AVACTA GROUP LTD

UPDATE II: PART I

23.05.2020

Ticker:	**AVCT.L**
Price (p):	**187.0**
Shares in issue (m):	**208.5**
Market cap. (£m):	**389.9**

Introduction

This update note follows on from our April Update Note on Avacta Group, viewable here:

https://aimchaos.files.wordpress.com/2020/04/avacta-group-update.pdf

And from our original Investment Thesis, viewable here:

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

Much has changed in our Covid-19-wracked world since we published our last Update Note on Avacta Group ('Avacta'), on 15 April 2020. The global death count has increased over the five-week period by 200k, from 141k to 341k. There are signs that the situation is improving, notably throughout East Asia and Europe, the first and second epicentres of the pandemic respectively. Many countries have gotten to grips with the virus and, through varying lockdown and social distancing measures, are successfully flattening the infection curve. Lockdowns are being eased across these geographies, and economies are slowly re-opening.

Conversely, the epicentre of the virus has shifted to the Americas – particularly Latin America – where countries are struggling to contain major outbreaks. Brazil has now reported the second most cases in the world, with the number of deaths surpassing 21k. It is believed that in Mexico the current death count of 7.0k has been under-reported by several multiples. South America is suffering from a combination of densely populated urban areas and a severe shortfall in testing capacity. In Brazil, 0.35% of the population has been tested; in Mexico, 0.16%. This compares to 6.5% and 4.8% in Spain and the UK, respectively.

There is no definitive, effective treatment yet for Covid-19. The US Food & Drug Administration ('FDA') has granted emergency use authorisation to two treatments thus far, namely Gilead's remdesivir, and chloroquine and hydroxychloroquine. Both are a form of existing, repurposed treatments (the first, an antiviral drug that failed in clinical trials against Ebola in 2014; and the second, oral drugs used for the prophylaxis and treatment of malaria). They may only be used in the most severe cases within hospitals, and the efficacy of both treatments is highly questionable. On the vaccination front, record pace is being set in the development of over one hundred vaccines across the world, with over ten now in clinical trials. However, even in the best-case scenario, mass production and rollout of a successful vaccine would not commence until early 2021. In reality, we believe that it is likely to be towards the end of next year.

With regards to testing, PCR capacity continues to be ramped up, but the nature of this testing has prevented wholesale population screening from occurring. On a more encouraging note, Swiss healthcare giant Roche has successfully commercialised the first truly reliable antibody test (100% sensitivity; 99.8% specificity). This test could play a significant role in easing global lockdowns. However, the test does not assist in screening for *currently infectious* people. Furthermore, there is uncertainty as to the effective level of immunity a person who has caught the virus, and subsequently recovered, now has. As such, the idea of introducing an 'immunity passport' for those who have already had the virus is potentially a dangerous strategy – at least until sufficient time has passed, and data generated and analysed, to be sure that naturally generated antibodies do indeed provide effective and long-lasting immunity.

We wrote extensively in our previous note of accurate, point-of-care ('POC') antigen tests being *the key tool* for lifting lockdown restrictions. Governments are now clearly very aware of this type of test and its implications; yet the mass media *still* remains relatively ignorant of it. We believe that at least one out of the handful of companies developing these tests will commence commercial production in July: in our view, Avacta will be one of, if not *the*, first to market. Furthermore, we feel that once there, it will have a first-in-class product. This week, the Company established its first distribution partnership for its COVID-19 POC antigen test, intended for the direct-to-consumer market: we anticipate that more commercial partnerships will be announced over the next fortnight.

Last week, Avacta discovered that several of its Affimer reagents that bind to the SARS-CoV-2 virus' spike protein (which will be used to develop its POC antigen test) also block the interaction between said spike protein and a receptor found on human cells, called ACE2, to which the virus spike protein binds, in order to infect cells. This opens up the potential for developing an Affimer-based neutralising therapy for COVID-19.

