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25 April 2023

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

### **Preliminary Results for the year ended 31 December 2022**

*A period of continued significant progress*

Avacta Group plc (AIM: AVCT), a life sciences company developing innovative, targeted oncology drugs and powerful diagnostics, is pleased to announce its unaudited preliminary results for the year ended 31 December 2022.

### **Operating highlights**

#### ***Therapeutics – clinical and pre-clinical progress***

- Avacta's lead pre|CISION™ programme, AVA6000 – a tumour microenvironment activated form of a chemotherapeutic agent, doxorubicin:
  - The first-in-human Phase 1 clinical trial (ALS-6000-101) progressed through the dosing of four cohorts (80 mg/m<sup>2</sup> up to 200 mg/m<sup>2</sup>) following positive reviews of safety and tolerability data.
  - Pre-clinical data regarding AVA6000 was presented at the American Association for Cancer Research ('AACR') 2022 Annual Meeting and the Theranostics FAP Summit.
  - The US Food and Drug Administration ('FDA') granted Orphan Drug Designation ('ODD') to AVA6000 for treatment of soft tissue sarcoma.
- The next pre|CISION™ drug candidate, AVA3996, a tumour-targeted proteasome inhibitor based on bortezomib, was selected for pre-clinical development aiming for an Investigational New Drug Application in late 2023 to 2024.
- AffyXell Therapeutics ('AffyXell'), the joint venture between Avacta and Daewoong Pharmaceutical ('Daewoong'):
  - Entered into collaborations with Biocytogen, a Chinese company specialising in developing new biological drugs, and with the Korea Non-Clinical Technology Solution Center ('KNTSC').
  - The strategic partnership with GenScript ProBio, a leading biopharmaceutical manufacturer was expanded.
  - Successfully completed a funding round to advance its lead mesenchymal stem cell ('MSC') programme towards the clinic, and to develop its wider pre-clinical pipeline of cell therapies.
  - Avacta's shareholding in AffyXell increased to 19% following the triggering of a milestone equity payment of £3.60 million.

- LG Chem Life Sciences ('LG Chem'), the life sciences division of the South Korean LG Group, exercised its renewal option as part of the ongoing collaboration with Avacta, triggering a licence renewal fee payment to Avacta of \$2 million.
- The Therapeutics Division relocated in April 2022 to new facilities at Scale Space, in Imperial College's White City Campus in London, bringing together the research and development teams in a single site.

### ***Events after the reporting period***

- Announced the completion of the fourth dose escalation cohort of the Company's Phase 1 clinical trial (ALS-6000-101) in January 2023.
- Analysis of tumour biopsy material shows that the active chemotherapy, doxorubicin, is being released in the tumour microenvironment, confirming the tumour-targeting potential of the pre|CISION™ technology.
- In February 2023, hosted a Science Day for fund managers and analysts providing a detailed review of the ongoing Phase 1a clinical trial (ALS-6000-101) and update on preclinical programmes.
- First patient was dosed in fifth cohort of AVA6000 Phase 1a dose escalation study at 250mg/m<sup>2</sup> in April 2023
- Announced the opening of the first two US clinical investigator sites for patient enrolment.
- Presented pre-clinical data regarding AVA3996 at the AACR 2023 Annual Meeting.

### ***Diagnostics – Significant progress towards establishing a fully integrated in vitro diagnostics business with first transformational acquisition***

- Through its Diagnostics Division, the Group initiated a long-term 'buy and build' strategy in the fragmented European diagnostics sector with a vision to build a substantial in-vitro diagnostics ('IVD') business, with global reach, serving centralised pathology laboratories in hospital settings and decentralised testing in GP clinics, pharmacies and by consumers themselves.
- In October 2022, the Group acquired Launch Diagnostics, a leading independent IVD distributor serving hospital pathology laboratories in the UK and France for an initial cash consideration of £24 million payable upon completion, in addition to consideration for other short-term non-operating assets of £0.9 million.
- Avacta Diagnostics built an extensive pipeline of further acquisition opportunities to feed its M&A-led growth strategy.

### **Financial and Corporate highlights**

- In October 2022, Avacta completed a fundraise of £61.3 million (gross) through a combination of:
  - £55.0 million senior unsecured convertible bonds issued at a 5% discount from a fund advised by Heights Capital Ireland LLC (equating to £52.25 million post-discount).
  - £9.0 million through a placing to new and existing shareholders and open offer
- Revenues of £9.7 million (2021: £2.9 million).
- Adjusted EBITDA loss (before non-cash and non-recurring items) of £15.1 million (2021: £21.7 million).
- Operating loss of £32.6 million (2021: £29.1 million).
- Reported loss from continuing operations of £39.5 million (2021: £26.4 million).
- Loss per ordinary share from continuing operations of 15.5p (2021: 10.6p).
- Cash and short-term deposit balances at 31 December 2022 of £41.8 million (31 December

2021: £26.2 million).

- Dr Christina Coughlin, a medical oncologist and immunologist and Chief Executive Officer of CytolImmune Therapeutics, Inc., appointed as Non-executive Director to the Board of Directors of Avacta in March 2022.

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

“I am very encouraged by the favourable safety data emerging from the ongoing phase 1a dose escalation study of AVA6000, which has confirmed the tumour targeting potential of the pre|CISION™ platform. We look forward to starting the dose expansion part of the phase 1 study later this year.

“The potential of the pre|CISION™ platform to create a pipeline of better tolerated chemotherapies and improved outcomes for patients has been further evidenced by the AVA3996 pre-clinical data recently presented at the 2023 American Association for Cancer Research Annual Meeting. These data not only support the pre|CISION™ mechanism of FAP activation, but also open up the possibility of treating solid tumours with a proteasome inhibitor for the first time, which would greatly expand the size of the market for this form of cancer therapy.

“I am delighted with the ongoing integration of Launch Diagnostics into the Avacta Diagnostics division following our acquisition of the largest independent in-vitro diagnostics distributor in the UK in October 2022. This is a first step towards our vision of building a fully integrated in-vitro diagnostics company supporting the healthcare professional and broadening access to diagnostics for consumers via a careful, disciplined M&A led growth strategy.

“The progress made during 2022 has positioned Avacta for further strong growth during 2023 and I look forward to updating the market fully as we hit key milestones across the Group.”

**– Ends –**

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**About Avacta Group plc - [www.avacta.com](http://www.avacta.com)**

Avacta Group plc is a life sciences company working to improve people's health and well-being through innovative oncology drugs and powerful diagnostics. Operating through two divisions, Diagnostics and

Therapeutics, the Group's mission is to provide professionals and consumers with solutions that improve healthcare, fitness and well-being.

Avacta's *Therapeutics Division*, a clinical stage oncology drug innovator, is building a wholly owned pipeline of novel Affimer® immunotherapies and pre|CISION™ tumour targeted chemotherapies. This approach is designed to address the lack of a durable response to current cancer immunotherapies experienced by most patients and reduce the severe systemic toxicities caused by chemotherapies. There are five programmes in the pipeline as well as several global research collaborations and licensing partnerships. Avacta's lead programme, AVA6000, is a pre|CISION™ tumour-targeted form of the established chemotherapy doxorubicin. AVA6000 is in Phase I clinical trials in patients with locally advanced or metastatic selected solid tumours.

The Affimer® platform is an alternative to antibodies that has been designed to address many of the drawbacks of antibodies which, despite their shortcomings, currently dominate the immuno-diagnostics and immuno-therapeutics markets.

The pre|CISION™ tumour targeting platform can be used to modify a chemotherapy in order to selectively release the active drug in tumour tissue thereby reducing the systemic exposure that causes damage to healthy tissues. pre|CISION™ modified chemotherapies are designed to reduce the side effects and improve the overall safety and therapeutic potential of these powerful anti-cancer treatments.

Avacta's *Diagnostics Division* develops and supplies a broad range of in-vitro diagnostic (IVD) solutions. The Division is growing rapidly through an M&A strategy to deliver a global scale IVD business providing market leading solutions for healthcare professionals and consumers to inform treatment and monitor health and well-being. In October 2022, Avacta acquired Launch Diagnostics which serves the hospital pathology laboratory market in the UK and Europe. Avacta Diagnostic's research and development centre in Wetherby, UK uses its proprietary Affimer® platform to differentiate immunodiagnostic products to provide marketing leading performance.

