hVIVO

formerly Open Orphan plc

Delivering today's healthcare by empowering tomorrow's innovation

Annual Report & Accounts 2022

hVIVO
formerly Open Orphan plc

Contents

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

Our Mission

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

We are pioneering in our approach, always curious. We use our unique scientific expertise to guide our clients towards successful outcomes. We embrace new opportunities and rise to new challenges. Our agility allows us to redefine our markets and be highly responsive to our clients' requirements.

Growth

We are dedicated to the growth of our colleagues, customers and shareholders. We are committed to our personal growth and the development of our colleagues. We aim to grow our client base and the value of their products. We will repay the trust of our shareholders in achieving greater returns on their investment. We will achieve this by creating a culture of intellectual freedom across the organisation.

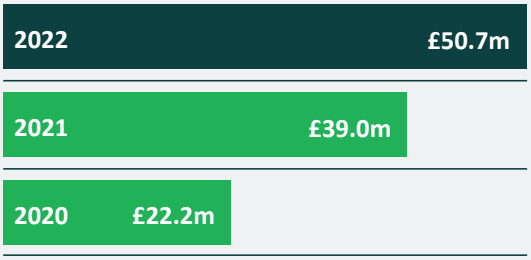
One Team

We are a diverse group of individuals working for one team to achieve common goals. Each one of us plays a crucial role in the team's success. We are committed to each other and the team. We learn from our failures together and celebrate our successes together. Diversity and inclusion are at the core of our organisation, and we consider our clients' success as our own.

Integrity & Welfare

We take personal ownership of our actions and always act in ways that builds trust and respect with all our stakeholders. We pride ourselves in maintaining the welfare and the rights of all individuals and ensuring the best outcomes for our volunteers and patients. We are honest, have strong moral and ethical principles and are reliable and consistent in our delivery.

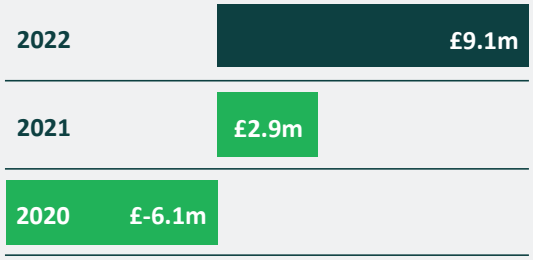
Financial Highlights



Revenue

£50.7m

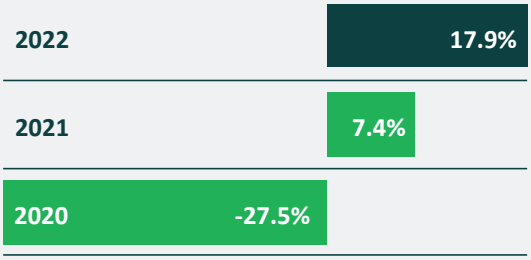
2021: £39.0m



EBITDA

£9.1m

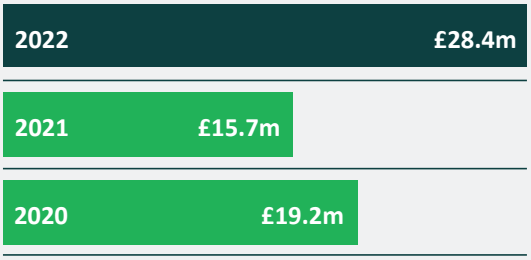
2021: £2.9m



EBITDA Margin

17.9%

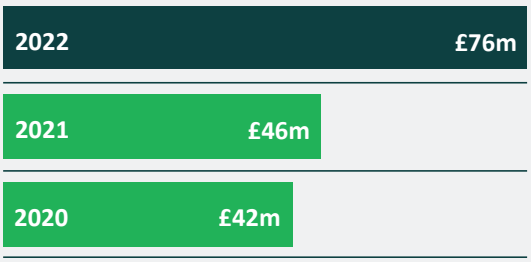
2021: 7.4%



Cash

£28.4m

2021: £15.7m



Contracted Orderbook

£76m

2021: £46m

Strong business development focus as services are diversified, new markets are targeted, and cross-selling increased.

This is outlined in the Chief Executive Officer's Statement on page 17

At a Glance

We are a rapidly growing specialist contract research organisation (CRO) and the world leader in testing infectious and respiratory disease vaccines and therapeutics using human challenge clinical trials. We provide end-to-end early clinical development services to our established and growing repeat client base, which includes four of the top 10 largest global biopharma companies.

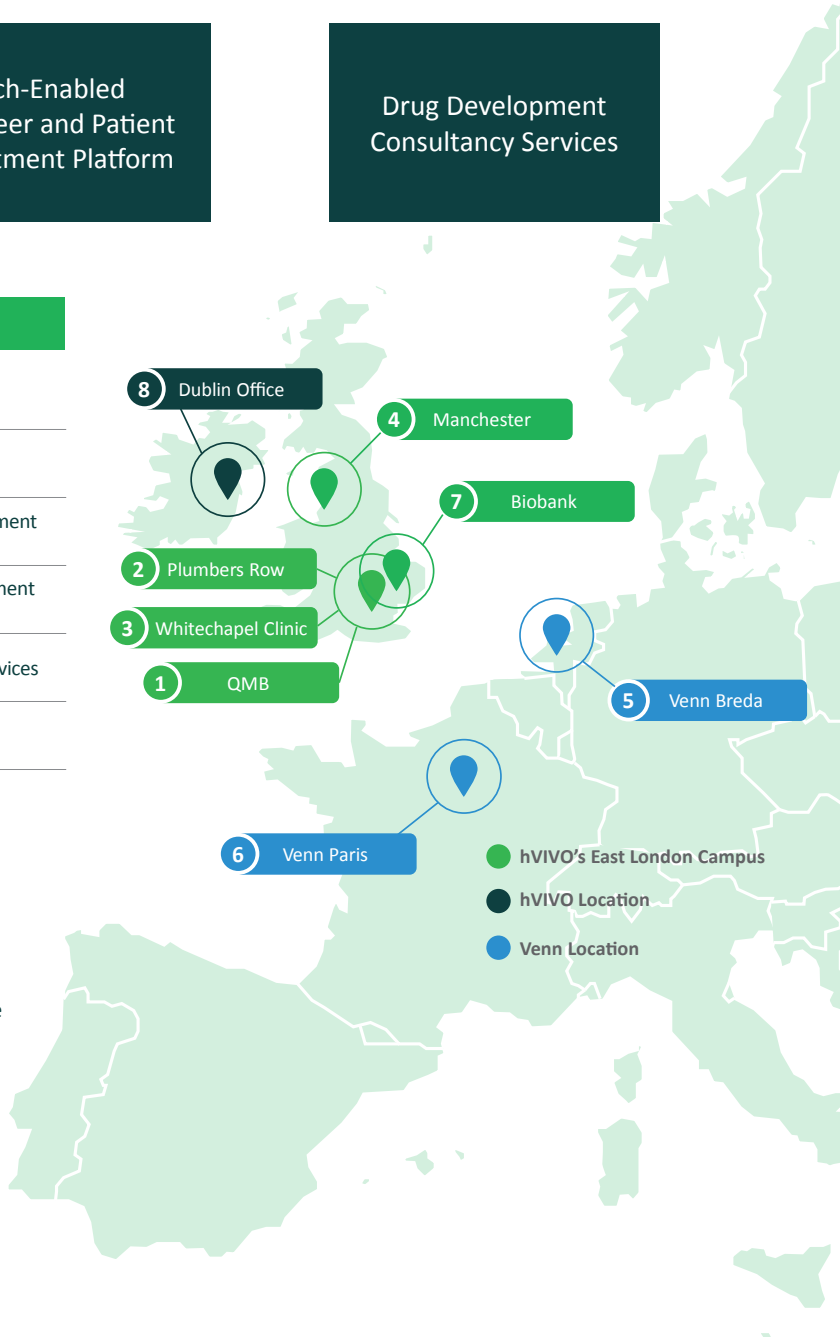
hVIVO *formerly* Open Orphan plc

FluCamp Clinical Trials Recruitment

Venn Life Sciences *part of* hVIVO

World Leader in Human Challenge Trials with Onsite Virology Labs	Tech-Enabled Volunteer and Patient Recruitment Platform	Drug Development Consultancy 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 Corporate Office
4	**Manchester**	FluCamp Volunteer Recruitment Vaccination Site
5	**Venn Breda**	IND & CMC Consultancy Services
6	**Venn Paris**	Biometric Services



11+
Challenge Study Models

50+
Years of Combined Service

70+
Number of Studies Completed

4,000+
Volunteers Inoculated

A brief history

We have an extensive history, that dates back to the UK Common Cold Unit in Salisbury which ran human challenge studies from 1946 until 1989. The facility was a former military hospital that was donated by Harvard University and began human challenge studies to try to find a cure for influenza.

Our Company's founders, Professor John Oxford and Pat Meeking, worked at the Common Cold Unit alongside Dr David Tyrell, and after it closed, went on to setup Retroscreen Virology Limited out of Queens Mary University in 1989.

Retroscreen was renamed hVIVO in 2015 as part of its IPO on the London Stock Exchange. In December 2019 hVIVO joined the Open Orphan plc group, which had previously added Venn Life Sciences' early clinical drug development services to its offering. In 2022 the parent group was renamed hVIVO plc and we are now the world leader in providing human challenge studies to test infectious and respiratory disease products.

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

What is a human challenge trial?

A human challenge trial involves the intentional infection of a healthy volunteer in a safe and controlled clinical environment with a known quantity of an infectious agent (virus, bacterial, other infectious agent) to derive scientifically useful information about the pathogen and/or the efficacy of a vaccine or drug.

Why do a Human Challenge Trial?

Scientific

- ✓ Generates invaluable dosing, safety and efficacy data
- ✓ Helps optimise for larger field trials
- ✓ De-risks Phase III program

Clinical Development

- ✓ Requires fewer subjects
- ✓ Significant time savings
- ✓ No seasonal dependence

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

Why hVIVO?

Building on decades of unrivalled experience, hVIVO is currently the only CRO focused on challenge studies, providing world class expertise and capabilities in challenge agent manufacture and characterisation, a unique portfolio of established human challenge models to test a broad range of infectious and respiratory disease products, and specialist drug development and clinical consultancy services.

End-to-End Human Challenge Services

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

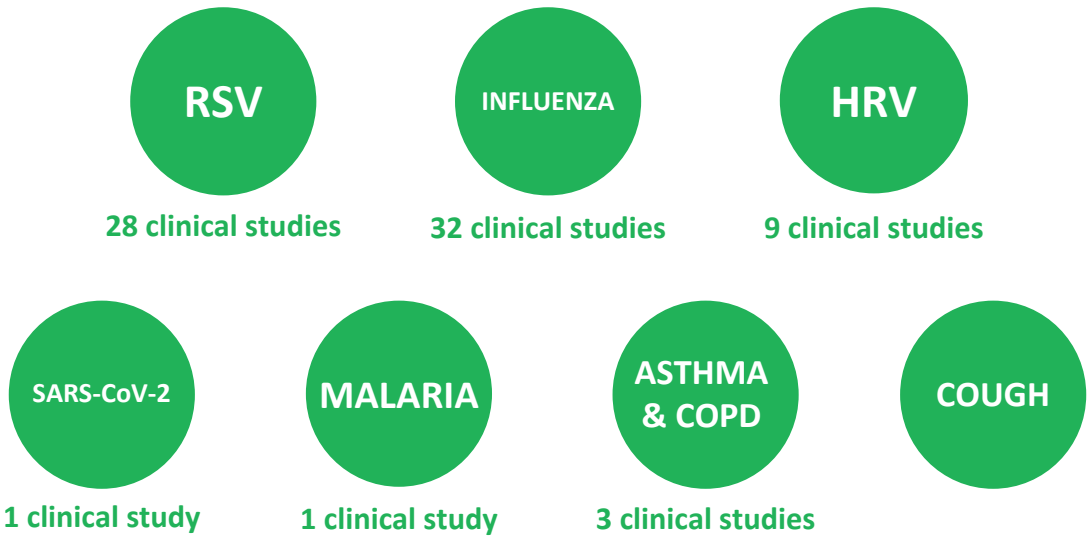
- Human Challenge Studies
- Phase II-III Vaccine Studies
- Non-first-in-human healthy Volunteer Studies
- Mild Condition Patient Studies

LABORATORY

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

Why hVIVO? *contd.*

Broad Portfolio of Human Challenge Models



Experience & Success

"We saw the strong capabilities in the team and were very impressed when we did meetings face to face with the team, on their knowledge and input to our study"

Douglas Thompson, CEO, Pneumagen (November 2022)

"I think hVIVO, give them credit, have been absolutely vital in global terms, in being able to drive these studies and work with academics to develop protocols that have enabled all of this science to have been discovered."

Peter Openshaw, Professor of Experimental Medicine, Imperial College London (November 2022)

"All roads lead to hVIVO"

Big Pharma

Benefits of Human Challenge

Big Pharma Case Study

The world's first RSV vaccines are expected to hit the market in 2023, accelerated by hVIVO's 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"

50M	4M	60k
People affected globally each year	Hospitalisations	In-hospital deaths in children <5 years

Biotech Case Study

The Challenge

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

The Solution

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

The Result

Significantly reduced viral load

Acquired for up to $525m

NEW YORK--(BUSINESS WIRE)--Pfizer Inc.(NYSE: PFE)

"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. Sisunatovirhas 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."

