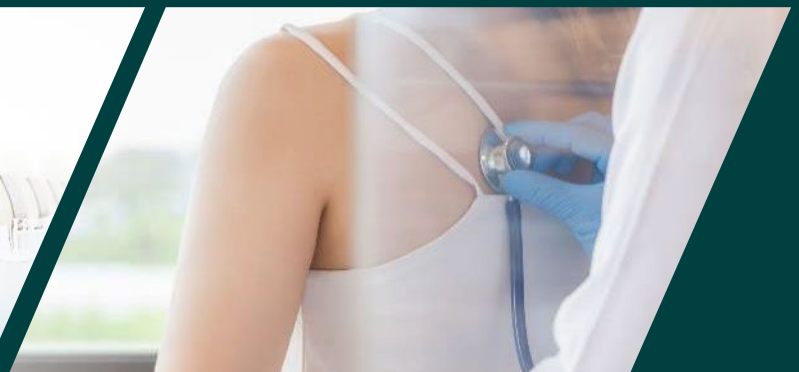

hVIVO

formerly Open Orphan plc

Capital Markets Day

2 November 2022

Ticker: HVO

Disclaimer

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Agenda

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Time	Speaker	Title
9.30	**Yamin 'Mo' Khan** **Chief Executive Officer, hVIVO**	**Welcome and overview**
9.45	**Andrew Catchpole** Chief Scientific Officer, hVIVO	**The unrivalled value of challenge trials**
10.05	**Douglas Thomson** Chief Executive Officer, Pneumagen	**Biopharma insights – Why do a challenge trial?**
10.20		**Q&A**
10.30		**Break**
10.45	**Peter Openshaw** Professor of Experimental Medicine, Imperial College London	**Insights into mechanisms of defenses and disease from human challenge trials**
11.00	**Chair** **Yamin 'Mo' Khan,** hVIVO **Speakers** **Peter Openshaw,** Imperial College London **Douglas Thomson,** Pneumagen **Andrew Catchpole,** hVIVO	**Fireside chat** **COVID-19 and challenge trials: A paradigm shift for drug development**
11.30	**Eglé Pavyde** Director of Business Development, hVIVO	**Strategy for growth – Market trends and growing interest in challenge trials**
11.45	**Stephen Pinkerton** Chief Financial Officer, hVIVO	**Financial outlook – Key performance metrics**
11.55	**Yamin 'Mo' Khan** Chief Executive Officer, hVIVO	**Closing remarks**
12.00	**All**	**Q&A**
12.10 – 13.00	**All**	**Lunch and networking session**

hVIVO Speakers

Yamin ‘Mo’ Khan
Chief Executive Officer

Yamin ‘Mo’ Khan has over 25 years of experience in clinical research and the CRO industry. Mo previously worked as a Consultant assisting CROs to develop growth strategies and helping prepare companies for future expansion, both organic and through M&A activity. In addition Mo worked with Private Equity firms providing insight in identifying potential targets and conducting due diligence in preparation for M&A activity. Prior to this Mo had a variety of senior roles at Pharm-Olam where he played a pivotal role in growing a small niche clinical monitoring business to a global full-service CRO with offices across all continents. In his time at Pharm-Olam Mo had leading roles in Clinical Operations, Project Management, Business Development and Executive Management functions. As a key member of the Executive Team Mo participated in the successful sale of the company in 2017, delivering substantial returns to its shareholders. Prior to this he worked at Innovex and Quintiles (IQVIA).

Mo holds a PhD in Biochemistry from the University of Southampton, UK, and a Bachelor’s degree in Biochemistry from the University of Liverpool, UK.

Stephen Pinkerton
Chief Financial Officer

Stephen is a chartered accountant with over 25 years of experience in senior financial roles, and has served as Commercial Financial Director of hVIVO since July 2017, and previously spent a year as a consultant to the Company. Prior to joining hVIVO, he spent 11 years in various senior financial roles at Thomson Reuters. He will be based in the Company’s Plumbers Row headquarters in East London.

Stephen has a strong background in financial planning & analysis, commercial finance, financial systems and financial control. As Commercial Financial Director of hVIVO, he has worked to transform the reporting and forecasting of the business, developed pricing models for contracts to help improve average contract value as well as driving margin improvements across the business, and has served as part of the business development team negotiating contract terms. As part of the leadership team, he has worked to help manage costs and restructure the business to improve efficiency, resulting in continued improvements in profitability.

hVIVO Speakers

Andrew Catchpole
Chief Scientific Officer

Dr. Andrew Catchpole first studied as a virologist at the University of Warwick before then furthering his education with postgraduate studies in influenza replication at Oxford University. Since then he has applied his scientific knowledge in a commercial setting. After working as part of a multidisciplinary R&D team developing nuclear medicine research tools at GE Healthcare, he then returned to the field of virology to work for hVIVO and Open Orphan, an industry-leading service provider of human viral challenge studies (controlled human infection studies). Andrew is now considered an expert in human viral challenge studies having played key roles in the development of influenza, RSV and HRV models at hVIVO. He has overseen the design and conduct of numerous antiviral and vaccine product efficacy studies and now works as Chief Scientific Officer, leading scientific strategy for the company as well as providing consultancy both internally and externally to hVIVO's clients and collaborators on challenge study design and data interpretation. In addition, he was PI on a recent successfully completed DARPA-sponsored research project to utilise the challenge model to identity human biomarkers and algorithms prognostic of influenza contagiousness.

Eglé Pavyde
Director of Business Development

Eglé is an experienced business development professional with a strong scientific background. Eglé is a Pharmacist by training and holds a PhD from the University of Pittsburgh in Stem Cell Research. She has won over 10 different national and international awards for scientific achievements and is an author of four scientific publications. Prior to joining hVIVO, Eglé spent nearly seven years at Biomapas, a Lithuanian pharmaceutical company, in a variety of roles including Head of Business Development.

Guest Speakers

Douglas Thomson
Chief Executive Officer of Pneumagen

Douglas has significant international experience as CEO, Chairman, NXD and Business Development Director. He has led executive teams generating rapid value creation at companies such as 4D Pharma. Working with Thomas Engelen to deliver the Company's strategic objectives, Douglas accesses an extensive network of industry experts and service providers to drive forward Pneumagen's products and technologies. He has executed multiple commercial deals with biotechnology and pharmaceutical companies.

Peter Openshaw
Professor of Experimental Medicine at Imperial College London

Peter is a respiratory physician and mucosal immunologist, studying how the immune system both protects against viral infection but also causes disease.

He has worked on RSV and influenza since the mid-1980s, leading a large Wellcome Trust funded national collaboration: Mechanisms of Severe Acute Influenza Consortium MOSAIC (2009-12), recruiting cases of severe influenza during the influenza pandemic of 2009-2010. He has run studies of human experimental infection of volunteers since 2008 and is Director of the MRC-funded HIC-Vac consortium established to promote the use of human experimental infection to accelerate vaccine development. for pathogens of high global impact.

hVIVO

formerly Open Orphan plc

Yamin ‘Mo’ Khan

Introduction

hVIVO

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Who we are

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

10+ Challenge Study Models

66+ Completed Human Challenge Studies

3,500+ Volunteers Inoculated

History of hVIVO

hVIVO
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1946
UK Government establishes the human challenge Common Cold Unit in Salisbury, UK.

1989
Common Cold Unit closes. Retroscreen Virology is founded by Prof John Oxford & Pat Meeking

2001
Retroscreen's first human challenge trial

2001-2007
Retroscreen recruits 800+ influenza volunteers

2008
Dedicated Volunteer recruitment platform

2011-2015
Major investment in facilities & challenge model development

2015
Retroscreen Virology rebrands as hVIVO

June 2019
Venn acquired by Open Orphan

Dec 2019
hVIVO acquired by Open Orphan

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

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

An Experienced Team

hVIVO
formerly Open Orphan plc

Chief Executive Officer
Yamin Khan

Chief Financial Officer
Stephen Pinkerton

Business Development
Rich Niemi • **Eglé Pavyde**

Quality Assurance
Teja Marathe-Sarvadikar

Clinical Operations
Adam French

Chief Scientific Officer
Andrew Catchpole

Group Legal
Dori Kadmon

Venn Life Sciences
part of hVIVO

Venn Life Sciences
SLT

Group HR
Andrew Frans

Group IT
Paul Beshaw

A Snapshot of our Business

formerly Open Orphan plc

Strong Financial Performance	**£50M** 2022 Forecast Revenue	**13-15%** FY22 Target EBITDA Margin	**c.£20m** Cash Balance at 1 Sept 2022
Well Positioned for Future Growth	**£80m +** Contracted Orderbook as 1 Sept 2022	**80%** FY23 Revenue Contracted as at 1 Sept 2022	**4 of Top 10** World's Largest Biopharma as Active Clients
Building on Solid Foundations	**£5m–£10m** Average Study Size	**8–10 Months** Average Study Length	**1,000+** Increased Weekly Onsite Screening Capacity
Future-Proofing our Business	**New Models** Influenza, Omicron and Malaria models	**New Revenue Streams** Expanded into Additional Areas	**New FluCamp** Screening Centre in Manchester

Strategy for Growth

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Our goal is to increase the size of the challenge trial market

Attractive Market Dynamics

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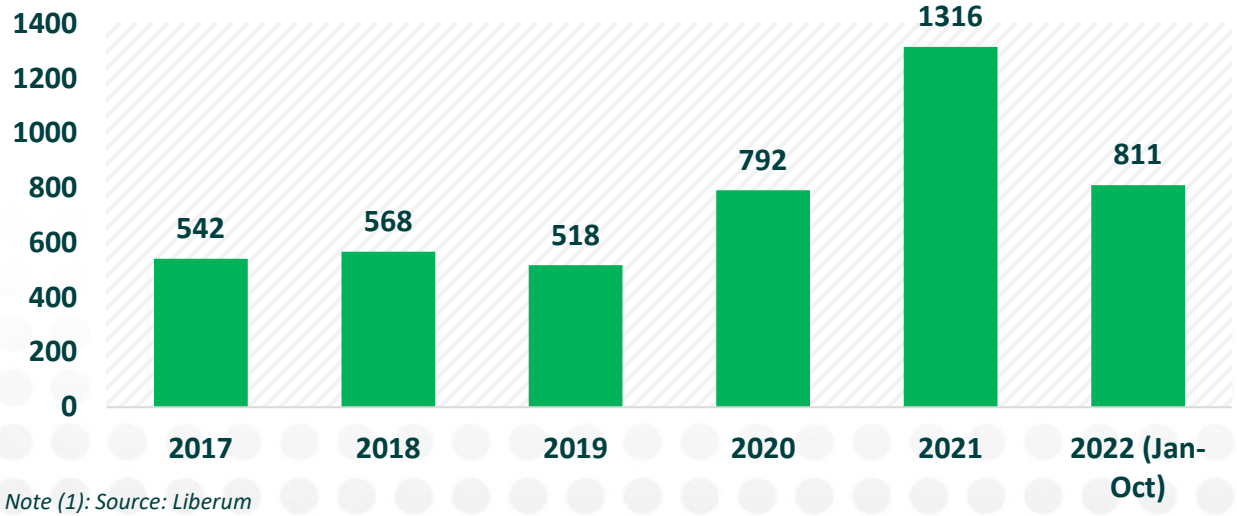
£700m+

The estimated market size for challenge study CRO services by 2028[1]

2,500+

Active vaccine, anti-viral and respiratory compounds currently in development – 86% increase from 2019 to 2021[2]

The number of vaccines studies is increasing every year…



hVIVO's portfolio of challenge models covers a large proportion of the most researched pathogens[3]

	Pathogen	# of clinical trials
1	**SARS CoV-2**	1364
2	**Influenza**	895
3	Bacterial Infections	741
4	HPV	394
5	HIV	360
6	Enterovirus	279
7	Hepatitis virus	266
8	**Malaria**	189
9	Poliovirus	132
10	Adenovirus	122
11	Herpes virus	118
12	**RSV**	89
13	Dengue virus	82
14	Ebola virus	77
15	Rabies virus	66
16	Rubella virus	42
17	Rotavirus	29

Note (1): Source: Liberum
Note (2): Sources: Pharmaprojects; Citeline
Note (3): Source: clinicaltrials.gov

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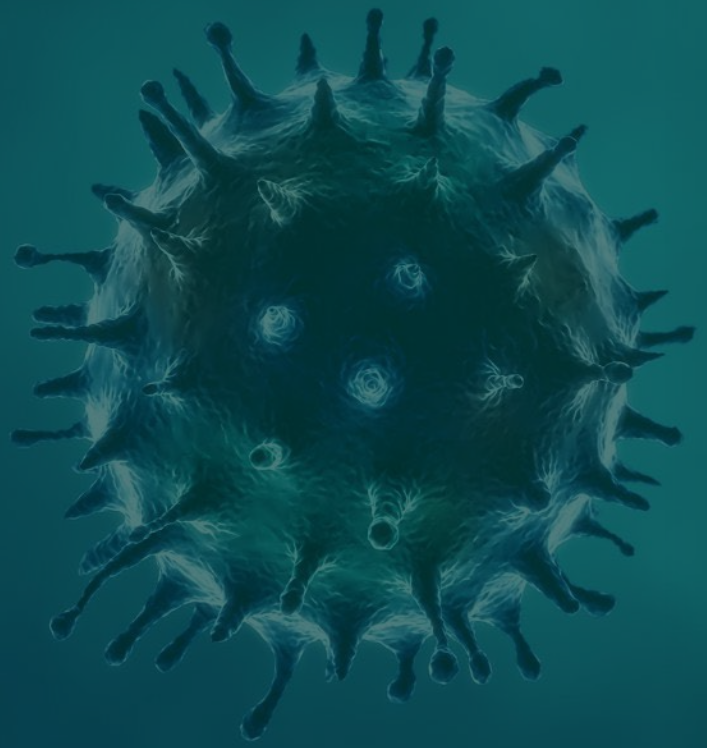

Andrew Catchpole

Chief Scientific Officer

The unrivalled value of challenge trials

What are Challenge Studies?

