



# Avacta Group plc Business Review

Annual General Meeting of Shareholders

28<sup>th</sup> June 2023

The Royal Society of Medicine, 1 Wimpole Street, London

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## **Therapeutics Division Strategic Objectives 2022-23**

- pre|CISION™ platform proof-of-concept in human : “Chemotherapy targeted to the tumour”
- Build value in the pre|CISION™ pipeline
- Progress the Affimer® platform towards the clinic

## **Diagnostics Division Strategic Objective 2022-23**

- Build a substantial commercial IVD business through M&A
- Profitable revenue with growth potential and synergy with the Affimer® platform

## Delivering strategic objectives across the Group

- pre | CISION™ platform PoC in human
- Build value in the pre | CISION™ pipeline
- Progress Affimer® platform towards clinic
- Build a substantial IVD business through M&A
- Profitable revenue, growth potential, synergies

**June 23** AVA6000 escalation to 6th dose cohort

**June 23** Appointment of Shaun Chilton as Non-executive Director

**June 23** Achievement of AffyXell 2nd milestone

**June 23** Acquisition of Coris Bioconcept

**April 23** AVA6000 US trial sites open and start recruiting

**April 23** AVA6000 first patient dosed in cohort 5 at 250mg/m<sup>2</sup> (2.25 x normal doxorubicin dose)

**April 23** AACR poster presentation: AVA3996 pre-clinical data

**February 23** Science Day

**January 23** AVA6000 4th dose cohort completion and biopsy data: pre | CISION™ platform validation in human

**October 22** Acquisition of Launch Diagnostics

**October 22** Completion of placing to raise £64 million gross

**September 22** Orphan Drug Designation for AVA6000 in Osteosarcoma

**September 22** AVA6000 escalation to 4th cohort: continued favourable safety profile

**July 22** AffyXell fund raise

**June 22** LG option renewal

**June 22** AVA6000 escalation to 3rd dose cohort: positive safety profile

**May 22** Therapeutics Division relocates to Scale Space, White City

## Extensive commercial and drug development experience



**Dr Eliot Forster**  
**Chairman**

- Former CEO of F-Star (NASDAQ: FSTX), Dr Forster brings over 30 years of experience in the pharmaceutical and biotechnology industry.
- Prior to joining F-Star, Eliot led Immunocore (NASDAQ: IMCR) as Chief Executive Officer to become a world-leading immuno-oncology biotech, raising over £230 million in equity and non-dilutive funding as well as securing partnerships with AstraZeneca and the Bill & Melinda Gates Foundation.
- The early part of Dr Forster's career was at GSK and then he went on to hold a number of senior roles in Pfizer.
- Dr Forster holds a PhD in neurophysiology from Liverpool University and an MBA from Henley Management College. He is an Honorary Visiting Professor at the University of Liverpool and the University of Pavia, a Board member of OSCHR (Office for Strategic Coordination of Health Research).



**Dr Christina Coughlin**  
**Non-executive Director**

- Christina Coughlin, MD, PhD is former Chief Executive Officer of CytImmune Therapeutics.
- Dr. Coughlin joined CytImmune from Rubius Therapeutics, Inc. where she served as the Chief Medical Officer and led the clinical development, translational medicine and regulatory efforts in the allogeneic red cell therapy platform.
- Prior to Rubius, Dr. Coughlin was with Tmunity Therapeutics, Inc., and Immunocore, Ltd where she led the development of Kimmtrak™, recently approved for the treatment of metastatic uveal melanoma.
- 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 and completed fellowships in Hematology and Oncology at the Children's Hospital of Philadelphia and in the Translational Research Group under the direction of Carl June, M.D. at the University of Pennsylvania.



**Dr Mark Goldberg**  
**Non-executive Director**

- Mark A. Goldberg, MD, is a medical oncologist and hematologist and a biotechnology executive.
- In addition to being a Non-executive Director of Avacta, he currently serves on the boards of directors of ImmunoGen, Idera Pharmaceuticals, GlycoMimetics, Blueprint Medicines, and Walden Biosciences. Dr. Goldberg was part of the executive management team of Synageva Biopharma from 2011 until 2014.
- Prior to that, he served in various management capacities of increasing responsibility at Genzyme Corporation.
- Prior to joining Genzyme, Dr. Goldberg was 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. Dr. Goldberg is also a longtime American Cancer Society (ACS) and ACS Cancer Action Network volunteer.
- Dr. Goldberg was a member of the American Cancer Society New England Division Board from 2010-2017. He has been a member of the national Board of Directors of the American Cancer Society since 2019.

## Extensive commercial and drug development experience



**Shaun Chilton**

### **Non-executive Director**

- Most recently Chief Executive Officer of the formerly London-listed Clinigen Group plc which was sold to Triton Partners for a total consideration of c.£1.3 billion in April 2022.
- Grew Clinigen through both an organic and a buy-and-build strategy which included successfully completing several transformational acquisitions.
- Extensive commercial and M&A experience
- Previously Non-Executive Chairman of C7Health, a disruptive, venture capital-backed medical technology and services business which executed an acquisitive growth journey before successfully being acquired by a strategic buyer in 2022.
- Shaun has held a number of senior and executive commercial positions over more than 30 years in companies in pharmaceutical and pharmaceutical services industries including include at Pfizer, Sanofi, Wolters Kluwer Health and KnowledgePoint360 Group (now part of UDG Healthcare).



**Paul Fry**

### **Non-executive Director, Chair of Audit Committee**

- Paul has extensive financial experience across a number of industries including biotech, pharmaceutical and telecommunications. He is currently Chief Financial Officer of Argenta Global.
- Prior to that Paul was Chief Financial Officer of Vectura plc, an industry leading inhaled drug delivery specialist listed on the FTSE Main Market. Paul joined Vectura from Immunocore Limited.
- Earlier in his career Paul served as Director of Global Finance Operations at Vodafone plc and spent more than 25 years at GlaxoSmithKline ("GSK"), where he held a number of senior roles including Head of Global Finance Services and Chief Financial Officer for GSK's Italian pharmaceutical business.
- Paul is Chair of the Audit Committee.



**Dr Trevor Nicholls**

### **Non-executive Director, Chair of Remuneration Committee**

- Trevor Nicholls has over 35 years of commercial experience building international businesses in the life sciences sector.
- As Chief Commercial Officer and Executive Vice President of Affymetrix, he was responsible for global operations including sales, marketing, product development and manufacturing.
- In addition, he has over 14 years of technical marketing and sales experience in the life science reagents and instrumentation sector and was Chief Executive Officer of the not-for-profit CAB International, an intergovernmental organisation whose mission is to solve problems in agriculture and the environment.
- He is also a Non-Executive Director of hVivo plc, the pioneer of human challenge models of respiratory disease and Conidia Bioscience Ltd.
- He was also founder and CEO of Oxagen where he successfully raised approximately £50 million over three venture-backed financing rounds and secured major commercial partnerships.
- Prior to that he had also worked in consultancy with McKinsey.

Improving cancer patients' lives through innovation and partnership

## VISION

Our vision is to deliver innovative oncology drugs that transform treatment outcomes to improve cancer patients' lives.



## STRATEGY

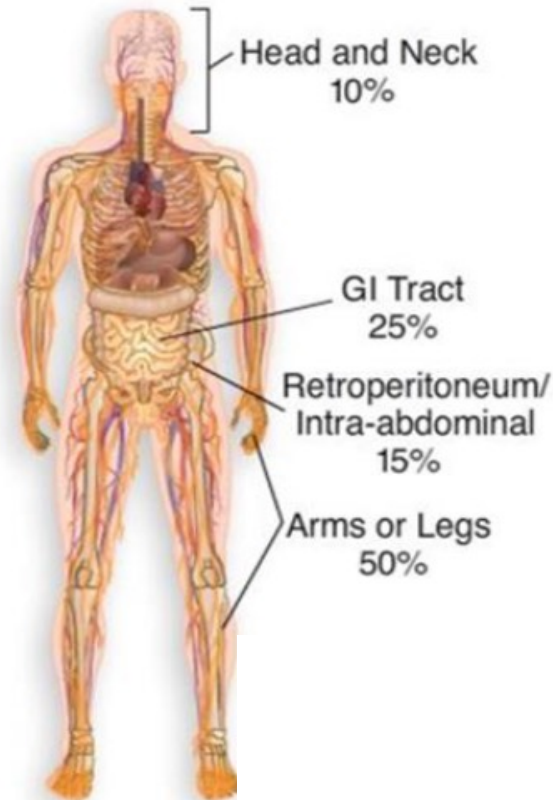
- Use our proprietary pre | CISION™ and Affimer® platforms to develop best-in-class and first-in-class cancer therapies.
- Grow our clinical pipeline alongside selective and focused out-licensing.
- Combine our in-house drug development expertise with a focused partnership strategy.

