





# FY23 Financial Results

April 2024

**Ticker: HVO** 

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# Company Overview



- World Leader in Human Challenge Trials
- Onsite Virology Laboratories
- FluCamp: tech-enabled volunteer and patient recruitment platform



- Early Clinical Drug Development Services
- Biometric services



# Who we are

### Mission

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

### Vision

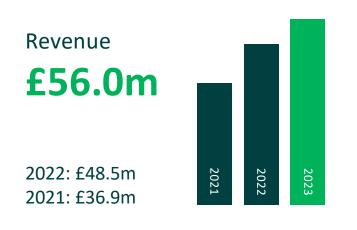
To transform global healthcare by revolutionising the drug development process through scientific ingenuity.

### Values

- ✓ Innovation & Agility
- ✓ Growth
- ✓ Integrity & Welfare
- ✓ One Team

# Building a Long-Term Sustainable Growth Model



















Stephen Pinkerton

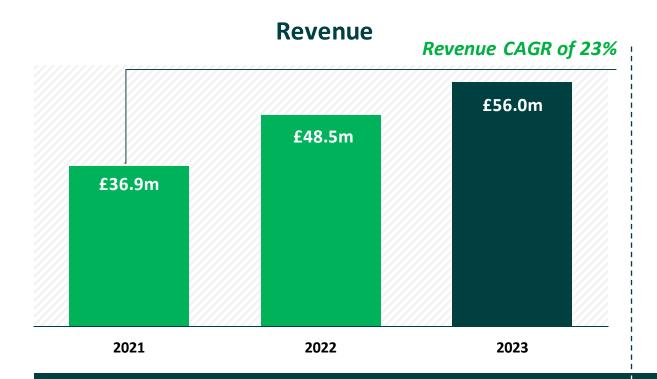
**Chief Financial Officer** 

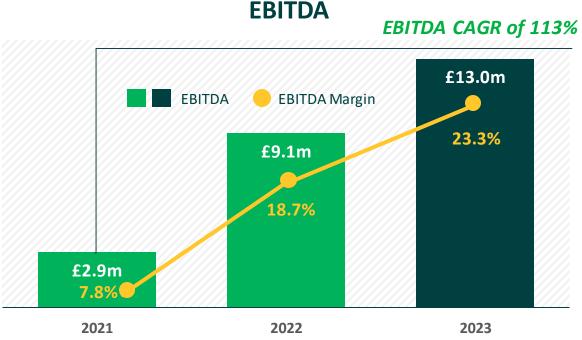


Financial performance review

### Another Record Year





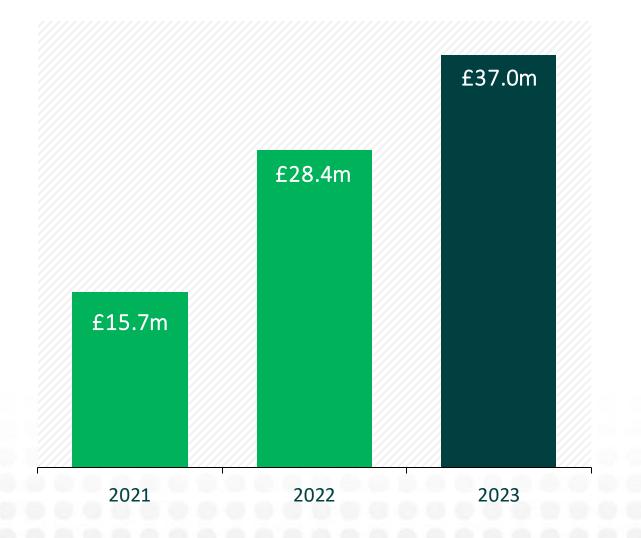


- Revenue increases 16% year-on-year
- Venn consulting revenue up >30%
- Multiple bespoke / full-service contract wins
- Larger studies and facility acceleration fees offset by impact of MHRA delays

- Strong performance from the operational delivery team
- Multiple studies run concurrently delivering recruitment efficiencies
- Greater volume leading to increased utilisation of staff and facilities