"The deliberate exposure of humans to known or putatively disease-causing material."

Source: Prof. M. Levine
(Centre of Vaccine Development; Univ of Maryland)

Human Challenge Trials - Not a New Concept

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- Challenge models have been an important part of medical research for hundreds of years
- UK has a particularly long and established history of the conduct of ethically approved challenge studies
- Right through to recent times with setting up of the world's first COVID challenge study, funded by UK government

Some key historical moments for challenge studies

1796
Edward Jenner
Smallpox

1822-1895
Louis Pasteur
Rabies

1900s
Walter Reed
Yellow Fever

1937
Smorodintseff
Influenza A/B

1946-1989
Common Cold Institute in operation in UK
Influenza / HRV / coronavirus

The Challenge Model Process & Concept

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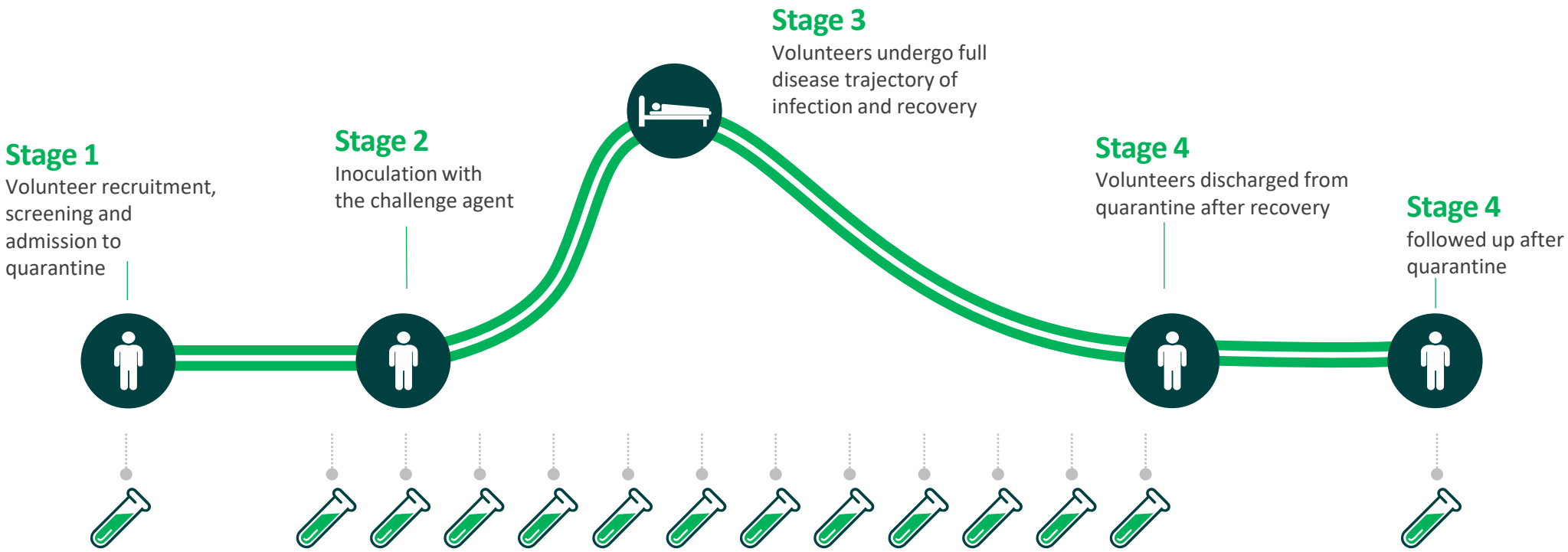

The Challenge Model Process & Concept

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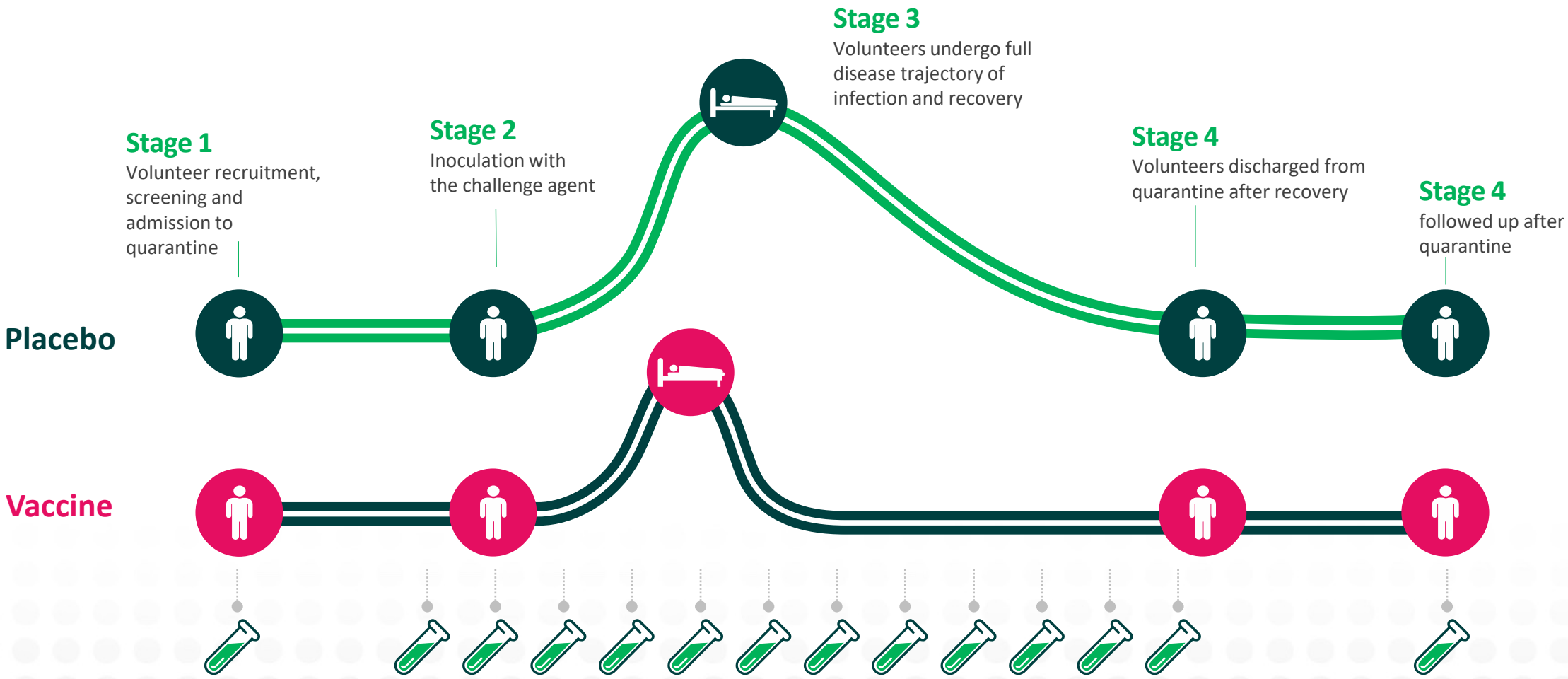

hVIVO's Challenge Models and Experience

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World leading portfolio and unrivalled experience

RSV

27 clinical studies
1,594 inoculated subjects

INFLUENZA

31 clinical studies
1,588 inoculated subjects

HRV

9 clinical studies
389 inoculated subjects

SARS-CoV-2

1 clinical study
36 inoculated subjects

MALARIA

1 clinical study
2 inoculated subjects

ASTHMA & COPD

3 clinical studies

COUGH

Summary: Challenge Studies vs Field Trials

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Phase Ib / IIa Challenge Study		Phase II Field Study	
Conduct all year round	Controlled environment	Seasonal recruitment	Uncontrolled environment
High attack rate	Known inoculation date	Low or unknown attack rate (prevalence)	Unknown inoculation date
Short duration (1-3m)	Low cost (£2-10M)	Long duration (>2yrs)	High cost (£10-25M)
Small cohorts (40-60)	Quick decision making	Large cohorts (250-300)	Extensive data analysis required for decisions

Vaccine Efficacy can Only be Measured by Infected Subjects

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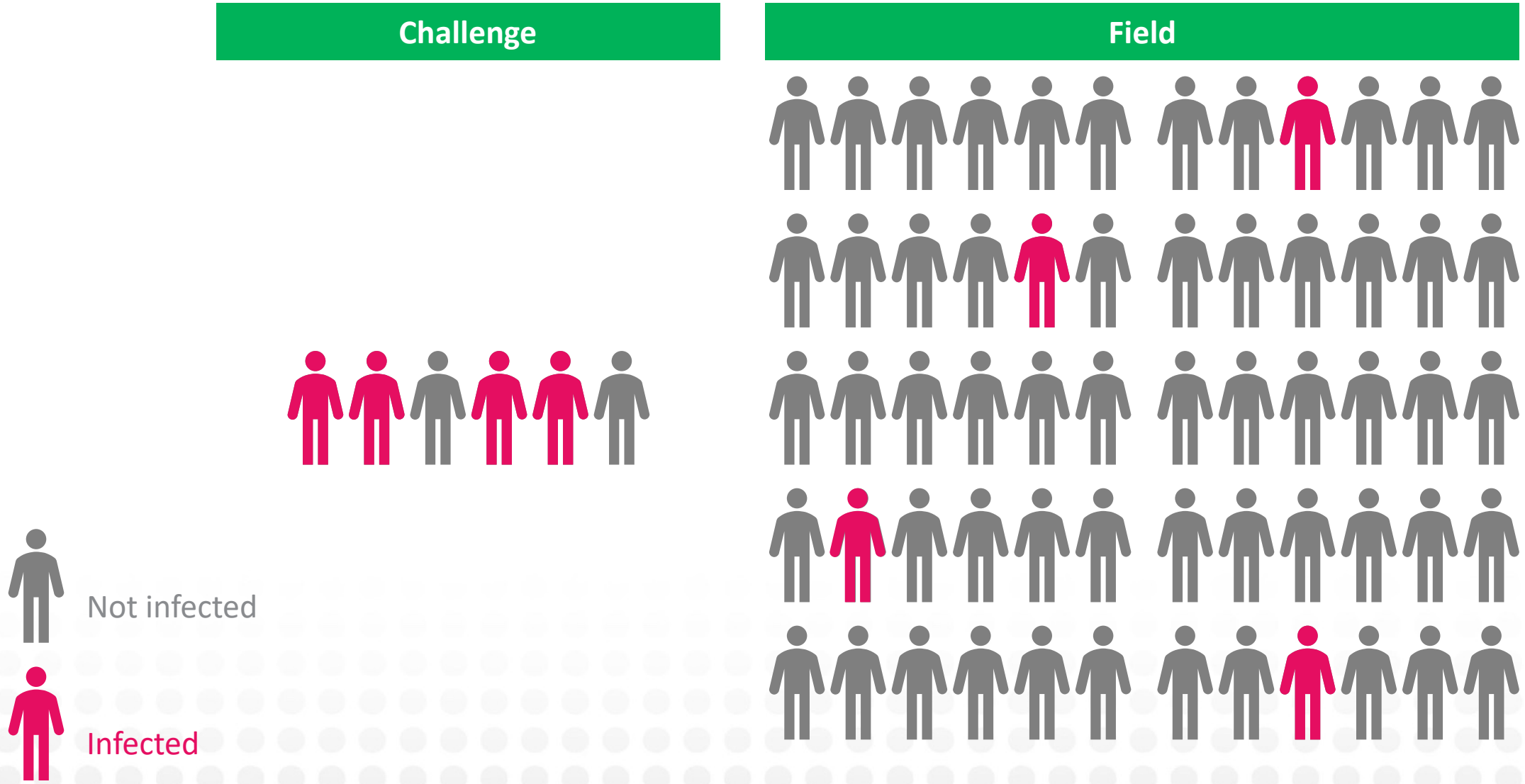

