





# Interim Results

September 2025



**AIM: HVO** 

### Disclaimer



The contents of this presentation and the information which you are given at the time of the presentation have not been approved by an authorised person within the meaning of the Financial Services and Markets Act 2000 (the "Act"). Reliance on this presentation for the purpose of engaging in investment activity may expose an individual to a significant risk of losing all of the property or other assets invested. This presentation does not constitute or form part of any offer for sale or subscription or solicitation of any offer to buy or subscribe for any securities in hVIVO plc (the "Company") nor shall it form the basis of or be relied on in connection with any contract or commitment whatsoever. No reliance may be placed for any purpose whatsoever on the information contained in this presentation and/or opinions therein. This presentation is exempt from the general restriction (in section 21 of the Act) on the communication of invitations or inducements to engage in investment activity on the grounds that it is made to: (a) persons who have professional experience in matters relating to investments who fall within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (b) high net worth entities and other persons to whom it may otherwise lawfully be communicated (all such persons together being referred to as "relevant person"). Any person (whether a relevant person or otherwise) is recommended to seek their own independent financial advice from a person authorised for the purposes of the Act before engaging in any investment activity involving the Company's securities. Any recipient who is not a relevant person should return this presentation to the Company's registered office and should not act upon it. By accepting this presentation and not immediately returning it, each recipient warrants, represents, acknowledges and agrees that it is a relevant person.

This presentation does not constitute or form part of any offer or invitation or inducement to sell, issue, purchase or subscribe for (or any solicitation of any offer to purchase or subscribe for) the Company's securities in the UK, US or any other jurisdiction and its distribution does not form the basis of, and should not be relied on in connection with, any contract or investment decision in relation thereto nor does it constitute a recommendation regarding the Company's securities by the Company or its advisers and agents. Nothing in the presentation shall form the basis of any contract or commitment whatsoever. The distribution of this presentation outside the UK may be restricted by law and therefore persons outside the UK into whose possession this presentation comes should inform themselves about and observe any such restrictions as to the distribution of this presentation. The Company has not registered, and does not intend to register, any securities under the US Securities Act of 1933, as amended or to conduct a public offering of any securities in the US.

This presentation contains "forward-looking" statements, beliefs, estimates, forecasts and opinions, including statements with respect to the business, financial condition, results of operations and plans of the Company and its group ("Group"). These forward-looking statements involve known and unknown risks and uncertainties, many of which are beyond the Company's control and all of which are based on the current beliefs and expectations of the directors about future events. Recipients should note that past performance is not necessarily an indication of future performance and no assurance can be given that they will be attained. Forward-looking statements are sometimes identified by the use of forward-looking terminology such as "believes", "expects", "may", "will", "could", "shall", "risk", "intends", "estimates", "plans", "predicts", "continues", "assumes", "positioned" or "anticipates" or the negative thereof, other variations thereon or comparable terminology or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward-looking statements may and often do differ materially from actual results.

The significant risks related to the Company's business which could cause the Company's actual results and developments to differ materially from those forward-looking statements are discussed in the Company's Annual Report and other filings. They appear in a number of places throughout this presentation and include statements regarding the intentions, beliefs or current expectations of the Company with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Group's business, concerning, amongst other things, the results of operations, financial condition, prospects, growth and strategies of the Group and the industry in which it operates. No one will publicly update or revise any forward-looking statements or any other information contained herein, either as a result of new information, future events or otherwise.

In considering the performance information contained herein, recipients should bear in mind that past performance is not necessarily indicative of future results, and there can be no assurance unrealised return projections will be met. Certain of the past performance information presented herein may not be representative of all transactions of a given type. Actual events could differ materially from those projected herein and depend on a number of factors, including the success of the Group's development strategies, the successful and timely completion of clinical studies, securing satisfactory licensing agreements for products, the ability of the Group to obtain additional financing for its operations and the market conditions affecting the availability and terms of such finances.

The Company reports under IFRS. Where foreign currency equivalents have been provided for convenience in this presentation, the exchange rates applied are those used in the relevant financial statements from which the figures have been extracted. This presentation is confidential and is being supplied to each recipient of it solely for its information. While this presentation has been prepared in good faith, no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by the Company or by its officers, employees or agents in relation to the adequacy, accuracy, completeness or reasonableness of this presentation, or of any other information (whether written or oral), notice or document supplied or otherwise made available to any recipient. This presentation has been prepared to assist a recipient make its own evaluations and does not purport to be all-inclusive or contain all of the information a recipient may desire.

# Full-Service Early Phase European CRO & World Leader in Human Challenge Trials



Cryostore

#### **Mission**

Delivering today's healthcare by empowering tomorrow's innovation.

