



Affimer<sup>®</sup>  
pre|CISION<sup>™</sup>

# Prelim Results for the 12 Months Period Ending 31<sup>st</sup> December 2021

April 6, 2022

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**Introduction**



# Today's Presentation Team



## **Dr Alastair Smith, CEO**

- Over 16 years experience as a life sciences public company CEO.
- Science background with 13 years in academia – established a leading UK biophysics group.
- Founded Avacta in 2006.
- World class scientific and technical knowledge with a highly commercial mindset.



## **Tony Gardiner, CFO**

- Over 20 years senior financial and operational experience across multiple sectors.
- 4 years as CFO of AIM listed Fusion IP plc, 5 years as Finance Director of Aedas/AHR Architects.
- Joined Avacta in 2016.



LSE: AVCT

## Therapeutics Division

- Clinical stage oncology drug company with in-house pre-clinical and clinical pipeline of novel cancer therapies based on the Affimer and preCISION technologies.
- Research and Clinical Development re-locating to Imperial College Campus, White City, London in April 2022 from Cambridge.
- Global partnerships (oncology, autoimmune, cell and gene therapy).

Affimer® pre|CISION™



## Diagnostics Division

- In-vitro diagnostics company based in Wetherby, UK.
- R&D Centre and plc Headquarters.
- In-house IVD product development pipeline.
- Global technology evaluations and partnerships.

Affimer®





Preliminary Results for the Period  
Ended 31<sup>st</sup> December 2021

# Preliminary Results for the Year Ending 31<sup>st</sup> December 2021: Income Statement

	2021 (£m)	2020 (£m)
Revenue	2.94	2.14
Gross profit	2.02	1.18
Research costs	(13.48)	(9.11)
Manufacturing costs	(2.14)	-
Admin costs	(8.14)	(5.93)
Amortisation/Depreciation/SBP	(7.34)	(4.95)
Operating loss	(29.08)	(18.81)
Net financial costs	(0.11)	(0.05)
Taxation	2.82	2.46
Discontinued operation	0.06	(2.49)
Retained loss	(26.31)	(18.89)
Loss per share	10.57p	7.27p

# Preliminary Results for the Year Ending 31<sup>st</sup> December 2021: Segmental Analysis

**Affimer**<sup>®</sup>  
pre|CISION<sup>™</sup>

	Diagnostics (£m)		Therapeutics (£m)		Animal Health (£m)	
	2021	2020	2021	2020	2021	2020
<b>Income Statement</b>						
Revenue	0.78	0.52	2.16	1.63	1.60	1.49
Gross profit	0.56	0.20	1.46	0.98	1.10	1.00
Research costs	(3.67)	(2.46)	(9.82)	(6.65)	(0.04)	(0.07)
Manufacturing costs	(2.14)	-	-	-	-	-
Admin costs	(2.89)	(2.52)	(1.89)	(1.70)	(0.92)	(0.97)
Amortisation/Dep'n/SBP	(2.31)	(1.82)	(3.93)	(1.59)	(0.07)	(0.28)
Impairment charge	-	-	-	-	-	(1.74)
Operating (loss)/profit	(10.45)	(6.60)	(14.18)	(8.96)	0.07	(2.06)
<b>Investment</b>						
Plant and equipment	0.54	0.71	0.60	0.56	0.02	0.05



# Preliminary Results for the Year Ending 31<sup>st</sup> December 2021: Cash Flow and Balance Sheet

	2021 (£m)	2020 (£m)
Operating activities	(21.52)	(14.07)
Working capital	(1.13)	0.73
Tax and interest	2.15	2.70
Investment	(1.31)	(21.90)
Financing	0.23	51.65
Net cash (outflow)/inflow	(21.58)	19.11
Cash and short-term deposits	26.19	47.91
PPE ( <i>inc. IFRS16 property leases</i> )	4.34	4.79
Intangible assets	7.93	9.42
Other net assets/(liabilities)	2.76	(0.19)
Net assets	41.22	61.93

