

30 September 2021

## Avacta Group plc

("Avacta", the "Company" or the "Group")

## Interim Results for the Period Ended 30 June 2021 and Business Update

Transformative period for both Diagnostics and Therapeutics Divisions

Avacta Group plc (AIM: AVCT), a clinical stage biopharmaceutical company developing innovative cancer therapies and powerful diagnostics based on its proprietary Affimer<sup>®</sup> and pre|CISION<sup>™</sup> platforms, announces its interim results for the period ended 30<sup>th</sup> June 2021 and business update.

## **Operating Highlights**

## **Avacta Diagnostics**

Transformation of Diagnostics Division to become an ISO 13485 accredited in-vitro diagnostic (IVD) products business, and first sales (post-period) of its high performance AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test. Global profile of Avacta and the Affimer® diagnostic reagents platform substantially increased over the period.

- Clinical validation study of Avacta's AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test carried out on 98 positive COVID-19 samples (31 with Ct<26; 65 with Ct 26-30 and 2 with Ct 30-31) and 102 negative samples demonstrates clinical sensitivity of 98.0% and clinical specificity of 99.0%. Additional data obtained post-period end from a further 134 negative samples has further defined the clinical specificity to be 99.6%.</li>
- AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test shown to detect the Delta variant of the SARS-CoV-2 virus in clinical samples and to outperform two lateral flow antigen tests that are widely commercially available in Europe. The test has also been shown to detect the Alpha, Beta and Gamma variants in an earlier study.
- Declaration of conformity for CE mark for professional use of AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test submitted to Medicines and Healthcare products Regulatory Agency (MHRA).
- Product registration received, in both the UK and EU, for the professional use AffiDX® SARS-CoV-2 antigen lateral flow test.
- Multiple collaborations and commercial partnerships entered into during the period and postperiod end:
  - Royalty bearing license agreement with Biokit, a Werfen Company, to develop and commercialise an undisclosed Affimer<sup>®</sup>-based *in-vitro* diagnostic test.
  - Collaboration agreement with Bruker Corporation to evaluate the clinical utility and commercial potential of a mass spectrometry-based SARS-CoV-2 antigen test developed with Adeptrix Inc.
  - Global distribution agreement with ABCAM plc (AIM: ABC; NASDAQ: ABCM) to sell the Group's recently developed AffiDX<sup>®</sup> SARS-CoV-2 research ELISA Affimer<sup>®</sup> reagents.
  - Non-exclusive distribution agreement with Calibre Scientific Inc. ("Calibre"), a global provider of life science products, for Avacta's AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test for professional use in the UK and European Economic Area (EEA).

## Post-period Highlights

- ISO13485 certification attained by Avacta Diagnostics Division.
- Shipment of AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test commenced.

## **Avacta Therapeutics**

Avacta Therapeutics Division becomes a clinical stage oncology drug company receiving approval from the MHRA for its phase I, first-in-human clinical study for AVA6000 pro-doxorubicin with the dosing of the first patient at the Royal Marsden Hospital in August 2021.

- Licensing agreement with Point Biopharma Inc., to provide access to Avacta's pre|CISION<sup>™</sup> technology for the development of tumour-activated radiopharmaceuticals. Under the terms of the agreement, Avacta has received an upfront fee and will receive development milestone payments for the first radiopharmaceutical prodrug totalling \$9.5 million. Avacta will also receive milestone payments for subsequent radiopharmaceutical prodrugs of up to \$8 million each, a royalty on sales of FAP-activated radiopharmaceuticals by POINT and a percentage of any sublicensing income received by POINT.
- MHRA approved the CTA for AVA6000 pro-doxorubicin for a phase I, first-in-human, open label, dose-escalation and expansion study in patients with locally advanced or metastatic selected solid tumours. AVA6000 is Avacta's first therapeutic product based on its proprietary pre|CISION™ technology.
- Series A venture capital investment round closed for AffyXell Therapeutics ('AffyXell'), the joint venture with Daewoong Pharmaceuticals ('Daewoong'), raising \$7.3m to further develop its pipeline of next generation Affimer-powered cell and gene therapies.

## Post-period Highlights

- First patient dosed in the phase I multi-centre trial evaluating AVA6000, a novel pre|CISION™ prodrug of doxorubicin.
- Pre-clinical milestone achieved in LG Chem Life Sciences partnership triggering undisclosed milestone payment.
- Dr Mark Goldberg, a medical oncologist and haematologist on the faculty of Brigham & Women's Hospital and Harvard Medical School, a veteran biotech executive, appointed as Non-executive Director to the Board of Directors of Avacta.
- Dr Fiona McLaughlin appointed as Chief Scientific Officer of the Therapeutics Division.
- New appointments to the Therapeutics Scientific Advisory Board, reflecting the progress of the Therapeutics Division and Avacta's transition to a clinical stage Company:
  - Professor James Spicer MB., BA., PhD., FRCP.
  - Professor Krishnan Komanduri, MD.
  - Dr Stéphane Champiat MD, PhD.

## **Financial Highlights**

- Cash and short-term deposits of £37.0 million (30 June 2020: £54.5 million; 31 December 2020: £47.9 million).
- Revenues increased to £2.3 million (6 months to 30 June 2020: £1.8 million; year ended 31 December 2020: £3.6 million).
- Operating loss of £11.3 million (6 months to 30 June 2020: £8.1 million; y/e 31 December 2020: £21.3 million), with research and amortisation of development costs increasing to £6.7 million (6 months to 30 June 2020: £4.2 million; y/e 31 December 2020: £10.0 million).
- Increased R&D investment leading to reported loss of £10.2 million (6 months to 30 June 2020: £7.0 million, y/e 31 December 2020: £18.9 million).

## Dr Alastair Smith, Chief Executive of Avacta Group plc, commented:

"It has been a period of very significant progress for the Group and a transformative one for both the Diagnostics and Therapeutics Divisions. The progress made during the reporting period has been

extraordinary, as indeed it has been over the last 18 months, under very challenging circumstances for staff with regards to restrictions on working conditions and the effects of the pandemic on our lives outside work. The progress that has been made is a reflection of the commitment and skills of our exceptional staff.