# Strong Cash Generation



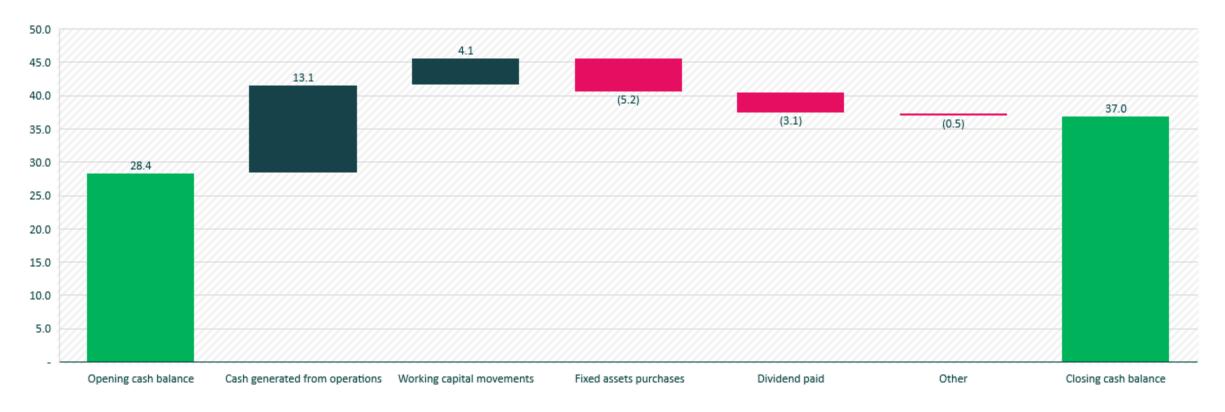


### Cash

- Strong cash position with £37.0m as at 31 Dec 2023
- Includes £3.1m dividend paid in 2023
- Debt free
- Advanced fees from orderbook growth & contract delivery milestones
- Facility fee receipts in advance of spend
- Increasing underlying operating margins

# A Sustainably Cash Generative Business

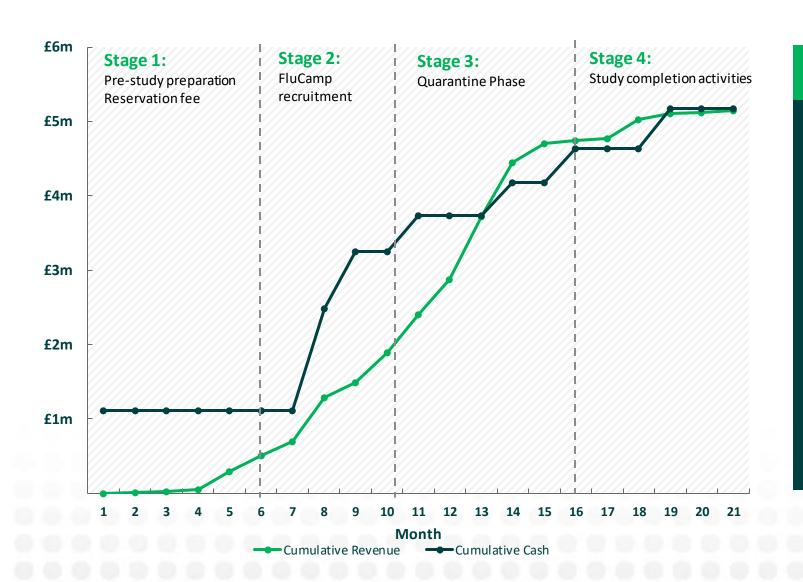




- Significant cash generated from operations up 46% vs 2022
- Growing business & advance fees resulting in positive working capital movement
- Fixed asset expenditure driven by new facilities and normal replacement of clinic / laboratory equipment

# Case Study - £6m Contract Revenue Recognition Profile





### Revenue Recognition

- Upfront, non-refundable booking of c.10-20% of total study value to reserve quarantine space
- Mitigating against the risk of cancellation or client delay
- Majority of revenue recognition relates to the recruitment and quarantine phase of the study

