



# H1 2022 Financial Results

September 2022

Ticker: HVO



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Open Orphan plc changes  
its name to hVIVO plc

# Open Orphan plc becomes hVIVO plc

## Why?

1. hVIVO is the operating brand
2. hVIVO brand is globally recognised by pharma, biotech, academics, and the media
3. hVIVO is a long standing, trusted partner to the biopharma industry for its unparalleled expertise and world class capabilities in human challenge trials

### Further details

**Completion Date**  
26 October 2022

**ORPH** ticker  
becomes **HVO**

[www.openorphan.com](http://www.openorphan.com)  
becomes  
[www.hvivo.com](http://www.hvivo.com)

**ISIN** remains  
unchanged

**Our  
Brands**



**Venn Life Sciences**  
*part of hVIVO*

**hVIVO**

**FluCamp**  
Clinical Trials Recruitment



# Who we are?

**World leader *in testing infectious & respiratory disease products* using human challenge studies addressing the growing infectious disease market**

**10+**

Challenge  
Study Models

**66**

Completed Human  
Challenge Studies

**3500+**

Volunteers  
Inoculated

# hVIVO – H1 Performance Summary



Steady Performance  
in H1

**£18.9M**

H1-2022  
Revenue

**£2.3m**

H1-2022 EBITDA  
12.1% EBITDA Margin

**£15.9m**

H1-2022  
Cash Balance



Well Positioned  
for Growth in 2022

**£50m**

Reaffirm Revenue Target  
£9m Revenue in Jul/Aug'22

**13-15%**

Target  
EBITDA Margin

**80%**

FY23 Revenue  
Contracted as at 1 Sept 2022



Strong Foundations

**£80m +**

Contracted Orderbook as  
1 Sept 2022

**1,000+**

Increased Weekly Onsite  
Screening Capacity

**4 of Top 10**

World's Largest Biopharma  
as Active Clients



Future-proofing  
our Operations

**New Models**

Influenza, Omicron and  
Malaria models

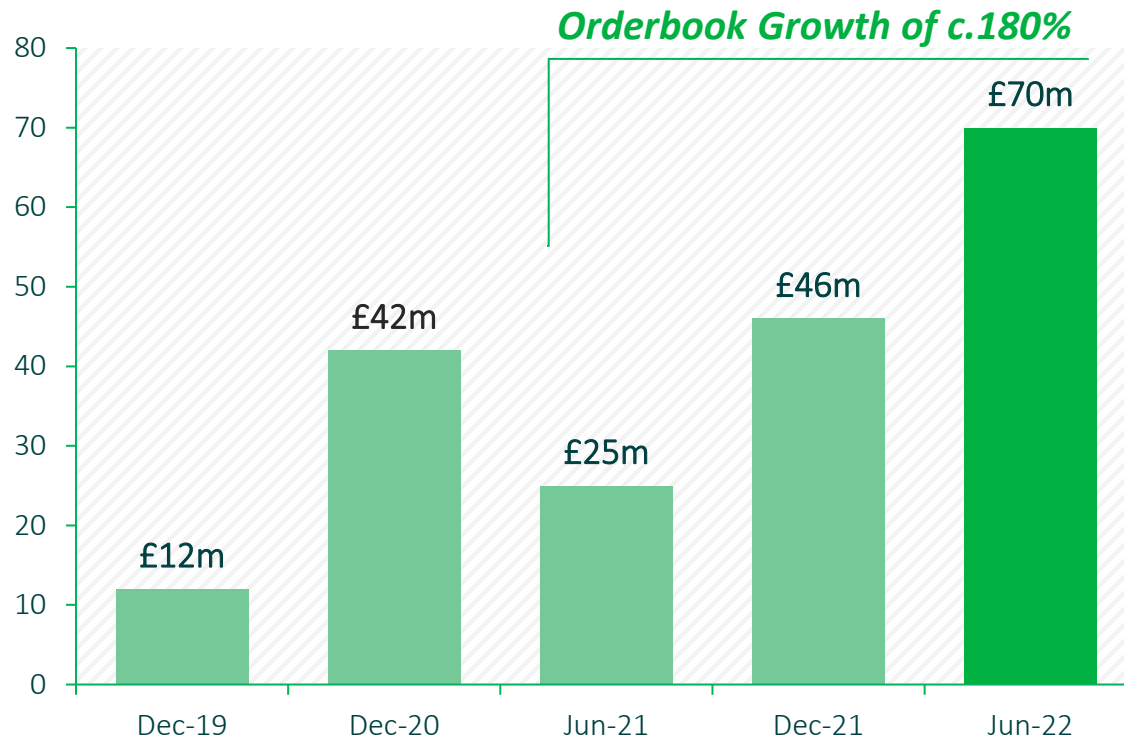
**New Revenue Streams**

Expanded into  
Additional Areas

**New FluCamp**

Screening Centre in  
Manchester

# Record Contracted Orderbook



**As at 1 Sept 22:**

- Contracted orderbook of £80m
- Reaffirm £50m revenue guidance for 2022
- c.80% FY23 Revenue Contracted