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## **Chairman's Statement**

I firmly believe that our pre|CISION™ and Affimer® technology platforms have the real potential to deliver an extensive pipeline of oncology drugs that will make a meaningful difference to cancer patients' lives. The AVA6000 clinical data to date is looking very promising, and as we progress into the Phase 1b study and demonstrate efficacy this will open up the commercial opportunities for AVA6000 and the pre|CISION™ technology platform.

As a Board and company, we understand the very different risk and return profiles of the Therapeutics and Diagnostic Divisions and we will ensure that there is appropriate allocation of capital between them so that we can deliver both near-term and long-term value inflection points across the Group.

In the Therapeutics and Diagnostics teams we have the strength and experience that is needed to deliver full value from our technology platforms. With these teams and the experienced Board that we have brought together, the future prospects for Avacta are very positive indeed.

**Dr Eliot Forster**

**Chairman**

25 April 2023

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

Avacta has made substantial progress during 2022 in both its Therapeutics and Diagnostics Divisions.

The favourable safety profile emerging from the Phase Ia dose escalation study of AVA6000, the Company's lead pre|CISION™ tumour-activated chemotherapy, indicates that tumour-specific activation of the chemotherapy by FAPα is significantly reducing the exposure of healthy tissues to the chemotherapy. Furthermore, analysis of tumour biopsies has confirmed that the active chemotherapy is being released at therapeutically relevant levels in the tumour tissue. These data combined are very encouraging, if early, signs for both AVA6000 as a safer form of doxorubicin and for the pre|CISION™ platform and its potential pipeline as a whole.

The safety and tolerability of AVA6000 for patients has meant that a maximum tolerated dose has not been reached as anticipated within the first four dose escalation cohorts. We are now in a position to proceed beyond the fourth cohort in the dose escalation study to even higher doses than originally anticipated, which is an unexpected and very positive development reflecting the very positive safety data that are emerging from the trial.

The Diagnostics Division initiated an M&A-led growth strategy to capitalise on the opportunity to consolidate in a fragmented European diagnostics sector. The Company set out a vision to build a substantial European IVD business serving both clinicians and consumers with pathology laboratory solutions for disease diagnostics and home testing to improve fitness, health and well-being.

In October 2022, Avacta completed a fundraise of £61.3 million (gross) through a combination of convertible bonds and a placing to new and existing shareholders with an open offer, primarily to fund the Diagnostics M&A strategy. Simultaneously the Company completed its first acquisition – of the UK's largest independent IVD distributor, Launch Diagnostics – which has provided Avacta with well-established sales channels in the professional, centralised hospital laboratory testing market in the UK and France.

## **Avacta Animal Health**

In March 2022, we sold our Animal Health Division to Vimian Group AB's specialty pharma segment Nextmune, a global veterinary health group headquartered in Sweden. The Animal Health Division had been a part of the Group since 2009. All the staff in the Animal Health Division moved across to Vimian and we wish them all well in the future. The sale will allow the Group to focus on growing and developing our core Therapeutics and Diagnostics businesses.

## **Board changes**

In March 2022, Dr Christina Coughlin joined the Board as a Non-executive Director. Dr Coughlin is the Chief Executive Officer of CytImmune Therapeutics, Inc., a clinical stage biotechnology company. Dr Coughlin has a broad background in biotechnology and global pharmaceuticals, with comprehensive drug development experience spanning programs in pre-IND studies through to late-stage trials and regulatory approval filings, and a track record of building drug development teams in global companies including Rubius Therapeutics, Inc. and Tmunity Therapeutics, Inc.

## **Our people**

I am proud of our people and thank them all for their hard work and commitment which resulted in the strong progress made in 2022. I am also delighted to welcome new colleagues in Launch Diagnostics to the Avacta family. We will continue to invest in developing our people, providing a positive work environment and rewarding careers.

## **Outlook**

The Board believe that the significant near-term value driver for the Group is the clinical data from the Phase I study of AVA6000. The pre|CISION™ FAPα-activation approach has the potential to reduce the systemic toxicities associated with many chemotherapies and as such has the potential to create safer and more effective oncology treatments that are affordable for all.

The outlook for AVA6000 and the pre|CISION™ platform as a whole looks very promising, based on the safety, pharmacokinetic and tumour biopsy data obtained to date. The next significant value driver for AVA6000 will be the initial efficacy data from the Phase 1b dose expansion phase in patients with soft tissue sarcoma.

Avacta Diagnostics continues to actively pursue other M&A opportunities to build a fully integrated and differentiated European diagnostics business. These focus on expanding our routes to market for both professional and consumer testing products, while adding further IVD products suitable for these markets to our portfolio.

I believe that the progress made during 2022 puts the Group in a very strong position and we are confident and excited about the future.

**Dr Alastair Smith**  
**Chief Executive Officer**  
25 April 2023

## **Therapeutics Division**

Avacta Therapeutics Division aims to leverage its two proprietary technology platforms, pre|CISION™ and Affimer®, to develop innovative oncology therapies that make a significant difference to cancer patients' treatment experience and outcomes.

The Therapeutics Division relocated its research activities from Cambridge to White City in London in April 2022, which has brought the research and drug development teams together at a single site. The relocation was completed on schedule with minimal down-time and the Therapeutics Division has rapidly settled into its new, world-class facilities. The team has also expanded to include experienced drug development professionals, including a Head of Chemistry, a Head of Biology, Head of IT and a Vice-President of Legal and Intellectual Property.

The team, supported by the Board and a world-class Scientific Advisory Board chaired by Dr Mike Owen, is committed to developing tumour-activated drugs using the pre|CISION™ platform and novel

immunotherapies and drug conjugates using the Affimer® platform, and will focus resources on its clinical and most advanced pre-clinical programmes to achieve near-term value inflection points.

### **AVA6000 FAP $\alpha$ -activated doxorubicin - the lead pre|CISION™ programme**

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

The ALS-6000-101 Phase 1 clinical trial involves a dose-escalation Phase 1 study in patients with locally advanced or metastatic-selected solid tumours, known to be FAP $\alpha$ -positive, in which cohorts of patients receive ascending doses of AVA6000 to determine the maximum tolerated dose and establish a recommended Phase 1b dose. The second part of the study is an expansion phase where patients receive AVA6000 to further evaluate the safety, tolerability and clinical efficacy at this recommended Phase 1b dose in soft tissue sarcoma. For more information visit [www.clinicaltrials.gov](https://www.clinicaltrials.gov) (NCT04969835).

Soft-tissue sarcoma is a relatively rare mesenchymal malignancy which accounts for less than 1% of all adult tumours. Despite the successful advancement of localised therapies, such as surgery and radiotherapy, these tumours can recur, often with metastatic disease. The American Cancer Society estimates that in 2022 approximately 13,190 new soft tissue sarcomas were diagnosed and about 5,130 people were expected to die of the disease in the US.

The Phase 1a dose escalation study is being carried out at several sites in the UK: The Royal Marsden NHS Foundation Trust in London, The Christie NHS Foundation Trust in Manchester, St James' Hospital in Leeds, The Beatson in Glasgow and The Freeman in Newcastle.

The starting dose with cohort 1 was 80 mg/m<sup>2</sup> of AVA6000, which is equivalent to 54 mg/m<sup>2</sup> of doxorubicin (about 90% of the normal doxorubicin dose). The Safety Data Monitoring Committee ('SDMC') reviewed the data from cohort 1 in February 2022 and recommended that the dose was escalated to 120 mg/m<sup>2</sup>, subsequently recommending that the trial progress to the third cohort in June 2022 at a dose of 160 mg/m<sup>2</sup>. In August 2022, the third cohort was completed and the SDMC approved dose escalation to 200mg/m<sup>2</sup> in the fourth cohort. The results of the fourth cohort were announced immediately post-period end on 17 January 2023. In April 2023, the SDMC recommended dose escalation to 250mg/m<sup>2</sup> in the fifth cohort.

The data emerging from the dose escalation study show a very favourable safety profile. AVA6000 in the four cohorts has been well tolerated by patients, with a marked reduction in the incidence and severity of the typical toxicities associated with the standard doxorubicin chemotherapy administration. Typical toxicities include alopecia, myelosuppression, nausea, vomiting, mucositis and cardiotoxicity. Importantly, even at the highest dosing levels in the fourth cohort, equivalent to more than double the normal dose of doxorubicin, the typical drug-related cardiotoxicity of doxorubicin was not observed.

Critically, analysis of a number of tumour biopsies obtained from patients in different cohorts has confirmed the release of the active chemotherapy, doxorubicin, in the tumour tissue. This analysis shows that AVA6000 targets the release of doxorubicin to the tumour tissue at therapeutic levels which are much higher than the levels being detected in the bloodstream at the same timepoint.

