

AVACTA GROUP LTD

REVISED INVESTMENT THESIS: SUMMARY

18.08.2021

Ticker: AVCT.L
Price (p): 105.0
Shares in issue (m): 253.7
Market cap. (£m): 266.3

Introduction

As a result of the COVID-19 pandemic, Avacta Group has experienced dramatic growth over the past 16 months. Consequently, we believe that our Investment Thesis published on 1 March 2020 is now outdated.

This Revised Investment Thesis is an updated version of our initial Thesis. It incorporates sections of that note, and subsequent notes that we published between April and October last year. We also provide extensive coverage of Avacta's progress over the past ten months. All our previous notes on Avacta Group can be found here:

<https://aimchaos.com/category/investment-notes/>

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Avacta Group ('Avacta') is a biotechnology company listed on the London Stock Exchange's growth market, AIM. At the core of its business is a proprietary technology, the Affimer® platform. Affimers are small, single domain binding proteins derived either from Stefin A in humans, or from Cystatin A in plants. They possess a number of qualities that make them ideal for use both in a therapeutic setting and in diagnostic applications. The Affimer platform is an 'antibody mimetic': it was specifically designed to overcome the numerous and varying limitations of *antibodies*, which are the market standard, core 'building blocks' in both therapeutics and diagnostics. The global market for antibody-based diagnostic and therapeutic applications was worth over \$120 billion in 2019, and is now estimated to be close to \$200 billion per annum. Thus there is evidently a colossal commercial opportunity for Avacta, if it is able to gradually displace monoclonal and polyclonal antibodies from diagnostic and therapeutic applications, and introduce its superior – and critically, *proprietary* – Affimer platform into these applications instead.

Avacta's operations are split into two core divisions, namely Avacta Diagnostics and Avacta Therapeutics. The Diagnostics division is comprised of circa 50 staff, based in Wetherby, UK. This division offers Affimer reagents (tools used in chemical testing) to the pharma industry in a wide variety of diagnostic and research applications. Over the past three years, the Diagnostics division has been involved in paid-for technology evaluations and custom Affimer services projects with a multitude of potential customers. Originally, the division's primary strategy was to convert these evaluations into (very high margin) licensing agreements that would deliver long-term royalties to Avacta. In late 2018, however, management realised that the average timeframe for a potential customer to carry out a thorough evaluation of the desired Affimer reagent was much longer than initially anticipated (in reality around 2 years). As such, in order to accelerate growth, the Diagnostics division has fast-tracked the design, development and launch of an in-house, in-vitro diagnostic ('IVD') product range, branded 'AffiDX'.

The first of Avacta Diagnostics' proprietary IVD products is the AffiDX SARS-CoV-2 Antigen Lateral Flow Test ('LFT'). Having commenced development of the LFT in April 2020 during the UK's first COVID-19 national lockdown, Avacta was able to commercially launch it in June 2021, following registration of its CE Mark in both the UK and the EU. The AffiDX LFT is currently being marketed for professional use only, and is being sold through a global distributor, Calibre Scientific. Management has alluded to numerous more commercial discussions – with other distributors, and directly with large end-user customers – being underway.

The data generated in the clinical validation of Avacta's AffiDX LFT demonstrate that it is one of the most accurate rapid antigen tests for SARS-CoV-2 in the world. It seems highly probable that testing – especially rapid, at-home testing – for the virus is going to be a part of life, all over the world, for at least the next several years. As a best-in-class LFT, we believe that the AffiDX LFT has a high chance of selling in the many millions of units per month, throughout that period. At present, Avacta is in the process of scaling up to capacity of 35 million units per month (5 million in the UK, 30 million abroad), with the aim of achieving that before year end.

The next three proprietary, AffiDX-branded products that the Diagnostics division intends to launch will be diagnostic applications for stress, sepsis and anaemia, respectively. The first of these is scheduled to be launched next year.