# AVA6000: A Tumour Targeted Form of Doxorubicin

The Doxorubicin market is US\$ 1,390.64 million in 2022 and expected to grow at a CAGR of 6.1% to reach US\$ 1,983.40 million by 2028<sup>1</sup>

- Doxorubicin has been a standard of care first-line treatment for advanced soft tissue sarcoma for 40 years. It is also used as part of treatment regimens for a range of other cancers.
- The eligible patient population and the amount of doxorubicin given is restricted by serious dose limiting toxicities such as cardio-toxicity and myelosuppression.
- The Avacta proprietary FAP-targeted form of doxorubicin, with reduced systemic toxicities, could expand the eligible patient population and increase the amount given.

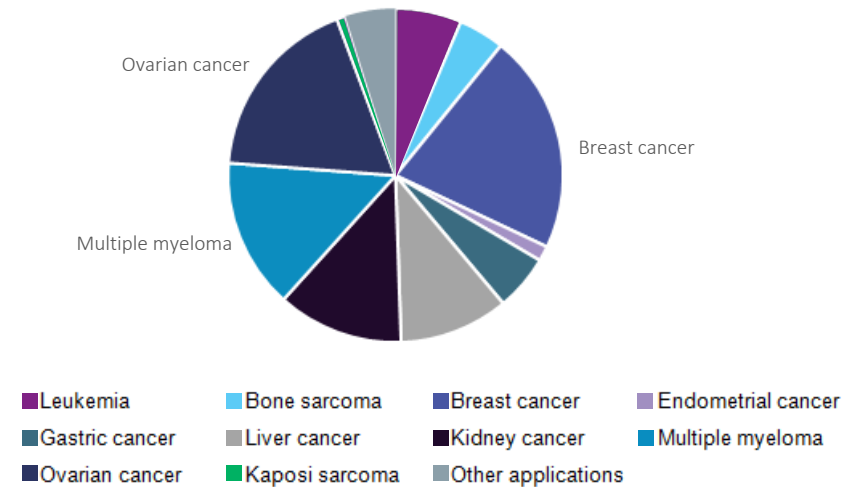
## Soft Tissue Sarcoma



- Heterogeneous disease with >50 subtypes

Source: Globe Life Sciences Market Report 2020

## Global Liposomal Doxorubicin Market by Application 2015



- Breast cancer was approximately 21.2% of the revenue generated in 2015.
- New formulations is one of the key factors enhancing the adoption and utilization of the drug to treat breast carcinoma.

Source: Globe Life Sciences Market Report 2020

1. <https://www.globenewswire.com/en/news-release/2022/07/12/2478328/0/en/Doxorubicin-Market-Revenue-to-Cross-1-983-40-million-by-2028-to-Rise-at-a-Stellar-CAGR-of-6-1-by-2028-Exclusive-Research-by-The-Insight-Partners.html>



## Positive safety profile and biopsies confirm the ability of pre|CISION™ to target the release of doxorubicin in the tumour tissue at therapeutic levels

- 29 patients with a range of solid tumours now dosed across five dose groups (80mg/m<sup>2</sup> – 250mg/m<sup>2</sup>).
- UK and US clinical sites open and recruiting patients; additional sites in US and Europe to support Phase 1b.

### Very Favourable Safety and Tolerability

- AVA6000 is well tolerated across all five dose groups (highest dose group so far is equivalent to 2.25x normal doxorubicin dose).
- Marked reduction in the incidence and severity of the usual doxorubicin related toxicities (including the most serious) to-date despite administering the equivalent of more than double the normal dose of doxorubicin.

### Biopsy Analysis Confirms Release of Doxorubicin in the Tumour

- Analysis of tumour biopsies taken from 6 patients in the first four dose groups confirms pre|CISION™ can deliver therapeutic levels of doxorubicin to tumour tissue.
- Analysis from 5<sup>th</sup> dose group not yet completed.

## Development Rationale for AVA6000 in Soft Tissue Sarcoma (STS)

- Advanced/metastatic soft tissue sarcoma (STS) tumours are highly FAP positive.
- Doxorubicin is the standard of care for advanced STS.
- Conventional doxorubicin has marginal efficacy & limitations due to cumulative dose limit.
- Pharmacokinetic data indicate that AVA6000 has the potential to increase treatment duration by 2-3 times.

### Phase 1b Dose Expansion Study

- Open-label, randomised design
- Metastatic soft tissue sarcoma
- Doxorubicin naïve patients
- FAP positive tumours
- Multiple AVA6000 dose levels and dosing frequency
- 20 US & European Investigator Sites

Randomise

### Indicative Trial Design

Up to 20 Patients  
AVA6000 Dose 1  
12-18 Cycles Q3W

Up to 20 Patients  
AVA6000 Dose 2  
12-18 Cycles Q3W

15-20 Patients  
Doxorubicin  
6 Cycles (75mg/m<sup>2</sup>) Q3W

Select AVA6000 Dose Regimen  
for Phase 2

### Potential Primary Endpoints

1. Progression-free survival.
2. Safety & tolerability.

### Potential Secondary Endpoints

1. Percentage of patients who are progression-free at 3 months.
2. Pharmacokinetics (AVA6000/Doxorubicin).
3. Objective Response Rate (ORR).
4. Doxorubicin levels in mandatory biopsies.

## Entering commercial phase for pre | CISION™ platform following excellent human safety data and proof-of-concept for tumour targeting via FAP

### AVA6000

- Progress AVA6000 through phase 1b to generate efficacy data and reach commercial stage for this asset
  - Efficacy data is a key deal value driver
- Potentially partner AVA6000 for phase 2 pivotal study in soft tissue sarcoma
  - Consider broader applications of AVA6000 in breast and ovarian cancer for example

### AVA3996

- Progress AVA3996 through to IND filing in 2024
  - Potential to partner early in specific solid tumour indications

### pre | CISION™ Platform

- Potential to license pre | CISION™ platform for use with partners' chemotoxins or drug conjugates

### pre | CISION™ Pipeline

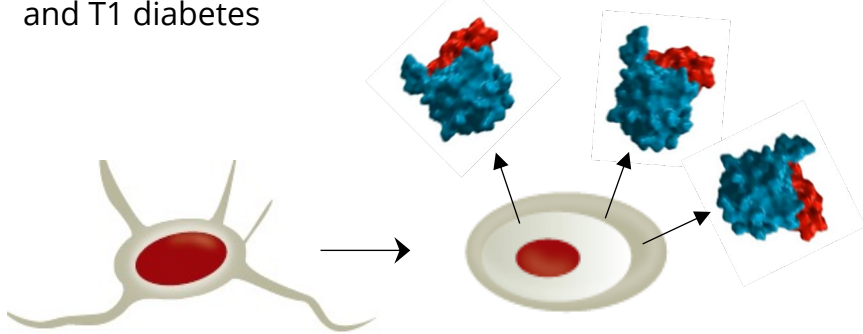
- Expand pre | CISION™ pipeline with modern highly potent chemotoxins such as those used as warheads in drug-conjugates



A joint venture in South Korea with Daewoong Pharmaceutical to develop engineered mesenchymal stem cells that express and secrete immuno-modulatory Affimer molecules to treat autoimmune diseases

### Next-generation Stem Cell Therapies

- Renewable “off the shelf” mesenchymal stem cells
- AFX001: MSC secreting anti-CD40L Affimer® for use in GvHD
- AFX002: MSC secreting agonist Affimer® for use in MS and T1 diabetes