## Significant contracts in H1 2022

- £7.2m (RSV) – challenge trial with top 5 global pharma client
- £7.3m (Influenza) – challenge trial with European biotech
- £5m (RSV) – challenge trial with European biotech
- £14.7m (Influenza) - manufacture, characterisation and challenge study for top 5 global pharma client
- (Omicron) – development of COVID-19 challenge model for Omicron challenge trial with Vaxart

## Post 30 June 2022

- £6.2m (Influenza) – challenge study with US biotech Cocrystal
- £10.4m (Influenza) – manufacture and challenge trial for top 5 global pharma client

# Expanding our Portfolio of Models

Growth in our portfolio of models with particular emphasis on full-service contracts for our Big Pharma clients

## High Value Full-Service Contracts

### New Omicron Model

- Developing Omicron COVID-19 model with Vaxart Inc.
- Intention to conduct Omicron challenge studies from 2023 onwards

### Bespoke Influenza Model

- First full-service influenza challenge programme with an existing for a top 5 global pharma client
- Characterisation and challenge study worth £14.7m

### New Influenza Model

- Manufacturing a new Influenza model with an existing top 5 global pharma client
- Agreement worth £10.4m to include challenge study

## Launched New Models

### Asthma Model

- First Asthma Study currently underway with global pharma client
- Pipeline of asthma opportunities growing

### Malaria Model

- Malaria human challenge model launched in H1-2022
- Anti-parasite challenge studies to commence in near future

***Opportunity for further challenge models  
to attract additional clients***



# FluCamp Recruitment Platform

Patient recruitment is the #1 problem for all CROs

***Our FluCamp recruitment platform has an experienced track record of delivering successful recruitment to our trials***

**250,000+**

Active Volunteers in Existing Database

**100%**

Trial Recruitment Success

**c.85%**

FluCamp Volunteers can be utilised in non-challenge trials

**80%**

*More than 80% of clinical trials in the US fail to meet their patient enrolment timelines<sup>1</sup>*

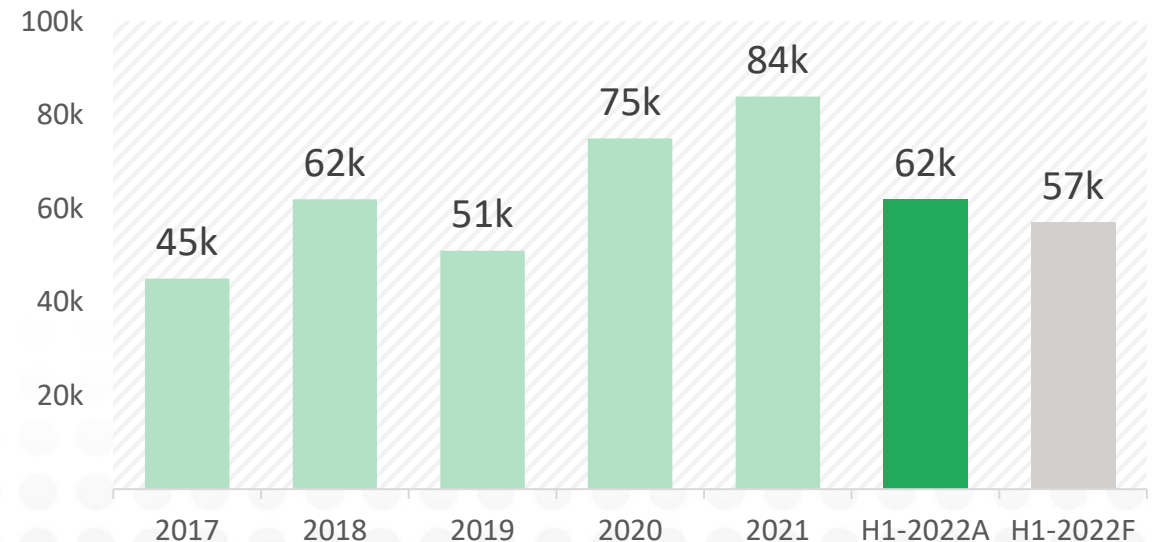
**55%**

*Patient recruitment issues account for 55% of cancelled clinical trials<sup>2</sup>*

## H1-2022 FluCamp Improvements

- Online Self Booking
- New CMS system
- Online screening for patients
- Expanded marketing channels – up to 3x more leads