Avacta's second business unit is the Therapeutics division. The division is located in Cambridge, UK, and is comprised of circa 50 employees. The Affimer platform can be used to develop therapeutics across an extensive variety of drug modalities, including immunotherapies, mRNA therapies, stem cell therapies, neutralising therapies, drug conjugates – to name but a few. The number of disease areas that Affimer-based therapeutics could target is equally broad. Avacta, being a small biotech with limited resources, is for now using the platform technology to primarily focus its efforts on novel therapeutics in the area of *immuno-oncology*, which is the use of immunotherapy in combatting cancer.

Avacta has also exclusively licensed a second platform technology, named pre|CISION™, from leading US research institution, Tufts University School of Medicine. At the heart of the pre|CISION platform is a novel linker technology that can be used to develop chemotherapy pro-drugs or drug conjugates. In short, the linker technology ensures that the drug will only be activated in the tumour micro-environment ("TME") itself. This compares to standard-of-care chemotherapies that are equally active in both the TME and in healthy tissue. The primary reason for most patients stopping chemotherapy is because of cardiotoxicity, i.e. damage to the heart by the chemotherapy itself. If the pre|CISION platform works in humans as well as it already has in preclinical studies in mice, cancer patients could endure multiple more cycles of pre|CISION pro-chemotherapies – and at much higher doses – thus *significantly* increasing their chances of survival.

This month, Avacta commenced a Phase I human trial for its first pro-chemotherapy, AVA6000 (pro-doxorubicin). Management expects first meaningful pharmacokinetic data by the end of this year.

If Phase I clinical trials for pro-doxorubicin and for the first – as yet undecided – Affimer-based therapeutic are both successful, Avacta will be in a position to advance a novel class of immuno-oncology drug conjugate that utilises both technology platforms, i.e. immunotherapies coupled with targeted chemotherapies. This third platform is referred to as "TMAC" ('tumour micro-environment activated drug conjugates'). Avacta has already generated highly encouraging data in preclinical animal studies for its first TMAC molecule. We believe that if the TMAC platform proves successful in the clinic and is ultimately brought to market, it could become a transformational therapy for cancer patients. As such, we consider the TMAC platform Avacta's crown jewel.

In addition to developing a proprietary pipeline of drugs in-house, Avacta is using its two therapeutic platforms to form collaborations with third parties in the pharmaceutical space. The Company currently has commercial partnerships in place with five major biotech / pharma entities. The partnerships are all potentially extremely lucrative for Avacta over an extended time period: we estimate that three of them alone (with Moderna, ADC Therapeutics and LG Chem) could be worth in excess of \$600m biodollars to Avacta over the coming 5-10 years, through various milestone payments. On top of that, Avacta would receive royalties on sales of any products that were successfully commercialised by the collaborations.

At its current share price of 105p, Avacta has a market capitalisation of £266m. We estimate it has net cash of circa £35m, which is sufficient to fund operations through to mid-2023 – regardless of sales of the AffiDX LFT. We believe that Avacta is chronically undervalued at the current price and offers substantial upside to investors in both the near-term and longer-term. The Company is an exceptionally rare beast on the public markets: owing to the launch of the Diagnostics division's AffiDX LFT, Avacta can now look to the future as a *cash generative, profitable* biotechnology business that is positioned to self-fund multiple, cutting-edge, in-house therapeutics through the clinic simultaneously.

Revised Investment Thesis

In this note, we have set out our rationale as to why we believe that there is a genuine possibility of Avacta becoming a multi-billion-pound company within the next 12 months. The reason for this is straightforward: the Company owns (or has the exclusive license for) four platform technologies – one diagnostic-focussed, three therapeutic-focussed – that between them could ultimately generate first-in-class products that target global markets worth several hundred billion dollars per annum.

Whilst the Affimer Diagnostics and Affimer Therapeutics platforms are, in our view, first-in-class amongst their respective competing technologies, the *greatest* value upside for Avacta resides in its second and third therapeutic platforms, pre|CISION and TMAC. These are truly disruptor technologies: if the first drugs from each of these platforms are proved safe in-man, the platforms could ultimately *dramatically* expand the size of the chemotherapy market from \$60 billion per annum, and the immunotherapy market from \$42 billion per annum.