On the basis of the very favourable safety profile of AVA6000 in the study to date, the SDMC has recommended continuation to higher dose cohorts with the aim of identifying a maximum tolerated dose ('MTD') necessary to inform the dosing levels for the Phase 1b and future studies. The Medical and Healthcare products Regulatory Agency approved a modification to the clinical trial protocol to allow the study to continue into additional higher dose cohorts. The Company expects to complete these cohorts and identify the MTD in the first half of 2023.

Following approval by the US Food and Drug Administration ('FDA') of an Investigational New Drug ('IND') application, two clinical trial sites in the US were being prepared to join the ALS-6000-101 study at the Memorial Sloan Kettering Cancer Center in New York and the Fred Hutchinson Cancer Center in Seattle, with both sites confirmed open to recruiting patients post period end in April 2023.

The FDA has also granted Orphan Drug Designation ('ODD') to the Company's lead pre|CISION™ drug candidate, AVA6000, for treatment of soft tissue sarcoma. The FDA can grant ODD based on a review of preclinical data from investigational treatments for rare diseases, such as soft tissue sarcoma, which are defined as conditions affecting fewer than 200,000 people in the US. This designation qualifies the developer of the drug for certain incentives, including seven years of market exclusivity upon drug approval from the FDA.

### **Pipeline of pre|CISION™ chemotherapies**

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

Emerging data from the AVA6000 Phase 1a study indicate that the pre|CISION™ chemistry is effective in reducing systemic exposure to the chemotherapy, creating the opportunity to apply it to a wide range of other established chemotherapies to potentially improve their safety and efficacy.

The next most advanced pre|CISION™ pro-drug candidate is AVA3996, a FAPα-activated proteasome inhibitor based on an analogue of Velcade. In January 2022, the Company announced that, following a review of efficacy studies in several liquid and solid tumour models, safety studies and of manufacturability, AVA3996 has been selected as a candidate for pre-clinical development with the aim of a Clinical Trial Authorisation ('CTA') and/or IND filing in 2023 and dosing of the first patient as soon thereafter as possible.

The global proteasome inhibitors' market size is expected to be worth \$2.3 billion by 2026, and Velcade represents just over half of that market. As with all chemotherapies, the benefit of these drugs is limited by toxicities and tolerability for patients. In the case of Velcade, there are significant side effects such as peripheral neuropathy, which has limited its approval, principally in treating multiple myeloma. A potentially safer proteasome inhibitor, such as AVA3996, could win significant market share for the treatment not only of multiple myeloma but also could be used to treat solid tumours, such as pancreatic cancer. Pancreatic cancer exhibits the highest level of FAP activity of any solid tumour and therefore a FAPα-activated drug could have significant potential in this area of high unmet need.

During 2022, AVA3996 was studied in several animal efficacy models for melanoma, colorectal cancer and sarcoma. In each of these cancer models AVA3996 was as effective as Velcade in preventing growth of the human tumour implanted in the mice. However, whereas the systemic toxicities caused by Velcade resulted in significant body weight loss in the animals, treatment with AVA3996 showed no such toxicities. It is this potential improvement in therapeutic window of AVA3996 created by the tumour targeting of the proteasome inhibitor that holds promise for the first effective use of a proteasome inhibitor in solid tumours.

The Company is continuing its pre-clinical development of AVA3996 with the aim of an IND filing late in 2023 or 2024 and anticipated first-in-human clinical trial starting in 2024. Post period end in April 2023,



pre-clinical data for AVA3996 was presented at the 2023 American Association for Cancer Research (AACR) Annual Meeting in Florida, USA, one of the largest international cancer research meetings.

### **Affimer® immunotherapy programmes**

Translation of the Affimer® platform into the clinic to demonstrate the safety and tolerability of this novel therapeutic protein platform is an important objective for the Company and represents a key value inflection point for the Affimer technology.

In the oncology field recent studies have shown that single cancer immunotherapies, or 'monotherapies', have potentially limited overall response rates. The Company's Affimer® immunotherapy strategy aims to harness the benefits of the Affimer® platform to build bispecific drug molecules which can address two drug targets simultaneously, and to use Affimer® molecules to target toxic payloads using conventional and pre|CISION™ linkers.

Whilst the Company is prioritising its pre|CISION™ programmes as the nearest term driver of key value inflection points, good progress has been made in the in-house Affimer® bispecific and TMAC® pre-clinical programmes which, along with the Company's commercial collaborations, are a key part of in-house research activities.

### **Drug Development Collaborations**

The Company has several important commercial collaborations covering both the Affimer® and pre|CISION™ platforms, and is active in pursuing future opportunities for licensing and partnerships.

#### **LG Chem Life Sciences**

Avacta has a strategic partnership with LG Chem Life Sciences focused on the development of a novel PD-L1 checkpoint inhibitor utilising the Affimer® platform incorporating Affimer XT® half-life extension. The partnership also provides LG Chem with rights to develop and commercialise other Affimer® and non-Affimer biotherapeutics combined with Affimer XT® half-life extension for a range of indications, and Avacta could earn up to \$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® product sales by LG Chem.

At the end of June 2022, LG Chem exercised its option to renew its rights under the ongoing collaboration with Avacta, triggering a licence renewal fee payment to Avacta of \$2 million. LG Chem is now focused on progressing the PD-L1/XT oncology drug candidate towards the clinic and has commenced pre-clinical studies which are intended to form the basis of an Investigational New Drug ('IND') submission.

#### **AffyXell Therapeutics**

AffyXell is a joint venture company with Daewoong Pharmaceuticals in South Korea that is developing mesenchymal stem cell therapies which have been modified to produce Affimer® immunotherapies *in vivo* at the site of action of the stem cells.

AffyXell has made good progress, advancing both its GMP-compliant human mesenchymal stem cell technology and its Affimer® discovery programmes against two of the three initial targets. AFX001 is a mesenchymal stem cell ('MSC') therapy which secretes anti-CD40L Affimer® for the treatment of Graft versus Host Disease in organ transplantation. AFX002 is an MSC secreting an agonist Affimer against an undisclosed target for use in multiple sclerosis and T1 diabetes.

In April 2022, a milestone equity payment was made by AffyXell to Avacta resulting in an increase in Avacta's shareholding in the joint venture. This payment was triggered by Avacta successfully developing and characterising Affimer® proteins against CD40L for AffyXell and transferring the

associated intellectual property into AffyXell. In exchange for this, Avacta has received an increase in its equity stake in AffyXell, which was diluted from its founding equity stake in February 2021 when AffyXell completed a Series A financing of \$7.3 million from a group of venture funds in February 2021. At 31 December 2022, Avacta's shareholding in the joint venture was 19%.

AffyXell also successfully completed a funding round in May 2022, raising an undisclosed amount of capital, to advance its lead mesenchymal stem cell programme towards the clinic, and to develop its wider pre-clinical pipeline of cell therapies.

### **POINT Biopharma Inc.**

Early in 2021, Avacta signed a licensing agreement with POINT Biopharma Inc. ('POINT'), to provide access to Avacta's pre|CISION™ technology for the development of tumour-activated radiopharmaceuticals.

Under the terms of the agreement, Avacta received an upfront fee and will receive development milestone payments for the first radiopharmaceutical FAPα-activated drug totalling \$9.5 million. Avacta will also receive milestone payments for subsequent radiopharmaceutical FAPα-activated drugs 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.

### **Diagnostics Division**

During 2022, Avacta's Diagnostics Division initiated an M&A-led growth strategy to take advantage of the fragmentation in the European in-vitro diagnostics ('IVD') sector with the aim of building an integrated and differentiated IVD business with global reach serving professionals and consumers.

In order to achieve this vision, the Company has, since late 2021, been building a pipeline of potential acquisition targets covering routes to market in the professional and consumer markets, as well as companies with product portfolios suitable for use in these sectors. The Company has focused its M&A strategy on profitable businesses engaged in developing or distributing immunodiagnostic and molecular diagnostic tests.

Avacta's mission is to support clinicians in the diagnosis of disease and to improve health and well-being through better access to self-testing for all.

Innovation remains a key strength of Avacta Diagnostics and in the competitive immunodiagnostics market the Affimer® platform provides a powerful tool to differentiate diagnostic products to gain competitive advantage and grow market share of acquired businesses.

In October 2022, Avacta completed a fundraise of £61.3 million (gross) through a combination of convertible bonds and a placing to new and existing shareholders with an open offer, primarily to fund the Diagnostics M&A strategy.

