

AVACTA GROUP LTD

UPDATE

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Ticker: AVCT.L
Price (p): 60.00
Shares in issue (m): 176.0
Market cap. (£m): 105.6

Introduction

This update note follows on from our Investment Thesis on Avacta Group, viewable here:

<https://aimchaos.files.wordpress.com/2020/03/avacta-group-investment-thesis-3.pdf>

Since we published our Investment Thesis for Avacta Group ('Avacta') on 1 March 2020, two significant announcements have been made. Firstly, the Company stated that it had raised £2m in new equity from two high net worth investors. Shortly after this, it announced that it had augmented the placing by £3.75m. Two days later, Avacta declared that it had entered into a collaboration with a global biopharma business, Cytiva, to "develop and manufacture an Affimer-based point-of-care rapid test intended for screening of large populations to diagnose the COVID-19 coronavirus infection". The implications of this are of huge significance, both with regards to the Company's prospects going forward and to the global battle against the coronavirus pandemic. In this note, we examine Avacta and Cytiva's intended product, and how it fits into the overall testing kit market for SARS-CoV-2, the virus that causes the coronavirus disease (which is itself known as 'COVID-19').

Types of test for SARS-CoV-2

Before we examine Avacta's test under development, we shall first explore the various test kits that are already being used worldwide to detect SARS-CoV-2. At present, there are two types of testing kit: PCR tests and antibody tests. In short, PCR tests reveal whether the patient currently *has* SARS-CoV-2. Antibody tests reveal whether the patient has *had* SARS-CoV-2 in the past.

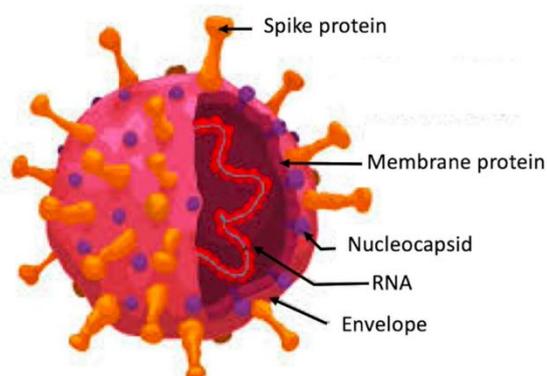
1) PCR tests

A polymerise chain reaction ('PCR') test detects the presence of a virus in a patient. It is effective from a few days after infection (even pre-symptomatic) to a couple of weeks after first symptoms (longer for acutely ill).

The test works by detecting a specific component of the virus. In order to test a patient, a swab is taken from the back of the throat or nose. The sample is sent to a laboratory, where it is processed via specialist machinery. The RNA, which holds the virus' genome, is extracted from the virus particle. Certain regions of the genome are then amplified by using a technique known as *reverse transcription PCR* ('RT-PCR'): this effectively converts the RNA into DNA, and then creates multiple copies which can be more easily detected.

PCR machines range considerably in size: the smaller models process several dozen samples simultaneously, whilst the largest, well over 1,000. The latest models yield results in approximately 45 minutes, compared to the older models that take up to four hours.

Exhibit 1: coronavirus structure



Because samples must be sent to the laboratory for testing, the turnaround time from the patient giving a sample to receiving the test result may range from several hours (e.g. if the patient is a nurse, working in a hospital that has its own PCR machinery installed onsite) to several days (e.g. if the patient is someone showing symptoms of COVID-19 and is self-isolating at home, having sent in his/her sample via post).

Generally speaking, the advantages of PCR testing are that they have high sensitivity (i.e. the ability of a test to correctly identify those with the virus); and high specificity (i.e. the ability of the test to correctly identify those without the virus). In short, they are extremely reliable in detecting the SARS-CoV-2 virus in patients.

Needless to say, PCR testing is of vital importance across the world in fighting the COVID-19 pandemic. It informs healthcare workers which patients currently *have* the virus, and consequently who should be treated for it. It is *the* fundamental triage tool for healthcare systems across the globe.

It is also crucial for governments in tracking the current infection rate across their respective nations, which is itself key in dictating the development of policies in fighting the virus across those nations.