Development stage						
Product Candidate	Target Indication	Discovery	Pre-clinical	Phase1	Phase2	Phase3
AFX-001	⊕ SOT	<div style="width: 100%; height: 10px; background: linear-gradient(to right, #00a08a, #0056b3);"></div>				
	⊕ GvHD	<div style="width: 100%; height: 10px; background: linear-gradient(to right, #00a08a, #0056b3);"></div>				
AFX-002	⊕ MS	<div style="width: 100%; height: 10px; background: linear-gradient(to right, #00a08a, #0056b3);"></div>				

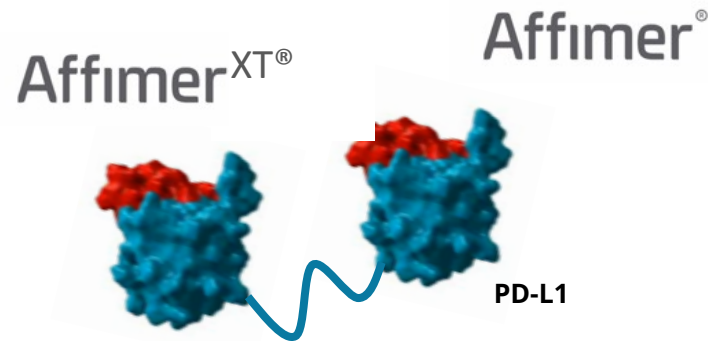
- Entered into collaborations with Biocytogen, a Chinese company specialising in developing new biological drugs, and with the Korea Non-Clinical Technology Solution Center (‘KNTSC’).
- The strategic partnership with GenScript ProBio, a leading biopharmaceutical manufacturer was expanded.
- Successfully 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.



A multi-target development partnership and licensing deal worth up to \$310 million with a focus on oncology and inflammatory diseases

### PDL1/XT Antagonist

- PD1/PDL1 axis Affimer® inhibitor
- Half-life extension using Affimer XT® a human serum albumin binder
- Small size potentially leads to better tumour penetration



LG Chem Life Sciences Innovation Center, Inc.		Solid Tumor	About Us	Research & Development	Media	Careers	Contact Us		
Disease Area	Code	Indication	Research	Preclinical	Phase I	Phase II	Phase III	NDA	Remark
Oncology	LR19129	Oncology	—————●						In partnership with CUE (USA)
	LR20009	Oncology	—————●						
	LR19023	Oncology	—————●						
	LR19128	Oncology	—————●						In partnership with Avacta <sup>®</sup>
	LR19155	Oncology	—————●						

- 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.

## VISION

Build a full spectrum, differentiated European in-vitro diagnostics (IVD) business supporting healthcare professionals and broadening access to diagnostics.



## MISSION

Innovate to make market leading diagnostic solutions available to all, to inform treatment and monitor health and fitness.

## REVIEW

- Diagnostics Division with strong sales channels in UK and France and a broad portfolio of products for professional healthcare and rapid, near-patient testing.
- £20M+ revenue (2023).



## GROWTH

- Organic growth through expansion of Launch Diagnostics into Germany, improved distribution of Coris products and cross-group synergies.
- Potential future spin-out opportunity.

# Strategic Objectives 2023-24

**A strategy to deliver long term sustainable value**

## **Therapeutics Division**

- Initiate and progress phase 1b
- Commercialise the pre | CISION™ platform
- IND filing for the Affimer® platform
- Progress AVA3996 through to IND filing

## **Diagnostics Division**

- Establish Launch GmbH
- Initiate first Coris/Affimer® product development
- Profitable revenues > £20M







Principle of tumour targeting through FAP activation of pre | CISION™ modified chemotherapy confirmed in AVA6000 phase 1 study.



AVA3996, an FAP-activated proteasome inhibitor, showing positive pre-clinical data; now in IND enabling studies with FIH planned late 2024.



First two acquisitions in the diagnostics M&A-led growth strategy completed: focus now on synergies and growth plans for these first two acquisitions.



October 2022 fund raise provides balance sheet flexibility for the Group.



[www.avacta.com](http://www.avacta.com)



**AVA6000**

**Phase 1a Clinical Study Update – ALS-6000-101**

Dr Andrew Saunders, Medical Advisor

Annual General Meeting of Shareholders

28<sup>th</sup> June 2023

The Royal Society of Medicine, 1 Wimpole Street, London

# AVA6000: A FAP-Targeted Next Generation Doxorubicin

- **Exploiting FAP specificity within the tumour by selectively cleaving AVA6000 & activating doxorubicin at tumour sites to...**

- ✓ Precisely target FAP-positive solid tumours
- ✓ Maximise tumour concentrations
- ✓ Limit systemic exposure to healthy tissues & organs
- ✓ Increase overall efficacy
- ✓ Enhance safety & tolerability

**Doxorubicin is a very successful chemotherapy due to its efficacy in fighting a wide range of cancers...but it has limitations**

- Injury to non-targeted tissues complicates cancer treatment by limiting therapeutic dosages & diminishes the quality of patients' lives during and after treatment
- The heart is a preferential target and cumulative doses above 450mg/m<sup>2</sup> increase risk of heart damage dramatically
- Improving tolerability increases patients' ability to continue treatment and improves cancer outcomes

**Hypothesis: Using the pre | CISION linker to mask doxorubicin until it reaches the tumour site where FAP removes the linker and activates doxorubicin within the tumour environment. Systemic concentrations of doxorubicin are lowered substantially while tumour concentrations are increased, sparing healthy tissues and organs.**

# Phase 1 & 2 Study Designs

## AVA6000 in Patients with Advanced, Metastatic Solid Tumours

### Phase 1a

#### Key Eligibility Criteria

- Locally Advanced, Metastatic Selected Solid Tumours

#### Endpoints

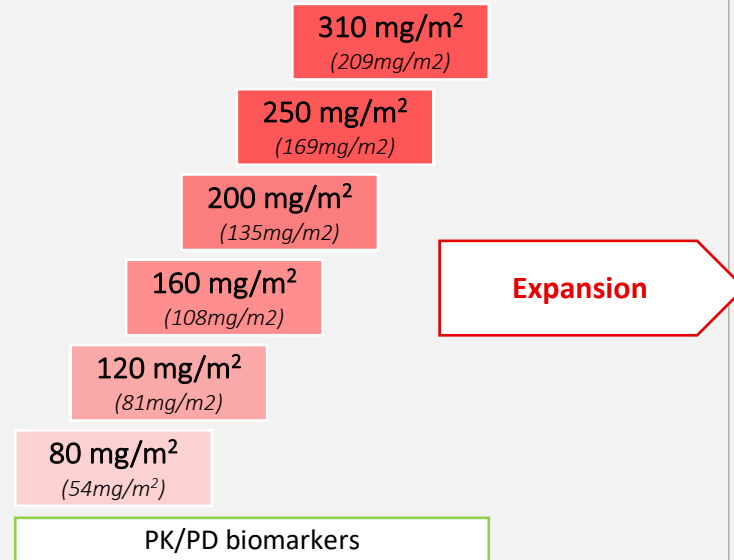
DLTs, Safety, Tolerability & Cardiac Safety  
PK profiles for Cycle 1 & 2  
Optional biopsies (AVA6000/Dox levels)  
Biomarker assessments  
Tumour assessments

#### Centres

5 UK  
2 US

Expand into additional centres for Phase 1b

### Phase 1a: Dose Escalation



#### Phase 1a Endpoints

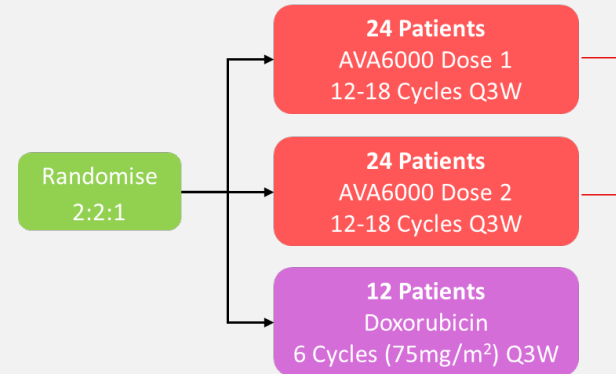
**Primary:** Safety, MTD, PK, RP2D

**Secondary:** ORR, DOR

**Design:** PK-Guided Dose Escalation (3+3)

- **PK-guided dosing:** cumulative systemic exposure of released doxorubicin guides dose escalation decisions
- 19 patients in four dose cohorts have received an IV dose of AVA6000 every 3 weeks until disease progression, unacceptable toxicity, or other discontinuation criteria were met