Simultaneously the Company completed its first acquisition, Launch Diagnostics, a leading independent distributor in the UK IVD market. This has provided Avacta with well-established sales channels in the professional, centralised hospital laboratory testing market in the UK and France. Avacta's plan to grow the Launch Diagnostics business includes expanding the company's product portfolio and investing in the sales teams in the UK and France. However, the most significant opportunity for growth lies in the geographical expansion of the business into Germany, which is Europe's largest diagnostics market.

Avacta Diagnostics continues to pursue a careful and disciplined M&A strategy focussed on expanding our routes to market for both professional and consumer testing products, while adding further IVD products suitable for these markets to our portfolio.

### **Financial Review**

## **Revenue**

Reported Group revenues for the year ended 31 December 2022 increased to £9.65 million compared to £2.94 million for the year ended 31 December 2021 ('2021').

Revenues for the Therapeutics Division increased to £5.48 million (2021: £2.16 million), due to achieving certain milestones in our collaborations with LG Chem (£1.65 million in cash) and AffyXell (£3.60 million in additional equity in the joint venture), together with further funded FTE reimbursement from collaboration partners.

Revenues for the Diagnostics Division were £4.17 million (2021: £0.78 million), with the increase coming from the acquisition of Launch Diagnostics in October 2022, which contributed £3.97 million and the remainder from a smaller number of custom Affimer® reagent projects as resources were focused on the development of future diagnostic tests.

## **Acquisitions**

On 21 October 2022, the Group acquired 100% of the shares and voting interests in Launch Diagnostics Holdings Ltd ('Launch Diagnostics'). Launch Diagnostics is a leading independent IVD distributor in the UK, providing immunodiagnostic and molecular test products, technical support and maintenance to healthcare providers. Total consideration for Launch Diagnostics included an initial consideration of £24 million in cash payable upon completion of the acquisition, in addition to £0.9 million for other short-term non-operating assets and an additional consideration of 50% of the gross margin on sales exceeding £2 million per annum of Launch Diagnostics' COVID-19 related products for three years capped at £13 million (in aggregate). The additional consideration to be paid based on future gross margin is estimated to be nil as at 31 December 2022.

The acquisition of Launch Diagnostics is the first step in a M&A-led growth strategy for the Group's Diagnostics Division, with the vision of building an integrated and differentiated IVD business with global reach servicing professionals and consumers.

For the period from acquisition to 31 December 2022, Launch Diagnostics contributed revenue of £3,971,000 and profit of £309,000 to the Group's results.

## **Research and amortisation of development costs**

During the year, the Group expensed through the income statement £11.10 million (2021: £13.48 million) research costs relating to the in-house Affimer® and pre|CISION™ therapeutic programmes, which are expensed given their pre-clinical stage of development, in addition to research costs on Affimer® diagnostics products that have not yet completed product development and obtained regulatory approval to become commercial products.

## **Selling, general and administrative expenses**

Administrative expenses have increased during the year to £11.23 million (2021: £8.14 million). This has increased because of the Launch Diagnostics acquisition (£1.43 million of administrative expenses) and the scale-up of the operations within both the Diagnostics Division, as it increased its product development capabilities to become a fully integrated IVD products business, and the Therapeutics Division as resource was increased to support the infrastructure required and transition into a clinical stage business.

## **Adjusted EBITDA**

The Consolidated Statement of Profit or Loss shows an Adjusted EBITDA loss position (before non-recurring items) of £15.09 million for the year (2021: £21.74 million), with the reduction in losses due to improved revenues and the resulting gross profit increases.

## **Amortisation and impairment of development costs**

Development costs capitalised in prior periods from the development of the Affimer® reagents and the

diagnostics platform have been amortised, resulting in a charge of £0.82 million (2021: £0.82 million). An impairment charge of £5.23 million (2021: £nil) was recognised in the year in relation to previously capitalised Affimer<sup>®</sup> reagents development costs. This reflects the change in focus within the Diagnostics Division to build on its M&A strategy; whereby the development of diagnostic products incorporating Affimer<sup>®</sup> reagents is now expected to occur through new development, manufacturing, and distribution partners as the Diagnostics Division expands in future periods. As the M&A activity was still in progress at 31 December 2022, it was not possible to provide certainty on the timelines of future acquisitions or, therefore, the timeframe in which cashflows from Affimer<sup>®</sup> reagent developed products would be received, necessitating an impairment charge to be recognised.

### **Share of loss of associate**

The share of loss of associate of £1.15 million arises from the Group's equity-accounted investment in AffyXell Therapeutics Co., Ltd. The share of losses reflects the Group's 19% ownership share of the losses accumulated since its inception in 2020. The Group investment increased from 5% to 19% at 31 December 2022 as a result of additional equity issued due to the Group achieving certain technical milestones for the collaboration during the year.

### **Share-based payment charges**

The non-cash charge for the year increased to £7.49 million (2021: £5.06 million) as a result of changes to the assumptions around the likelihood of vesting of options. There were no new options issued during the year.

### **Convertible bond costs**

In October 2022, the Group issued senior unsecured convertible bonds ('the Bonds') of £55.00 million to a fund advised by Heights Capital Ireland LLC, a global equity and equity-linked focussed investor. The Bonds were issued at 95% par value with total net proceeds of £52.25 million, and accrue interest at an annual rate of 6.5% payable quarterly in arrears.

The Bonds contain various conversion and redemption features. The Bonds have a maturity of five years, and are repayable in 20 quarterly amortisation repayments, of principal and interest over the five-year term, in either cash or in new ordinary shares at the Group's option. If in shares, the repayment is at the lower of the conversion price (118.75p) or a 10% discount to the volume weighted average price ('VWAP') in the five- or ten-day trading period prior to election date. The conversion price may reset downwards at 18 months, depending on share price performance, and save in limited circumstances there is a reset price floor of £0.95.

The bond agreement contains embedded derivatives in conjunction with an ordinary host debt liability. As a result, the convertible bonds are shown in the Consolidated Statement of Financial Position in two separate components, being 'Convertible bond – debt' and 'Convertible bond – derivative'. At issuance, the total inception value was £55.00 million, being the principal amount of the Bonds, with the initial carrying amount of the debt liability element being the difference between the inception value of the convertible bond and the fair value at inception of the derivative element. Given the option of the bondholder to convert the bond at their discretion, the debt and derivative liability elements have been classified as current liabilities.

The derivative element has been measured at fair value using a Monte-Carlo option pricing model, which estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the bondholders. This therefore falls under Level 3 of the fair value hierarchy. Significant assumptions used in the fair value analysis include the volatility rate, risk-free rate and expected dividend yield. At inception, the fair value of the derivative component was measured at £35.00 million. The fair value at the year-end date was measured to be £39.10 million, resulting in charge in revaluation of the derivative being recognised of £4.10 million.

Transaction costs of £3.41 million have been apportioned between the derivative and debt liability components according to the relative inception values. This has resulted in £2.29 million of transaction costs being recognised at acquisition, with £1.13 million adjusted for in the carrying amount of the debt

liability at acquisition.

### **Losses before taxation**

Losses before taxation from continuing operations for the year were £41.64 million (2021: £29.19 million).

### **Taxation**

The Group claims each year for research and development tax credits and, since it is currently 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 £2.23 million (2021: £2.82 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.

### **Discontinued operations**

In March 2022, the Animal Health Division was sold to Vimian Group AB and the results for the current year up to disposal and prior year have been disclosed in the Consolidated Statement of Profit or Loss as Discontinued Operations. Revenues were £0.41 million (2021: £1.60 million) and the Animal Health Division made a small operating profit of £0.05 million (2021: £0.07 million). An up-front payment of £0.9 million was received with deferred contingent consideration of up to £1.4 million dependent on the combined performance of the consolidated business, of which £0.7 million was recognised in the current year based on the anticipated performance of the combined business. The profit on disposal recognised in the year was £0.31 million.

### **Loss for the period**

The reported loss for the period was £39.19 million (2021: £26.31 million). The loss per ordinary share increased to 15.35 pence (2021: 10.55 pence) based on a weighted average number of shares in issue during the period of 259,007,001 (2021: 253,555,925).

### **Cash flow**

The Group reported cash and short-term deposit balances of £41.78 million at 31 December 2022 (2021: £26.19 million).

Operating cash outflows from operations amounted to £15.95 million (2021: £22.66 million).

During the year, capital expenditure was £0.56 million (2021: £1.16 million) as the facility move from Cambridge to London was completed.