## FluCamp Leads Generated



Note (1): Sources: Perspective in Clinical Research

Note (2): Sources: GlobalData

# Delivered on Key Value Adding Initiatives in H1

Continuing to develop new revenue streams to offer new and existing clients additional services

## Expanding Lab Services



- Increased volume of lab services contracts with external clients
- Received CAP accreditation, increasing the marketability of our lab services to external clients

## Launch Research Site Services



- Leveraging our upgraded infrastructure at Plumbers Row for use as a clinical site
- First contract signed with Global Pharma company in H1

## Recruitment Strategies



- Marketing FluCamp to provide trial recruitment as standalone service utilising volunteers not suitable for a challenge study

# Venn is a Key Driver of the Business

Venn offers an integrated package of consulting services from preclinical through late phase and approval; accelerating the development of its clients' products

## Expanding our Core Offering ↓

1

- Expansion within our key clients ("land-and-expand")
- Growth into ATMP clinical development services
- Key strategic hires to expand our service offering

## Cross selling opportunities within hVIVO ↓

2

- Client 1** - £5m RSV human challenge study contract stemming from multi-year early clinical development
- Client 2** - Secured our first site study award with a Venn client with 20+ year relationship



**Venn Life Sciences**

*part of hVIVO*

### Venn Life Sciences Services Offering

Drug Development  
Consultancy

Clinical PK &  
Pharmacometrics

Non-Clinical  
Development

CMC Consulting

Medical Writing &  
Regulatory Affairs

Trial Management

Data Management

Statistics, Study Design  
& Methodology

RTSM

Training

# Attractive Market Dynamics

**\$46.7B+**

*The global clinical CRO market was estimated to be worth \$46.7bn in 2021 and to grow at a 10% CAGR to 2024<sup>1</sup>*

**\$5.5B+**

*The infectious disease clinical trial market is projected to reach over \$5.5 billion by 2027<sup>2</sup>*

**£700m+**

*The estimated market size for challenge study CRO services by 2028<sup>3</sup>*

**2,500+**

*Active vaccine, anti-viral and respiratory compounds currently in development – 86% increase from 2019 to 2021<sup>4</sup>*

## Our Challenge Trials have Supported Breakthrough Therapy Designation with the FDA

### Bavarian Nordic

Bavarian Nordic's RSV vaccine candidate, MVA-BN® RSV received Breakthrough Therapy designation in 2022

### Top 5 Big Pharma

Breakthrough Therapy designation received following successful phase 2a RSV challenge trial in over 60s

## Impact of COVID-19 on Funding for Infectious Disease

- Pandemic Preparedness
- Increased funding for vaccines and anti-virals

Note (1): Sources: Results Healthcare (2021) CRO Sector M&A drivers and market trends

Note (2): Sources: Global Market Insights

Note (3): Sources: Liberum

Note (4): Sources: Pharmaprojects; Citeline



# Why do a Human Challenge Trial?

## SCIENTIFIC



Generates invaluable dosing, safety and efficacy data

Helps optimise for larger field trials

## CLINICAL DEVELOPMENT



Requires fewer subjects

Significant time savings

De-risk Phase III program

## REGULATORY



Potential for Fast Track or Break Through designation

Potential approval and Emergency Use Authorisation

## FINANCIAL



Significant valuation uplift for Biotech sponsor

Allows products to “Succeed fast” or “Fail Fast”

# Partner of Choice for Big Pharma

## Preferred partner for 4 of the top 10 global biopharma<sup>1</sup>

3

Active Challenge  
Studies

with Big Pharma in H1-2022

2

Full-Service Challenge  
Programmes

value exceeding £25m

8

Challenge Studies

signed with Big Pharma  
since 2018

100%

Repeat Customers

Percentage of our Big  
Pharma customers are  
repeat customers

c.40%

Contracted Orderbook

relates to our  
Big Pharma clients

## hVIVO's Biotech Clients

- hVIVO work with a large number of biotechs – challenge studies are a key inflection point
- c.60% of our orderbook relates to our biotech customers
- Omicron model developed with key customer
- 3 new biotech challenge clients in H1-2022 (further win in August)
- c.80% repeat business for Venn's biotech clients