#### Vision

To transform global healthcare by revolutionising the drug development process through scientific ingenuity.

100+

**Years Service** 

5

Clinical Sites

1.9k+

**Trials Completed** 

6

Key Areas of Expertise

10k+

**Trial Participants** 

7

Top 10 Global Pharma Clients



Venn Life Sciences

# A Full-Service Early Phase CRO



#### Service Lines

#### **HCT**

- hVIVO challenge services
- hVIVO laboratory
- Venn Life Sciences medical writing & biometry

#### Clinical Services

- CRS Phase I/II CRO services
- hVIVO & CRS clinical site
- FluCamp recruitment
- Venn Life Sciences medical writing & biometry

#### hLAB

- hVIVO standalone laboratory services
- Cryostore biobank & storage services

#### Consultancy

 Standalone Venn Life Sciences consulting services

#### **Key Areas of Expertise**











Renal/Hepatic Impairment



#### Supporting Clients Across the Drug Development Pathway

CMC Consulting

Preclinical Consulting

Phase I-II **CRO Services** 

Human **Challenge Trials**  Phase II & III **Site Services** 

Marketing Authorisation

Specialist virology & immunology laboratory services

**Consulting services** 

**Biobank & storage services** 

Participant recruitment

### H1 25 Interim Results



#### **Key Financial Highlights**

£24.2m

Revenue

H1 24: £35.6m

12.5%

**EBITDA Margin** 

H1 24: 24.5%

0.29p

**Adjusted Basic EPS** 

H1 24: 0.81p

£3.0m

**EBITDA** (pre-exceptionals)

H1 24: £8.7m

£23.3m

Cash

H1 24: £37.1m

£40m

Orderbook

H1 24: £71m

#### **Future Financial Guidance**

£47m

**FY25 Revenue Forecast** 

Low-Single Digit

**FY25 EBITDA Margin Forecast** 

**Returning to Growth in 2026** 

#### **Operational Highlights**

- Synergistic acquisitions of two Clinical Research Units from CRS, and Cryostore
- Integration near completion & sales synergies being realised
- £5.5m CRS contracts signed, majority expected to be recognised 2025
- Strong progress with Clinical Services & hLAB services completed delivery of 817 participant Phase II influenza trial
- £3.2m hLAB contract for multi-site Phase II field trial
- Letter of Intent for world's first pivotal Phase III HCT
- Bacterial lab fit-out ahead of future bacterial HCTs & hLAB contracts.

#### **Post-Period End Highlights**

- c.£2m & c.£5m new awards for Clinical Services & hLAB respectively
- Phase III clinical site study awarded
- World's only contemporary-strain hMPV human challenge model now available for HCT
- Appointment of Shaun Chilton as independent Non-Executive Chair





Stephen Pinkerton

**Chief Financial Officer** 

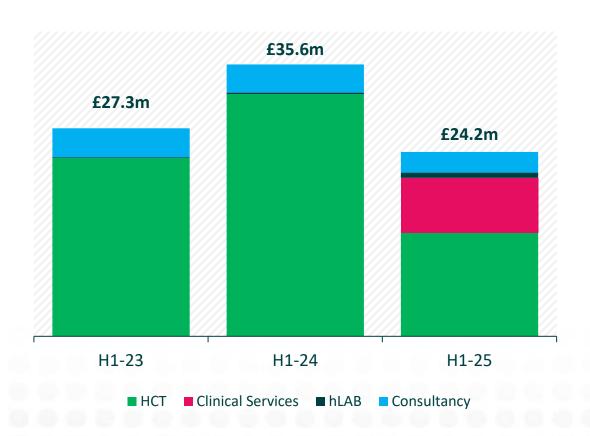


Macroeconomic & sector-specific headwinds impacted H1 25 Expect to return to growth in 2026 and beyond