Net cash outflow from investing activities amounted to £25.04 million (2021: inflow of £18.70 million) arising principally from the acquisition of Launch Diagnostics, an outflow of £24.88 million net of cash acquired. The disposal of the Animal Health discontinued operation generated £0.55 million cash proceeds, net of transaction costs, in the period.

In October 2022, the Group completed a fundraising of £61.27 million (gross) through a combination of £55.00 million senior unsecured convertible bonds issued at a 5% discount from a fund advised by Heights Capital Ireland LLC, and £9.02 million through a placing to new and existing shareholders and open offer (2021: £nil). There were also proceeds from the exercise of share options by employees amounting to £0.47 million (2021: £0.52 million).

### **Financial position**

Net assets as at 31 December 2022 were £18.44 million (2021: £41.22 million) of which cash and cash equivalents amounted to £41.78 million (2021: £26.19 million).

The IFRS 16 Leases presentation results in the recognition of a 'right-of-use' asset amounting to £5.42 million (2021: £1.73 million) in relation to the Group's leasehold properties and other leased assets, together with a corresponding lease liability of £5.11 million (2021: £1.70 million); the increase arising due to the longer term lease on the London facility and the acquisition of Launch Diagnostics.

Intangible assets increased to £26.32 million (2021: £7.93 million) due to the acquisition of Launch Diagnostics and the recognition of £12.69 million of goodwill. Further details on the acquisition accounting are detailed in Note 26 to the Financial Statements.

Liabilities in relation to the convertible bonds issued during the period have been recognised, with £39.10 million relating to the fair value of the derivative element at 31 December 2022, and £18.73 million relating to the debt liability element.

## **Dividends**

No dividends have been proposed for the year ended 31 December 2022 (2021: £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® and pre|CISION™ technologies into clinical trials within the Therapeutics Division; and
- the development of Affimer® reagents to feed into future diagnostic products within the M&A-led growth strategy in the Diagnostics Division.

The financial key performance indicators focus around three areas, that allow an assessment of the performance of the business as the Diagnostics Division in particular progresses through the M&A-led growth strategy, and of the funding available as the Therapeutics Division progresses into clinical trials

- Group revenues
- Adjusted EBITDA
- Cash and short-term deposit balances

## **Tony Gardiner**

Chief Financial Officer

25 April 2023

## *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.

The preliminary statements use Alternative Performance Measures ('APMs') to assist in presenting information in an easily analysable and comparable form. The APMs used provide a meaningful basis on which to analyse the Group's financial performance, which is helpful to the reader, however it is noted that they are not substitutes for IFRS measures and may not be directly comparable to similarly titled measures used by other companies. APMs are defined in Note 1 to the preliminary statements.

**Unaudited Consolidated Statement of Profit or Loss and Other Comprehensive Income  
for the Year Ended 31 December 2022**

£000	Note	2022	2021
<b>Continuing operations</b>			
Revenue	3	9,653	2,941
Cost of sales		(2,410)	(924)
		-----	-----
<b>Gross profit</b>		<b>7,243</b>	<b>2,017</b>
Research costs		(11,100)	(13,480)
Manufacturing costs		-	(2,143)
Selling, general and administrative expenses		(11,232)	(8,136)
		-----	-----
<b>Adjusted EBITDA</b>		<b>(15,089)</b>	<b>(21,742)</b>
Impairment charge		(5,225)	-
Depreciation expense		(1,904)	(1,462)
Amortisation expense		(1,050)	(821)
Share of loss of associate		(1,152)	-
Acquisition-related expenses	7	(735)	-
Share-based payment expense		(7,490)	(5,058)
		-----	-----
<b>Operating loss</b>		<b>(32,645)</b>	<b>(29,083)</b>
Convertible bond – professional fees	5	(2,287)	-
Convertible bond – interest expense	5	(2,606)	-
Convertible bond – revaluation of derivative	5	(4,100)	-
Finance income		91	17
Other finance costs		(95)	(128)
		-----	-----
<b>Loss before tax</b>		<b>(41,642)</b>	<b>(29,194)</b>
Taxation		2,102	2,820
		-----	-----
<b>Loss from continuing operations</b>		<b>(39,540)</b>	<b>(26,374)</b>
		-----	-----
<b>Discontinued operation</b>			
Profit from discontinued operation	8	351	58
		-----	-----
<b>Loss for the period</b>		<b>(39,189)</b>	<b>(26,316)</b>
Foreign operations – foreign currency translation differences		46	4
		-----	-----
<b>Other comprehensive income</b>		<b>46</b>	<b>4</b>
		-----	-----
<b>Total comprehensive loss for the period</b>		<b>(39,143)</b>	<b>(26,312)</b>
		-----	-----
<b>Loss per share:</b>			
Basic and diluted	4	(15.35p)	(10.55p)
<b>Loss per share – continuing operations</b>			
Basic and diluted	4	(15.48p)	(10.57p)

**Unaudited Consolidated Statement of Financial Position as at 31 December 2022**

	Note	2022 £000	2021 £000
<b>Assets</b>			
Property, plant and equipment		2,380	2,612
Right-of-use assets		5,418	1,729
Intangible assets		26,324	7,925
Investment in associate		2,976	-
<b>Non-current assets</b>		<b>37,098</b>	<b>12,266</b>
Inventories		1,681	189
Trade and other receivables		5,579	4,327
Income tax receivable		6,510	2,750
Cash and cash equivalents		41,781	26,191
<b>Assets held for sale</b>		<b>55,551</b>	<b>33,457</b>
		-	1,279
<b>Current assets</b>		<b>55,551</b>	<b>34,736</b>
<b>Total assets</b>		<b>92,649</b>	<b>47,002</b>
<b>Liabilities</b>			
Lease liabilities		(3,753)	(1,412)
Deferred tax		(2,845)	-
<b>Non-current liabilities</b>		<b>(6,598)</b>	<b>(1,412)</b>
Trade and other payables		(8,423)	(3,731)
Lease liabilities		(1,361)	(291)
Convertible bond - debt	5	(18,729)	-
Convertible bond – derivative	5	(39,100)	-
		<b>(67,613)</b>	<b>(4,022)</b>
Liabilities directly associated with the assets held for sale		-	(346)
<b>Current liabilities</b>		<b>(67,613)</b>	<b>(4,368)</b>
<b>Total liabilities</b>		<b>(74,211)</b>	<b>(5,780)</b>
<b>Net assets</b>		<b>18,438</b>	<b>41,222</b>
<b>Equity</b>			
Share capital		26,685	25,472
Share premium		62,184	54,530
Reserves		(4,434)	(4,687)
Retained earnings		(65,997)	(34,093)
<b>Total equity</b>		<b>18,438</b>	<b>41,222</b>

Unaudited Consolidated Statement of Changes in Equity for the Year Ended 31 December 2022

Reserve



	Share capital £000	Share premium £000	Other reserve £000	Translation reserve £000	for own shares £000	Retained earnings £000	Total equity £000
<b>Balance at 1 January 2021</b>	<b>25,343</b>	<b>54,137</b>	<b>(1,729)</b>	<b>-</b>	<b>(2,961)</b>	<b>(12,861)</b>	<b>61,929</b>
Loss for the period	-	-	-	-	-	(26,316)	<b>(26,316)</b>
Other comprehensive income for the period	-	-	-	4	-	-	<b>4</b>
<b>Total comprehensive loss for the period</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>4</b>	<b>-</b>	<b>(26,316)</b>	<b>(26,312)</b>
<i>Transactions with owners of the Company:</i>							
Exercise of share options	129	393	-	-	-	-	<b>522</b>
Equity-settled share-based payment	-	-	-	-	-	5,083	<b>5,083</b>
	129	393	-	-	-	5,083	<b>5,605</b>
<b>Balance at 31 December 2021</b>	<b>25,472</b>	<b>54,530</b>	<b>(1,729)</b>	<b>4</b>	<b>(2,961)</b>	<b>(34,093)</b>	<b>41,222</b>
Loss for the period	-	-	-	-	-	(39,189)	<b>(39,189)</b>
Other comprehensive income for the period	-	-	-	46	-	-	<b>46</b>
<b>Total comprehensive loss for the period</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>46</b>	<b>-</b>	<b>(39,189)</b>	<b>(39,143)</b>
<i>Transactions with owners of the Company:</i>							
Issue of shares	949	7,448	-	-	-	-	<b>8,397</b>
Exercise of share options	264	206	-	-	-	-	<b>470</b>
Transfer of own shares	-	-	-	-	206	(206)	<b>-</b>
Equity-settled share-based payment	-	-	-	-	-	7,490	<b>7,490</b>
	1,213	7,654	-	-	206	7,284	<b>16,357</b>
<b>Balance at 31 December 2022</b>	<b>26,685</b>	<b>62,184</b>	<b>(1,729)</b>	<b>50</b>	<b>(2,755)</b>	<b>(65,997)</b>	<b>18,438</b>

