THE INFORMATION COMMUNICATED WITHIN THIS ANNOUNCEMENT IS DEEMED TO CONSTITUTE INSIDE INFORMATION AS STIPULATED UNDER THE MARKET ABUSE REGULATION (EU) NO. 596/2014. UPON THE PUBLICATION OF THIS ANNOUNCEMENT, THIS INSIDE INFORMATION IS NOW CONSIDERED TO BE IN THE PUBLIC DOMAIN.



22 April 2021

# **Avacta Group plc**

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

# Preliminary Results for the year ending 31 December 2020

Significant progress in Diagnostics and Therapeutics Divisions

Avacta Group plc (AIM: AVCT), the developer of diagnostics and innovative cancer therapies based on its proprietary Affimer<sup>®</sup> and pre|CISION™ platforms, is pleased to announce its preliminary results for the year ending 31 December 2020.

# **Operating highlights**

# **Operating highlights - Diagnostics**

- Rapid generation of a range of Affimer® reagents that bind the SARS-CoV-2 coronavirus spike antigen for diagnostic testing applications.
- Collaboration with several partners to develop a rapid test for the COVID-19 infection for mass population screening.
- Appointed BBI Solutions, part of BBI Group ('BBI'), and Abingdon Health to manufacture the salivabased rapid SARS-CoV-2 antigen test.
- Entered a collaboration with the Liverpool School of Tropical Medicine ('LSTM') to provide analytical and clinical validation of the rapid coronavirus antigen test.
- Announced launch of an ELISA laboratory test for the SARS-CoV-2 spike protein to support global research efforts into the coronavirus that causes COVID-19.
- Collaboration with Adeptrix (Beverly, MA, USA) to develop a high throughput Affimer-based SARS-CoV-2 antigen bead-assisted mass spectrometry test ('BAMS<sup>TM'</sup> test) to be used on hospitals' existing installed base of mass spectrometers to diagnose COVID-19 infection. Initiated clinical evaluation of BAMS<sup>™</sup> SARS-CoV-2 antigen test at a UK NHS hospital site.
- Exclusive distribution agreement announced with Medusa19 Limited ('Medusa19') for direct-to-consumer sales of a rapid antigen self-test for Covid-19.
- Major licensing agreement with Astrea Bioseparations Limited ('Astrea') for the use of the Affimer<sup>®</sup> platform in affinity purification applications.
- Successfully passed first audit by the Group's Notified Body (BSI Group) of the Company's Quality
  Management System as first step in establishing ISO13485 accreditation, a critical quality
  assurance system for a developer and legal manufacturer of diagnostic products and medical
  devices. The final audit will take place in April 2021.
- Strengthened and expanded diagnostics management team with the appointment of a Product Manager, Head of Product Development and Operations Director.

# Post-period highlights - Diagnostics

- AffiDX® SARS-CoV-2 Antigen Lateral Flow Test shows excellent analytical sensitivity of 50 pg/ml of S1 spike protein with a read time of 20 minutes. As far as the Group is aware and on the basis of laboratory testing to date, this is currently the most sensitive S1 spike lateral flow test available. On 16 February 2021, we announced the initial clinical evaluation of this test using anterior (front) nasal swab samples (30 positive and 26 negative samples) which demonstrated a sensitivity of 96.7% for samples with an infectious viral load (PCR Ct value < 26) and a specificity of 100%. Subsequently, on 20 April we announced the completion of the clinical validation of the AffiDX® SARS-CoV-2 antigen lateral flow test with excellent performance data (clinical sensitivity of 98.0% for samples with Ct values up to 31 and clinical specificity of 99.0%).</p>
- On 28 January 2021, we entered a collaboration agreement with Bruker Corporation to evaluate the clinical utility and commercial potential of the BAMS™ SARS-CoV-2 Antigen Test.
- On 8 February 2021, we established a commercial partnership with Mologic following several
  months' collaborative work to provide Avacta with a faster route to market for the lateral flow rapid
  antigen test by CE marking it for professional use under Mologic's existing ISO13485 quality
  system. The CE mark will then be transferred to Avacta after it receives ISO13485 accreditation,
  which is expected in April 2021.
- The collaboration with Mologic also provides initial manufacturing capacity with the benefit of a short set-up time for the lateral flow test with Global Access Diagnostics ('GAD'), in addition to the agreements with BBI Group, Abingdon Health and others, that will provide manufacturing capabilities that can be scaled to several millions of tests per month.
- On 9th March 2021, we announced a royalty bearing license agreement with Biokit, a Werfen Company, to develop and commercialise an Affimer-based in-vitro diagnostic test.

# Operating highlights - Therapeutics

- Established a partnered programme ('AffyXell Therapeutics') in South Korea with Daewoong Pharmaceutical Co. Ltd., to develop the next generation of cell and gene therapies, incorporating Affimer® proteins to enhance the immune-modulatory effects. Programme subsequently expanded to provide access to the Affimer® platform for neutralising Affimer® therapies for the treatment of seriously ill patients with COVID-19 and to also prepare to rapidly develop similar therapies for future global pandemics.
- Demonstrated initial proof-of-concept for its proprietary new class of drug conjugate, 'TMAC®', in a pre-clinical animal model of cancer.
- Expanded the existing multi-target collaboration and development agreement with LG Chem Life Sciences ('LG Chem') to include new programmes incorporating Avacta's Affimer XT™ serum half-life extension system, deal worth up to \$98.5 million plus royalties.
- Appointment of Neil Bell as Chief Development Officer responsible for the late stage pre-clinical and early clinical development of Avacta's pipeline of pre|CISION™ pro-drugs and Affimer® immunotherapies.
- Submitted the Clinical Trial Authorisation (CTA) to the UK Medicines and Healthcare products Regulatory Agency (MHRA) for a phase I dose-escalation and expansion study of AVA6000 prodoxorubicin, Avacta's first pre|CISION™ FAP-activated prodrug.
- On schedule to select the next pre|CISION™ prodrug chemotherapy clinical development candidate from the pipeline by the end of 2021.
  - Significant progress with in-house Affimer<sup>®</sup> bispecific programmes towards selection of a clinical development candidate by the end of 2021. Two new programmes initiated, building on the AVA004 PD-L1 antagonist programme: AVA027, a PD-L1/TGfβ receptor trap combination, and AVA028, a PD-L1/IL2 bispecific.

# Post-period highlights - Therapeutics

- On 7 January 2021, we announced the licensing agreement with Point Biopharma Inc to provide access to Avacta's pre|CISION™ technology for the development of tumour-activated radiopharmaceuticals.
- Key appointments of Head of Chemistry, Manufacturing and Controls (CMC), Head of Clinical Operations and Head of Translational Sciences will together manage an extensive outsourced network of drug development service providers.
- On 1 February 2021, AffyXell Therapeutics ('AffyXell'), the partnered programme with Daewoong Pharmaceuticals ('Daewoong'), closed a series A venture capital investment of \$7.3m to further develop its pipeline of next generation cell and gene therapies.
- On 18 February 2021, the Medicines and Healthcare products Regulatory Agency ('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. The Group anticipates dosing first patients in mid-2021 subject to COVID-19 restrictions on hospital resources with first pharmacokinetics read-out possible before the year end.

# **Financial and Corporate highlights**

- Fundraisings completed during the period raising £53.8 million to expand Diagnostics and Therapeutics programmes.
- Cash and short-term deposit balances at 31 December 2020 of £47.9 million (31 December 2019: £8.8 million)
- Revenues of £3.6 million for year ended 31 December 2020 (17-month period to 31 December 2019: £5.5 million)
- Operating loss of £21.3 million for year ended 31 December 2020 (17-month period to 31 December 2019: £18.0 million)
- Increased R&D investment across diagnostics and therapeutic programmes, leading to reported loss of £18.9 million (17-month period to 31 December 2019: £15.6 million)
- Loss per ordinary share 8.4p (17-month period to 31 December 2019: 13.0p)
- Paul Fry appointed as Non-executive Director. Paul is Chief Financial Officer of Vectura Group plc, an industry-leading inhaled drug delivery specialist listed on the FTSE Main Market.

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

"There is no doubt that 2020 was a momentous year for Avacta. I am enormously proud of the entire team who have been instrumental in delivering this transformational growth and creating substantial commercial and clinical opportunities for the Group for 2021 and beyond, despite the difficult working conditions imposed on laboratory working by the COVID-19 pandemic.

We are now very close to self-declaration of the CE mark of the AffiDX® rapid antigen test for professional use and commercial launch in early May. We have made very good commercial progress with potential distributors, licensing partners and large-scale end users and demand is strong. We also expect to see the first pharmacokinetic data for AVA6000 before the end of the year which will give us the first indication of the effectiveness of the pre|CISION™ chemistry in humans so I am very much looking forward to updating the market on these events and other progress across the Group during the coming months."

For further information from Avacta Group plc, please contact:

**Avacta Group plc** Tel: +44 (0) 844 414 0452

Alastair Smith, Chief Executive Officer www.avacta.com

Tony Gardiner, Chief Financial Officer

finnCap Ltd (Nominated Adviser and Joint Broker) Tel:

Geoff Nash / Giles Rolls - Corporate Finance www

Tim Redfern - ECM

Tel: +44 (0) 207 220 0500

www.finncap.com

Stifel Nicolaus Europe Limited (Joint Broker) Tel: +44 (0) 207 710 7600

Nicholas Moore / Nick Adams / Fred Walsh / Ben www.stifel.com

Maddison

**FTI Consulting** (Financial Media and IR) Tel: +44 (0) 203 727 1000
Simon Conway / Stephanie Cuthbert Avacta.LS@fticonsulting.com

Zyme Communications (Trade and Regional Tel: +44 (0) 7787 502 947

Media)

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

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

The Affimer® 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 \$100 billion. 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™ 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 Life Sciences divisions - Therapeutics and Diagnostics - and an Animal Health division. Therapeutics development activities are based in 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 and an Animal Health division also based in Wetherby.