### Revenue

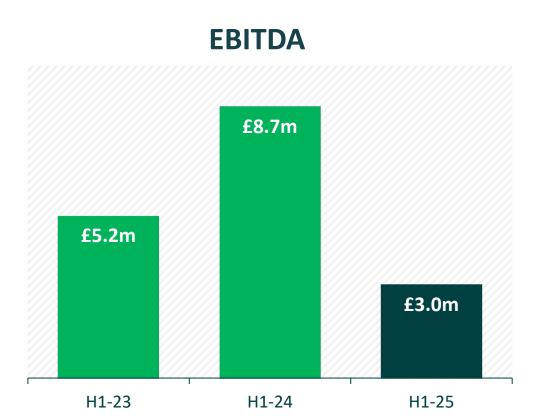


### **Revenue by Service**



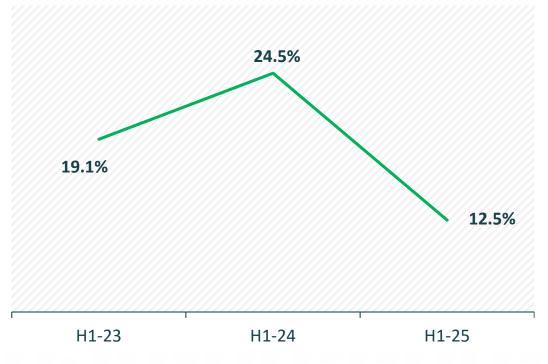
- Delivering on diversification strategy
- hLAB & Clinical Services, including acquisitions, accounted for £7.9m versus minimal revenues in H1 24
- Acquisitions delivered £5.5m:
  - CRS £5.2m & Cryostore £0.3m since acquisition date
- Broader therapeutic areas & customer base
- Cancellation fees higher than normal
- Consultancy & HCT services lower
- Revenue guidance of £47 million for FY25





- Excludes exceptional costs of £1.4m ie acquisition & restructuring
- Acquisitions contributed an expected EBITDA loss of £0.5m
- Benefitted from the positive impact of operational efficiencies, cost management & cancellation fees

### **EBITDA Margin**

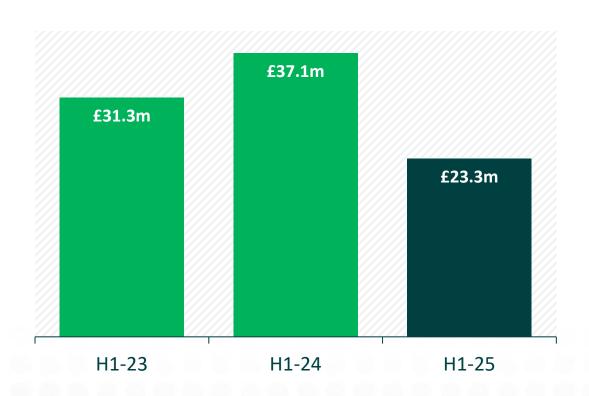


- Headcount 24% lower vs H1 24, flexibility of using temporary staff, efficiencies driven by consolidation of facilities
- Investments continue in automation to drive efficiencies
- FY25 EBITDA expected to be low-single digit loss

### Healthy Cash Balance - No Debt



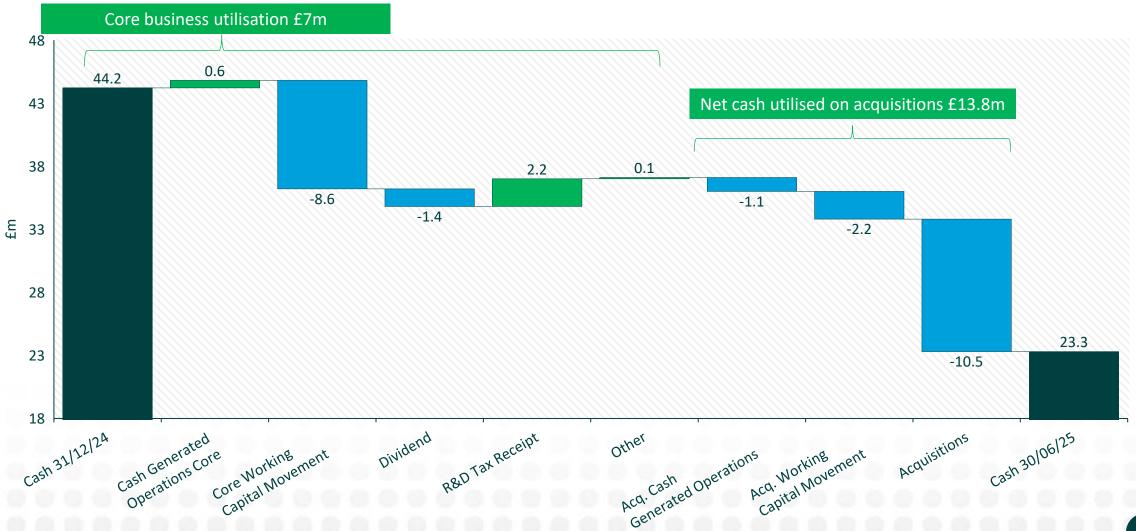
#### Cash



- Cash balance impacted by:
  - Acquisitions account for net £13.8m (operating loss & related working capital movement)
  - Reduction in deferred revenue/advance receipts due to cancellations & lower volume of HCT contracts signed
- Tight cost control while driving further diversification
- In the absence of material HCT contracts in 2025 expect cash balance to decline further through H2 25
- Sufficient cash to continue to invest & grow the business
- Expect to become cash generative again when HCT business returns to normal activity levels