# Annual Dividend Policy





Reflecting sustainable cash generation in addition to our robust balance sheet

| c.£1.4 million   0.20 pence per Ordinary Share |                  |  |  |  |  |
|--|------------------|--|--|--|--|
| 9 April  | Final Results    |  |  |  |  |
| 18 April                                       | Ex-dividend date |  |  |  |  |
| 19 April                                       | Record date      |  |  |  |  |
| 20 May   | Payment date     |  |  |  |  |





# Dr. Yamin "Mo" Khan

**Chief Executive Officer** 



A year of record growth

# Utility of Human Challenge Trials

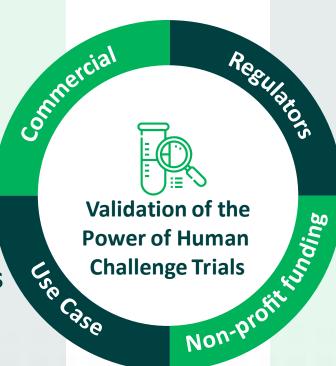


### **Commercial**

- Pfizer RSV vaccine approval
- ReViral acquired
- Cidara asset acquired
- Multiple positive readouts

### **Optimising Late-Stage Studies**

- Define endpoints for Phase III
- Define dosing regimen
- Bespoke models



### Regulators

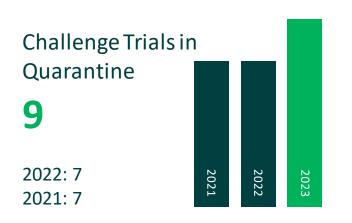
- FDA Fast Track Designation
- FDA Breakthrough Designation
- Strong support from UK regulators

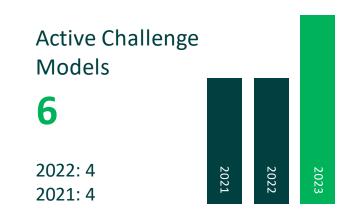
### **Non-Profit Funding**

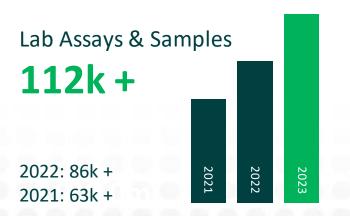
- CEPI
- Wellcome Trust
- Bill & Melinda Gates Foundation