Neutralising therapies can be used either to treat already infected patients, by limiting disease progression; or as a prophylactic, providing temporary passive immunity to those most at risk of exposure to the virus, such as healthcare workers.

There are numerous neutralising therapies for COVID-19 currently being developed worldwide, with hundreds of millions of dollars having been invested in them. These are all antibody-based therapies. In a similar vein to antigen testing, an *Affimer* neutralising therapy would offer numerous advantages over an *antibody* neutralising therapy – most notably in speed and cost of manufacture.

In its announcement last week, Avacta essentially declared an open invite to Big Pharma, seeking a partner with the resources to fast-track an Affimer-based neutralising therapy. We anticipate that the Company will secure one in the coming weeks, given the substantial commercial interest being shown in the space at present. For us, the most obvious partner for Avacta is British-Swedish multinational pharmaceutical company, AstraZeneca. On 8 April, AstraZeneca announced that it was "joining forces with government and academia with the aim of discovering novel coronavirus-neutralising antibodies." This is one of the most challenging aspects of developing a neutralising therapy – and Avacta has declared that it has *already* discovered its own Affimer-equivalents. As we cover extensively in our original Investment Thesis, Affimers were essentially designed to be superior protein scaffolds to antibodies: they overcome many of the limitations of antibodies. Consequently, it seems fairly obvious to us that Big Pharma will be extremely eager to lay its hands on these particular Affimer reagents with the aim of fast-tracking the development of a neutralising therapy.

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Owing to the rapid and constant developments in the war against COVID-19, and the incredible speed at which Avacta is moving to assist in it, we have broken our third note on the Company into three components, so as to publish as quickly as possible.

This first section of the three-part Update Note focuses on the point-of-care antigen testing market for SARS-CoV-2, the virus that causes the coronavirus disease (which is itself known as 'COVID-19'). We detail the recent progress that Avacta has made in developing its two types of antigen test, and our view on how and when each test will be brought to market.

In the second section of the Update Note, we will examine neutralising therapies for COVID-19, and how Avacta and a partner could be well-placed to fast-track the development of an Affimer-based neutralising therapy.

In the third and final section of the Update Note, we will provide a detailed valuation analysis and updated Investment Thesis for Avacta.

We intend to publish both the second and third sections of this Update Note within the next fortnight.

Antigen testing for SARS-CoV-2: Overview

Please see pp.6-11 of our Update Note, 15.04.2020, for a detailed examination of the POC antigen test market for SARS-CoV-2, and of Avacta's lateral flow test under development.

Point-of-care testing: governments are waking up to the technology and its implications

In our previous note, we remarked that the reason for the general public's lack of awareness of the POC antigen test is that, to date, only a handful of companies worldwide have 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

In the subsequent five weeks, however, we have gained greater clarity on the various tests in development. Moreover, top political figures, influential medical professionals and academics alike have begun to reference the POC antigen test as a key tool in easing lockdown restrictions – provided, of course, it is successfully commercialised.

Dr. Deborah Birx, the White House coronavirus task force coordinator, in an interview on NBC News (Sunday 26 April), stated:

"*We have to have a breakthrough in innovation in testing. We have to be able to detect antigen… RNA testing (PCR) will carry us certainly through the Spring… but we need to have a huge technology breakthrough and we're working on that.*"

The day afterwards, Paul Romer, a former World Bank chief economist who won the 2018 Nobel Memorial Prize in Economic Sciences for modelling the US and global economies, called for a $100 billion COVID-19 testing programme, *per annum* (or until a vaccine has been universally administered), in the US alone. He stated that the government should be testing every person, every two weeks, and isolate anyone who tested positive.

Earlier in April, Harvard University published a report entitled *Roadmap to Pandemic Resilience*, which called for 5 million tests per day in the US by early June, increasing to 20 million tests per day by midsummer.

Given that the US has completed a cumulative total of circa 14 million tests this year, it is abundantly clear that there is no chance that PCR capacity – even if it were scaled up by several multiples in the coming weeks – would be sufficient to implement the desired wholesale population screening.