EMA's updated guideline to include broader coverage on Human Challenge Trials

Human Challenge Trials – becoming part of mainstream clinical trial design

January 2023

The European Medicines Agency (EMA) published an updated Guideline on clinical evaluation of vaccines (EMEA/CHMP/VWP/164653/05 Rev. 1). This guideline was updated following EMA`s experience in the past decade with new vaccines applications, including the approval of the COVID-19 vaccines.

These applications have raised several issues for vaccine clinical development programmes that were not addressed in the previous guideline. EMA also encountered requests for scientific advice on vaccine clinical development programmes that have pointed to the need to provide updated or additional guidance on some issues. For example, on considerations for conducting vaccine efficacy trials, identification of immune correlates of protection, vaccines intended to be used in heterologous prime-boost regimens and vaccines to be administered to pregnant women to protect their infants during the first months of life.

The updated guideline also clarifies the role human challenge trials can play in the development of vaccines. Next to the use as proof-of-concept trials in early clinical development, it particularly highlights the possibility to use a human challenge trial to support the development of vaccines in a number of ways:

When there is no appropriate non clinical model (e.g., when a candidate vaccine is intended to protect against an infectious disease that is confined to humans)

No possibility of comparing immune responses between a candidate vaccine and a licensed vaccine for which there is documented efficacy or effectiveness

When there is no known immune correlate of protection (ICP) or threshold value that could be applied to interpret immune responses

When vaccine efficacy field trials are not feasible

The guideline also offers the possibility to use human challenge trials to assist in dose and/or regimen selection.

Recent examples of the use of human challenge trials in vaccine development are:

- The WHO pre-qualification of **Typbar-TCV,** a typhoid conjugate vaccine based on immunogenicity studies and the data on efficacy from the human challenge trial
- The marketing authorisation of **Vaxchora** a live oral cholera vaccine intended to prevent cholera disease in travellers based on a human challenge trial as pivotal efficacy trial
- The PRIME and Breakthrough Designation of the **Bavarian Nordic RSV vaccine** based on immunogenicity and the human challenge trial

FluCamp
Clinical Trials Recruitment

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Volunteer Recruitment

hVIVO's dedicated recruitment arm, FluCamp, has an extensive database of over 250,000 potential volunteers and has unrivalled screening capacity via its state-of-the-art facilities in central London and Manchester, which provides access to large populations and rapid volunteer screening, with capacity for over 1,000 screenings per week.

More than 80% of clinical trials in the US fail to meet their patient enrolment timelines, and patient recruitment issues account for 55% of cancelled clinical trials. FluCamp addresses these issues by screening volunteers for suitability for any challenge study that the Company is running.

- This has contributed to hVIVO's 100% recruitment success via FluCamp, which is a key challenge in executing clinical trials
- c.85% of screened volunteers for human challenge trials can be utilised in non-challenge trials by FluCamp

The unique and approved generic screening programmes enables the Group to recruit volunteers before a study starts. These potential volunteers are screened at hVIVO's facilities in Manchester and Plumbers Row, London.

- Screening facilities in different cities reduces the travel burden for volunteers,
- hVIVO is continuing to look at ways to increase the number and reach of FluCamp's screening sites
- Recently increased volunteer recruitment capacity enables the Company to recruit larger cohorts more quickly, cementing FluCamp's position and reputation in volunteer recruitment.

Human challenge trials are conducted at the Company's quarantine facilities at Plumbers Row and its Whitechapel and QMB clinics.

250,000 +
Active Volunteers in Existing Database

1,000 +
Weekly Screening Capacity

122,000 +
New Leads in 2022 through FluCamp.com

100%
Trial Recruitment Success

c. 85%
of Volunteers Screened for Human Challenge Trials can be Utilised in Non-Challenge Trials

Lab Services

hLAB is a highly specialised virology and immunology laboratory offering a suite of services to support pre-clinical and clinical respiratory drug and vaccine discovery and development.

Our work includes assay development, transfer and optimization across immunology, molecular and cell-based assays, including offering extensive options in sample matrix and stability testing and stability analysis. All assays validated to FDA, EMA and ICH guidelines.

With specialists focusing on virology, immunology and molecular biology, our hLAB is well equipped within our Biosafety Level 2 and 3 facilities to provide high quality data outputs to enable clients to arrive at a proof of concept, or to make a breakthrough discovery in the pathology and possible treatment of diseases with unmet medical needs.

In 2022, our clinical laboratories in QMB and Plumbers Row were awarded accreditation by the College of American Pathologists ("CAP").

hLAB

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

Over 86,000 samples
each year, generating more than **300,000 aliquots**

Bio-repository stores **in excess of 500,000 samples**

Biosafety Level 3 (CAT 3)
lab services available
SARS-CoV2-assays validated

Quality Standards
GCLP, CAP Accredited and external QA, HTA, FLUCOP

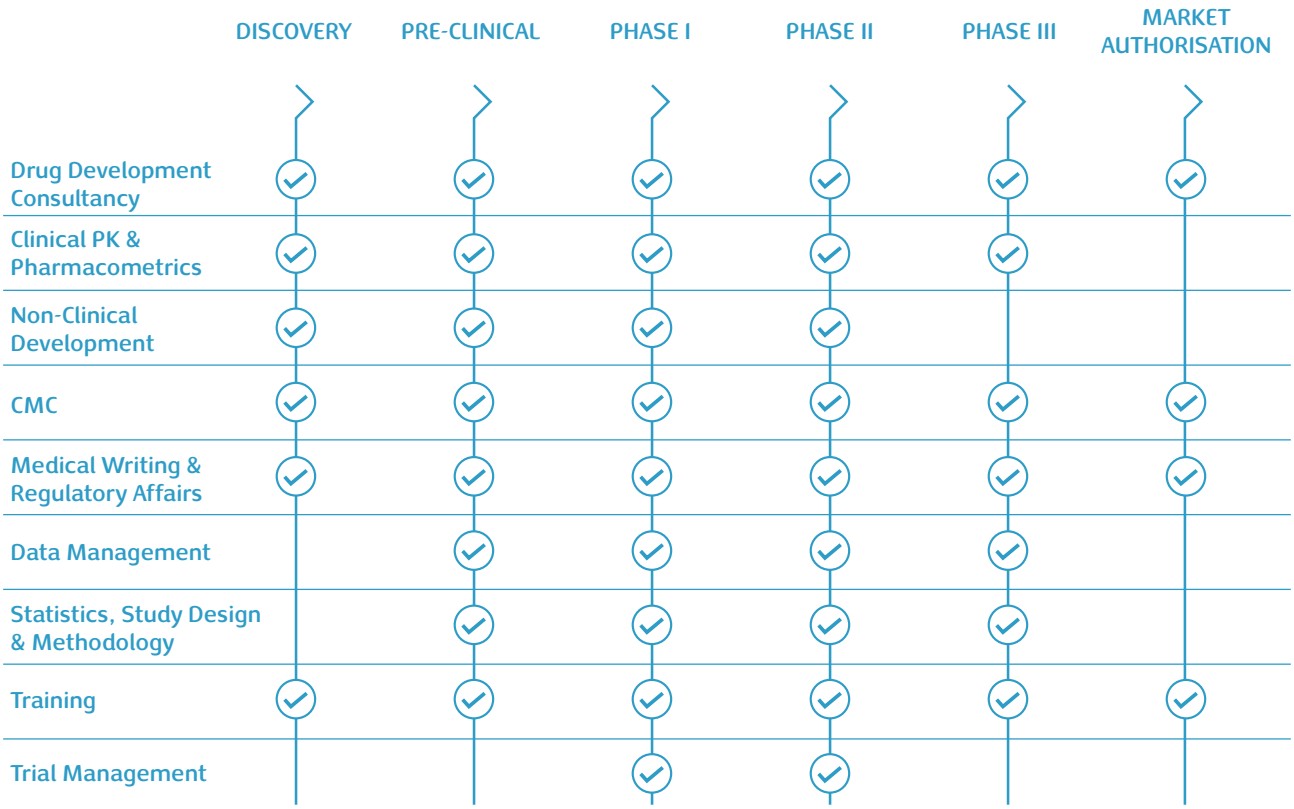
Venn Life Sciences
part of hVIVO

hVIVO
formerly Open Orphan plc

Venn Life Sciences

Venn Life Sciences is an integrated drug development partner offering a unique combination of drug development consultancy, clinical trial design and execution. These carefully combined services enable us to provide our customers with a complete service on all the stages of their drug development programs, from the early planning phase to final execution.

Venn Life Sciences has longevity within the industry and a team of motivated experts, which combined helps to accelerate the development of our clients' requirements.



25 years

Trusted partner to the life science industry

Cross-selling clients to hVIVO challenge studies, lab services & field trials

Biometry

Delivering key services to hVIVO's challenge studies

Investment in ATMP & Drug Device Consulting

Investment case

A long-term sustainable growth model

£50.7M
FY22 Revenue

17.9%
FY22 EBITDA Margin

£28.4m
Cash Balance at 31 Dec 2022

1 . Strong Financial Profile

- ✓ Record revenue and EBITDA delivered with a strong cash position
- ✓ Driven by increase in active challenge studies with larger study sizes and full service human challenge contracts
- ✓ Improved operational efficiencies driving utilisation and margins
- ✓ Clear validation of our long term sustainable growth model to deliver shareholder value

$5.5bn
Infectious disease clinical trial market is projected to reach $5.5bn by 2027(1)

£700m+
The estimated market size for challenge study CRO services by 2028(2)

2500+
Active vaccine, anti-viral and respiratory vaccines currently in development – 86% increase from 2019 to 2021

2. Expanding Market

- ✓ Significant expansion in human challenge trials
- ✓ Human challenge trials now a key part of a growing number of biopharma's clinical development plans
- ✓ Clear, tangible advantages of human challenge trials
- ✓ High hurdle to entry for competitors ensure hVIVO's position as the market leader

Note (1): Sources: Global Market Insights. Note (2): Sources: Liberum.

4 of Top 10
Global Pharma Repeat Customers

70+
Completed Human Challenge Trials

New Revenue Streams
Expanded into Additional Areas

3. World Leading Capabilities

- ✓ The world leader in the testing of vaccines and anti-virals using human challenge studies with unparalleled expertise and experience having delivered 70+ studies and inoculated more than 4,000 volunteers
- ✓ Greatest depth and breadth of delivery with 11+ challenge models
- ✓ A growing diverse and loyal client base across the biopharma spectrum including 4 of the world's top 10 Global Pharma companies
- ✓ Diversification into new revenue streams such as clinical site services and laboratory services

£55m
FY23 Forecast Revenue

Mid-high teens
Target FY23 EBITDA

£76m+
Contracted Orderbook at 31 Dec 2022

4. Positive Outlook for 2023 and Beyond

- ✓ Full visibility on 2023 revenue and into H1 of 2024
- ✓ Increased market awareness and enhanced sales strategy leading to exceptional contracted orderbook
- ✓ Growing demand for human challenge trials combined with trend for larger study sample size and more end- to-end full-service challenge contracts
- ✓ Diversified offering improving utilisation and operational efficiencies, driving increased margins

Chairman's Statement

For the year ended 31 December 2022

2022 – A Transformative Year for hVIVO

2022 was a record year for hVIVO and its subsidiaries (the "Group"), in which we delivered another period of profitable and significant growth, as the Group reaffirmed its position as the world leader in the testing of vaccines and therapeutics using human challenge studies. hVIVO ended the year in a strong financial position, with revenues up 30% year-on-year, EBITDA increasing threefold and EBITDA margins increasing to 17.9%, substantially above market expectations. This exceptional performance has resulted in strong cash generation in 2022. To recognise the Group's performance, the Group will make a one-off, special dividend to shareholders of 0.45p per share (c. £3.0 million aggregate payment).

hVIVO made excellent operational progress during the year, as the Group delivered seven challenge trials supported by expanded FluCamp screening facilities while building a record contracted orderbook that provides excellent visibility on future revenues that now stretches into H1 2024. hVIVO also broadened and diversified its offering to include new human challenge models, as well as new laboratory and clinical services, which have added additional revenue streams and improved both utilisation and margins.

Organisational excellence

In 2022, the Group continued to deliver on its strategy to build a world-class and focused CRO business. In February 2022, we appointed Yamin 'Mo' Khan as CEO to continue our growth trajectory and build upon the Group's foundations. Mo brought over 25 years of specialist CRO experience to hVIVO and significant industry pedigree, and I am delighted by his impact on the business. Under his leadership, the Group has built a record orderbook of £76m, a sixfold growth since 2019, and demonstrated highly efficient operational delivery, resulting in much improved margins, continued outstanding growth and significant momentum.

Mo has been supported by Stephen Pinkerton, who was appointed CFO in October 2022. Stephen has been with hVIVO since 2017 and has played a leading role in transforming hVIVO's financial position and how we report and forecast our business model, developing pricing models for contracts to help improve average contract value as well as driving margin improvements across the business.