Let us first recap on Affimer Diagnostics. Despite its horrors, the coronavirus pandemic has – for Avacta – brought about a once-in-a-lifetime opportunity. That opportunity lies in rapid testing for the SARS-CoV-2 virus: specifically, antigen-based lateral flow tests powered by the Company’s proprietary technology, Affimers. Avacta has over the past 18 months developed – and recently commercially launched – one of the most accurate SARS-CoV-2 lateral flow tests (‘LFT’) in the world. It has named the test, AffiDX SARS-CoV-2 LFT. In an independent clinical validation study, the AffiDX LFT detected 100% of positive cases that are generally considered to be *infectious*. As the global testing market matures, we believe that only the highest quality tests (that can be also be manufactured at a competitive price) will survive. The market-leading sensitivity of Avacta’s AffiDX LFT, coupled with its very low cost of manufacture will in our view ensure that it is one such test.

Shipment of Avacta’s AffiDX SARS-CoV-2 LFT began in the first week of August. Pre-orders of the LFT from early July ensured that the test was sold out several weeks *before* first shipment. We have been informed that delivery recommences next week. Whilst the Company has not provided details of production levels to date, we estimate that it will deliver one to two million tests in August. Currently, the production output is entirely down to a single manufacturing partner, namely Global Access Health (‘GAH’) (formally called *Global Access Diagnostics*). Avacta’s second UK-based manufacturing partner, Abingdon Health, is set to come online in the next several weeks. We believe that once both GAH and Abingdon are manufacturing the AffiDX LFT at their contracted full capacity, Avacta’s output will be in the region of four to five million units per month.

Given that demand is indisputably already outstripping supply, we believe that Avacta will also mobilise an international manufacturer (based in Mainland Europe, in our view) in the coming weeks. [Eight weeks ago, management stated in a presentation that the tech transfer to said manufacturing partner that was already underway, would take 6-8 weeks.] This unnamed manufacturer will have the capacity to scale to 30 million units per month.

Management has stated that gross profit per LFT sold will be in the region of €1 to €2. In our model, we have conservatively assumed £1 gross profit per LFT sold. Excluding sales of the AffiDX LFT, we estimate that Group free cash flow for 2022 will be in the region of -£20m, increasing to circa -£25m in 2023 (depending on the results of the Phase 1 trial for AVA6000). As such, Avacta need only sell 2 million AffiDX LFTs per month, for the next 30 months, to achieve and retain a cash flow breakeven position – even when self-funding ongoing clinical trials throughout that period.

However, if Avacta *does* reach its (implied) stated target capacity of 35 million per month going into 2022, it’ll be looking at a pre-tax profit of approximately £400m pa – assuming no further erosion of margins. A question the cynical observers of Avacta have been asking is, “*How long will testing for COVID-19 actually be around for? We rarely tested for flu prior to the coronavirus pandemic; why will testing for COVID-19 continue on once the world is largely vaccinated?*” Our answer to this, as we explain in depth on p.xx, has several components.

As has recently come to light, the vaccines are doing relatively little to prevent *transmission* of the virus. In tandem, whilst the vaccines (especially the mRNA-based vaccines of Moderna and Pfizer / BioNTech) are highly effective at preventing death, vaccinated people are nevertheless getting ill. This both prevents economies from

functioning at full capacity (as many people at once can be off sick), and clogs up healthcare systems that would otherwise be treating patients with other serious diseases.

Moreover, we believe that so great has been the damage caused on a global scale by the SARS-Cov-2 virus – economically, socially and psychologically – that testing for it is likely to be around for *many* years, even after the virus has been largely eradicated (if that ever does occur). In the wake of 9/11, airport security across the globe underwent a transformation. Two decades later, that material step up in security remains in place. We believe that long-term testing for SARS-CoV-2 will not be dissimilar.

