stock implications. We believe COVID-19 stocks, including Synairgen, Avacta, Genedrive, Omega Diagnostics and Open Orphan, remain good buying opportunities. Synairgen (TP 420p): countries will still want to stockpile SNG001 as there is currently no broad spectrum antiviral and there isn't enough data on how effective this vaccine is on elderly or sick people. Avacta (TP 310p) and genedrive (TP U/R): there is a continued need for rapid and convenient tests. Omega Diagnostics (TP U/R): antibody tests could be used to confirm immunity. Open Orphan (TP 28p): challenge studies could be used to perform head-to-head clinical trials between different first generation vaccines, and the eventual second generation COVID-19 vaccines.

Avacta*

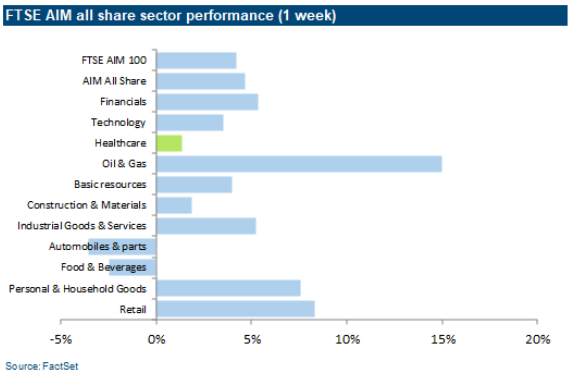
Positive Progress Report

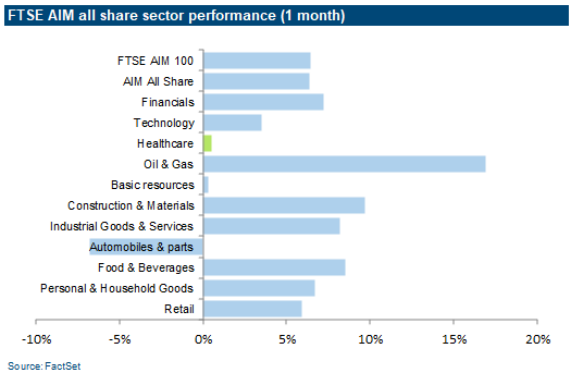
Avacta remains on track to meet its key Q4 2020 milestones, namely (i) complete first pilot batch and carry out a clinical evaluation of the professional use of SARS-CoV-2 rapid antigen test, (ii) clinical evaluation and partnership for the BAMS™ SARS-CoV-2 test and (iii) UK regulatory filing for AVA6000 (pre|CISION™ chemotherapy). Confirmation that BBI Solutions has developed a scalable manufacturing

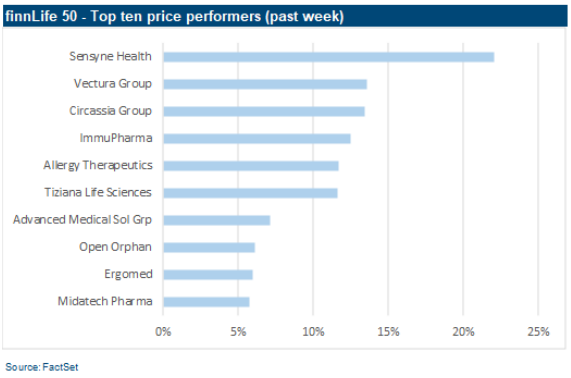
process for the SARS-CoV-2 antigen test with very good analytical sensitivity, using laboratory samples of COVID-19, is a key milestone that derisks this programme further. Near-term, we expect data from clinical evaluations highlighting the sensitivity and specificity of the antigen test to be released, before the final clinical validation, using final production batch tests, is undertaken. We maintain our target price of 310p (with a range of 211-796p).

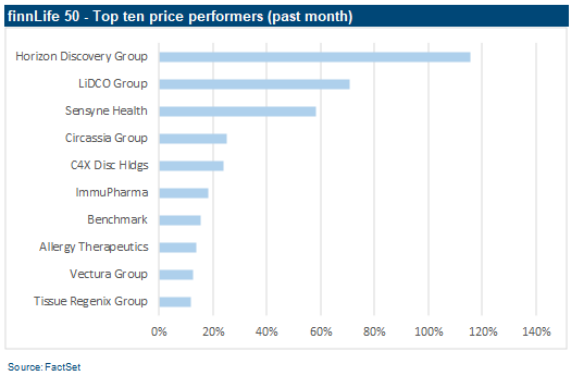
-Lateral flow antigen test update: Confirmed that very that very good analytical sensitivity with laboratory samples is being obtained with a highly scalable test device developed by BBI Solutions, with sensitivity in the expected clinical range for the spike protein. Avacta confirmed also that is developing in parallel both saliva and anterior nasal swab sampling methods, which should broaden the commercial opportunity and ensure that it can address a range of use cases.

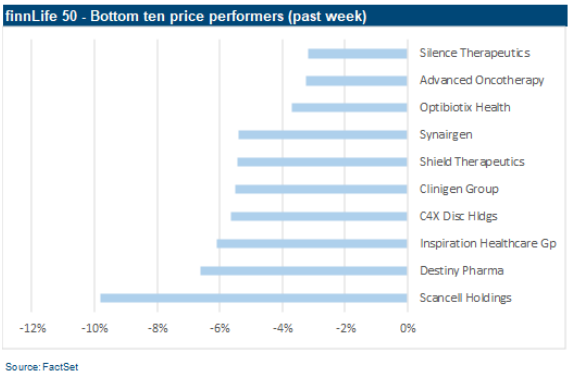
-Next steps: Confirmed that clinical samples will now be evaluated as a precursor to a much larger clinical evaluation study with COVID-19 patients of known viral load to determine the clinical sensitivity of the test. In parallel, BBI Solutions is working to finalise and validate the manufacturing process so that a full clinical validation can be carried out on the final product to support the regulatory approval process for the test.

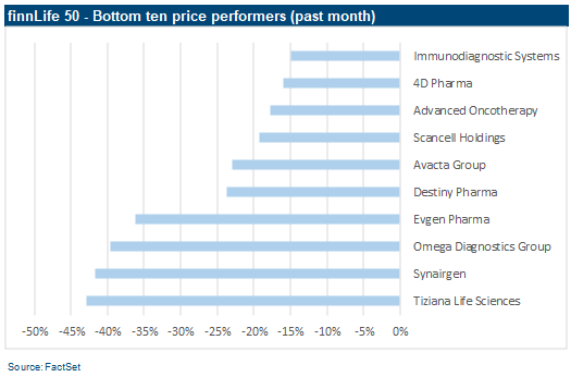












Research reports and comments in the past two weeks

Company	Date	Title
finnCap Sector Note	23-Nov	Rude Health: COVID-19 news alert, AstraZeneca's early vaccine data
Evgen Pharma*	23-Nov	STAR trial (COVID-19) starts enrolment
Avacta*	23-Nov	Positive progress report
finnCap Sector Note	17-Nov	Rude Health: COVID-19 news alert, moderna's early vaccine data
genedrive*	17-Nov	£2.5m influenza challenge study contract win
finnCap Sector Note	10-Nov	Rude Health: COVID-19 news alert, Pfizer/BioNTech early vaccine data
Destiny Pharma*	10-Nov	Up to £11.5m funding and acquisition

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Download our latest Q3 Quarterly Report, on the theme of Cell and Gene Therapy here.

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