### Phase 1b: Dose Expansion



#### Phase 1b Endpoints

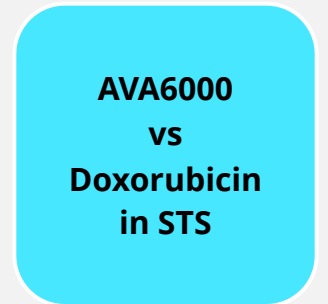
**Primary:** Safety

**Secondary:** ORR, DOR, PFS, Pop PK

**Design:** Open, randomised, parallel group, doxorubicin comparator

- Advanced, metastatic Soft Tissue Sarcoma
- 60 randomised patients
- 2 AVA6000 dose levels for Phase 1b
- Tumour Biopsies in a subset of pts
- Population PK

### Phase 2



#### Phase 2 Endpoints

**Primary:** PFS

**Secondary:** Safety, OS, ORR, DOR

**Design:** Open, randomised, parallel group, doxorubicin comparator

- Advanced, metastatic Soft Tissue Sarcoma
- 120 randomised patients
- RP2D AVA6000

# Overview of Clinical Study ALS-600-101

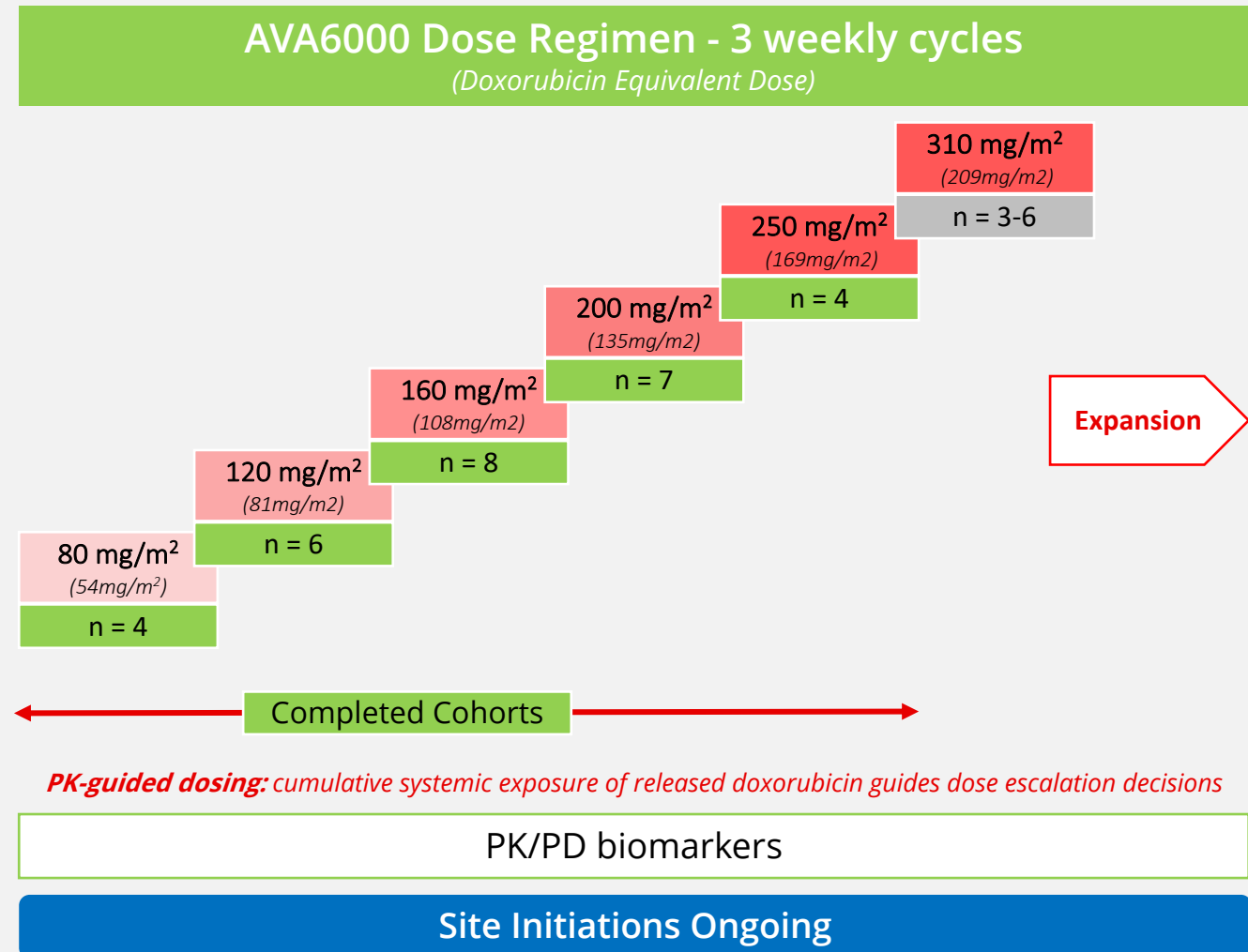
## Phase 1 Dose Escalation of AVA6000 across a range of solid tumours known to be FAP +ve

### Interim Data Supports AVA6000 Mechanism

29 patients dosed across 5 AVA6000 cohorts

- Median (range) = 2 Cycles (1-8 Cycles) from cohorts 1-4
- AVA6000 has a modest and predictable safety profile
- The most frequent adverse events were grade 1-2 nausea, fatigue & decreased appetite
- PK data indicate systemic levels of doxorubicin are considerably lower compared to standard 75mg/m<sup>2</sup> doxorubicin
  - Maximal concentrations of doxorubicin reduced by 80-90%
  - Exposure (AUC) reduced by 60-90%
- PK exposure data suggest that AVA6000 may have the potential to be used for 12-18 cycles depending on dose
- Tumour biopsies across 3 cohorts confirm higher concentrations of doxorubicin compared to systemic levels at same timepoint

Ongoing Phase 1 Dose Escalation Study in metastatic solid tumours (ALS-6000-101):  
ClinicalTrials.gov Identifier: NCT04969835



# Patient Demographics & Baseline Characteristics

## Study ALS -6000-101

	<b>80mg/m<sup>2</sup> (n=4)</b>	<b>120mg/m<sup>2</sup> (n=6)</b>	<b>160mg/m<sup>2</sup> (n=6)</b>	<b>200mg/m<sup>2</sup> (n=3)</b>
Median Age (range), years	58 (56-71)	58 (30-76)	63 (50-73)	63 (53-72)
Female, n (%)	3 (75)	2 (33)	0 (0)	1 (33)
Male, n (%)	1 (25)	4 (66)	6 (100)	2 (66)
Race, n (%)				
White	3 (75)	5 (83)	6 (100)	3 (100)
Asian	1 (25)	0 (0)	0	0
Black	0	0 (0)	0	0
Other	0	1 (17)	0	0
ECOG PS, n (%)				
0 (Capable of normal activity)	2 (50)	1 (17)	3 (50)	1 (33)
1 (Restricted in strenuous activity)	2 (50)	5 (83)	3 (50)	2 (66)
Tumour Types, n				
Colorectal	2	5	1	3
Pancreatic	1	1	3	0
Ovarian	1	0	0	0
Soft Tissue Sarcoma	0	0	1	0
Oesophageal	0	0	1	0
Prior lines of anticancer therapy, median (range)	4 (1-7)	3 (2-4)	3 (0-6)	5 (4-8)
Anthracycline Prior Treatment n (%)	2 (50)	0	0	0