It's also worth noting that prior to this pandemic, not even 100th of the infrastructure that is being used for coronavirus testing today, was in place. Even when the COVID-19 pandemic recedes, the billions of dollars' worth of new infrastructure in place in the global diagnostics industry can be reconfigured to test for numerous other viruses alongside SARS-CoV-2, that previously were tested for only on a small scale.

This brings us back to Avacta Diagnostics and its new AffiDX range of in-vitro diagnostic ('IVD') products. The AffiDX SARS-CoV-2 LFT is only the first product in this newly branded IVD range. Having secured ISO 13485 certification last month – which enables Avacta to become the legal manufacturer of its IVD products – the Company is now well positioned to build out its AffiDX range.

The total addressable market for antigen-based LFTs is currently in the tens of billions of dollars per annum (a market that has been significantly augmented by the arrival of the pandemic). If Avacta can secure only a very small fraction of this market, the cash flows generated from sales will prove transformational to the Company. The first-in-class status of the SARS-CoV-2 LFT that Avacta has developed and commercialised, gives us comfort that it can and will secure that small fraction of the market. It is only the Company's first CE Marked IVD product: as the division's experience builds and its budget increases, we think the quality of future IVD products in the AffiDX range when compared to competing (primarily antibody-based) products will only increase.

It is important to note that the Affimer scaffold most frequently used in IVDs – namely, the Cystatin A-derived scaffold – is under patent until 2033. Avacta has global exclusive rights over it for the next 12 years.

Avacta is currently selling its AffiDX LFT through a major global distributor, Calibre Scientific. At present, the Company has been authorised to sell it as a professional use only device in the UK and in the EU. However, it is our understanding that Avacta has been working with another partner, Medusa19, to secure home-use authorisation ('HUA') in the EU (and potentially in the UK). Last year, Avacta and Medusa19 entered into an agreement that granted Medusa19 the global, exclusive rights for direct-to-consumer ('DTC') sales and marketing of the AffiDX SARS-CoV-2 LFT, as well as other at-home IVD products that Avacta produces in the future. Medusa19 has also 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).

Medusa19 was established last year by entrepreneurs Mahmud Kamani and Richard Hughes. Both are founder shareholders of e-commerce giant and fellow AIM peer, boohoo. They have immense experience in DTC sales and marketing, which we believe bodes very well for sales of Avacta's AffiDX LFT, once HUA has been secured – and indeed for all future AffiDX products. Moreover, Medusa19 has established its own LFT manufacturing facilities near Liverpool: whilst it has hitherto been manufacturing a COVID-19 antibody test that it has licensed from a third party, we think it is possible that its manufacturing capacity could be reconfigured to produce AffiDX LFTs. Last October, Medusa19 claimed that its facilities could be scaled up to produce 50 million tests per month. Although we believe this to be unlikely, even one quarter of that output reconfigured to manufacture the AffiDX LFT would be an enormous boost for Avacta.

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As appealing as the cash generation potential of the Diagnostics division may sound to investors, the key to the Avacta Investment Thesis is in how the Diagnostics division could entirely finance the activities of the Therapeutics division – notably in funding its cutting-edge immuno-oncology therapeutics and chemotherapies through clinical trials.

Firstly, the Affimer Therapeutics platform. As we discuss in detail on p.xx-xx, Affimers in therapeutic applications have numerous advantages over the market standard, monoclonal antibodies – notably in their small size; flexible functionalisation; engineered specificity; and simple, cheap, consistent and ethical manufacturing process.

Avacta has not yet brought an Affimer-based therapeutic into the clinic, primarily as it shifted its focus to first securing in-human data for its second platform, pre|CISION (see below). However, as we discuss on p.xx, the Company does have at least four Affimer-based immuno-oncology drugs at the preclinical stage (two monotherapies and two bispecific therapies). By the end of the year, Avacta intends to have selected its first candidate that it will bring into Phase I clinical trials.

