



hVIVO

formerly Open Orphan plc

Full Year Results Presentation

April 2023

Ticker: 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 Open Orphan 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, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). 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”, “should”, “shall”, “risk”, “intends”, “estimates”, “aims”, “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 directors 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.

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



2022 – A Transformational Year

 <p>Strong Financial Performance</p>	<p>£50.7M FY22 Revenue</p>	<p>17.9% FY22 EBITDA Margin</p>	<p>£28.4m Cash Balance at 31 Dec 2022</p>
 <p>Exceptional Operational Execution</p>	<p>7 Challenge Trials in Quarantine in 2022</p>	<p>413 Volunteer Inoculations in 2022</p>	<p>120k+ FluCamp Leads Generated in 2022</p>
 <p>Building on Solid Foundations</p>	<p>11+ Challenge Study Models</p>	<p>70+ Challenge Trials Completed</p>	<p>4,000+ Volunteers Inoculated since Foundation</p>
 <p>Well Positioned for Future Growth</p>	<p>£76m + Contracted Orderbook at 31 Dec 2022</p>	<p>£55m FY23 Forecast Revenue</p>	<p>Mid-high teens Target FY23 EBITDA Margin</p>



Stephen Pinkerton

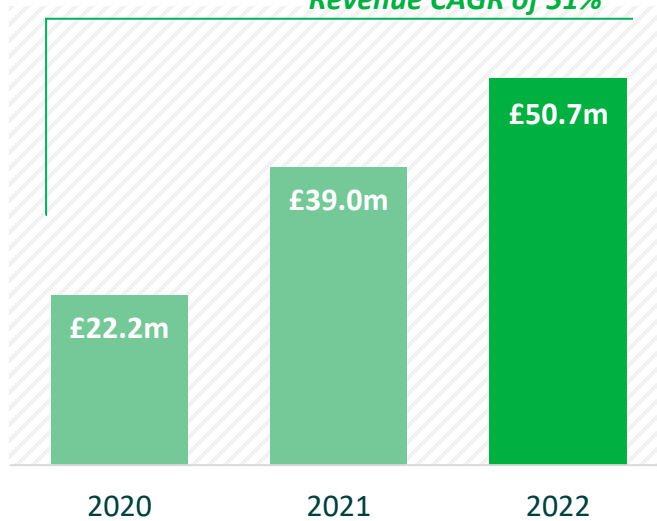
Chief Financial Officer

Financial performance review

A Growing Profitable Business

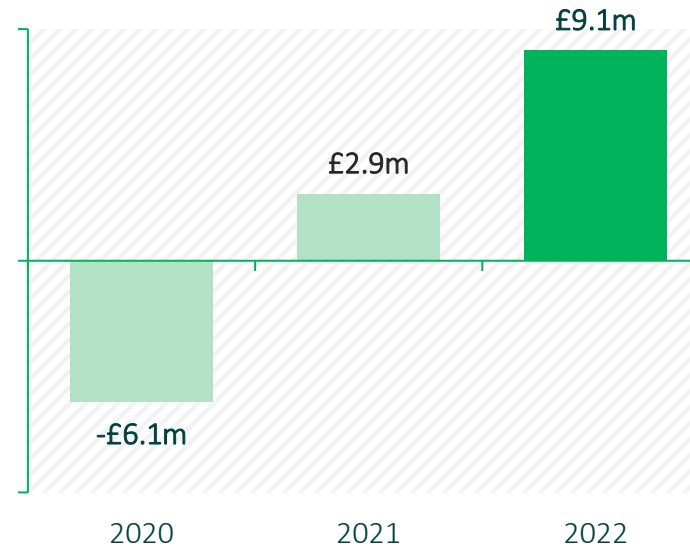
Revenue

Revenue CAGR of 51%



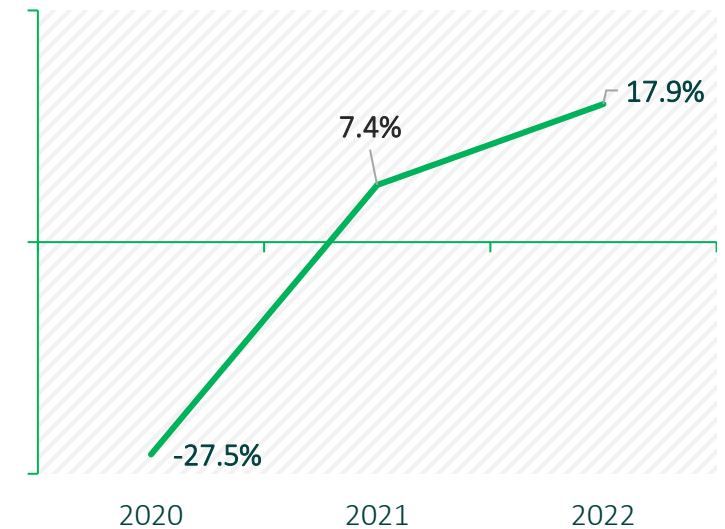
- Revenue increase of 30% year-on-year
- More full-service human challenge contracts, increased number of active studies and more volunteers per study
- Clear validation of long-term sustainable growth model