# AVA6000 Safety Profile (80-200 mg/m<sup>2</sup> Q3W)

## Treatment-Related Adverse Events

	Cohort 1 80mg/m <sup>2</sup> (N = 4)	Cohort 2 120mg/m <sup>2</sup> (N = 6)	Cohort 3 160mg/m <sup>2</sup> (N = 6)	Cohort 4 200mg/m <sup>2</sup> (N = 3)	Total (N=19)
<b>Dose Limiting Toxicity</b>	0	1	0	0	1 (5%)
<b>Subjects ≥ Grade 3</b>	0	0	1	1	2 (11%)
Neutropenia	0	0	0	1	1 (5%)
Lymphopenia	0	0	0	1	1 (5%)
Mouth ulceration	0	0	1	0	1 (5%)
<b>Subjects Grade 1-2</b>	3	5	6	3	17 (89%)
Neutropenia	0	1	0	1	2 (11%)
Anaemia	1	1	1	0	3 (16%)
Platelet Count Decreased	1	0	0	0	1 (5%)
Heart Failure	0	1	0	0	1 (5%)
Fatigue	0	2	3	1	7 (37%)
Nausea	1	2	2	3	8 (42%)
Decreased appetite	0	2	1	1	4 (21%)
Alopecia	0	1	1	2	4 (21%)

- Overall AVA6000 has a modest and predictable safety profile
- 2 patients had Grade 3 related AEs
  - Neutropenia & lymphopenia (1 pt); mouth ulceration (1 pt)
- Most frequent adverse events were nausea, fatigue, decreased appetite & alopecia
- One dose-limiting toxicity (120mg/m<sup>2</sup>)
  - Grade 1 heart failure during Cycle 1
- Excluding DLT patient, no patient had AVA6000 related cardiac toxicity
- Classical acute doxorubicin related toxicities were infrequent across the dose range
  - Myelosuppression
  - Alopecia



# Safety Profile: AVA6000 vs Doxorubicin

Treatment-Emergent Adverse Event (TEAE)	<sup>1</sup> AVA6000 (80-200mg/m <sup>2</sup> Q3W) N = 19 Median No. Cycles = 2 (Range 1-8)		<sup>2</sup> Doxorubicin (75mg/m <sup>2</sup> Q3W) N = 249 Median No. Cycles = 7 (Range 1-8)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
	n (%)	n (%)	n (%)	n (%)
Nausea	10 (52.6)	0	166 (66.7)	6 (2.4)
Fatigue	11 (57.9)	0	147 (59)	12 (4.8)
Lethargy	4 (21.1)	0	NR	NR
Decreased appetite	4 (21.1)	0	92 (36.9)	1 (0.4)
Vomiting	6 (31.6)	1 (5.3)	69 (27.7)	2 (0.8)
Constipation	5 (26.3)	0	87 (34.9)	2 (2.8)
Diarrhoea	4 (21.1)	0	75 (31.1)	3 (1.2)
Abdominal Pain	3 (15.8)	0	53 (21.3)	3 (1.2)
Weight Decrease	2 (10.5)	0	NR	NR
Mucositis	3 (15.8)	1 (5.3)	NR	NR
Stomatitis	1 (5.3)	0	NR	NR
ALT increase	6 (31.6)	0	19 (7.6)	4 (1.6)
AST Increase	4 (21.1)	0	NR	NR
Bilirubin	3 (15.8)	1 (5.3)	NR	NR
<b>Anaemia</b>	<b>6 (31.6)</b>	<b>0</b>	<b>113 (45.4)</b>	<b>31 (12.4)</b>
<b>Neutropenia</b>	<b>2 (10.5)</b>	<b>1 (5.3)</b>	<b>144 (57)</b>	<b>122 (49)</b>
<b>Thrombocytopenia</b>	<b>1 (5.3)</b>	<b>0</b>	<b>62 (24.9)</b>	<b>21 (8.4)</b>
Lymphopenia	2 (10.5)	1 (5.3)	NR	NR
Alopecia	5 (26.3)	0	124 (49.8)	1 (0.4)
Heart Failure	1 (5.3)	0	NR	NR
Dyspnoea	3 (15.8)	0	36 (14.5)	2 (0.8)
Pyrexia	2 (10.5)	0	46 (18.5)	0
Cough	1 (5.3)	0	61 (24.5)	1 (0.4)
Rash	3 (15.8)	0	23 (9.2)	0
Troponin T increase	1 (5.3)	0	NR	NR
Upper respiratory tract Infection	2 (10.5)	0	25 (10)	1 (0.4)
Urinary Tract Infection	1 (5.3)	1 (5.3)	22 (8.8)	1 (0.4)
Arthralgia	1 (5.3)	0	NR	NR

- No Dose related increase in frequency or severity of AVA6000 TEAEs with increasing dose (80, 120, 160 & 200mg/m<sup>2</sup>)
- AVA6000 Tumour Type heavily pre-treated metastatic CRC (11), Pancreatic (5), STS (1), Ovarian (1) & Oesophageal (1)
- Doxorubicin Tumour Type: first line metastatic soft tissue sarcoma

Common Terminology Criteria for Adverse Events was used to categorize TEAEs. Grades; mild (grade 1), moderate (grade 2), severe or medically significant but not immediately life-threatening (grade 3), life-threatening (grade 4), and death related to TEAE (grade 5).

TEAE: Treatment-Emergent Adverse Events are undesirable events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment. TEAEs may therefore be treatment-related or unrelated as assessed by the treating physician.

## References

<sup>1</sup>Ongoing Phase 1 Dose Escalation Study in metastatic solid tumours (ALS-6000-101: ClinicalTrials.gov Identifier: NCT04969835)

<sup>2</sup>Tap WD, Wagner AJ, Schöffski P, et al. Effect of Doxorubicin Plus Olaratumab vs Doxorubicin Plus Placebo on Survival in Patients With Advanced Soft Tissue Sarcomas: The ANNOUNCE Randomized Clinical Trial. JAMA. 2020;323(13):1266-1276. doi:10.1001/jama.2020.1707

# Tumour Biopsy Data

## Plasma vs Biopsy Doxorubicin Concentrations

Cohort	AVA6000 (Dox Dose) mg/m <sup>2</sup>	Patient	DOX Plasma @24h ng/ml	DOX Biopsy @24h		DOX Ratio** Biopsy:Plasma	Biopsy Source
				ng/g	nM		
Cohort 1	80 (54)	101-006 (1 <sup>st</sup> )	4.9	135	248nM	28:1	Liver
		101-006 (2 <sup>nd</sup> )	4.9	43	79nM	9:1	Liver
Cohort 3	160 (108)	103-021*	4.4	376	690nM	85:1	Liver
		103-022*	2.4	270	496nM	113:1	Liver
		102-023*	7.5	875	1607nM	117:1	Liver
Cohort 4	200 (135)	103-017	15.9	553	1015nM	35:1	Liver
		103-018	10.5	1317	219nM	125:1	Lung

\*Preliminary Data  
\*\* ng/ml ~ ng/g

Doxorubicin Target Activity	DOX IC50
DNA adduct formation <sup>1</sup>	25nM
Free radical formation/cardiomyocyte apoptosis <sup>1</sup>	100nM
Topoisomerase Inhibition <sup>1</sup>	400nM
In vitro cytotoxicity <sup>2</sup>	30nM-3µM