Whilst not at the forefront of investors' minds at present – with Affimer Diagnostics (i.e. AffiDX SARS-CoV-2 LFT) and pre|CISION (i.e. AVA6000) dominating the limelight – the potential value of the Affimer Therapeutics platform is immense. Avacta currently has four ongoing commercial partnerships with major pharma and biotech entities – three of which could be worth in excess of \$600m biodollars to Avacta over the coming 5-10 years, through various milestone payments. On top of that, Avacta would receive royalties on sales of any products that were successfully commercialised by the collaborations. These partnerships are not only commercially valuable to Avacta, but equally assist in building the Company's intellectual capital around the Affimer scaffolds. They are experimenting with drug modalities that Avacta's in-house pipeline is not (e.g. stem cell therapy, mRNA therapy), as well as targeting disease areas that Avacta is not yet focussing on (e.g. autoimmune and inflammatory diseases).

We are particularly excited by Avacta's ongoing collaboration with Moderna, the industry leader in the now established field of mRNA, following the commercial launch of its SARS-CoV-2 vaccine. Over the past 24 months, Moderna's share price has increased by circa 30 times, giving it a market cap of \$150 billion. Moderna has been exploring the use of Affimers in its mRNA therapies since 2015; in 2019, it exercised an option to enter into an exclusive licensing agreement with respect to certain Affimers against an undisclosed therapeutic target. The concept is that Moderna's mRNA technology will prime the patient's own cells to generate specific Affimers that would then target the present disease – that is to say, once generated within the patient's body, the Affimers would set to work as an immunotherapy, neutralising therapy, etc. Success in Moderna's first potential clinical trial (yet to be announced) would open up Avacta's two libraries of 10 billion+ other Affimers to the budding mRNA industry.

If proved safe in-man (and very positive results from an ex-vivo immunogenicity study in 2017 using human samples suggested that this would likely be the case), the Affimer Therapeutics platform has the potential to become extremely valuable. Avacta has a strong patent protection programme that not only safeguards the background platform IP, but also ensures that any individual Affimer loop sequence that the Company generates can be uniquely patented.

Herein lies the true value of the Affimer Therapeutics platform: it provides the owner (or licensee) with *freedom to operate*. Almost any drug that is antibody-based can be remade using the Affimer protein scaffolds. Indeed, as we have explained in this note, Affimers offer numerous advantages (such as cost of manufacture and ease of formatting) over antibodies in the development of drug molecules. Even if an antibody-based drug is still on patent, the owner / licensee of the Affimer technology could create an equivalent drug that has almost identical therapeutic effects, and yet not be infringing on the patent of the existing antibody-based drug. Accordingly, Avacta has freedom to operate in developing alternative, Affimer-based therapies wherever there is already existing antibody-based IP.

The last antibody mimetic platform to be acquired was Ablynx's Nanobody technology. Ablynx was acquired for \$4.8 billion cash by Sanofi, in June 2018. In FY 2017, Ablynx generated revenue of €56m, and recorded an operating loss of €54m.

Secondly, the pre|CISION platform. In our view, this is the platform that is most likely to propel Avacta to a multi-billion pound valuation in the next twelve months. The preclinical data for the first pro-chemotherapy, AVA6000 (a pro-drug form of doxorubicin) speak for themselves:

In mouse models, the administration of standard doxorubicin resulted in approximately the same concentration of the drug in heart tissue as in tumour tissue. This 1:1 ratio was expected: doxorubicin is not targeted, thus causing dose limiting, severe cardiotoxicity. Conversely AVA6000 – even when administered at a dose 6 times as potent as the control dose of doxorubicin – produced *less* doxorubicin exposure in the heart, while producing *18 times* as much doxorubicin in the target tumour tissue compared with the heart.

This resulted in dramatic tumour shrinkage and a 100% survival rate at 60 days of the mice treated with AVA6000, compared with a 0% survival rate of the mice treated with standard doxorubicin.

This month, Avacta commenced a Phase I human trial for AVA6000. Management expects first meaningful pharmacokinetic data by the end of this year. It is probable that that data will reveal explicitly whether the technology that has worked so extraordinarily well in mice, has been as effective in humans.