Avacta's Diagnostics division works with partners world-wide to develop bespoke Affimer<sup>®</sup> reagents for third-party products. The Group is also developing an in-house pipeline of Affimer-based diagnostic assays including the AffiDX<sup>®</sup> SARS-CoV-2 Antigen Lateral Flow Test and an AffiDX<sup>®</sup> BAMS<sup>™</sup> SARS-CoV-2 Assay in partnership with Adeptrix Inc.

Avacta's Therapeutics division is addressing a critical gap in current cancer treatment - the lack of a durable response to current immunotherapies experienced by most patients. By combining its two

proprietary platforms, the Group is building a wholly owned pipeline of novel cancer therapies deigned to be effective for all cancer patients. In 2021 Avacta will commence a phase I first-in-human, open label, dose-escalation and expansion study of AVA6000 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 \$400 million, a partnered programme in South Korea with Daewoong Pharmaceutical focused on cell and gene therapies incorporating Affimer<sup>®</sup> immune-modulators, a partnership with ADC Therapeutics to develop Affimer-drug conjugates and a collaboration with Point Biopharma to develop radiopharmaceuticals based on the pre|CISION™ platform. Avacta continues to actively seek to license its proprietary platforms in a range of therapeutic areas.

To register for news alerts by email go to www.avacta.com/investor-news-email-alerts

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

The significant progress achieved in both the Diagnostics and Therapeutics divisions during 2020 has already enabled us to deliver further major value inflection points during the first four months of 2021.

We are very excited by the commercial potential of our scalable, rapid coronavirus test. The recently announced excellent clinical validation data (sensitivity of 98.0% for samples with Ct values up to 31 and specificity of 99.0%) strongly reflects the excellent analytical performance demonstrated in the lab and suggests that it may be, to date, the most sensitive S1 spike protein lateral flow test.

Despite unprecedented pressures on the Diagnostics division, we now have the infrastructure in place to support the commercial launch of this test. Importantly, we are close to completing the establishment of a complex supply chain for the scalable manufacture of the test kits and we are making timely progress in instituting a quality management system to support the required ISO13485 accreditation for medical devices.

In line with commitments we made during the fund-raise last summer, in the Therapeutics division we expanded our in-house pre-clinical pipeline and kept our partnered programmes moving forwards despite the restrictions of COVID-19 safe-working. We also appointed Neil Bell as Chief Development Officer, who has now established a clinical development team to drive the Company's transition to a clinical stage biotech.

In December, we submitted a Clinical Trial Authorisation ('CTA') to the UK's MHRA for our lead  $pre|CISION^{TM}$  platform drug candidate, AVA6000 pro-doxorubicin, and I am delighted that we recently received approval from the Agency to proceed with the phase I study, which we expect will dose first patient around the middle of the year.

# **Fund-raising**

During 2020, the Group completed two fund-raises, which delivered a combined £53.8 million, transforming the Group's abilities to develop both its diagnostics and therapeutics businesses. These fund-raises have significantly strengthened the Group balance sheet, with £47.9 million of cash and short-term deposits at 31 December 2020 and will provide funding for the Group into 2023.

# **Board changes**

In February 2020, Paul Fry joined the Board as a Non-executive Director and has become the Chairman of the Audit Committee. Paul, who is also Chief Financial Officer of Vectura plc, brings with him a wealth of financial experience across several sectors including biotech, pharmaceutical and telecommunications.

On 24 March 2021, Dr Mike Owen stepped down from his Board role as Non-executive Director having served as a Director since 2015. We would like to thank Mike for his significant commercial and scientific input to the Board. Mike will continue to chair the Scientific Advisory Group in a non-Board role.

## Our people

The commitment of our employees during the last year has been exceptional. Despite significant restrictions on normal working practices due to the pandemic their efforts have transformed the Group. Our employees are actively engaged in our strategic plans and in delivering shareholder value, and many of them are also shareholders in the Group. Their work in implementing quality systems, developing Affimer® reagents for COVID-19 development projects in very short timescales, submitting the relevant submissions for our first clinical trials and maintaining development programmes with our partners across the world has been truly inspiring.

## Effects of the COVID-19 pandemic

The ability of the Group's Diagnostics division to react to the COVID-19 pandemic and help provide a solution, which could bring the impacts of pandemic on daily life to an end has been transformational for the Group. The interest generated with shareholders created the opportunity to raise significant funds to support the Group in developing its diagnostics and therapeutics platforms.

The downsides of the pandemic have led to many challenges in working practices across the Group, with scientific staff working shifts to ensure safe laboratory working practices and support staff working from home where possible to reduce the number of staff at each site. Additional premises have been taken on in both Cambridge and Wetherby and either have been fitted out, or are being fitted out, to provide further laboratory space for all the scientific teams to return to the laboratories full time and allow for the expansion of the teams over the coming months.

There has been an impact on the therapeutic programmes and some changes to work programmes were necessary in the early lockdown period whilst we managed staff numbers on site. Our contract manufacturing and clinical operations partners also reduced staffing levels, which caused some delays to programmes. This also had an impact on our partnered programme revenues recognised during 2020, with some revenues based on FTE work slipping back into 2021. However, the teams are now focused on bringing the programmes to fruition with our partners.

The dosing of first patients in our AVA6000 phase I study, now that we have regulatory approval, is due to commence in the middle of 2021. The exact timings of this will be determined by how quickly the pressure on clinicians and hospitals is reduced from the COVID-19 pandemic.

Our Animal Health division's revenues were impacted during the first lockdown as veterinary practices were focusing on emergency cases, with more routine appointments in relation to allergy or therapy testing being put on hold. The division took the opportunity to assess its product portfolio and routes to market during this time. Whilst some staff transferred across to our diagnostics team there were unfortunately two redundancies because of this process and new routes to market. Following a non-cash impairment charge of £1.74 million, and with the business recovering strongly in the second half of the year to deliver a small operating profit, it is now positioned well for trading in 2021.

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

# Outlook

We are very proud of the Avacta team and how they have overcome the substantial challenges presented by the pandemic and continued to progress our programmes and generate substantial shareholder value. There are several significant milestones to deliver during 2021, with the dosing of the first patient in the AVA6000 clinical trial, the anticipation of initial pharmacokinetic data for AVA6000 and the pre|CISION™ platform before year end, and the launch of the SARS-CoV-2 antigen lateral flow test with the potential to generate substantial revenues. We look forward to updating the market on these very exciting milestones ahead of us in due course.

Eliot Forster Non-executive Chairman 22 April 2021 Alastair Smith Chief Executive Officer 22 April 2021

# **Diagnostics Division**

- Poised to capitalise on a substantial commercial opportunity for high quality rapid testing for COVID-19.
- A pipeline of non-COVID-related in-house diagnostic tests for a range of diseases and conditions being developed to be brought to market from 2022 onwards, adding to longterm COVID-19 testing revenues.
- Affimer® reagent licensing deals for diagnostic and other applications now being delivered for a pipeline of Affimer® technology evaluations creating the potential for long-term royalty income.

# AffiDX® SARS-CoV-2 Lateral Flow Rapid Antigen Test for potential mass deployment

During the past year Avacta, in conjunction with its partners, has made substantial progress in the development of its Affimer® based, SARS-CoV-2 antigen lateral flow test. Laboratory studies showed that it may be the most sensitive S1 spike protein lateral flow test available to date and recent clinical validation data has reflected this strong analytical performance. The clinical study tested 98 positive COVID-19 samples across a broad range of high and low viral loads (31 with Ct<26; 65 with Ct 26-30 and 2 with Ct 30-31). The test identified 96/98 of these correctly as positive with a 20 minute read time resulting in a clinical sensitivity of 98.0% for samples within this broad range down to low viral loads. Out of a total of 102 negative samples tested with the lateral flow device, the test correctly identified 101 as negative, giving a clinical specificity of 99.0%.

The test is therefore capable of identifying individuals with infectious viral loads using an anterior nasal swab sample. Such a test is suitable for mass deployment to identify those people who are likely to infect others so that they can isolate and reduce the spread of the infection.

Lateral flow tests are a complement to, not a replacement for, PCR testing.

How a diagnostic test is used, called the 'Intended Use Case', is extremely important and it must be adhered to in order to avoid a test being used inappropriately. A rapid antigen test with high specificity and good sensitivity can be used effectively to identify the majority of people with a high viral load that makes them infectious so that they can isolate themselves. Frequent testing, at least once every few days and ideally daily, is important so that as soon as the viral load of an infected person becomes high enough to be infectious that person is identified.

The first challenge in developing a clinically useful rapid coronavirus test for mass population screening is to understand what viral load should be considered infectious.