EBITDA



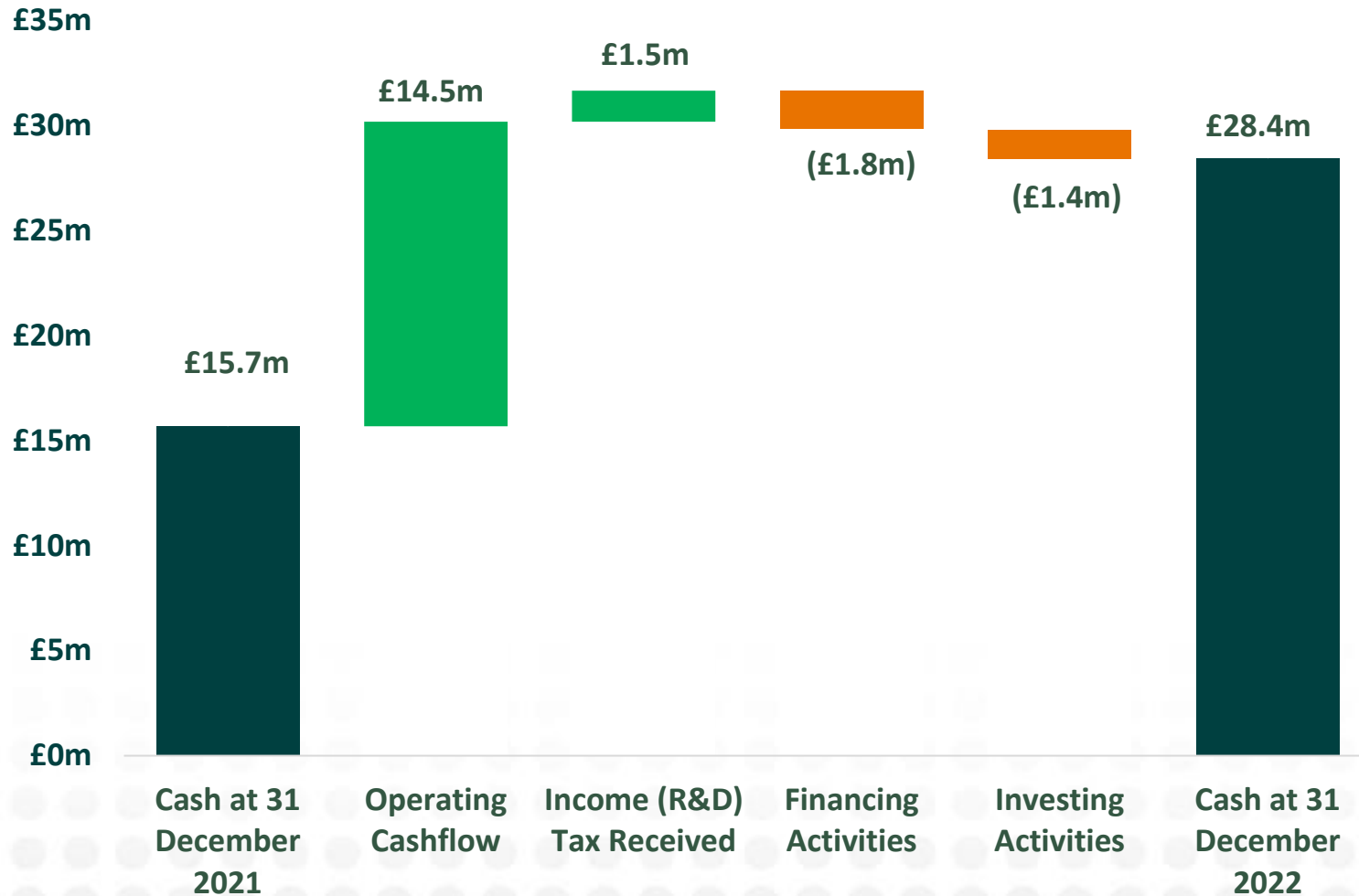
- 2022 EBITDA of £9m driven by strong trading in H2 2022
- Significant operational efficiencies and improvements generated by conducting multiple concurrent trials

EBITDA Margin



- 2022 EBITDA margin of 17.9%
- One-time positive impact from recognition of postponement and cancellation fees for an aggregate of over £1m

A Sustainable Cash Generative Business



Exceptional year end cash position

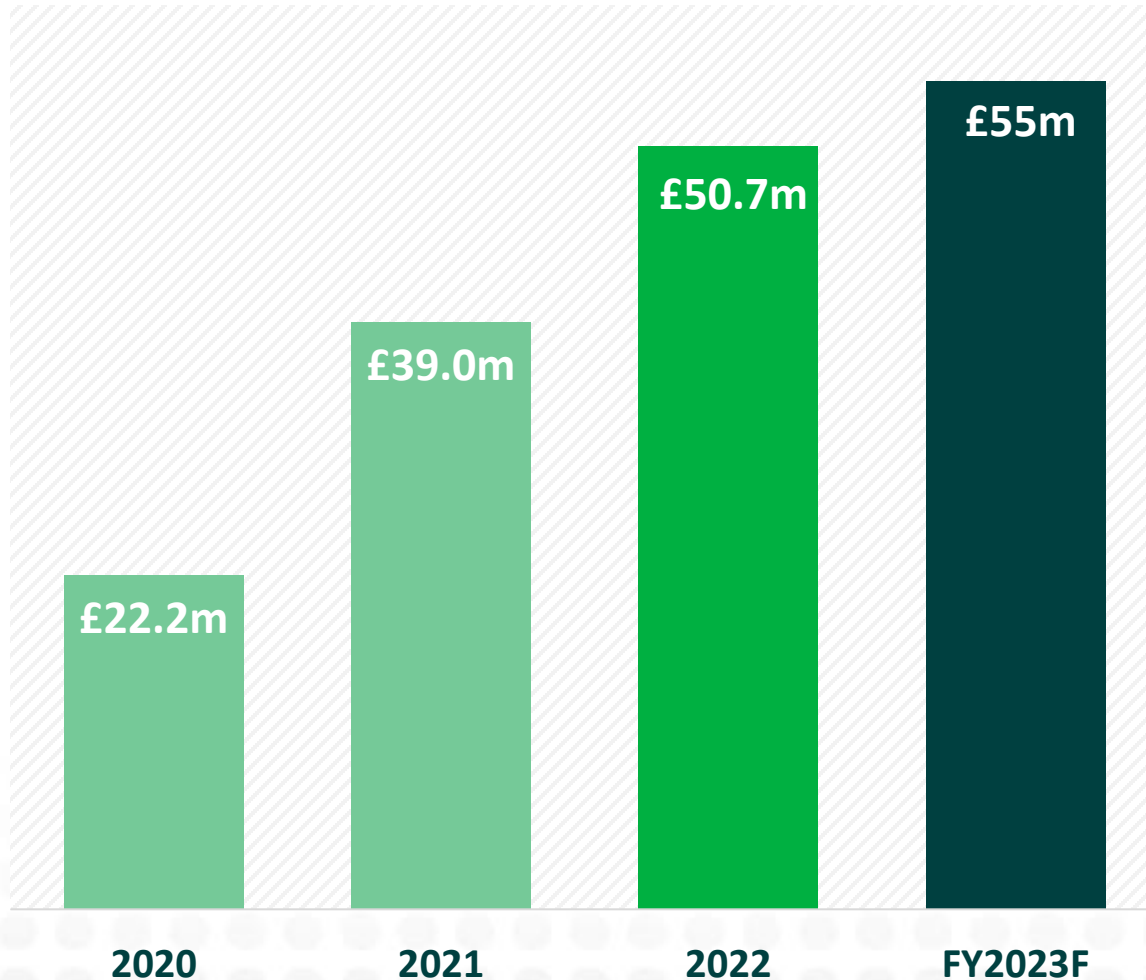
- Strong cash position with £28.4m as at 31 December 2022
- No debt at year end
- Robust net working capital position
- Key drivers:
 1. Advanced fees from record sales
 2. Efficient operational delivery
 3. Disciplined allocation of capital resources

Rewarding our Shareholders

Special, one-off dividend of 0.45p per share, equating to an aggregate of c.£3m to be approved at the Annual General Meeting, reflecting exceptional cash generation in addition to our robust balance sheet

25 April	Financial Results announcement date
4 May	Ex-dividend date
5 May	Record date
23 May	Shareholder approval at AGM
9 June	Payment date