<sup>1</sup> Active customers for 2021-2023+

# Financial Performance & Outlook

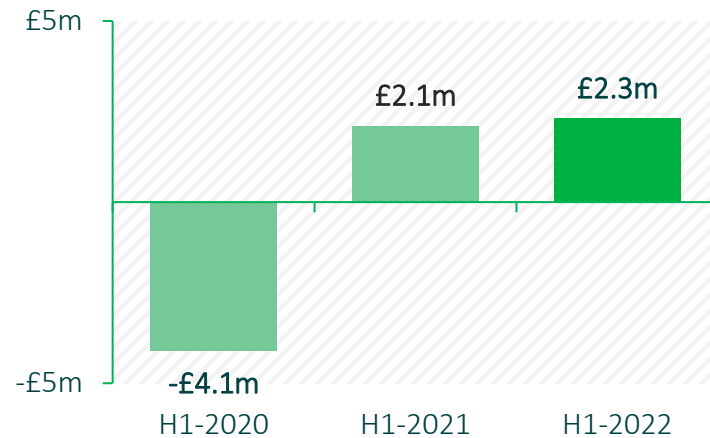
# Summary Financial Highlights

£'m	H1-2022	H1-2021	Comment
<b>Revenue</b>	18.9	23.2	<ul style="list-style-type: none"> <li>✓ H1-2022 revenues of £18.9m</li> <li>✓ 2022 revenue weighted to H2</li> <li>✓ Reaffirm revenue guidance of £50m for 2022</li> <li>✓ Revenue for July &amp; August 2022 of c.£9m</li> <li>✓ hVIVO division is the core growth driver representing over 80% of H1-2022 revenue</li> <li>✓ Venn division is expanding services &amp; increasingly supporting hVIVO studies</li> </ul>
<b>EBITDA</b>	2.3	2.1	<ul style="list-style-type: none"> <li>✓ EBITDA margin increased to 12.1%</li> </ul>
<b>Cash</b>	15.9	14.9	<ul style="list-style-type: none"> <li>✓ Strong working capital management</li> <li>✓ Cash of c.£20m as at 1 Sept. 2022</li> </ul>
<b>Order Book</b>	70	25	<ul style="list-style-type: none"> <li>✓ Orderbook increased almost threefold year-on-year</li> <li>✓ Increased to c.£80m as at 1 Sept. 2022</li> </ul>



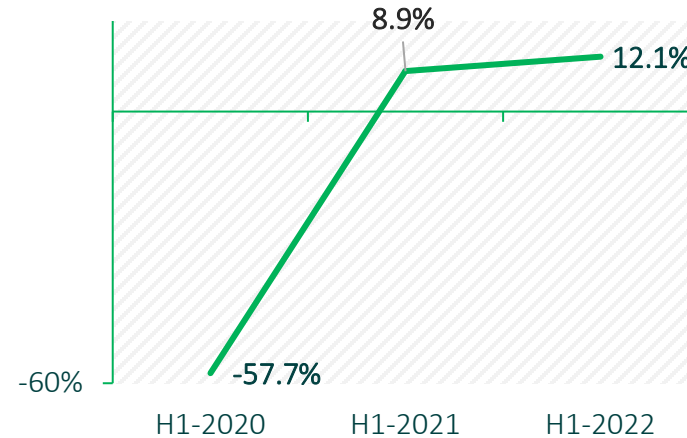
# A Sustainably Profitable & Cash Generative Business

## EBITDA



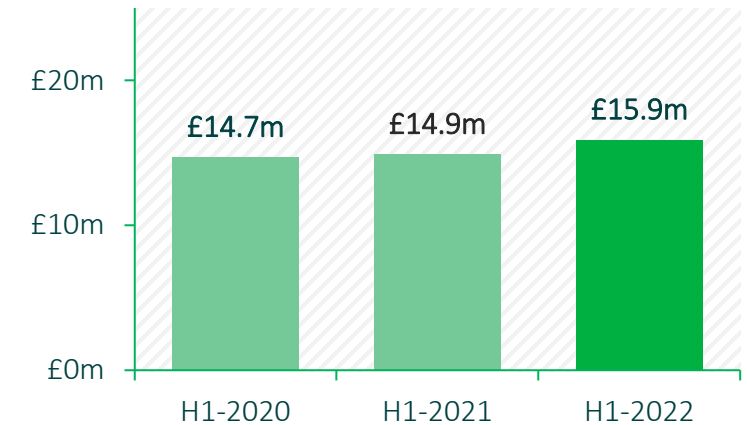
- Increased H1-2022 EBITDA of £2.3m
- Improved productivity gains in operations & overhead efficiency