In our previous Update Note, we listed numerous examples of how POC antigen tests could be used to ease lockdowns (pp.9-10). It is worth highlighting that since then, screening measures have been introduced by numerous entities that could be *drastically* improved with POC antigen testing. For example, we stated:

"*…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 the week following the publication of our note, the CEO of Heathrow Airport, John Holland-Kaye, wrote to health secretary Matt Hanocock, calling for an internationally agreed package of testing measures for SARS-CoV-2, which could include temperature checks and antibody tests. The very fact that temperature checks had been called for is yet further evidence that even the most prominent of industry captains are unaware that POC antigen testing is only weeks away from being commercialised.

On the subject of testing at airports, other nations have imposed much stricter measures on the flow of people through their borders. For example, passengers landing in Hong Kong are subject to an eight-hour screening process (the majority of which involves waiting for the PCR test to be taken, processed and returned).

We also suggested:

"*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).*"

It has been widely reported that corporations across the world are now installing and using thermal scanner technology that employees must pass through on entrance to their workspace each day.

Needless to say, thermal scanning is hardly a reliable tool for detecting those infected with SARS-CoV-2, even if it is only to be used as a preliminary diagnostic that is intended to be followed by PCR testing for suspected cases. A person might have a temperature for any number of reasons: enforcing a PCR test on every single person who has one would be a colossal waste of valuable PCR capacity.

In our illustrative forecasts in our previous note (p.11), we suggested that the global market per annum for POC antigen tests for SARS-CoV-2 could be between 1 billion to 3 billion units – at least until a vaccine had been successfully developed and administered en masse. However, the expert opinions mentioned on the previous page are suggesting testing amount to *7 to 8* billion per annum – and that is *just in the US*, a country that accounts for only 4.2% of the global population.

Furthermore, in light of *already existing* practises in airports such as Hong Kong International Airport, and the recent demands of the Heathrow CEO, it really might become a reality that all passengers globally are required to take a POC antigen test, pre-boarding. That alone would amount to several billion tests.

In summary, the global demand for POC antigen tests could ultimately come in many multiples above our previous best case estimate of 3 billion units per annum.

Antigen testing for SARS-CoV-2: Avacta's point-of-care test

Developments on Avacta's Affimer-based POC antigen test

Having announced that it was developing a POC antigen test for SARS-CoV-2 on 8 April via its partnership with Cytiva, Avacta has since updated the market several times on progress made:

22.04.2020
Only two weeks after having announced the partnership, Avacta stated that it had "*successfully generated multiple Affimer reagents that bind the SARS-COV-2 viral antigen*". Crucially, the reagents are "*highly specific… and do not cross-react with other very closely related viruses, such as SARS and MERS*."

01.05.2020
Avacta announced a diagnostic collaboration with Adeptrix to utilise the Affimer binders to the SARS-COV-2 virus in a high throughput COVID-19 antigen test. We discuss this in greater detail in the next section (pp.10-11).

06.05.2020
The Company published its Annual Results for FY 2019. Within it, management stated:

"*We believe that the technical risk of developing a COVID-19 diagnostic is significantly reduced now that we have a large number Affimer reagents to work with, and our objective is to have a saliva test ready for production as early as possible in the summer… The Group has established two commercial partnerships and is in discussion with several others to establish multiple routes to market for the Affimer reagents. This will minimise risk and time to market and maximise the commercial opportunity…*"

In the open investor presentation aired on the same day, CEO Alastair Smith also stated:

"*The types of manufacturing relationships we have will be either licensing and OEM, so that a third party can manufacture and produce the test under its own name; or it will be purely a manufacturing relationship where the product bears our name and is then taken to market through distributors.*"

With regards to the manufacturing of the Affimer reagents, Avacta has capacity to manufacture sufficient quantities for the development of prototype tests. However, in anticipation of mass production, it will appoint a contract manufacturing organisation ('CMO') to carry out this work going forward. Affimer production is a relatively simple process, and the technology transfer to the CMO should be straightforward.