Strong Momentum into 2023 and Beyond



Well positioned for future growth

- Full year guidance of £55m revenue for 2023
- Full visibility for FY23 and into H1 2024
- Targeting 2023 EBITDA margin in the mid-to-high teens
- Key focus for 2023:
 1. Conversion of contracted orderbook to revenue
 2. Operational improvements to continue profitable momentum
 3. Increased focus on diversifying into new revenue streams



Yamin "Mo" Khan

Chief Executive Officer

A long-term sustainable growth model

1. Academia

- Zika
- Escherichia coli
- Norovirus
- Shigella
- Hepatitis C

2. Regulators

- FDA
 - 4x Fast Track
 - Pending Pfizer RSV vaccine
- MHRA
 - Pending Pfizer RSV vaccine
 - Direct customer interactions

Market Influencers

3. Commercial

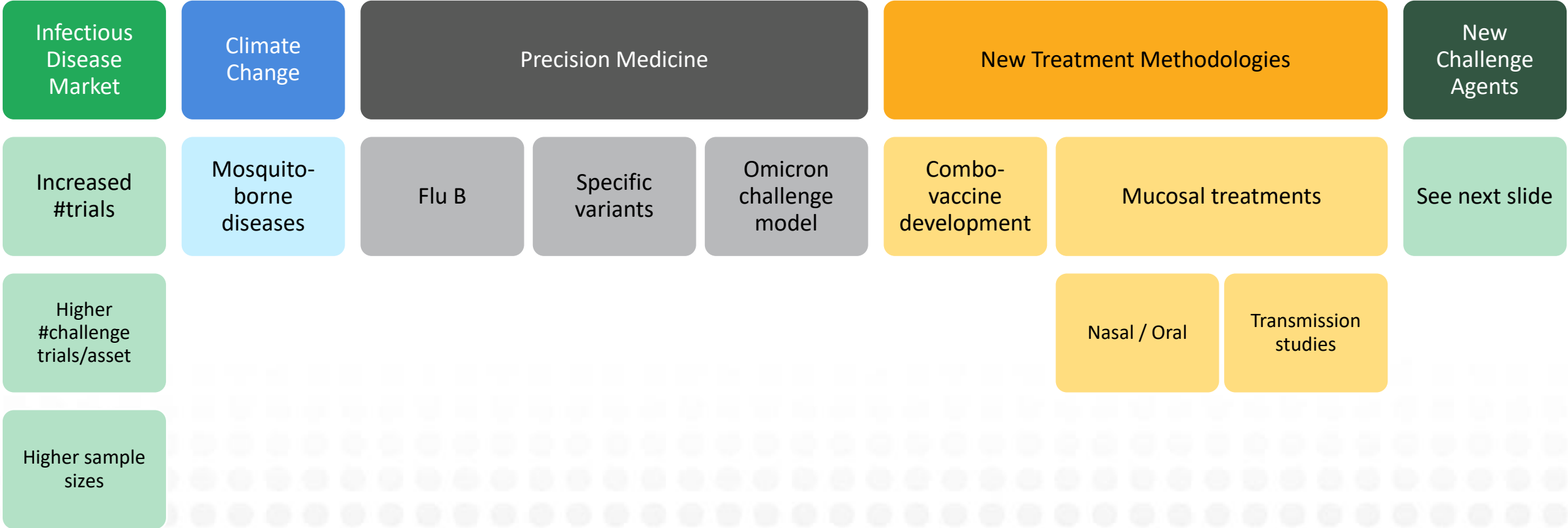
- Reviral RSV
 - Series A funding - acquired
- Cidara Flu
 - Asset acquired
- Pfizer RSV
 - Faster to market

4. Non-Profit Organisation

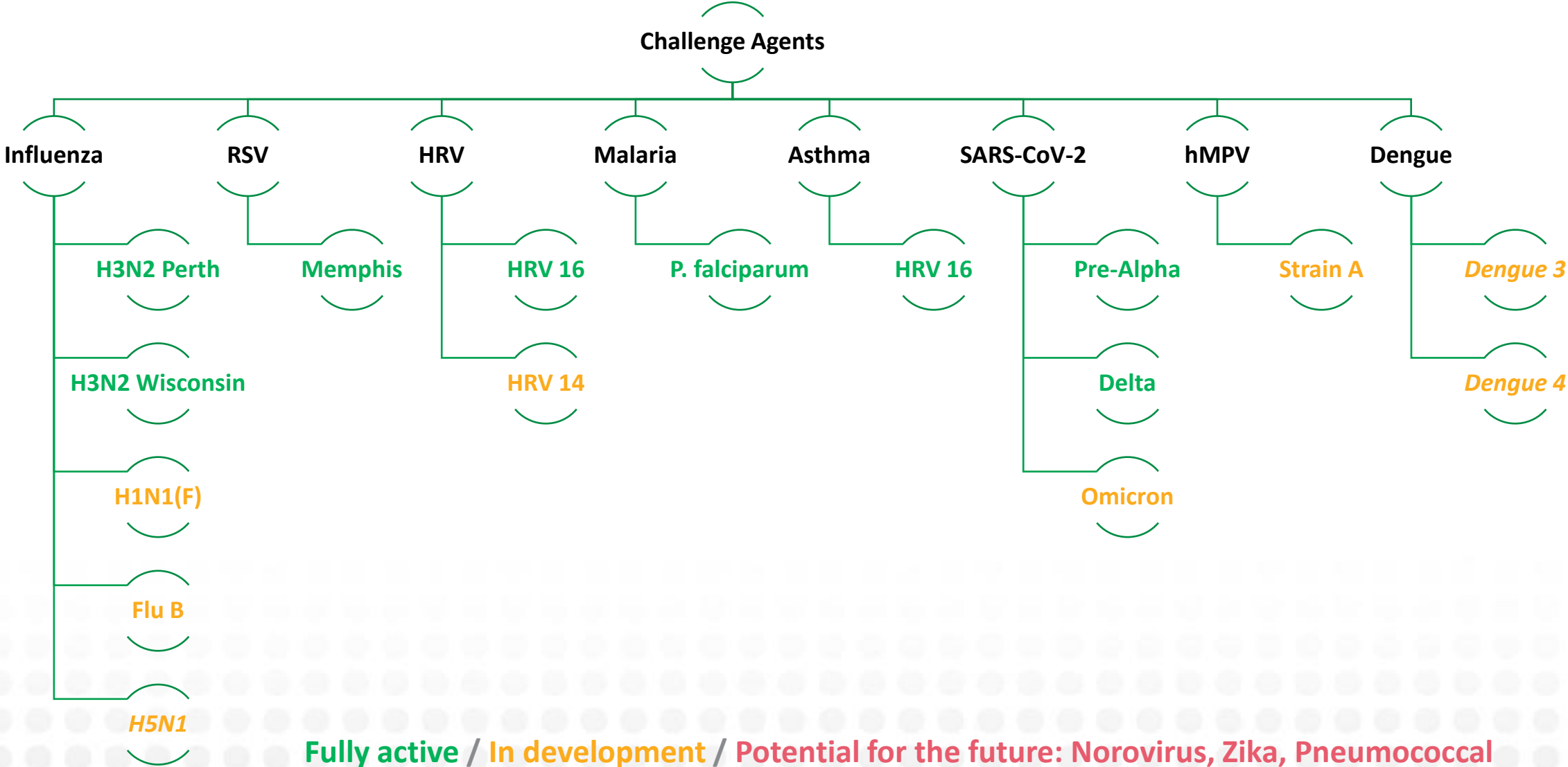
- Wellcome Trust
- HIC-Vac
- 1Day Sooner
- CEPI / WHO