There have also been further changes to the Board, with Martin Gouldstone joining as an Independent Non-Executive Director in June 2022. Martin brings 30 years of corporate development experience in the CRO, healthcare and pharmaceutical sectors. His experience executing deals across Europe has been important as we continue to internationalise the use of human challenge trials. Following Mo's appointment, I have reverted to the position of Non-Executive Chairman of the Board. I remain fully committed to hVIVO and look forward to continuing to support Mo as he continues to drive our growth strategy forward.

In February 2022, the results from the world's first COVID-19 human challenge trial were published in peer reviewed journal *Nature Medicine*. The results provided unique insights into COVID-19 disease progression and underlined that a COVID-19 human challenge trial is safe in healthy young adults. The study was a strong endorsement for human challenge trials and we believe it was pivotal in bringing greater worldwide attention to hVIVO, acting as a catalyst to our subsequent growth.

ESG has become an area of significant importance for UK corporates, and I am delighted to report that the Group has established a cross-business working group ("ESG Group"), which is focused on identifying the risks and opportunities arising from climate change and other social and governance topics. Mo leads the ESG Group which contains representatives from each area of our business and reports directly into the Audit and Risk Committee. The ESG Group will report twice yearly to the Committee, which are responsible for reviewing the Group's ESG reporting and making recommendations to the Board.

Non-Core Assets

Due to the challenging market conditions, the Board has made a number of updates in relation to hVIVO's non-core assets. The Group holds 62.62% of PrEP Biopharm Limited and despite dedicating resources to realising value from this asset over the past number of years, due to difficult market conditions the directors of PrEP Biopharm will commence the process of a solvent liquidation of PrEP Biopharm in the coming months. In 2018 the Group's investment in PrEP Biopharm was fully impaired and since then has had a nil value in the Group's financial statements.

The Group also holds 49% of Imutex Limited with PepTcell Limited holding 51%. Management have performed an impairment assessment of this asset and determined that a full impairment of the carrying amount of the investment in Imutex is prudent. This impairment reflects a write down from £7,005,000 to Nil as at 31 December 2022.

The Board has decided to postpone all activities relating to the spin-out of Disease in Motion and pursue other growth opportunities that are more aligned with our near term strategic objectives as a human challenge trial business.

Outlook

hVIVO has had a strong start to 2023 with the Group well capitalised, debt free, and with full visibility for the current financial year and into H1 2024. I believe we have a world-class organisation led by a specialist management team that is well placed to lead and leverage the growth in the human challenge trial market and further strengthen our position as the world leader in the field. While we have had one cancellation in the year, the growing and diverse orderbook from new and existing Big Pharma and biotech clients provides excellent forward visibility and the ability to drive operational leverage through improved utilisation. We remain confident that the Group will continue to leverage its world leading position amidst favourable market dynamics and that hVIVO will continue to deliver profitable and sustainable growth into 2023 and beyond.

Cathal Friel
Chairman

24 April 2023

Chief Executive Officer's Statement

For the year ended 31 December 2022

Building a Long-Term Sustainable Business Model

I am pleased to report that hVIVO has delivered its most significant year of growth to date, establishing our position as the leading provider of human challenge trial services. Our strong performance has resulted in record revenues and EBITDA, with no debt and a robust cash balance of £28.4 million, laying a strong foundation for building sustainable future growth. The record contracted orderbook is indicative of the growing human challenge market and positions us well for 2023 and beyond.

Since my appointment in February 2022, building our contracted orderbook has been our first priority to provide a strong foundation, increase our forward visibility and open avenues for increased efficiencies in managing our cost base. Our contracted orderbook and operational model of running multiple challenge trials concurrently have enabled us to increase the utilisation of our quarantine facility, achieve operational efficiencies, and drive our EBITDA margins to record levels. I am also delighted with Venn Life Sciences' solid performance, where we continue to provide drug development consulting services to a broad range of clients. We are now generating an increased volume of cross-selling opportunities between Venn and hVIVO, creating an end-to-end early clinical development service offering.

The excellent growth and operational delivery in 2022 are a testament to our outstanding team of world-class scientists, clinicians and staff who are turning the human challenge trials concept into a vital cog in the global clinical development pathway. I would also like to take this opportunity to thank our volunteers who unselfishly dedicate their time to improving healthcare for the rest of society.

Record Results

The Group reported record full year revenues of £50.7 million (2021: £39.0 million), a significant increase of 30% compared to 2021. The Group's contracted orderbook increased to £76 million, up 65% year-on-year (2021: £46 million), and over sixfold since 2020 (2019: £12 million). Driving this growth is the continued expansion of the human challenge market and the increasing utility of challenge study data. hVIVO has led the industry in creating market awareness and educating the global biopharma industry to the value of human challenge data as a means of de-risking late-stage clinical trials. This has manifested in increased demand for larger sample sizes (i.e., more volunteers) and unique full-service contracts that include bespoke challenge agent manufacturing, characterisation study, and human challenge trial. hVIVO is in the unique position to deliver these end-to-end full-service projects.

EBITDA profit margins increased to 17.9% (2021: 7.4%), significantly ahead of previous guidance of 13-15%. This was driven by strong trading and execution of challenge trials, operational efficiencies achieved through running multiple concurrent trials and the recognition of postponement and cancellation fees (for a one-time aggregate of over £1 million). The advanced fees from the orderbook growth and increased operational delivery resulted in a record cash position of £28.4 million as at 31 December 2022 (2021: £15.7 million).

Due to the excellent financial performance in 2022, the Group will make a one-off, special dividend to shareholders of 0.45p per share, to be approved at the Annual General Meeting. This reflects the Group's exceptional cash generation in the year, in addition to its robust balance sheet.

Chief Executive Officer's Statement

Continued

Superb customer delivery

In 2022, hVIVO continued to solidify its position as the world leader in human challenge trials by serving several new and repeat customers. Our global client base has access to our unrivalled portfolio of infectious and respiratory disease challenge models. Most notable of these is four of the top 10 global biopharma companies. This trend highlights the growing inclusion of human challenge trials into the clinical development pathway of their clinical assets. We anticipate that this year-on-year repeat business from influential decision makers in the global biopharma industry will continue to have a positive impact on the worldwide demand for human challenge trials.

hVIVO also provided services to several new and repeat biotech customers, further expanding our diverse and loyal client base across the biopharma spectrum. As a result, there is immense potential for growth among biotech companies, as the cost-effective human efficacy data generated by human challenge trials becomes increasingly appealing in a tight funding environment. Positive efficacy data can significantly boost the value of an asset, which can be transformative for biotechs. Additionally, challenge trial data can accelerate time-to-market for vaccines and antivirals by up to three years, enabling biopharma companies to maximise revenues for their products whilst their patents are active.

Key projects

In 2022, we delivered several landmark projects for our clients across our world-leading portfolio of human challenge study models. These projects included the inoculation of 413 volunteers, representing a 32% increase from the previous year.

Two key themes among our contract wins in 2022 were the end-to-end human challenge contracts and larger volunteer sample size per challenge study. Notably, the trend towards larger sample sizes indicates that the industry is recognising the value of human challenge data as a means of achieving greater utility of data and pursuing lower frequency trial endpoints to further de-risk their programs ahead of late-stage field studies.

Our enhanced sales strategy and increased market awareness have led to record sales numbers, with several significant contracts highlighted below:

- £14.7m contract for manufacture, characterisation and challenge study for Big Pharma client
- £13.6m contract for a challenge trial with a US-based biopharmaceutical client
- £10.4m contract for manufacture and challenge trial for a Big Pharma client
- £7.3m challenge trial for a leading biotech
- £7.2m challenge trial with a Big Pharma client

The value proposition of human challenge trials has been further reinforced by the positive results from human challenge trials conducted by hVIVO. For example, Pfizer received FDA breakthrough designation for its RSV vaccine candidate for older adults following a successful Phase IIa human challenge study conducted by hVIVO. The FDA is now expected to make a final decision on whether to approve the candidate in 2023 as the world's first RSV vaccine. Similarly, Bavarian Nordic received FDA breakthrough designation in 2022 for its RSV vaccine candidate, MVA-BN® RSV, following a successful human challenge trial conducted by hVIVO. We are proud to have played a significant role in advancing the clinical development of several important RSV vaccine and antiviral candidates that have the potential to alleviate the significant burden of RSV on patients as well as global healthcare systems.

Efficiency initiatives

The significant growth in profitability during the period can be attributed to the implementation of operational efficiency initiatives across the business. Previously, hVIVO conducted only one challenge trial at a time, which heightened the financial impact of any cancellations or postponements. However, the Group can now concurrently run multiple human challenge trials across its facilities and has devised a flexible booking model with quarterly slot assignments that provides greater adaptability. This capability enables hVIVO to maintain high levels of occupancy at its quarantine clinics, regardless of changes or delays in clients' programs. This will be a key driver in improving EBITDA margins from historical levels.

The increased throughput of challenge studies is supported by the re-vamped FluCamp platform. Enhancements to the volunteer recruitment system include the implementation of online self-booking, online screening, and a new CRM to manage more effectively the database of volunteers. These technological upgrades, in addition to the new London and Manchester volunteer screening sites and greater utilisation of volunteers, have resulted in more consistent lead generation through new and existing marketing channels, as well as improved conversion rates. A considerable number of volunteers recruited possess pre-existing immunity to specific strains, and we now screen volunteers against multiple challenge agents, significantly increasing the probability of volunteers entering our challenge trials and improving volunteer utilisation. These changes have been vital as hVIVO continues to expand and deliver on its growth strategy.

Diversifying our services

hVIVO has continued to expand its revenue streams by offering additional services which can benefit our clients' clinical development portfolios. Our full-service offering is a unique proposition that involves custom challenge agent manufacturing and characterisation followed by a human challenge trial. This has generated significant interest from both Big Pharma and biotechs, especially as the global biopharma industry seeks to test vaccine and antivirals against specific virus subtypes that are circulating in the population.

In 2022, we launched our Malaria human challenge model and completed the manufacture of an Omicron human challenge agent in Q1 2023. We are in discussions with a number of potential customers in relation to these new models. The continued diversification of our portfolio of challenge models will be a key market differentiator, consolidating our position as the world leader in challenge trials. We plan to add more new models in 2023 and beyond to address growing demand from new and existing customers.

We have also expanded our CRO service offering, increasing staff and facility utilisation at our clinical and laboratory facilities. Our new clinical site services include utilising the upgraded infrastructure at our Plumbers Row facility for single site or multi-centre Phase II-III vaccine field trials. Our first contract in this area was signed with a global pharma company in 2022. These studies enable us to leverage our valuable database of volunteers who are ineligible to participate in human challenge trials.

In addition, our laboratory services have been expanded by increasing the volume of stand-alone laboratory services contracts. We received the College of American Pathologists (CAP) accreditation as part of our ongoing commitment to maintaining the best-in-class quality systems. This key accreditation provides additional quality assurances of our laboratory services for our clients, particularly in the US, and has increased the marketability of our laboratory services.

A long-term market focus – APAC

While our main client base remains in the US and Europe, we have identified the Asia Pacific (APAC) region as a key long term market focus. The APAC clinical market is growing rapidly, with nearly 8,000 clinical trials initiated in the APAC region in 2021, with China being the main driver. At the start of 2023, the Group signed its first human challenge trial contract with an APAC client in over a decade, and this region remains a key focus for our BD team. We will continue to capitalise on opportunities from the APAC region.

Venn Life Sciences

The Venn Life Sciences subsidiary has demonstrated solid performance in 2022, buoyed by ongoing robust relationships with repeat customers. The team in Breda (Netherlands) has shown steady growth across all disciplinary areas (CMC, Non-Clinical, Clinical, QA). The Pharmacokinetics and Biomarker PM Services in particular have experienced a strong business expansion by providing dedicated services. The Paris team continues to deliver Data Management and Biostatistics services to third-party customers, as well as increasing collaboration on hVIVO's challenge studies. We are excited by the cross-selling opportunities with hVIVO in the areas of clinical site and laboratory services and seamless drug development support service ("Bench-to-Bed") through our expertise, making it attractive for clients to conduct hVIVO challenge studies.

Chief Executive Officer's Statement

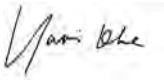
Continued

Summary

I am delighted to report that the Group's performance in 2022 exceeded expectations, with hVIVO delivering record growth numbers across the board. I am very proud of our team's adaptability and commitment to achieving these results despite the changes we have implemented. The financial performance for 2022 is only beginning to reflect the commitment of the team and the excitement we have as we start this new journey.

Looking forward, it is critical to establish a long-term sustainable growth model. A key forward looking metric is our record contracted orderbook, with full visibility for the current financial year and into H1 2024. I am confident that our improved sales and operational strategies will enable us to address the growing human challenge market. Our focus will be on marketing our existing challenge models, developing new models and targeting new markets, such as the APAC region. Furthermore, we will expand our non-challenge work including clinical consulting in new areas such drug-device combination and ATMP, as well as Laboratory Services and Clinical Site Services.

I strongly believe that our operational model is now optimised to deliver long-term, sustainable growth and improved profitability. As the world leader in the human challenge market, we remain confident in our ability to deliver value for our shareholders.