The CEO also stated in the presentation:

"*I can tell you that we have developed a number of lateral flow tests ourselves, and so have our partners. Some of those evaluations that we talked about being successfully completed are exactly for lateral flow tests. So we can have a great deal of confidence that lateral flow tests using Affimers can be developed… The regulatory process is a process – there is no reason at all why we should regard that as a significant risk. I think that the risk of development at this point – having now generated the Affimer binders that are specific to the target – that's the key technical risk overcome, so I think we should be pretty confident from this point.*"

11.05.2020
Avacta shipped its Affimer reagents to both Cytiva and Adeptrix so that they could begin working on their respective test prototypes, which should both be ready within a few weeks. In the announcement, the Company also announced that it had made another important discovery during its research:

"*…there are Affimer reagents that can work in pairs, both binding to the spike protein at the same time. This allows tests to be developed that detect both the intact virus particle and the detached spike proteins which become separated from the virus particle*

during the development of the COVID-19 disease, which may also be important in monitoring disease progression…. This means that we should have the best possible COVID-19 antigen test."

In our view, this is a hugely positive development: it will ensure an even higher level of sensitivity for Avacta's test, as well as a lower (i.e. improved) limit of detection. This will be vital for the test to receive regulatory approval.

20.05.2020

This week, Avacta entered into its first distribution agreement for its COVID-19 lateral flow test. The distributor is Medusa19 Ltd ('Medusa'), a company newly established by two of the co-founders of e-commerce giant boohoo. Medusa will be marketing and selling Avacta's COVID-19 test – and other at-home tests developed in the future by Avacta – with a primary focus on the direct-to-consumer ('DTC') market. We discuss this in greater detail in a later subsection (p.8).

Considerations and our confidence in the probability of successful commercialisation

Avacta still faces challenges in its commercialisation efforts for its POC antigen test. On the technical front, we believe that the risk is very small – as CEO Alastair Smith himself explained in the recent investor presentation (see previous page). Affimers have been successfully incorporated into, and worked successfully on, lateral flow devices designed for other viruses. Consequently, we do not think that Cytiva or other original equipment manufacturers ('OEM') will struggle with production.

Likewise, we know that Affimers are highly specific and have a high affinity (i.e. they will bind strongly to the viral proteins). We also now know that the test will be highly sensitive. High sensitivity and specificity are two of the key metrics that clinical validation will focus on – and ,ultimately, what regulatory approval hinges upon.

Affimers are robust and resistant to high or low temperatures. Previous Affimer-based lateral flow tests have demonstrated long shelf lives. As such, we envisage very little risk of damage to the tests throughout the supply chain.

Management also appears confident that mass production of Affimers will be a straightforward process, although we are conscious that Affimers have never before been produced at even a fraction of the anticipated quantity that will be required in the coming months.

In summary, we see a very low probability of failure to commercialise from this point in time. The technical risk of developing the reagent has been overcome; and so great is the pan-global need of a POC antigen test that we believe regulatory approval will be fast-tracked.

The competition: antibody-based POC antigen tests under development

We have identified three companies who have developed POC antigen tests so far:

- COVID-19 Ag Respi-Strip, by Coris BioConcept[1]
  Sensitivity: 60.3%
  Specificity: 98.3%

- BIOCREDIT COVID-19 Ag, by RapiGEN[2]
  Sensitivity: 92.0%
  Specificity: 98.0%

[1] https://www.corisbio.com/Products/Human-Field/Covid-19.php
[2] http://rapigen-inc.com/wp/portfolio-items/covid-19ag/?lang=en

- STANDARD Q COVID-19 Ag, by SD BIOSENSOR[3]
  Sensitivity: 84.4%
  Specificity: 100.0%

It must be noted that the parameters in the validation processes for these tests were not stringent – for example, the number of sample specimens tested in calculating sensitivity and specificity was in some cases below 100. None of these tests have received either FDA or CE Marking approval. As such, those percentages should not be wholly relied upon. None of these tests are available for sale in the UK and seem to be used only for research purposes in limited jurisdictions. All three of the companies are small, with no apparent backing from Big Pharma. In short, we would surmise that the above three tests are of dubious quality.