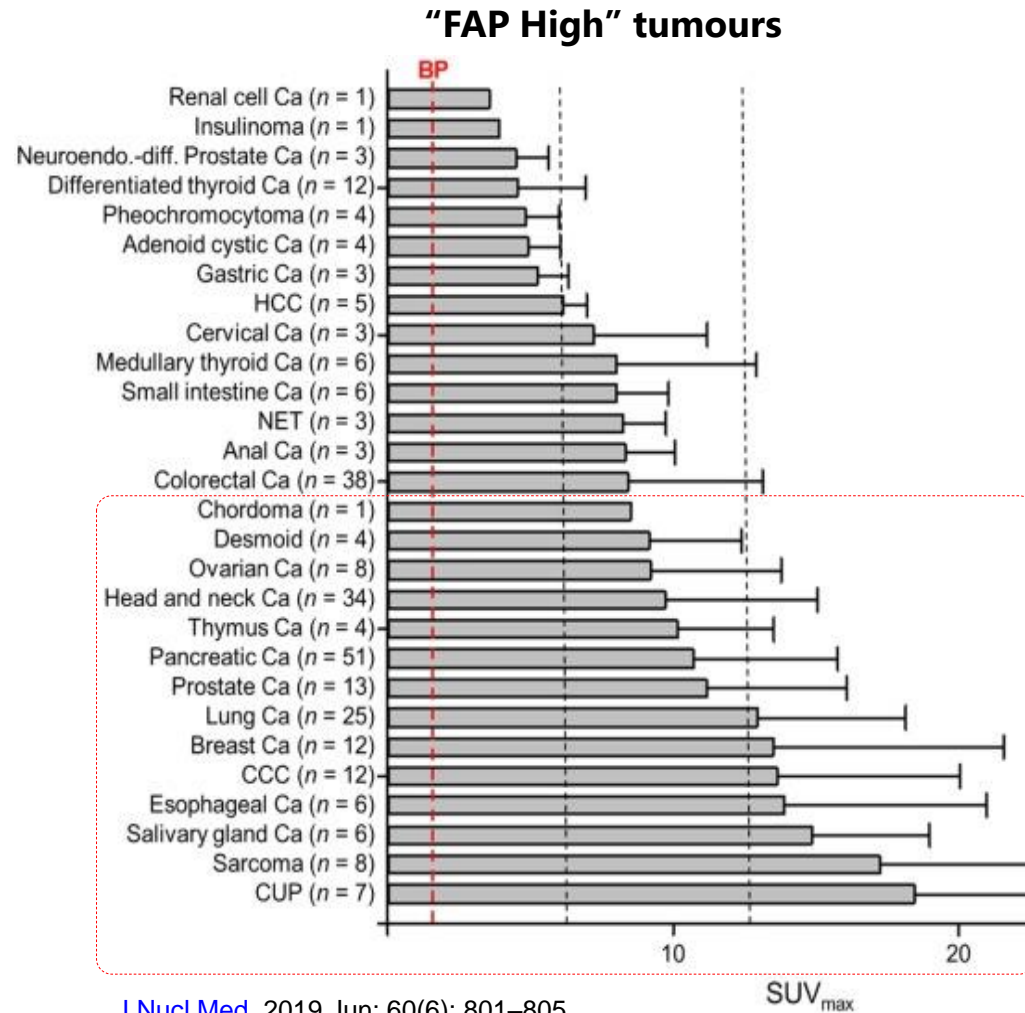
# Therapeutic Division Update

*Improving the lives of people with cancer through tumour-targeted therapies*



## What is pre|CISION™?

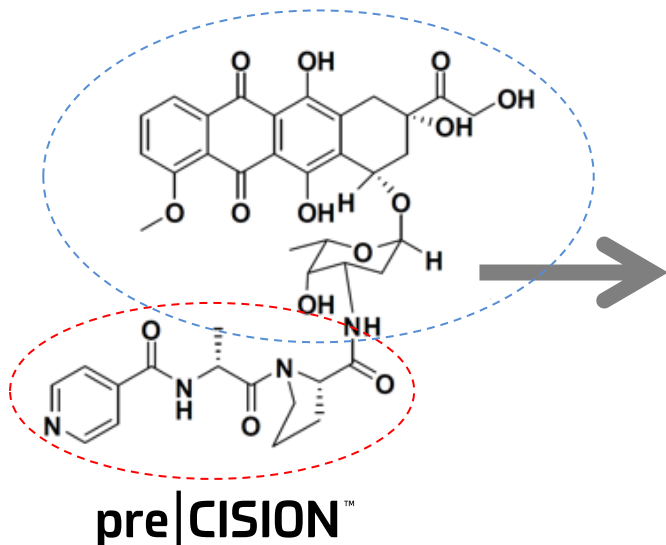
- pre|CISION is a highly specific substrate for fibroblast activation protein- $\alpha$  (FAP $\alpha$ ), an extracellular enzyme that is upregulated in most solid tumours.
- pre|CISION prevents chemotherapeutics from entering cells rendering them inert until it is removed in the tumour microenvironment by FAP.
- Chemotherapy market worth \$56.5B with CAGR of 11.50%.
- pre|CISION can also be incorporated into a drug conjugate linker for release of the targeted warhead in the tumour microenvironment.
- pre|CISION exclusively licensed from Tufts University Medical School.