However, it has been extensively documented in the media just how dramatically PCR testing has varied from nation to nation. In Exhibit 2 below, we provide data for a selection of countries to demonstrate this variation:

Exhibit 2: nationwide tests taken to date by a selection of countries

Country	Population (m)	Total tests	Tests as a % of population
Iceland	0.34	36,339	10.7%
Italy	60.5	1,073,689	1.8%
Iran	84.0	299,204	0.4%
Spain	46.8	600,000	1.3%
UK	67.9	382,650	0.6%
USA	331.0	2,832,258	0.9%

Source: worldometers.info

There are numerous factors as to why such major variation exists. Besides the most obvious – population size – we feel that it is largely due to a combination of pre-existing testing capacities of individual countries (primarily in private sector labs), and the markedly different responses in 2020 by counties in scaling up their existing capacity as rapidly as possible. The latter is itself dictated by a combination of the quality of a nation’s healthcare system as well as its pharmaceuticals sector, and of the specific policies a nation’s government has adopted for SARS-CoV-2 testing. For example, some governments opted from the very outset to test as many of its population as possible, whilst others only permitted the testing of those who showed clear symptoms or who had recently travelled to and from known virus hotspots across the world.

Exhibit 3: examples of PCR tests currently in use worldwide

Company	PCR test name
LabCorp	COVID-19 RT-PCR Test
Thermo Fisher Scientific	TaqPath COVID-19 CE-IVD RT-PCR Kit
Novacyt / Primerdesign	genesig 2019-nCoV test
Cepheid	Xpert® Xpress SARS-CoV-2 Test
Abbott Laboratories	Abbott ID NOW™ COVID-19 Test
Hologic	Panther Fusion® SARS-CoV-2 Test
Roche Molecular Systems	cobas® SARS-CoV-2 Test

2) *Antibody tests*

When a virus (or other pathogen) enters the human body, the immune system creates certain proteins – *antibodies* – that bind to the virus structure and neutralise it. It takes at least several days after transmission for the human immune system to create antibodies that are specific to the pathogen in question. Once produced, however, antibodies can last for a long time in the body – many months, and often many years. During this time, the body is protected from subsequent attacks by the pathogen. This is, of course, known as *immunity*.

In relation to the SARS-CoV-2 virus, not enough time has yet passed for the global medical community to have gained a complete picture of how long antibodies will remain in the body and provide immunity. It has been reported that some patients have already been re-infected with the virus.

The incubation period for the SARS-CoV-2 virus is anywhere between one and 14 days. It takes 1-2 weeks for the human immune system to produce antibodies (in detectable quantities) against SARS-CoV-2. A patient will usually recover in days 10-14 after having contracted the virus.

An antibody *test* detects the presence of a specific type of antibody that is produced by the immune system against a specific pathogen. Antibodies are found in the bloodstream (or ‘serum’). The test works by taking a blood sample and testing for the presence of the specific type of antibody in it. [Accordingly, antibody tests are also referred to as *serological tests*.]

The antibody / serological test thus reveals whether a patient has *had* the virus.

The technology of the antibody test is very simple: it does not require a reagent, but simply tests the patient’s blood for the antibodies using virus proteins installed on the strip. There are many models in use and under development – but in brief, they are small, handheld devices that can be used by the patient without the need for the assistance of a healthcare worker. They are point-of-care (‘POC’) tests. A blood sample is taken (via a finger prick) and fed it into the device, which provides a positive or negative reading after 10-20 minutes.

There are a number of reasons why the antibody test is of high importance to governments. It could be a key tool in understanding the percentage of the population that has already been infected; it could assist in understanding how long immunity lasts; and it could indicate who should be prioritised for vaccination (when one is successfully developed).

Most significantly, however, is its value in being used as a so called ‘immunity passport’. This concept is currently being investigated by a number of countries, such as Germany: if a person tests positive (i.e. has *had* the virus), that person would be permitted to return to work, as he/she would now have immunity. This would be a crucial tool for governments in easing lockdown restrictions.

Given the simplicity of the device, there are well over a hundred models that have been, or are being, developed worldwide. Owing to this simplicity, and in tandem with the urgent need for testing, the US’ Food and Drug Administration (‘FDA’) decided to waive initial review of the tests as part of its emergency response to the coronavirus outbreak. This has resulted in dozens of sub-par devices that do not have high enough sensitivity and specificity. The sale and distribution of such antibody tests for SARS-CoV-2 to the general public could have disastrous consequences, as those who have *not* actually contracted the virus in the past and built up immunity, might be led to believe (by an inaccurate test) that they have – and then go out and about, *actually* contract the virus, and subsequently spread it.