We have also identified three companies who are in the process of developing POC antigen tests:

- Sona Nanotech[4]
- BATM Advanced Communications[5]
- OraSure Technologies[6]

Sona's test is the most advanced along its development pathway: a prototype has been completed and it is now in the process of being validated. However, its announcement on 12 May suggests that this process is taking longer than – and indeed is not as straightforward as – initially anticipated by management.[7]

There is not much information in the public domain on BATM's test, except that it is following a similar development timeline to Avacta's test. BATM has stated that it initially will be sold only in Israel (where the company is headquartered).

OraSure is 2-3 months behind Avacta and BATM in the development of its POC antigen test.

Importantly, all six of these competing point-of-care antigen tests are antibody-based. In our previous Update Note (pp.6-8), we suggested that Affimers could offer a number of advantages over antibodies, when used as reagents in diagnostic kits.[8] Recent announcements by Avacta have validated this hypothesis:

- Affimer reagents were successfully generated within only four weeks, a remarkably short timeframe. For example, whilst OraSure first declared that they were developing a POC rapid antigen test two days *before* Avacta announced its collaboration with Cytiva, OraSure has guided that its test probably won't be ready for FDA approval until October this year.

- The reagents are highly specific and do not cross-react with other very closely related viruses. They also demonstrate a high affinity, which will assist in driving up sensitivity. As the first three POC antigen tests to market demonstrate (see above), specificity and sensitivity of antibody-based reagents are sometimes questionable.

- Avacta expects the cost of manufacture per test to be only $2, and possibly <$1 once mass production has been achieved. We believe that manufacturers of tests using antibody reagents will struggle to match this.

[3] sdbiosensor.com/xe/product/7672
[4] https://sonanano.com/news/
[5] http://www.batm.com/rns-rnr/posts/2020/march/batm-partners-with-novamed-for-at-home-covid-19-diagnostics-kit/
[6] https://orasure.gcs-web.com/news-releases/news-release-details/orasure-technologies-receives-barda-contract-rapid-oral-fluid
[7] https://sonanano.com/sona-nanotech-provides-covid-19-antigen-test-progress-update/
[8] https://avacta.com/2017-04-10/ for an article on the benefits of Affimers over antibodies for use in lateral flow tests

The distribution agreement with Medusa19

This week, Avacta entered into its first distribution agreement for its COVID-19 lateral flow rapid test. The distributor is Medusa19 Ltd ('Medusa'), a company newly established by entrepreneurs Mahmud Kamani and Richard Hughes. Both are founder shareholders of e-commerce giant and fellow AIM peer, boohoo (LON:BOO, market cap. of £4.4bn). Kamani is chairman of boohoo and remains its largest shareholder, with a 12.5% stake. boohoo specialises in own-brand affordable fashion clothing and is known for its innovative online platform, first rate marketing strategies and rapid, global growth.

The agreement between Avacta and Medusa is a global, exclusive, direct-to-consumer sales and marketing agreement for Avacta's COVID-19 POC antigen test, as well as other at-home testing products that Avacta produces in the future. Medusa also has secured non-exclusive rights to supply Avacta's products to businesses for workforce testing. The agreement is based on a profit-sharing arrangement (the percentage split has not been disclosed).

Direct-to-consumer ('DTC') marketing and selling is a form of e-commerce that involves a direct transaction between manufacturer and buyer, often enabled through mobile and digital channels. It allows the manufacturer to cut out the retailer 'middlemen'.