"Significant value inflection points lie ahead of us with the potential to transform cancer therapy with the next generation of safer preCISION<sup>™</sup> chemotherapies and Affimer immunotherapies, and with the opportunity to generate significant profitable revenues from the market leading AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test and future AffiDX<sup>®</sup> in-vitro diagnostic products.

"We are confident and excited about the immediate and long-term future for the Group."

#### -Ends-

This announcement contains information which, prior to its disclosure, was considered inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 (MAR).

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## About Avacta Group plc - https://www.avacta.com

Avacta Group is developing novel cancer immunotherapies and powerful diagnostics based on its two proprietary platforms - Affimer<sup>®</sup> biologics and pre|CISION<sup>™</sup> tumour targeted chemotherapies.

The Affimer<sup>®</sup> platform is an alternative to antibodies derived from a small human protein. Despite their shortcomings, antibodies currently dominate markets, such as diagnostics and therapeutics, worth in excess of \$100bn. Affimer technology has been designed to address many of these negative performance issues, principally: the time taken to generate new antibodies and the reliance on an animal's immune response; poor specificity in many cases; their large size, complexity and high cost of manufacture.

Avacta's pre|CISION<sup>™</sup> targeted chemotherapy platform releases active chemotherapy in the tumour, which limits the systemic exposure that causes damage to healthy tissues, and thereby improves the overall safety and therapeutic potential of these powerful anti-cancer treatments.

The Group comprises two divisions: The therapeutics development activities are based in London and Cambridge, UK and the Group is generating near-term revenues from Affimer reagents for diagnostics, bioprocessing and research, through a separate diagnostics business unit based in Wetherby, UK.

Avacta's Diagnostics Division is developing an in-house pipeline of Affimer-based diagnostic assays, including the AffiDX<sup>®</sup> SARS-CoV-2 Lateral Flow Rapid Antigen Test, and works with partners worldwide to develop bespoke Affimer<sup>®</sup> reagents for third party products.

Avacta's Therapeutics Division is working to deliver a more tolerable and durable treatment response for oncology patients who do not respond to existing immunotherapies. By combining its two proprietary platforms the Group is building a wholly owned pipeline of clinically differentiated cancer therapies, aiming to extend the therapeutic benefits to all cancer patients. In 2021 Avacta transitioned to become a clinical stage biopharmaceutical company, commencing a phase I first-in-human, open label, dose-escalation and expansion study of AVA6000, a pro-doxorubicin, the Group's lead pre|CISION™ prodrug, in patients with locally advanced or metastatic selected solid tumours.

Avacta has established drug development partnerships with pharma and biotech, including a research collaboration with ModernaTX, Inc. (formerly Moderna Therapeutics Inc.), a multi-target deal with LG Chem worth up to \$400m, a joint venture in South Korea with Daewoong Pharmaceutical focused on cell and gene therapies incorporating Affimer immune-modulators and a collaboration with Point Biopharma to develop radiopharmaceuticals based on the pre|CISION<sup>™</sup> platform. Avacta continues to actively seek to license its proprietary platforms in a range of therapeutic areas.

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## **Chairman and Chief Executive Officer's Statement**

#### **Avacta Diagnostics Division**

During the reporting period the Avacta Diagnostics Division has transformed into an ISO13485 accredited *in-vitro* diagnostics product business with the CE marking and subsequent commercial launch of the first ever Affimer-powered diagnostic product, a SARS-CoV-2 antigen lateral flow test.

There is significant commercial potential for this rapid antigen test in the private UK market, in Europe and further afield and the Company believes that it is well positioned to compete in these markets because of the test's high quality and excellent clinical performance; its UK origins; its ability to detect the variants of the SARS-CoV-2 virus, in particular the Delta variant; and its convenient nasal sampling method. What is now also clear is that these commercial opportunities will persist for a much longer period of time than initially anticipated, with the potential for use in a seasonal testing market.

#### AffiDX® SARS-CoV-2 Antigen Lateral Flow Test

During the reporting period the Company completed the clinical validation of the AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test which was shown to have 100% sensitivity for clinical samples with Ct≤27 (considered as a high to medium infectious viral load) and 98% sensitivity for clinical samples with Ct values up to 31 (low viral load) obtained from 98 positive COVID-19 patients. The clinical specificity was 99% obtained from 102 negative samples. Additional data (a further 134 negative samples) obtained more recently has further defined the clinical specificity to be 99.6%.

These data represent key differentiating features of the AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test, allowing the Company to compete on performance rather than price. Details of the transfer pricing to distributors and the price of direct sales are confidential, but the key performance benefits allow Avacta to competitively maintain these prices above that of cheaper tests.

The declaration of conformity for CE mark for professional use of the AffiDX<sup>®</sup> antigen test was submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) and a European competent authority in May, and the product registration, which allows the test to be placed on the market, was obtained in both the UK and EU in mid-June.

Early challenges with the supply chain were quickly resolved and the commercial roll-out of the AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test is progressing both through direct sales and through distributors. Avacta's direct sales efforts are focused on large businesses, primarily but not exclusively in the UK, for workforce testing and on a range of other users of professional use tests such as elite professional sports teams and the travel industry. Commercial traction is building driven by the key benefits of the test previously described.

The first distributor for the product in the UK and Europe, Calibre Scientific, was appointed towards the end of June in a non-exclusive capacity. Avacta is working with additional distributors in the Asia Pacific (APAC) region, and in other territories, to obtain the additional local regulatory approvals to place an IVD product with a CE mark on the market in those territories. These approvals are expected to be received in Q4 2021 which would allow for sales in those additional territories.

It is now widely expected that SARS-CoV-2 antigen testing will be a long-term market and will become a seasonal testing market similar to that for influenza. The high quality and excellent performance of the AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test puts Avacta in a strong position to gain market share in this long-term diagnostic market. In 2020 the total global SARS-CoV-2 antigen test market size

(including PCR and other antigen test formats) was valued at \$5.3 billion and is expected to expand at a compound annual growth rate of 6.7% from 2021 to 2027<sup>1</sup>.