# Cash Utilisation Analysis









Dr Yamin 'Mo' Khan

**Chief Executive Officer** 



A resilient and well-diversified organisation with strong fundamentals, diversified revenue streams, and a healthy sales pipeline

### Market Trends



- Changes at Health & Human Services (HHS)
- Changes in US regulatory bodies
- FDA timelines unpredictable
- Drug pricing reforms & tariffs
- Vaccine policy
- Depressed biotech funding
- Broader industry impacted
- Reduced childhood vaccine uptake

Market Dynamics

#### **Opportunities**

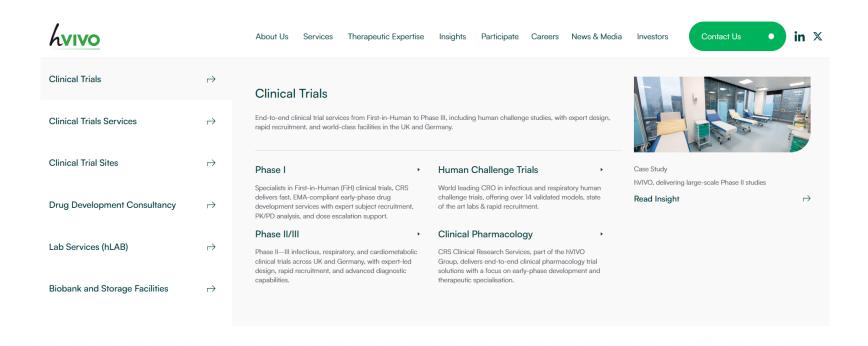
- UK Life Sciences Sector Plan
- Regulatory changes UK & Germany
- Oxford Vaccine Group five-year project
- Diversification in location of trials
- Diversification of services
- Broader therapeutic expertise larger markets
- Broader client base & cross-selling opportunities
- HCT reduced data review, faster, cheaper
- Antiviral R&D
- Vaccine R&D & uptake necessary public health risks

#### **Headwinds**

### Realisation of Synergies – Combined Service Offering

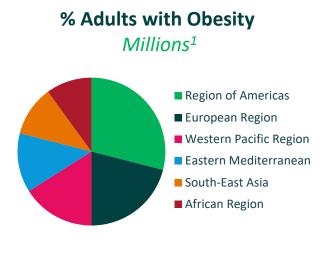


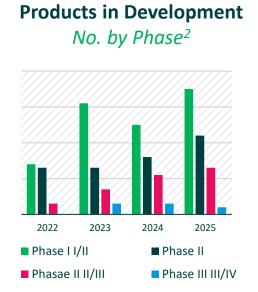
- Integration nearing completion
- Cost rationalization: >£1m annualised cost savings
- Cross-selling being realised
- £2.1m Venn opportunities in CRS sales pipeline
- Establishment of four key hVIVO service lines
- Cryostore earnings accretive
- CRS expected to become earnings accretive 2026

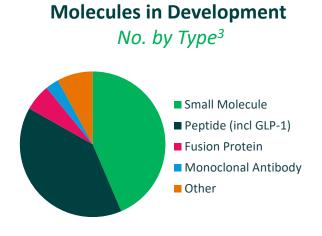


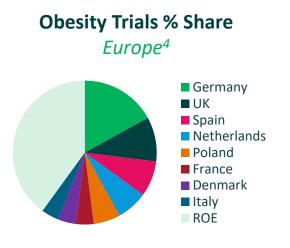
# CRS Acquisition Unlocks Evolving Obesity Market











#### **CRS – A Trusted Partner in Obesity Trials**



**Dr Thomas Forst Chief Medical Officer** 

Key Opinion Leader in Endocrinology

- \$64B by 2034<sup>5</sup> global obesity clinical trials market<sup>4</sup>
- 33 cardiometabolic trials completed by CRS since 2019
- c.60% CRS contract wins H1 25 cardiometabolic
- c.150k overweight/obese participants in FluCamp & CRS database