# Building a Long-Term Sustainable Growth Model











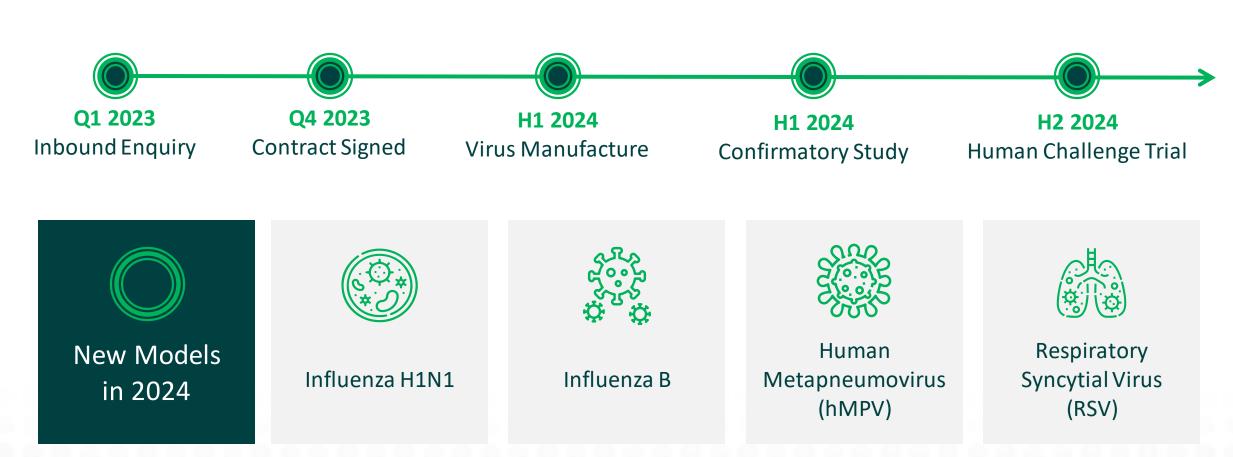
### 2023 Operational Highlights

- New and repeat customers contracted
- Record inoculations
- 4 new models under development
- Multiple Master Services Agreements
- Leiden Office opened
- Construction started at Canary Wharf
- New cybersecurity system software
- Successful MHRA inspection
- Mitigation of MHRA delays
- ESG Group formalised

# Case Study: End-to-End Human Challenge Service



Repeat Big Pharma client goal: generate rapid data

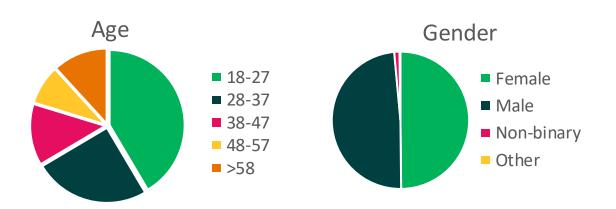


Further diversifying hVIVO's leading portfolio of human challenge models

# FluCamp – A Leading Recruitment Platform



#### **FluCamp Volunteer Profile**



97% Volunteers who complete a trial would recommend FluCamp to others<sup>1</sup>

Volunteers rate enrolment process as **GOOD to EXCELLENT**<sup>1</sup>



Average **Trust Pilot** rating. More 5-star reviews than competitor clinical trials companies

#### **Lead Generation**



>50%

more **UNIQUE** website visits 2023 versus our nearest CRO competitor<sup>2</sup>

>17k

Volunteers screened in 2023



PROFESSIONAL UK based engagement centre supporting enrolment and onboarding activities

# Venn – Growing with our Clients



part of hVIVO

### Seamless drug development support service ("Bench-to-Bed")



>30% revenue growth driven by Venn's early clinical services

24%

Increase in Venn employees year-on-year

**75%** 

**Repeat Business** 

100%

Customers surveyed would work with Venn again



Investment in key growth areas - ATMP & Drug Device Consulting



Cross-selling clients to hVIVO services

#### **New office at Leiden Bio Science Park**

Driving collaboration & interaction with potential customers from the largest life science community in Benelux