The DTC market in the field of in vitro diagnostic ('IVD') medical devices is nascent. The major global IVD players (Roche, Abbott, Thermo Fisher, Danaher, Becton Dickinson, etc.) have only relatively recently begun to build out their DTC capabilities. Moreover, to our knowledge there are no major distributers who focus primarily on this budding IVD-DTC market.

DTC has grown at exponential rates in other industries – examples are Dollar Shave Club and Harry's in the razor industry; and Jessica Alba's the Honest Company in the home cleaning and baby products space. It is quite obvious that there is substantial near- and long-term global growth potential for DTC marketing in the IVD industry, particularly in light of the current global pandemic. Specifically, with regards to Avacta's POC antigen test, it doesn't really need pointing out that most consumers would prefer to order the test at an online store, to be delivered to their home or workplace the next day, rather than having to go to a physical retail outlet such as Boots.

Medusa's founders have mastered the art of DTC marketing and selling in the affordable fashion industry, and are now investing significantly "in global e-commerce, logistics and customer support infrastructure" to prepare Medusa for the launch of Avacta's POC antigen test. We believe that they envisage a similar growth trajectory in the DTC IVD market to that which the fashion industry has enjoyed over the past decade.

The profit-sharing nature of the agreement effectively means that Medusa is an associate company of Avacta. Medusa will be responsible not only for all e-commerce activities (including marketing and selling), but also logistics and delivery, and – equally importantly – customer support and post-market surveillance.

Had Avacta opted to go down the Amazon / Alibaba DTC route (which of course management would have considered minutely), it would have had to have taken responsibility for a great deal of the above. The distribution agreement with Medusa will save Avacta substantial sums in upfront capital expenditure and ongoing operating expenditure and, moreover, will free up management time to focus on what it is best at. We believe that the agreement will have been the most economically attractive to Avacta, with the added bonus that Medusa (unlike other small distributors that could have been appointed) will be focussing *exclusively* on selling Avacta's POC test. We would remind readers that boohoo's marketing and advertising strategies have been integral to its phenomenal success. Kamani will bring this expertise to Medusa. In the longer run too, Medusa will sell other Avacta products through its DTC platform, essentially becoming Avacta's dedicated DTC distribution arm.

The expertise, track record and financial resources of Medusa's founders – coupled with the fact that Avacta's test could, in the coming weeks, quite literally become the most in-demand product in the word – gives us great confidence that this distribution agreement will become a major success for both Avacta and Medusa.

The next steps for the POC antigen test

We believe that the next steps in the development of Avacta's POC antigen test will be approximately as follows:

- Cytiva will have a prototype lateral flow test ready within two weeks (maximum) from now.
- Over the next 2-3 weeks, Avacta will announce various additional partnerships, including:
    - an OEM for large scale production of Affimer reagents;
    - additional OEMs for lateral flow test manufacturing (beyond Cytiva);
    - commercial partnerships (either white-labelling, or distribution / profit sharing);
    - major customers and/or pre-orders (such as (from) Public Health England).
- Once the prototype has been developed, clinical validation at various UK sites (using real patient samples) will be arranged by Avacta (we believe that this would take up most of June). This would be followed by gaining regulatory approval in Europe, namely CE Marking. We believe that FDA Emergency Use Authorisation ('EUA') would shortly follow.
- Manufacturing to commence in July.
- Sales to commence in late July / August.

Antigen testing for SARS-CoV-2: Avacta's and Adeptrix's point-of-care test

The Affimer-based BAMS antigen test

On 1 May, Avacta announced that it had entered into a second collaboration to develop antigen tests for SARS-CoV-2. The partner, US-based Adeptrix Corporation, provides proteomic and diagnostic products using its proprietary bead-assisted mass spectrometry (BAMS™) platform.

This novel analytical platform is based on single bead immunoaffinity capture and single bead analysis by mass spectrometry. It combines enrichment of the sample to improve sensitivity with the power of mass spectrometry to improve specificity.

Most of Adeptrix's currently available BAMS assays are configured for detecting proteins and protein modifications. Consequently, the platform technology is ideally suited to rapidly develop a test that will detect the spike proteins on the surface of coronavirus particles.