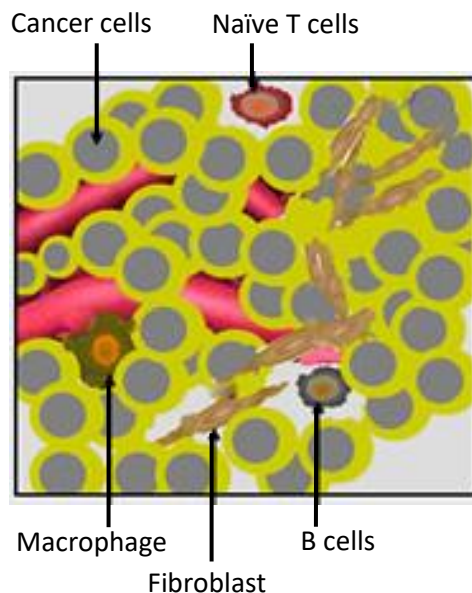
# The pre|CISION<sup>™</sup> Platform in Detail

Reducing the side-effects of chemotherapy by tumour-specific activation

**AVA6000**

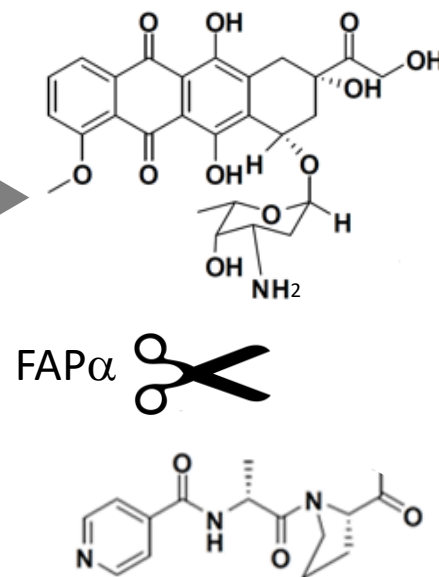


**Tumour Microenvironment**



FAP $\alpha$  +ve fibroblasts and cancer cells

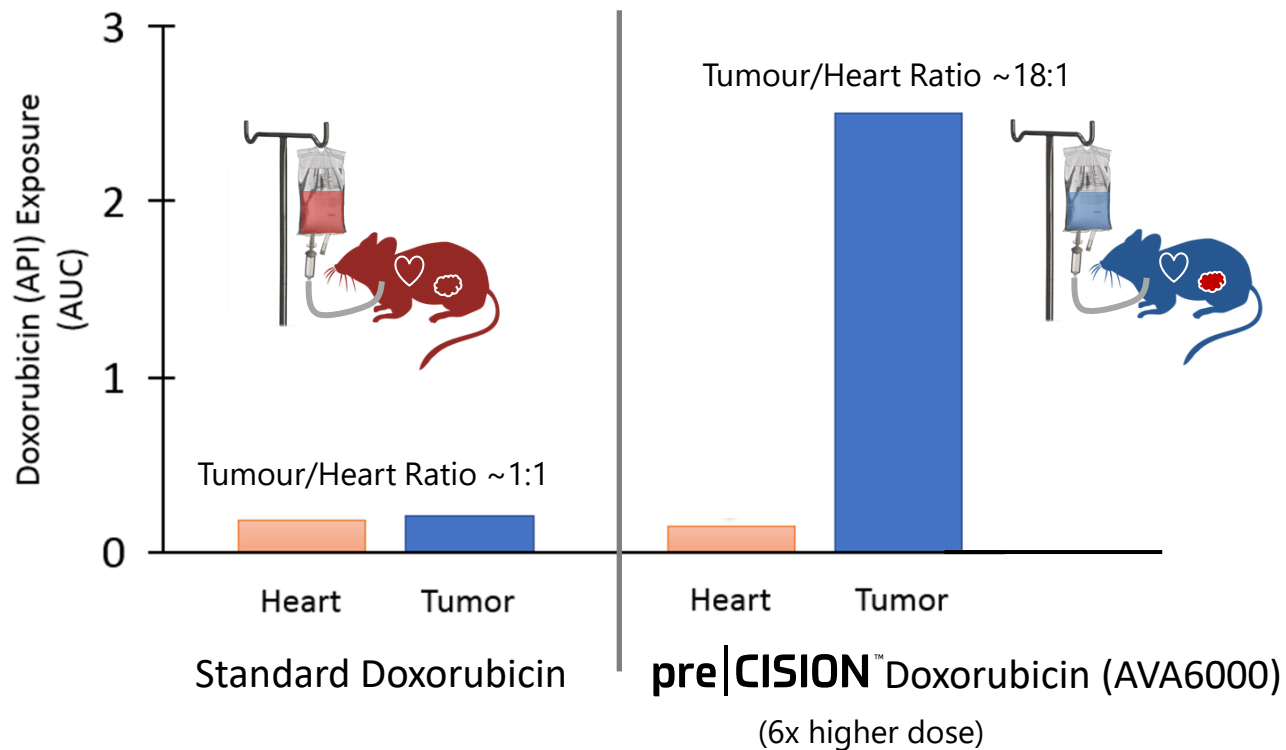
**Active Doxorubicin**





## AVA6000 addresses the safety issues of a \$1bn generic chemotherapy

Targeting of Active Chemotherapy to Tumour Tissue in a Mouse Model



Publication of key AVA6000 pre-clinical data at American Association of Cancer Research (AACR) New Orleans Convention Center, 11-13th April 2022. The abstract is available via the AACR annual meeting website, here: <https://www.aacr.org/meeting/aacr-annual-meeting-2022/abstracts/>

## AVA6000 pre|CISION™ Pro-doxorubicin

**AVA6000 market opportunity**

- Doxorubicin has been a standard of care treatment for advanced soft tissue sarcoma (ASTS) for 40 years.
- Its use is limited by serious dose limiting toxicities such as cardio-toxicity and myelosuppression.
- Despite this the global market for this generic drug is \$1bn.
- AVA6000: The estimated market size (peak sales) of a safer/more efficacious form of doxorubicin in just three indications (ASTS, breast and ovarian cancer), in the US/EU alone, is \$1.5bn\* pa.
- A licensing agreement with a large pharma partner should deliver 10% royalties on sales to Avacta.

(Commercial Evaluation: AVA6000, Globe Life Sciences, March 2020).