Building momentum into 2024

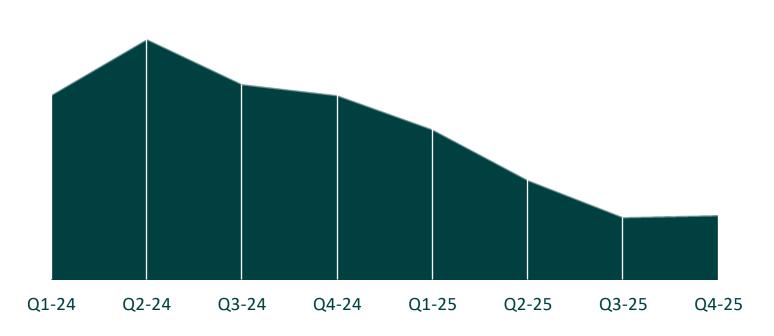
### Record Contracted Orderbook



### **Net Contracted Orderbook**



### **Gross Orderbook Providing Record Visibility**

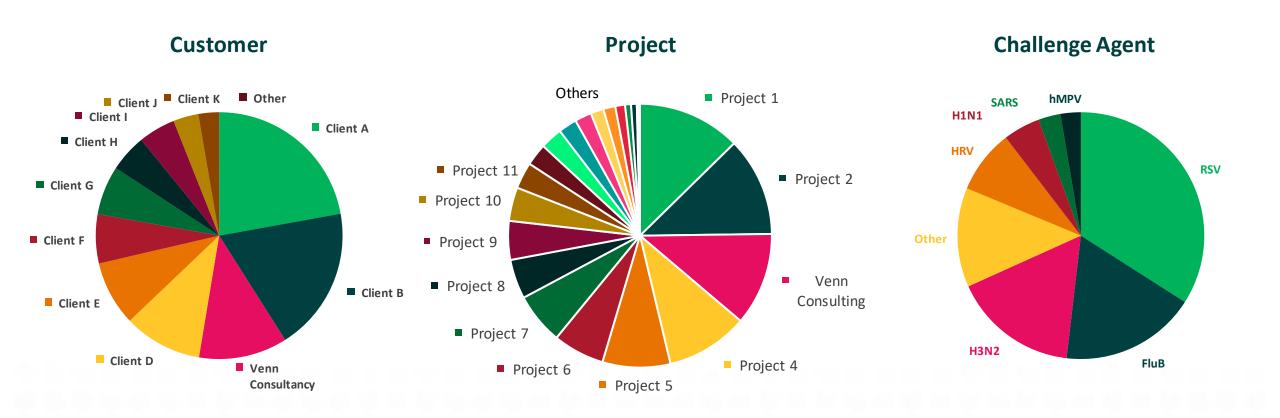


- Strong sales performance in 2023
- Growing orderbook after record revenue performance

- 90% of 2024 revenue covered by existing orderbook
- Good visibility into 2025

### Diverse Contracted Orderbook

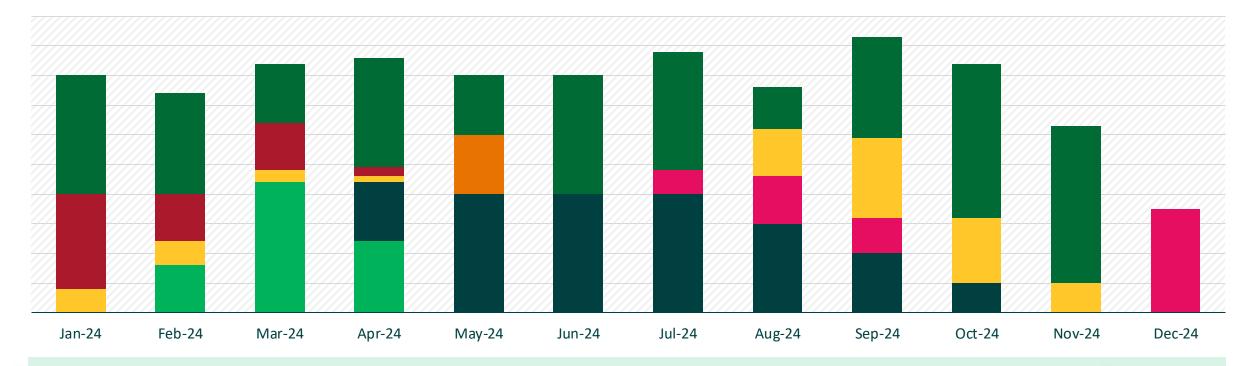




# Diverse Orderbook - Driving Efficiencies



### #Inoculations by Challenge Model 2024



- Goal: utilise 3 different virus agents per month
- Multi-agent screening of volunteers
- Improves project delivery

- Increases efficiency
- Improved resource and site utilisation

## World's Largest Commercial Human Challenge Trial Unit





### The Leading Volunteer Experience

- Views of Canary Wharf from Level 25
- State-of-the-art facility
- Individual room temperature control
- In house kitchen with new food menu
- Upgraded entertainment options

### Positive Operational Impact

- Future CL-3 capability
- Individual quarantine zones
- Multiple concurrent trials
- Improved bed / staff utilisation

# State-of-the-Art Facility





CL-3 Virology & Immunology Labs

- Significantly increased sample throughput
- Expanding capability to work with a broader range of pathogens

Outpatient Unit

• Facilitating Phase II and III field trials

Corporate Office

• Improving company culture

# Improving Automation – Driving Efficiency



### Shifting from paper-based processes to a fully integrated digital system

### Lab Information Management System (LIMS)

- Streamlined lab processes
- Enhanced interrogation readiness
- Integrated lab operation
- Improved efficiency