Patient samples can be characterised in a number of ways, but the most common are as follows:

- Genome copies per millilitre (i.e., how many copies of the virus RNA are present in a millilitre of sample)
- Plaque forming units ('pfu') per millilitre (i.e., how many viable viruses that can infect cells and multiply are present in a millilitre of sample). The number of pfu/ml and genomes/ml are different because there is RNA present in samples that is not assembled into viable virus particles (i.e., the genomes per ml is higher than the pfu per ml). These two measures of infection vary in a way which has not yet been fully characterised, but there is probably between 10 10,000 more genomes/ml than pfu/ml in a sample
- Cycle time ('Ct'), which is the number of amplification cycles of PCR required to detect the virus (i.e., a low Ct value means that the person has higher viral load because it took fewer amplification cycles to become detectable). Ct values vary between different PCR tests, and even between different laboratories running the same test, so this should also be taken into account

A reasonable assumption, based upon the growing combined understanding of SARS-CoV-2 and COVID-19, is that a person is infectious and likely to infect others if their viral load is > 10,000 genomes/ml (i.e., approximately > 100 pfu/ml and Ct < 25). According to recently published data from the Liverpool Covid Smart Pilot, a viral load of < 10,000 genome/ml leads to a likelihood of infecting others of around 10%. Therefore, at this low end of the infectious range the risk of infecting others appears to be quite low. Whereas the risk of a person with a viral load ~1,000,000 genome copies/ml is around 50%. Highly infectious people can have viral loads > 100,000,000 genome copies/ml.

With all this in mind, for a rapid antigen test to have clinical utility (and therefore sustainable commercial value) it should be able to detect SARS-CoV-2 viral load of a few hundred pfu/ml, or Ct of 25 or below, or > 10,000 genomes/ml. Clearly, the lower the detection limit the better, and a test must be able to achieve this limit of detection in real patient samples and not just in contrived 'clean' laboratory samples.

Laboratory testing suggests that the AffiDX® SARS-CoV-2 Antigen Lateral Flow Test could be the most sensitive spike antigen test so far available.

The AffiDX® SARS-CoV-2 Antigen Lateral Flow Test detects the SARS-CoV-2 S1 spike protein and has an analytical limit of detection ('LOD') in nasal swab samples of 50 pg/ml. This can be achieved with a visual read time of 10 minutes. The test line is clearer if a longer read time is used, therefore a read time of 20 minutes has been adopted as the standard for this test.

How does this analytical sensitivity translate into pfu/ml of virus, which is the clinically relevant measure? Avacta has established this relationship using Avacta's research ELISA for S1 protein and inactivated virus provided by Public Health England (Porton Down, UK). Using this safe form of the virus, we have shown that an analytical LOD of 50pg/ml corresponds to the amount of S1 spike protein in a virus sample containing 500 pfu/ml.

A significant proportion of the development time of the AffiDX® SARS-CoV-2 Antigen Lateral Flow Test has been focused on achieving this level of sensitivity in human saliva and nasal swab clinical samples. The development work has been carried out in-house and with our development partners using saliva and anterior nasal swab samples taken from healthy volunteers to which the S1 spike protein has subsequently been added to known concentrations to generate a contrived clinical sample. The key challenge in developing the test has been to get these complex human fluids to flow properly in the device and to eliminate false positive results arising from unknown material in nasal samples and saliva. This has been achieved through detailed studies evaluating a range of different additives to the lateral flow test and sample extraction buffer for both nasal and saliva samples. The Group announced in Q4 2020 that it would focus on anterior nasal sampling because of the variability of saliva samples, although the test works with both sample types. The UK Department of Health and Social Care has also recently focused on nasal and other swab samples rather than saliva.

In summary, the AffiDX® SARS-CoV-2 Antigen Lateral Flow Test has excellent analytical sensitivity (LOD) of 50 pg/ml S1 spike protein, which appears sensitive enough to detect the lowest viral loads of relevance to the Intended Use Case, with a read time of 20 minutes. As far as the Group is aware, this is the most sensitive S1 spike lateral flow test available.

The analytical specificity of the Affimer® reagents has been reported previously with no cross-reactivity with the S1 spike proteins from closely related coronaviruses: MERS-CoV S1, SARS-CoV-1 S1, HCoV-229E S1, HCoV-HKU1 S1, HCoV-NL63 S1 or HCoV-OC43 S1.

The test detects the D641G mutant of the original coronavirus, and the Group expects that the test will also detect the newer coronavirus variants. Work is ongoing with Public Health England to confirm this.

# Clinical evaluation of AffiDX® SARS-CoV-2 Antigen Lateral Flow Test

The clinical performance of a diagnostic test cannot simply be inferred from the analytical performance because of the complex pathology of diseases which control the amount of a biomarker that is available in a sample when added to the test. In the case of COVID-19, there is a complex series of biological processes that determine how much of the virus spike protein is actually present in the anterior (front) part of the nose to be picked up on a swab and then released into a buffer to be added to the lateral flow test strip. A clinical evaluation of the test is the only way to determine whether it is capable of identifying infectious individuals.

The initial evaluation of Avacta's lateral flow rapid antigen test with clinical samples was carried out at two sites, one in the EU and one in the UK using patient samples with viral loads confirmed by PCR. 30 positive samples were tested with Ct values of 26 and below, with half of those in the range 22-26, and the lateral flow test identified 29/30 of these correctly as positive. This indicates a clinical sensitivity of 96.7% for samples with a Ct value below 26. Importantly, out of a total of 26 negative samples tested with the lateral flow device, the test correctly identified all 26 as negative, giving a clinical specificity of 100%. High specificity is critical for a lateral flow test for mass screening so that large numbers of false positives are not generated, which would create a major burden on follow-on testing resources, and result in a significant socio-economic cost of unnecessarily isolating people.

The second clinical validation for CE marking purposes was carried out at a single site in Europe and reported on recently. The study tested 98 positive samples (31 with Ct<26; 65 with Ct 26-30 and 2 with Ct 30-31). Avacta's rapid antigen test identified 96/98 of these correctly as positive with a 20 minute read time resulting in a clinical sensitivity of 98.0% for samples within this broad range down to low viral loads. Out of a total of 102 negative samples tested with the lateral flow device, the test correctly identified 101 as negative, giving a clinical specificity of 99.0%.

On the basis of these excellent clinical data, the Group will now complete the technical file, including accelerated stability data, for CE marking the test for professional use early in May followed immediately by commercial roll-out.

Avacta Diagnostics division expects ISO13485 accreditation early in Q2 2021

Avacta's Diagnostics division has completed the two audits of the Group's Quality Management System that are required by its external auditor in order to award ISO13485 accreditation and is awaiting confirmation of the outcome.

Medical device manufacturing is a highly regulated sector in which stringent quality systems and product performance requirements must be satisfied. These regulatory requirements are intended to ensure that manufacturers consistently design, produce and place onto the market medical devices that are safe and fit for their intended purpose. ISO13485 certification provides a practical foundation for diagnostics and medical device manufacturers to address these regulatory requirements and obligations of the industry, as well as demonstrating a commitment to device safety and quality.

The Diagnostics division has established a Quality Management System and the first external audit by the Group's Notified Body (BSI Group) was passed in December successfully. The second and final audit was scheduled in March 2021, but due to a COVID-19 case at Avacta's Wetherby site, the second audit has been split into two with the final site visit now occurring in early April. The Group is awaiting confirmation of a positive outcome to this second audit. This certification sets the organisational and operational framework for all current and future diagnostic product developments and it is an essential accreditation that underpins future commercial success.

Whilst the Group establishes its own ISO13485 accreditation, in order to achieve the fastest possible and lowest risk route to CE marking, Avacta has established a partnership with Mologic Ltd. so that the AffiDX® SARS-CoV-2 Antigen Lateral Flow Test can be CE marked for professional use quickly under Mologic's established ISO13485 Quality System. The CE mark will then be transferred to Avacta when it achieves ISO13485 accreditation, which is expected early in May 2021. As part of the collaboration between the two companies, Avacta and Mologic are also exploring the possibility of combining Avacta's spike antigen test with Mologic's nucleocapsid antigen test in a single device which would be a world first and has the potential to deliver the most sensitive rapid antigen test possible. The two companies will evaluate whether the two tests can be combined in a single device and then make a commercial decision on whether to pursue this second generation COVID-19 diagnostic.

Avacta will immediately be able access initial manufacturing capacity through Mologic's close partner Global Access Diagnostics (GAD), in addition to scale-up manufacturing capacity with BBI and Abingdon Health. Combined, these manufacturing partnerships can scale up to several million tests per month and potentially much higher with further investment. Avacta is also continuing its discussions with other manufacturers in the UK and overseas in order to be able to access additional capacity to ensure that it can meet the expected demand.

The Group continues its commercial discussions with potential customers for the AffiDX® SARS-CoV-2 Antigen Lateral Flow Test and expects demand to be present for rapid testing for at least two years and probably for longer. Only by having a high-quality test that identifies the majority of infectious individuals can this clinical need be translated into commercial success and the Group believes that the recent initial clinical data are extremely encouraging in that regard.

Healthcare services providers and governments are likely to be the largest volume customers of a professional use rapid antigen test and with an estimated price point in the mid-single digit GBP range. A higher price point is anticipated for sales to corporates for workforce testing.

#### BAMS™ SARS-CoV-2 assay

In collaboration with Adeptrix Inc, Avacta has developed a mass spectrometry assay on Adeptrix's BAMS™ platform which combines enrichment of the sample using Avacta's SARS-CoV-2 spike protein Affimer® binders to improve sensitivity with the power of mass-spectrometry for analysis. Up to one thousand samples per day can be analysed by a single technician using BAMS, exceeding the capacity of a single PCR machine.