Yamin 'Mo' Khan
CEO

24 April 2023

The Board

Cathal Friel, Non-Executive Chairman (aged 58)

Cathal Friel is a seasoned serial entrepreneur with a long-running and successful history in business. Cathal is Managing Director of Raglan Capital and Chairman and co-founder of hVIVO plc (formerly Open Orphan plc). Cathal is also Chairman and co-founder of Poolbeg Pharma plc, which was created as a spin-out of hVIVO plc in 2021. Cathal also co-founded Amryt Pharma plc which IPO'd on the London Stock Exchange in 2016 and was successfully sold to Chiesi Farmaceutici for $1.48bn in April 2023. Prior to that, he was co-founder and Chairman of Fastnet Oil & Gas plc, which listed on the London Stock Exchange in 2011.

Cathal began his working career a little earlier than most by having to step in to help run the family business in 1981 at the relatively young age of 16 due to a family illness. He went on to complete his education by taking night classes and received an MBA from the University of Ulster in 1990. Cathal then spent the following five years lecturing on a part-time basis on International Marketing and Business Planning at the University of Ulster whilst in tandem running his own technology services business.

In 2001, Cathal was part of the team that successfully established Merrion Stockbrokers in Dublin. Following Merrion's successful trade sale in 2006, he founded Raglan Capital which is renowned for building in-house companies that are quickly listed on the public stock markets and are scaled rapidly post-IPO generally via M&A transactions. Cathal was a finalist in the international category of the EY Entrepreneur of the Year 2020.

Dr. Yamin 'Mo' Khan, Chief Executive Officer (aged 53)

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 (aged 59)

Stephen is a chartered accountant with over 25 years of experience in senior financial roles and has worked at the company for six years. He has developed a strong end to end understanding of the business, working across all key commercial operational decisions. During his time at the company, he helped transform the financial reporting, monthly accounts and forecasting of the business, overhauled the project accounting system, developed pricing models for all the contracts that range in value from £2m to £15m, improved pricing and margin on contracts, oversaw forecast models for mergers, acquisitions and operational performance, and supported on the restructuring of the business to improve efficiencies. Stephen has an extensive career in a range of leadership positions. Prior to joining hVIVO, he worked in Thomson Reuters for eleven years, most recently as Finance Director for Enterprise Risk Management. He holds an Honours Degree in Bachelor of Commerce and a Bachelor's Degree in Accounting and Finance from the University of Cape Town.

Prof. Brendan Buckley, Non-Executive Director (aged 72)

Prof. Brendan Buckley holds professorial titles in the faculties of Medicine at universities in Cork and Dublin. A medical graduate of University College Cork and a doctoral graduate of Oxford University, he practiced for most of his career as a consultant physician in endocrinology and diabetes. He has over 30 years' experience in clinical research in roles as chief investigator, chair of data and safety monitoring committees and on institutional review boards. He was Chief Medical Officer of ICON plc, prior to which he had co-founded Firecrest Clinical, a company focused on improving the performance of clinical trial sites, and which was acquired by ICON. He was a member of ICON plc's Executive Leadership Team and was actively involved in M&A targeting, assessment and diligence. Brendan was non-executive director of the Irish regulatory authority (now the Health Products Regulatory Authority) between 2004 and 2011. He was a member of the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) and of the EMA Scientific Advisory Group for Diabetes and Endocrinology as well as teaching on FDA advanced courses on clinical trials. He serves on the boards of various pharma development and services companies, some of which he has co-founded. Brendan has over 150 scientific publications, including the key opinion-leading book 'Re-Engineering Clinical Trials'.

Dr. Elaine Sullivan, Non-Executive Director (aged 62)

Elaine is a senior pharmaceutical and biotech industry executive with a successful track record in science, investment, business development, and start-ups. Elaine has extensive global leadership experience including membership of the top senior global R&D management teams at Eli Lilly (US) and AstraZeneca (UK) as well as experience in partnerships with venture, equity, and strategic collaborations. As Vice President Global External Research & Development (Lilly, US) Elaine led teams across US, UK, Japan, China, and India to identify, evaluate and conduct due diligence of external molecules and technologies. Elaine was also a key stakeholder collaborating with strategic VC partners to create a portfolio of companies and develop molecules from Investigational New Drug to Clinical proof-of-concept which, if successful, could be licenced by Lilly or sold. Elaine was member of the steering and investment boards of Capital Funds, Lilly Ventures, and Lilly Asian Ventures.

Elaine has delivered over 250 collaborations and transactions including spinouts, joint ventures, strategic partnerships and multi-million US$ acquisitions and has extensive experience in executing deals world-wide including US, Europe, and China. Former positions include Co-founder and CEO of Carrick Therapeutics raised $95 million Series A. Winner of the Ernst Young Emerging Entrepreneur of the Year (Ireland). Member of the Supervisory Board of Evotec AG, Non-Executive Director of IP Group plc, Active Biotech AB and Nykode Therapeutics ASI and Chair of the R&D committee. Member of the Scientific Advisory Board at Poolbeg Pharma.

Martin Gouldstone, Non-Executive Director (aged 56)

Martin has 30 years of corporate development experience in the CRO, healthcare and pharmaceutical sectors, holding a number of senior roles at healthcare AI businesses. Martin has expertise in executing multi-billion dollar deals across Europe and the US, architecting end-to-end portfolio out-sourcing deals, and negotiating multi-year research partnerships. Martin is currently Global SVP, Business Development at Owkin, a French-American start-up using artificial intelligence to discover and develop better treatments for unmet medical needs. Previously, Martin has held the roles of Chief Business Officer at both Benevolent AI and Sensyne Health and was a Partner at Results Healthcare, an international M&A advisory firm, where he co-led the company's healthcare practice. Prior to this, Martin was Head of Life Sciences for BDO UK LLP, Senior Director responsible for M&A and joint venture opportunities in Europe for Quintiles (now IQVIA), and Business Development and Licensing Lead at Confirmant Ltd, Pharmacopeia Inc, Sareum Ltd. Martin holds a BSc in Genetics and has completed a range of post graduate management courses.

Strategic Report

For the year ended 31 December 2022

Review of the business

A comprehensive review of the year is given in the Chairman's Statement on page 15 and Chief Executive Officer's Statement on page 17. The directors' duty under section 172 of the Companies Act 2006 is outlined on page 32.

Principal risks and uncertainties

The Directors continually identify, monitor and manage the risks and uncertainties of the Group. Risk is inherent in all businesses. Set out below are certain risk factors which could have an impact on the Group's long-term performance and mitigating factors adopted to alleviate these risks. This list does not purport to be an exhaustive summary of the risks affecting the Group.

Management and employees

The Group's future success will be dependent on key employees and their on-going relationships with customers. It is believed that the Group is of a size that the departure of no one individual represents a significant risk to the Group. The Group ensures that customer contacts be maintained by more than one individual. All client facing employees are incentivised through a mixture of sales commission and/or profit related bonuses. The Board of Directors are incentivised as detailed in the Directors' Remuneration Report.

Political risk

The Group operates in politically stable jurisdictions and seeks to reduce risk by carefully assessing the clients it works with and sub-contractors or suppliers that support its operations. Nevertheless, there is an ongoing risk to hVIVO Plc due to unexpected global events that may negatively impact its ability to operate.

This includes the outbreak of future strains of COVID-19 or escalation of geopolitical events in Europe. Such events have led to high rates of inflation, exchange rate volatility, higher cybersecurity risk and supply chain disruptions and could adversely impact hVIVO's business. To the extent possible, hVIVO aims to monitor the macro-economic and political environment so as to take such actions it deems in its best interests to mitigate the impact of various shocks.

The Board continue to monitor the impact of the COVID-19 pandemic on all aspects of the group, most notably the safety of our employees and the impact on the development of our pipeline. The ultimate impact of COVID-19 is regularly reviewed and our management team ensure that all operational and clinical plans are designed and reviewed with sufficient flexibility to allow for any future disruptions.

hVIVO continues to invest in its IT infrastructure and support systems in order to improve its security and resilience and ability to operate in the event of cyber-attacks.

Inflation risk is managed through a combination of providing forward prices on future projects, including inflationary clauses in contracts and proposals and detailed client budgets that itemise costs with current prices that are subject to change.

Regulatory risk

There can be no guarantee that the Group will be able to maintain the necessary regulatory approvals in any or all of the territories in which it operates. Where regulatory approvals are obtained, there can be no guarantee that the conditions attached to such approvals will not be considered too onerous by the Group or its partners in order to be able to market their products effectively. The Group seeks to reduce this risk by focusing on services with low-risk profiles, by seeking advice from regulatory advisers, through consultations with regulatory approval bodies and by working with experienced industry partners.

Competition risk

The Group's current and future potential competitors include, amongst others, major international CROs and drug development consultancy companies with substantially greater resources than those of the Group. There can be no guarantee that competitors will not succeed in developing services that are more effective or economic than any of those developed by the Group. The Group seeks to reduce this risk by providing high-quality specialised services which differentiate the Group in the marketplace.

Effect of foreign currency

The Group has limited foreign currency exposure by contracting its sales as much as possible in the functional currency of the jurisdictions where it operates. The cost base of operations in these jurisdictions is predominantly in the functional currency of those jurisdictions. In the limited cases where the Group has foreign currency exposure on receipts in a particular currency, it seeks to hedge or match the payment of any expenses in this currency to mitigate this risk.

Financial risk management

The Group has instigated certain financial risk management policies and procedures which are set out in Note 3 to the financial statements.

Future outlook

The future developments and events since the end of the year are set out in the Chairman's Statement and Strategic Report. Post year end events can be found in Note 30 of the Financial Statements.

Further details of the Group's Financial Risk and management policies are set out in Note 3 of the Financial Statements.

Key Performance Indicators (KPIs)

The key performance indicators used by the Group are revenue (2022: £50.7m; 2021: £39.0m), EBITDA (before exceptional items) (2022: £9.1m; 2021: £2.9m), contracted order book (2022: £76m; 2021: £46m) and cash (2022 £28.4m; 2021: £15.7m). The Company also uses non-financial key performance indicators such as measuring staff and quarantine utilisation, staff turnover, quality assurance metrics and pipeline tracking.

Review of strategy and business model

The Board of Directors judge the Group's financial performance by reference to the internal budget which it establishes at the beginning of each financial year.

As noted in the Chief Executive Officer's Statement, we continue to invest in new challenge models as we seek to capitalise on the significant growth in funding for infectious and respiratory disease post-pandemic. Our quarantine facilities and operations in the UK together with the number of successful human challenge trials completed reaffirm our position as the world leader in the delivery of human challenge trials.

The Group is focused on delivering on its significant contracted orderbook, continuing to grow its pipeline of new opportunities and to develop new revenue streams.

Environmental, Social & Governance (ESG)

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

Our approach to ESG

At hVIVO, we play an important role in improving global health by supporting the clinical development of medicinal products, especially infectious and respiratory disease products, through human challenge trials. As a growing organization, we recognise the importance of continually improving our governance and prioritising social and environmental concerns in all our work.

We are committed to operating as a responsible business; and as part of this commitment, we are currently assessing the Company's environmental, social and governance protocols and policies. hVIVO has established a cross-business working group, called the ESG Group, which focuses on identifying risks and opportunities related to climate change and other social and governance topics. Yamin 'Mo' Khan leads the ESG Group and report directly to the Audit and Risk Committee. The ESG Group consists of representatives from various areas of our business and report to the to Audit and Risk Committee, which is responsible for reviewing the Company's ESG reporting and recommending it to the Board.

Our ESG Values

1. **Commitment to Ethical & Compliant Business Practices**
2. **Advancing Heath & Research**
3. **Commitment to Volunteers & Patients**
4. **Commitment to our Staff**
5. **Social & Community Investment**
6. **Operating Sustainably**

"Our ESG policies have been developed in-line with hVIVO's core values to ensure we engage in ethical and compliant business practices, from the execution of our clinical trials to our interactions with colleagues, volunteers, clients, vendors, investors and all other stakeholders.

In the workplace, we aim to build and maintain a diverse and inclusive environment to allow our talented team to thrive."

"We recognise our responsibility to reduce our impact on the environment whenever possible and strive to minimise our carbon footprint through energy efficient practices, sourcing from local and sustainable suppliers, and reducing waste."

Yamin 'Mo' Khan, CEO & Head of the ESG Group

Environmental

hVIVO is committed to effective environmental management and to minimising the impact of our business on the environment. We are working towards implementing the principles of ISO14001. In 2022, our Environmental Policy was implemented and made available to all staff to ensure awareness of their roles and responsibilities in relation to environmental management.

We are currently conducting a review of our operations to identify any processes that impact key environmental issues, including energy use, waste control, purchasing, contractor management, transport, and emergency response. Once we have obtained adequate measurable information on our environmental impact, we intend to implement environmental targets.

Streamlined Energy and Carbon Reporting ('SECR')

hVIVO plc has reported greenhouse gas (GHG) emissions for Scope 1 and 2 (and associated Scope 3) in accordance with the requirements of Streamlined Energy and Carbon Reporting (SECR). This includes emissions for the first mandatory reporting year, which covers the 12 months from 1 January 2022 to 31 December 2022.