Significant Reduction in Number of Volunteers

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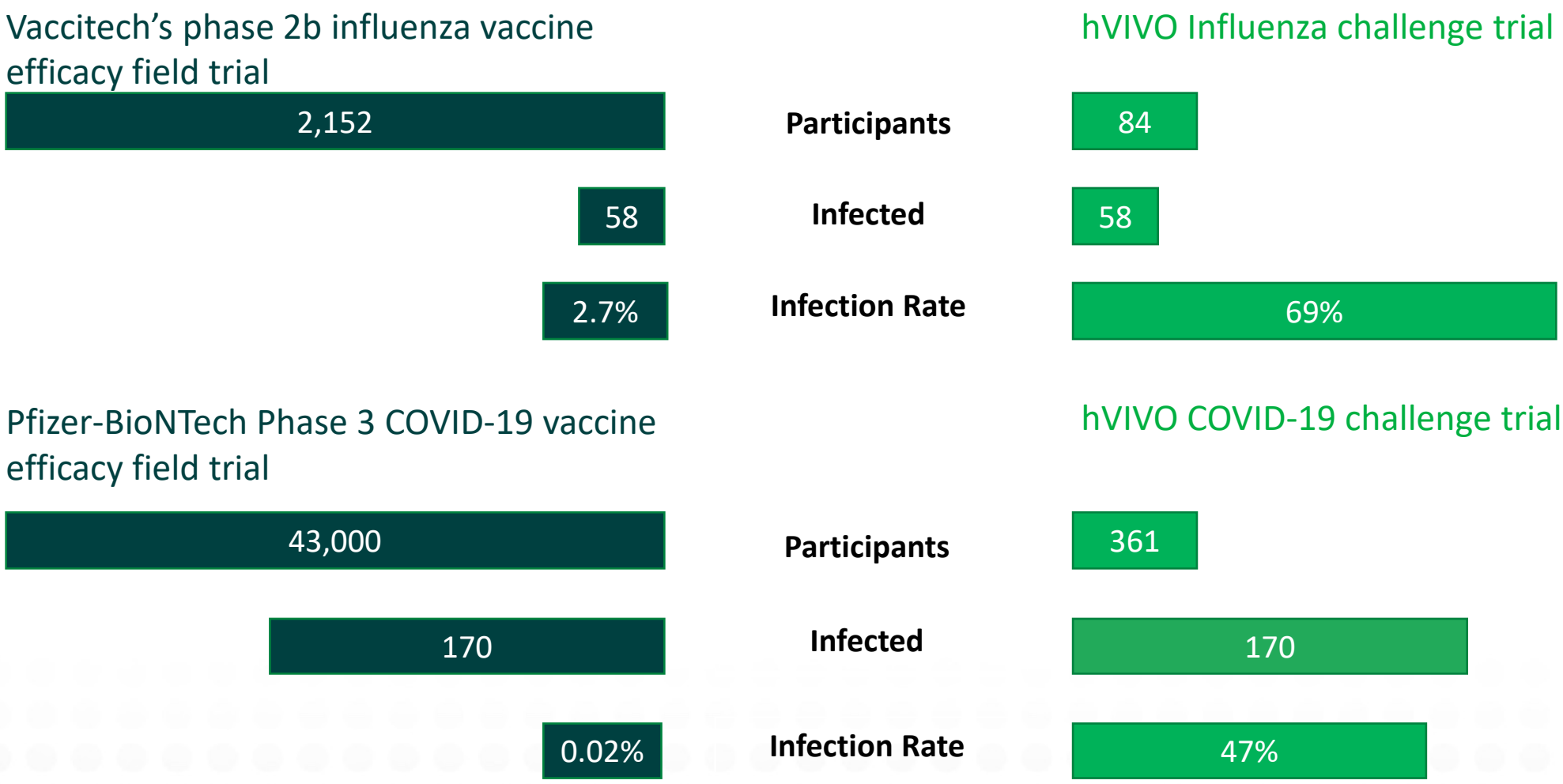

How Symptoms are Measured and Compared

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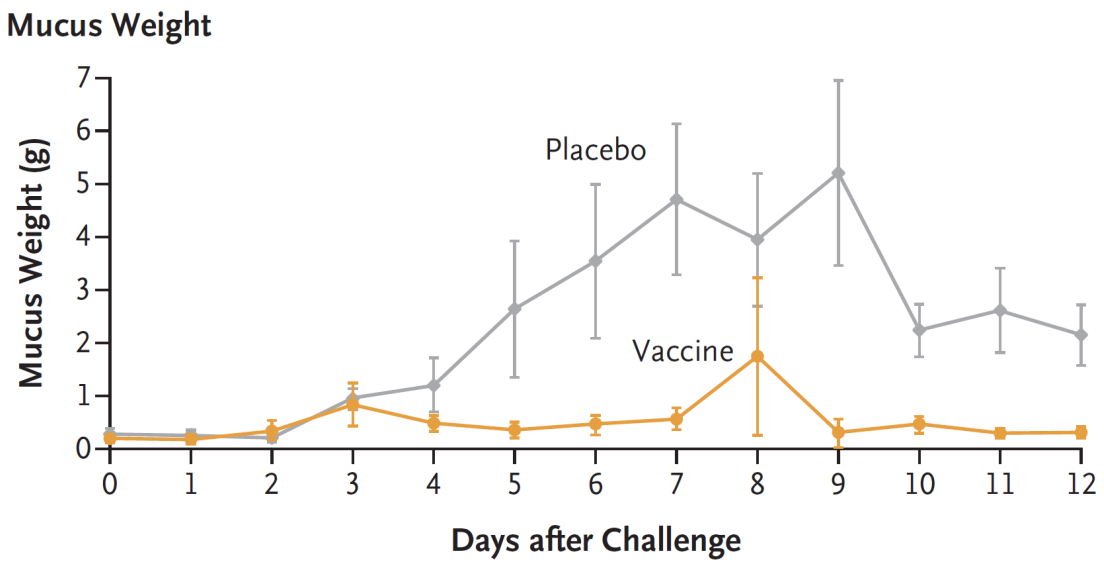
Assessing nasal discharge (mucus weight)

- Weighing tissues is a crude but effective tool



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Protocol: **Visit**

Subject Initials: ____

Subject No.: ____

Symptom Diary Card

Date dd mmm yyyy **Time** hh : mm

Morning ☐ **Afternoon** ☐ **Evening** ☑

Symptoms Please report the highest level of symptoms you have experienced since completing the last diary card (if applicable), including any symptoms you currently have (tick ONE in each row)	I have NO symptoms	Just noticeable	It's clearly bothersome from time-to-time, but it doesn't interfere with me doing my normal daily activities	It's quite bothersome most or all of the time, and it stops me from participating in activities
Runny Nose	☐ 0	☐ 1	☐ 2	☐ 3
Stuffy Nose	☐ 0	☐ 1	☐ 2	☐ 3
Sneezing	☐ 0	☐ 1	☐ 2	☐ 3
Sore Throat	☐ 0	☐ 1	☐ 2	☐ 3
Earache	☐ 0	☐ 1	☐ 2	☐ 3
Malaise/Tiredness	☐ 0	☐ 1	☐ 2	☐ 3
Headache	☐ 0	☐ 1	☐ 2	☐ 3
Muscle and/or Joint Ache	☐ 0	☐ 1	☐ 2	☐ 3
Chilliness / Feverishness	☐ 0	☐ 1	☐ 2	☐ 3
Cough	☐ 0	☐ 1	☐ 2	☐ 3
Chest Tightness	☐ 0	☐ 1	☐ 2	☐ 3
Shortness of breath	☐ 0	☐ 1	☐ 2	☐ 3
Wheeze	☐ 0	☐ 1	☐ 2	☐ 3

Volunteer's Initials _____

 Symptom Diary Card RVL-OCS-001 Page 1 of 2

Extensive Experience results in Improved Trial Design

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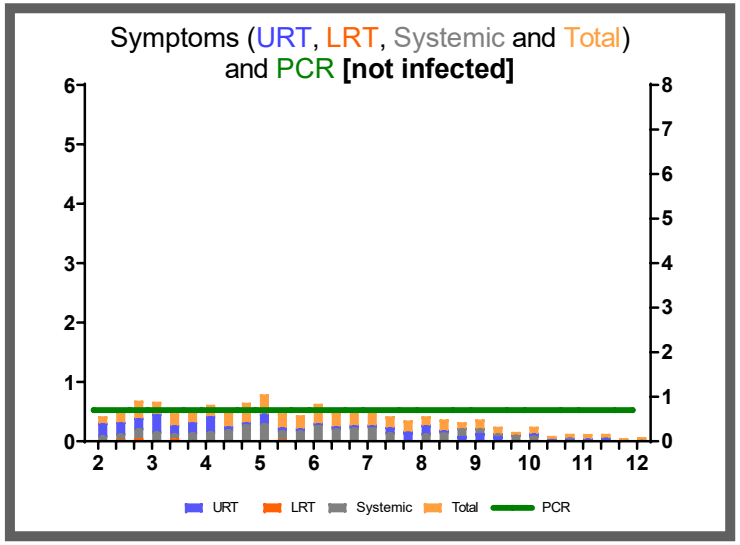
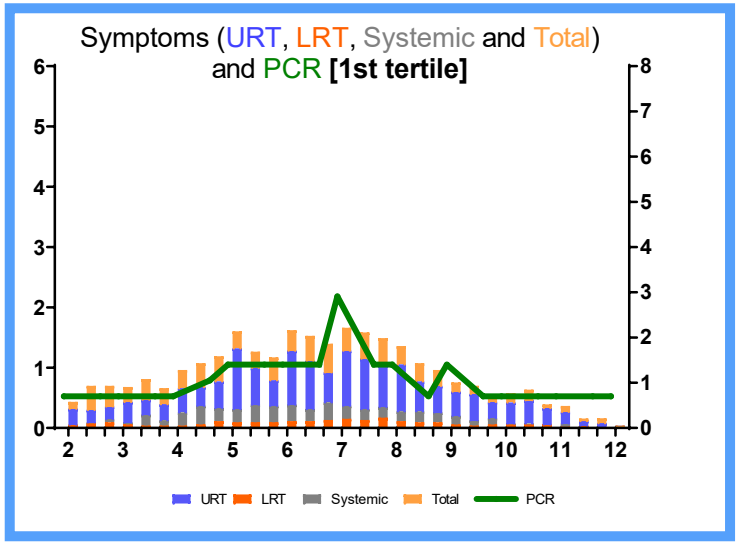
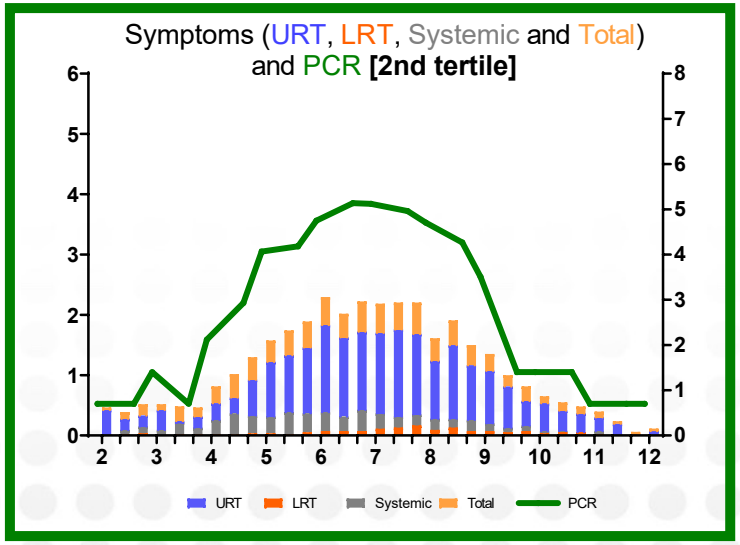
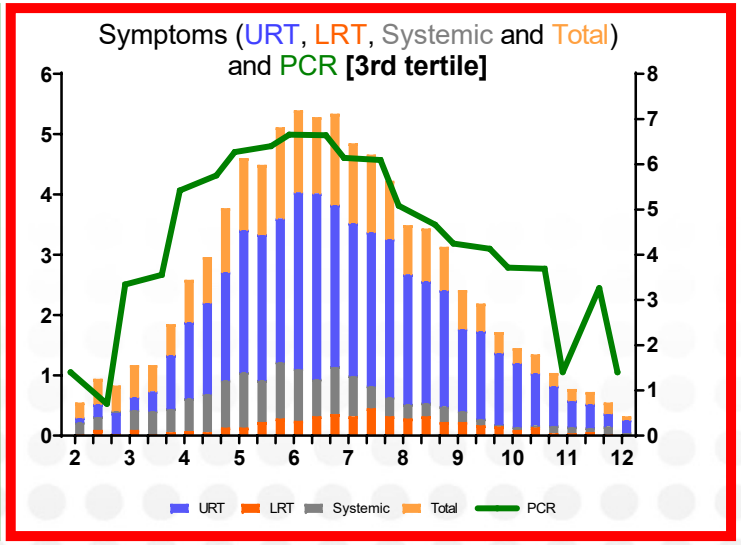
A meta-analysis combining all RSV subjects in our database across multiple studies