The APAC region accounted for the largest portion of the market so far for SARS-CoV-2 antigen testing, representing 37.0% of the market in 2020<sup>1</sup> and, in the lateral flow testing market, there is a shift globally towards self-testing products. These market trends are key drivers of Avacta's AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test commercial strategy – to expand regulatory approvals in the APAC region and to bring a self-test product to market.

The regulatory approval of a self-test version of the AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test is a critical milestone because self-administered testing represents a significantly larger commercial opportunity than professional use testing. Avacta is working closely with its partner Medusa19 to support Medusa19's application for a CE mark for an AffiDX<sup>®</sup> SARS-CoV-2 antigen self-test. Good progress is being made in this regard with the submission of the regulatory documentation to a notified body in Europe. Medusa19 and Avacta are currently awaiting the response of the notified body and will update the market when a response is received.

The AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test is being manufactured by Global Access Diagnostics and the transfer of this process to Abingdon Health is now being validated to allow commercial product to be manufactured and released. In combination these two UK-based manufacturers will be able to supply 3-5 million tests per month. Further capacity, if required, is being put in place in Europe and potentially in Asia.

## **Avacta Therapeutics Division**

The past 12 months has seen significant progress in Avacta's Therapeutics Division with the submission and approval of a Clinical Trial Application in the UK leading to the dosing of the first patient in the phase I, first-in-human, open label, dose-escalation and expansion study of its lead pre|CISION<sup>™</sup> prodrug, AVA6000, in patients with locally advanced or metastatic selected solid tumours. This marks the transformation of Avacta into a clinical stage oncology drug company.

## AVA6000 pro-doxorubicin

Anthracyclines such as doxorubicin, a generic chemotherapy for which the broader market is expected to grow to \$1.38bn by 2024, are widely used as part of standard of care in several tumour types, but their use is limited by cumulative toxicity, and, in particular, cardiotoxicity. Avacta's pre|CISION™ prodrug approach is designed to reduce the systemic exposure of healthy tissues to the active chemotherapy, leading to improved safety and therapeutic index, potentially resulting in improved dosing regimens, better efficacy and better outcomes for patients.

The AVA6000 phase I clinical trial involves a dose-escalation phase I study in patients with locally advanced or metastatic selected solid tumours, known to be fibroblast activation protein (FAP)-positive, in which cohorts of patients receive ascending doses of AVA6000 to determine the maximum tolerated dose and establish a recommended phase II dose. The second part of the study is an expansion phase where patients receive AVA6000 to further evaluate the safety, tolerability and clinical activity at this recommended phase II dose across selected tumour types. For more information visit www.clinicaltrials.gov (NCT04969835).

The first patient received their first dose of AVA6000 at The Royal Marsden NHS Foundation Trust postperiod end in early August 2021 and has now received their second and third cycles of treatment. The phase I study is being initiated across a small group of leading UK cancer centres with an established

<sup>&</sup>lt;sup>1</sup> <u>https://www.grandviewresearch.com/industry-analysis/covid-19-antigen-tests-market</u>

reputation for early cancer clinical research in the phase I setting. The dose escalation phase is anticipated to complete by Q2 2022 followed by the dose expansion phase which should complete by Q2 2023.

The Company also remains on track for an IND submission before the end of 2021 for AVA6000 for a phase I clinical trial at two identified clinical trial sites in the US.

## Pipeline of pre|CISION<sup>™</sup> chemotherapies

Avacta's pre|CISION<sup>™</sup> platform is a proprietary chemical modification which renders the modified chemotherapeutic drug inactive in the circulation until it enters the tumour micro-environment where it is activated by an enzyme called FAP. FAP is in high abundance in most solid tumours but not in healthy tissues such as the heart. This is expected to lead to a significantly greater amount of active drug in the tumour tissue compared with healthy tissues and a concomitant improvement in tolerability for patients and better clinical outcomes.

If the AVA6000 study shows that the pre|CISION <sup>™</sup> chemistry is effective in reducing systemic toxicity of Doxorubicin in humans, then it can be applied to a range of other established chemotherapies to improve their safety and efficacy. This would be a significant value inflection point since it would open up a pipeline of next generation of safer chemotherapies for the Group with significant clinical and commercial value in a chemotherapy market that is expected to grow to \$56 billion by 2024.

The next most advanced pre|CISION<sup>™</sup> pro-drug is AVA3996, a FAP-activated analogue of Velcade, Takeda's proteasome inhibitor which comes off patent in 2022. The global proteasome inhibitors market size is expected to be worth \$1.7 billion by 2023<sup>2</sup> and Velcade represents just over half of that market. As with all chemotherapies the benefit of these drugs is limited by toxicities and tolerability for patients. In the case of Velcade, there are significant side effects such as peripheral neuropathy which has limited its approval, principally to multiple myeloma. A potentially safer proteasome inhibitor, such as AVA3996, could win significant market share for the treatment of multiple myeloma and also be used to treat solid tumours, such as pancreatic cancer. Pancreatic cancer also exhibits the highest level of FAP activity of any solid tumour and therefore a FAP activated pro-drug could have significant potential in this area of high unmet need.

Excellent progress has been made in the AVA3996 programme which remains on track for clinical development candidate selection by the end of 2021. A number of *in-vivo* studies aimed at de-risking the pre-clinical and clinical development of AVA3996 have been completed. A contract manufacturing organisation for the drug substance and drug product has been identified and the Company is investigating potential fast-track approval options.

A longer term pipeline of preCISION pro-drug chemotherapies is in the Company's early research pipeline working closely with Professor Bill Bachovchin's group at Tufts University Medical School.

#### Affimer Immunotherapy Programmes

One of the highest priorities for Avacta's Therapeutics Division is to translate the Affimer<sup>®</sup> platform into human and demonstrate the safety and tolerability of this novel therapeutic protein platform.

In the oncology field it has become clear in recent years that cancer immunotherapies used singly, socalled 'monotherapies', have limited overall response rates. The Company's Affimer<sup>®</sup> immunotherapy strategy is to harness the benefits of the Affimer<sup>®</sup> platform to build bispecific drug molecules that can

<sup>&</sup>lt;sup>2</sup> <u>https://www.biospace.com/article/releases/proteasome-inhibitors-market-size-worth-1-7-billion-by-2023-technavio/</u>

hit two drug targets simultaneously and to use Affimer<sup>®</sup> molecules to target toxic payloads using conventional and pre|CISION<sup>™</sup> linkers.