Energy efficiency action

The Company's Progress in 2022

- Energy consumption monitoring has been introduced
- Remote working has led to reduced energy consumption in the corporate office
- Sensor lights implemented across most sites
- The Employee Cycle to Work scheme successfully implemented
- Employees encouraged to utilise virtual meeting technology instead of business travel whenever practical
- Low carbon modes of transport encouraged where possible (season ticket loan)

Plans for the Group in 2023 and beyond

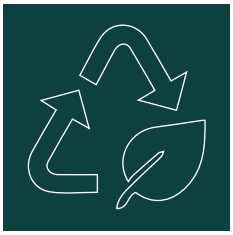
- Electric Vehicle (EV) scheme implemented in the UK (March 2023)
- Seek renewable energy sources
- Implement energy targets
- Implement process to switch off energy sources when not in use across all sites
- Increase Company / Employee engagement on implementing environmental initiatives

Emissions (tCO_2e)	2022
Scope 1 Emissions from combustion of gas	63.8
Scope 2 Emissions from purchased electricity	12.9
Scope 3 Emissions from business travel in rental cars or employee vehicles where company is responsible for purchasing the fuel	27.6
Total	104.3
Other metrics	
Intensity ratio from Scope 1, 2 & 3 (tCO_2e / £10,000 turnover)	0.021
Intensity ratio: tCO_2e from Scope 1, 2 and 3 / FTE	0.497
Total energy used (GWh)	**517,113**

Methodology: Emissions were calculated using data, estimates or extrapolations collected by the Company, according to the 2022 UK Government Greenhouse Gas Conversion Factors for Company Reporting

Environmental

Continued



7,500
KG Recycled *

6,000 KG
Waste Converted
to Energy*

*Corporate office and volunteer screening sites

Waste Management

hVIVO is committed to monitoring and reducing our waste

- We monitor the amount of waste produced and have implemented recycling facilities at all hVIVO sites
- We vet and monitor our waste contractors

2023 and beyond:

- hVIVO will ensure that any sites producing more than 200kg of hazardous waste in a 12-month period are registered
- We will develop new initiatives to reduce waste generation

E-Waste, Electronic & Hazardous Waste, Machinery

hVIVO is committed to monitoring and reducing our carbon emissions

- We now monitor total E-Waste emissions
- Electronic waste is disposed of in line with WEEE regulations
- Hazardous waste is monitored and disposed of in line with regulations and reduced where possible

A planned preventative maintenance program is in place to ensure all plant and equipment is maintained at its optimum level and is replaced at the end of its lifecycle.

Social

235
Permanent Staff at Year End

48%
of employees have been with the company > 3 years

62%
Female Staff at Year End

18%
Turnover 2022

Our Team

Our Employees are the key to our success, we are focussed on building a strong corporate culture that places diversity and equality at its centre.

Equality, Inclusion, Diversity

At hVIVO, we aim to foster a culture of equality, inclusion and diversity that enables us to build a strong team and deliver exceptional results for our clients. We believe that a diverse, welcoming and collaborative workplace allows our team to thrive, and we are committed to providing equal opportunities for all. We value and respect the differences that make each individual unique and strive to create a culture that promotes meritocracy, openness, fairness, and transparency.

We treat all employees on the basis of merit and ability alone and do not discriminate against anyone on the grounds of age, race, gender, religion, sexual orientation, or any other protected characteristic. We are committed to creating an environment where everyone is treated with respect and dignity and has the opportunity to reach their full potential.

Social & Community Investment

At hVIVO, we believe in giving back to our community and those in need. To achieve this goal, we have implemented the following initiatives:

- In 2022, we introduced hVIVO's Volunteering Policy, which offers all employees the opportunity to participate in volunteering schemes.
- The Venn Breda team volunteer annually at NL Doet, in support of their local community.
- Any surplus food from the FluCamp quarantine experience is donated to local homeless charities.
- Any outdated entertainment equipment following a FluCamp upgrade is donated to the local community.

Looking ahead to 2023 and beyond we will continue to invest in social and community initiatives including:

- The establishment of a Charitable Donations Policy, which aims to both support employee fundraising activities and identify qualified charitable organisations that align with hVIVO's mission and values. We will also provide monetary donations or donations in-kind in support of our Volunteering Policy.
- We are finalising a formal Community Engagement Programme across the Group.

Social

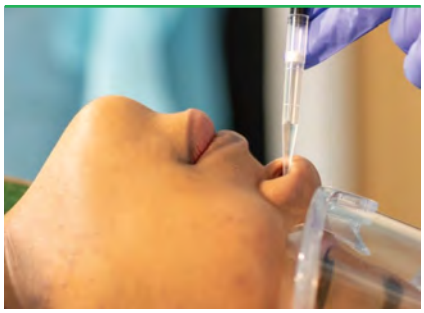
Continued

Developing Vital Medicines

The lack of access to appropriate medical healthcare is a significant challenge to global health, and at hVIVO, we recognise our important role in helping our customers bring vital medical products to the market faster through our clinical development consulting and clinical trial services.

We prioritise the safety and well-being of our volunteers and patients, and are committed to upholding ethical standards in clinical research, including data privacy and protection. We value the feedback of our participants, and continually seek to improve our processes to ensure their voices are heard.

Our work in developing vital medicines is a key part of our commitment to social responsibility, and we will continue to strive for excellence in this area.



Sharing Knowledge & Tackling Infectious Disease

We are committed to sharing knowledge and expertise to help tackle infectious diseases. We collaborate with industry organisations, academic centres (e.g. Imperial College, Royal Free Hospital, Emory Institute etc.) and non-profit organisations such as The Wellcome Trust and HIC-VAC to promote and expand the knowledge around human challenge trials. We have led a non-profit consortium which published 'Considerations on the Principles of Development and Manufacturing Qualities of Challenge Agents For Use In Human Infection Models' in 2022. This document will support the development, characterisation and manufacture of challenge agents in low and middle-income countries (LMIC). We believe that this will enable research to take place locally, and expedite the development of much needed new therapies for diseases that are prevalent in LMICs.

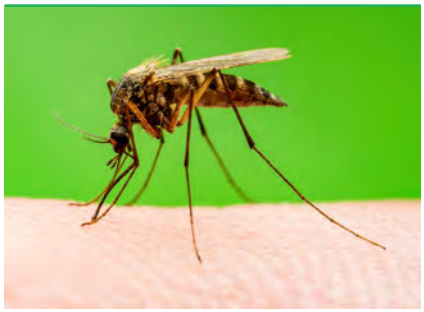
As a company we actively participate in scientific events and conferences worldwide, where we present data and insights from Human Challenge Trials, and foster scientific discussion. We regularly publish our findings together with our trial sponsors in scientific journals.

Neglected Tropical Diseases

Until recent years, hVIVO's wide portfolio of challenge models have focussed upon respiratory infections, but from 2022 we now offer Malaria human challenge trials to assist in the advancement of novel antimalarial drug and vaccine candidates.

Malaria is a serious and life-threatening illness that disproportionately effects vulnerable populations in tropical and sub-tropical regions. With increasing resistance to current antimalarial regimens, new drugs are urgently required to address a growing medical need. New therapies will not only reduce mortality and disease in vulnerable populations, but also to help the move towards the ambitious goal of malaria elimination. Malaria is classified as an unmet need in healthcare. In 2015 the World Health Assembly endorsed aims to reduce malaria burden by 90% by 2030.

We continue to explore new potential challenge models to help provide our clients with high quality efficacy data.



Governance

To further enhance our governance practices, hVIVO is committed to upholding the highest standards of ethical conduct and transparency in all our operations. We provide services to one of the world's most closely regulated industries.

The Directors recognise the value and the importance of high standards of corporate governance and, given the Group's size and the constitution of the Board, have decided to apply the recommendations of the Corporate Governance Code, published by the Quoted Companies Alliance in April 2018 ("QCA Code"). Read the Corporate Governance statement on page 36.

Dedication to Ethical, Safety and Quality Standards

Our commitment to maintaining & continuously improving our quality systems and policies goes beyond meeting the minimum standards required by regulatory bodies. We have implemented comprehensive Standard Operating Procedures (SOPs) and policies under a controlled Quality Management System (QMS) overseen by our Head of Quality Assurance. This ensures that we conduct our trials in the highest quality, safety, regulatory and ethical environment. In addition, we have established an independent audit system and Corrective and Preventive Action (CAPA) process to maintain continuous oversight of quality throughout the conduct of studies, as stated in our Quality Policy.

To ensure compliance with relevant regulatory authorities, ethics committees and institutional review boards, we maintain regular engagement with them. Our commitment to honesty, transparency and quality is embedded in our Clinical Governance Policy and Business Code of Ethics. We conduct all of our Clinical Trials to the highest standards in accordance with Good Clinical Practice (GCP) and applicable national and international regulations.

All our trials are approved by the Medicines and Health Products Regulatory Agency (MHRA) – the UK medicines regulator – and / or an independent Research Ethics Committee (REC) to ensure they meet the highest standards of safety and ethics.

The safety of the participants in our clinical trials is our number one concern and our priority in all our activities. Before submitting a clinical trial for approval to the relevant authorities our internal experts assess the available data on the product to ensure the all the required data are available.

Our trials are designed in such a way that risk for participants is minimised. Once participants are enrolled on the study, ongoing medical oversight is maintained at all stages of the study as outlined in the Medical Management Policy.

To ensure the highest standards of quality and data integrity, our staff undergo regular training on Good Clinical Practice (GCP) and data integrity principles. All data generated in the clinical trials and laboratory assays is subject to rigorous quality control measures, ensuring that it meets the highest quality and standards.

Governance

Continued

Section 172 Companies Act 2006

The Directors acknowledge their duty under section 172 of the Companies Act 2006 and consider that they have, both individually and together, acted in the way that, in good faith, would be most likely to promote the success of the Company for the benefit of its members as a whole. In doing so, they have had regard (amongst other matters) to:

Cathal Friel
Chairman

Dr. Yamin 'Mo' Khan
CEO

Stephen Pinkerton
CFO

Brendan Buckley
NED

Elaine Sullivan
Independent NED

Martin Gouldstone
Independent NED

Section 172 Companies Act 2006

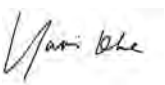
- The long-term consequences of any decision we make: We recognise that the decisions we make today can have a significant impact on the future success of the company. As such, we carefully consider the potential long-term consequences of our decisions and take steps to mitigate any risks.
- The interests of our employees (see page 29, Social): Our employees are fundamental to achieving our long-term strategic objectives. We value their contributions and consider their interests in all decision-making processes.
- The impact of our operations on the community and the environment (see page 27, Environmental): As a responsible corporate citizen, we operate honestly and transparently. We are committed to minimising our impact on the environment and take steps to ensure that our day-to-day operations are conducted in an environmentally sustainable manner.
- The importance of maintaining a reputation for high standards of business conduct: We believe that maintaining a reputation for ethical conduct is essential for the long-term success of the Company. We are committed to upholding the highest standards of corporate governance and good business conduct, as highlighted in our Corporate Governance Statement.
- Our obligation to act in the interests of all shareholders (see page 38): We recognise our responsibility to act in the best interests of all shareholders of the Company. We are committed to treating all shareholders fairly and equally so that they may benefit from the successful delivery of our strategic objectives.

Our Board of Directors

Our Board of Directors is made up of a diverse range of professionals who are experts in their fields. A commitment to quality and integrity filters from the Board, company wide.

To ensure that our governance practices are effective, we have established robust internal controls and risk management systems. Our Board of Directors oversees these systems and ensure that they are regularly reviewed and updated as needed. We believe that a strong governance framework is essential to maintaining the trust of our stakeholders, including our customers, employees, investors, and the wider community.

The Strategic Report was approved by the Board on 24 April 2023 and signed on its behalf by:



Yamin 'Mo' Khan
CEO

Report of the Directors

For the year ended 31 December 2022

The Directors are pleased to submit this report together with the audited financial statements of hVIVO Plc (formerly Open Orphan Plc) for the year ended 31 December 2022.

Directors

The Directors who held office during the year and as at the date of signing the financial statements were as follows:

Prof. Brendan Buckley
Cathal Friel
Leo Toole (Resigned 18 October 2022)
Dr Elaine Sullivan
Yamin 'Mo' Khan
Martin Gouldstone (Appointed 8 June 2022)
Stephen Pinkerton (Appointed 18 October 2022)

Principal activities

hVIVO is a rapidly growing specialist contract research organisation (CRO) providing end-to-end early clinical development services to the biopharmaceutical industry, including world leading human challenge trial services.

Specific information, including key risks and future developments are shown in the Strategic Report, Chairman's Statement and Chief Executive Officer's Statement as permitted by section 414C (11) of the Companies Act.

Going concern

The Directors have considered the applicability of the going concern basis in the preparation of these financial statements. This included the review of internal budgets and financial performance which show that the Group will be able to operate within the level of its current financing position. For more detail refer to Note 1.

Whilst COVID-19, and the associated uncertainties are now receding, the conflict in eastern Europe, accompanied by rising inflation, interest rates and a broad degree of macro-economic and political disruption continue to create challenges for the global economy. The Group itself is well capitalised and debt-free, meaning it is able to benefit from rising interest rates on its cash reserves without any exposure to increased costs of debt. Suppliers and key stakeholders have all made adjustments to minimise disruptions and to facilitate the continued efficient running of their businesses and the Group does not foresee any significant problems in relation to its operations in the coming year.

The Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. The Group therefore continues to adopt the going concern basis of preparation for its consolidated financial statements.

Directors' interests

The interests of those Directors serving at 31 December 2022 and as at the date of signing of these financial statements, all of which are beneficial, in the share capital of the Company hVIVO Plc (formerly Open Orphan Plc) were as follows:

	% Holding of Ordinary Shares of 0.1p each	On 31 December 2022 Ordinary Shares of 0.1p each	On 1 January 2022 Ordinary Shares of 0.1p each
Cathal Friel*	7%	47,087,086	47,087,086
Yamin 'Mo' Khan	<1%	510,204	–
Prof. Brendan Buckley	1%	8,034,539	8,034,539

*Held via Raglan Road Capital Ltd, Horizon Medical Technologies Ltd, a nominee account and/or through a family member

Report of the Directors

Continued

Substantial shareholdings

The Company has been notified of the following holdings of 3% or more of the issued Ordinary Share capital as at 12 April 2023:

Share register	Number of Shares	Percentage of issued share capital
Cathal Friel*	47,087,086	6.94%
Allan Rankin	20,702,209	3.09%

*Held via Raglan Road Capital Ltd, Horizon Medical Technologies Ltd, a nominee account and/or through a family member

Events after the end of the reporting period

The following events have taken place since the year end:

a) The Directors propose a special, one off dividend of 0.45 pence per share. The payment is subject to approval by shareholders at the Company's Annual General Meeting on 23 May 2023.

b) The Company issued 7,716,964 shares @ £0.056/Share as a result of share options being exercised by a former employee.

c) hVIVO Holdings Limited owns 62.62% of PrEP Biopharm Limited. In 2018 the carrying value was fully impaired so the investment has a value of Nil at 31 December 2022. The Directors of PrEP Biopharm will commence the process of a solvent liquidation. The liquidation is expected to complete in 2023.

Statement of Directors' responsibilities

The Directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare financial statements for each financial year. Under that law the Directors have prepared the Group and Parent Company financial statements in accordance with UK adopted international accounting standards ("IFRS"). Under Company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and the Company and of the profit or loss of the Company and Group for that period. In preparing these financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and accounting estimates that are reasonable and prudent;
- state whether applicable IFRSs as adopted by the United Kingdom have been followed, subject to any material departures disclosed and explained in the financial statements; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Company will continue in business.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and the Group and enable them to ensure that the financial statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the Company and the Group and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Directors are responsible for the maintenance and integrity of the Company's website (www.hvivo.com). Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

Directors' liability insurance

The Group has entered into deeds of indemnity for the benefit of each Director of the Group in respect of liabilities to which they may become liable in their capacity as Director of the Group and of any Company in the Group. Those indemnities are qualifying third party indemnity provisions for the purposes of Section 234 of the Companies Act 2006 and have been in force during the whole of the financial year and up to the date of approval of the financial statements.

Auditors

Jeffreys Henry LLP has indicated that it will not seek re-appointment as the Group's auditor at the Annual General Meeting as, following a business reorganisation, the firm will provide audit services to clients from another company in the Group, Gravita Audit Limited. A resolution to appoint Gravita Audit Limited as the Group's auditor will be proposed at the Annual General Meeting.

Disclosure of information to the Auditors

The Directors who hold office at the date of approval of this report confirm that so far as they are each aware, there is no relevant audit information of which the Group and Company's auditors are unaware, and each Director has taken all the steps that he ought to have taken as a Director in order to make him aware of any relevant audit information and to establish that the Company's auditors are aware of that information.

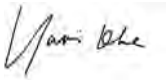
Annual General Meeting

The resolutions to be proposed at the forthcoming Annual General Meeting are set out in the formal notice of the meeting which has been posted to you together with this Annual Report.

Recommendation

The Board considers that the resolutions to be proposed at the Annual General Meeting are in the best interests of the Company and it is unanimously recommended that shareholders support these proposals as the Board intends to do in respect of their own holdings.

The Directors' report was approved by the Board on 24 April 2023 and signed on its behalf by



Yamin 'Mo' Khan
CEO

Corporate Governance Statement

For the year ended 31 December 2022

Compliance

The Directors recognise the value and the importance of high standards of corporate governance and, given the Group's size and the constitution of the Board, have decided to apply the recommendations of the Corporate Governance Code, published by the Quoted Companies Alliance in April 2018 ("QCA Code").

The Board has established high standards of corporate governance since its inception and agrees that its success is enhanced by the imposition of a strong corporate governance framework. Accordingly, in recognition of the need to maintain continued best practice the Board actively monitors its composition and skills balance to ensure we uphold the ten principles outlined in the QCA Code, so far as practicable and having regard to the size and nature of the Company's business.

Board composition and responsibility

The Board currently comprises a Non-Executive Chairman, two Executive Directors and three Non-Executive Directors. The Board has determined that Elaine Sullivan and Martin Gouldstone are independent in character and judgement and that there are no relationships or circumstances which could materially affect or interfere with the exercise of their independent judgement. The Board is satisfied with the balance between Executive and Non-Executive Directors which allows it to exercise objectivity in decision making and proper control of the Group's business. The Board considers this composition is appropriate in view of the size and requirements of the Group's business and the need to maintain a practical balance between Executives and Non-Executives.

All Directors are subject to election by shareholders at the first Annual General Meeting after their appointment and are subject to re-election at least every three years. Non-Executive Directors are appointed for a specific term of office which provides for their removal in certain circumstances, including under section 168 of the Companies Act 2006. The Board does not automatically re-nominate Non-Executive Directors for election by shareholders. The terms of appointment of the Non-Executive Directors can be obtained by request to the Company Secretary.

The Board's primary objective is to focus on adding value to the assets of the Group by identifying and assessing business opportunities and ensuring that potential risks are identified, monitored and controlled. Matters reserved for Board decisions include strategic long-term objectives and capital structure of major transactions. The Non-Executive Chairman is responsible for developing the overall strategy of the Group in conjunction with all Board members and then ensures that the CEO and CFO oversee its implementation through the Senior Management Team, which is accountable for the operational performance of the Group.

Board meetings

12 Board meetings were held during the year. The Directors' attendance record (in their respective roles) during 2022 is as follows:

Cathal Friel (Non-Executive Chairman)	12	
Leo Toole (Chief Financial Officer)	9	(of a possible 10)
Prof. Brendan Buckley (Non-Executive Director)	10	
Elaine Sullivan (Non-Executive Director)	9	
Yamin 'Mo' Khan (Chief Executive Officer)	10	
Martin Gouldstone(Non-Executive Director)	4	(of a possible 7)
Stephen Pinkerton (Chief Financial Officer)	2	(of a possible 2)

Audit and Risk Committee

The principal duties of the Audit and Risk Committee include ensuring the integrity of the Group's risk management systems, internal control environment, and corporate reporting including the review of half-yearly and annual financial statements before their submission to the Board and to consider any matters raised by the auditors. The Committee also reviews the independence and objectivity of the auditors. The terms of reference of the Committee reflect current best practice, including authority to:

- Recommend the appointment, re-appointment and removal of the external auditors
- Ensure the objectivity and independence of the auditors including occasions when non-audit services are provided
- Ensure appropriate 'whistle-blowing' arrangements are in place
- Recommend Group's policy on auditor rotation, together with the tenure of the current auditors and date of last tender and advance notice of any retendering plans

The Audit and Risk Committee comprises Martin Gouldstone as Chair, with Brendan Buckley and Elaine Sullivan as the other members of the Committee. The Committee intends to meet at least twice a year and have not found any significant issues.

Remuneration Committee

The Group has established a formal and transparent procedure for developing policy on Executive remuneration and for fixing the remuneration packages of individual Directors. No Director is involved in deciding his own remuneration. The Committee considers the employment and performance of individual Executive Directors and determines their terms of service and remuneration. It also has authority to grant options under the Company's Executive Share Option Scheme. The Committee does so within its formal terms of reference and having due regard to the interests of shareholders.

The Remuneration Committee comprises Brendan Buckley as Chair with Elaine Sullivan and Martin Gouldstone as the other members of the Committee. The Committee intends to meet at least twice a year.

The Remuneration Committee's report for the 2022 financial year is set out on page 39.

Nomination Committee

The Nomination Committee identifies and nominates for the approval of the Board, candidates to fill Board vacancies as and when they arise.

The Committee comprises Elaine Sullivan as Chair with Brendan Buckley and Martin Gouldstone as the other members of the committee. The Committee intends to meet at least twice a year.

Internal control

The Directors are responsible for ensuring that the Group maintains a system of internal control to provide them with reasonable assurance regarding the reliability of financial information used within the business and for publication, and also that the assets of the Group are safeguarded. There are inherent limitations in any system of internal control and accordingly even the most effective system can provide only reasonable, but not absolute, assurance with respect to the preparation of financial reporting and the safeguarding of assets.

The Group, in administering its business has put in place strict authorisation, approval and control levels within which senior management operates. These controls reflect the Group's organisational structure and business objectives. The control system includes clear lines of accountability and covers all areas of the organisation. The Board operates procedures which include an appropriate control environment through the definition of the above organisation structure and authority levels and the identification of the major business risks.

Corporate Governance Statement

Continued

Internal financial reporting

The Directors are responsible for establishing and maintaining the Group's system of internal reporting and as such have put in place a framework of controls to ensure that the on-going financial performance is measured in a timely and correct manner and that risks are identified as early as is practicably possible. There is a comprehensive budgeting system and monthly management accounts are prepared which compare actual results against both the budget and the previous year. They are reviewed and approved by the Board, and revised forecasts are prepared on a regular basis.

Communications with shareholders

The Board attaches great importance to communication with both institutional and private shareholders and engages in regular shareholder communication via Company RNS announcements, the Company website www.hvivo.com, investor presentations, and shareholder meetings as appropriate.

The Group reports to shareholders twice a year. The Group dispatches the notice of its Annual General Meeting, together with a description of the items of special business, at least 21 days before the meeting. Each substantially separate issue is the subject of a separate resolution, and all shareholders have the opportunity to put questions to the Board at the Annual General Meeting. The Chair of the Audit and Remuneration Committees normally attend the Annual General Meeting and will answer questions which may be relevant to their work. The Chairman advises the meeting of the details of proxy votes cast on each of the individual resolutions after they have been voted on in the meeting.

The Chairman and the Non-Executive Directors intend to maintain a good and continuing understanding of the objectives and views of the shareholders.

Report of the Remuneration Committee

For the year ended 31 December 2022

Statement of compliance

This report sets out the Group policy on Directors' remuneration, including emoluments, benefits and other share-based awards made to each Director.

Policy on Executive Directors' remuneration

Remuneration packages are designed to motivate and retain Executive Directors to ensure the continued development of the Group and to reward them for enhancing value to shareholders. The main elements of the remuneration package for Executive Directors are basic salary or fees, performance related bonuses, benefits and share option incentives.

Directors' remuneration

The remuneration of the Directors serving for the year ended 31 December 2022 is shown below and in Note 6:

	Salary/Fee £'000	Annual Bonus £'000	Pension £'000	Total 2022 £'000	Total 2021 £'000
Executive Directors:					
Cathal Friel[1]	108	68	–	176	172
Yamin 'Mo' Khan[2]	260	212	27	499	–
Stephen Pinkerton[3]	35	10	4	49	–
Leo Toole[3]	110	–	11	121	189
Sub-Total	**513**	**290**	**42**	**845**	**361**
Non-Executive Directors:					
Cathal Friel[1]	28	–	–	28	–
Brendan Buckley	45	–	–	45	45
Elaine Sullivan	47	–	–	47	30
Yamin 'Mo' Khan[2]	46	–	–	46	57
Martin Gouldstone[4]	25	–	–	25	–
Former Directors (resigned in 2021)	–	–	–	–	50
Sub-Total	**191**	**–**	**–**	**191**	**182**
Total	**704**	**290**	**42**	**1,036**	**543**

(1) Cathal Friel became a Non-Executive Chairman of the Board on 18th October 2022.
(2) Yamin 'Mo' Khan was a Non-Executive Director up to 24th February 2022 when he became the Chief Executive Officer.
(3) Stephen Pinkerton replaced Leo Toole on 18th October 2022 as CFO and Executive Director.
(4) Martin Gouldstone joined the Board on 8th June 2022 as a Non-Executive Director.

Base salaries are reviewed annually, with the levels of increases for Executive Directors taking account of the performance of the Group, individual performance, additional responsibilities and external indicators such as inflation and industry comparatives.

Report of the Remuneration Committee

Continued

Directors' share options and warrants

Yamin 'Mo' Khan was granted 7,227,273 share options via a new Long Term Incentive Plan ("LTIP") on his appointment as CEO in February 2022. Vesting of the options is conditional upon a three year total shareholder return performance. They have an exercise price of 0.1p.

Stephen Pinkerton holds 67,364 share options via the LTIP scheme put in place in January 2020 on acquisition of hVIVO Group. They have an exercise price of 2p.