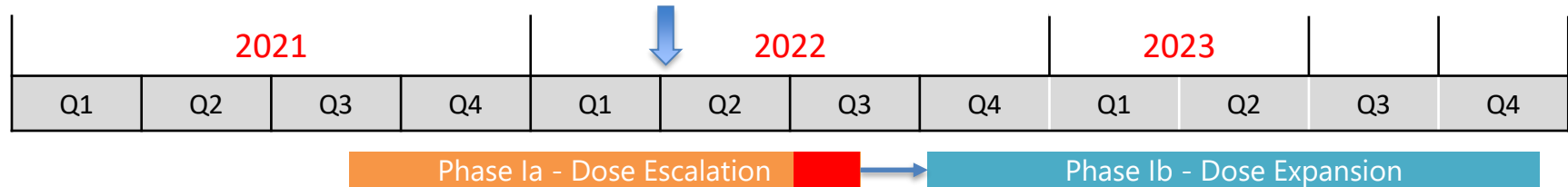
# The Wider pre|CISION™ Pro-drug Opportunity

**pre|CISION™ can be widely applied to a range of other chemotherapies in a market worth \$56.5B with CAGR of 11.50% driven by increased cancer detection rates**

## Example: Velcade

- Bortezomib (Velcade, Takeda Pharmaceuticals) had annual sales of \$1.2bn (2018)
  - **BUT – approval limited to multiple myeloma because of dose limiting toxicities,**
  - **AND - coming off patent by 2022.**
  - AVA3996 is a preCISION proteasome inhibitor and an analogue of Velcade.
  - AVA3996 has been selected as a candidate for preclinical development.
  - Clinical Trial Authorisation (CTA) and/or Investigational New Drug (IND) filing expected H1 2023 and dosing of the first patient later in 2023.
- **Ideal for pre|CISION™ tumour activation to create safer and proprietary pro-drugs.**
  - **Conservatively assume the pre|CISION™ prodrug versions of these can achieve similar market sizes delivering 5-10% royalty to Avacta plus development milestones.**
  - Potential for a pipeline of pre|CISION pro-drugs, some of which have already been synthesized, with an addressable market of many \$bn pa.
  - Including but not limited to:
    - preCISION Velcade analogue (AVA3996)
    - preCISION Paclitaxel
    - preCISION Oxaliplatin
    - preCISION Gemcitabine
    - preCISION Capecitabine
    - preCISION PARP inhibitor
    - preCISION PD-1 Inhibitor
    - preCISION AKT inhibitor
    - preCISION Balixafortide