This is why the UK, for instance, has to date rejected numerous models of antibody tests for use within the NHS and the wider public sector, and for distribution to the public (try typing ‘coronavirus test’ into Amazon’s search box!).

However, other nations have been using antibody tests extensively. A private UK-based firm, SureScreen, that states that its antibody test for SARS-CoV-2 is 98% accurate, is currently selling its tests to private companies in mainland Europe for £6 a test.

In the US, NASDAQ-listed SCWorx Corp announced this week that it had received a \$35m purchase order from Rethink My Healthcare, a US-based virtual healthcare network, for two million of its antibody tests, *IgM/IgG Rapid Detection Kit*.

We believe that it will be a matter of weeks at most until the UK sources an antibody test that it feels is accurate enough to use within the NHS and for distribution to the general public.

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There has been substantial attention paid to antibody testing in the mainstream media – particularly in the UK. In short, it could be a key tool in easing lockdown restrictions via wholesale population screening and the provision of the ‘immunity passport’. The idea of ‘at-home’ testing also seems to have caught the imagination of the general public.

As antibody testing only indicates whether the patient has *had* the virus, it has a number of limitations. Antibody testing will not reveal whether the patient is still infectious and shedding the virus. Accordingly, for the portion of a population that has not yet contracted the virus, there will be a necessity to test regularly going forward – at least until a vaccine has been universally administered. We discuss this more extensively in the next section.

Point-of-care antigen tests

There is a third type of SARS-CoV-2 test under development that the mainstream media has not widely picked up on: *antigen testing*. This type of testing combines the key benefits of both PCR and antibody testing; it reveals whether the patient currently *has* SARS-CoV-2; and it can be developed as a point-of-care (‘POC’) device that yields a result within a few minutes.

An antigen is a molecule (usually a protein) that is specific to a pathogen and is normally found on the pathogen’s surface. In the case of SARS-CoV-2, the antigens are the spike proteins on the outside of the coronavirus structure and the nucleocapsid proteins embedded on its surface (see Exhibit 1, p.1). It is the presence of the antigens specifically that catalyses the immune system to generate antibodies that will subsequently neutralise the virus (as explained on p.2).

An antigen test works by using the specific antibody (or *antibody memetic*) that recognises the specific antigen of any given pathogen. A saliva sample taken from the patient is inserted into/onto the device: if viral particles are present, the antibodies incorporated into the test bind to the antigens of the particles – and the test records a positive result.

Antigen tests can be developed in a lateral flow rapid test format. Lateral flow tests are simple cellulose-based devices intended to detect the presence of a particular substance (such as an antigen) in liquid sample – without the need for specialized and costly equipment. The most well-known and widely used lateral flow rapid test is the home pregnancy test. In brief, these tests run a liquid along the surface of a pad with reactive molecules that show a visual positive or negative result (e.g. one blue line appears – the test is negative; two blue lines appear – the test is positive). Lateral flow tests are simple, economic and generally show results in around 5-10 minutes. As such, they are well suited for home / POC testing.

As we examine in detail on pp.9-10, an accurate and rapid POC test for whether a patient currently *has* the virus could be nothing short of a gamechanger in the battle against the coronavirus pandemic.

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The reason for the general public’s lack of awareness of the POC antigen test is that only a handful of companies worldwide have yet announced that they are working on developing such models for the SARS-CoV-2 virus. Certainly, no POC antigen test has yet been approved by any governing bodies worldwide.

The POC antigen test is much more difficult to develop than a POC antibody test. Whereas the antibody test requires only the virus proteins in its diagnostic assay (which are easy to obtain, given that the virus’ genetic sequence has been publicly available since January), the antigen test requires the development of a *reagent* to capture the virus. A novel virus such as SARS-CoV-2 requires a novel reagent, and this reagent takes time to develop – often many months.