Steady progress has been made with the in-house Affimer<sup>®</sup> bispecific programmes towards selection of a clinical development candidate as quickly as possible. The two lead programmes build upon the AVA004 PD-L1 antagonist; these are AVA027, a PD-L1/TGF- $\beta$  receptor trap combination, and AVA028, a PD-L1/IL2 bispecific.

As a result of the clinical data from Merck KGaA and their Bintrafusp alfa (a dual TGF-beta/PD-L1 inhibitor antibody), the Company has decided to pause the AVA027 programme. This will afford the Company time to further understand the issues arising in the Bintrafusp alfa clinical trials and whether they are related to the trial design, and can therefore potentially be dealt with by better trial design, or whether there is a more fundamental issue with this bispecific combination. In the meantime, the Company is using this pause to focus resources on AVA028 to deliver an Affimer<sup>®</sup> development candidate as quickly as possible.

AVA028 combines an Affimer PD-L1 antagonist with IL-2 which is a cytokine that plays a signalling role in expanding the number of activated immune cells (T and NK cells). IL-2 has been developed as a stand-alone cancer therapy, but it suffers from challenging systemic toxicity and therefore the concept of AVA028 is to combine IL-2 with a PD-L1 inhibitor in a bispecific drug molecule to not only support the immune response in the tumour through blocking of the PD-L1 / PD-1 interaction but also to help target the IL-2 to tumours which have an increased level of PD-L1 compared with healthy tissue.

Good progress has been made in the AVA028 programme. Lead candidate molecules have demonstrated *in-vivo* activity in a pilot efficacy study. Further *in-vivo* efficacy and safety studies have been initiated to confirm dose selection for further non-clinical *in-vivo* studies and ultimately for a clinical first-in-human study. A clinical development candidate selection decision is planned for H1 2022.

## TMAC<sup>®</sup> and other drug conjugates

Drug conjugates use a chemical linker to combine a toxic payload such as a chemotoxin or radioligand with a targeting system such as an Affimer<sup>®</sup> or antibody that binds to a cancer biomarker usually on the surface of tumour cells. Conventional drug conjugates target a biomarker that is frequently internalised by the tumour cells taking with it the drug conjugate where the toxic payload is released by enzymatic breakdown of the linker. The tumour microenvironment activated drug conjugate (TMAC<sup>®</sup>) uses the pre|CISION<sup>™</sup> chemistry in the linker so that the toxic payload can be released outside the tumour cell in the tumour microenvironment, synergistic, mechanisms of action to be envisioned between the toxin and the targeting system which could have immunotherapeutic properties. TMAC<sup>®</sup> is a new class of drug conjugate for which the Company has made a patent application with Tufts University Medical School.

*In-vivo* studies of the lead TMAC<sup>®</sup> programmes are ongoing to support the selection of a clinical development candidate from the pipeline. The first of these programmes is AVA04-VbP, a TMAC<sup>®</sup> combining a PD-L1 Affimer<sup>®</sup> antagonist with a powerful chemotherapy called AVA100 I-DASH (also known as Val-boro-Pro (VbP)) that kills macrophage in the tumour microenvironment leading to a significant inflammatory event that attracts the immune system to the tumour. The postulated mechanism of action is that the immune response to the pro-inflammatory cell killing in the tumour is then supported by the presence of the Affimer<sup>®</sup> PD-L1 blockade. The second TMAC<sup>®</sup> programme combines an Affimer<sup>®</sup> against an undisclosed target with VbP. These *in-vivo* studies will continue through 2021 with potential to select the first TMAC<sup>®</sup> drug candidate during 2022 for pre-clinical and clinical development.

The Therapeutics Division is also reviewing conventional drug conjugate opportunities that leverage the key benefits of the Affimer<sup>®</sup> platform to deliver toxic payloads into tumour cells.

#### Partnered programmes

LG Chem Life Sciences: Very good progress has been made in our strategic partnership with LG Chem Life Sciences towards the clinical development of a novel checkpoint inhibitor utilising the Affimer<sup>®</sup> platform. LG Chem Life Sciences has recently committed to move from the discovery phase into preclinical develop and ultimately IND-enabling studies with a PD-L1 antagonist candidate drug molecule utilising Afffimer XT<sup>®</sup> half-life extension. This is a major step forwards in our close collaboration with LG Chem Life Sciences and moves the Affimer<sup>®</sup> platform significantly closer to the clinic.

AffyXell: AffyXell is an Affimer-engineered cell therapy joint venture with Daewoong Pharmaceuticals in South Korea. During the reporting period AffyXell closed a Series A round of \$7.3m with a syndicate of venture capital firms including Samsung Venture Investment Corporation. The company has made excellent progress, advancing both its GMP-compliant human mesenchymal stem cell technology and its Affimer<sup>®</sup> discovery programs against two of the three initial targets. Proof-of-concept studies are planned for 2022 to form the basis for a Series B fund raise to move candidate cell therapies into the clinic.

Moderna: In 2019 Moderna exercised a commercial option to an Affimer<sup>®</sup> programme and took a number of lead Affimer molecules against that particular target in-house for development. Avacta is not actively involved with this ongoing internal development work at Moderna. The next key milestone would occur if Moderna submits an IND package to the FDA.

ADC Therapeutics: Avacta has provided Affimer<sup>®</sup> molecules to ADC Therapeutics under the evaluation agreement. This evaluation agreement has now concluded, and ADC Therapeutics is not taking this programme further.

## Chief Scientific Officer and Scientific Advisory Board

The Therapeutics Division has made a series of new appointments in recent months with Dr Fiona McLaughlin joining as Chief Scientific Officer and with several appointments to its Scientific Advisory Board (SAB), reflecting Avacta's transition to a clinical stage oncology drug company.