If it is, then it stands to reason that the pre|CISION linker technology will also be effective when applied to other standard, currently non-targeted chemotherapies. In effect, it would open a very large segment of the global chemotherapy market – currently valued at approximately \$60 billion per annum – to Avacta. Moreover, that current \$60 billion market could be expanded dramatically. How? Not only could patients who had hitherto been limited to a handful of cycles (due to cardiotoxicity caused by standard doxorubicin) now receive *multiple* more cycles, using the pro-drug; but those who could not endure conventional chemotherapy *at all* could now receive chemotherapy in pro-drug form.

Many conventional chemotherapies (such as doxorubicin) are soon-to-be or already off-patent: with the pre|CISION platform, Avacta could re-patent its newly formed pro-drugs. It seems reasonable to assume (provided costs are not materially increased) that the pre|CISION pro-drugs could rapidly displace many of the conventional chemotherapies. Accordingly, bar incredibly effective novel technologies coming to market, the owner (or licensee) of a pre|CISION platform that is proved effective in-man, could be in a position to become a major player in the global oncology market going forward.

What is the probability of success for the AVA6000 Phase I ('P1') trial? Oncology has a notoriously lower success rate in clinical trials than other disease areas do. For P1, the average success rate for all other therapeutic areas is 73%, whilst for oncology, it is 58%. However, it is critical to remember that in the case of AVA6000 (and indeed all of Avacta's pre|CISION pro-drugs under development), the *efficacy* of the drug is not in reality being tested. Standard doxorubicin is an extremely potent drug that has been used to treat multiple types of tumour for over four decades. Rather, it is AVA6000's enhanced safety profile over doxorubicin that is being examined. As such, we believe that AVA6000 stands a *considerably* higher chance of success in P1 trials than the average oncology P1 trial does. Furthermore, many clinical P1 trials are considered a success if they show improved efficacy (or safety) over the control of as little as 10% to 15%. In mouse models, Avacta's pro-doxorubicin demonstrated a safety profile of *many multiples* greater than standard doxorubicin. There is thus ample margin for error, e.g. partial cleavage of the pre|CISION linker when it is *not* in the tumour micro-environment ('TME').

Finally, Avacta's third platform technology: TMAC. The success of this platform is dependent on both pre|CISION and Affimer Therapeutics proving safe and effective in-man first.

To recap: the TMAC drug conjugate destroys tumours by a triple combination of deployment of toxic warheads (e.g. chemotherapies) in the TME; triggering of the innate immune system (turning cold tumours 'hot' to mobilise white blood cells against the tumour); and synthetic support of the immune system's response (i.e. Affimers working as an immunotherapy to boost the response of the white blood cells). To our knowledge, the TMAC platform is the *only* drug class in existence that combines immunotherapy with targeted chemotherapy in a single drug molecule.

As with the preclinical data for the pre|CISION platform (AVA6000), the initial in-mouse data generated by Avacta's first TMAC molecules have been extraordinary. In a preclinical trial of one particular (undisclosed) TMAC drug conjugate, the Company used a colorectal tumour model ('CT26'), which is renowned as a tough, 'cold' tumour model. 60% of the animals experienced full regression of the tumours. Moreover, those animals

that experienced full tumour regression then had a T-cell mediated immunity to being re-challenged with the same tumour, 60 days later.

The TMAC platform could be a truly game-changing development for the oncology industry; but as an entirely novel therapeutic platform, its route to commercialisation will be significantly longer than that of the pre|CISION platform. It also carries a much higher development risk.

Even so, with a global exclusive patent extending out to 2038, it is straightforward to comprehend why management has stated that there has been significant interest from Big Pharma in the TMAC platform, even at its current preclinical status.

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In light of the above, the obvious question is, why is Avacta only being valued at £266m? It could conceivably be entering 2022 on a run-rate of as much as £400m pre-tax profit per annum; and within the next several months, investors will have a good indication of whether the pre|CISION platform works in-man. If it does, then a large slice of the \$60 billion chemotherapy market is there for the taking – and more on top, as the pro-drugs open up chemotherapy to many more patients, as well as many more cycles for all patients. And it is reasonable to assume that the probability of success in the AVA6000 P1 trial is significantly higher than 50%.