As such, Avacta and Adeptrix have partnered to develop an Affimer-based BAMS SARS-CoV-2 antigen test that will make use of the substantial available testing capacity in hospitals and laboratories. This spare testing capacity resides in the form of the installed base of hundreds of thousands of mass spectrometers ('MS') dotted in such sites all across the world, which have not yet been configured to process a test for the SARS-CoV-2 virus.

The test will consist of beads coated with Affimer reagents that are used to capture the virus particles from patient samples (these could be saliva, nasopharyngeal swabs or serum). Individual beads are then analysed in an MS to detect the presence of the virus.

Practically speaking, the BAMS antigen test will work in the same manner as PCR testing: a sample taken from the patient will be run in an MS, with results then returned to the patient (who has either been tested – and waited – on-site; or has posted in a sample).

The appeal of the BAMS antigen test

CEO Alastair Smith stated in the 1 May announcement, "*the BAMS diagnostic platform is highly sensitive and specific*." This is naturally of fundamental importance, if the test is to be rolled out at mass scale.

Mass spectrometers all across the world are standing idle (at least, with regards to the war against COVID-19). The BAMS antigen test will instantly mobilise this fleet of equipment. Avacta has stated that each machine will be able to process "hundreds of samples per day… exceeding the capacity of single PCR machine".

It is also important to note that BAMS uses various different materials in its tests compared to PCR, which is of high importance as the rollout of testing on MSs will not be constrained by bottlenecking (through lack of materials) that PCR testing has been subject to, as has been well documented in the media.

Finally, the BAMS test will be much faster than existing PCR testing (5-20 minutes per cycle): as such, it will be more practical in triage at hospitals (by drastically reducing the processing time of newly arrived patients).

In short, Affimer-based BAMS testing will add substantially to the existing global PCR testing capacity.

The implications of a successfully commercialised BAMS antigen test for Avacta

As referenced above, the BAMS test is very likely to be highly specific and sensitive. These are both of critical importance in gaining the necessary regulatory approvals. Given that it is not a DTC-IVD, the clinical validation

process to receive regulatory approval will be simpler – and faster – than it will be for the DTC sales element of Avacta's lateral flow test.

For Avacta, this will mean a faster and more certain route to first revenues than that which the lateral flow test offers. We believe that commencement of sales in late June is a distinct possibility.

The second important point to note is that the rollout of the BAMS test will significantly de-risk the investment proposition. In our opinion, Avacta's share price has appreciated almost entirely as a result of it developing its POC antigen test (the lateral flow test). The commencement of revenue generation as early as next month from royalties received from the sales of BAMS tests will begin to validate the Company's substantially enlarged market capitalisation.

Finally, on the note of the royalty-based agreement between Adeptrix and Avacta, once distribution partners have been secured, we believe that there will be limited ongoing work for Avacta. The Company will simply be providing the key ingredient of the test, the Affimer reagent. As with the Medusa partnership, this will free up valuable time for management.

The next steps for the BAMS antigen test

We believe that the next steps in the development of Avacta's BAMS antigen test will be approximately as follows:

- Over the next two weeks, Avacta and Adeptrix will announce multiple distribution partners. These will consist of the manufacturers of the mass spectrometers, namely Agilent, Waters, Shimadzu, Bruker, etc. These MS manufacturers will sell the BAMS tests directly to hospitals and laboratories.

- As with the Avacta POC antigen test, we could reasonably expect pre-orders and orders for the BAMS test even before manufacturing commences, i.e. in the next 2-3 weeks.

- Adeptrix will have a prototype test ready within two weeks, at most (and likely next week).

- Once the prototype has been developed, clinical validation at various UK sites (using real patient samples) will be arranged by Avacta (we believe that this would be completed in the first half of June). This would be followed by receipt of CE Marking and FDA EUA.

- Manufacturing to commence in June.

- Sales to commence in late June.

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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