# AVA6000 Phase I Design and Anticipated Timeline



## Phase 1a

- **Objective:** Assess safety and tolerability of AVA6000; determine MTD and/or recommended dose for further development.
- **Approximately 4 Cohorts** of 3-5 patients per cohort to achieve maximum tolerated dose (MTD) - 15 to 20 patients.
- **Patient Population:** Locally advanced and/or metastatic pancreatic, colorectal, non-small cell lung, breast, head and neck (SCCHN), soft tissue sarcoma, ovarian and bladder cancer.

## Phase 1b

- **Objective:** Confirm safety and tolerability of AVA6000 at the MTD (or recommended dose) determined in Part 1; explore preliminary anti-tumour activity.
- Up to 3 cohorts & 15-20 patients/cohort
- **Patient Population:** Selected on the basis of Part 1 data.

MTD - Maximum Tolerated Dose



# Phase 1a Dose Escalation Study

- Up to six clinical trial sites in UK:
  - Active sites: St James' Leeds, The Royal Marsden, London and The Christie, Manchester.
  - The Beatson, Glasgow now open and screening patients.
  - UK sites Q2: The Freeman, Newcastle and Western Park, Sheffield.
- Starting dose with cohort 1 was 80 mg/m<sup>2</sup> AVA6000 which is equivalent to 54 mg/m<sup>2</sup> of Doxorubicin.
- First patient dosed on 11<sup>th</sup> August 2021 at The Royal Marsden.
- Dose escalated February 2022 to 120 mg/m<sup>2</sup> in ongoing second cohort.
- US IND approved by FDA in November 2021:
  - Two US clinical trial sites being initiated and should contribute to the dose escalation phase in Q2.



# Phase 1a Dose Escalation Study



## Primary Objectives:

- To evaluate the safety and tolerability of AVA6000.
- To determine the maximum-tolerated dose (MTD) and/or the Recommended Phase 2 Dose (RP2D) for the dose expansion phase.

## Secondary Objectives:

- To characterise the pharmacokinetics (PK) in plasma, urine and tumour of AVA6000, of the preCISION leaving group, and of active metabolites (doxorubicin and doxorubicinol) when given as monotherapy, after a single dose and after multiple dosing.
- To evaluate the initial anti-tumour activity of AVA6000 according to RECIST.1.1 criteria (overall response rate [ORR], duration of response [DoR], disease control rate [DCR] progression free survival [PFS ] and overall survival).

# Key Partnerships Update (2021)



- (2018) multi-target agreement to develop Affimer® therapeutics in several disease areas.
- (2020) partnership expanded to include Avacta's Affimer XT™ technology for serum-half life extension.
- (2021) LG has successfully carried out certain in vivo studies with a PD-L1/XT molecule and is taking that asset into pre-clinical development which triggered an undisclosed milestone payment to Avacta in September 2021.
- Successful pre-clinical development of the PD-L1/XT asset will trigger further development milestones.



- (2020) JV (AffyXell) developing next generation cell and gene therapies incorporating Affimer proteins.
- The cell and gene therapy market is expected to grow from \$4.39B in 2020 to \$15.48B by 2025.
- (2021) AffyXell Series A funding of \$7.3m to achieve key pre-clinical milestones.
- (2021) Affimer molecules successfully generated against first two targets by the Avacta Therapeutics team.
- Current focus on generating in-vitro and in-vivo data using lead Affimer molecules and engineered MSCs to support next stage in AffyXell development.

# Therapeutic Division Relocation

- Co-location of Avacta's Research & Development organisations into a single location in state of the art laboratories and office space in Scale Space, White City.
- Imperial College's White City campus in West London is bringing together scientific researchers, corporate partners, entrepreneurs to turn cutting-edge scientific research into real-world benefits for society.
- White City is a focal point for West London's emerging biotech cluster.
- 5,000 sq ft of laboratory and office space.
- Improved opportunities to network with investors, partners & collaborators.
- Relocation will be completed, on schedule, by the end of April 2022.