This is primarily due to reagents being antibody-based. It is the antibody component that takes the most time to develop. As we explain in the following section, Avacta’s proprietary antibody memetic technology, Affimers, can be used in the reagent instead of antibodies. Affimers take significantly *less* time to develop than antibodies: that is why we believe that Avacta could enjoy first mover advantage in the development and commercialisation of POC antigen testing for SARS-CoV-2.

To our knowledge, only two other companies besides Avacta have publicly announced that they are developing a POC antigen test for the SARS-CoV-2 virus: Sona Nanotech and Mammoth Biosciences.

Avacta's collaboration with Cytiva

The detail of the collaboration

On 8 April, Avacta announced that it had entered into a collaboration with a global biopharma business, Cytiva, to “develop and manufacture an Affimer-based point-of-care rapid test intended for screening of large populations to diagnose the COVID-19 coronavirus infection.”

Cytiva is a global provider of technologies and services that help advance and accelerate the development and manufacture of therapeutics. Cytiva has nearly 7,000 employees and operations in 40 countries. Its revenues in 2019 amounted to \$3.2bn. Formerly known as GE Healthcare Life Sciences, the business was acquired in March 2020 by NYSE-listed Danaher Corporation (NYSE:DHR), for \$21.4 billion. Danaher is a globally diversified conglomerate. It generated revenues of ~\$18bn in 2019 and has a current market capitalisation of \$104bn.

Avacta is already generating Affimer reagents that detect the COVID-19 virus. It intends to have them fully developed by the end of next month. Cytiva will then transfer this diagnostic assay onto its proprietary point-of-care test strip platform – a lateral flow test device. Subsequently, Avacta and Cytiva will work together to complete analytical and clinical validation of the test as quickly as possible.

The device will work by testing a respiratory sample (saliva) for the antigens on the surface of the virus particle. It will yield a result within 10 minutes.

No commercial details have been disclosed (although we make some assumptions for the purpose of providing illustrative financials on p.11). Avacta *has* stated that it will own the intellectual property relating to the COVID-19 Affimer reagents that it generates, and that it will retain all the commercial rights to future products. This is of high importance: it ensures that Avacta will be able to use the same reagents in other collaborations with third parties. Indeed, the CEO has disclosed that the Company is currently in discussions with other potential global partners to use the Affimer reagents in their own test strips. We expect further collaborations to be announced in the coming weeks.

How has Avacta been able to take the lead in the development of a POC antigen test?

Avacta is leading the race to develop and commercialise a POC antigen test for SARS-CoV-2 due to its proprietary Affimer technology, and the advantages it enjoys over standard antibodies in creating reagents for novel viruses. Below, we have copied in a section from p.3 of our Investment Thesis, in order explain these advantages:

“Affimers are based on the naturally occurring human protein, stefin A: they constitute a ‘protein scaffold’ and are an alternative to antibodies (known as an ‘antibody mimetic’). In the same way as an antibody, an Affimer molecule is capable of binding to and capturing a target molecule (such as a peptide or another protein). Affimers have a number of technical advantages over antibodies that make them a first-in-class therapeutic protein platform:

- Affimers are approximately 90% smaller than antibodies. This provides several performance advantages, such as allowing for better tissue penetration and increased packing density on surfaces.

- Affimers are approximately 90% cheaper to produce than antibodies. Antibodies are often generated by immunising an animal and purifying the antibodies from the animal's blood. This process can take many months. In contrast, Affimers are generated via a standard in-vitro process which does not use animals, but E. coli – consequently the process takes only a matter of weeks.

- In addition to a lower cost, the method of manufacturing guarantees a consistent and high-quality supply, which is not always the case with antibody production.

- As Affimers are ‘fully-human’ proteins – as opposed to antibodies which are often generated from animals – this ensures a low immunogenicity risk (i.e. they are more likely to have a good safety profile in humans).

- *The loop structure of an Affimer creates an antigen binding surface: this ensures flexible formatting, which in short makes Affimers easier to modify and develop than many antibodies.”*

It is simple to perceive from the above why Avacta could be the fastest company to bring an effective POC antigen test to market – notably, it takes weeks to develop Affimers, as opposed to many months for antibodies.

Moreover, we would add that Affimers are *highly specific*. They are able to detect a specific target and have a very low risk of cross-reacting with other closely related targets. This reduces the probability of the POC tests yielding false positive results.