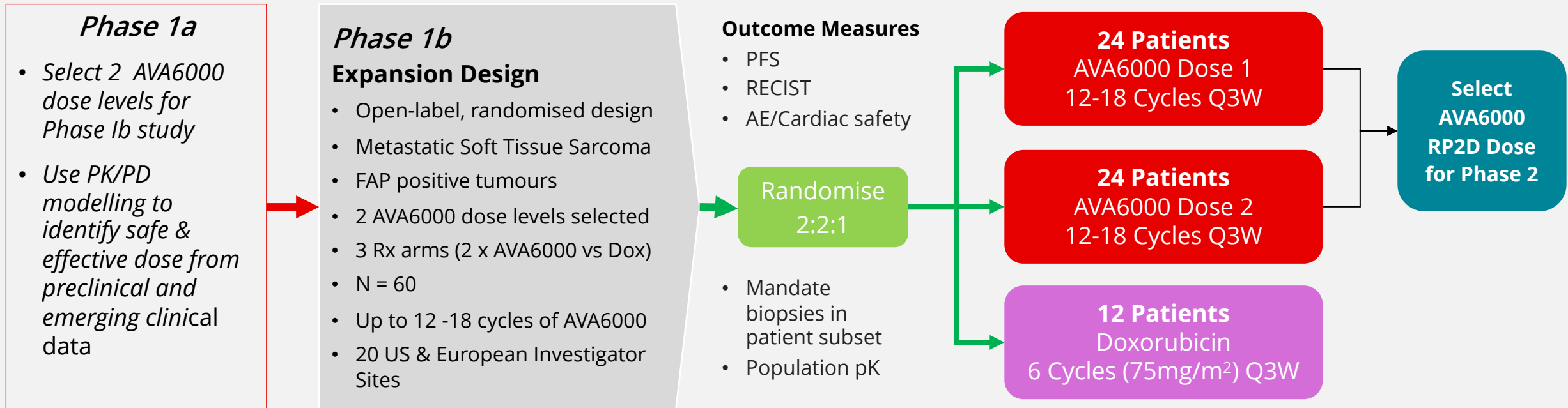
<sup>1</sup> doi:10.1007/s11095-018-2456-8  
<sup>2</sup> internal data

# AVA6000: Phase Ib Study

## Clinical Development in Soft-Tissue Sarcoma (Phase 1 to 2)

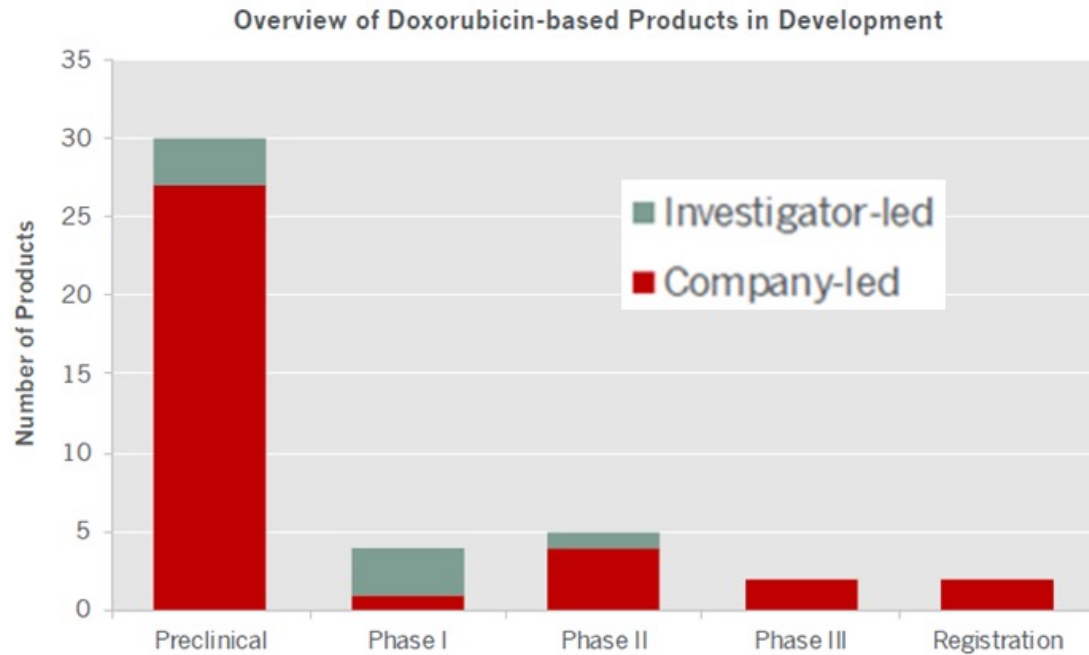
### Development Rationale in Soft Tissue Sarcoma (STS)

- Advanced, Metastatic STS tumours
- Doxorubicin is the only therapy indicated for first-line monotherapy in advanced STS
- No current or near future competition for doxorubicin in 1<sup>st</sup> line STS
- Conventional doxorubicin has marginal efficacy (18% ORR; 6mth PFS) & Rx limitation due to cumulative dose limit (450mg/m<sup>2</sup> – 6 cycles maximum)
- AVA6000 has potential to safely increase Rx duration beyond 6 cycles (18 weeks) by x2-3 times (12-18 cycles – 36-54 weeks) with increased efficacy



# Soft Tissue Sarcoma Drugs in Development

- Modest number of products in clinical development for STS with majority of R&D activity in early stage
- KOLs indicate no serious competition in Soft Tissue Sarcoma indication for 1<sup>st</sup> Line Therapy



# Market Potential for AVA6000

- There is huge potential for an improved next generation doxorubicin product considering:
- The market value being generated by current doxorubicin therapies and the expectation that doxorubicin-based therapies will continue to be a key approach for oncology treatment
- There is considerable scope for improvement on the profile of conventional and liposomal doxorubicin, around both safety / tolerability and efficacy
- There is modest future competitor activity exploring new doxorubicin approaches and few products identified to be in direct competition to AVA6000's approach

## Indications approved for unencapsulated / liposomal doxorubicin

- Soft tissue sarcoma – Advanced 1L setting
- Breast cancer – Neoadjuvant / adjuvant and metastatic setting
- Ovarian cancer – Advanced recurrent setting (2L)

- Hodgkin lymphoma
- Non-Hodgkin lymphoma

- Acute myeloblastic leukaemia
- Bladder cancer
- Endometrial cancer
- Gastric cancer
- Lung carcinoma
- Multiple myeloma
- Thyroid cancer
- Acute lymphoblastic leukaemia
- AIDS-related Kaposi sarcoma
- Ewing's sarcoma
- Osteosarcoma
- Neuroblastoma
- Wilm's tumour

Potentially attractive opportunities as initial target indications

Other potential indications

Apparent limited role of doxorubicin / niche target indications

# AVA6000 Conclusions

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- **Dose Escalation**
- AVA6000 has a modest and predictable safety profile across the dose range (80-200mg/m<sup>2</sup>)
- PK data for released doxorubicin highlights a positive profile
  - Doxorubicin Exposure (AUC) & Maximal Concentrations (C<sub>max</sub>) substantially reduced across doses
  - Doxorubicin concentrations are higher in tumour biopsies compared to plasma at 24 hrs timepoint
  - Emerging PK profiles offer the opportunity to increase dosing duration & intensity of doxorubicin targeted to the tumour
- **Confidence in Development Strategy for AVA6000 in 1st Line Soft Tissue Sarcoma (STS)**
- Advanced, Metastatic STS tumours are known to be highly FAP positive
- Doxorubicin monotherapy is the only therapy indicated for first-line advanced, metastatic STS
- Large unmet clinical need in STS to improve patients outcomes in difficult to treat tumours
- AVA6000 preferentially targets the tumour environment using FAP specificity to activate doxorubicin
- AVA6000 can safely deliver larger doses of doxorubicin to tumour whilst sparing healthy tissues and organs.

# Investigators

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## United Kingdom

### **Professor Chris Twelves, Chief Investigator**

Leeds Teaching Hospitals NHS Trust, Leeds

### **Professor Udai Banerji**

The Royal Marsden NHS Foundation Trust, London

### **Professor Jeff Evans**

The Beatson West of Scotland Cancer Centre, Glasgow

### **Dr Natalie Cook**

The Christie NHS Foundation Trust, Manchester

### **Professor Ruth Plummer**

The Freeman Hospital, Newcastle Hospitals NHS Foundation Trust,  
Newcastle upon Tyne

### **Dr Robin Young**

Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield

## United States

### **Dr William D. Tap**

Memorial Sloan Kettering Cancer Centre, New York

### **Dr Lee D. Cranmer**

Fred Hutchinson Cancer Centre, Seattle



Avacta Diagnostics

*M&A-led Growth Strategy in the European Diagnostics Sector*

Annual General Meeting of Shareholders

28<sup>th</sup> June 2023

The Royal Society of Medicine, 1 Wimpole Street, London



# Avacta Diagnostics: M&A Led Growth Strategy

## VISION

Build a full spectrum, differentiated European in-vitro diagnostics (IVD) business supporting healthcare professionals and broadening access to diagnostics.