### Volunteer Management System

- End-to-end visibility of volunteer journey
- State-of-the-art CRM system
- Improving volunteer recruitment process
- Segmentation & profiling driving efficiency

### eConsent / eSource / EDC

- Volunteer consent
- Instant access to data
- Increased compliance
- Enhanced study oversight



# A Growing Market





Increase in academic and nonprofit funding in



**Growing Healthcare Funding:** \$13Bn Q1 2024 \$5Bn Q1 2023

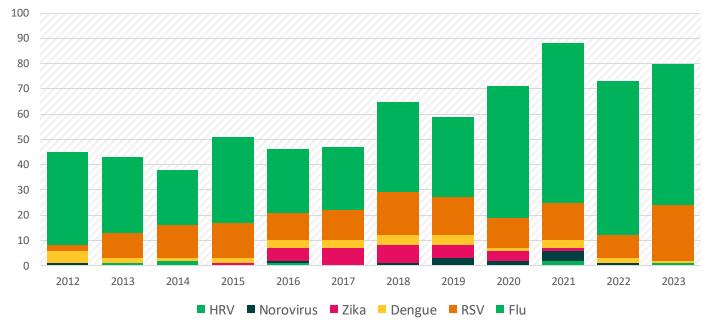


**Growing number of academic** and 'commercial' human challenge units

Doherty

Clinical Trials III











€9.5 million



**\$124Bn** by 2030

Infectious Disease **Drug Market** 

**\$150Bn** by 2024

# Growth Drivers to £100m by 2028





- Increase in Phase I / II trials
- M&A activity
- Non-profit funding
- Climate change



### **Growth in Challenge Trials**

- More challenge trials
- Larger trial size
- New challenge models
- Next generation vaccines
- Precision medicine





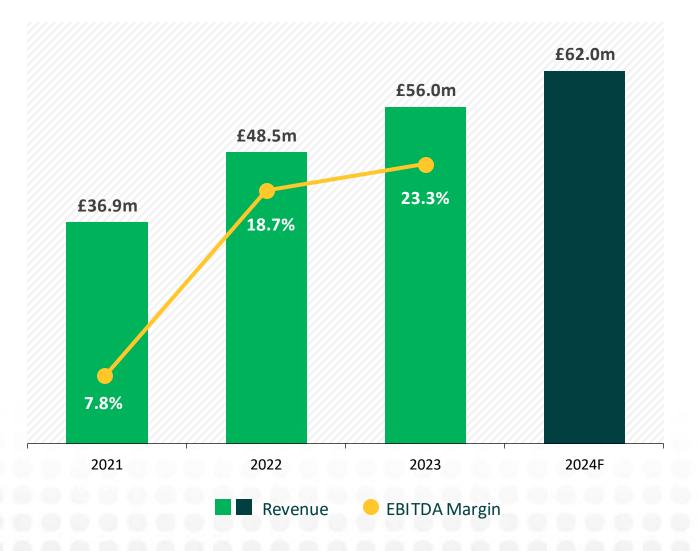
- Phase II / III site services
- Patient recruitment
- Larger lab & expanded services
- Expansion of Venn consulting



- Small bolt-on acquisitions
- Drug development consulting
- Patient recruitment
- Clinical trial site services

### Financial Outlook into 2024





- Full year revenue guidance of £62m, H1 weighted
- Sustainable EBITDA margins
- 90% of 2024 revenue contracted
- Good visibility into 2025
- Supported by weighted orderbook of £80m

<sup>1</sup>Revenue excludes other income, such as R&D tax credits

### Investment Case



### **Continued Delivery**



- Strong revenue, EBITDA, and sales
- Robust cash position
- Record inoculations
- Improving operational efficiencies and margins

### Scaling & Driving Efficiencies



- New 50-bedroom facility
- Increased lab capacity
- Increase outpatient capacity
- New challenge models
- New services