Dr McLaughlin is a highly experienced oncology drug developer, bringing over 25 years' experience in research and translational drug development in the pharmaceutical and biotech sectors, having led teams from early research through to clinical development. Fiona started her career at GlaxoSmithKline and has subsequently held leadership positions in multiple biotech companies including Vice President, Translational Research at Antisoma plc and Director of Pre-clinical Development at BTG plc (now part of Boston Scientific).

Other roles include Head of Biology at TopoTarget A/S, where she was responsible for the pre-clinical development of belinostat which went on to gain FDA approval to treat peripheral T-cell lymphoma. Most recently, Fiona was Vice President of New Opportunities at Algeta ASA (acquired by Bayer), a Norwegian biotech developing alpha radio-pharmaceuticals, that gained FDA approval of Xofigo to treat castration resistant prostate cancer.

Fiona has also gained broad experience during her career as a Consultant, providing scientific and strategic advice to biotechs, Not-for-Profit Organisations, and Venture Capitalists in UK, Europe, USA and Australia, including helping drive oncology strategy at the CRUK/AstraZeneca Alliance Laboratory. Fiona received a PhD from the Haematology Department at Cambridge University and has a BSc in Biochemistry from Glasgow University.

The SAB provides the Therapeutics Division with scientific and clinical advice to support its drug development decision making and pipeline strategy. The three new members of the SAB are Professor James Spicer MB., BA., PhD., FRCP, Professor Krishnan Komanduri, MD, and Dr Stéphane Champiat MD, PhD.

James Spicer is Professor of Experimental Cancer Medicine at King's College London and Consultant in Medical Oncology at Guy's & St. Thomas' Hospitals, London. He has established and runs a world-leading Phase 1 clinical trials programme in solid tumour oncology at Guy's Hospital, where the portfolio of studies includes novel immunotherapies discovered and developed at King's as well as many externally sponsored studies.

Krishna Komanduri is Chief of the Division of Transplantation and Cellular Therapy, and Associate Chief Medical Officer for Clinical Innovation, at the Sylvester Comprehensive Cancer Center, Miami. He is also a Professor of Medicine, Microbiology and Immunology and a physician-scientist with a laboratory focusing on T-cell immunology in cancer. Dr. Komanduri serves on the United Health Care Oncology Advisory Committee and is a past Chair of the American Society of Hematology Scientific Committee on Host Defense, is the current Chair of the ASTCT Cellular Therapy Committee and Chair-Elect of the Government Relations Committee.

Stéphane Champiat MD, PhD is a physician at the Gustave Roussy Cancer Center in Paris, where he focuses on the development of cancer therapeutics, in particular, new immunotherapies. He has been principal investigator or co-investigator of more than 50 Phase I clinical trials run by many of the world's leading pharmaceutical and biotech companies. He is particularly involved in the coordination of the immunotherapy toxicity management program and the development of the intra-tumoral immunotherapy strategy at Gustave Roussy.

#### **Avacta Animal Health Division**

Avacta Animal Health provides specialised laboratory services to veterinary professionals worldwide. Trading over the reporting period has improved following the re-focus of the business on its core product and service offerings around allergy and therapy testing with growth in the UK and overseas. Revenues for the period were £0.81 million compared to £0.68 million in the comparable period in 2020. Operating costs for the business have been reduced following the changes made last year and this has seen the business achieve an operating break-even position compared to an operating loss of £0.27 million in the comparable period.

Trading since the end of the reporting period continues to improve as the business strengthens its position providing veterinary testing services, contract research services and sales of laboratory testing kits in the UK and overseas.

## **Financial Review**

Revenue for the 6 months ended 30 June 2021 increased to £2.32 million compared to the same period in 2020 (6 months to 30 June 2020: £1.81 million; year ended 31 December 2020: £3.64 million).

Revenue contribution from the Group's Therapeutics Division increased to £1.43 million (6 months to 30 June 2020: £0.80 million; year ended 31 December 2020: £1.63 million) due to the continuation of funded research projects and certain milestone payments. Revenue from the Diagnostic Division decreased to £0.09 million (6 months to 30 June 2020: £0.34 million; year ended 31 December 2020: £0.52 million) as resources were focused on the development and launch of the AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test with a reduced number of custom projects during the period. Revenues from Avacta Animal Health, the allergy and diagnostic testing business, increased to £0.81 million (6 months to 30 June 2020: £1.49 million).

Research costs from the development of the AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test and the expanding Therapeutics Division increased to £6.29 million (6 months to 30 June 2020: £3.57 million; year ended 31 December 2020: £8.96 million), as the Company continues to make significant investments in the Affimer<sup>®</sup> and pre|CISION<sup>™</sup> therapeutics programmes.

Selling, general and administrative costs have increased to £4.06 million (6 months to 30 June 2020: £3.14 million; year ended 31 December 2020: £7.32 million). Depreciation has also increased to £0.65 million (6 months to 30 June 2020: £0.52 million; year ended 31 December 2020: £1.13 million). Sharebased payment charges have remained constant at £1.44 million (6 months to 30 June 2020: £1.44 million; year ended 31 December 2020: £3.11 million).

Amortisation of development costs has reduced to £0.41 million (6 months to 30 June 2020: £0.66 million; year ended 31 December 2020: £1.00 million) as the research and development costs for the AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test and the pre-clinical development costs of the Therapeutics Division have been expensed during the period. The value of intangible assets on the balance sheet, which includes capitalised development costs and goodwill has reduced from the prior year end as a result of the amortisation to £9.07 million (30 June 2020: £12.02 million; 31 December 2020: £9.42 million).

The Group's operating loss increased to £11.34 million (6 months to 30 June 2020: £8.11 million; year ended 31 December 2020: £21.29 million) and the reported loss after taxation increased to £10.20 million (6 months to 30 June 2020: £6.99 million; year ended 31 December 2020: £18.89 million).

The basic loss per share increased to 4.09p (6 months to 30 June 2020: 3.74p; year ended 31 December 2020: 8.37p) due to the increase in reported losses.