The Expanding Human Challenge Trial (HCT) Market

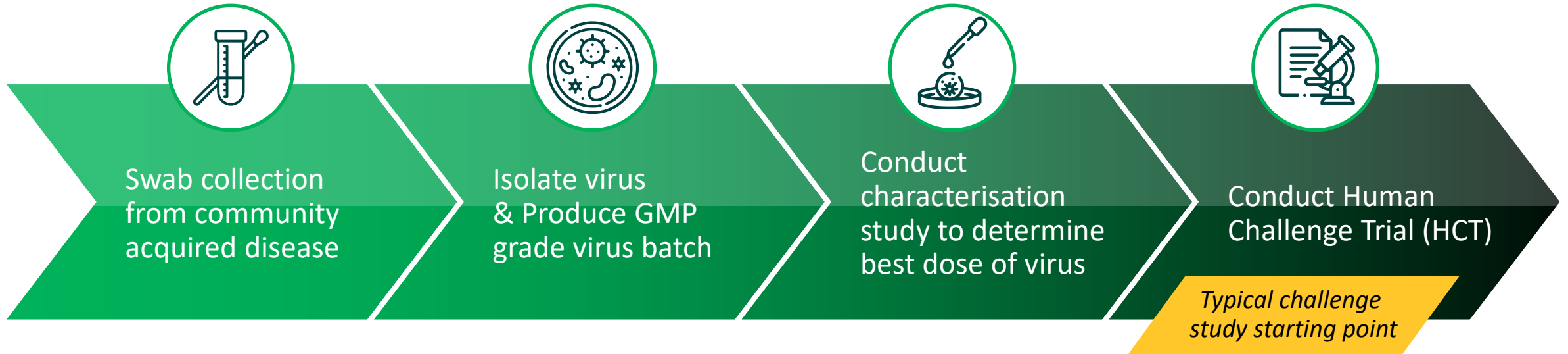
Challenge Study Market – what are the key drivers?



World Leading Human Challenge Model Offering



Unique End-to-End Human Challenge Service



1

Broader scope of work resulting in increased revenue

2

Bespoke challenge agents to match specific target strain

3

Increased market opportunities as potential to test new products that require new virus strain

2022 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

FluCamp Recruitment Platform

80% More than 80% of clinical trials in the US fail to meet their patient enrolment timelines¹

55% Patient recruitment issues account for 55% of cancelled clinical trials²

250,000+
Active Volunteers in
Existing Database

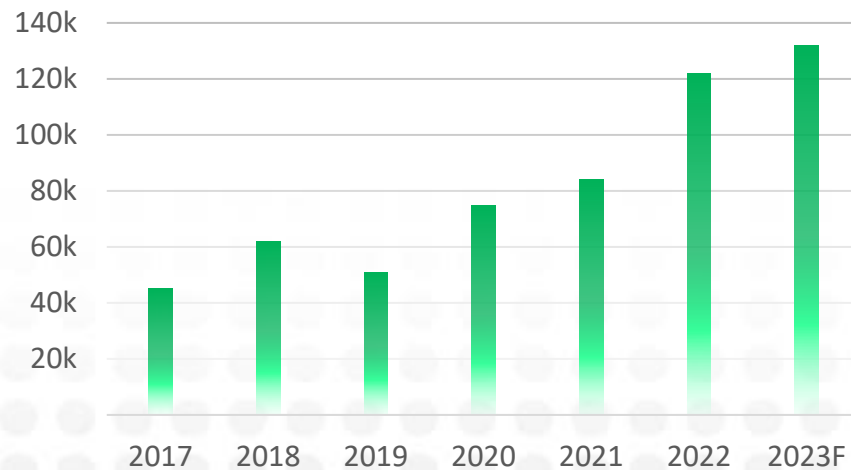
100%
Trial Recruitment
Success

c.85%
FluCamp Volunteers can be
utilised in non-challenge trials

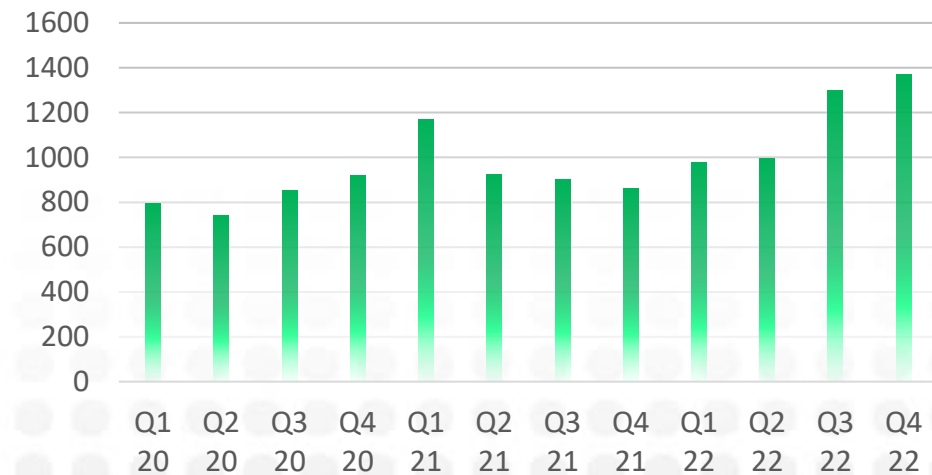
2022 FluCamp Improvements

- Online Self Booking
- New CMS system
- Online pre-screening for volunteers/patients
- Increased capacity (London & Manchester)
- Expanded marketing channels