That Avacta is well positioned to create one of the first POC antigen tests for SARS-CoV-2 should not come as a surprise to investors. In 2016, the Company successfully generated Affimer binders for Zika virus diagnostics (i.e. reagents). Within just 13 weeks of having received the virus target, Avacta had generated – and validated – three distinct and highly specific binders to Zika virus.

Below, we quote the RNS (22.06.2016) verbatim:

- *Highlights the potential of Affimer technology to support global rapid response for novel point-of-care diagnostics and health screening...*

The three Affimer binders are highly specific to the Zika NS1 protein and can differentiate in human serum from five other closely related viruses that give similar symptoms: Dengue, Yellow Fever, West Nile, and Japanese and Tick-borne Encephalitis. Since these viruses are very similar, there is currently no validated antibody that detects Zika virus specifically, which is a limiting factor in the development of a reliable, quick diagnostic test...

The ability to rapidly generate new diagnostic reagents in response to outbreaks of infectious agents is critical to meeting an urgent medical need, as recently evidenced by the SARS and Ebola virus outbreaks. The very high specificity of Avacta's Affimer technology, together with the speed with which new Affimer binders can be identified and characterised, makes the technology ideal for rapidly responding to the need for detection and monitoring of new outbreaks.

The Group intends to commercialise Affimer based rapid diagnostics through co-development and licensing to third party diagnostics developers...

The CEO's statement from the RNS is equally significant:

“Avacta's Affimer technology offers a distinct advantage over antibodies in infectious disease diagnostics in terms of both rapid development times and specificity. The identification of these three Affimer binders means that new diagnostic tests could be developed that have the potential to diagnose a Zika infection from its early stages, and would be suitable for low cost, rapid point-of-care diagnostics that could be deployed widely in the field or at US transport hubs for example.”

It is also worth noting that the following year, in November 2017, a PHD student at the University of Leeds published a thesis entitled *Production of a novel Affimer based biosensor for the detection of porcine reproductive and respiratory syndrome virus (PRRSV) nucleocapsid protein* (viewable online at <http://etheses.whiterose.ac.uk/19759/>).

The thesis makes for fascinating reading, in light of what the world currently faces. To quote from the abstract (p.ii):

“Porcine reproductive and respiratory syndrome virus (PRRSV) is an economically important infection with no current point of care diagnostic available. PRRSV causes reproductive and respiratory illness in swine with the recent emergence of highly pathogenic strains. This highlights the need for measures to control the spread of this infection to be taken more seriously in order to reduce the economic impact of this virus. Current diagnostics for PRRSV are laboratory based and inherently these tests are expensive and are not rapid enough for the adequate management of outbreaks of the virus and implementation of biosecurity measures.

This study presents a novel lateral flow device, using Affimer binding proteins to detect the nucleocapsid protein of PRRSV within a clinical sample to provide a cheap, rapid and reliable diagnostic for this infection in clinical samples.”

Even more extraordinarily, the thesis extensively references the use of Affimers in reagents not just for detecting PRRSV, but for *coronaviruses* and other similar viruses within the nidovirus order.

Finally, we would urge readers to look at another subsection of the thesis, entitled: *Use of Affimers to overcome antibody limitations* (p.179). It explains in detail why Affimers are far more suited than antibodies to be used in reagents on lateral flow devices designed to test for the presence of a coronavirus.

To put it simply, previous research – and successful testing with a similar virus, Zika virus – has already demonstrated that Affimers are very likely the ideal protein scaffold for usage in lateral flow rapid tests designed to detect the novel SARS-CoV-2 virus.

Almost four years ago, Avacta in effect proved that its Affimer technology could be a key tool in battling a viral pandemic such as that which the world now faces.

The potential global market for a POC antigen test

You cannot fight a fire blindfolded. And we cannot stop this pandemic if we don't know who is infected.

We have a simple message for all countries: test, test, test.

WHO Director-General, Tedros Adhanom Ghebreyesus, 16 March 2020

As stated on p.2, PCR testing is of vital importance across the world in fighting the COVID-19 pandemic. It informs healthcare workers which patients currently *have* the virus, and consequently who should be treated for it. It is *the* fundamental triage tool for healthcare systems across the globe.

It is also crucial for governments in tracking the current infection rate across their respective nations, which is itself key in dictating the development of policies in fighting the virus across those nations.