### hLAB – At a Glance



#### **Leading Virology & Immunology Laboratory Services**

580m<sup>2</sup>
Laboratories

Bacterial

Lab
operational

9x

Growth in proposals

#### **Bolstered by Cryostore Acquisition**

32
Sample storage
freezers

~260m<sup>2</sup>
Scope for future expansion

~9 years

Avg client tenure, recurring revenue

#### **Key Team Members**



**Chris Forsdyke Head of hLAB** 



Maria Menikou hLAB BD Director

#### **Business Progress**

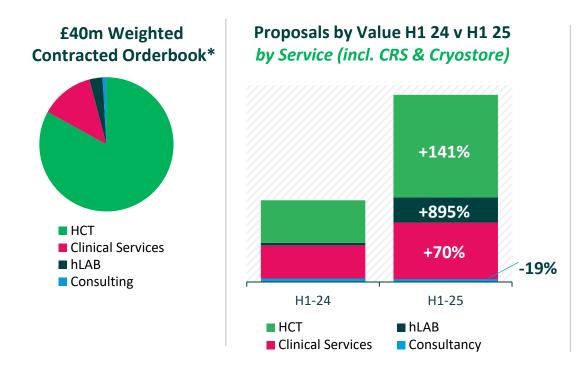
- Revenues grew strongly in H1 25
- Strong sales in H2 25: c.£5 million new awards
- 895% increase in proposals by value H1 24 vs H1 25
- Strong uptick in orderbook
  - o Phase IIb influenza trial signed in H1 25 (£3.2 million)

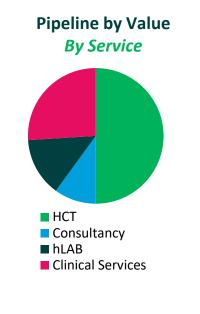
#### **Phase III hLAB Contract**

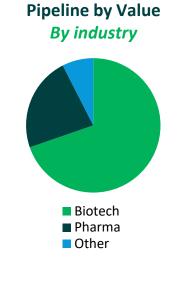
- Clinical Trial Kits & virology analysis for all subjects recruited in the international, multi-site trial
- Expected to commence Q4 25
- Majority of revenue expected to be recognised in 2026
- Expected to meaningfully support ongoing BD efforts

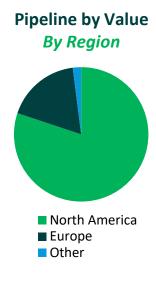
### Orderbook & Pipeline – 30 June 2025











- Highly diversified orderbook, does not include ILiAD HCT\*
- Total value of proposals in H1 25 exceeds FY24
- Good interest in new models hMPV & Flu B
- Some pipeline projects represent largest ever value HCTs

- Significant increase in hLAB interest
- Good growth in Clinical Services improved conversion rate of proposals to contracts for CRS vs 2024
- Cross-selling opportunities being realised

### Outlook



- Revenue guidance of £47 million for FY25
- Low-single digit EBITDA loss pre-exceptionals, improvement on previous guidance
- Increase in multi-service contracts
- CRS on track to become earnings accretive in 2026
- Diversification delivering results, expected to reduce volatility over time
- Expect high-single digit revenue growth in 2026 on the back of anticipated growth in newly diversified services & moving towards a normalisation of HCT activity

#### **Strong Fundamentals**

- · Unique early-phase clinical provider
- Trusted partner & experienced team

#### **Diversification of Revenues**

- New organic services delivering
- CRS & Cryostore integration on track

#### **Market Headwinds**

- US market volatility (esp. in vaccines) impacting HCT
- · Opportunities from headwinds

#### **Strong Sales Pipeline**

- Growing number of RFPs
- Large HCT opportunities in advanced discussions
- New disease indications in significant markets