## EBITDA Margin

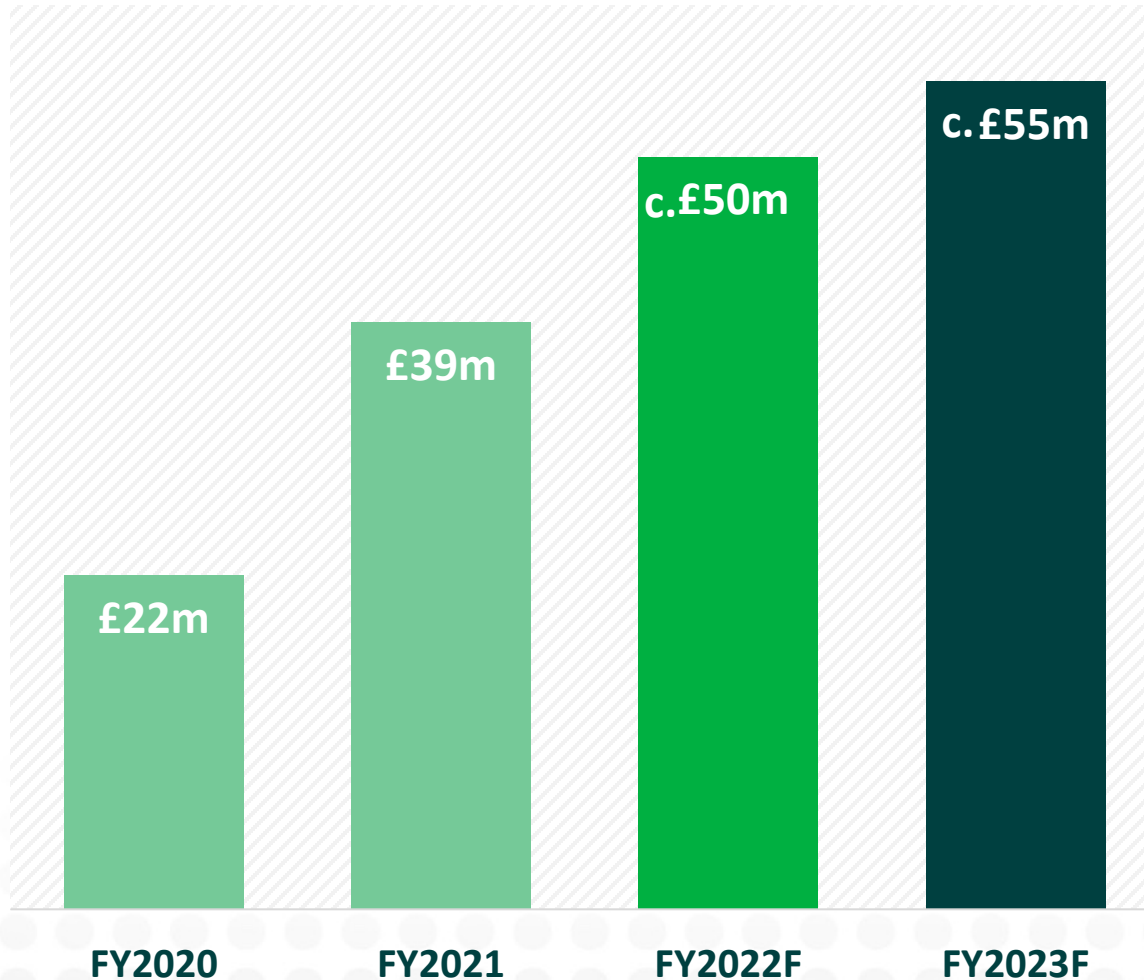


- H1-2022 EBITDA Margin increased to 12.1%
- Growth towards sustainable double digit EBITDA margin of 13–15%

## Cash



- Strong cash position with £15.9m as at 30 June 2022
- Cash generative with modest investments made to improve infrastructure
- Cash balance as at 1 Sept. 2022 of c.£20m



## Revenue

- Full year guidance remains at c.£50m revenue for 2022 (revenue for July & August 2022 of c.£9m)
- Drive efficiencies and productivity to achieve double digit EBITDA margin for full year 2022
- Focus on orderbook conversion into 2023 targeting c.£55m of revenue – c.80% of 2023 revenue already contracted
- Continue to close strong sales pipeline and progress development of new revenue streams

## ↓ 01 Strong Market Dynamics

- Attractive market dynamics across rapidly growing infectious disease space
- World leader in challenge trials for infectious and respiratory disease
- Increased adoption of challenge trials by Big Pharma

## ↓ 03 Trusted Partner

- Repeat revenue with big pharma; a trusted “go-to” partner; served 4 of top 10 global biopharma in H1-2022
- Increased volume of biotech awards

## ↓ 02 Scalable Infrastructure

- Investment in the operational infrastructure to deliver further growth
- Increased bed capacity
- Expansion of FluCamp screening platform

## ↓ 04 Orderbook Growth

- Record order book of c.£80m as at 1 September 2022
- Growth in new models; expansion of pipeline
- Growth into new revenue streams e.g. site services, lab services