In January, Avacta established a collaboration with Bruker Corporation (Billerica, MA) (NASDAQ: BRKR, 'Bruker') to evaluate the Affimer-based SARS-CoV-2 BAMS<sup>TM</sup> assay and assess the suitability of the test as a professional-use *in-vitro* diagnostic ('IVD') product for SARS-CoV-2 infection to run on Bruker's MALDI-TOF instruments.

Bruker is one of the world's leading analytical instrumentation companies, providing high-performance scientific instruments and high-value analytical and diagnostic solutions to scientists globally. It is also one of the foremost suppliers of mass spectrometers with a significant installed based in clinical microbiology laboratories in hospitals world-wide.

Having successfully developed a prototype test with Adeptrix, Avacta, has been working with its clinical partners in the UK to refine the assay to fit into the typical workflows in a clinical microbiology laboratory and to work well on the type of simplified mass spectrometer that is found in this setting. Avacta is working closely Bruker and Adeptrix on this process.

There is now a well-established PCR-testing capacity in most countries that is capable of dealing with current demand, making the commercial case for mass spectrometer based additional capacity less compelling than anticipated by the two companies. In light of this rapidly changing COVID-19 hospital testing market Avacta is working closely with Bruker and Adeptrix to review the commercial strategy for the SARS-CoV-2 assay and for a wider range of BAMS proteomics tests in general.

# Non-COVID diagnostics update

Post-period end, the Group entered into a licence agreement with Astrea for the use of the Affimer® platform in affinity purification applications.

Astrea is a leading provider of affinity separation solutions to the pharmaceutical and biomanufacturing industries. It is a division of Gamma Biosciences, the life sciences tools platform created by KKR, to build a leading position in next generation bioprocessing for advanced therapies.

This is an important validation of one part of the Group's business model for non-therapeutic Affimer® applications – that of third-party technical evaluations of bespoke Affimer® reagents generated for a specific application leading to licensing of those Affimer® reagents and long-term royalty-based revenue streams. Astrea has evaluated certain Affimer® reagents for affinity separation, resulting in the agreement between the two companies for a non-exclusive licence for the use of the Affimer® technology in this field.

The agreement includes a £0.5 million upfront payment to Avacta which gives Astrea the rights to generate and develop Affimer® reagents in-house for affinity separation using an Affimer® library to be provided by Avacta. It also provides Astrea with an option to convert the agreement into an exclusive licence if certain commercial performance criteria are met over the next three years and subject to the payment of an additional undisclosed option exercise fee.

Avacta will receive royalties on future sales of Astrea's purification products that contain Affimer® reagents.

Although the pandemic has affected the Group's business development activities, it continues to generate new projects and to work on established Affimer® evaluations with partners to generate further licensing agreements.

The Group is also developing an in-house pipeline of Affimer-based diagnostic tests. Resources have been focused during 2020 primarily on the immediate COVID testing opportunities, and since the lateral flow test is now in clinical evaluation the Group is in a position to begin to refocus its research and development resources onto non-COVID diagnostic tests, which include assays for D-dimer, cortisol, vitamins D and B12 and C-reactive protein, a test with regard to liver function. Avacta has recently appointed a Product Manager who joined the Group in March whose role is to define the market opportunity and performance requirements for new tests to feed the product development pipeline in the future. This appointment is part of a wider expansion of the Diagnostics division's management team which also includes a Head of Product Development and Operations Director.

During the pandemic, in order to maintain a COVID safe working environment the Group has not been able to have all laboratory staff on site at the same time and has worked in two teams. New CAT 2 laboratory facilities in Wetherby have been completed and equipment that has been installed and validated to satisfy the requirements of ISO13485. The new facilities can house about 20 staff and all scientific staff are now able to work full time in the laboratories.

## **Therapeutics Division**

# Wholly-owned Therapeutic Pipeline

- Poised to transition into a clinical stage biotech with the dosing of first patient in mid-2021 with the first pre|CISION™ pro-drug, AVA6000 pro-doxorubicin, in a phase I study in patients with locally advanced or metastatic selected solid tumours.
- Pipeline of multiple Affimer<sup>®</sup> and pre|CISION<sup>™</sup> clinical candidates to be generated in 2021 and 2022 for pre-clinical and clinical development.

Approval of CTA for AVA6000, the Group's lead pre|CISION™ prodrug, is a key milestone.

The Group achieved a significant milestone with the submission in Q4 2020 and subsequent approval on 19 February 2021 from the MHRA (Medicines and Healthcare products Regulatory Agency) of the Clinical Trial Authorisation (CTA) for AVA6000 pro-doxorubicin, the Group's lead pre|CISION™ prodrug, for a phase I, first-in-human, open label, dose-escalation and expansion study in patients with locally advanced or metastatic selected solid tumours. The Group anticipates dosing first patients in mid-2021, subject to COVID-19 restrictions on hospital resources, with first pharmacokinetics read-out possible before the year-end.

Instrumental in achieving the CTA submission milestone was the appointment of Chief Development Officer, Neil Bell, who has rapidly established a highly experienced clinical development team including a Head of Chemistry, Manufacturing and Controls (CMC), Head of Clinical Operations and Head of Translational Medicine appointed in-house to manage an extensive outsourced network of service providers.

In AVA6000, Doxorubicin has been modified with Avacta's pre|CISION™ chemistry, which renders the modified drug inactive in the circulation until it enters the tumour micro-environment. Here it is activated by an enzyme called FAP (fibroblast activation protein), which is in high abundance in most solid tumours but not in healthy tissue such as the heart. AVA6000 has been shown in animal models to significantly increase the amount of active drug in a tumour compared with the heart and should thereby improve tolerability and achieve better clinical outcomes for patients

Phase I study will be clinical proof-of-concept of the pre|CISION<sup>™</sup> platform

The phase I study is a first-in-human, open-label, multi-centre study to be carried out in the UK in patients with locally advanced or metastatic solid tumours which are known to be FAP positive, including pancreatic, colorectal, breast, ovarian, bladder and non-small cell lung cancers, squamous cell carcinoma of the head and neck and soft-tissue sarcoma.

The dose-escalation phase of the study, which will be carried out in 15 to 20 patients, is designed to evaluate the safety of AVA6000 in humans and establish the appropriate dosing levels for the dose expansion phase of the study.

The dose expansion phase will consist of up to three studies in specific tumour types to further evaluate safety and tolerability and to explore the anti-tumour activity of AVA6000 when administered as a monotherapy. This phase of study will comprise 45 to 60 patients in total.

If the AVA6000 study shows that the pre|CISION™ 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 open up a pipeline of next generation 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 Group is on schedule to select the next clinical development candidate by the end of 2021 from the pre|CISION™ prodrug pipeline. Lead programmes include: AVA3996, a FAPα activated proteasome inhibitor; AVA7500, a FAPα activated platin; and AVA7000, a FAPα activated taxane. These are being developed in close collaboration with Professor William Bachovchin at Tuft's University School of Medicine.

Building a pre-clinical pipeline of valuable chemotherapy/immunotherapy drug assets

In the oncology field it has become clear in recent years that cancer immunotherapies used singly, so-called 'monotherapies' have limited overall response rates and that combining immune checkpoint modulators such as PD-1, or PD-L1, with chemotherapy improves patients' outcomes. Avacta is in a unique position, with two proprietary platforms, to address this urgent clinical need.

The Company's strategy is to harness the benefits of the Affimer<sup>®</sup> platform to build single Affimer<sup>®</sup> drug molecules that can hit two drug targets simultaneously, called 'bispecifics', and to bring together Affimer<sup>®</sup> immunotherapies with the pre $|CISION^{\mathsf{M}}|$  targeted chemotherapies, in order to develop superior cancer treatments with better patient outcomes.

# Bispecifics Affimer® immunotherapies

Good progress has also been made with the in-house Affimer® bispecific programmes towards selection of a clinical development candidate by the end of 2021. Two new programmes have been initiated that build upon the AVA004 PD-L1 antagonist programme: AVA027, a PD-L1/TGF-β receptor trap combination, and AVA028, a PD-L1/IL2 bispecific.

TGF- $\beta$  largely plays a pro-tumour signalling role by suppressing the immune response and helping to build the blood supply to the tumour, as well as promoting the growth of the tumour in other ways. Reducing the amount of TGF- $\beta$  in the tumour microenvironment is therefore expected to have an anticancer effect which can be combined with PD-L1 checkpoint inhibition to support the immune response to the tumour. In AVA027 this is being achieved by combining a TGF- $\beta$  trap that helps to mop up the TGF- $\beta$  in the tumour along with an Affimer® PD-L1 blockade in a single drug molecule.

IL-2 is a cytokine that plays a signalling role in expanding the number of activated immune cells (T and NK cells). It has been developed as a cancer therapy, but it suffers from challenging systemic toxicity and therefore the concept in AVA028 is to combine IL-2 with an Affimer® 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.

The Group has set the objective of selecting a bispecific clinical candidate from either the AVA027 or AVA028 programmes by the end of 2021 to be taken into pre-clinical development.

# TMAC® drug conjugates

The pre|CISION™ substrate can also be incorporated into a chemical linker joining an Affimer® immunotherapy with a chemotoxin to create a single drug conjugate molecule that can be delivered to the patient in a single infusion. The linker is cut by the FAP enzyme in the tumour microenvironment releasing and activating the chemotherapy in the tumour alongside the Affimer® immunotherapy. By selecting the chemotherapy to have a mechanism of action that stimulates and recruits the immune system to the tumour, the Affimer® checkpoint blockade provides synergistic support for this immune

response. This *tumour microenvironment activated drug conjugate* (TMAC®) is a new class of drug conjugate for which the Company has made a patent application with Tufts University Medical School. The first of Avacta's TMACs combines an Affimer® PD-L1 inhibitor 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® PD-L1 blockade.