It is useful to consider how Avacta's share price has moved since April last year, when the development of the AffiDX LFT was first announced to the market. From a base of around 20p prior to the RNS, the share price hit a high of 290p a little over year later, in April 2021. This peak market capitalisation of £735m was achieved in the week subsequent to the clinical validation of the AffiDX LFT. Since then:

- Avacta's AffiDX LFT has been CE Marked for professional use only in both the UK and the EU – which not only enables sales to commence in both regions, but also represents a major milestone for the Affimer Diagnostics platform, with the AffiDX LFT being the first IVD product powered by Affimers to be CE Marked;
- The Diagnostics division has secured ISO 13485 certification, enabling it to be the legal manufacturer of all of its in-house developed products going forward;
- Avacta has signed up Calibre Scientific as a distributor for professional use only in the UK and EU, with sales commencing in July and delivery in early August (with initial output being very quickly sold out);
- The Company transitioned to a clinical stage company, with first dosing of patients in the AVA6000 trial.

Despite all of this progress, the share price has fallen by 64% over the past four months, from 290p to 105p. We attribute this to several key issues:

- Slower commercial launch of AffiDX LFT than anticipated by the market (and guided by management);
- Lack of clarity on current output of AffiDX LFT, and slower than expected scale up of manufacturing capacity – including the failure of former manufacturing partner BBI Solutions to complete tech transfer;
- Failure to secure a contract with the UK's Department of Health and Social Care ('DHSC'), and the associated additional manufacturing capacity (up to 30 million per month) that such a contract may have provided Avacta with access to;
- Shareholder register that is weighted heavily to retail, which inevitably increases volatility (emotional trading; often shorter term investment horizons than institutional investors);
- Largely as a result of the previous point, the stock has become a target of shorts (notably Jupiter Investment Management).

Has the rapid decline in the share price been fair? In our view, not at all. However, the majority does evidently think so. Management is focussed on building the business through a plethora of workstreams – both in-house and through collaborations. Due to a combination of the £54m cash raised via placings in 2020 and the anticipated sales of the AffiDX SARS-CoV-2 LFT, Avacta will not be required to raise funds for the foreseeable future. As much as many investors may disagree on this point, management’s primary job should be on operations, and building the business; not on share price management. The share price will take care of itself, if and when key operational goals are achieved.

In an ideal world, what would we like to see in the coming months?

- Completion of tech transfer to Abingdon in the next several weeks, so that it can join GAH in scaling up UK-based production of AffiDX LFTs to 4-5 million per month.
- Completion of tech transfer to an international manufacturer in the next several weeks (we think Mainland Europe), which management has stated has the capacity to scale up to 30 million per month.
- Granting of home-use authorisation in the EU (and potentially the UK) in the next several weeks.
- Update on the partnership with Medusa19, concerning its DTC sales strategy – and *potentially* using Medusa19’s manufacturing capacity in Liverpool to produce AffiDX LFTs.
- Licensing out the AffiDX LFT, via white-labelling, to large diagnostic players operating in Rest of World territories (notably, the US).
- Commence work on a dual NASDAQ listing, where the inherent value of the Company’s four proprietary platforms would be much more appreciated by investors than they currently are in the UK.
- To establish – or acquire – *proprietary* manufacturing capacity for LFTs and other IVD products that Avacta plans to launch. With regards to the latter option, the obvious takeover candidate would be existing manufacturing partner, Abingdon Health. The business has a weakened balance sheet, having been messed around by the DHSC, which has seen its market capitalisation collapse from circa £100m, following its IPO last year, to a mere £25m. Not only would the acquisition of Abingdon result in an immediately increased manufacturing capacity for the AffiDX LFT, but it would be an extremely useful asset for Avacta in future product development (making it a much faster – and cheaper - process). Given the current valuations of both companies, an all-share offer would, in our view, be highly value accretive to both sets of shareholders.
- *If* AVA6000 initial pharmacokinetic data are positive, for Avacta to select a TMAC molecule as its first Affimer-based therapeutic, to bring into the clinic (as opposed to an Affimer-based immunotherapy).