**Unaudited Consolidated Statement of Cash Flows  
for the Year Ended 31 December 2022**

Note                      **2022**                      **2021**

		£000	£000
<b>Operating cash outflow from operations</b>	6	<b>(15,953)</b>	(22,656)
Interest received		75	17
Interest elements of lease payments		(202)	(139)
Income tax (paid) / received		(168)	2,291
Withholding tax paid		(184)	(19)
		-----	-----
<b>Net cash used in operating activities</b>		<b>(16,432)</b>	(20,506)
		-----	-----
<b>Cash flows from investing activities</b>			
Purchase of plant and equipment		(558)	(1,162)
Proceeds from sale of plant and equipment		50	-
Acquisition of subsidiary, net of cash acquired		(24,878)	-
Disposal of discontinued operation, net of cash disposed of		705	-
Transaction costs related to disposal of discontinued operation		(160)	-
Acquisition of right-of-use assets		(165)	-
Purchase of intangible assets		(36)	(152)
Decrease in balances on short-term deposit		-	20,017
		-----	-----
<b>Net cash (used in) / generated from investing activities</b>		<b>(25,042)</b>	18,703
		-----	-----
<b>Cash flows from financing activities</b>			
Proceeds from issue of share capital		9,016	-
Transaction costs related to issue of share capital		(618)	-
Proceeds from exercise of share options		470	522
Principal elements of lease payments		(800)	(290)
Proceeds from issue of convertible bonds	5	52,250	-
Transaction costs related to issue of convertible bonds	5	(3,414)	-
		-----	-----
<b>Net cash from financing activities</b>		<b>56,904</b>	232
		-----	-----
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>15,430</b>	(1,571)
Cash and cash equivalents at 1 January 2022		26,191	27,894
Effects of movements in exchange rates on cash held		160	4
		-----	-----
		<b>41,781</b>	26,327
Cash and cash equivalents forming part of assets held for sale		-	(136)
		-----	-----
<b>Cash and cash equivalents at 31 December 2022</b>		<b>41,781</b>	26,191
		-----	-----

Notes to the Preliminary Results to 31 December 2022

## **1 General Information**

These preliminary results have been prepared on the basis of the accounting policies which are set out in Avacta Group plc's annual report and financial statements for the year ended 31 December 2022.

The consolidated financial statements of the Group for the year ended 31 December 2022 were prepared in accordance with UK adopted international accounting standards.

The financial information set out above for the year ended 31 December 2022 and the year ended 31 December 2021 does not constitute the Company's statutory accounts for those years.

Statutory accounts for the year ended 31 December 2021 have been delivered to the Registrar of Companies and distributed to shareholders. The auditors' report on those accounts was unqualified, did not draw attention to any matters by way of emphasis, and did not contain a statement under 489(2) or 498(3) of the Companies Act 2006.

The financial information for the year ended 31 December 2022 is unaudited. The statutory accounts for that year will be delivered to the Registrar of Companies following the Company's Annual General Meeting.

### *Basis of preparation*

The Group's consolidated financial statements have been prepared in accordance with UK adopted international accounting standards.

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

### *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 £39.1 million and operating cash outflows of £16.0 million for the year ended 31 December 2022. The Directors consider this to be appropriate for the following reasons.

The Directors have prepared detailed cash flow forecasts that extend to at least twelve 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 1 clinical trials, diagnostic M&A opportunities, product development projects and the Launch 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 development programmes and the Diagnostics Division's M&A activity.

Whilst there are inherent uncertainties regarding the cash flows associated with the development of both the therapeutic 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 twelve months from the date of approval of the financial statements. The key factors considered in reaching this conclusion are summarised below:

- As at 31 December 2022, the Group's short-term deposits and cash and cash equivalents were £41.8 million (2021: £26.2 million),
- The Group has a tax refund in relation to R&D tax credits for the 2021 financial year of £2.8 million which was received in January 2023.
- The Group does have external borrowings in the form of a £55 million convertible bond with quarterly amortisation settlements by the issue of new equity, or by cash at the discretion of the Group.
- 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 continue to explore additional sources of income and finance available to the Group to continue the development of the therapeutic and diagnostic platforms beyond 2024. The sources of income could come through the licensing of assets/targets from the proprietary Affimer® and pre|CISION™ platforms or through additional therapeutic collaborations, similar to the LG Chem and Daewoong collaborations, which may include up-front technology access fees and significant early-stage development income, or through additional equity fundraises.

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 twelve 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 1C of the financial statements for the year ended 31 December 2021, as to the timing and nature of revenue recognised in relation to the achievement of milestones.

*Share-based payments* – Judgements arise from the choice of inputs to the share option valuation models underlying the share-based payment charge, as disclosed in Note 5 of the financial statements for the year ended 31 December 2021.

*Capitalisation of development costs* – Judgements arise as to whether research and development projects meet the criteria under IAS 38 to be capitalised, further information on the specific judgements made is included within Note 1I of the financial statements for the year ended 31 December 2021 .

*Investment in associates* – Judgements arise as to whether the relationship with AffyXell is an associate or an equity investment, the rationale for the presentation as an associate is disclosed in Note 23 of the financial statements for the year ended 31 December 2021.

The Directors consider that the assumptions and estimation uncertainties at 31 December 2022 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 such as the amount and timing of future cash flow growth, and the

achievement of future development milestones, underlie the recoverable amounts used in these impairment tests.

*Acquisitions* – Estimation uncertainty is inherent in the methods used to determine the fair value of the assets acquired and liabilities assumed. These include the valuation of acquired intangible assets and the estimate of deferred consideration payable.

*Convertible bond* – Determining the fair value of the embedded derivative within the convertible bond, both at inception and at the reporting date.

### **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 2022, 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.

This Group presents an alternative performance measure ('APM'), adjusted EBITDA, in the Consolidated Statement of Profit or Loss. Adjusted EBITDA is presented to enhance an investor's evaluation of ongoing operating results, by facilitating both a meaningful comparison of results between periods and identification of the underlying cash used by operations within the business. Items of expenditure included from the adjusted EBITDA measure are those where the relative magnitudes year-on-year are not directly reflective of year-on-year performance, or are not closely linked to the underlying cashflows from operations. There is a clear reconciliation between adjusted EBITDA and operating loss in the Consolidated Statement of Profit or Loss. It is noted that the above APM is not a substitute for IFRS measures, and may not be directly comparable to similarly titled measures used by other companies.

## **2 Segment reporting**

### ***Operating segments***

In the view of the Board of Directors, the Group has two (2021: three) distinct reportable segments, which are Diagnostics and Therapeutics (2021: 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 in the current and prior year are as follows:

Diagnostics: development and sale of innovative, next generation diagnostic solutions and disruptive immunodiagnostic products, including Affimer® reagents

Therapeutics: development of novel cancer therapies harnessing proprietary technology

Animal Health: provision of tools and contract services to assist diagnosis of conditions in animals to enable faster treatment for veterinarians. The Animal Health operating segment was sold in March 2022, and has been classified as a discontinued operation from the start of the prior year.

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

The Group's revenue from continuing operations to destinations outside the UK amounted to 74% (2021: 82%) of total revenue. The revenue analysis below, for continuing operations, is based on the country of registration of the customer:

	<b>2022</b>	2021
	<b>£'000</b>	£'000
UK	<b>2,532</b>	540
France	<b>1,296</b>	86
Rest of Europe	<b>158</b>	25
North America	<b>179</b>	815
South Korea	<b>5,481</b>	1,400
Rest of Asia	<b>7</b>	74
	-----	-----
	<b>9,653</b>	2,940

During the year, transactions with two external customers, both in the Therapeutics segment, amounted individually to 10% or more of the Group's revenues from continuing operations, being £3,798,000 and £1,682,000 respectively. In the year ended 31 December 2021 transactions with three external customers, two in the Therapeutics segment and one in the Diagnostic segment, amounted to 10% or more of the Group's revenues from continuing operations, being £966,000, £736,000 and £523,000 respectively.