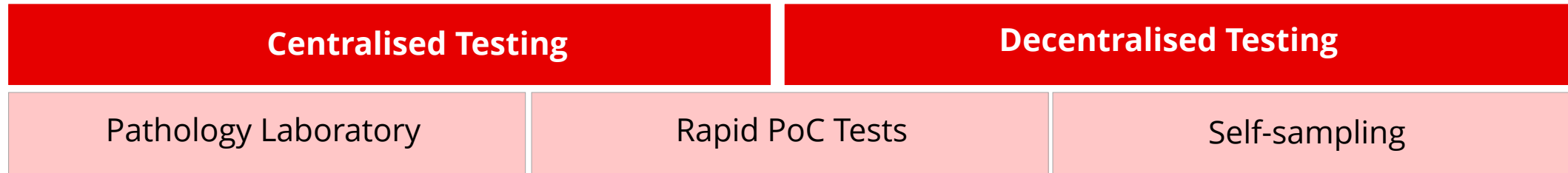


## MISSION

Innovate to make market leading diagnostic solutions available to all, to inform treatment and monitor health and fitness.

# A Full Spectrum IVD Business

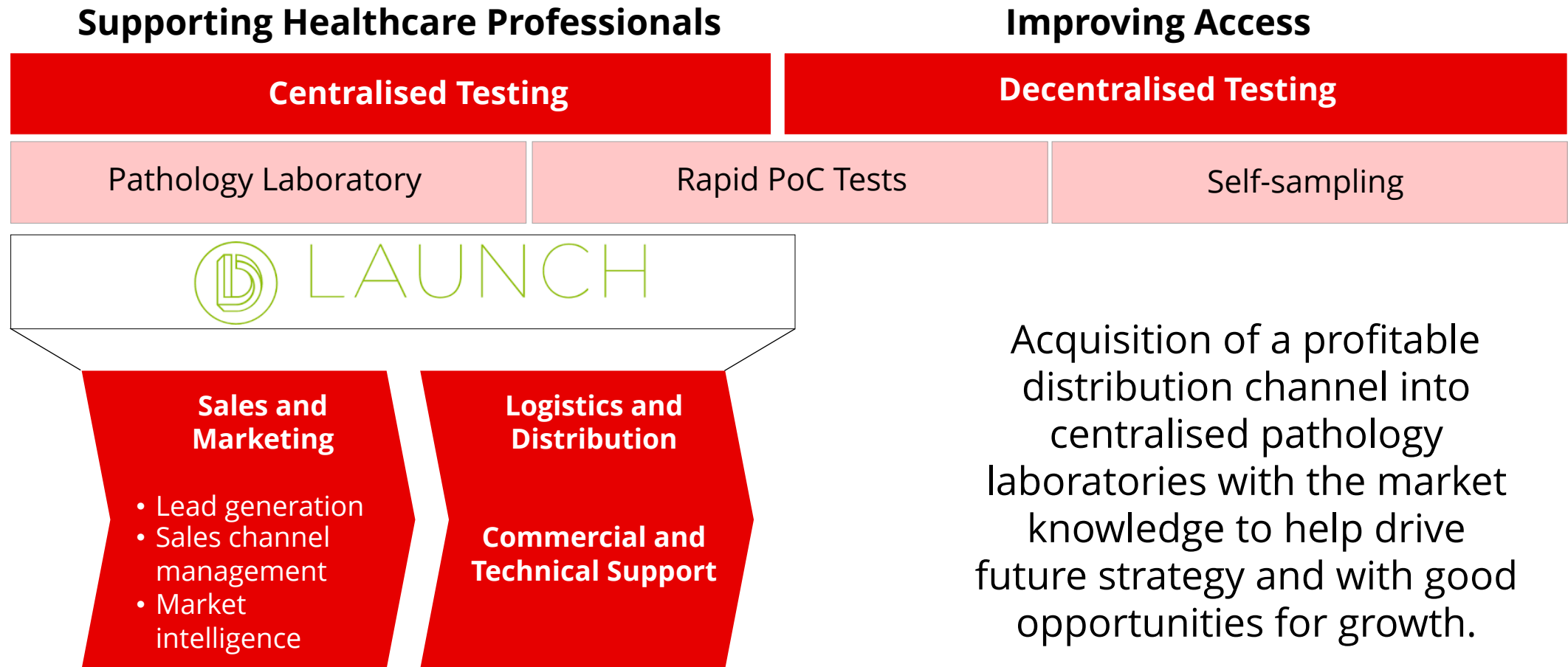
Supporting healthcare professionals ..... and broadening access to diagnostics



## Diagnostics Value Chain



# Rationale for Acquisition of Launch Diagnostics



# Launch Diagnostics

## Key Facts

- Founded in 1990 and headquartered in UK.
- Launch provides immunodiagnostic and molecular test products, technical support and maintenance to healthcare providers in the UK, France, Belgium and Luxemburg and ROI.
- Customers include both public and private sector (e.g. hospitals, clinical trial units, cancer centres, commercial laboratories).
- Long-established and experienced team with an outstanding reputation in the industry for customer service.
- Sales delivered through tenders, contracts such as long term and exclusive Managed Equipment Services with global manufacturers, and annual quotations.

## Launch by Numbers

- FY21 **£14.17M** core, non-COVID related business.
  - Total FY21 revenue **£32.75M**.
  - **£23.85M** UK and **£8.90M** France/Benelux.
  - Gross margin on sales FY19-21 **44-50%**.
  - **£8.52M** adjusted\* EBITDA FY21.
- FY22 **£16.5M** non-COVID revenue.
- Over **4,000** products from **31** suppliers.
- **501** active customers (UK **356**, France/Belux/ROI **145**).
- Typically on **3-5 year** contracts and **c.95%** repeat business.
- **c.70 FTEs** (60% commercial, 40% technical).
- **17,295 ft<sup>2</sup>** offices and warehouse facilities in UK.
- **230 m<sup>2</sup>** logistics facilities in Houille, Northern France.

\* Adjusted to a market rate Managing Director salary and removal of non-recurring professional fees.

# Launch Diagnostics: Growth Opportunities

Opportunities for growth in sales and margin through geographical expansion, cross-selling to customers gained during the pandemic and expansion of product range

## Investment in Sales and Marketing

- Investment in sales and marketing team.
- Cross-selling of non-COVID products into the recently expanded installed base of PCR equipment post-COVID.

Short Term

## Portfolio Expansion

- Expansion of centralised and decentralized testing product portfolio.
- e.g. New automated system for autoimmune and allergy testing (HOB).

Medium Term

## Geographical Expansion

- Investment to expand commercial, logistics and support teams to expand into German market over a 3 year period.
- New logistics site already established in northern France.

Long Term

# Spotlight on HOB Autoimmune and Allergy Testing

**The HOB BioCLIAs are used to detect autoimmune disease and allergy in patients' blood samples**

## Target Market

Hospitals with routine immunology laboratories. From small hospitals (utilizing the BioCLIA500) to large teaching hospitals (utilising the BioCLIA6500).



## Indications

The BioCLIAs test for autoantibodies, present in the patient's blood (serum), associated with diseases such as: Coeliac disease, antiphospholipid syndrome, SLE, rheumatoid arthritis and other connective tissue diseases, autoimmune liver diseases, vasculitic diseases, pernicious anaemia.

In addition, the system also tests for a range of antibodies against environmental allergens (tree/grass pollens, mites, epidermal – cat/dog) and food allergens (eg egg, fish, wheat, peanut) from a patient's blood sample.

## Business Model

Reagent rental contract where the cost of the instrument is spread across the price of the reagents and consumables over a 3, 5 or 7 year period.

Contracts can be direct with Launch Diagnostics or part of a Managed Service Contract where Launch acts as a third party to a primary contractor such as Roche, Abbott or Siemens.

## Key Benefits

- Faster throughput and more extensive product offering than competitor analysers.
- Autoimmune and allergy testing on the same analyser and at the same time.
- New markers with little competition.