Needless to say, ideal scenarios very seldom play out in full. We – and very likely, the market – would be delighted if only a fraction of the above were to come to fruition!

It’s also vital to highlight the risks in the Avacta Investment Thesis. There are many, and some of them very significant:

- The pre|CISION technology has yet to be proved safe and effective in-man. This is ***the greatest near-term risk for investors***, and one that all should be extremely mindful of. As we have explained, we believe that there is an above-average probability of success in the AVA6000 Phase 1 trial. Nevertheless, there is a distinct possibility of failure. Not only would this render the pre|CISION platform obsolete, but the TMAC platform too.
- The Affimer Therapeutics platform has yet to be proved safe and effective in-man. Whilst a longer-term risk (the first P1 trial will likely not begin until late 2022 / early 2023), failure would dramatically reduce the value of the platform.

- Superior oncology technologies are developed that would displace chemotherapies (even highly targeted chemotherapies) from the market.
- Superior technologies for SARS-CoV-2 rapid testing are developed that could substantially reduce the total addressable market for the AffiDX LFT.

These are *considerable* risks – commensurate to the potential blue sky upside on offer to Avacta shareholders.

However, despite these risks, we firmly believe that the Company’s current market capitalisation is nonsensical. As a result of the development and commercial launch of the AffiDX SARS-CoV-2 LFT (which not only represents a *major* source of cash generation for the Group, but also the validation of the Affimer platform in commercial diagnostic applications); the rapid expansion of the Diagnostics division; and its pivot to focussing on developing its in-house AffiDX IVD product range; we feel that the Diagnostics division alone should now command a valuation considerably more than Avacta’s current market capitalisation of £266m.

Calibre Scientific is, at the time of writing (we checked this morning), out of stock of Avacta’s AffiDX SARS-CoV-2 LFT. In fact, it was sold out before it even received first shipment of the product. It stands to reason, therefore, that Avacta will indeed be bringing online its international manufacturing contractor (capacity of up to a further 30 million per month) as soon as possible. To reiterate: management has stated that gross profit per LFT sold will be in the region of €1 to €2. Its implied target output of 35 million per month (5 million in the UK; 30 million abroad) would therefore suggest £420m gross profit per year. We assume £20m Group cash burn for CY 2022, excluding AffiDX LFT activities.

In short, as the valuation of Avacta’s Diagnostics division more than underwrites the Company’s current market capitalisation, the Therapeutics division is essentially being valued at nil. A division that in just a handful of months will know whether it possesses a platform technology that could go on to revolutionise the chemotherapy market, expanding it dramatically from its current \$60 billion per annum value.

If AVA6000 were to fail in clinic, Avacta still has its Diagnostics division that at last looks set to generate huge profits. The Company also has its Affimer Therapeutics platform, the development of which it could fund with cash generated from Diagnostics. As a reminder, a competing antibody mimetic technology to Affimer Therapeutics was acquired three years ago for \$4.8 billion cash. Although 5-6 years ahead in terms of clinical development, the antibody mimetic platform in question – Nanobodies – was not being used in Diagnostic applications.

We will end our Revised Investment Thesis with the same words we used to conclude our original Investment Thesis in March 2020:

Were the initial pharmacokinetic data for the AVA6000 Phase I trial to be positive, it is not difficult to imagine that Avacta would hit mainstream news. A well-known, established chemotherapy has been redeveloped so that it no longer causes horrible side-effects and, critically, can now be used for many more cycles and by many more patients (as it no longer causes toxicity to the heart) – thus significantly increasing the probability of destroying patients’ tumours. Interest in the Company, both from within the pharmaceutical and biotech industries and from the international investment community, would explode.

The data are likely to be published before Christmas.

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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.

This paper is non-independent research. It has not been prepared in accordance with legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of the investment research.

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Myles McNulty has no business relationship with Avacta or with any other company mentioned in this paper, and has received no compensation from any party for writing it.