*In-vivo* studies of the lead TMAC® 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® combining a PD-L1 Affimer® antagonist with VbP. The second TMAC® programme combines an Affimer® against an undisclosed target with VbP.

These *in vivo* studies will continue through 2021 and are expected to support the selection of the first TMAC® drug candidate during 2022 for pre-clinical and clinical development.

# **Drug Development Collaborations**

- Good progress in existing partnered programmes during 2020 despite the restrictions imposed by COVID safe working.
- Expansion of the partnership with LG to include Affimer XT<sup>™</sup> half-life extension platform.
- AffyXell, a partnered programme with Daewoong Pharmaceutical, established in South Korea to develop next-generation cell and gene therapies incorporating Affimer<sup>®</sup> immuno-therapies; successful series A funding for AffyXell of \$7.3 million post-period end.
- Establishment of new collaboration with POINT Biopharma for pre|CISION™ radiopharmaceuticals.

The Group has established several significant therapeutic partnerships with biotech and pharma partners including Moderna Therapeutics Inc., LG Chem Life Sciences, Daewoong Pharmaceuticals, ADC Therapeutics and recently with POINT Biopharma. Despite the effects of the pandemic, the Group has continued to make solid progress on those programmes in which Avacta plays an active research and development role (LG Chem, Daewoong and ADC Therapeutics).

In August 2020 Avacta agreed to expand the existing multi-target collaboration and development agreement with LG Chem to include new programmes incorporating Avacta's Affimer XT<sup>™</sup> serum half-life extension system. The expansion of the partnership includes an undisclosed additional upfront payment, plus near-term pre-clinical milestones and longer-term clinical development milestones totalling up to \$98.5 million for two therapeutics to be developed using the Affimer XT<sup>™</sup> technology. Under the terms of the extended agreement, LG Chem has the exclusive rights to develop and commercialise, on a world-wide basis, Avacta's Affimer® PD-L1 inhibitor with Affimer XT<sup>™</sup> serum half-life extension.

The expanded partnership also provides LG Chem with rights to develop and commercialise other Affimer<sup>®</sup> and non-Affimer<sup>®</sup> biotherapeutics combined with Affimer  $XT^{\text{TM}}$  half-life extension for a range of indications and Avacta could earn up to an additional \$55 million in milestone payments for each of these new products. In addition, under the agreement Avacta will earn royalties on all future Affimer  $XT^{\text{TM}}$  product sales by LG Chem.

The Group is working with ADC Therapeutics SA (Lausanne, CH) to develop conventional Affimer-drug conjugates combining Avacta's Affimer<sup>®</sup> technology with ADC Therapeutics' pyrrolobenzodiazepine (PBD)-based warhead and linker technologies.

As part of the multi-target collaboration, Avacta is in the process of generating and optimising Affimer® binders against three undisclosed cancer targets so that ADC Therapeutics can use these to target its cytotoxic PBDs to the site of the tumour. ADC Therapeutics will carry out pre-clinical research and development programmes to evaluate each of the Affimer-drug conjugates with a view to generating clinical candidates.

The Group continues to make excellent progress in its collaboration with Daewoong Pharmaceutical through the partnered programme, AffyXell. AffyXell was established in January 2020 by Avacta and Daewoong as a partnered programme to develop novel stem cell therapies. AffyXell is combining Avacta's Affimer® platform with Daewoong's mesenchymal stem cell (MSC) platform such that the stem cells are primed to produce and secrete therapeutic Affimer® proteins *in situ* in the patient. The Affimer® proteins are designed to enhance the therapeutic effects of the stem cells, creating a novel, next-generation cell therapy platform.

The Group recently announced, post-period end, that AffyXell has closed a Series A venture capital investment of \$7.3 million to further develop its pipeline of next-generation cell and gene therapies. The Series A funding has been raised from a group of venture funds including Samsung Venture Investment Corporation, Shinhan Venture Investment, Smilegate Investment, Shinhan Investment Corporation, Kolon Investment, Stonebridge Ventures, and Gyeongnam Venture Investment.

The capital raised will be used by AffyXell to continue the development of MSCs engineered to produce Affimer® molecules generated by Avacta that inhibit inflammatory and autoimmune pathways and promote tissue regeneration.

While initially focusing on inflammatory and autoimmune diseases and prevention of organ transplant rejection, longer term goals could also include applications in regenerative medicine, infectious diseases and oncology.

Post-period end the Group entered into a new licensing agreement with POINT Biopharma Inc. to provide access to Avacta's pre|CISION™ technology for the development of tumour-activated radiopharmaceuticals.

The radiopharmaceutical market is expected to grow to \$15 billion by 2025<sup>1</sup> and there is a substantial opportunity to grow much faster if safety and tolerability of these effective treatments can be improved. POINT Biopharma is a clinical-stage pharmaceutical company focused on developing radioligands<sup>2</sup> as precision medicines for the treatment of cancer.

Avacta's proprietary pre|CISION™ chemistry can be used to modify a radioligand drug to form a tumour-activated prodrug. The prodrug form is inactive in circulation until it enters the tumour microenvironment, where it is activated by an enzyme called fibroblast activation protein (or FAP) that is present in high abundance in most solid tumours but not in healthy tissue. Avacta's pre|CISION™ technology therefore has the potential to improve the tolerability and achieve better clinical outcomes for patients compared with standard radiopharmaceuticals by targeting the radioligand treatment more specifically to cancer cells.

The agreement provides POINT with an exclusive licence to the pre $|CISION^{\text{m}}|$  technology for use in the first radiopharmaceutical prodrug the company intends to develop, and a non-exclusive licence to the pre $|CISION^{\text{m}}|$  platform for the development of a broader pipeline of FAP-activated radiopharmaceuticals.

Under the terms of the agreement, Avacta will receive an upfront fee and development milestones 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.

 $<sup>^{1}\ \</sup>text{https://www.marketresearchfuture.com/reports/radio-pharmaceutical-market-1650}$ 

<sup>&</sup>lt;sup>2</sup> For more information about radioligands visit https://www.radioligands.org

#### **Animal Health Division**

Avacta's Animal Health division, is a UK-based laboratory, research and development business focused on delivering evidence-based animal health solutions, centred on the work-up and management of allergic disease. The business works in partnership with veterinary professionals and allergy experts to offer unrivalled service and technical support to its customers, with a tailored and personal approach. Its customers include veterinary professionals, laboratories, large commercial organisations, SMEs and academic groups.

The division's revenues were impacted during the first UK lockdown as veterinary practices were forced to focus only on emergency cases, meaning more routine consultations, including allergy or therapy testing, were put on hold. Face-to-face contact with customers also ceased but the launch of Avacta Animal Health's new website in April 2020 allowed them to continue providing veterinary practices with a wealth of valuable digital resources throughout, via the dedicated Practice Portal. This was supported by a strengthening of the social media campaign.

During this time, the division took the opportunity to assess its product portfolio and routes to market. Following a non-cash impairment charge of £1.74 million, and with the business recovering strongly in the second half of the year to deliver a small operating profit, it is now positioned well for trading in 2021.

# Competitive strengths

Avacta Animal Health remains the only UK laboratory with end-to-end test control, with years of dedication to research and development that underpins its constant drive to make a real-life difference to animal health.

- Experts in the work-up and management of allergic disease
- Strong veterinary focused team including a number of qualified vets and vet nurses
- Experienced and innovative research and development team
- Evidence-based test and therapy solutions
- Dedicated technical team including dermatology consultants
- Renowned for exceptional level of service and support
- Practice Portal providing a wealth of comprehensive and practical veterinary literature
- Informative pet owner resources
- Educational and training resources for veterinary professionals

# Products and market focus

As the change within the veterinary industry continues at a rapid pace both in practice, for suppliers and for pet owners, Avacta Animal Health's commitment to innovation within the field of allergy remains its core focus and its key to success. The development of the new Avacta Allergy+ portfolio (launched in March 2021) was a key focus throughout 2020 and now offers veterinary practices a range of testing options with enhanced performance. Avacta Animal Health continues to support vets in their interpretation of results and supply tailor-made allergen-specific immunotherapy ('ASIT') to aid with the long-term management of allergic skin disease for veterinary practices in the UK.

Avacta Animal Health's export reach and international customer base is growing, alongside dedicated provision of tailored and trusted support to veterinary professionals across the UK. In addition to providing UK-specific testing services and therapy options via its own authorised laboratories. it continues to expand in Europe, as well as in parts of the Asian and Latin American markets.

# Research and development

The dedicated in-house team of development scientists are highly regarded in the field of dermatology and work alongside world-leading dermatologists to develop, manufacture and run our own tests, allowing them the aforementioned end-to-end control. Development of the new Avacta Allergy+ tests were a key focus of the research and development team in 2020, with enhancements to both the canine and feline environmental tests, as part of the focused new portfolio.

Avacta Animal Health have a strong team, including a number of qualified vets and vet nurses, who maintain regular communication to gain insight from veterinary professionals and experts in the field, allowing them to analyse and review what is clinically relevant on a regular basis.

Avacta Animal Health will attend and support a number of UK conferences and events throughout 2021, providing visibility within the industry and ensuring it remains informed of developments. These events also provide the opportunity to convene and converse in person with new and existing customers, as well as with industry experts and academics.