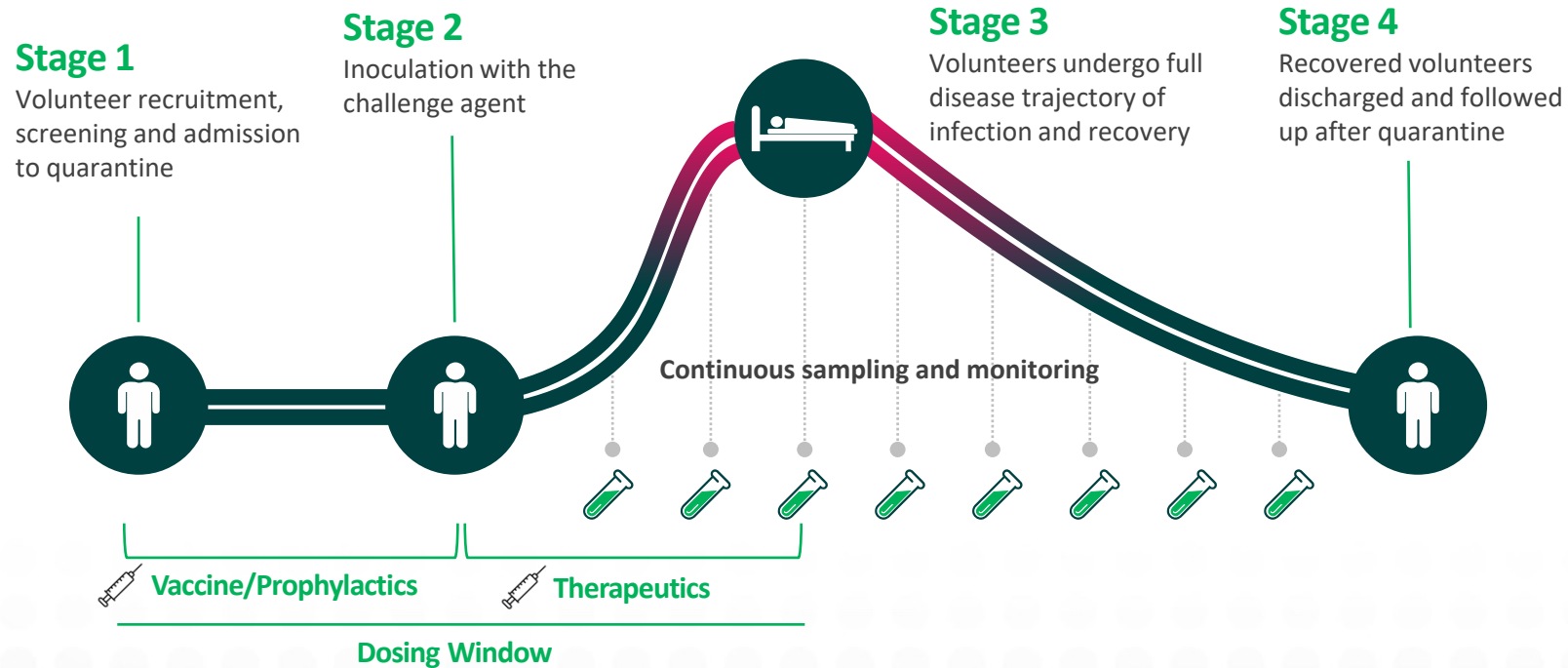
*Support continued revenue growth and long term, sustainable profitability*