#ONLINE LEADS GENERATED, PER YEAR



#VOLUNTEERS SCREENED, PER QUARTER

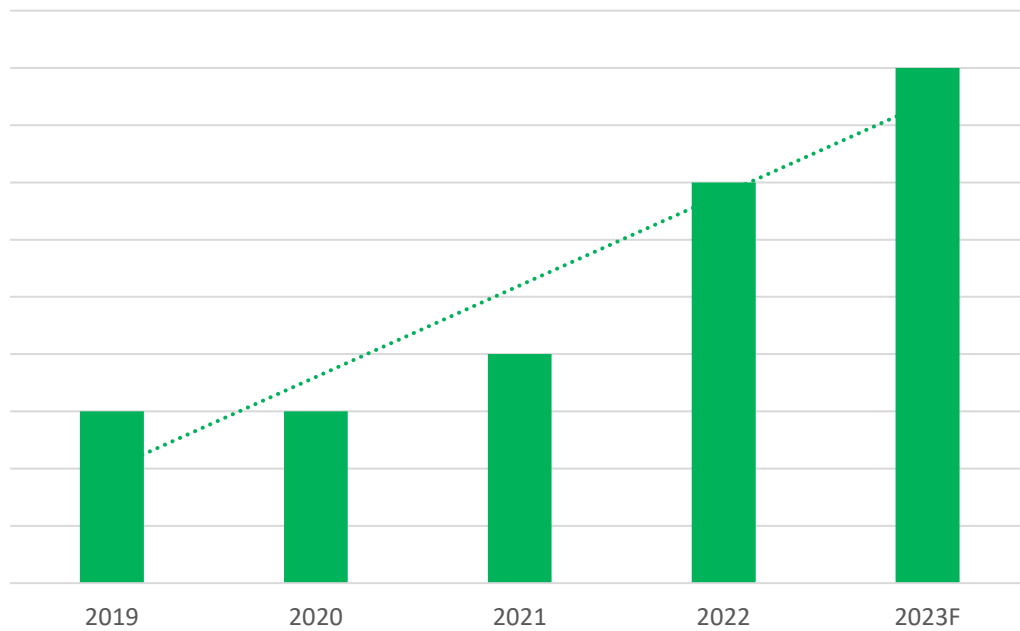


Note (1): Sources: Perspective in Clinical Research

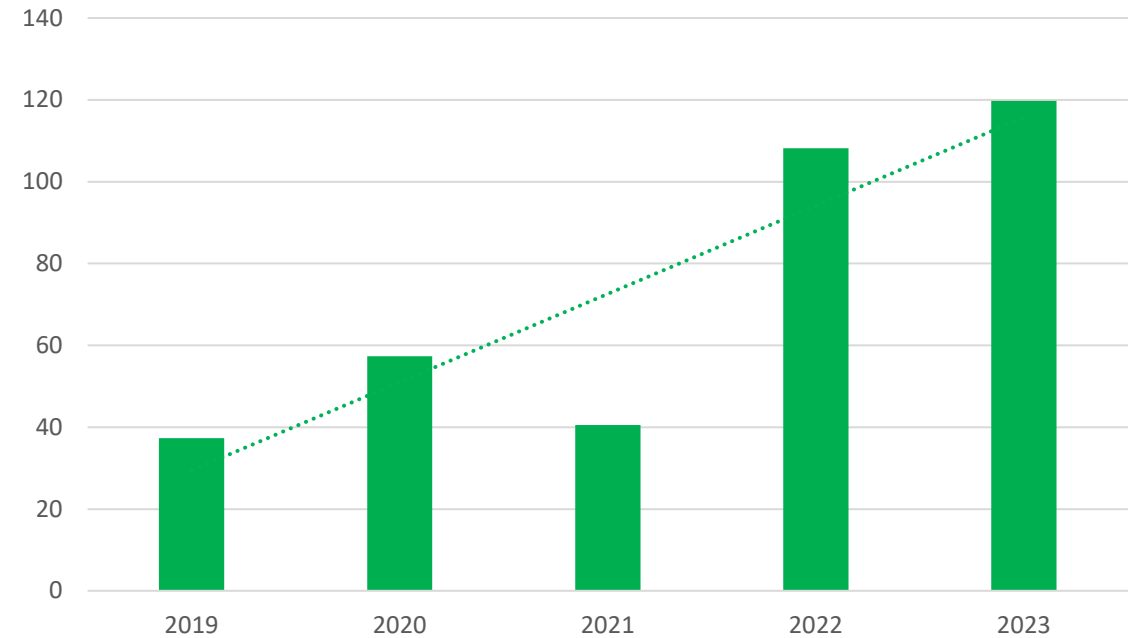
Note (2): Sources: GlobalData

A Growing Trend

Increasing Number of Active HCTs



Increasing Number of Volunteers per HCT



- Higher number of HCTs:

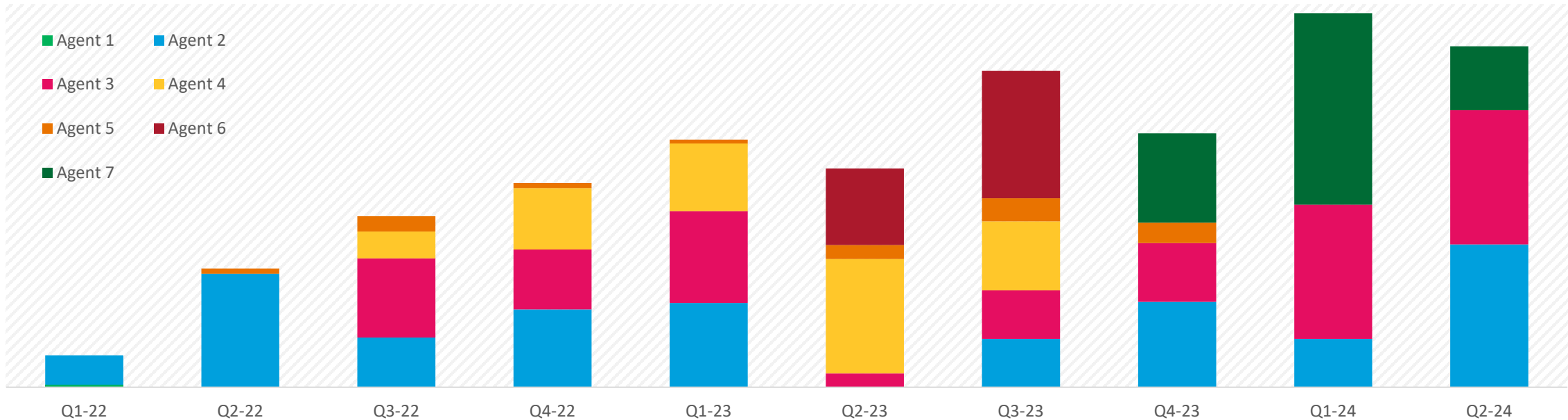
- Increased demand for HCTs
- Multiple challenge agent models
- Improved volunteer recruitment
- Concurrent conduct of trials

- Larger sample size (#volunteers/trial)

- To achieve greater utility of data
- Targeting lower frequency endpoints
- Comparing dose regimens
- Optimising platform selection

Multiple Challenge Agents – Driving Efficiency

#Inoculations per Quarter per Challenge Agent (Contracted)



- Volunteers screened against multiple challenge agents
- Fewer screenings per inoculated volunteer
- Improved volunteer conversions rates
- Increased quarantine utilisation
- Leverage efficiencies to enhance delivery

- Increased profit margin
- Long-term planning
- Principle of scarcity
- Investments in new models
- New models generating revenue

Biotech



SAN DIEGO, March 01, 2023 — Cidara Therapeutics, Inc. (NASDAQ: CDTX)

Cidara Therapeutics announces promising interim Phase 2a data assessing the safety and efficacy of a single dose of CD388 in an influenza challenge model

The study is being conducted under an exclusive worldwide license and collaboration agreement with Janssen Pharmaceuticals, Inc.