### ***Operating segment analysis 2022***

Diagnostics	Therapeutics	Central	<b>Total</b>	Animal Health
-------------	--------------	---------	--------------	---------------

	£000	£000	overheads <sup>1</sup> £000	(continuing) £000	(discontinued) £000
Revenue	4,172	5,481	-	9,653	412
Cost of goods sold	(2,282)	(128)	-	(2,410)	(118)
<b>Gross profit</b>	<b>1,890</b>	<b>5,353</b>	<b>-</b>	<b>7,243</b>	<b>294</b>
Research costs	(2,309)	(8,791)	-	(11,100)	-
Selling, general and administrative expenses	(4,706)	(2,403)	(4,122)	(11,231)	(240)
<b>Adjusted EBITDA</b>	<b>(5,125)</b>	<b>(5,841)</b>	<b>(4,122)</b>	<b>(15,088)</b>	<b>54</b>
Impairment charge	(5,225)	-	-	(5,225)	-
Depreciation expense	(627)	(1,269)	(9)	(1,905)	(11)
Amortisation expense	(1,033)	(8)	(9)	(1,050)	-
Share of loss of associate	-	(1,152)	-	(1,152)	-
Acquisition-related expenses	-	-	(735)	(735)	-
Share-based payment expense	(1,438)	(2,713)	(3,339)	(7,490)	-
<b>Segment operating loss</b>	<b>(13,448)</b>	<b>(10,983)</b>	<b>(8,214)</b>	<b>(32,645)</b>	<b>43</b>

<sup>1</sup>Central overheads, which relate to operations of the Group functions, are not allocated to the operating segments.

### ***Operating segment analysis 2021***

Diagnostics	Therapeutics	Central	<b>Total</b>	Animal Health
-------------	--------------	---------	--------------	---------------

	£000	£000	overheads <sup>1</sup> £000	(continuing) £000	(discontinued) £000
Revenue	779	2,162	-	2,941	1,604
Cost of goods sold	(223)	(700)	-	(923)	(506)
<b>Gross profit</b>	<b>555</b>	<b>1,462</b>	<b>-</b>	<b>2,017</b>	<b>1,098</b>
Research costs	(3,665)	(9,815)	-	(13,480)	(39)
Manufacturing	(2,143)	-	-	(2,143)	-
Selling, general and administrative expenses	(2,893)	(1,899)	(3,344)	(8,136)	(915)
<b>Adjusted EBITDA</b>	<b>(8,146)</b>	<b>(10,252)</b>	<b>(3,344)</b>	<b>(21,742)</b>	<b>144</b>
Amortisation expense	(821)	-	-	(821)	-
Depreciation expense	(505)	(950)	(7)	(1,462)	(50)
Share-based payment expense	(984)	(2,981)	(1,093)	(5,058)	(25)
<b>Segment operating loss</b>	<b>(10,456)</b>	<b>(14,183)</b>	<b>(4,444)</b>	<b>(29,083)</b>	<b>69</b>

<sup>1</sup>Central overheads, which relate to operations of the Group functions, are not allocated to the operating segments.

### 3 Revenue

Year ended 31 December 2022



	Diagnostics	Therapeutics	Continuing operations	Animal Health (discontinued)	Total
	£000	£000	£000	£000	
<b>Nature of revenue</b>					
Sale of goods	3,779	-	3,779	259	4,038
Provision of services	393	229	622	153	775
Licence-related income	-	5,252	5,252	-	5,252
	<b>4,172</b>	<b>5,481</b>	<b>9,653</b>	<b>412</b>	<b>10,065</b>
<b>Timing of revenue recognition</b>					
Products or services transferred at a point in time	3,780	5,251	9,031	391	9,422
Products or services transferred over time	393	229	622	21	643
	<b>4,173</b>	<b>5,480</b>	<b>9,653</b>	<b>412</b>	<b>10,065</b>

#### Year ended 31 December 2021

	Diagnostics	Therapeutics	Continuing operations	Animal Health (discontinued)	Total
	£000	£000	£000	£000	
<b>Nature of revenue</b>					
Sale of goods	19	-	19	864	883
Provision of services	260	1,058	1,318	740	2,058
Licence-related income	500	1,104	1,604	-	1,604
	<b>779</b>	<b>2,162</b>	<b>2,941</b>	<b>1,604</b>	<b>4,545</b>
<b>Timing of revenue recognition</b>					
Products or services transferred at a point in time	520	1,105	1,625	1,540	3,165
Products or services transferred over time	259	1,057	1,316	64	1,380
	<b>779</b>	<b>2,162</b>	<b>2,941</b>	<b>1,604</b>	<b>4,545</b>

#### 4 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 2022, 20,444,462 options (2021: 25,545,539) have been excluded from the diluted weighted-average number of ordinary shares calculation because, due to the loss for the period, their effect would have been anti-dilutive.

At 31 December 2022, 5,314,010 potentially dilutive shares relating to the convertible bond (2021: nil) have been excluded from the diluted weighted-average number of ordinary shares calculation because, due to the loss for the period, their effect would have been anti-dilutive. Further details on the convertible bond are set out in Note 5.

	Continuing operations	2022 Discontinued operation	Total	Continuing operations	2021 Discontinued operation	Total
Loss (£000)	<b>(39,540)</b>	<b>351</b>	<b>(39,189)</b>	(26,374)	58	(26,315)
	-----	-----	-----	-----	-----	-----
Weighted average number of shares (number)			<b>255,369,066</b>			249,478,070
	-----	-----	-----	-----	-----	-----
Basic and diluted loss per ordinary share (pence)	<b>(15.49p)</b>	<b>0.13p</b>	<b>(15.35p)</b>	(10.57p)	0.02p	(10.55p)
	-----	-----	-----	-----	-----	-----

In January 2023, 3,068,421 new ordinary shares of 10 pence each were issued in settlement of the quarterly principal of £2.75 million and interest repayment of £0.89 million in respect of the unsecured convertible bond.

In February 2023, 2,400,000 new ordinary shares of 10 pence each were issued and allotted in relation to a Notice of Conversion in respect of £2.85 million of the £55.00 million unsecured convertible bonds.

In April 2023 2,906,097 new ordinary shares of 10 pence each were issued in settlement of the quarterly principal of £2.6 million and interest repayment of £0.80 million in respect of the unsecured convertible bond.

## 5 Convertible bond

In October 2022, the Group issued senior unsecured convertible bonds ('the Bonds') of £55 million to a fund advised by Heights Capital Ireland LLC, a global equity and equity-linked focussed investor.

The Bonds were issued at 95% par value with total net proceeds of £52.25 million, and accrue interest at an annual rate of 6.5% payable quarterly in arrears.

The Bonds contain various conversion and redemption features. The Bonds have a maturity of five years, and are repayable in 20 quarterly amortisation repayments, of principal and interest over the five-year term, in either cash or in new ordinary shares at the Group's option. If in shares, the repayment is at the lower of the conversion price (118.75p) or a 10% discount to the volume weighted average price ('VWAP') in the five- or ten-day trading period prior to election date. The conversion price may reset downwards at 18 months, depending on share price performance, and save in limited circumstances there is a reset price floor of 95p.

Additionally, the bondholder has the option to partially convert the convertible bond at their discretion, though did not do so during the period. Such a partial conversion did occur after the reporting period.

The bond agreement contains embedded derivatives in conjunction an ordinary host debt liability. As a result, the convertible bonds are shown in the Consolidated Statement of Financial Position in two separate components, being 'Convertible bond – debt' and 'Convertible bond – derivative'. At issuance, the total inception value was £52,500,000, being the 5% issue discount to the principal amount of the Bonds, with the initial carrying amount of the debt liability element being the difference between this inception value of the convertible bond and the fair value at inception of the derivative element. Given the option of the bondholder to convert the bond at their discretion, the debt and derivative liability elements have been classified as current liabilities.

The derivative element has been measured at fair value using a Monte-Carlo option pricing model, which estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the bondholders. This therefore falls under Level 3 of the fair value hierarchy. At inception, the fair value of the derivative component was measured at £35,000,000, resulting in an initial carrying amount of the debt liability element of £16,123,000. The fair value at the year-end date was measured to be £39,100,000 resulting in a revaluation of the derivative being recognised of £4,100,000.

Significant assumptions used in the fair value analysis include the volatility rate and recovery amount. A volatility of 67.4% was used in the determination of the fair value of the derivative element, a reduction of 10% would have resulted in a reduction in the fair value at inception by £4,401,000 with an increase of 10% resulting in an increase in the fair value at inception of £4,561,000. An estimated recovery amount of 75% was also used in the determination of fair value, with an increase of 10% resulting in an increase in fair value by £1,351,000 and a decrease by 20% resulting in a decrease in the fair value by £3,390,000.