# Non-Executive Director Appointments



**Mark A. Goldberg, MD**  
Non Executive Director

- Medical oncologist and hematologist and a biotechnology executive.
- Currently serves on the boards of ImmunoGen, Idera, Glyco-Mimetics, Blueprint Medicines, and Walden Biosciences.

- Dr. Goldberg began his career as a full-time staff physician at Dana-Farber Cancer Institute and Brigham and Women's Hospital, where he still holds an appointment.
- He is an associate professor of Medicine (part-time) at Harvard Medical School and was a member of the American Cancer Society New England Division Board from 2010-2017, and a member of the national Board of Directors of the American Cancer Society since 2019.



**Christina Coughlin, MD**  
Non Executive Director

- Chief Executive Officer of CytolImmune Therapeutics.
- Dr. Coughlin joined CytolImmune from Rubius Therapeutics, Inc. where she served as the Chief Medical Officer.
- Prior to Rubius, Dr. Coughlin was Chief Medical Officer at Tmunity Therapeutics, Inc., and before that with Immunocore, Ltd.
- Dr. Coughlin has held other leadership roles in the pharmaceutical and biotechnology fields in her career including Oncology Asset Team Leader at Pfizer and Clinical Program Team Lead at Novartis.
- Dr. Coughlin is an oncologist and immunologist, having received her M.D. and Ph.D. from the University of Pennsylvania.



# Diagnostics Division Update

*Powerful diagnostics to improve health and well-being for all*

# Key Trends in Diagnostics

- Decentralised (“Point-of-care”) and Home-testing:
  - Chronic disease monitoring;
  - Health screening driving early intervention;
  - Health/well-being monitoring – in tandem with digital health monitoring (“wearables”);
  - Increasing availability of PoC molecular and immunodiagnostic platforms;
  - Pandemic-driven familiarity with lateral flow self-testing.
- Digital connectivity:
  - Using AI to transform physiological and IVD information into actionable, trackable medical intervention.
- Companion diagnostics:
  - Identifying the sub-set of patients who will benefit from specific therapies – major focus for oncology therapies due to very high cost of treatment and limited durable response rates.



**Uniquely positioned UK diagnostics company with proprietary Affimer immunodiagnostics technology to address key unmet market needs and drive competitive advantage and shareholder value**

- Maintain a strong decentralised (Point of care) testing focus.
- Serve the professional use market and build the consumer home-test market.
- Primary focus on in-house development of IVD products.





# AffiDX® SARS-CoV-2 Antigen Rapid Test



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



- Consumer self-testing CE mark (in partnership with Medusa19) in December 2021 as Omicron variant emerged.
  - > 30 mutations difference between Omicron (BA.1) and Delta.
  - > 30 mutations difference between Omicron and BA.2.
- AffiDX SARS-CoV-2 antigen test is in re-development due to reduction in performance with Omicron variant to deliver a solution that is as robust to future variants.
- Timescale depends on development process and regulatory requirements.
- Avacta will update the market as soon as the timeline to product re-launch is clear.

# Broader Diagnostics Product Vision

## Infectious Diseases

- Respiratory diseases (e.g. COVID19, Flu A/B)
- Sexually transmitted diseases
- Sepsis/Bloodstream infections
- Antimicrobial resistance
- Congenital infections

## Chronic Disease / Treatment Monitoring

- Cardiac disease (e.g. heart failure, AML, stroke)
- Cancer markers
- Diabetes (e.g. HbA1c)
- Neurodegeneration (e.g. Alzheimer's risk)
- Therapeutic drug monitoring

## Health Screening

- Cancer markers
- Thyroid function
- Liver function
- Kidney function
- Heart function

## Fitness and Well-being

- Hormones (e.g. Cortisol)
- Vitamins
- Iron
- Cholesterol

# Summary

**2020/21 was a transformational period with the transition of the Therapeutics Division to clinical stage and the launch of the first Affimer® IVD product**

## **Therapeutics – the key value driver for the Group**

- AVA6000 pro-doxorubicin: Conducting Phase 1a dose escalation study (in UK and with IND approved for US sites) with expected read-out in Q3.
- Pivotal moment for the preCISION platform and the Group.
- Multiple clinical and pre-clinical development milestones anticipated through 2022/23.

## **Diagnostics**

- ISO13485 certified IVD product development and commercialisation business.
- Development of IVDs with a focus on decentralised testing markets.
- Re-development of the antigen test as part of a much broader diagnostic product pipeline.

**Strong balance sheet to support core businesses through mid-2023.**



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