Via Avacta's Diagnostics business there is an opportunity to scope out new projects using the Affimer® technology and, with experience in reproducible research and statistical analysis, all future work will continue to see a strong steer towards data-driven projects involving machine learning and data visualisation. Such analytical techniques will benefit both internal projects and contracted project work.

#### **Financial Review**

#### Revenue

Reported Group revenues for the year ended 31 December 2020 decreased to £3.64 million compared to the longer 17-month period ended 31 December 2019 ('2019'): £5.51 million.

Revenues for the Diagnostics division were £0.52 million (2019: £0.81 million), with the reduction due to a decrease in the number of custom Affimer® reagent projects given the working restrictions with some customers and a re-focus of the business on developing the COVID-19 lateral flow tests and other related COVID-19 projects.

Revenues for the Therapeutics division were £1.63 million (2019: £2.52 million), with the 2019 revenue including an upfront technology access fee arising from the LG Chem collaboration, whilst 2020 revenues reflected a much smaller milestone payment in the LG Chem collaboration and reduced revenues from funded FTE development projects due to restricted working practices at the Cambridge site.

Revenues for the Animal Health division were £1.49 million (2019: £2.18 million), with the revenues in the second quarter of 2020 severely restricted due to the closure of most veterinary practices during the first lockdown. Revenues for the second half of 2020 recovered and were only slightly behind the corresponding period for 2019.

## Research and amortisation of development costs

During the year, the Group expensed through the income statement £8.96 million (2019: £7.86 million) research costs relating to the in-house Affimer<sup>®</sup> and pre|CISION<sup>™</sup> therapeutic programmes which are expensed given their pre-clinical stage of development in addition to research costs on Affimer<sup>®</sup> diagnostics products which have not yet completed product development and obtained regulatory approval to become commercial products.

In addition, development costs capitalised in prior periods from the development of the Affimer® reagents and diagnostics platform together with new Animal Health allergy tests have been amortised, resulting in a charge of £1.01 million (2019: £2.20 million).

Furthermore, development costs amounting to £0.17 million (2019: £1.88 million) were capitalised within intangible assets during the period and will be amortised over future periods.

The share of losses from the research costs of the therapeutics partnered programme with Daewoong Pharmaceutical, AffyXell Therapeutics, accounted for as an investment in associate, amounting to £0.22 million (2019: £nil) have been expensed using the equity method.

Following completion of the annual impairment reviews, an impairment charge of £1.74 million (2019: £nil) has been recognised against the intangible assets associated with the Animal Health division comprising of goodwill and capitalised development costs. The charge arose as the business restructured, in the light of the COVID-19 pandemic and how the business intends to operate in the veterinary industry, with short-term revenue estimates being revised downwards.

# Selling, general and administrative expenses

Administrative expenses have fallen during the year to £7.32 million (2019: £10.06 million) alongside depreciation at £1.13 million (2019: £1.64 million) due to the 12-month versus 17-month reporting

comparative reporting period.

#### Net finance costs

The Group adopted the new accounting standard IFRS16 Leases during the previous reporting period, which resulted in an interest charge of £0.1 million (2019: £0.1 million) being recognised.

#### Losses before taxation

Losses before taxation from continuing operations for the year were £21.34 million (2019: £18.05 million).

#### **Taxation**

The Group claims each year for research and development tax credits and, since it is loss-making, elects to surrender these tax credits for a cash rebate. The amount is included within the taxation line of the consolidated statement of profit and loss in respect of amounts received and receivable for the surrender of research and development expenditure amounting to £2.45 million (2019: £2.44 million). The Group has not recognised any tax assets in respect of trading losses arising in the current financial year or accumulated losses in previous financial years.

# Loss for the period

The reported loss for the period was £18.89 million (2019: £15.62 million). The loss per ordinary share reduced to 8.37 pence (2019: 12.98 pence) based on an average number of shares in issue during the period of 229,673,873 (2019: 120,336,858).

#### Cash flow

The Group reported cash and short-term deposit balances of £47.91 million at 31 December 2020 (2019: £8.79 million).

Operating cash outflows from operations amounted to £13.35 million (2019: £14.44 million). Within the net operating cash outflows there were cash receipts in respect of research and development tax credits amounting to £2.75 million (2019: £1.63 million) which represented the tax refund for the previous 17-month financial period.

During the year, capital expenditure increased to £1.28 million (2019: £0.62 million) as facility expansion at both Wetherby and Cambridge sites were underway. Capitalised development costs fell during the year to £0.17 million (2019: £1.88 million) as the majority of diagnostic development work was not at the stage of gaining regulatory approval for commercial launch of products.

The Group completed two fund-raises via a combination of placings and subscriptions during the reporting period. The first fund-raise, which was announced in April 2020, raised £5.75 million gross (£5.36 million net). The second fund-raise was announced in June 2020 and raised £48.00 million gross (£45.43 million net).

# Financial position

Net assets as at 31 December 2020 were £61.93 million (2019: £25.81 million) of which short-term deposits, cash and cash equivalents amounted to £47.91 million (2019: £8.79 million).

Intangible assets reduced to £9.42 million (2019: £11.80 million) following the impairment of the Animal Health goodwill and the amortisation charge of £1.01 million (2019: £2.20 million) exceeding the capitalised development costs in the period of £0.17 million (2019: £1.88 million).

The adoption of IFRS16 Leases and the expansion of leasehold premises in both Wetherby and Cambridge results in the recognition of a 'right-of-use' asset amounting to £2.10 million (2019: £0.78 million) in relation to the Group's three leasehold properties together with a corresponding lease liability of £2.04 million (2019: £0.82 million).

#### Dividends

No dividends have been proposed for the year ended 31 December 2020 (2019: £nil).

# Key performance indicators

At this stage of the Group's development, the non-financial key performance indicators focus around two areas:

- the progression of the Affimer<sup>®</sup> and pre|CISION<sup>™</sup> technologies into clinical trials within the Therapeutics division; and
- the development of Affimer® diagnostic products and the number of customers evaluating Affimer® reagents which might lead to commercial licensing agreements within the Diagnostics division.

The financial key performance indicators focus around three areas:

- Group revenues
- Research and development expenditure, which is either expensed through the Income Statement or capitalised
- Cash and short-term deposit balances

# Going concern

These financial statements have been prepared on a going concern basis, notwithstanding a loss of £18.89 million and operating cash outflows of £13.35 million for the year ended 31 December 2020. The Directors consider this to be appropriate for the following reasons.

The Directors have prepared detailed cash flow forecasts that extend at least 12 months from the date of approval of the financial statements. The forecasts take into account the Directors' views of current and future economic conditions that are expected to prevail over the period. These forecasts include assumptions regarding the status of therapeutic development collaborations, the AVA6000 prodoxorubicin phase I clinical trials, diagnostic product development projects and sales pipeline, future revenues and costs together with various scenarios which reflect growth plans, opportunities, risks and mitigating actions. The forecasts also include assumptions regarding the timing and quantum of investment in the therapeutic and diagnostic research and development programmes.

Whilst there are inherent uncertainties regarding the cash flows associated with the development of both the therapeutic and diagnostic platforms, together with the timing and delivery of diagnostic product development projects and future therapeutic collaboration transactions, the Directors are satisfied that there is sufficient discretion and control as to the timing and quantum of cash outflows to ensure that the Company and Group are able to meet their liabilities as they fall due for at least 12 months from the date of approval of the financial statements. The key factors considered in reaching this conclusion are summarised below:

 The Group continues to develop its therapeutic and diagnostic platform technologies. The development of a SARS-CoV-2 antigen lateral flow test, which is in the late stages of clinical validation and CE marking, could generate significant revenue and profits for the Group in the near term, which have not been included in the base case assessment.

- As at 31 December 2020, the Group's short-term deposits and cash and cash equivalents were £47.91 million (2019: £8.79 million).
- The Group has a tax refund in relation to R&D tax credits due in the second half of 2021 amounting to £2.20 million (a comparable tax refund of £2.75 million was received in October 2020 relating to the 17-month period to 31 December 2019).
- The Group does not have external borrowings, or any covenants based on financial performance.
- The Directors have considered the position of the individual trading companies in the Group to
  ensure that these companies are also in a position to continue to meet their obligations as they fall
  due.

The Directors have also reviewed these cash flow forecasts in the light of potential impacts from the COVID-19 pandemic. The short-term impact centres around the commencement of clinical trials for the AVA6000 pro-doxorubicin phase I clinical trials which are due to commence in mid-2021, the ability to recruit patients to the trial given potential COVID-19 follow-on issues and any delay this may have on the initial phase I study readouts. This could potentially delay expenditures and reduce cash burn during the forecast period. The Directors are confident that the current level of funding will be sufficient for the Group and Company to meet their liabilities for the forecast period

Based on these indications, the Directors are confident that the company will have sufficient funds to continue to meet its liabilities as they fall due for at least 12 months from the date of approval of the financial statements and therefore have prepared the financial statements on a going concern basis.

# Cautionary statement

The preliminary statements contain forward-looking statements that are subject to risk factors associated with, amongst other things, economic and business circumstances occurring from time to time within the markets in which the Group operates. The expectations expressed within these statements are believed to be reasonable but could be affected by a wide variety of variables outside of the Group's control. These variables could cause the results to differ materially from current expectations. The forward-looking statements reflect the knowledge and information available at the time of preparation.