Big Pharma

RSV vaccines are expected to hit the market in 2023, accelerated through the use of human challenge



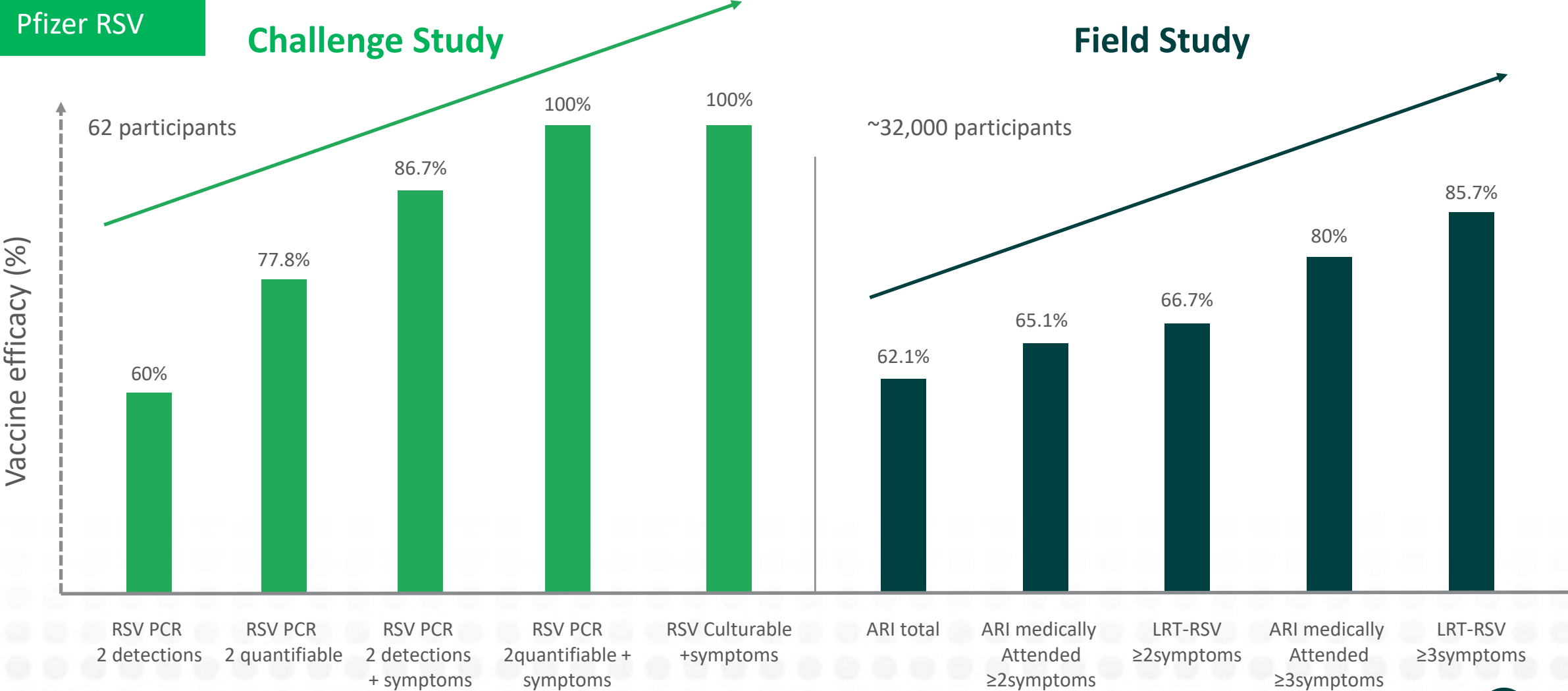
The FDA is expected to make a final decision on the approval of this RSV vaccine in 2023

FDA Breakthrough Designation - 2022

*“Primarily informed by the positive results of a proof-of-concept, Phase 2a study evaluating the safety, immunogenicity, and efficacy of a single dose of 120 µg RSVpreF in a **human viral challenge model** in healthy adults”*