PCR testing takes a minimum of several hours – and frequently several days, in many countries – for the patient to be given the result of the test after the sample has been taken.

The point-of-care antigen test, which yields a result within 5-10 minutes, could revolutionise testing policies. Initially, it would likely be granted only to healthcare systems, to be used by professionals on patients and frontline healthcare workers. Even so, the rapidity of the test would dramatically improve the current testing systems of nations across the world. POC antigen tests in general use within healthcare systems would:

- Drastically accelerate the triage process, thus ensuring that patients much more rapidly receive the correct treatment;
- Determine whether patients who have been diagnosed with the infection require further treatment and testing;
- Ensure infectious patients remain isolated;
- Avoid unnecessary isolation of no-longer-infectious patients;
- Free up significant time for healthcare workers (who could then for example spend more time caring for hospitalised patients);
- Substantially decrease the demand for personal protective equipment ('PPE'), swabs and other items that is already in extremely short supply worldwide;
- Dramatically improve efficiencies of healthcare systems (notably, via the removal of administrative burdens that are part and parcel of PCR testing).

To an extent, POC antigen testing would not only augment – by multiples – the existing testing capacity provided by PCR testing, but it could in fact *displace* a significant portion of that existing POC testing capacity.

However, it is *retail distribution* of POC antigen tests that could be the real gamechanger in the battle against COVID-19. When such tests are granted approval for marketing to the public, via high street retailers such as Boots and e-commerce platforms like Amazon, government testing strategies could be transformed. POC antigen tests available to the public would:

- Remove unnecessary quarantine measures for those who have not been infected;
- Verify if infected patients are ready for release from quarantine;
- Enable governments to much more efficiently track current national infection rates (if for example a government App was launched, to be used by everyone in tandem with the POC antigen test);
- Enable rapid responses (such as mini lockdowns) to emerging virus hotspots across the nation (assuming the aforementioned App is launched);
- Enable the screening of individuals entering closed environments such as planes and cruise ships, cinemas and restaurants, schools and universities, offices and factories, sports stadiums and concert venues.

In effect, an accurate POC antigen test for the SARS-CoV-2 virus could prove to be a *crucial tool* in lifting lockdowns across the world.

In 2019, it was almost unimaginable that the lockdowns now in place across many of the world's most democratic of countries could have ever occurred. In light of the unprecedented measures taken to battle the pandemic, it would now be entirely reasonable to suggest that airlines across the world may *insist* on all passengers taking a POC antigen test before boarding. With the test only taking 5-10 minutes, the extra admin would hardly be prohibitive. We imagine that queuing for flights could be split into two segregated areas, with passengers only permitted into the second area once they have submitted their completed tests (which they would collect upon entrance to the first area).

In just this example of how POC antigen tests could be used at strategic checkpoints, it is noteworthy that circa *4.3 billion* passengers were carried on scheduled flights in 2018.

Another example of POC antigen checkpoint testing could be corporations only permitting entry to the office to their employees once they have submitted a POC test, at the office door. It may be that a test is only required of each employee on a weekly basis (Monday morning being the obvious choice).

Another point to consider is that millions of households are likely to stock up on these tests once they become available to the public, to be held as a staple in their medical supply cabinets. We have seen panic buying of toilet roll in the UK (and ammunitions in the US!); it is not difficult to imagine people hoarding POC antigen tests. The likes of Boots and Amazon would be sold out of the tests constantly.

The implications for Avacta in developing the first POC antigen test for COVID-19

The successful development of a POC antigen test will unlock a major, immediate-term revenue opportunity for Avacta. The commercial details of the collaboration with Cytiva have not been disclosed: in order to demonstrate what financials might look like for the Company (for illustrative purposes), we have made some simple assumptions (N.B. this should *not* be considered as guidance by the Company):

- We assume that the collaboration will be structured as a royalty-bearing agreement, and that Avacta (as it is only providing one – albeit critical – component of the lateral flow rapid test) will be entitled to a royalty of somewhere between 5% and 20% of gross product sales.
- We assume a price range of between \$3 and \$8 per test, based on the prices of antibody tests already on the market and of other lateral flow devices in widespread use such as home pregnancy tests; and on the necessity to ensure the product is affordable for wholesale population screening.
- Until a vaccine is developed, we consider that between one and three billion POC antigen tests for SARS-CoV-2 could be sold worldwide per annum ('pa').
- We assume that Avacta will bear none of the costs for production, marketing, sales and distribution.
- We assume that Avacta and Cytiva's lateral flow test will acquire and maintain a steady 10% share of the global market for POC antigen tests for SARS-CoV-2.