Alastair Smith
Chief Executive Officer
22 April 2021

**Tony Gardiner**Chief Financial Officer
22 April 2021

# Consolidated Statement of Profit or Loss and Other Comprehensive Income for the year ended 31 December 2020

		2020	2019*
	Note	£000	£000
Revenue	4	3,636	5,511
Cost of sales			(1,440)
Gross profit		2,181	4,071
Research costs		(8,961)	(7,860)
Share of loss of associate		(217)	-
Amortisation of development costs		(1,007)	(2,202)
Impairment of intangible fixed assets		(1,741)	-
Selling, general and administrative expenses		= =	(10,064)
Depreciation expense		(1,125)	(1,636)
Share-based payment charge		(3,108)	(338)
Operating loss		(21,293)	(18,029)
Finance income		43	73
Finance costs	6	(93)	(98)
Net finance costs		(50)	(25)
Loss before tax		(21,343)	(18,054)
Taxation		2,452	2,439
Loss and total comprehensive loss for the period			(15,615)
Loss per ordinary share: Basic and diluted	5	(8 37n)	(12.98p)

<sup>\*</sup> These results relate to the 17-month period ended 31 December 2019 All activities relate to the continuing operations of the Group.

# Consolidated Statement of Financial Position as at 31 December 2020

Consolidated Statement of Financial Position as at 31 Dece	mber 2020		
	Note	2020 £000	2019 £000
Assets			
Property, plant and equipment		2,696	2,304
Right-of-use assets	6	2,095	780
Intangible assets		9,417	11,800
Non-current assets		14,208	14,884
Inventories		248	156
Trade and other receivables		2,895	2,082
Income tax receivable		2,200	2,500
Short-term deposits		20,017	-
Cash and cash equivalents		27,894	8,788
Current assets		53,254	13,526
Total assets		67,462	28,410
Liabilities			
Lease liabilities	6	(1,752)	(646)
Non-current liabilities		(1,752)	(646)
Trade and other payables		(3,491)	(1,778)
Lease liabilities	6	(290)	(177)
Current liabilities		(3,781)	(1,955)
Total liabilities		(5,533)	(2,601)
Net assets		61,929	25,809
Equity			
Share capital		25,343	17,671
Share premium		54,137	9,877
Other reserve		(1,729)	(1,729)
Reserve for own shares		(2,961)	(2,932)
Retained earnings		(12,861)	2,922
Total equity		61,929	25,809

# Consolidated Statement of Changes in Equity for the Year Ended 31 December 2020

Tota equity	Retained earnings	Reserve for own shares	Capital reserve	Other reserve	Share premium	Share capital	
£000	£000	£000	£000	£000	£000	£000	
21,413	16,299	(2,802)	 - 1,899	 - (1,729)	770	6,976	Balance at 1
(15,615	(15,615)	-	-	-	-	-	August 2018 Total comprehensive loss for the period
					Company:	vners of the C	Transactions with ov
19,299	-	-	-	-	8,674	10,625	Issue of shares
373	-	-	-	-	341	32	Exercise of share options
	-	(130)	-	-	92	38	Own shares
338	338	-	-	-	-	-	acquired Equity-settled share-based
	1,899	-	(1,899)	-	-	-	payment Transfer <sup>1</sup>
20,011	2,237	(130)	(1,899)	-	9,107	10,695	
25,809	2,922	(2,932)	-	(1,729)	9,877	17,671	Balance at 31 December 2019
(18,891)	(18,891)	-	-	-	-	-	Total comprehensive loss for the period
					Company:	vners of the C	Transactions with ov
50,791	-	-	-	-	43,596	7,195	Issue of shares
1,112	-	-	-	-	645	467	Exercise of share options
•	-	(29)	-	-	19	10	Own shares acquired
3,108	3,108	-	-	-	-	-	Equity-settled share-based payment
55,011	3,108	(29)	-	-	44,260	7,672	
61,929	(12,861)	(2,961)	-	(1,729)	54,137	25,343	Balance at 31 December 2020

<sup>&</sup>lt;sup>1</sup> The transfer from the capital reserve to retained earnings related to the elimination of the original acquisition accounting of Avacta Health Limited, which was dissolved during the comparative period.

Consolidated Statement of Cash Flows for the Year Ended 31 December 2020		
	2020	2019*
	£000	£000
Cash flows from operating activities		
Loss for the period	(18,891)	(15,615)
Adjustments for:		
Amortisation	1,029	2,313
Impairment losses	1,741	-
Depreciation	1,125	1,636
Net loss on disposal of property, plant and equipment	6	19
Share of loss of associate	217	-
Equity-settled share-based payment transactions	3,108	338
Net finance costs	50	25
Taxation	(2,452)	_
TUALION	(2,402)	(2, 100)
Operating cash outflow before changes in working capital	(14 067)	(13,723)
Decrease/(increase) in inventories	(91)	30
Increase in trade and other receivables	(814)	
Increase in trade and other payables	1,627 	
Operating cash outflow from operations		(14,440)
Interest received	• • •	72
Interest elements of lease payments		(86)
Tax credit received		1,631
	2,734	
Withholding tax paid		(192)
Net cash used in operating activities	(10,642)	(13,015)
Cook flows from investing activities		
Cash flows from investing activities	(4.070)	(040)
Purchase of plant and equipment		(618)
Purchase of intangible assets	(221)	
Investment in associate	(217)	
Development expenditure capitalised		(1,875)
Increase in balances on short-term deposit	(20,017)	-
Net cash used in investing activities	(21,899)	(2,527)
Cash flows from financing activities		
Proceeds from issue of share capital	53,750	19,331
Transaction costs related to issue of share capital**	(2,960)	-
Proceeds from exercise of share options	1,112	-
Principal elements of lease payments	(255)	(221)
Net cash from financing activities	51,647	19,110
Net increase/(decrease) in cash and cash equivalents	19,106	3,568
Cash and cash equivalents at 1 January 2020	8,788	5,220
Cash and cash equivalents at 31 December 2020	27,894	8,788

<sup>\*</sup> These results relate to the 17-month period ended 31 December 2019

<sup>\*\*</sup> Please see Note 2 for further information

#### Notes to the Preliminary Results to 31 December 2020

#### 1 General Information

These preliminary results have been prepared on the basis of the accounting policies which are to be set out in Avacta Group plc's annual report and financial statements for the year ended 31 December 2020.

The consolidated financial statements of the Group for the year ended 31 December 2020 were prepared in accordance with International Financial Reporting Standards ("IFRSs") as adopted for use in the EU ("adopted IFRSs") and applicable law.

The financial information set out above does not constitute the Company's statutory financial statements for the year ended 31 December 2020 or the 17-month period ended 31 December 2019 but is derived from those financial statements. Statutory financial statements for 2019 have been delivered to the Registrar of Companies and distributed to shareholders, and those for 2020 will be respectively delivered and distributed on or before 30 June 2021. The auditor has reported on those financial statements and their report was:

- (i) unqualified;
- (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their report; and
- (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006 in respect of the financial statements for 2018 or 2019.

#### 2 Basis of preparation

The Group's consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ('IFRSs') as adopted by the European Union. The Company has elected to prepare its parent company financial statements in accordance with applicable UK accounting standards, including Financial Reporting Standard 102 – *The Financial Reporting Standard applicable in the United Kingdom and Republic of Ireland* ('FRS 102'), and with the Companies Act 2006.

The financial statements have been prepared on the historical cost basis.

During the prior period, the Group changed its accounting period to 31 December to bring it in line with the calendar year and therefore the accounts are showing a 12-month financial year to the comparative 17-month financial period. As such, amounts presented in the financial statements are not readily comparable.

# Functional and presentation currency

These consolidated financial statements are presented in pound sterling, which is the Company's functional currency. All amounts have been rounded to the nearest thousand, unless otherwise indicated.

#### Going concern

These financial statements have been prepared on a going concern basis, notwithstanding a loss of £18.9 million and operating cash outflows of £13.3 million for the year ended 31 December 2020. The directors consider this to be appropriate for the following reasons.

The Directors have prepared detailed cash flow forecasts that extend to at least 12 months from the date of approval of the financial statements. The forecasts take into account the Directors' views of current and future economic conditions that are expected to prevail over the period. These forecasts include assumptions regarding the status of therapeutic development collaborations, the AVA6000 pro-doxorubicin phase I clinical trials, diagnostic product development projects and sales pipeline, future revenues and costs together with various scenarios which reflect growth plans, opportunities, risks and mitigating actions. The forecasts also include assumptions regarding the timing and quantum of investment in the therapeutic and diagnostic research and development programmes.

Whilst there are inherent uncertainties regarding the cash flows associated with the development of both the therapeutic and diagnostic platforms, together with the timing and delivery of diagnostic product development projects and future therapeutic collaboration transactions, the Directors are satisfied that there is sufficient discretion and control as to the timing and quantum of cash outflows to ensure that the Company and Group are able to meet their liabilities as they fall due for at least 12 months from the date of approval of the financial

statements. The key factors considered in reaching this conclusion are summarised below:

- The Group continues to develop its therapeutic and diagnostic platform technologies. The development of a SARS-CoV-2 antigen lateral flow test, which is in the late stages of clinical validation and CE marking, could generate significant revenue and profits for the Group in the near term, which have not been included in the base case assessment.
- As at 31 December 2020, the Group's short-term deposits and cash and cash equivalents were £47.9 million (2019: £8.8 million).
- The Group has a tax refund in relation to R&D tax credits due in the second half of 2021 amounting to £2.2 million (a comparable tax refund of £2.8 million was received in October 2020 relating to the 17-month period to 31 December 2019).
- The Group does not have external borrowings, or any covenants based on financial performance.
- The Directors have considered the position of the individual trading companies in the Group to ensure that these companies are also in a position to continue to meet their obligations as they fall due.