There was a cash outflow from operations and working capital movements of £10.20 million (6 months to 30 June 2020: £4.39 million; year ended 31 December 2020: £13.35 million) and an outflow from investing activities (excluding movements on short-term deposits) of £0.80 million on capital expenditure and capitalised development costs (6 months to 30 June 2020: £1.02 million; year ended 31 December 2020: £1.88 million). Cash inflow from financing activities, being amounts received from the issue of shares and exercise of share options net of lease payments amounted to £0.11 million (6 months to 30 June 2020: inflow £51.09 million; year ended 31 December 2020: inflow £51.65 million). The Group ended the period with £36.97 million net cash and short-term deposits (30 June 2020: £54.45 million; 31 December 2020: £47.91 million).

## Our people

We wish to acknowledge the continuing effort and commitment of our staff in what has continued to be difficult circumstances during the first half of 2021. We would like to thank them again for their hard work and commitment that has led to the success of all the Group's businesses and has delivered significant progress towards numerous major value inflection points.

## Effects of the COVID-19 pandemic

The Board continues to monitor and assess the impact of the COVID-19 pandemic on staff and on the Group's businesses.

The Diagnostics Division has launched a high-performance SARS-CoV-2 antigen lateral flow test and expects to see significant revenue from sales of that product for a number of years. The intense focus of technical resources on the SARS-CoV-2 lateral flow test product development and the establishment

of the Quality Management System that supported the ISO13485 certification, is now being eased and the business can turn the majority of its technical resources to future product development that will underpin non-COVID-19 related future revenue.

During the reporting period the Therapeutics Division overcame the limitations on working practices imposed by the pandemic and did not experience any significant delays with sub-contractors or regulatory bodies, allowing it to successfully initiate the phase I clinical study of AVA6000 in August 2021. The business is not currently expecting to see any significant effects on the ability of the phase I clinical trial sites to recruit patients but there remains a potential risk of delays in this regard through the autumn and winter.

## Outlook

The Group has made strong progress during the reporting period, and over the past 18 months, despite the additional pressures and restrictions imposed on the businesses by the pandemic. This is a testament to the commitment and hard work of our staff, and we will continue to invest in them through training, development, and an active focus on organisational mental health to continue to drive performance.

The Board believe that the most significant near-term value driver for the Group is the clinical data from the phase I study of AVA6000. The pre|CISION prodrug approach has the potential to complement chemotherapy and to create new oncology treatments that are affordable for all. If the pre|CISION platform is shown to improve the safety of Doxorubicin in the AVA6000 phase I study then it not only creates a significant commercial opportunity for the Group with a proprietary safer form of Doxorubicin, but also opens up a large, and very valuable, pipeline of future pre|CISION<sup>™</sup> chemotherapy prodrugs.

The Diagnostics Division has launched its first Affimer-powered in-vitro diagnostic product, the AffiDX<sup>®</sup> SARS-CoV-2 antigen lateral flow test which has raised the global profile of the Affimer platform and the Group immensely. It is clear that the Diagnostics Division has the potential to generate significant revenue from sales of this product over a longer period than originally anticipated, creating the basis for a profitable Diagnostics Division. The team will continue to expand its distributor network and extend the regulatory approvals outside of the UK and EU to drive sales over the longer term and will scale its manufacturing capacity as required to meet demand, as well as develop a pipeline of additional *in-vitro* diagnostic products.

In the next 12 months we expect to see further strong progress in both Divisions and anticipate several significant value inflection points to be achieved.

Dr Eliot Forster Chairman 30 September 2021 Dr Alastair Smith Chief Executive Officer 30 September 2021

# Condensed Consolidated Statement of Profit or Loss for the 6 months ended 30 June 2021

	Unaudited 6 months ended 30 June 2021	Unaudited 6 months ended 30 June 2020	Audited Year ended 31 December 2020
	£000	£000	£000
Revenue	2,321	1,810	3,636
Cost of sales	(811)	(586)	(1,455)
Gross profit	1,510	1,224	2,181
Research costs	(6,285)	(3,574)	(8,961)
Share of loss of associate	-	-	(217)
Amortisation of development costs	(410)	(664)	(1,007)
Impairment of intangible fixed assets	-	-	(1,741)
Selling, general and administrative expenses	(4,062)	(3,141)	(7,315)
Depreciation expense	(652)	(515)	(1,125)
Share-based payment charge	(1,438)	(1,435)	(3,108)
Operating loss	(11,337)	(8,105)	(21,293)
Finance income	13	15	43
Finance costs	(72)	(28)	(93)
Net finance costs	(59)	(13)	(50)
Loss before tax	(11,396)	(8,118)	(18,891)
Taxation	1,199	1,124	2,452
Loss and total comprehensive loss for the period	(10,197)	(6,994)	(18,891)
Loss per ordinary share: - Basic and diluted	(4.09p)	(3.74p)	(8.37p)

All activities relate to the continuing operations of the Group.

# Condensed Consolidated Statement of Financial Position as at 30 June 2021

Assets	Unaudited As at 30 June 2021 £000	Unaudited As at 30 June 2020 £000	Audited As at 31 December 2020 £000
Property, plant, and equipment	2,920	2,020	2,696
Right-of-use assets	1,937	678	2,095
Intangible assets	9,069	12,018	9,417
Non-current assets	13,926	14,715	14,208
Inventories	222	161	248
Trade and other receivables	5,786	2,176	2,895
Income tax receivable	3,400	3,625	2,200
Short-term deposits	5,023	-	20,017
Cash and cash equivalents	31,951	54,451	27,894
Current assets	46,382	60,413	53,254
Total assets	60,308	75,128	67,462
Liabilities			
Lease liabilities	(1,599)	(568)	(1,752)
Non-current liabilities	(1,599)	(568)	(1,752)
Trade and other payeblas	(4.070)	(2,060)	(2.404)
Trade and other payables Lease liabilities	(4,979) (300)	(2,969) (164)	(3,491) (290)
Current liabilities	(5,279)	(3,133)	(3,781)
Total liabilities	(6,878)	(3,701)	(5,533)
Net assets	53,430	71,427	61,929
Equity attributable to equity holders of the Company			
Share capital	25,443	24,957	25,343
Share premium	54,297	53,797	54,137
Other reserve	(1,729)	(1,729)	(1,729)
Reserve for own shares	(2,961)	(2,961)	(2,961)
Retained earnings	(21,620)	(2,637)	(12,861)
Total equity	53,430	71,427	61,929

Total equity is wholly attributable to equity holders of the parent Company. Approved by the Board and authorised for issue on 30 September 2021.