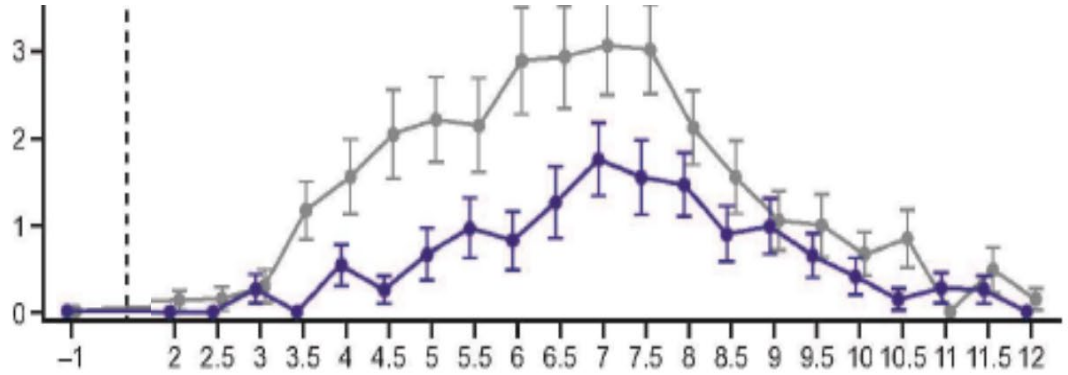


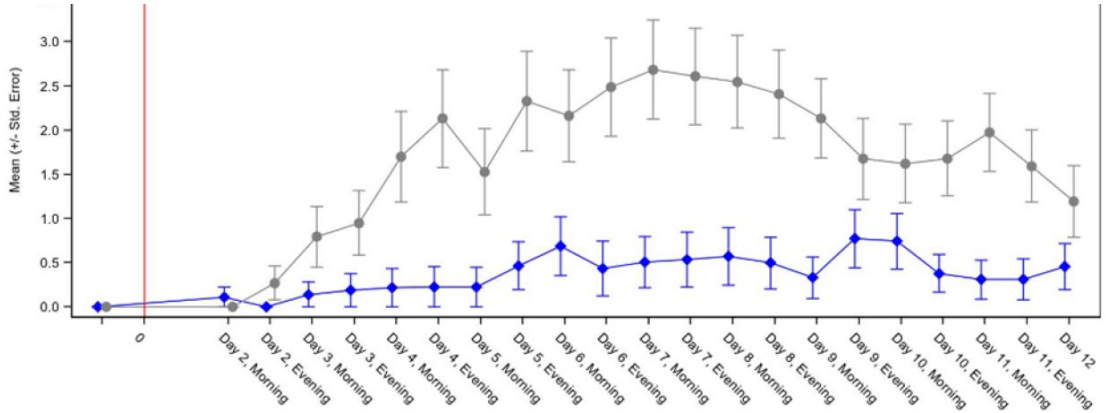


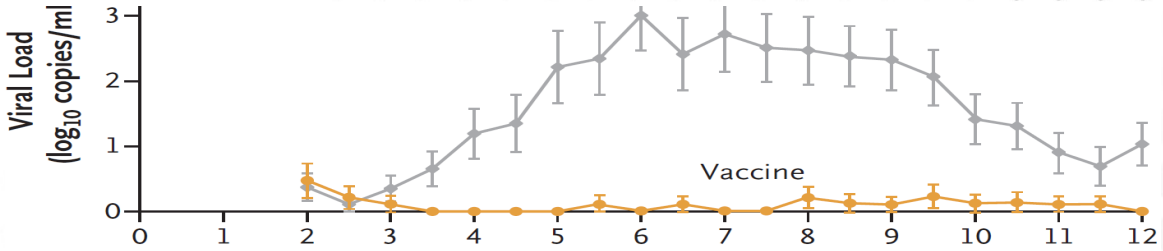




Strong Regulatory Benefits – Key Driver for Clients







FDA Breakthrough Designation

J&J (Sadof et al, 2021)
Ad26.RSV.preF vaccine
- vaccine in purple
- placebo in grey

FDA Breakthrough Designation

Bavarian Nordic (corporate website Sep 2021)
MVA-BN RSV vaccine
- vaccine in blue
- placebo in grey

FDA Breakthrough Designation

Pfizer (Schmoele et al, 2022)
RSVPreF vaccine
- vaccine in orange
- placebo in grey

Expanding the Revenue Potential

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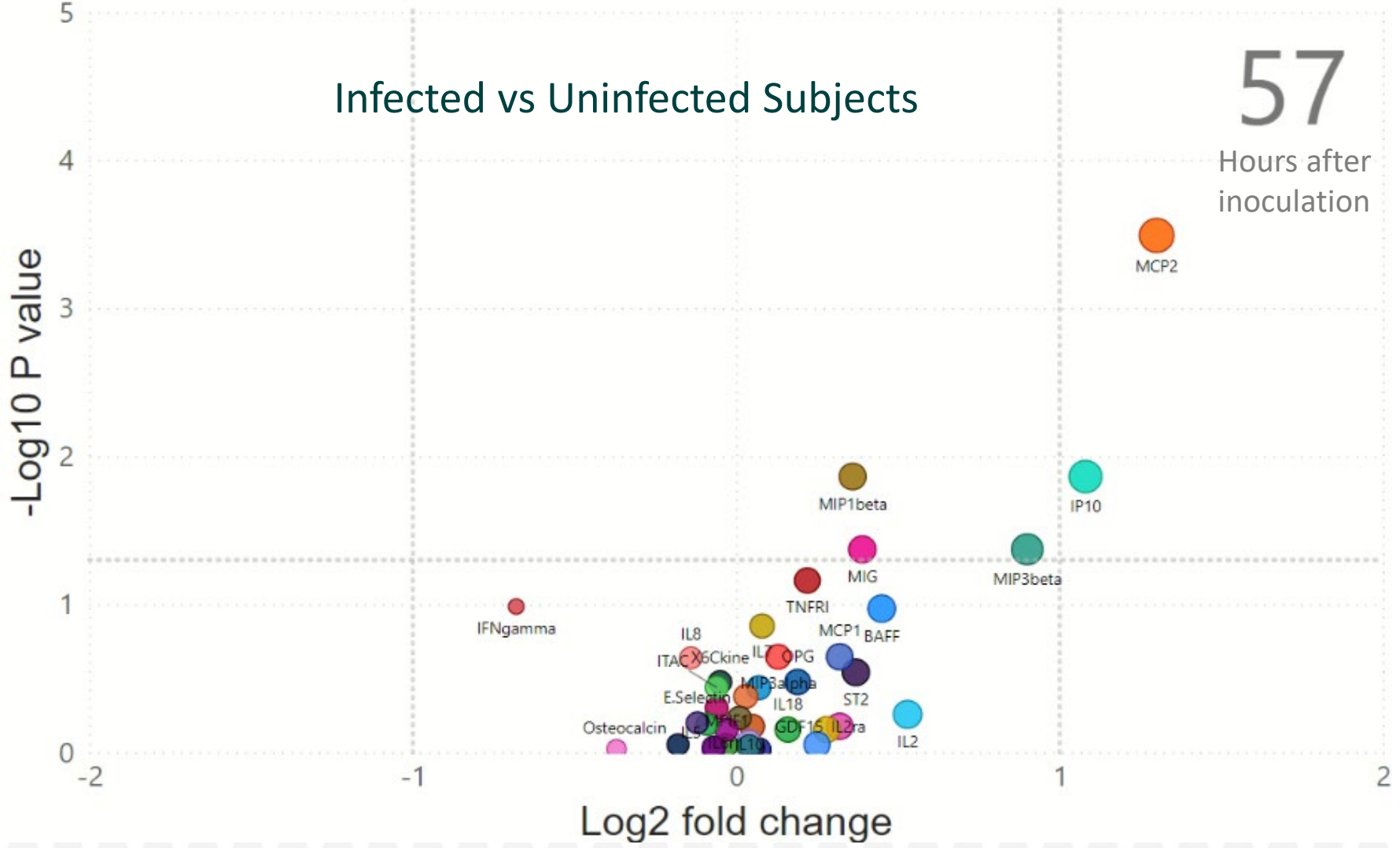
Pharma & biotech can now gain vital data as an add-on service



Challenge studies facilitate close examination of the body's response to infection and / or vaccination

An End-to-End Service for Vaccine Testing

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Swab collection from community acquired disease

CLINICAL SAMPLE

Isolate virus and matched to vaccine target

Produce GMP grade virus batch

Conduct characterisation study to determine best dose of virus

Conduct vaccine challenge study

Typical challenge study starting point

1. Larger revenue as numerous extra steps contracted
2. Better meets clients needs as virus matches specific target strain
3. Increased market opportunities as potential to test new products that require new virus strain

Recent Contracts

- Bespoke Influenza model with Big Pharma client (£14.7m)
- New Influenza model with Big Pharma client (£10.4m)
- Omicron COVID-19 challenge model with Vaxart Inc

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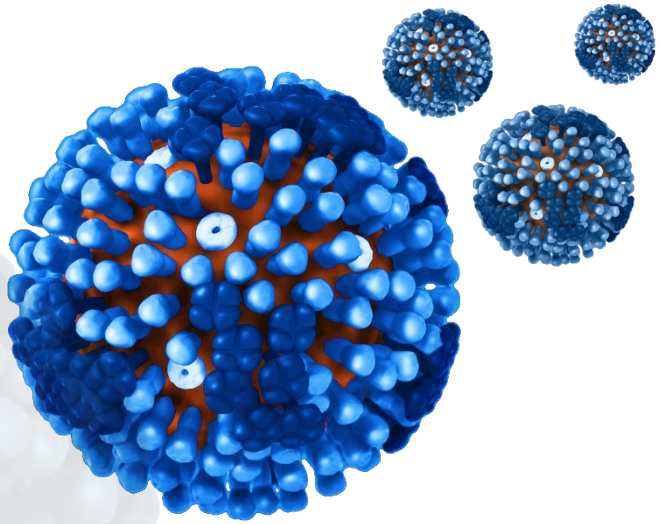
Douglas Thomson

Chief Executive Officer
Pneumagen

Biopharma insights – Why do a challenge trial?

Pneumagen



Broad-Spectrum Anti-Virals

hVIVO Capital Market Day

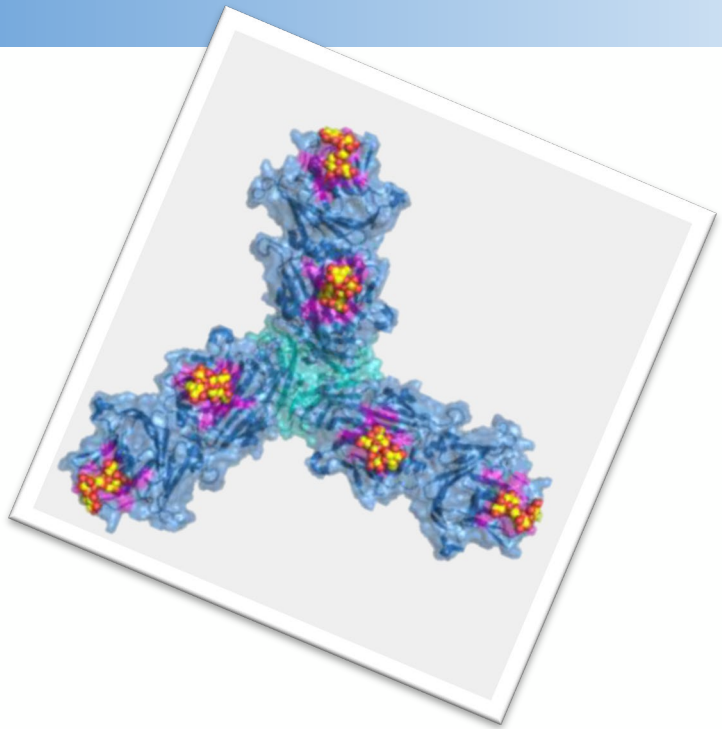
2 November 2022

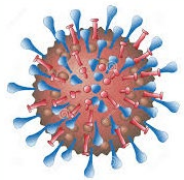
Pneumagen

- Pneumagen & Neumifil
- Major Value Inflection from CHIM
- Undertaking a Controlled Human Infection Model
- Execution certainty
- Big Pharma Validation
- Selecting hVIVO for our study

Pneumagen – A Clinical Stage Biotech Business

- Neumifil - broad-spectrum anti-viral for prevention of exacerbation in patients with respiratory disease
- $Bn+ Target Addressable Market
- Further upside in other high-risk groups




Influenza


Coronavirus


Rhinovirus


RSV

Experienced Executive Team, Board, SAB & Clinical Advisory Group

+£18M of funding in total raised to 2022

Eight - granted & pending - **owned** patent families Platform, **Composition** & Use

IP protection to **2041+**

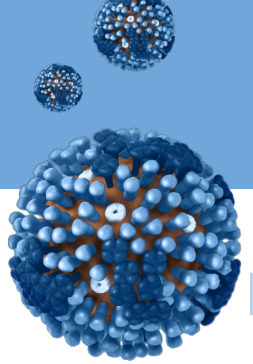
Neumifil – A Broad-Spectrum Anti-Viral

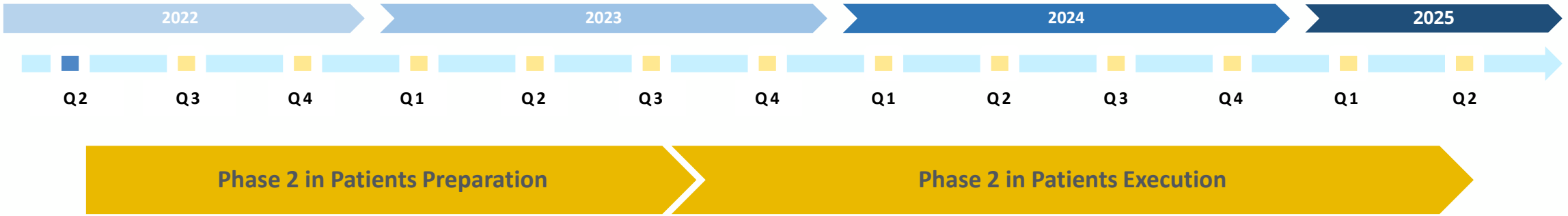
- **Neumifil**, a **Broad-Spectrum** anti-viral product for the prevention of exacerbation in patients with respiratory disease
- Demonstrated broad-spectrum preclinical efficacy
- Phase 1 study completed – **safe and well-tolerated**
- Phase 2 CHIM initiated in August 2022 – delivers clinical **Proof of Concept in mid-2023**
- $Bn+ Target Addressable Market