Accordingly:

- Global sales pa of antigen-based lateral flow rapid tests for SARS-CoV-2: \$3bn - \$24bn
- Avacta / Cytiva's product sales pa: \$0.3bn - \$2.4bn
- Avacta's royalty receipts pa (conservatively assuming 10%): \$30m - \$240m

To reiterate, we have had no guidance from the Company for these figures: we provide these figures only to demonstrate how we feel the market for POC antigen testing might develop in the coming months, and how Avacta could be positioned to take advantage of it. There is of course a risk that its Affimer reagents are not suitable for Cytiva's lateral flow rapid tests – they may lack the required specificity, etc – and that the reagents are not commercialised at all.

Conversely, on successful development of the reagents and installation into Cytiva's devices, we could reasonably argue that the device's global market share could far exceed 10%, in light of the absence of other companies developing POC antigen tests for SARS-CoV-2. Avacta's crucial advantage over its competitors is the much shorter time it takes to develop Affimer-based reagents in comparison to antibody-based ones. With Cytiva's global scale and expertise, we can see no reason why the product could not achieve a global market share of say 25% to 50%, at least in the early months.

It could also be argued that the quantum of POC antigen tests produced globally pa could ultimately far exceed our estimate of 1-3 billion. Annual passenger flight numbers alone are almost 50% higher than the top of our estimate range (at least, in a 'normal' year!). It is not beyond the realms of possibility that a universal law could be enacted to enforce the testing measures for flights that we suggested on the previous page.

In our view, successful development and commercialisation of a POC antigen test will provide three key benefits to Avacta:

1) An immediate, and potentially very substantial, revenue stream

This revenue will be very high margin, as it will (we assume) be royalty-based. This could be funnelled into the Company's much more cash-hungry Therapeutics division, which intends to launch as many as three Phase I human trials for various cancer therapies within the next 24 months. As such, future equity dilution should be minimised – a crucial factor for shareholders to consider.

2) *Showcasing Avacta's antibody memetic, the Affimer technology, to a global audience*

A successfully developed POC antigen test for SARS-CoV-2 that is based on Affimer reagents will draw the eyes of industry participants and the investment community alike to Avacta, from across the globe. Antibody memetic platforms are becoming increasingly sought after: as we examine on pp.21-23 of our Investment Thesis, Ablynx, the owner of a competing antibody memetic named *Nanobody*, was acquired in June 2018 by global pharmaceutical company Sanofi for a total equity value of **€3.9 billion**, paid in cash. It is important to note that there was a bidding war for Ablynx, which indicates that there are other tier one players still in the hunt for antibody memetics such as Avacta's Affimer technology.

3) *Bringing Avacta's therapeutics pipeline to the attention of the global investment community*

In our Investment Thesis, we analyse Avacta's cancer therapies under development: its multi-specific immunotherapies; its reformulated, targeted chemotherapies; and its Affimer-based drug conjugates. In the paper, we provide our rationale as to why we feel that these therapeutics have the potential to genuinely change the landscape of the cancer treatment market. As investors are drawn to Avacta in the coming weeks because of its new work in SARS-CoV-2 antigen testing, they will examine other aspects of the business. For us, the potential upside residing within the Company's Therapeutics division dwarfs that of its Diagnostics division, even accounting for a global rollout of the lateral flow rapid test under development. We believe that most new investors will likewise perceive this and realise that the Company has been trading at a mammoth discount to fair value for years.

The £5.75m equity raise

On 2 April, Avacta announced that it was raising £2m via a subscription for new equity from two high net worth investors – one being billionaire businessman Mahmud Kamani, the co-founder and executive chairman of leading online fashion retail group, boohoo. We believe that the two investors directly approached the Company with the offer of their investment. After all, management had already stated to the market that it had sufficient cash resources until early 2021.

On 6 April, the Company announced that it would be augmenting the equity placing by £3.75m, to £5.75m. We are led to believe that this was to appease the existing major shareholders, who demanded pre-emption rights.