657,285 warrants are legally held by Cathal Friel CMF Pension Fund. These warrants were issued on 11 December 2018 in connection with the 2018 hVIVO Plc (formerly Open Orphan Plc) Loan Note and expire on 10 December 2023 and have an exercise price of 0.1/2.2 p.

Independent auditor's report

to the members of hVIVO Plc (formerly Open Orphan Plc)

Opinion

We have audited the financial statements of hVIVO Plc (formerly Open Orphan Plc) (the 'parent company') and its subsidiaries (the 'group') for the year ended 31 December 2022 which comprise the consolidated statement of comprehensive income, the consolidated and company statements of financial position, the consolidated and company statements of changes in equity, the consolidated and company statements of cash flows and notes to the financial statements, including a summary of significant accounting policies.

The financial reporting framework that has been applied in the preparation of the financial statements is applicable law and United Kingdom adopted International Accounting Standards and as regards the parent company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

In our opinion:

- the financial statements give a true and fair view of the state of the group's and of the parent company's affairs as at 31 December 2022 and of the group's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with United Kingdom adopted International Accounting Standards;
- the parent company financial statements have been properly prepared in accordance with United Kingdom adopted International Accounting Standards and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006;

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions related to going concern

In auditing the financial statements, we have concluded that the director's use of the going concern basis of accounting in the preparation of the financial statements is appropriate. Our evaluation of the directors' assessment of the entity's ability to continue to adopt the going concern basis of accounting included a detailed review of cashflow forecasts.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the Group's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue. Further explanation on the work we have performed for the evaluation of the directors' assessment of the entity's ability to continue to adopt the going concern basis of accounting is included in the Key Audit Matters section of this report.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy,

Independent auditor's report

Continued

the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. This is not a complete list of all risks identified by our audit.

- Carrying value of investments and intangibles
- Revenue recognition
- Carrying value of investments
- Carrying value of inventory
- Going concern assumption
- Carrying value of Investments in subsidiary undertakings and inter-company debtors (Company only risk)

These are explained in more detail below.

Key audit matter	How our audit addressed the key audit matter
Carrying value of intangibles All intangibles are being held at cost less impairment. The Group had intangible assets of £6,023,708 (2021: £6,219,000) at 31 December 2022. Of this, £5,600,000 relates to capitalised goodwill recognised on acquisitions and £423,708 relates to software, preferred right to reserve a slot and WBS Development. There have been no impairments in the year.	Our audit procedures: • we have tested items which were not capitalised as additions to intellectual property and checked that the conditions for capitalisation had not been met; • Intangibles are only assessed for impairment when indicators of impairment exist; • where an impairment test was necessary, we audited management's assumptions and sensitivities; • we considered whether management had exercised any bias in assumptions used or the outputs produced in the forecasts prepared; • we performed an analytical review to compare the profitability of components and discussed the findings with management; and The analysis work undertaken by the directors shows that the Group is expected to become cash generative. We have understood and assessed the methodology used by directors in this analysis and determined it to be reasonable.

Key audit matter	How our audit addressed the key audit matter
Revenue recognition The amount of revenue recognised by the Group was £48,477,379 (2021: £ 36,864,000). The Group recognises revenue from clinical trial services provided to customers, incrementally as work is performed, using service milestones noted in the contracts and percentage of completion of contract when recognising revenue over time. The percentage of completion is determined using level of work completed to date in respect of each individual milestones assigned to the clinical services contract. The milestones are measured using metrics assigned to the individual contracts. These metrics determines how the progress of each milestone can be measured. This requires management to estimate both the allocation of revenue to milestones in the contract at contract inception date, and the percentage of completion of each milestone at each reporting date. Contract assets and liabilities have been reviewed by the board in detail including each contract with all major customers and revenue has been recognised in accordance with IFRS 15. We identified a risk of inaccurate or incomplete recognition of revenue due to the incorrect allocation of milestones to service contracts and percentages of completion in calculating revenue and cost of sales. The assumptions and judgements made in estimating the percentage of completion require a significant degree of management judgement and are susceptible to management override and represent a fraud risk. We therefore determined this to be a key audit matter.	Our audit approach: • assessed the appropriateness of the Group's revenue recognition accounting policies; • reviewed a sample of contracts with customers and tested that the Group has correctly accounted for the revenue arising from these contracts in accordance with the accounting policies and reviewed management's judgement on the contract price and the allocation to performance obligations; • performed detailed testing on individually significant contracts, including substantiating a sample of transactions with underlying documents such as contracts, progress metrics data, internal forecasts and project completion reports, as well as discussions with project managers; • we checked a sample of time sheets and supporting information which were used to calculate the postings to the revenue account; • we reviewed the calculation of revenue to be accrued and tested a sample of items for the hours and rates applied from the time sheet system and agreed contract rates to the amount posted in the nominal ledger; • where appropriate we considered the remaining amount of accrued revenue which still required to be invoiced including calculations of that revenue and considered the recoverability of a sample of balances; • we performed a walk-through of the process followed and related controls with regard to the recognition of revenue; and • evaluated whether revenue has been appropriately presented and disclosed in the financial statements. Based on the audit work performed, we are satisfied that management have appropriately accounted for revenue in line with their accounting policy and in accordance with the requirements of IFRS 15. We are also satisfied that all necessary disclosures have been made in the consolidated financial statements.

Independent auditor's report

Continued

Key audit matter	How our audit addressed the key audit matter
Carrying value of investments in associates The Group held a material investment in an associate which was fully impaired in the year (2022 : £6.9m ; 2021: Nil) Given that the investment is in the early-stage research and development phase, there is a risk of incorrect valuation of equity accounted balances held by one of hVIVO's subsidiaries, hVIVO Holdings Limited. The risk of failure in elevated due to emergence of competition with similar products, which increases the risk of inaccurate valuation of investments. Furthermore, should impairment indicators be identified, there is a level of judgement exercised by management in estimating fair value of investments in associates, which may result in inaccurate valuation of balances.	We have performed the following audit procedures: • obtained and reviewed management's assessment of impairment of the associate and factors; • ensured key judgements are robust by review of events surrounding the judgement and validating the judgements by agreeing to supporting evidence; • where indicators of impairment were identified, we challenged management's assessment of the any recoverable amount from the investment in associates; • where no indicators of impairment were highlighted by management, we challenged the judgements made in management's assessment by identifying contradictory signs of any potential indicators of impairment; and • considered the appropriateness of the Group's disclosures in relation to any impairment in the financial statements. Based on the audit work performed, we are satisfied that management have appropriately recognised Impairment of the Investment in Associate in line with their accounting policy and in accordance with the requirements of IAS 27, IAS 36. We are also satisfied that all necessary disclosures have been made in the consolidated financial statements.

Key audit matter	How our audit addressed the key audit matter
Carrying value of inventory hVIVO Services Limited, subsidiary undertaking, produces and purchases viruses which require special considerations for estimation of the future value in use, expected life of the asset and impairment in light of evolution of virus strains around the world. Management is required to use their judgement to assess the future value in use of strains held in inventory at the balance sheet date and evaluate if the shelf life of the virus inventory will be sufficient for it to be useful for future human challenge studies. In doing so, management review their high probability pipeline of potential contracts and estimate the usage of virus over its useful life. There are inherent risks associated with the forecasted usage which may be affected where contracted studies are cancelled, and future studies are signed at a date later than the shelf life of the existing inventory. There is also a risk that the virus strains may evolve beyond the current research and development undertaken, thus decreasing the monetary value of the inventory held.	We have performed the following audit procedures: • obtained management's forecasts for future value in use of the virus inventory; • assessed the reliability of forecasts by agreeing to historical use and ensuring future contracted use; • reviewed management and challenged management on their judgements of the forecasted usage and estimated useful life of the virus inventory; • tested the clerical accuracy of management's forecast; and • considered the appropriateness of the Group's disclosures in relation to inventory in the financial statements. Based on the audit work performed we are satisfied that although there are uncertainties associated with the useful life of the virus stock, the Group's revenue pipeline will utilise the current inventory within a reasonable timeframe. We are also satisfied that all necessary disclosures have been made in the consolidated financial statements.

Independent auditor's report

Continued

Key audit matter	How our audit addressed the key audit matter
Going concern assumption The Group is dependent upon its ability to generate sufficient cash flows to meet continued operational costs and hence continue trading. Due to the slim profit margins, foreign exchange risk continues to be a key risk which can affect results. The management of employee and contractor costs is also key to profitability of the Group. The key assumptions that impact the conclusions are the levels of future revenue, and the ability to control the operating costs. There are, therefore, inherent risks that the forecasts may overstate future revenue due to the timing of closure of future contracts, or understate future costs, and that the Group will not be able to operate within its cash resources and continue to operate as a going concern. The going concern assumptions are dependent on the future growth of the current business.	Our audit procedures: • obtained management's forecasts and cash flow analysis, and their going concern assessment; • assessed the reliability of forecasts to date by agreeing historical actuals to budgets, and challenging the current forecasts; • tested the clerical accuracy of management's forecast; • reviewed the directors' assessment, including challenging the liquidity position; • agreeing the assumed cash flows to the business plan and walking through the business planning process and testing the central assumptions and external data; • challenged management's forecast assumptions, including reviewing the forecast revenue and corroborated the assumptions over the conversion of new contracts and the levels of costs that are forecast through observation of correspondence with potential customers to assess the likelihood of contracts being awarded; • assessing the sensitivities of the underlying assumptions; • comparing future cashflows with historical data; and • considered the appropriateness of the Group's disclosures in relation to going concern in the financial statements. Based on the audit work performed we are satisfied that although there are inherent uncertainties associated with the forecast, the Group's revenue pipeline, contracts won post year end and current cash position will provide required support to the business. We are also satisfied that all necessary disclosures have been made in the consolidated financial statements.

Key audit matter	How our audit addressed the key audit matter
Carrying value of investment in subsidiaries and carrying value of inter-company debtors (Company only risk) The Company had investments of £22,377,460 (2021: £22,377,460) at 31 December 2022 relating exclusively to the investments in subsidiary undertakings. We identified a risk that the investment of the parent company (hVIVO plc) in its subsidiaries and amounts receivable, may be impaired. Management's assessment of the recoverable amount of investments in subsidiaries requires estimation and judgement around assumptions used, including the cash flows to be generated from continuing operations. Changes to assumptions could lead to material changes in the estimated recoverable amount, impacting the value of investment in the subsidiary and impairment charges.	We have performed the following audit procedures: • reviewed management's assessment of future operating cashflows and indicators of impairment; • assessed the methodology used by management to estimate the future profitability of its subsidiaries and recoverable value of the investments, in conjunction with any intra-group balances, to ensure that the method used is appropriate; • assessed the reasonableness of the key assumptions used in management's estimates of recoverable value, in line with the economic and industry statistics relevant to the business; • challenged cash inflows from revenue generating activities and the key assumptions applied in arriving at these, including the milestones achieved in research programmes; the number and monetary value of clinical studies in the foreseeable future, and the market share of studies in key areas of disease focus; • assessed the reasonability of cash outflows, including contracted delivery costs, and research and capital spend; • assessed the appropriateness and applicability of discount rate applied to the current business performance; • confirmed that any adverse change in key assumptions would not materially increase the impairment loss; • considered the appropriateness of the Parent Company's disclosures in relation to any impairment in the Company only financial statements; and • ensured that disclosures of the key judgements and assumptions, and sensitivity of the impairment loss recognised was appropriately disclosed. Based on the audit work performed we are satisfied that the management have accounted for the impairment loss appropriately and in accordance with accounting standards, and the impairment loss is appropriately disclosed in the Parent Company financial statements.

Independent auditor's report

Continued

Our application of materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Based on our professional judgment, we determined materiality for the financial statements as a whole as follows:

	Group financial statements	Company financial statements
Overall materiality	£484,000 (2021: £390,000)	£92,300 (2021: £220,000)
How we determined it	Based on 1% of revenue	Based on 5% of net profit/loss
Rationale for benchmark applied	We believe that revenues are a primary measure used by shareholders in assessing the Group's performance. This is considered a standard industry benchmark.	We believe that Net Profit/ Loss is the primary measure used by shareholders in assessing the Group's performance given that this is a Holding Company with Recharges from Group entities. This is considered a standard industry benchmark.

For each component in the scope of our Group audit, we allocated a materiality that is less than our overall Group materiality. The range of materiality allocated across components was between £10,000 and £420,000.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £5,000 as well as misstatements below those amounts that, in our view, warranted reporting for qualitative reasons.

An overview of the scope of our audit

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we looked at where the directors made subjective judgments, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the directors that represented a risk of material misstatement due to fraud.

How we tailored the audit scope

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the Group and the Company, the accounting processes and controls, and the industry in which they operate.

The Group financial statements are a consolidation of 8 reporting units, comprising the Group's operating businesses and holding companies.

We performed audits of the complete financial information of hVIVO Plc, hVIVO Holdings Limited, hVIVO Services Limited and hVIVO Inc. We also performed specified audit procedures over goodwill and other intangible assets, as well as certain account balances and transaction classes that we regarded as material to the Group at the 8 reporting units.