Dr Alastair Smith Chief Executive Officer Tony Gardiner Chief Financial Officer

# Condensed Consolidated Statement of Changes in Equity for the 6 months ended 30 June 2021

	Unaudited Share	Unaudited Share	Unaudited Other	Unaudited Reserve	Unaudited Retained	Unaudited Total
	Capital	premium	reserve	for own shares	earnings	Equity
	£000	£000	£000	£000	£000	£000
At 1 January 2020	17,671	9,877	(1,729)	(2,932)	2,922	25,809
Total comprehensive loss for the period	-	-	-	-	(6,994)	(6,994)
Total transactions with owners of the						
company:	7 104	42 507				E0 704
Issue of shares	7,194 82	43,597 304	-	-	-	50,791 386
Exercise of options	82 10	304 19	-	-	-	380
Own shares acquired Equity-settled share-	10 -	- 19	-	(29)	- 1,435	- 1,435
based payment	-	-	-	-	1,435	1,433
At 30 June 2020	24,957	53,797	(1,729)	(2,961)	(2,637)	71,427
Total comprehensive	_	_		-	(11,897)	(11,897)
loss for the period	-	-	-	-	(11,097)	(11,097)
Total transactions with						
owners of the						
company:						
Exercise of options	386	340	-	-	-	726
Equity-settled share- based payment	-	-	-	-	1,673	1,673
At 31 December 2020	25,343	54,137	(1,729)	(2,961	(12,861)	61,929
			., ,	. /	• • •	
Total comprehensive	-	-	-	-	(10,197)	(10,197)
loss for the period						
Total transactions with						
owners of the						
company:						
Exercise of options	100	160	-	-	-	260
Equity-settled share-	-	-	-	-	1,438	1,438
based payment					.,	.,
At 30 June 2021	25,443	54,297	(1,729)	(2,961)	(21,620)	53,430

# Condensed Consolidated Statement of Cash Flows for the 6 months ended 30 June 2021

	Unaudited 6 months ended 30 June 2021 £000	Unaudited 6 months ended 30 June 2020 £000	Audited Year ended 31 December 2020 £000
Cash flow from operating activities	<i></i>	<i>(</i> )	<i></i>
Loss for the period	(10,197)	(6,994)	(18,891)
Adjustments for:	400	075	4 000
Amortisation	428	675	1,029
Impairment losses	- 652	- 515	1,741 1,125
Depreciation Net (gain) / loss on disposal	032	515	1,125
of property, plant, and equipment	-	(1)	6
Share of loss of associate	_	_	217
Equity-settled share-based payment charges	1,438	1,435	3,108
Net finance costs	58	13	50
Taxation	(1,199)	(1,124)	(2,452)
Operating cash outflow before changes in working capital	(8,820)	(5,481)	(14,067)
Decrease / (increase) in inventories	26	(4)	(91)
Increase in trade and other receivables	(2,888)	(95)	(814)
Increase in trade and other payables	1,486	1,192	1,627
Operating cash outflow from operations	(10,196)	(4,388)	(13,345)
Interest received	13	15	42
Interest elements of lease payments	(66)	(29)	(93)
Tax credit received	-	-	2,754
Net cash used in operating activities	(10,249)	(4,402)	(10,642)
Cash flows from investing activities			
Purchase of plant and equipment	(718)	(128)	(1,279)
Purchase of intangible assets	(81)	(3)	(221)
Investment in associate	-	-	(217)
Development expenditure capitalised	-	(889)	(165)
Decrease/(increase) in balances on short-term deposit	14,994	-	(20,017)
Net cash used in investing activities	14,195	(1,020)	(21,899)
Cash flows from financing activities			
Proceeds from issue of new shares	-	53,750	53,750
Transaction costs related to issue of share capital**	-	(2,960)	(2,960)
Proceeds from exercise of share options	259	386	1,112
Principal elements of lease payments	(148)	(91)	(255)
Net cash flow from financing activities	111	51,085	51,647
Net increase/(decrease) in cash and cash equivalents	4,057	45,663	19,106
Cash and cash equivalents at the beginning of the period			
ousin and busin equivalents at the beginning of the period	27,894	8,788	8,788

\*\* Please see Note 1 for further information

# Notes to the unaudited condensed consolidated financial statements for the 6 months ended 30 June 2021

#### 1) Basis of preparation

Avacta Group plc ('the Company') is a company incorporated in England and Wales under the Companies Act 2006. These condensed consolidated interim financial statements ('interim financial statements') as at and for the 6 months ended 30 June 2021 comprise the Company and its subsidiaries (together referred to as 'the Group').

The interim financial statements for the 6 months ended 30 June 2021 are unaudited. This information does not constitute statutory accounts as defined in Section 435 of the Companies Act 2006. The financial figures for the year ended 31 December 2020, as set out in this report, do not constitute statutory accounts but are derived from the statutory accounts for that financial year. The statutory accounts for the year ended 31 December 2020 were prepared under IFRS and have been delivered to the Registrar of Companies. The auditors reported on those accounts. Their report was unqualified, did not draw attention to any matters by way of emphasis and did not include a statement under Section 498 of the Companies Act 2006.

The Board confirms that, to the best of its knowledge, these condensed financial statements have been prepared in accordance with IAS34 *Interim Financial Reporting* and should be read in conjunction with the Group's last annual consolidated financial statements as at and for the year ended 31 December 2020 ('last annual financial statements'). They do not include all the financial information required for a complete set of IFRS financial statements. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual financial statements.

In the prior interim period, the Consolidated Statement of Cash Flows presented proceeds from the issue of share capital net of transaction costs related to the issue of share capital as £50,790,000.

The Board approved these interim financial statements for issue on 30 September 2021.

#### 2) Use of judgements and estimates and significant accounting policies

The preparation of the interim financial statements requires management to make judgements and estimates that affect the application of accounting policies and the reported amounts of assets and liabilities, income, and expense. Although these estimates are based on management's best knowledge of the amount, events or actions, actual events ultimately may differ from those estimates.