Returning to growth in 2026 and beyond





### Experienced Board of Directors





Shaun Chilton
Independent NonExecutive Chair









Dr Yamin 'Mo' Khan CEO







**Stephen Pinkerton CFO** 



**Deloitte.** 

Euromoney Institutional Investor PLC



Elaine Sullivan
Senior Independent NED









Prof Brendan Buckley NED



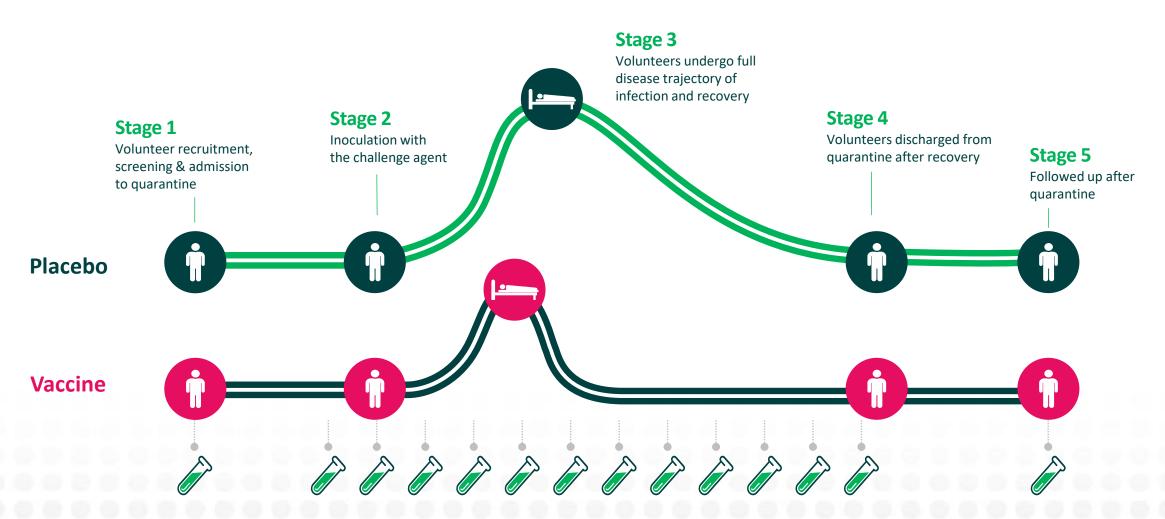




### What is a Human Challenge Trial?



A clinical trial where healthy volunteers are exposed to a pathogen to test the effectiveness of vaccine and treatments



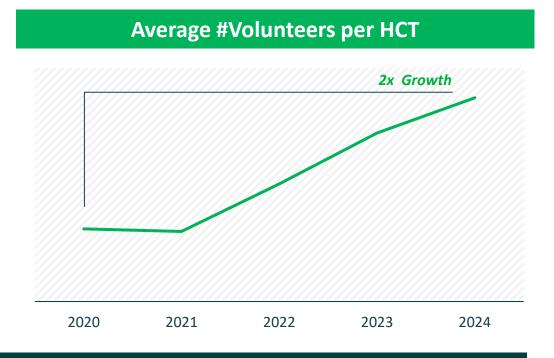
# Human Challenge Trials



#### **Benefits**

- Generates valuable dosing, safety and efficacy data
- Helps optimise & derisk larger field trials
- Requires fewer subjects, significant time savings
- No seasonal dependence

- Significant valuation uplift for biotech
- Quick, cost-effective data in a tight funding environment
- Potential for Fast Track / Breakthrough designation accelerating time to market
- Potential approval & Emergency Use Authorisation