### Well Positioned for Future Growth



- Guiding £62m revenue 2024 & sustainable EBITDA margins
- £80m weighted contracted orderbook
- 90% of 2024 revenue contracted
- Annual dividend
- Medium-term target of £100m revenue

### A long-term sustainable growth model



World Leading Capabilities



**Expanding Market** 



High Barrier to Entry



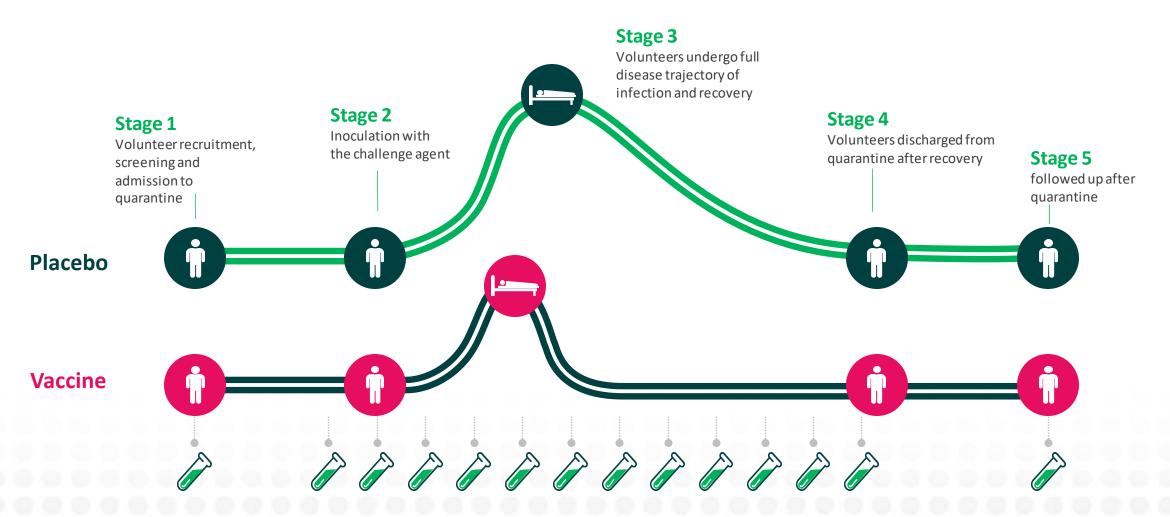
Strongest Ever Sales
Pipeline



# 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...



# History of hVIVO





#### 1946

UK Government establishes the human challenge Common Cold Unit in Salisbury, UK.







#### **Dec 2019**

hVIVO acquired by Open Orphan

#### **June 2019**

Venn acquired by Open Orphan



### RETROSCREEN VIROLOGY CONQUERING VIRAL DISEASE

#### 1989

Common Cold Unit closes. Retroscreen Virology is founded by Prof John Oxford & Pat Meeking



#### 2015

Retroscreen Virology rebrands as hVIVO

### 2011-2015

2001

trial

Retroscreen's first

human challenge

Major investment in facilities & challenge model development



Retroscreen recruits 800+ influenza volunteers



#### 2008

**Dedicated Volunteer** recruitment platform

### UK COVÎD CHALLENGE

#### 2020

hVIVO partner with UK Government to conduct world's first COVID-19 challenge trial



#### 2021

Spin out of infectious disease product portfolio: Poolbeg Pharma plc

### FluCamp

Clinical Trials Recruitment

#### 2022

Expanded facilities: increased lab offering and expanded clinical trial offering



**Open Orphan plc** rebranded to hVIVO plc

Continuing to expand offering to drive new streams of revenue

# World Leading Human Challenge Model Offering



| Influenza         | RSV     | HRV     | Malaria       | Asthma | SARS-CoV-2 | hMPV      | Dengue    |
|-------------------|---------|---------|---------------|--------|------------|-----------|-----------|
| H3N2 Perth        | Memphis | HRV 16  | P. falciparum | HRV 16 | Pre-Alpha  | Strain A* | Dengue 1* |
| H3N2<br>Wisconsin |         | HRV 14* |               |        | Delta      |           | Dengue 3* |
| H1N1(F)           |         |         |               |        | Omicron*   |           | Dengue 4* |
| Flu B*            |         |         |               |        |            |           |           |