Courtesy of Aptar Pharma

Pneumagen

Neumifil – CHIM Delivers a Major Value Inflection





Phase 2
Influenza Human Challenge

CHIM Major Value Inflection

- Market recognises value of CHIM Phase 2 study
- Mitigates risk of later clinical development
- Translates Preclinical Safety & Efficacy to Humans
- Demonstrates Drug Mechanism of Action in Humans
- Further CHIMs later in development

Pneumagen

CHIM Delivers Execution Certainty

Recruitment of Healthy Subject

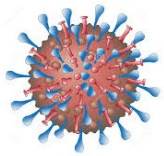
~100 subjects – statistical power

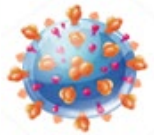
Certain delivery infectious dose – not a field study

Understanding of Infection kinetics & symptomology – Endpoint definition feasible

Deep regulatory experience of CHIMs in UK

Multiple disease models


Influenza

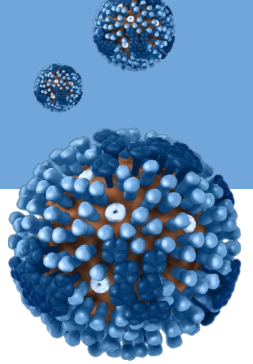

Coronavirus


Rhinovirus


RSV

Pneumagen

Neumifil – Phase 2 Controlled Human Infection Model



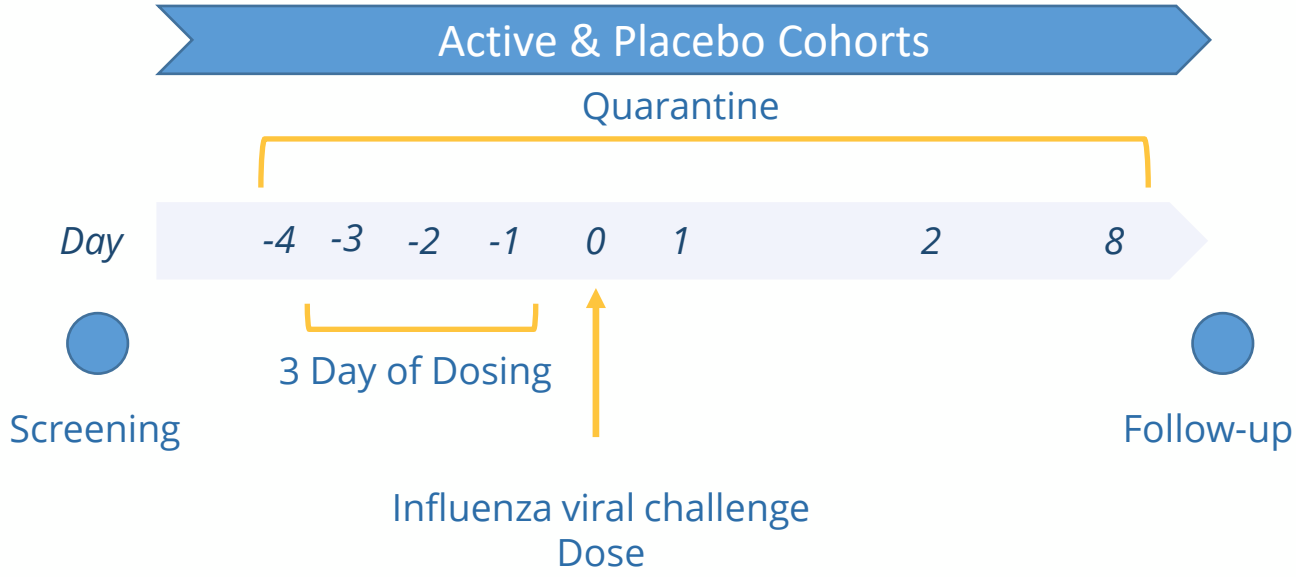
Neumifil Phase 2 PoC Influenza Challenge Study

Controlled Human Infection Model (CHIM)

Limited execution risk

- Controlled study with defined timelines & population
- Healthy subjects (18-55) screened for Serosuitability

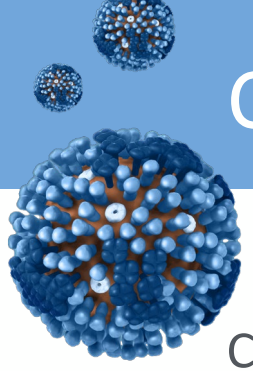
Study Design	Placebo controlled, double-blinded phase 2 study
End Points	Infection & Symptomology
Cohorts	3 cohorts; 100 subjects
Challenge Strain	Influenza (H3N2)



Cohort	D-3	D-2	D-1
Placebo	Placebo	Placebo	Placebo
Single Active Dose	Neumifil	Placebo	Placebo
Three Active Doses	Neumifil	Neumifil	Neumifil

Pneumagen

CHIMs – Pharma Validation



CHIMs widely used by Big Pharma for in-house development - J&J, Pfizer, etc…

- PoC
- Dose Ranging
- Dose schedule
- Updating Vaccine antigens
- Biologics, vaccines, small molecule or antibodies

Big Pharma Recognition of CHIM value

- Pfizer acquires Reviral for $525M on CHIM data

"All Roads Lead to **hVIVO**" – Big Pharma

Pfizer Completes Acquisition of ReViral

Thursday, June 09, 2022 - 10:00am

.q4default .bwalignc { text-align: center; list-style-position: inside }.q4default .bwlistdisc { list-style-type: disc }

Acquisition expands Pfizer's anti-infective pipeline and reinforces commitment to developing both medicines and vaccines to help combat respiratory syncytial virus (RSV)
NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced the successful completion of its acquisition of ReViral, a privately held, clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing novel antiviral therapeutics that target respiratory syncytial virus (RSV).

ReViral brings to Pfizer a portfolio of promising therapeutic candidates, including sisunatovir, an orally administered inhibitor designed to block fusion of the RSV virus to the host cell. Sisunatovir has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA). It significantly reduced viral load in a phase 2 RSV human challenge study in healthy adults and is currently in phase 2 clinical development in infants. The development program for sisunatovir is expected to continue in both adult and pediatric populations. A second program is focused on the inhibition of RSV replication targeting the viral N protein. The lead candidate in this program is currently in phase 1 clinical development.

"We are excited to bring ReViral's promising investigational treatments for RSV into our anti-infective pipeline at Pfizer. This acquisition further demonstrates our commitment to advancing pioneering science – both through our in-house expertise and our work with leading, innovative companies – with the goal of delivering new breakthroughs to patients suffering from serious infectious diseases," said Mikael Dolsten, M.D., Ph.D., Chief Scientific Officer and President, Worldwide Research, Development and Medical of Pfizer. "We believe these therapeutic candidates – and the scientific expertise that has advanced their development – will complement our ongoing work to help combat RSV infections, and we look forward to welcoming our new colleagues to further support these endeavors."

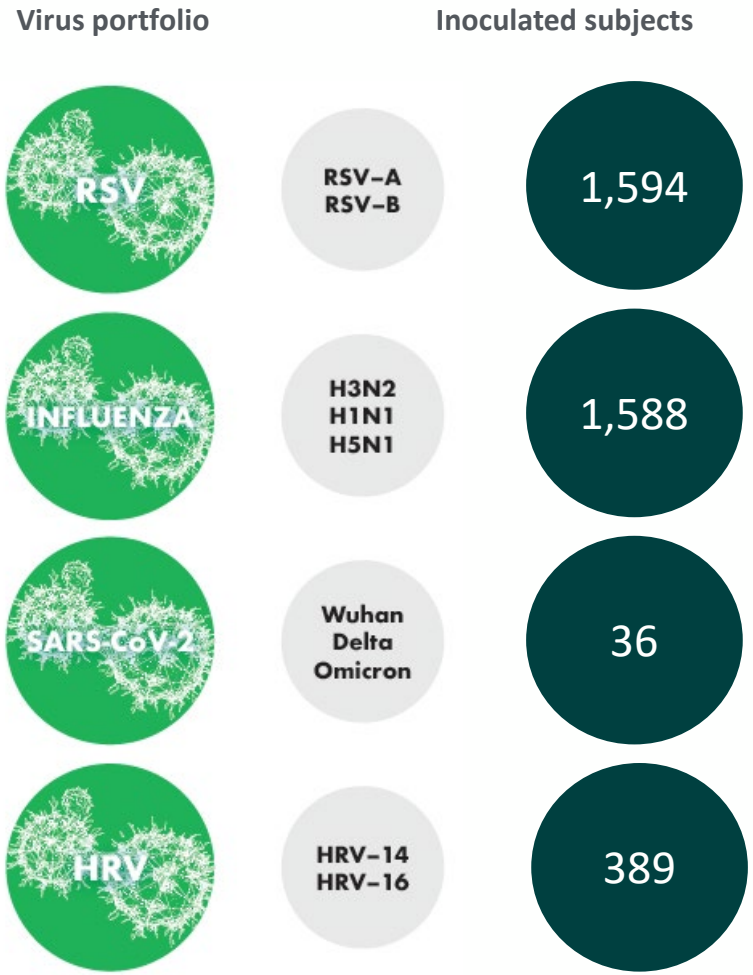
RSV is a respiratory pathogen, which can lead to severe and life-threatening lower respiratory tract infections (LRTIs) in high-risk populations, including young children, immunocompromised individuals, and older adults. It is estimated to cause infections in approximately 64 million people, resulting in about 160,000 deaths, globally each year. Currently, treatment options for RSV are limited, with care management focused primarily on supportive measures for people with the illness.

Additional Transaction Details

Under the terms of the agreement, Pfizer acquired ReViral for a total consideration of up to $525 million, including upfront and development milestones. If successful, Pfizer believes annual revenue for these programs has the potential to reach or exceed $1.5 billion.

Selecting *hVIVO* in H2 2021

- ✓ Competitive bid process in Q4 2021
- ✓ Diligence conducted - site visits, F2F meetings, & desk research
  - ✓ *Facilities & logistics*
  - ✓ *Track record of CHIMs*
  - ✓ *Budget*
  - ✓ *Contractual*
- ✓ Strong capability of senior team
- ✓ No national barriers to supply (supply chain all UK based)
- ✓ MHRA regulatory submission



Pneumagen

Selecting *hVIVO* in H2 2021

Specialist Challenge CRO – focus on CHIMs

- Conducting CHIMs since 2001

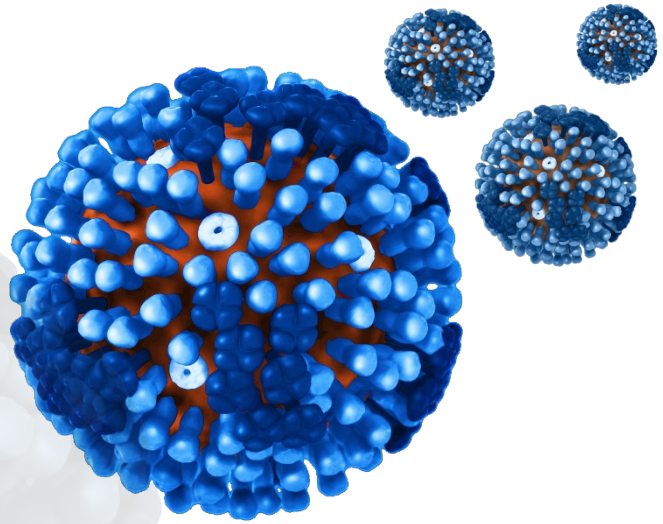
Multiple CHIMs conducted

- 7 studies conducted with H3N2 influenza strain
- **Deep understanding of performance of challenge strain**
- Viral load & symptomology data available to power study

Trade references taken up with Big Pharma

- "Strongly recommends" *hVIVO* as Challenge CRO

Pneumagen



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hVIVO

formerly Open Orphan plc

Peter Openshaw

Professor of Experimental Medicine
Imperial College London

Insights into mechanisms of defences and disease from human challenge trials

hVIVO

formerly Open Orphan plc

Fireside chat

Peter Openshaw, Imperial College London
Douglas Thomson, Pneumagen
Andrew Catchpole, hVIVO