# Rationale for Acquisition of Coris BioConcept

## Supporting Healthcare Professionals

## Improving Access

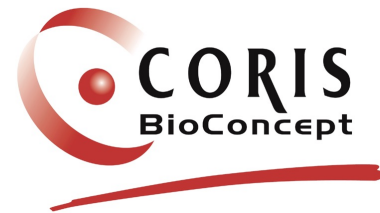
### Centralised Testing

### Decentralised Testing

Pathology Laboratory

Rapid PoC Tests

Self-sampling



### Research

- Affimer® reagents
- Sampling devices
- Software/apps
- IP

### Product Development

- Market led
- Lateral flow tests
- IP

### Manufacturing

- High volume
- High quality
- Competitive costs



# Coris BioConcept

## Key Facts

- Based in Gembloux, Belgium and established in 1996, Coris BioConcept develops, manufactures and markets rapid diagnostic test kits, mainly lateral flow tests, for professional use.
- The product portfolio comprises diagnostic tests for respiratory, gastro-enteric and blood-borne pathogens (bacteria, viruses and parasites) and for the detection of antibiotic resistance markers (RESIST range).
- Coris BioConcept was at the forefront to tackle COVID-19 by developing a rapid ICT assay for SARS-CoV-2 antigen detection.
- Coris BioConcept also provides services for custom test development and contract manufacturing.
- Coris BioConcept is ISO 13485 certified and markets its product through distributors in Europe, Asia, South America, Africa and Oceania.

## Coris by Numbers

- FY22 **£4.6M** total revenues (mostly non-COVID related)
- Gross margin on sales FY21-22 circa **50%**.
- **£0.35M** EBITDA FY22.
- Revenues split: **80%** Europe, **12%** America, **8%** MEA/APAC
- c.**35 FTEs** across Production, Sales & Marketing, Quality/Regulatory and Administration.
- **10,700 ft<sup>2</sup>** new production, offices and warehouse facility in Gembloux completed in March 2023.



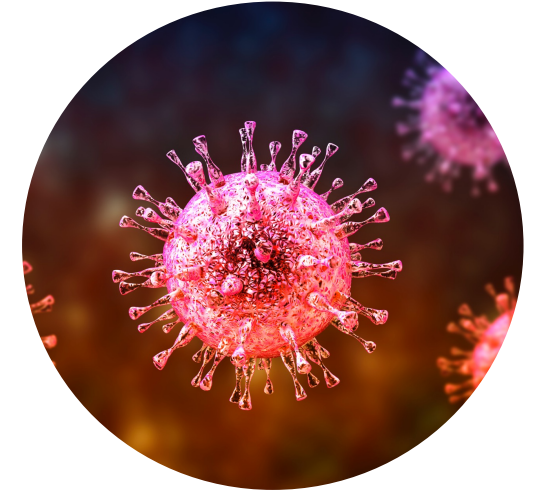
# Coris BioConcept Lateral Flow Test Product Range

## Anti-microbial Resistance

- OXA
- NDM
- KPC
- VIM
- IMP
- Carbapenemases
- CTXM
- Combinations of above

## Infectious Diseases

- Giardia/crypto
- Rotavirus/adenovirus
- C.diff GDH
- H.pylori Antibody
- H.pylori Antigen
- Legionella
- Adenovirus antigen
- Flu A+B
- RSV
- SARS-CoV-2 Ag
- HAT



# Spotlight on Anti-microbial Resistance (AMR) Testing

**Antimicrobial Resistance (AMR) occurs when pathogens no longer respond to antimicrobial medicines making infections difficult to treat – testing for AMR is critical**

## A Global Challenge

- 1.27 million deaths attributable to bacterial AMR globally in 2019<sup>1</sup>.
- Key pathogens: Methicillin-resistant *S. aureus*, third-generation cephalosporin-resistant *E.coli*, carbapenem-resistant *A. baumannii*, fluoroquinolone-resistant *E.coli*, carbapenem-resistant *K.pneumoniae*, and third-generation cephalosporin-resistant *K.pneumoniae*.
- Since 1 October 2020 all diagnostic laboratories in England have a duty to notify the identification of carbapenemase-producing Gram-negative bacteria in human samples to the UKHSA<sup>2</sup>.
- Development of new rapid diagnostic tests to track antimicrobial resistance patterns is considered as one of the priority core actions by international experts and health authorities.

1. Murray *et al. Lancet* 2022; 399:629-55

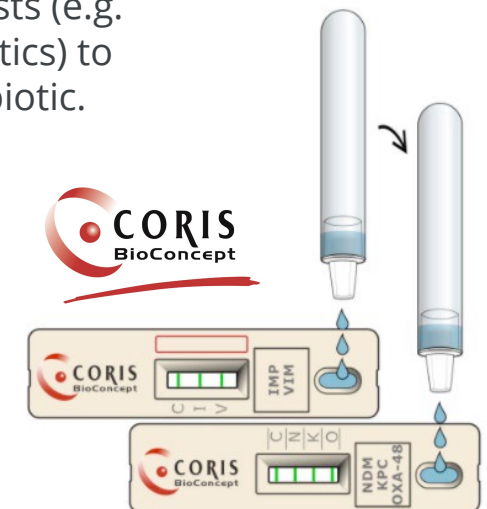
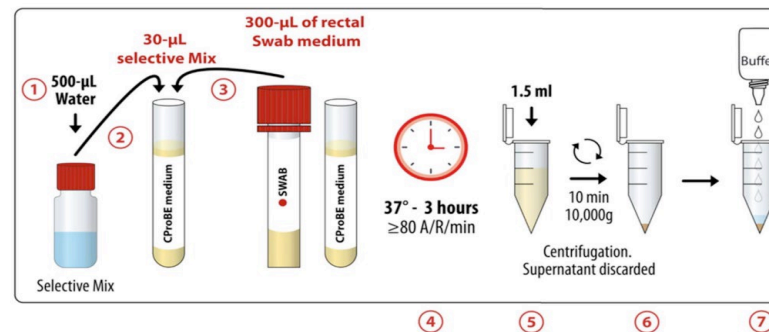
2. UKHSA, Commercial assays for the detection of acquired carbapenemases, 2022

## Coris AMR Products

Coris Lateral Flow Tests (LFTs) allow rapid detection of the proteins responsible for AMR (e.g. carbapenemases) directly from stool samples, bacterial colonies or blood cultures.

Near-patient rapid testing is carried out after sample preparation to identify if samples contain bacteria expressing one, or more of the resistance conferring carbapenemases (OXA-48, KPC, NDM, VIM or IMP).

Follow-up testing of the infectious organism is performed using anti-microbial susceptibility tests (e.g. Liofilchem MIC Test Strips from Launch Diagnostics) to allow correct selection of a clinically useful antibiotic.



# Coris BioConcept: Growth Opportunities

Opportunities for growth through improved distribution network and broadened product portfolio

## Distribution Network

- Improvement in the quality and management of the distributor network in Europe.
- Synergy with Launch Diagnostics as a distribution partner in UK, France and ROI.

Short Term

## Product Portfolio Expansion

- Market-led product development and product acquisition, to build a complete professional-use point-of-care rapid test portfolio.
- e.g.
  - Infectious diseases: STIs, Strep A
  - Gastro-enteric: C. difficile GDH/Tox AB combo
  - Respiratory: RSV/Flu AB/ SARS-CoV-2 combo
  - Cardiac, women's health, cancer

Medium/Long Term

# Differentiation in a Competitive POCT Market

## Affimer®

Avacta's proprietary technology with significant technical and commercial benefits to differentiate lateral flow tests and other immunodiagnostic products.



## Competitive Advantages

- High specificity and sensitivity.
  - Rapidly generated.
- No immune response required.
- Flexible formatting for different read-out mechanisms.
- Low cost, reliable manufacturing.
  - Freedom to operate around antibody IPR.

# Summary



Ideal conditions for M&A led growth strategy to consolidate European diagnostics SMEs in a market with strong future growth drivers.



Launch Diagnostics: UK/France IVD sales channel into the centralised professional healthcare market for own products, acquired products and third party products.



Coris Bioconcept: Complementary lateral flow test range in anti-microbial resistance, infectious diseases and gastrointestinal disorders for professional-use.



Our immediate focus now is on growing the acquired businesses and benefiting from synergies across the division.



October '22 fund raise provides balance sheet flexibility for the Group.



[www.avacta.com](http://www.avacta.com)