# **Key Growth Drivers**



Larger trial sizes



13 characterised models



Bivalent / multivalent



Mucosal



**Antivirals** 



hMPV



CL-3 capability



**Bacterial laboratory** 



Transmission studies



Market awareness

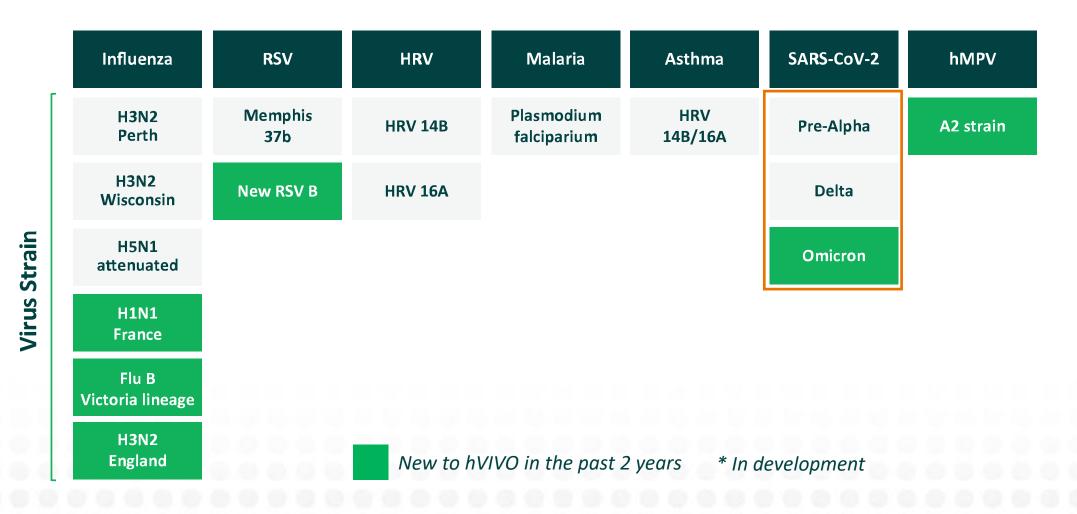


Phase III

# hVIVO's Expanding Challenge Agent Portfolio

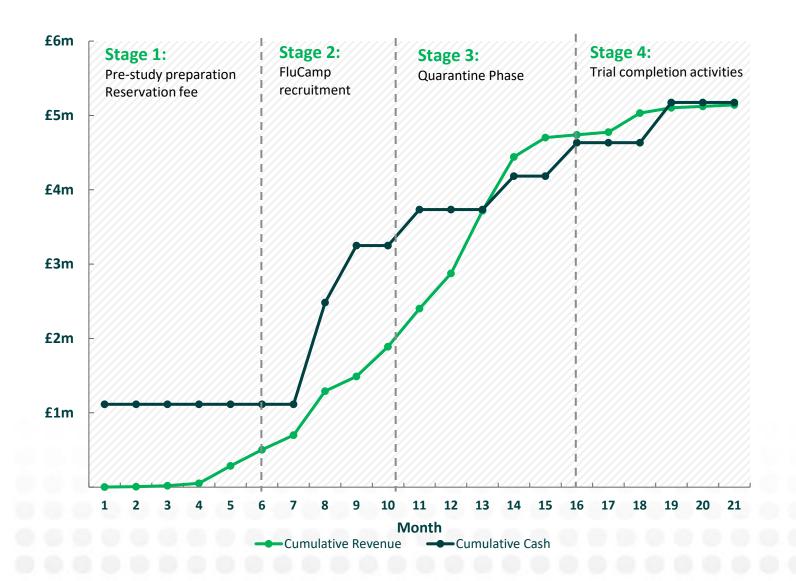


10 challenge agents manufactured in the past three years – investing in sustainable growth



# Challenge Trial Revenue Recognition Profile

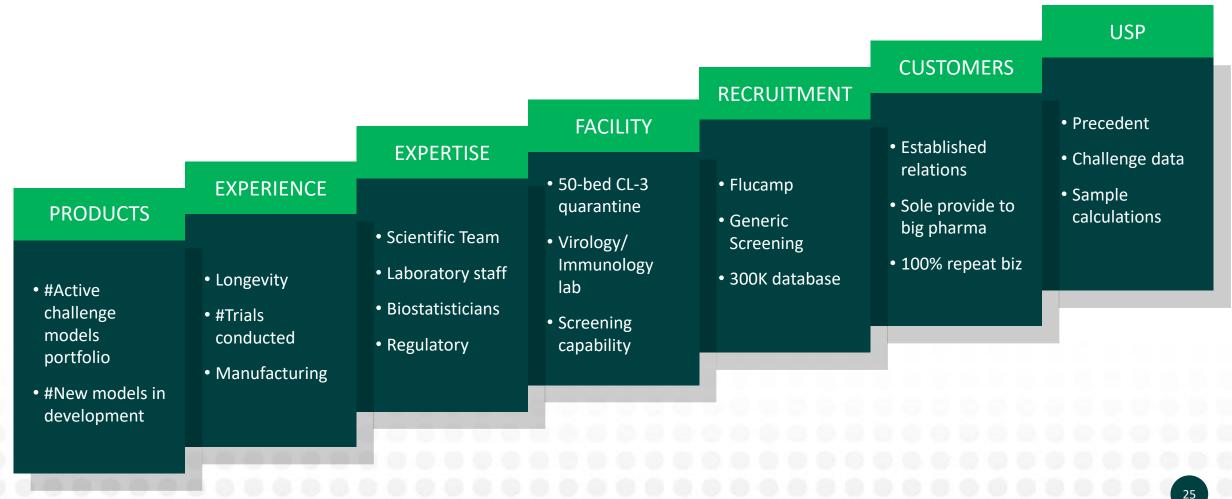




- hVIVO receives an upfront, nonrefundable booking of c.10-20% of total trial value to reserve quarantine space
- This mitigates against the risk of cancellation or client delay
- Majority of revenue recognition relates to the recruitment and quarantine phase of the trial

# HCT Services: Significant Barriers to Entry





# The World's Largest Human Challenge Unit





### Cryostore Acquisition - Strengthening hLAB Offering

A specialist provider of biological and clinical materials storage

GMP & GDP compliant

HTA license

Home officecontrolled drugs licence

GMO approved

CL-3 approved







Earnings enhancing, highly stable & recurring revenue stream

1999

Established

32

**Freezers** 

c.2,800 sqft

Scope for future expansion

37

Clients 2024

c.9 years

Avg client tenure

£0.9m

Revenue FY24

### Strategic Acquisition of CRS Mannheim & Kiel

#### Long-term track record as early-phase specialist

**Expanding hVIVO's Site Services** 

Phase I-II

SAD/MAD

Proof of Concept

BE/BA, QTc, DDI

**Expanding hVIVO's Therapeutic Expertise** 

Cardiometabolic

Dermatology

Renal / Hepatic Impairment

Immunology /
Inflammation

**Expanded European Footprint** 

94 Beds Mannheim

26 Beds Kiel

37,000 + Subject Pool

100+ Specialists & Experts

A full-service offering supported by Venn

**Cross-selling opportunities** 

**Multi-site capability** 

Strengthening hVIVO's Early Clinical Development Offering

45+

Years of experience

120

Beds (78 long-term)