Correlation Between Field and Challenge Trial Data

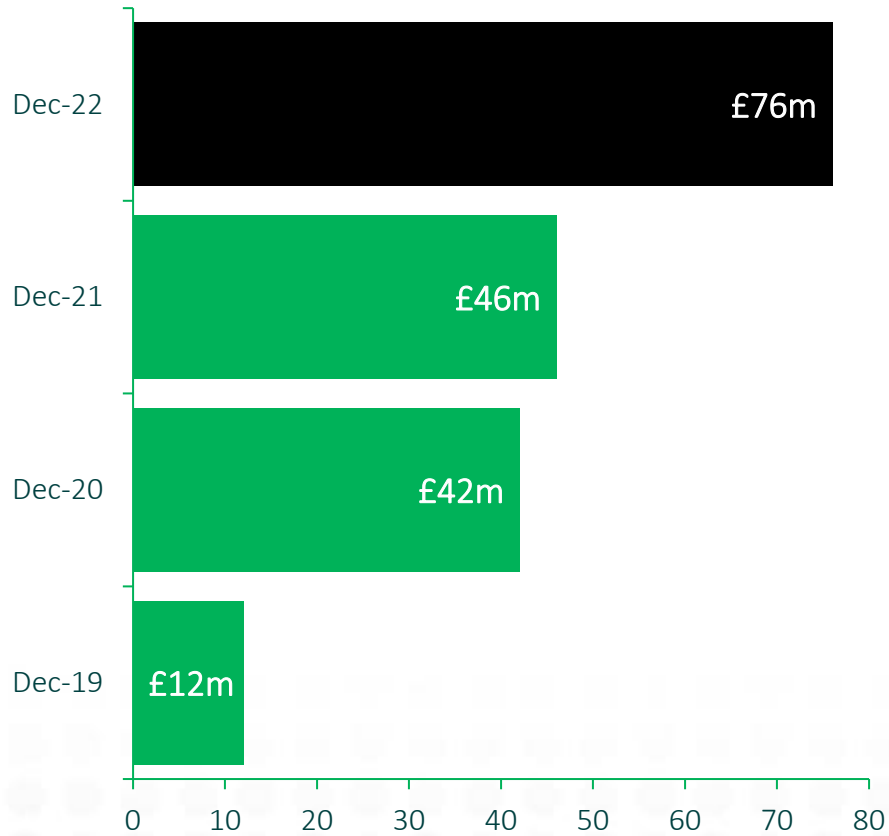
Pfizer RSV



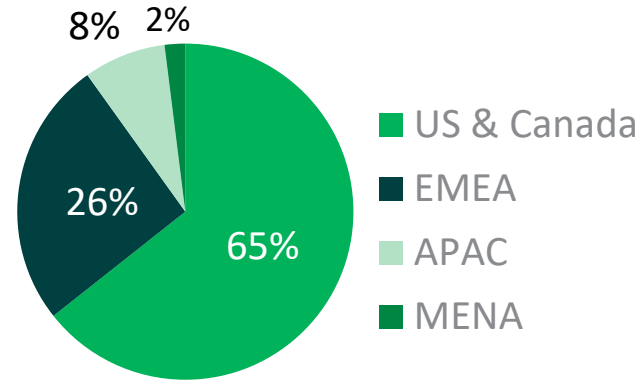
Schmoele-Thoma et al. 2022, Pfizer 2023

Diverse and Growing Sales Pipeline

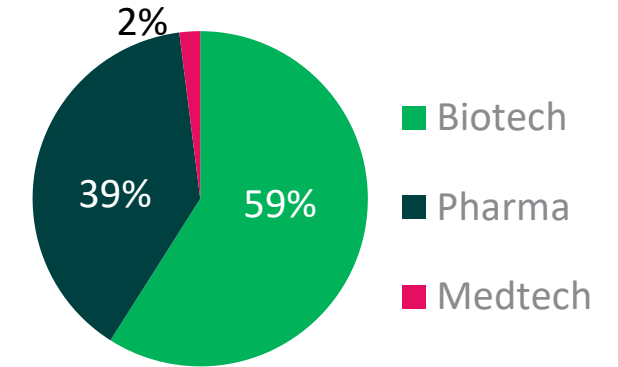
Record Contract Orderbook



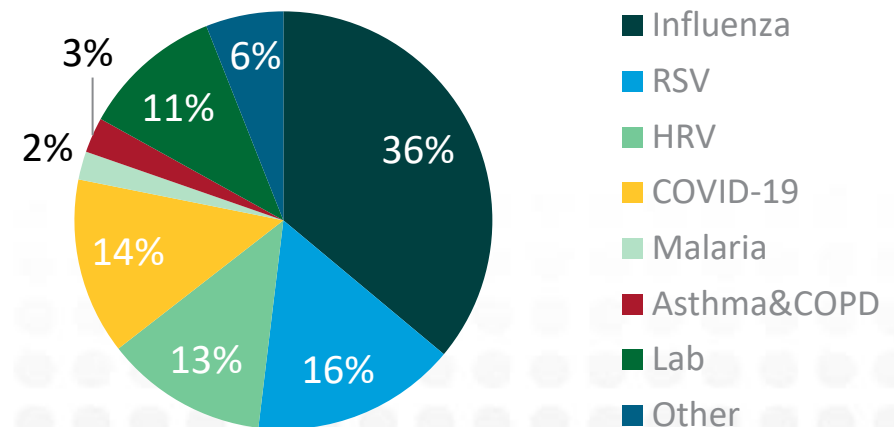
Pipeline Distribution by Region



Pipeline Distribution by Client Type



Pipeline Distribution by Model



Non-Challenge Offerings

Bench-to-Bed Model

hVIVO Non-Challenge Services

Venn Consulting Services

Clinical Site

Laboratory

QA Consulting

Volunteer

Regulatory

CMC

Non-Clinical

Clinical

Biometry

New Services

Phase II/III

CAP accreditation

B2B marketing

Pre- and Post Challenge work

Re-purposing

Drug-Device combos

ATMP

Venn - Continuing to Grow and Expand

25 Years

Strong relationships with repeat customers



Investment in key growth areas - ATMP & Drug Device Consulting



Cross-selling clients across group - field trials / labs

€3.2m

2-year contract announced with major global pharma client

Paris

Delivering key services to hVIVO's challenge studies



Cross-selling clients to hVIVO challenge studies

Seamless drug development support service (“Bench-to-Bed”)

New office at Leiden Bio Science Park

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



Attractive Market Dynamics

£700m+

The estimated market size for challenge study CRO services by 2028¹

\$5.5B+

The infectious disease clinical trial market is projected to reach over \$5.5 billion by 2027⁴

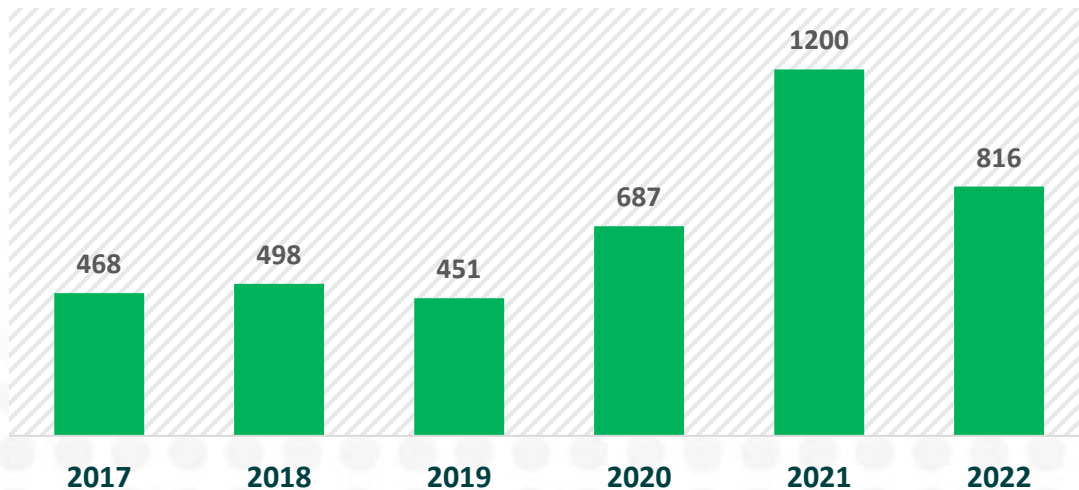
2,500+

Active vaccine, anti-viral and respiratory compounds currently in development – 86% increase from 2019 to 2021²

2,500+

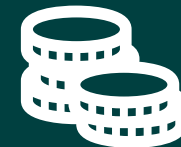
Active vaccine, anti-viral and respiratory compounds currently in development – 86% increase from 2019 to 2021⁵

The number of vaccines studies is increasing every year...