# Appendix



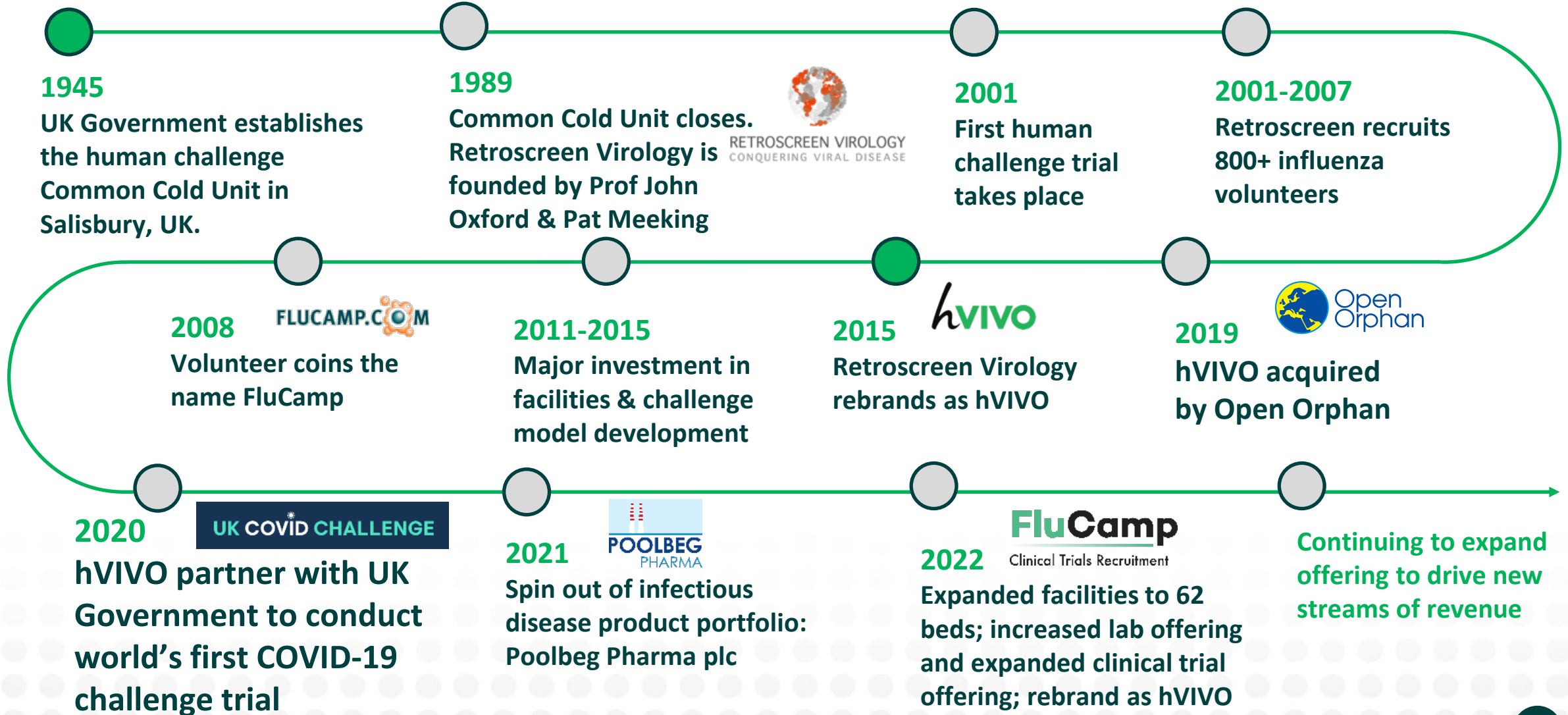
# What is a Human Challenge Trial?

## Progression of a Volunteer While in Quarantine During a Typical Human Challenge Trial



- ✓ Generic screening
- ✓ Volunteers are randomly stratified to placebo or active
- ✓ All volunteers are inoculated with the challenge agent (virus)
- ✓ Trials typically include 50-100 healthy volunteers
- ✓ Quarantine duration: 10-15 days
- ✓ Outpatient follow-up visits

# History of hVIVO



# RSV Human Challenge: A tool for a break-through designation



## The Challenge

To speed up the development process by achieving fast proof of efficacy to fast-track regulatory discussions

## The Solution

Phase IIa, double-blinded, placebo-controlled human challenge

## The Result

79% efficacy in preventing symptomatic infections



Break-through designation



De-risk Phase III clinical trials



47

days to obtain CA/EC approval



62

volunteers recruited on time



11

weeks to recruit volunteers with a 85% screen-failure rate



*"I was really impressed by the professional and timely implementation of this trial, helping us to bring our RSV vaccine candidate into late-stage development. The collaboration with your team was really enjoyable, everyone in your team was highly supportive."*

Dr. Med. Heinz Weidenthaler (VP, Clinical Strategy)