The significant judgements made by management in applying the Group's accounting policies, and the key sources of estimation uncertainty were the same as those described in the last annual financial statements.

The accounting policies applied in these interim financial statements are the same as those applied in the Group's consolidated financial statements as at and for the year ended 31 December 2020. A number of new standards are effective from 1 January 2021, but they do not have a material effect on the Group's financial statements.

#### 3) Segmental reporting

The Group has three distinct operating segments: Diagnostics, Therapeutics and Animal Health. These are the reportable operating segments in accordance with IFRS 8 *Operating Segments*. The Directors recognize that the operations of the Group are dynamic and therefore this position will be monitored as the Group develops.

Segment revenue represents revenue from external customers arising from sale of goods and services, plus inter-segment revenues. Inter-segment transactions are priced on an arm's length basis. Segment results, assets and liabilities include items directly attributable to a segment as well as those that can be allocated on a reasonable basis.

The Group's revenue to destinations outside the UK amounted to 77% (6 months to 30 June 2020: 73%; year to 31 December 2020: 70%). The revenue analysis below is based on the country of registration of the customer:

	6 months	6 months	Year ended
	ended 30	ended 30	31 December
	June 2021		2020
£000			
UK	542	483	1,076
Rest of Europe	292	328	685
North America	748	239	402
Asia	739	759	1,473
	2,321	1,810	3,636

The central overheads, which primarily relate to the operation of the Group function are not allocated to the operating segments.

#### Operating segment analysis for the six months ended 30 June 2021

	Diagnostics £000	Therapeutics £000	Animal Health £000	Total £000
Revenue	91	1,425	805	2,321
Cost of goods sold	(50)	(497)	(264)	(811)
Gross profit Research costs	<b>41</b> (2,068)	<b>928</b> (4,190)	<b>541</b> (27)	1,510 (6,285)
Amortisation of development costs	(410)	-	· · ·	(410)
Selling, general and administrative expenses Depreciation expense Share-based payment expense	(1,232) (248) (371)	(869) (376) (390)	(483) (25) (17)	(2,584) (649) (778)
Segment operating loss Central overheads	(4,288)	(4,897)	(11)	(9,196) (2,141)
<b>Operating loss</b> Finance income Finance expense				(11,337) 13 (72)
Loss before taxation Taxation				(11,396) 1,199
Loss for the period				(10,197)

#### Operating segment analysis for the six months ended 30 June 2020

	Diagnostics £000	Therapeutics £000	Animal Health £000	Total £000
Revenue	337	795	678	1,810
Cost of goods sold	(169)	(192)	(226)	(587)
Gross profit	168	603	452	1,223
Research costs	(12)	(3,543)	(19)	(3,574)
Amortisation of development costs	(549)	-	(114)	(664)
Selling, general and administrative expenses	(1,151)	(611)		(2,315)
Depreciation expense	(142)	(255)	(14)	(411)
Share-based payment expense	(371)	(389)	(17)	(777)
Segment operating loss Central overheads	(2,057)	(4,195)	(265)	(6,517) (1,588)
Operating loss Finance income				(8,105) 15
Finance expense				(28)
Loss before taxation				(8,118)
Taxation				1,124
Loss for the period				(6,994)
erating segment analysis for the year ended 31	December 2020			
erating segment analysis for the year ended 31	December 2020			

Diagnostics

s Therapeutics

Animal Health

Total

	£000	£000	£000	£000
Revenue	519	1,625	1,492	3,636
Cost of goods sold	(321)	(641)	(493)	(1,455)
Gross profit	198	984	999	2,181
Research costs	(2,458)	(6,432)	(71)	(8,961)
Share of loss of associate	-	(217)	-	(217)
Amortisation of development costs	(824)	-	(183)	(1,007)
Selling, general and administrative expenses	(2,525)	(1,702)	(966)	(5,193)
Impairment charge	-	-	(1,741)	
Depreciation expense	(357)	(701)	(62)	(1,120)
Share-based payment expense	(636)	(893)	(38)	(1,567)
Segment operating loss	(6,602)	(8,961)	(2,062)	(17,625)
Central overheads				(3,668)
<b>Operating loss</b> Finance income Finance expense				(21,293) 43 (93)
Lana hafana (anafan				(04.040)
Loss before taxation				(21,343) 2 452
Loss before taxation Taxation Loss for the period				(21,343) 2,452 
Taxation				

#### 4) Revenue

The Group's operations and main revenue streams are those described in the last annual financial statements. The Group's revenue is all derived from contracts with customers.

#### **Disaggregation of revenue**

In the following table, revenue is disaggregated by its nature. The table also includes a reconciliation of the disaggregated revenue with the Group's reportable segments (see Note 4).

#### Six months ended 30 June 2021

£'000	Diagnostics	Therapeutics	Animal Health	Total
Nature of revenue				
Sale of goods	-	-	462	462
Provision of services	91	689	343	1,123
Licence-related income	-	736	-	736
	91	1,425	805	2,321

#### Six months ended 30 June 2020

£'000	Diagnostics	Therapeutics	Animal Health	Total
Nature of revenue				
Sale of goods	-	-	392	392
Provision of services	337	795	285	1,417
Licence-related income	-	-	-	-
	337	795	677	1.809

#### Year ended 31 December 2020

£'000	Diagnostics	Therapeutics	Animal Health	Total
Nature of revenue				
Sale of goods	-	-	846	846
Provision of services	519	1,436	646	2,601

Licence-related income	- 189 -		- 189
	519	1,625	1,492 3,636
i) Earnings per share			
	Unaudited	Unaudited	Audited
	6 months ended 30	6 months ended 30	Year ended 31
	June 2021	June 2020	December 2020
Loss (£000)	10,197	6,994	18,891
Weighted average number of shares (number)	249,127,610	187,187,754	225,578,759
Basic and diluted loss per ordinary share (p)	(4.09)	(3.74)	(8.37)

#### 6) Standards issued but not yet effective

A number of new standards and amendments to standards are effective for annual periods beginning after 1 January 2021 and earlier application is permitted; however, the Group has not early adopted any of the forthcoming new or amended standards in preparing these condensed consolidated interim financial statements.