\$67.2B

Global vaccines market is projected to reach \$67.2 billion by 2026⁶



Tighter funding environment for biotech's increase the appeal of human challenge study data

Note (1): Source: Liberum

Note (2): Sources: Pharmaprojects; Citeline

Note (3): Source: clinicaltrials.gov

Note (4): Sources: Global Market Insights

Note (5): Sources: Pharmaprojects; Citeline

Note (6): Source: Markets & Markets

hMPV & Dengue – New Market Potential

Human metapneumovirus (hMPV)

Increasing focus by biopharma

4-18%

Of people with lower respiratory tract infections have hMPV⁽¹⁾

5-16%

Of children infected with hMPV develop more severe symptoms⁽²⁾

>16K

Deaths worldwide in children under 5 years could be attributed to hMPV⁽³⁾

0

No vaccine or specific antiviral treatment approved to treat hMPV⁽⁴⁾

Dengue

One of the top ten global health threats according to WHO

>50%

Of the worlds population is at risk of dengue infection⁽⁵⁾

141

Countries effected⁽⁵⁾

390M

Infections per year resulting in up to 36,000 deaths⁽⁵⁾

0

No specific antiviral treatment approved with just 1 vaccine approved⁽⁶⁾

(1) Howard LM, et al. 2021

(2) American Lung Association

(3) Wang X, et al. 2021

(4) CDC

(5) World Mosquito Program

(6) Clinical Trials Arena

Update on Non-Core Assets

PrEP Biopharm

- hVIVO holds 62.62% of PrEP Biopharm Limited
- PrEP Biopharm Limited to commence solvent liquidation in 2023

Imutex

- hVIVO holds 49% of Imutex Limited, joint venture with PepTcell
- Full impairment of the £7m carrying value of the investment in Imutex is prudent

Disease in Motion

- Postpone all activities relating to the spin-out

Focus on core activities – delivering challenge and non-challenge services

Environmental, Social & Governance

hVIVO's success is underpinned by rigorous governance and a growing focus on its environmental & social impact

hVIVO has a long history of scientific research and discovery which has helped to advance global health

A focus on a culture of equality, inclusion and diversity supporting our team with 62% female employees

Driving corporate social responsibility initiatives across the Group

ISO14001 accreditation planned in 2024

QCA guidelines adopted by our diverse Board

ESG Group established for initiating, progressing, and monitoring our ESG objectives



hVIVO's ESG Values

- 1** *Commitment to ethical & compliant business practices*
- 2** *Advancing Health & Research*
- 3** *Commitment to Volunteers & Patients*
- 4** *Commitment to our Staff*
- 5** *Social & Community Investment*
- 6** *Operating Sustainably*

Strong Fundamentals

- Record revenue, EBITDA and Sales
- Strong cash position
- Improving operational efficiencies and margins

Expanding Market

- Significant expansion in HCT market, number & size
- Tangible advantages of human challenge trials
- New biotech and new Big Pharmas targeted
- High hurdle to entry

World Leading Capabilities

- The only HCT-dedicated CRO
- Team with unique experience and expertise
- Sole HCT provider for Big Pharma

Positive Outlook

- Guiding £55m revenue, mid-to-high teens EBITDA margin
- Full visibility on 2023 revenue, into 2024
- New markets, new HCT indications, new services
- Strongest ever sales pipeline

A long-term sustainable growth model

Appendix

History of hVIVO

1946

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



RETROSCREEN VIROLOGY
CONQUERING VIRAL DISEASE

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



Dec 2019

hVIVO acquired by Open Orphan



Venn Life Sciences
Think Research

June 2019

Venn acquired by Open Orphan

hVIVO

2015

Retroscreen Virology rebrands as hVIVO

2011-2015

Major investment in facilities & challenge model development



2008

Dedicated Volunteer recruitment platform

UK COVID 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

hVIVO

Open Orphan plc rebranded to hVIVO plc

Continuing to expand offering to drive new streams of revenue

Facilities Overview

QMB Clinic

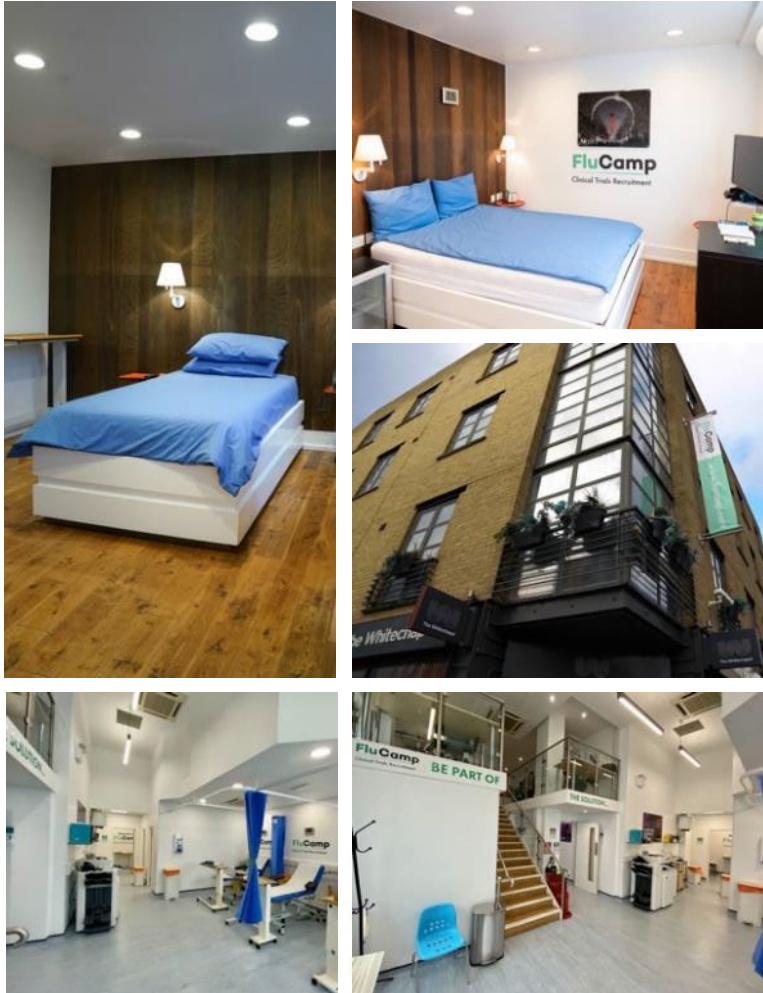


QMB Laboratories



Facilities Overview

Whitechapel Clinic and Screening Centre



Plumbers' Row Corporate Office & Screening Facility



Manchester Screening Centre



Biobank



Stay in touch