# Facilities Overview

QMB Clinic



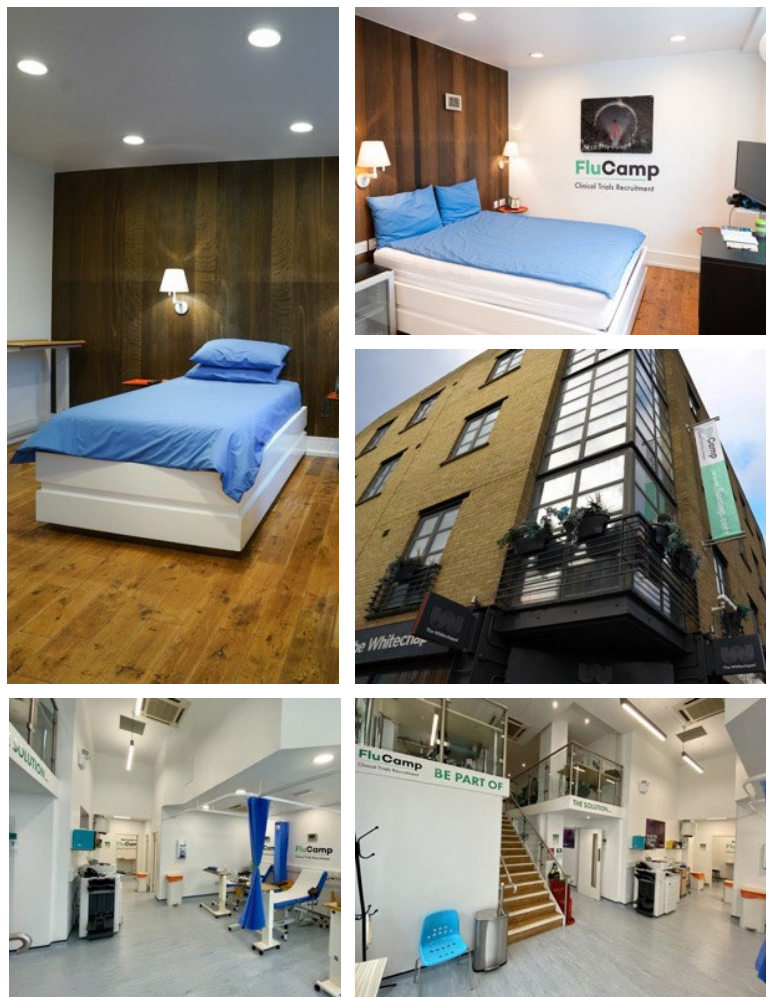
QMB Laboratories



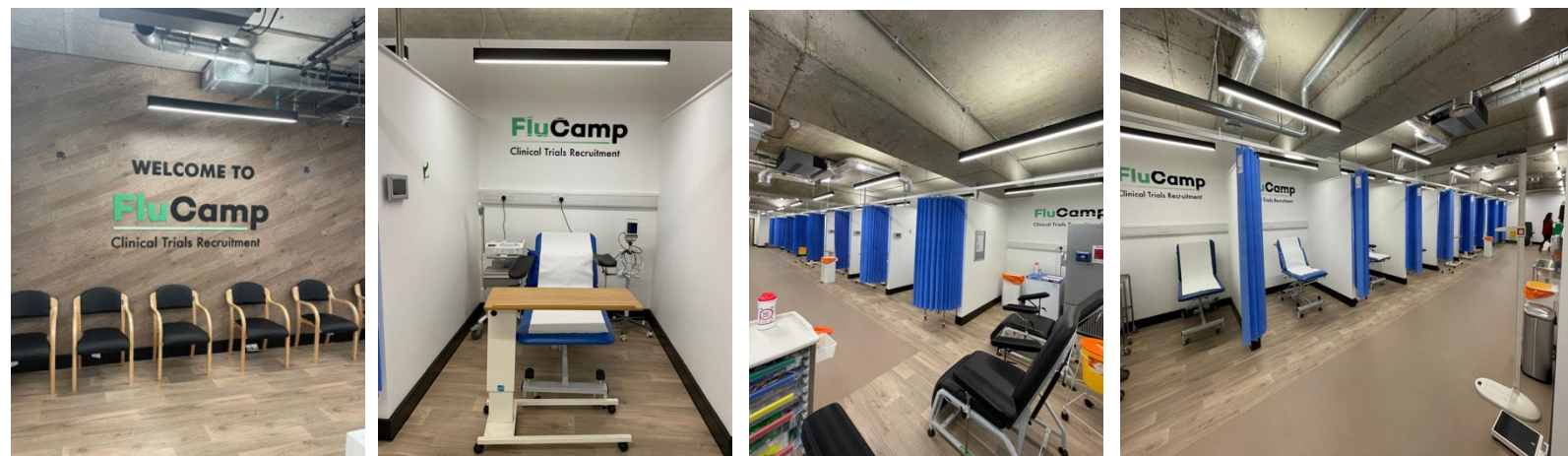


# Facilities Overview

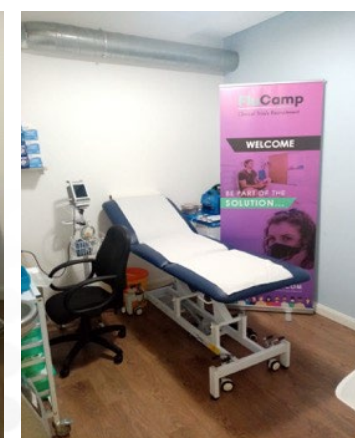
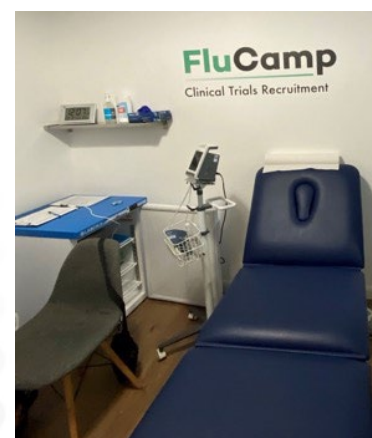
## Whitechapel Clinic and Screening Centre



## Plumbers' Row Corporate Office & Screening Facility



## Manchester Screening Centre



## Biobank





# hVIVO

*formerly* Open Orphan plc

## Stay in touch



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