The cash injection will provide Avacta with a runway until the end of 2021 – and that does not account for any revenue generated from sales of lateral flow rapid tests, or for any potential upfront payment by a partner following successful results in the upcoming Phase I human trial for pro-doxorubicin (we estimate that this could be in the region of \$50m).

In short, we have high hopes that this could be the last equity raise that the Company carries out for the foreseeable future.

Potential near-term news flow

In the coming weeks, we expect that Avacta might report on the following:

- The securing of grant funding from the UK government and/or from charitable institutions to fast-track the development of the POC antigen test.
- Pre-orders of Avacta and Cytiva's POC lateral flow rapid tests. Avacta's CEO has already stated in a panel discussion on ITV's Good Morning Britain (9 April) that the Company is in discussions with Public Health England (who would of course be a key initial customer).
- Further collaborations to develop lateral flow rapid tests for SARS-CoV-2. This was specifically alluded to by Avacta's CEO in the Cytiva collaboration announcement: "...We are aiming to have developed Affimer reagents for a COVID-19 test by the end of May that can be transferred to Cytiva and *potentially to other global diagnostic manufacturers* to implement in a test strip."
- Collaborations to develop Affimer-reagent-based immunoassays. Immunoassay testing is a similar type of testing to PCR testing (it tests for whether the patient *has* the virus and is processed via large-scale laboratory equipment). Again, Avacta's CEO alluded to developing this sort of test during the Good Morning Britain discussion. Our opinion is that he would not have done so, had he not been certain that Affimer reagents could work well in such testing systems.
- Completion of generation of Affimer reagents and transfer to Cytiva. This should occur within six weeks.
- Production of prototype by Cytiva, validation work, and receipt of CE marking. We believe that this workstream will take between 8 and 12 weeks.
- Launch of the commercial product. Assuming all of the workstreams in the previous two bullet points are completed successfully, we estimate that commercial sales of the product could begin in August.

It should also be noted that Avacta's Preliminary Results for FY 2019 are due on Tuesday next week. The Company has already provided headline numbers for the year in recent trading updates, including revenues of £5.5m and net cash at 31 December of £8.7m. Of importance however will be the guidance provided on how the Company intends to progress its various in-house workstreams going forward, in light of COVID-19, and updates on its various ongoing collaborations.

Conclusion

COVID-19 was only identified in Wuhan, China, in December 2019. The virus spread with such velocity across the globe that on 11 March, less than three months after it was first identified, the World Health Organisation declared COVID-19 a pandemic. At the time of writing, just over 2 million people have been confirmed as having contracted the virus. 128,035 of those people have died. Furthermore, it is a certainty that that figure significantly understates the real death count. It has been well documented in the media that China might have under-reported its count by many multiples. Furthermore, most nations across the world have not included deaths caused by coronavirus that have occurred outside of hospitals (such as in houses or in care homes).

Nor is there any sign that the pandemic is abating. Whilst some nations have proved that lockdown measures have been highly effective in curbing the spread of the virus, it is too early to say what will happen when lockdown measures are lifted (which will of course happen many months, possibly years, before a vaccine is developed and administered universally – indeed it has already occurred in some countries). Whatever the case, prolonged lockdowns across the world are obliterating economies (unprecedented job losses, companies folding, debt skyrocketing), and causing immeasurable damage to society (to marriages and families, to mental health, etc). Lockdowns *must* come to an end shortly.

Nations must be prepared for this. ICU space in hospitals can be augmented, production of PPE and ventilators can be ramped up, even novel treatments can be developed. But until a vaccine is developed, *testing* is the most effective weapon in countries' arsenals in the war against the pandemic.

In this paper, we have explained why we believe that point-of-care antigen testing will be the most important type of test in this war. We have also detailed why Avacta is perfectly positioned to be a leading player in the development of such tests.

In our Investment Thesis, we set out our rationale as to why we believe that Avacta has the potential to attract a multi-billion-pound valuation in the years ahead. Simply put, the coronavirus pandemic has the potential to bring forward that target valuation, considerably.

Disclosure

The author of this paper, Myles McNulty, is a private investor. He and his family hold 1.0% of the ordinary shares of Avacta Group.

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