+1,850

Trials completed

4

Top 10 global pharma clients

12

Clients 2024

**EUR19.9m** 

Revenue FY24

28

# CRS: Long History & Recognised Quality





1977

#### Prof. Dr. Lücker GmbH

Institut für klinische Pharmakologie Bobenheim



1992

#### **Pharm PlanNet**

Contract Research



2006

### CRS Clinical Research Services

Kiel, Mannheim, Mönchengladbach Member of LTS group Established as a merger of 3 Phase I CROs



2013

### **CRS Clinical Research Services**

Berlin, Wuppertal Strategic Partnership -Take over of BAYER RESEARCH



2017

### Management buy-out

Acquisition of LTS shares by APLEONEX



2025

Acquired by hVIVO



#### **FDA Inspected & Passed**

1991 | 1996 | 2002 | 2008 | 2009 2010 | 2011 | 2014 | 2024



#### **GCP Inspected & Passed**

2003 | 2018 (system audit by local & federal authorities)



#### **ANVISA Inspected & Passed**

- ▶ 200+ audits by clients since 2006
- 2012 | 2016









# CRS Experience (5 Years)



#### First-in-Human

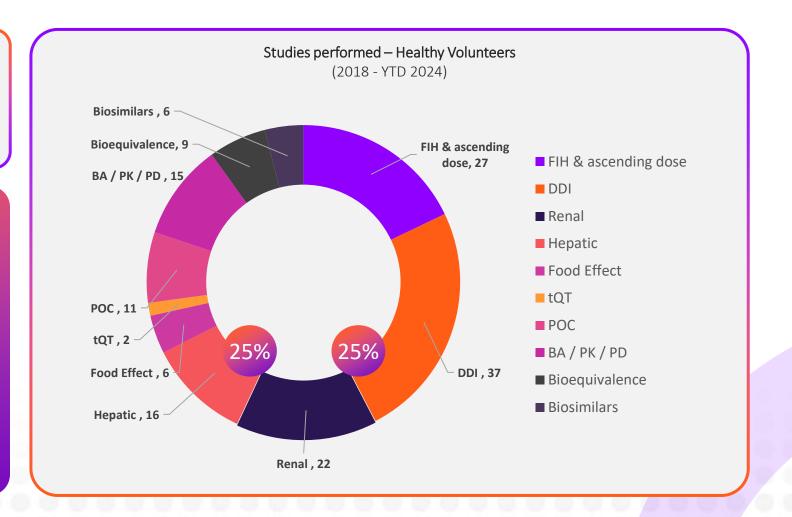
Top 5 CRO in Europe for FIH SAD/MAD, #1 in the DACH region.

# Clinical Pharmacology during Later Clinical Development

Largest European CRO for impairment studies with renal and hepatic patients and

strong reputation for subsequent DDI studies (6-10 studies per year)

other pharmacokinetic studies (FE, tQT, special populations)





# Venn Life Sciences Service Offering



Discovery/Lead **Drug Development** Lifecycle Management NDA, BLA, MAA **Optimization** Gap Analysis, Due diligence Quality (Chemistry, Manufacturing, and Controls) Variations/ Changes Quality development (CMC): process development, analytical development, product Quality: Process changes characterization, specification setting, stability studies, formulation, CDMO selection and improvements and management (Q)TPP, DDP **Nonclinical** Nonclinical development: proof of concept, ADME, toxicology, Toxicokinetics, safety pharmacology etc... Biomarker Safe Phase I Phase III **Post-Marketing Studies** Phase II starting dose Clinical development: clinical trial design, PK/PD, M&S, project management (Phase I), medical writing (clinical operations only for phase I) CTA, IND CTA, IND CTA, IND Marketing Authorization **Regulatory Affairs** Scientific Advice meetings CTD Pre-IND meeting, EOP1 meeting authoring

### Focus on ESG

- Sustainability is integral to our corporate ethos & operational framework
- ESG Group reports to the Audit & Risk Committee
- We play a pivotal role in expediting the development of vital medicines through our full-service offering







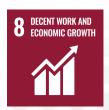






We strive to align with the 17 United Nations Sustainable Development Goals, prioritising specific goal that hold greater relevance to our business operations:











### **ESG Highlights**



ISO 14001 accreditation achieved at Canary Wharf site 2024



Expanded facilities & services support the development of a wider range of medicines



Energy & carbon reporting, waste reduction & Electronic document management



Strong focus on ethical and compliant business practices



Empowering staff to give back to the community through charitable donations & volunteering policies



Staff well-being and development – flexible working, training & development programme



Collaborative culture and ESG focus broadening to new subsidiaries

### hVIVO's State-of-the-Art Facilities



#### Canary Wharf Quarantine Unit



hLAB Virology & Immunology Laboratories













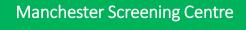












Biobank