Virus Strain

H5N1\*

Potential for the future: Norovirus, Zika, Pneumococcal

<sup>\*</sup> In development

# Benefits of Human Challenge Trials



### **SCIENTIFIC**



Generates invaluable dosing, safety and efficacy data

Helps optimise for larger field trials

De-risks Phase III programs

# CLINICAL DEVELOPMENT



Requires fewer subjects

Significant time savings

No seasonal dependance

### **REGULATORY**



Potential for Fast
Track or Breakthrough
designation accelerating time to
market

Potential approval and Emergency Use Authorisation

### **FINANCIAL**



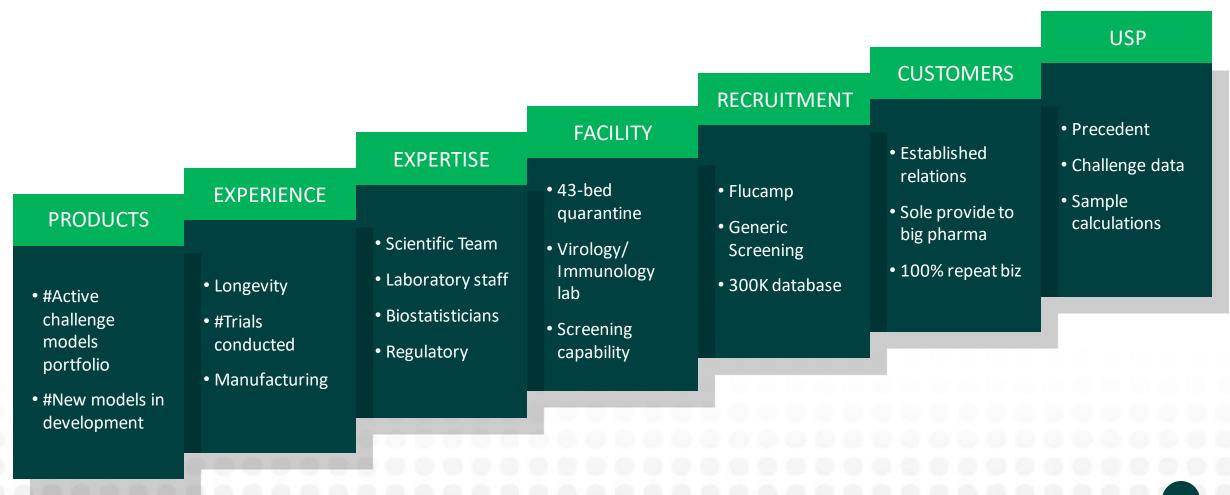
Significant valuation uplift for Biotech sponsor

Quick, cost-effective data in a tight funding environment

Allows products to "Succeed fast" or "Fail Fast"

# Significant Barriers to Entry





# Environmental, Social, Governance



# hVIVO ESG Group established in 2023 for initiating, progressing, and monitoring our ESG objectives

Canary Wharf have a strong focus on ESG and will help us to reach our goals for improving and enhancing or corporate social responsibility

#### hVIVO's ESG Values

- Commitment to ethical & compliant business practices
- Advancing Heath & Research

Commitment to Volunteers & Patients

5 Commitment to our Staff

Social & Community Investment

6 Operating Sustainably

# Canary Wharf ESG



# Facilities Overview



### QMB Clinic



### QMB Laboratories

















### Facilities Overview



### Canary Wharf Quarantine Unit

Opening

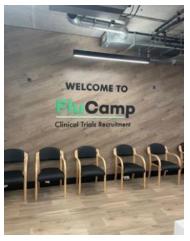
2024







### Plumbers' Row Corporate Office & Screening Facility









#### Manchester Screening Centre







### Biobank







# Stay in touch









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