COVID-19 and challenge trials:
A paradigm shift for drug development

hVIVO

formerly Open Orphan plc

Eglé Pavyde

Director, Business Development

Strategy for growth

Market trends & growing interest in challenge studies

hVIVO

formerly Open Orphan plc

Service Offering

Company Overview

hVIVO

formerly Open Orphan plc

hVIVO

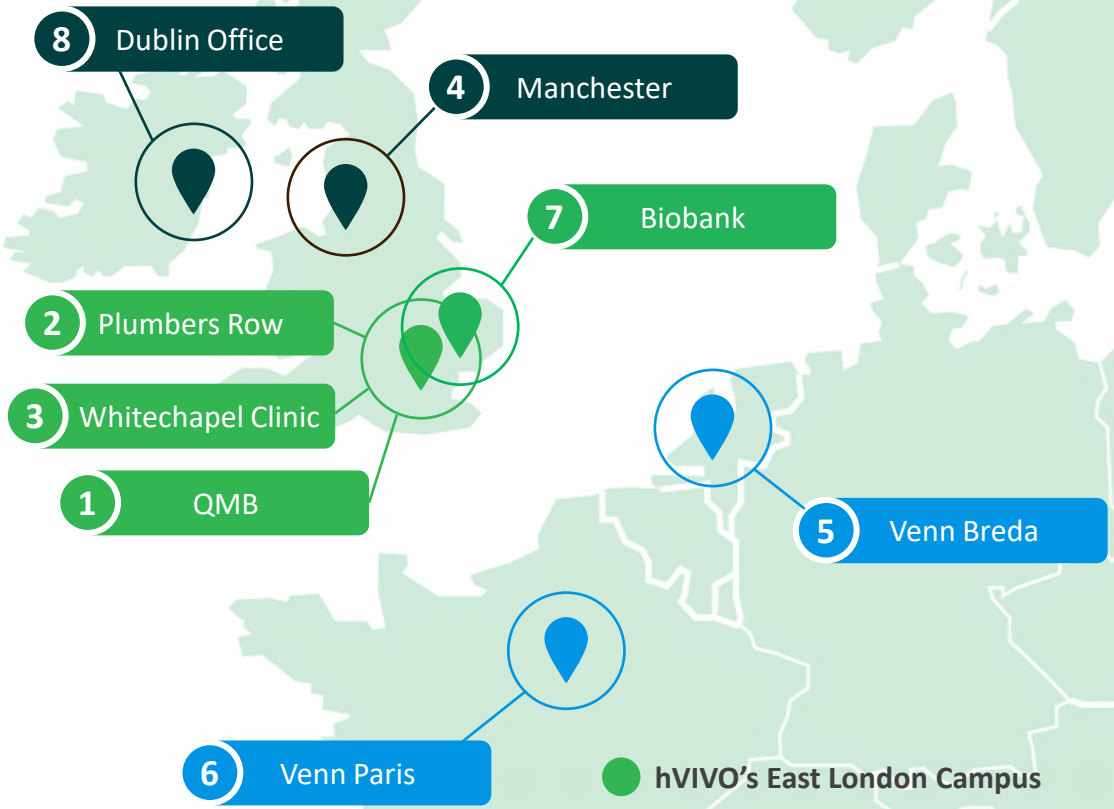
- World Leader in Human Challenge Trials with Onsite Virology Labs
- FluCamp: tech-enabled volunteer and patient recruitment platform

Venn Life Sciences

part of hVIVO

- Early Clinical Drug Development Services
- Biometric services

	Location	Facility
1	**Queen Mary's BioEnterprise Centre (QMB)**	Quarantine unit Virology Laboratory
2	**Whitechapel Clinic**	Quarantine Unit
3	**Plumbers Row**	FluCamp Volunteer Recruitment Phase I / II Site Facility Corporate Office
4	**Manchester**	FluCamp Volunteer Recruitment Vaccination Site



Venn Life Sciences – from Discovery to Marketing Authorization

hVIVO
formerly Open Orphan plc

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

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**

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

hVIVO – A Full-Service Human Challenge CRO

hVIVO
formerly Open Orphan plc

SCIENTIFIC

- **Study** Design
- **Protocol Writing**
- **Development of new** Challenge Models
- **Clinical Study Report Writing**
- **Scientific** Publications

REGULATORY

- **Interactions with Competent Authorities**
- **Scientific Advice**
- **Clinical Trial Applications**
- **CA/EC** Submissions

CLINICAL

- Human Challenge Studies
- **Phase II-III Vaccine Studies**
- **Non-first-in-human healthy** Volunteer Studies
- **Mild** Condition Patient Studies

LABORATORY

- **Assay Development**
- **Virology** Lab Services
- **Filed trial** Biologistics
- **Biomarker Analysis**
- **Biobank Services**

Benefits of Human Challenge Trials

hVIVO
formerly Open Orphan plc

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 Break Through designation
- Potential approval and Emergency Use Authorisation

FINANCIAL

- Significant valuation uplift for Biotech sponsor
- Allows products to “Succeed fast” or “Fail Fast”

hVIVO
formerly Open Orphan plc

Strategy for Growth

Strengthening Business Development

Rich Niemi
Senior Director Business Development
US & Canada

Eglé Pavyde
Director Business Development
Europe & APAC

BUSINESS DEVELOPMENT

SCIENTIFIC SUPPORT

Additional scientist assigned to support interactions with clients and proposal preparation process

BUSINESS OPERATIONS AND MARKETING

New FTEs added to increase prospecting / lead generation activities and support
Revised marketing structure to focus on **B2B marketing**

LEGAL AND FINANCE

2 new FTEs to Legal and Finance functions to speed-up proposal budgeting and contract review process

CLINICAL OPERATIONS

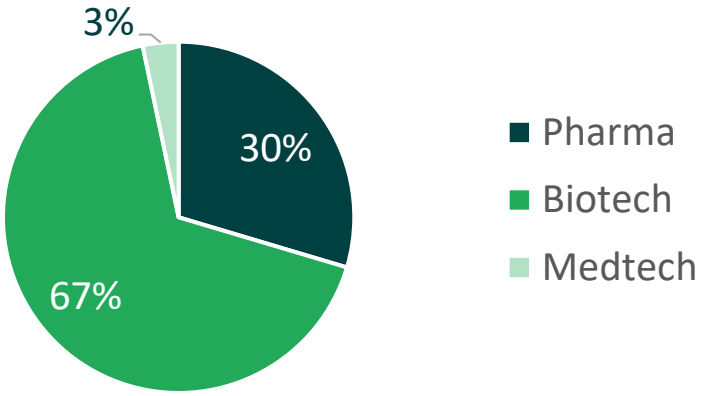
PI assigned to support proposals for field studies

SALES FOCUSED ORGANISATION

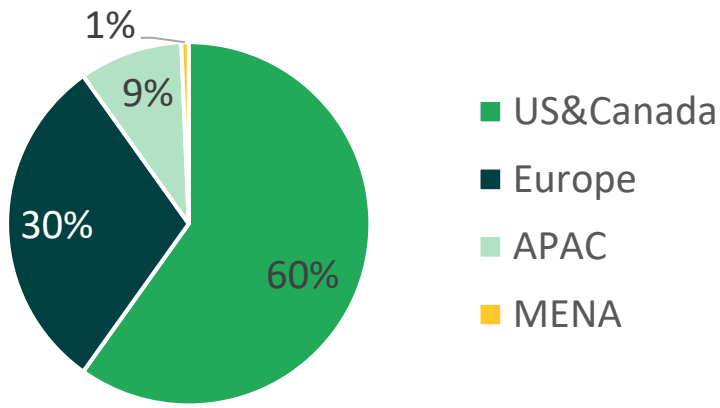
Diverse and Growing Pipeline

formerly Open Orphan plc

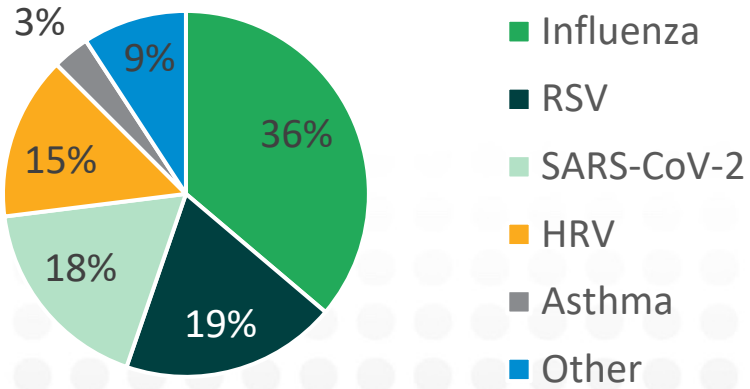
Pipeline distribution by client type



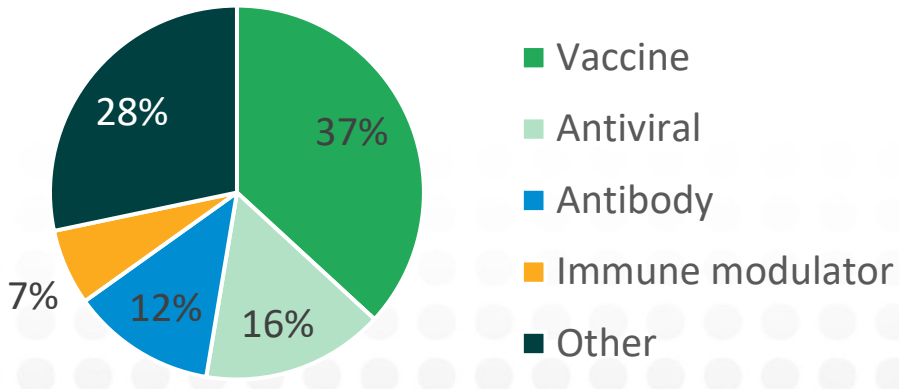
Pipeline distribution by region



Pipeline distribution by model



Pipeline distribution by IMP



New Challenge Models Following Customer Demand

hVIVO
formerly Open Orphan plc

Existing Models

- Influenza
- COVID-19 (Wuhan)
- RSV
- Asthma
- HRV
- Malaria

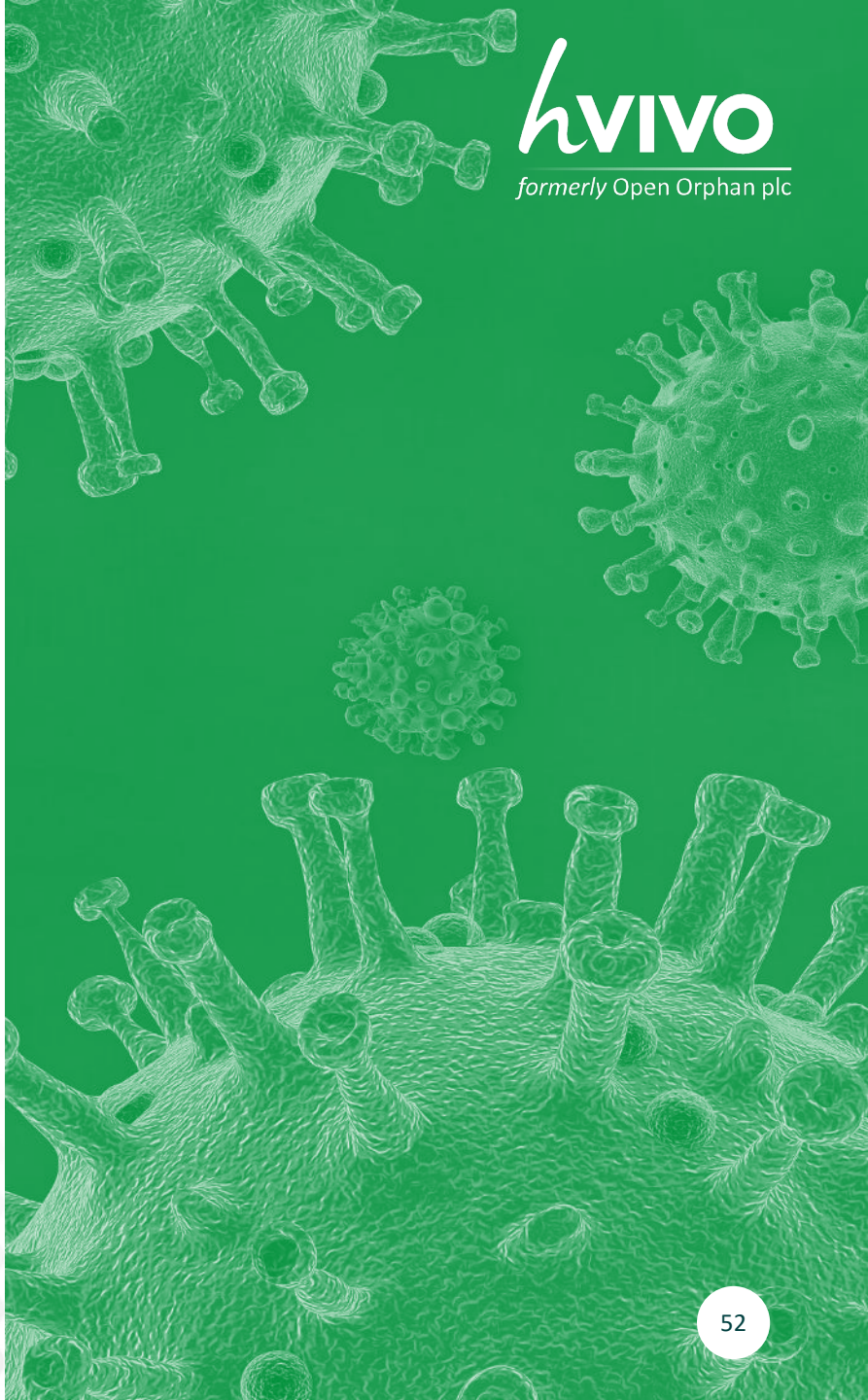
Models Under Development

- Omicron
- New Influenza model
- Dengue

Opportunity for further challenge models to attract additional clients

Potential Infections Suitable for Challenge

Common cold *(Adenovirus, Human coronavirus 229E,* Parainfluenza viruses, Rhinovirus)	Hookworm disease
Tuberculosis	Gonorrhoea
Diarrhoea (*Campylobacter jejuni, Giardia lambia, Rotavirus)*	Neisseria lactamica
Thrush (*Candida albicans)*	Norovirus
Chlamydia	Slapped cheek disease (*Parvovirus)*
Cryptosporidiosis	*Listeria*
Cyclosporiasis	Pneumonia, meningitis (*Streptococcus pneumoniae)*
Dengue	Typhoid fever
E. coli	Salmonella
Tularaemia	Scabies
Chancroid	Schistosomiasis
Peptic ulcer, gastric cancer (*Helicobacter pylori)*	Dysentery
Influenza	Strep throat, rheumatic heart disease *Streptococci (non-pneumococcal)*
Lactobacillus	Strongyloidiasis
Leishmaniasis	Cholera