The Directors have also reviewed these cash flow forecasts in the light of potential impacts from the COVID-19 pandemic. The short-term impact centres around the commencement of clinical trials for the AVA6000 prodoxorubicin phase I clinical trials, which are due to commence in mid-2021, the ability to recruit patients to the trial given potential COVID-19 follow-on issues and any delay this may have on the initial phase I study readouts. This could potentially delay expenditures and reduce cash burn during the forecast period. The Directors are confident that the current level of funding will be sufficient for the Group and Company to meet their liabilities for the forecast period.

Based on these indications, the Directors are confident that the Company will have sufficient funds to continue to meet its liabilities as they fall due for at least 12 months from the date of approval of the financial statements and therefore have prepared the financial statements on a going concern basis.

#### Use of judgements and estimates

In preparing these consolidated financial statements, management has made judgements and estimates that affect the application of the Group's accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to estimates are recognised prospectively.

Information about judgements and estimates made by management that have the most significant effects on the amounts recognised in the financial statements is given below.

The Directors consider that the key judgements made in preparation of the financial statements are:

Going concern - The judgement of whether or not the accounts should be prepared on a going concern basis has been disclosed above.

Revenue recognition – Judgements arise from the application of IFRS 15 to the Group's revenue streams, as disclosed in Note 1 C of the financial statements.

The Directors consider that the assumptions and estimation uncertainties at 31 December 2020 that have a significant risk of resulting in a material adjustment to the carrying amounts and liabilities in the next financial year are:

Impairment – Impairment tests have been performed on the carrying amounts of the Group's cash generating units. Key assumptions underlie the recoverable amounts used in these impairment tests, including the recoverability of development costs. Information on the key assumptions used is disclosed in Note 10 of the financial statements.

# Significant accounting policies

The Group has consistently applied the accounting policies to all periods presented in these preliminary statements. Whilst there are a number of new standards effective from periods beginning after 1 January 2020, the Group has not early adopted the new or amended standards and does not expect them to have a significant impact on the Group's consolidated financial statements.

#### Transaction costs related to the issue of share capital

In the prior period, the Consolidated Statement of Cash Flows presented proceeds from the issue of share capital, £20,617,000, net of transactions related to the issue of share capital, £1,286,000. The Directors have reviewed this prior year presentation and have not restated the prior year figures as they have concluded that the net presentation was not material to the financial statements.

#### 3 Segment reporting

# Operating segments

In the view of the Board of Directors, the Group has three (2020: three) distinct reportable segments, which are Diagnostics, Therapeutics and Animal Health (2019: Diagnostics, Therapeutics and Animal Health), and segment reporting has been presented on this basis. The Directors recognise that the operations of the Group are dynamic and therefore this position will be monitored as the Group develops.

The principal activities of each reportable segment are as follows:

Diagnostics: development of custom Affimer® proteins for incorporation into customer products and in-house diagnostic assays.

Therapeutics: development of novel cancer immunotherapies combining proprietary platforms.

Animal Health: provision of tools and contract services to assist diagnosis of conditions in animals to enable faster treatment for veterinarians.

Segment revenue represents revenue from external customers arising from sale of goods and services, plus intersegment 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 70% (2019: 69%) of total revenue. The revenue analysis below is based on the country of registration of the customer:

	For year ended 31 December 2020	17 months ended 31 December 2019
	£'000	£'000
UK	1,076	1,691
Rest of Europe	685	851
North America	402	496
Asia	1,473	2,473
	3,636	5,511

During the year, transactions with three external customers, two in the Therapeutics segment and one in the Animal Health segment, amounted individually to 10% or more of the Group's revenues, being £768,000, £694,000 and £440,000 respectively. In the 17-month period ended 31 December 2019, transactions with one individual customer amounted to 10% or more of the Group's revenues. These revenues were £2,442,000 for a customer in the Therapeutics segment.

# Operating segment analysis 2020

Revenue	Diagnostics £000 519	Therapeutics £000 1,625	Animal Health £000 1,492	Total £000 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)	(1,741)
Depreciation expense	(357)	(701)	(62)	(1,120)
Share-based payment expense	(636)	(893)	(38)	(1,567)
Segment operating loss Central overheads	(6,602)	(8,961)	(2,062)	(17,625) (3,668)
Operating loss Finance income Finance expense			-	(21,293) 43 (93)
Loss before taxation Taxation				(21,343) 2,452
Amount attributable to equity holders of the Company				(18,891)

Operating profit/loss is the measure of profit or loss regularly reviewed by the Board. Central overheads, which relate to operations of the Group function, are not allocated to the segments.

The information reported to the Board does not include balance sheet information at the segment level. The key segmental balance sheet information is considered to be the segment's non-current assets.

All material segmental non-current assets are located in the UK.

# Operating segment analysis 2019

	Diagnostics	Therapeutics	Animal Health	Total
	£000	£000	£000	£000
Revenue	812	2,515	2,184	5,511
Cost of goods sold	(454)	(284)	(702)	(1,440)
Gross profit	358	2,231	1,482	4,071
Research costs	(620)	(7,240)	-	(7,860)
Amortisation of development costs	(1,600)	-	(602)	(2,202)
Selling, general and administrative expenses	(3,605)	(2,269)	(1,776)	(7,650)
Depreciation expense	(612)	(678)	(52)	(1,342)
Share-based payment expense	(55)	(101)	(34)	(190)
Segment operating loss	(6,134)	(8,057)	(982)	(15,173)
Central overheads				(2,856)
Operating loss			-	(18,029)
Finance income				73
Finance expense				(98)
Loss before taxation				(18,054)
Taxation				2,439
Amount attributable to equity holders of the Company				(15,615)

# 4 Revenue

The Group's revenue is all derived from contracts with customers.

In the following table, revenue is disaggregated by both its nature and the timing of revenue recognition. The table also includes a reconciliation of the disaggregated revenue with the Group's reportable segments (see Note 2).

# For year ended 31 December 2020

	Diagnostics	Therapeutics	Animal Health	Total
	£000	£000	£000	
Nature of revenue				
Sale of goods	-	-	846	846
Provision of services	519	1,436	646	2,601
License-related income	-	189	-	189
	519	1,625	1,492	3,636
Timing of revenue recognition				
Products or services transferred at a point in time	8	189	1,459	1,656
Products or services transferred over time	511	1,436	33	1,980
	519	1,625	1,492	3,636

# 17 months ended 31 December 2019

	Diagnostics	Therapeutics	Animal Health	Total
	£000	£000	£000	
Nature of revenue				
Sale of goods	-	-	1,101	1,101
Provision of services	812	556	1,083	2,451
License-related income	-	1,959	-	1,959
	812	2,515	2,184	5,511
Timing of revenue recognition				
Products or services transferred at a point in time	13	1,959	2,031	4,003
Products or services transferred over time	799	556	153	1,508
	812	2,515	2,184	5,511

# 5 Earnings per ordinary share

The calculation of earnings per ordinary share is based on the profit or loss for the period and the weighted average number of equity voting shares in issue excluding own shares held jointly by the Avacta Employees' Share Trust and certain employees and the shares held within the Avacta Share Incentive Plan ('SIP').

At 31 December 2020, 22,904,846 options (2019: 10,588,313) have been excluded from the diluted weighted-average number of ordinary shares calculation because their effect would have been anti-dilutive.

	2020	2019
Loss (£000)	(18,891)	(15,615)
Weighted average number of shares (number)	225,578,759	120,336,858
Basic and diluted loss per ordinary share (pence)	(8.37p)	(12.98p)

# 6 Leases

The Group leases a small number of properties for office and laboratory use, as well as some laboratory equipment. Information about leases for which the Group is a lessee is presented below.

a) Amounts recognised in the balance sheet

Right-of-use assets £'000		Property	Lab	oratory ed	quipment	Total
As at 1 August 2018		1,067			-	1,067
Depreciation charge		(288)			-	(288)
As at 31 December 2019	9	779			-	779
Additions		1,382			179	1,561
Depreciation charge		(235)			(9)	(244)
As at 31 December 2020	)	1,926 			170 	2,096 
£'000		31 December 2	020		31 Dece	ember 2019
	Property	Laboratory e	quipment	Total		Property
Lease liabilities						£000
Current	232		58	290		177
Non-current	1,659 		93	1,752		646
	1,891		151	2,042		823
Reconciliation of chang	je in lease liability					£000
As at 1 August 2018						1,033
Payment of lease liability	<ul> <li>principal element</li> </ul>					(222)
Payment of lease liability	<ul> <li>interest element</li> </ul>					(86)
Interest expense						98
As at 31 December 2019	)					823
Additions to lease liability						1,474
Payment of lease liability	<ul> <li>principal element</li> </ul>					(255)
Payment of lease liability	<ul> <li>interest element</li> </ul>					(93)
Interest expense						93
As at 31 December 2020	)					2,042
h) Amounta rocagnis	and in profit or loss					
b) Amounts recognis	sed in profit or loss				2020	2019
					£000	£000
Depreciation charge on r	ight-of-uso assots				£000	2000
Property	igiii-oi-use assets				235	286
Equipment					233 9	200
Equipment					<b></b>	
					244	286
Interest on lease liabilities					93	98
Expenses relating to lease:	s of low-value assets				2	2
					_	_

The total cash outflow for leases in the period was £348,000.