Transaction costs of £3,413,000 have been apportioned between the derivative and debt liability components according to the relative inception values. This has resulted in £2,287,000 of transaction costs being recognised as an expense at acquisition, with £1,127,000 adjusted for in the carrying amount of the debt liability at acquisition.

Convertible bond -  
derivative

Convertible bond -  
debt

	£000	£000
At inception	35,000	16,123
Interest expense	-	2,606
Revaluation of derivative	4,100	-
	-----	-----
<b>At 31 December 2022</b>	<b>39,100</b>	<b>18,729</b>
	-----	-----

## 6 Operating cash outflow from operations

	<b>2022</b> <b>£000</b>	<b>2021</b> <b>£000</b>
Loss for the period	<b>(39,189)</b>	(26,316)
Adjustments for:		
Amortisation expense	<b>1,051</b>	865
Impairment losses	<b>5,225</b>	-
Depreciation	<b>1,961</b>	1,511
Net loss on disposal of property, plant and equipment	<b>52</b>	30
Share of loss of associate	<b>1,152</b>	-
Equity-settled share-based payment transactions	<b>7,490</b>	5,083
Profit on lease modification	<b>(31)</b>	-
Gain on sale of discontinued operation	<b>(308)</b>	-
Net finance costs	<b>9,000</b>	121
Increase in investment in associate	<b>(4,127)</b>	-
Taxation	<b>(2,102)</b>	(2,820)
	-----	-----
<b>Operating cash outflow before changes in working capital</b>	<b>(19,826)</b>	(21,526)
Decrease in inventories	<b>52</b>	13
Decrease/(increase) in trade and other receivables	<b>2,225</b>	(1,599)
Increase in trade and other payables	<b>1,596</b>	456
	-----	-----
<b>Operating cash outflow from operations</b>	<b>(15,953)</b>	(22,656)
	-----	-----

## 7 Acquisition of subsidiary

On 21 October 2022, the Group acquired 100% of the shares and voting interests in Launch Diagnostics Holdings Ltd ('Launch Diagnostics'). Launch Diagnostics is a leading independent IVD distributor in the UK, providing immunodiagnostic and molecular test products, technical support and maintenance to healthcare providers.

The acquisition of Launch Diagnostics is the first step in an M&A-led growth strategy for the Group's Diagnostics Division, with the vision of building an integrated and differentiated IVD business with global reach servicing professionals and consumers.

For the period from acquisition to 31 December 2022, Launch Diagnostics contributed revenue of £3,971,000 and profit of £309,000 to the Group's results. If the acquisition had occurred on 1 January 2022, management estimates that consolidated revenue would have been £27,845,000 and consolidated loss for the year would have been £34,601,000. In determining these amounts, management has assumed that the fair value adjustments that arose on the date of acquisition would have been the same if the acquisition had occurred on 1 January 2022.

#### **A. Consideration transferred**

	<b>£000</b>
Cash	28,350
Deferred consideration	851
	-----
<b>Total consideration transferred</b>	<b>29,201</b>

In addition, the Group has agreed to pay the selling shareholders additional consideration of 50% of the gross margin on sales exceeding £2 million per annum of Launch Diagnostics' COVID-19 related products for three years capped at £13 million. Based on an assessment of forecast future sales, the fair value of this contingent consideration at the acquisition date is £nil. At 31 December 2022, the contingent consideration estimated has remained at £nil.

#### **B. Acquisition-related costs**

The Group incurred acquisition-related costs of £712,000 on legal fees and due diligence costs. These costs have been included in 'Acquisition-related expenses'.

#### **C. Identifiable assets acquired and liabilities assumed**

The following table summarises the recognised amounts of assets acquired and liabilities assumed at the date of acquisition.

	<b>£000</b>
Property, plant and equipment	293
Right-of-use assets	1,121
Intangible assets – brand	1,216
Intangible assets – customer relationships	10,746
Intangible assets – other	2
Inventories	1,545
Trade and other receivables	3,233
Income tax receivable	1,369
Cash and cash equivalents	3,472
Trade and other payables	(2,696)
Deferred taxation	(2,901)
Lease liabilities	(893)
	-----
<b>Total identifiable net assets acquired</b>	<b>16,507</b>

Trade receivables comprises gross contractual amounts of £2,493,000 with £nil expected to be uncollectable at the date of acquisition. Amounts receivable from selling shareholders were settled at acquisition at their gross contractual amount.

#### **D. Goodwill**

Goodwill arising from the acquisition has been recognised as follows:

		<b>£000</b>
Consideration transferred	A	29,201
Fair value of identifiable net assets	C	(16,507)
		-----
<b>Goodwill</b>		<b>12,694</b>

The goodwill is attributable mainly to the skills and technical talent of Launch Diagnostics' work-force and the synergies expected to be achieved from integrating the company into the Group's Diagnostics business. None of the goodwill recognised is expected to be deductible for tax purposes

## **8 Discontinued operation**

On 15 March 2022, the Group sold its entire Animal Health segment (see Note 2). An up-front payment of £860,000 was received with deferred contingent consideration ('earn-out payment') of up to £1,433,000. There were associated costs to sell of £181,000. Management committed to a plan to sell the segment in late 2021 following a strategic decision to place focus on the Group's key competencies – the development of diagnostic products and cancer therapies.

Contingent consideration of £717,000 has been estimated as at 31 December 2022. The earn out payment is tiered based on revenues achieved by the combined performance of the Animal Health segment and its acquirer. Based on the maximum revenues achieved in any twelve month period of the 3 years to 31 December 2024 (the 'earn-out period'), the earn-out payment will be nil, £717,000 or £1,433,000. Management's estimate has been derived from the information on performance for the period to 31 December 2022 and growth rates expected over the remaining earn-out period.

The Animal Health segment was classified as held for sale in the consolidated financial statements for the year ended 31 December 2021.

#### **A. Effect of the disposal on the financial position of the Group**

The carrying amounts of assets and liabilities in the disposal group are summarized as follows:

	<b>£000</b>
Property, plant and equipment	<b>(20)</b>
Right of use asset	<b>(122)</b>
Intangible asset	<b>(778)</b>
Inventories	<b>(81)</b>
Trade and other receivables	<b>(192)</b>
Cash and cash equivalents	<b>(194)</b>
Trade and other payables	<b>175</b>
Lease liabilities	<b>124</b>
	-----
<b>Net assets and liabilities</b>	<b>(1,088)</b>
Consideration received in cash	<b>860</b>
Contingent consideration	<b>717</b>
Transactions costs directly relating to disposal	<b>(181)</b>
	-----
<b>Gain on disposal</b>	<b>308</b>

#### **B. Results of discontinued operation**

	2022 £000	2021 £000
Revenue	411	1,604
Cost of sales	(117)	(506)
<b>Gross profit</b>	<b>294</b>	<b>1,098</b>
Research costs	(6)	(39)
Selling, general and administrative expenses	(233)	(915)
Depreciation expense	(10)	(50)
Share-based payment charge	-	(25)
<b>Operating profit</b>	<b>45</b>	<b>69</b>
Finance costs	(2)	(11)
<b>Profit before tax</b>	<b>43</b>	<b>58</b>
Taxation	-	-
<b>Profit from operating activities</b>	<b>43</b>	<b>58</b>
Gain on sale of discontinued operation	308	-
<b>Profit for the period</b>	<b>351</b>	<b>58</b>

### C. Cash flows from (used in) discontinued operations

Cash flows generated by the Animal Health segment for the reporting periods under review until its disposal are as follows:

	2022 £000	2021 £000
Net cash (used in) / from operating activities	(47)	225
Net cash from / (used in) investing activities	505	(19)
Net cash (used in) / from financing activities	(6)	30
<b>Net cash flows for the period</b>	<b>452</b>	<b>236</b>

## 9 Events after the reporting period

On 23 January 2023, 3,068,421 new ordinary shares were issued in settlement of the quarterly principal of £2.75 million and interest repayment of £0.89 million in respect of the convertible bond, reducing the principal remaining to £52.25 million.

On 10 February 2023, 2,400,000 new ordinary shares were issued in settlement of a received Notice of Conversion in respect of £2.85 million of the convertible bond, reducing the principal remaining to £49.40 million.

On 21 April 2023, 2,906,097 new ordinary shares were issued in settlement of the quarterly principal of £2.6 million and interest repayment of £0.80 million in respect of the convertible bond, reducing the principal remaining to £46.80 million.

- Ends -