Expansion of Services

hVIVO formerly Open Orphan plc

Expanding service portfolio by utilising existing expertise and resources – increasing efficiency

hVIVO

- Phase II-III vaccine field studies
- Non-first-in-human healthy volunteer studies
- Mild condition patient studies

Venn Life Sciences part of hVIVO

- Advanced therapy medicinal products
- Medical devices

CHALLENGE STUDIES REMAINS CORE BUSINESS FOCUS

FluCamp Recruitment Platform

formerly Open Orphan plc

Volunteer 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+	100%	c.85%
Active Volunteers in Existing Database	Trial Recruitment Success	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[1]*

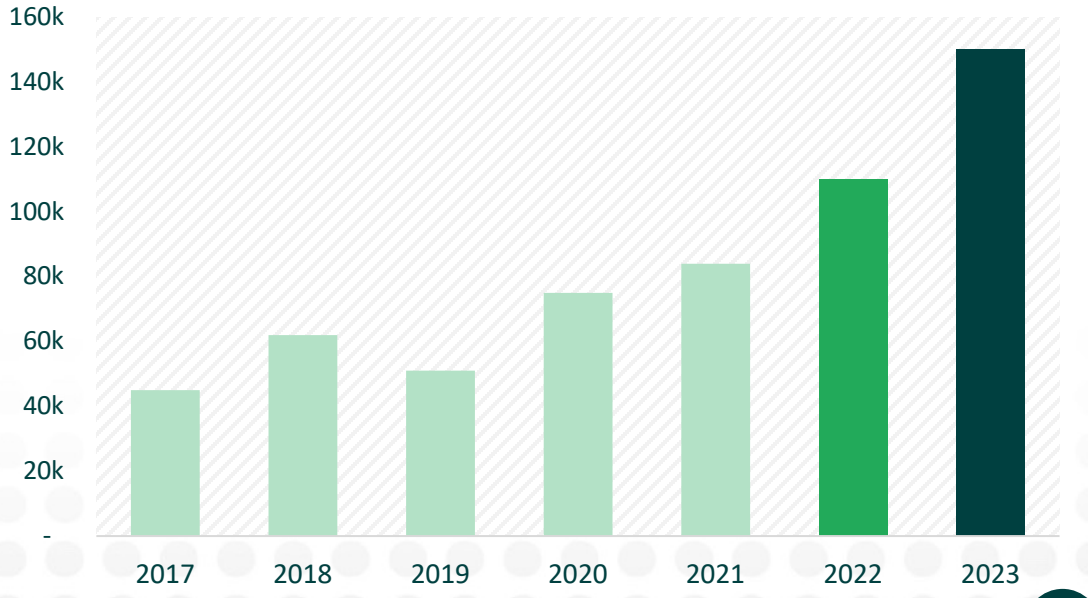
55% *Volunteer recruitment issues account for 55% of cancelled clinical trials[2]*

London Manchester

2022 FluCamp Improvements

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

FluCamp Leads



Note (1): Sources: Perspective in Clinical Research
Note (2): Sources: GlobalData

BD strategy for hLAB / Venn Life Sciences

hVIVO
formerly Open Orphan plc

B2B Marketing

Increase hLAB and Venn **brand awareness**

Lead generation

Increase business for hLAB as **stand-alone service**

Increase **cross-sell** and **upsell**

BD team collaboration

hVIVO

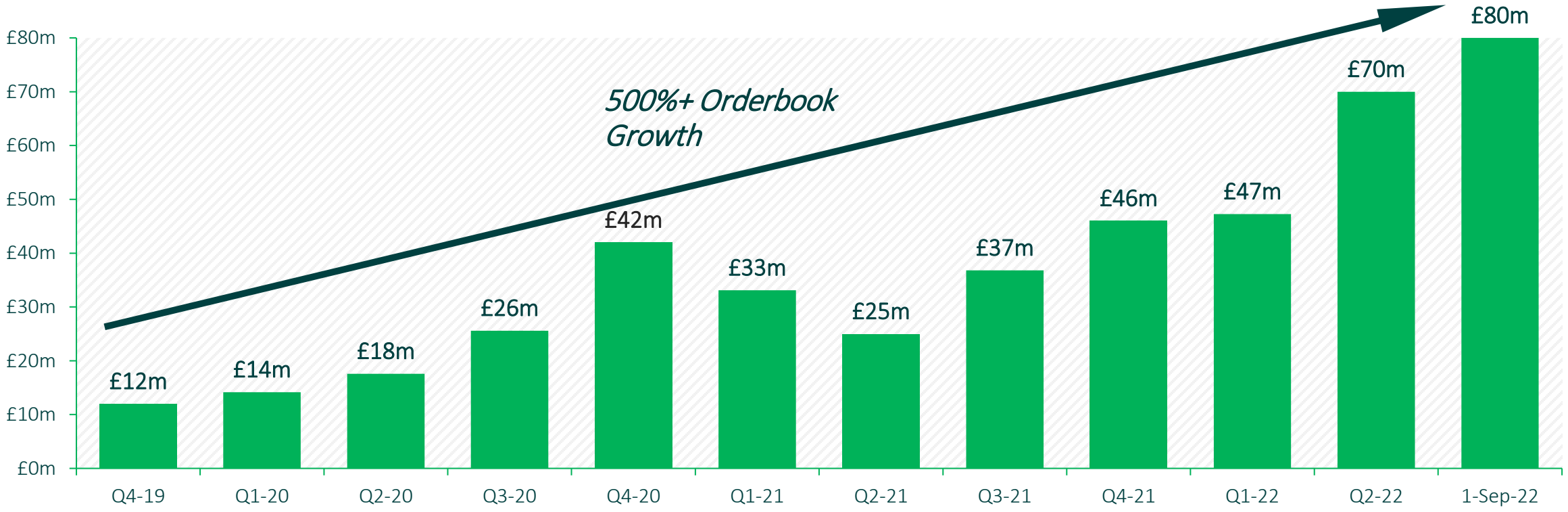
formerly Open Orphan plc

Stephen Pinkerton

Chief Financial Officer

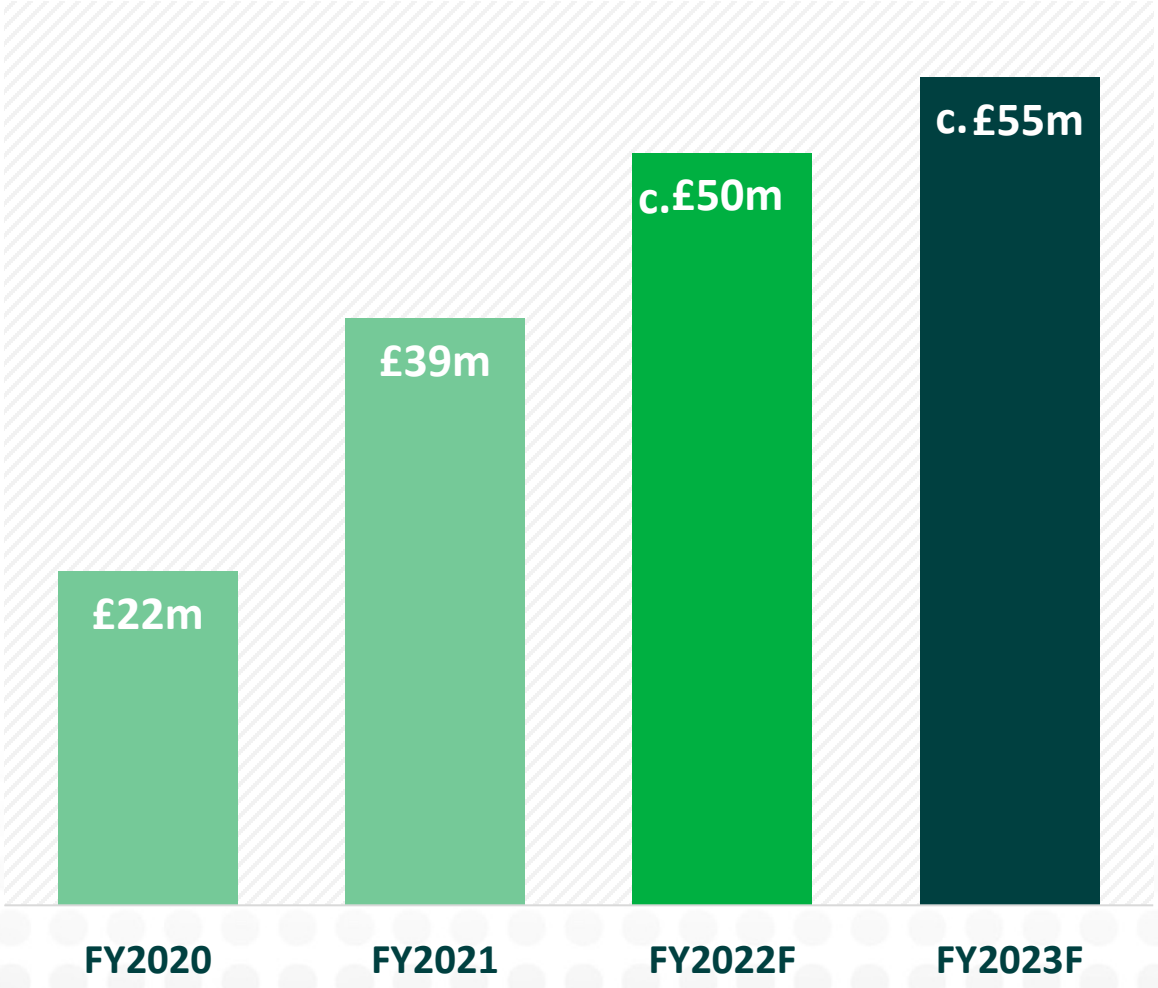
Financial outlook – key performance metrics

Record Contracted Orderbook



- ***C.45% of orderbook is comprised of Big Pharma customers***
- ***c.80% FY23 Revenue contracted***
- ***Building revenue visibility into 2024***

Market Consensus



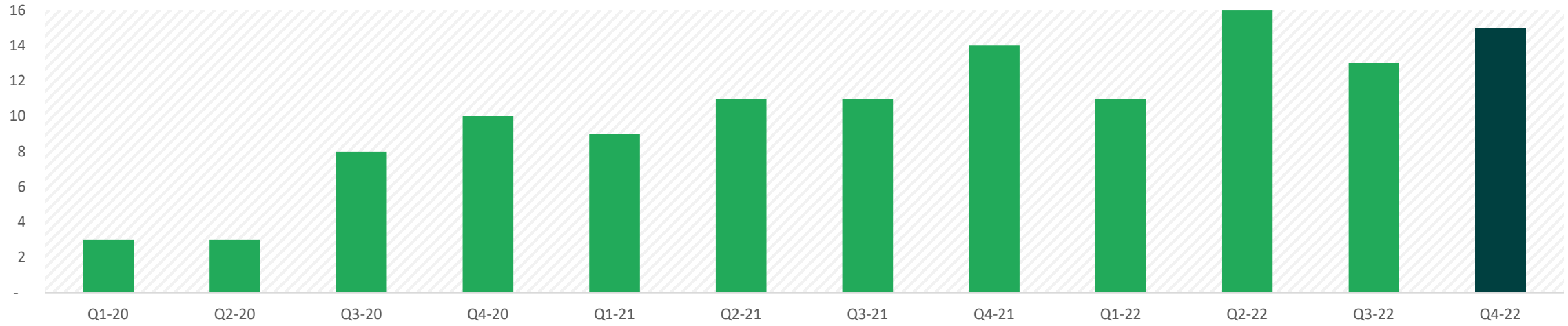
Revenue

- Full year guidance remains at c.£50m revenue for 2022
- On target through to the end of September 2022
- Focus on orderbook conversion into 2023 targeting c.£55m of revenue
- c.80% of 2023 revenue already contracted

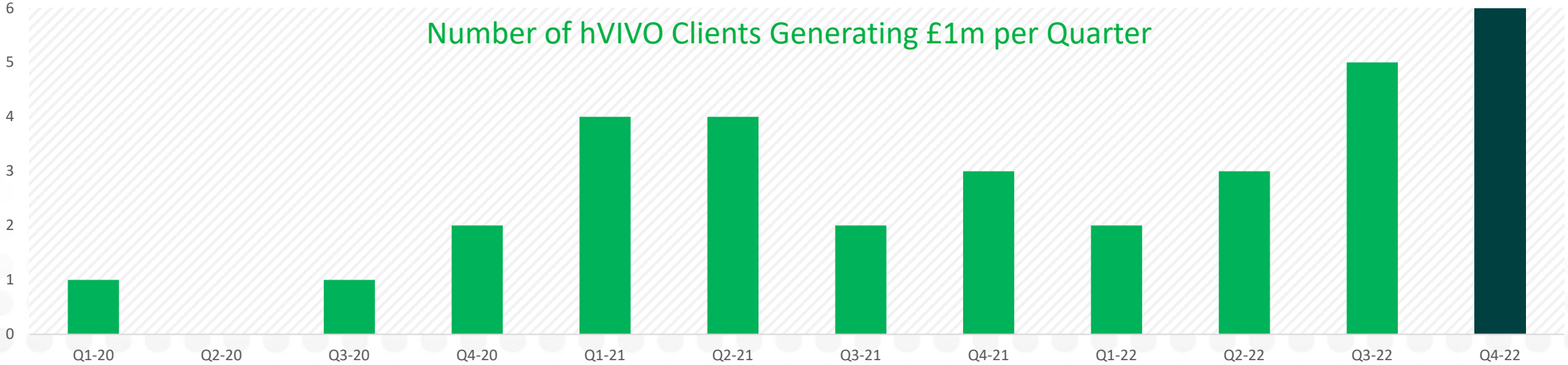
Our Challenge Study Business - Busier Than Ever

hVIVO formerly Open Orphan plc

Number of Active hVIVO Studies per Quarter

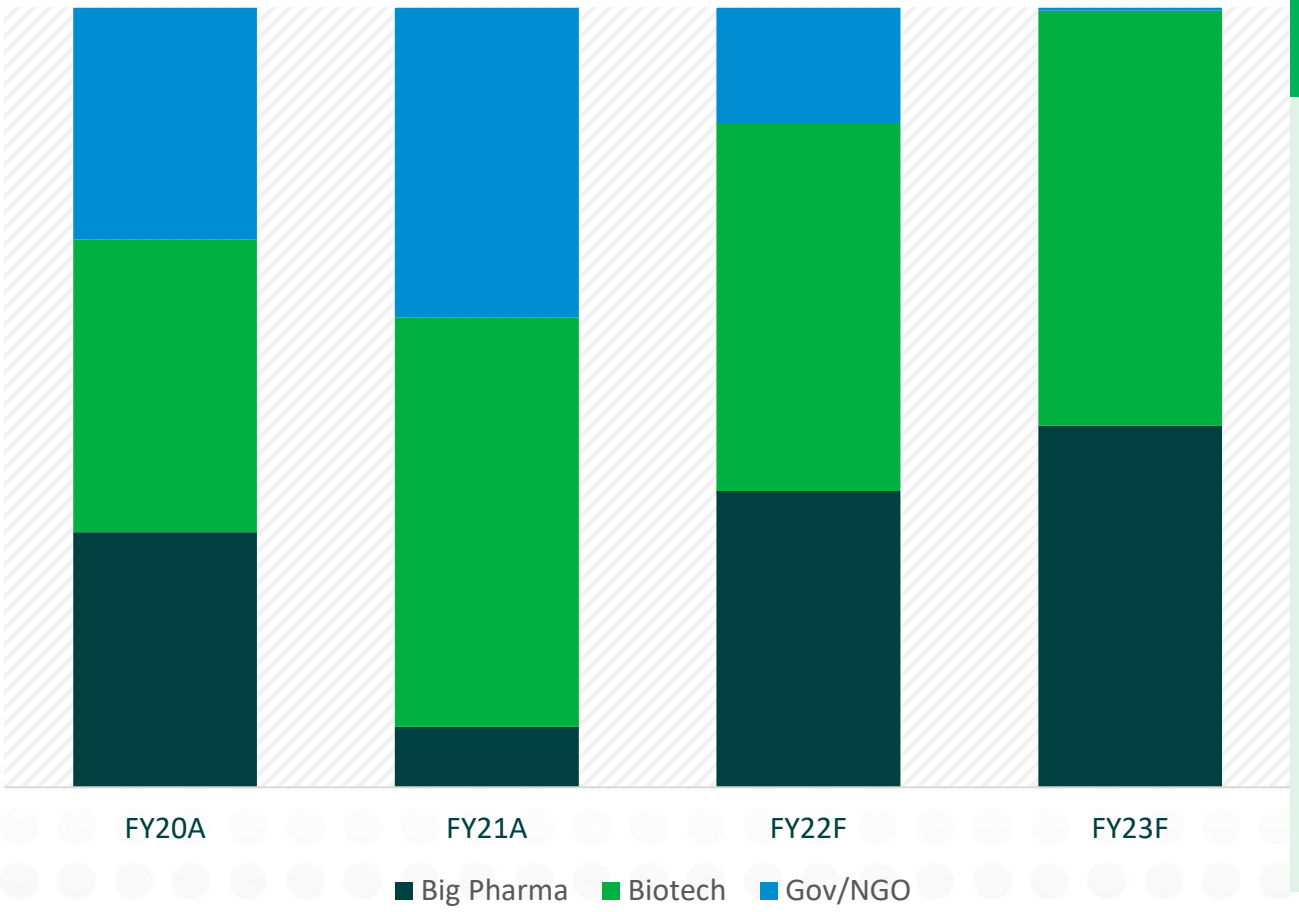


Number of hVIVO Clients Generating £1m per Quarter



hVIVO's Revenue Mix

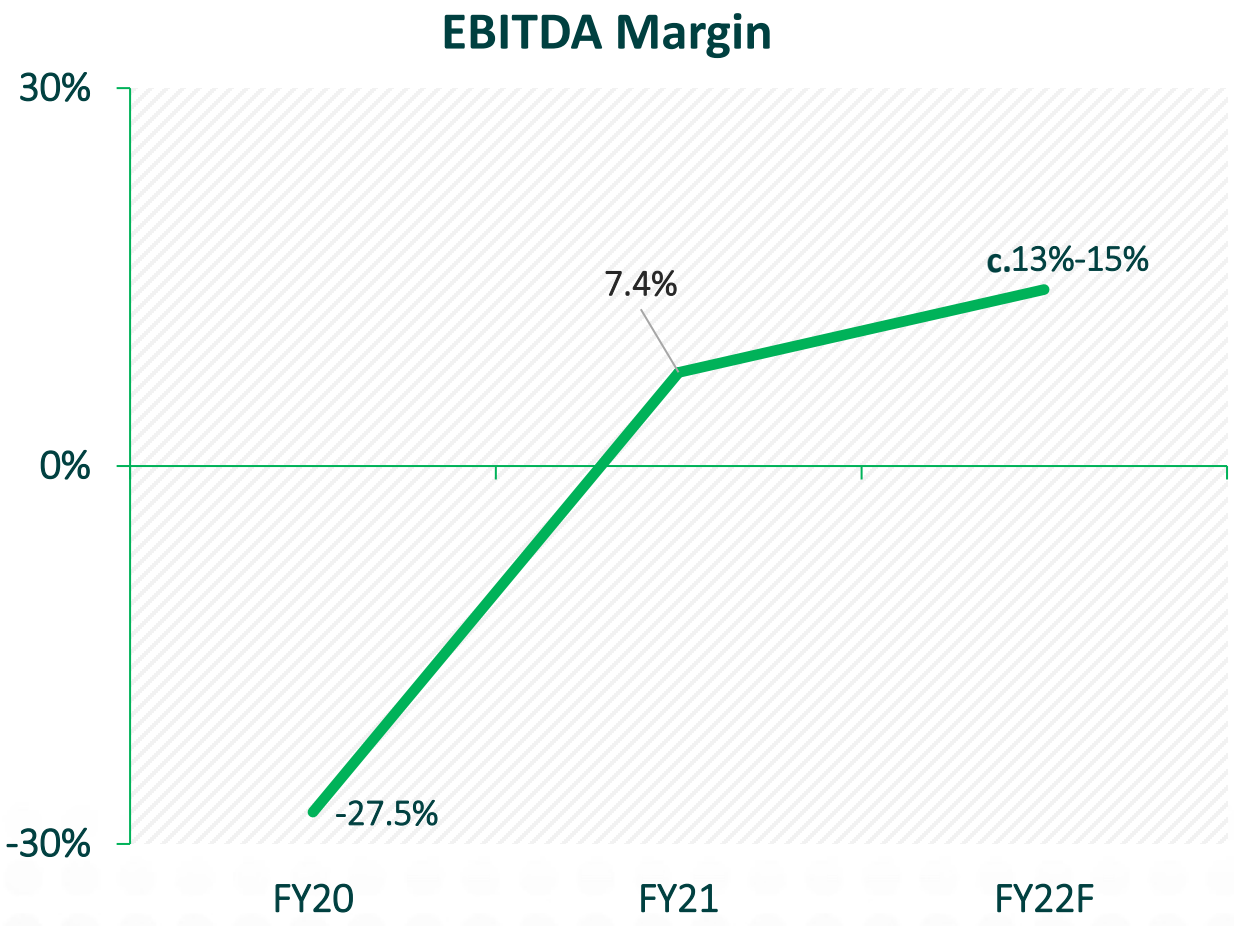
% of Revenue Mix by year



Revenue Mix

- ✓ As we continue to grow rapidly, commercial challenge studies with Big Pharma & Biotech are the key drivers of our revenue mix
- ✓ Several notable recurring Big Pharma clients completing studies in FY22 and FY23
- ✓ Reduced reliance on Government / Non-Profit studies

Sustainably Profitable



Significant Operational Efficiencies

Significant turnaround within two years – in-line with projections of 13-15% EBITDA margin for FY22. This improvement is driven by:

- ✓ Productivity gains
- ✓ Increased utilisation of staff & facilities
- ✓ FluCamp - generic screening & increased volunteer reach
- ✓ Operational leverage gains

Well positioned to deliver sustainable revenue & EBITDA growth into the future

hVIVO

formerly Open Orphan plc

Yamin ‘Mo’ Khan

Chief Executive Officer

Closing remarks

Investment Case

formerly Open Orphan plc

01 Exciting Market Dynamics

- World leader in challenge trials with a growing library of challenge models
- Increasing number and size of challenge trials
- Reasons to conduct challenge trials continue to grow
- Rapidly growing infectious disease (virus) market

02 Scalable Infrastructure

- Resourcing and infrastructure in place for growth
- Leveraging current infrastructure to open new revenue streams
- Expansion of FluCamp, to meet increasing volunteer demands
- Capacity not a revenue limiting factor

03 Strong Customer Base

- Proven regulatory and financial successful outcomes
- Scientific partnership with customers
- Trusted partner of Big Pharma
- End-to-end challenge program capability
- Increased volume of biotech awards
- Cross-selling opportunities

04 Strong Financial Position

- 2022 guidance re-iterated
- Revenue guidance of £50m, 13-15% EBITDA Margin
- C.80% of FY23 revenue already contracted
- Well capitalised with c.£20m as at 1-Sept
- Under promise/over deliver sentiment

05 Well Positioned for Future Growth

- Exceptional order book of c.£80m as at 1 Sept 2022
- Expansion into new services
- New challenge models unlocking new markets
- Growth into new geographies
- Expansion into new areas of consulting services

Support continued revenue growth and long term, sustainable profitability

Making a Difference

hVIVO
formerly Open Orphan plc

The Guardian

Should we give people diseases in order to learn how to cure them?

With the right ethical safeguards, could 'challenge trials' defend against future pandemics?

Saloni Dattani

Mon 31 Oct 2022 12.30 GMT

"For Respiratory syncytial virus (RSV)... with their [challenge studies] help, the world will soon have.. the first vaccines against RSV, which kills tens of thousands of infants each year."

hVIVO

formerly Open Orphan plc

Appendix

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

hVIVO
formerly Open Orphan plc

BAVARIAN NORDIC

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)

ESG Values

hVIVO
formerly Open Orphan plc

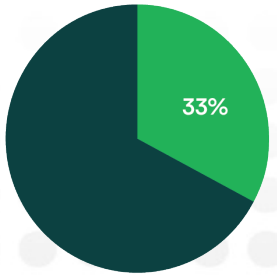
- Commitment to ethical & compliant business practices
- Advancing Health & Research
- Commitment to Volunteers & Patients
- Commitment to our staff
- Operating sustainably
- Governance

2022 at a Glance

- 40 Trees Saved
- 3,500 KG's Waste to Energy
- 4,250 KG's recycled
- 6 Tonnes CO^2 Saved

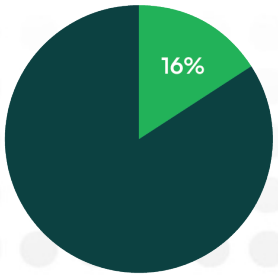
- Health and Safety Focus
- Volunteer Work Policy
- 295 Training Hours

Independent Director



Percentage of Independent Directors

Female Board of Directors



Percentage of Female Board of Directors

Facilities Overview

formerly Open Orphan plc

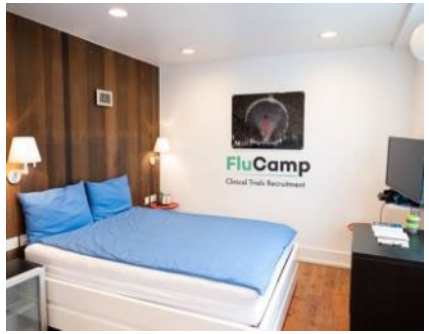
QMB Clinic

QMB Laboratories

Facilities Overview

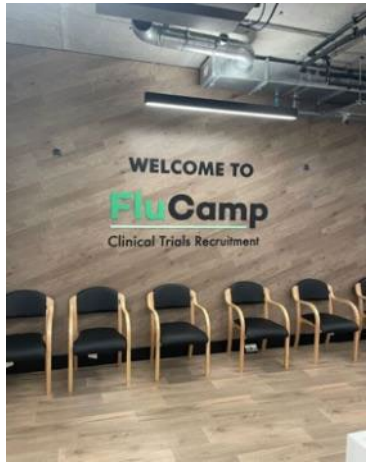
formerly Open Orphan plc

Whitechapel Clinic and Screening Centre



Plumbers' Row Corporate Office & Screening Facility




Manchester Screening Centre

Biobank

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