The Group engagement team performed all audit procedures, with the exception of the audit of Venn Life Sciences Limited, Venn Life Sciences Biometry Services SAS, Venn Life Sciences (EDS) B.V. (Netherlands) and Open Orphan DAC. These components were audited by component auditors and we reviewed and controlled the audit work undertaken in those components.

Other information

The other information comprises the information included in the annual report other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon. Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the course of the audit, or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Opinions on other matters prescribed by the Companies Act 2006

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the strategic report and the directors' report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the strategic report and the directors' report have been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception

In the light of the knowledge and understanding of the group and parent company and its environment obtained in the course of the audit, we have not identified material misstatements in the strategic report or the directors' report.

We have nothing to report in respect of the following matters in relation to which the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- the parent company financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

Responsibilities of directors

As explained more fully in the directors' responsibilities statement set out on page 34, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the group's and parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the parent company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion.

Independent auditor's report

Continued

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below.

The extent to which the audit was considered capable of detecting irregularities including fraud

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, was as follows:

- the senior statutory auditor ensured the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations.
- we identified the laws and regulations applicable to the group through discussions with directors and other management.
- we focused on specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the company, including taxation legislation, data protection, anti-bribery, employment, environmental, health and safety legislation and anti-money laundering regulations.
- we assessed the extent of compliance with the laws and regulations identified above through making enquiries of management and inspecting legal correspondence.
- identified laws and regulations were communicated within the audit team regularly and the team remained alert to instances of non-compliance throughout the audit; and
- we assessed the susceptibility of the group's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:
    - making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
    - considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates set out in Note 4 of the Group financial statements were indicative of potential bias;
- investigated the rationale behind significant or unusual transactions; and
- in response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:
    - agreeing financial statement disclosures to underlying supporting documentation;
    - reading the minutes of meetings of those charged with governance;

- enquiring of management as to actual and potential litigation and claims; and
- reviewing correspondence with HMRC and the group's legal advisors.

There are inherent limitations in our audit procedures described above. The more removed those laws and regulations are from financial transactions, the less likely it is that we would become aware of noncompliance. Auditing standards also limit the audit procedures required to identify non-compliance with laws and regulations to enquiry of the directors and other management and the inspection of regulatory and legal correspondence, if any.

Material misstatements that arise due to fraud can be harder to detect than those that arise from error as they may involve deliberate concealment or collusion.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at:

www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

Use of this report

This report is made solely to the company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Sudhir Rawal (Senior Statutory Auditor)

For and on behalf of
Jeffreys Henry LLP (Statutory Auditor)
Finsgate
5-7 Cranwood Street,
London EC1V 9EE

24 April 2023

Consolidated Statement of Comprehensive Income

For the year ended 31 December 2022

	Notes	Year to 31 December 2022 £'000	Year to 31 December 2021 £'000
Operations			
Revenue, from contracts with customers		**48,477**	36,864
Other operating income	29	**2,220**	2,141
Direct project and administrative costs	5	**(41,625)**	(36,117)
EBITDA before exceptional items		**9,072**	2,888
Depreciation & amortisation	5,12,13,32	**(2,930)**	(2,565)
Exceptional items	5	**(119)**	267
Operating profit		**6,023**	590
Finance income/(expense)	9	**617**	(215)
Share based payment charge	28	**–**	(27)
Impairment of investment in associate	14b	**(6,957)**	–
Share of loss of associate using equity method	14b	**(48)**	(71)
(Loss)/Profit before income tax		**(365)**	277
Income tax (charge)	10	**(411)**	(351)
(Loss) for the year		**(776)**	(74)
(Loss) for the year is attributable to:			
Shareholders		**(776)**	(74)
Other comprehensive income			
Currency translation differences		**27**	(111)
Total comprehensive (loss) for the year		**(749)**	(185)
Earnings per share from operations attributable to shareholders during the year:			
Basic and diluted (loss) per ordinary share			
From operations	11	**(0.12p)**	(0.01p)
Earnings per share from operations attributable to shareholders during the year:			
Adjusted and diluted profit/(loss) per ordinary share			
From operations	11	**0.90p**	(0.19p)

All activities relate to continuing operations.

The notes on pages 56 to 84 are an integral part of these consolidated financial statements.

Consolidated and Company's Statement of Financial Position

As at 31 December 2022

	Notes	Group 2022 £'000	Group 2021 £'000	Company 2022 £'000	Company 2021 £'000
Assets					
Non-current assets					
Intangible assets	13	**6,023**	6,219	**–**	–
Property, plant and equipment	12	**1,513**	927	**–**	–
Investment in associates	14b	**–**	7,005	**–**	–
Investments in subsidiaries	14a	**–**	–	**22,377**	22,377
Right of use asset	32	**1,610**	2,788	**–**	–
Total non-current assets		**9,146**	16,939	**22,377**	22,377
Current assets					
Inventories	16	**499**	659	**–**	–
Trade and other receivables	17	**12,900**	8,944	**11,636**	9,692
Current tax recoverable		**391**	38	**15**	10
Cash and cash equivalents	18	**28,444**	15,694	**2,799**	8,663
Total current assets		**42,234**	25,335	**14,450**	18,364
Total assets		**51,380**	42,274	**36,827**	40,741
Equity attributable to owners					
Share capital	22	**671**	671	**671**	671
Share premium account	23	**4**	1	**4**	1
Merger reserves	23	**(6,856)**	(6,856)	**(2,241)**	(2,241)
Share based payment reserve	23	**578**	327	**578**	327
Foreign currency reserves	23	**1,358**	1,331	**2,014**	2,014
Retained earnings	23	**24,463**	25,206	**35,438**	36,767
Total equity		**20,218**	20,680	**36,464**	37,539
Liabilities					
Non-current liabilities					
Lease liabilities	32	**737**	863	**–**	–
Leasehold provision	34	**660**	40	**–**	–
Total non-current liabilities		**1,397**	903	**–**	–
Current liabilities					
Trade and other payables	19	**28,869**	18,396	**363**	3,202
Lease liabilities	32	**826**	1,991	**–**	–
Leasehold provision	34	**70**	10	**–**	–
Borrowings		**–**	294	**–**	–
Total current liabilities		**29,765**	20,691	**363**	3,202
Total liabilities		**31,162**	21,594	**363**	3,202
Total equity and liabilities		**51,380**	42,274	**36,827**	40,741

The notes on pages 56 to 84 are an integral part of these financial statements.

The financial statements were approved and authorised for issue by the Board on 24 April 2023.

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the parent Company's Statement of Comprehensive Income. The loss for the parent Company for the year was £1,362,000 (2021: loss of £1,522,000).

Yamin Mo Khan – CEO

hVIVO Plc (formerly Open Orphan Plc)
Registered no: 07514939

Consolidated and Company's Statement of Changes in Shareholders' Equity

Group	Share capital £'000	Share premium £'000	Merger reserve £'000	Share Option reserve £'000	Foreign currency reserve £'000	Retained earnings £'000	Total £'000
At 1 January 2021	731	44,480	(6,856)	493	1,442	(17,993)	22,297
Changes in equity for the Year ended 31 Dec 2021							
Loss for the year	–	–	–	–	–	(74)	(74)
Currency differences	–	–	–	–	(111)	–	(111)
Total comprehensive losses for the year	–	–	–	–	(111)	(74)	(185)
Transactions with the owners							
Share based payment res.	–	–	–	(166)	–	193	27
Shares issued	3	37	–	–	–	–	40
Capital reduction	(63)	(44,516)	–			44,579	–
Distribution in specie (note 33)	–	–	–	–	–	(1,500)	(1,500)
Total contributions by and distributions to owners	(60)	(44,479)	–	(166)	–	43,272	(1,433)
At 31 December 2021	671	1	(6,856)	327	1,331	25,206	20,680
Changes in equity for the Year ended 31 Dec 2022							
Loss for the year	**–**	**–**	**–**	**–**		**(776)**	**(776)**
Currency differences	**–**	**–**	**–**	**–**	**27**	**–**	**27**
Total comprehensive income/(loss) for the year	**–**	**–**	**–**	**–**	**27**	**(776)**	**(749)**
Transactions with the owners							
Share based payment res.	**–**	**–**	**–**	**251**	**–**	**33**	**284**
Shares issued	**–**	**3**	**–**	**–**	**–**	**–**	**3**
Total contributions by and distributions to owners	**–**	**3**	**–**	**251**	**–**	**33**	**287**
At 31 December 2022	**671**	**4**	**(6,856)**	**578**	**1,358**	**24,463**	**20,218**

Company	Share capital £'000	Share premium £'000	Merger reserve £'000	Share option reserve £'000	Foreign currency reserve £'000	Retained earnings £'000	Total £'000
At 1 January 2021	731	44,480	(2,241)	493	2,573	(4,983)	41,053
Changes in equity for the year ended 31 December 2021							
Total comprehensive loss for year	–	–	–	–	–	(1,522)	(1,522)
Share based payment res.	–	–	–	(166)	–	193	27
Currency differences	–	–	–	–	(559)	–	(559)
Shares issued	3	37	–	–	–	–	40
Capital reduction	(63)	(44,516)	–	–	–	44,579	–
Distribution in specie (note 33)	–	–	–	–	–	(1,500)	(1,500)
Total contributions by and distributions to owners	(60)	(44,479)	–	(166)	(559)	41,750	(3,514)
At 31 December 2021	671	1	(2,241)	327	2,014	36,767	37,539
Changes in equity for the year ended 31 December 2021							
Total comprehensive loss for year	**–**	**–**	**–**	**–**	**–**	**(1,362)**	**(1,362)**
Share based payment res.	**–**	**–**	**–**	**251**	**–**	**33**	**284**
Shares issued	**–**	**3**	**–**	**–**	**–**	**–**	**3**
Total contributions by and distributions to owners	**–**	**3**	**–**	**251**	**–**	**(1,329)**	**(1,075)**
At 31 December 2022	**671**	**4**	**(2,241)**	**578**	**2,014**	**35,438**	**36,464**

Consolidated and Company's Statement of Cash Flows

For the year ended 31 December 2022

	Notes	**Group 2022 £'000**	Group 2021 £'000	**Company 2022 £'000**	Company 2021 £'000
Cash Flow from operating activities					
Continuing operations					
Cash generated/(used) in operations	24	**14,508**	(539)	**(5,888)**	680
Income tax (R & D) received		**1,473**	1,304	**–**	
Net cash generated /(used) in operating activities		**15,981**	765	**(5,888)**	680
Cash flow from investing activities					
Investment in new subsidiary		**–**	–	**–**	(43)
Purchase of property, plant and equipment		**(1,275)**	(329)	**–**	–
Purchase of intangible asset		**(87)**	(410)	**–**	
Net cash used in investing activities		**(1,362)**	(739)	**–**	(43)
Cash flow from financing activities					
Lease payments	32	**(2,178)**	(2,329)	**–**	–
Proceeds from issuance of ordinary shares & options	28	**3**	40	**3**	40
Exceptional Costs re RTO, spin-out & restructuring	5	**–**	(1,169)	**–**	(409)
Interest & FX gains received /(paid)		**635**	(21)	**19**	–
Stamp Duty re capital reduction	33	**–**	–	**–**	(7)
Repayment of Convertible Debenture Security		**(294)**	(45)	**–**	(45)
Net cash (used)/generated by financing activities		**(1,834)**	(3,524)	**22**	(421)
Net increase/(decrease) in cash and cash equivalents		**12,785**	(3,498)	**(5,866)**	216
Cash and cash equivalents at beginning of year		**15,694**	19,205	**8,663**	8,689
FX translation		**(35)**	(13)	**2**	(242)
Cash and cash equivalents at end of year	18	**28,444**	15,694	**2,799**	8,663

Notes to the Financial Statements

For the year ended 31 December 2022

1. Presentation of the financial statements

Description of business

hVIVO Plc (formerly Open Orphan Plc) is a rapidly growing specialist CRO pharmaceutical services group of companies which is the world leader in the testing of vaccines and antivirals using human challenge clinical trials. The Group has a presence in the UK, Ireland, France and Netherlands.

Its parent company hVIVO Plc is a company incorporated in England and Wales. The Company is a public limited company, limited by shares, listed on the AIM market of the London Stock Exchange and on Euronext Growth in Dublin.

Basis of preparation

The financial statements have been prepared in accordance with the Group's accounting policies approved by the Board and described in Note 2, 'Summary of significant accounting policies'. Information on the application of these accounting policies, including areas of estimation and judgement is given in Note 4, 'Critical accounting estimates and judgements'. The preparation of the financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The financial statements have been prepared in accordance with UK adopted international accounting standards ("IFRS"), and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS. Figures are presented in £000s.

Parent company financial statement

The financial statements of the parent company, hVIVO plc, have been prepared in accordance with IFRS and with UK accounting presentation. The Company's Statement of Financial Position is presented on page 53 and the accounting policies are given on pages 56 to 84.

Composition of financial statements

The consolidated financial statements are drawn up in GBP£, the functional currency of hVIVO plc, and in accordance with IFRS accounting presentation. The financial statements comprise:

- Consolidated statement of comprehensive income
- Consolidated statement of financial position
- Consolidated statement of changes in equity
- Consolidated cash flow statement
- Notes to the financial statements

Composition of the Group

The Group comprises hVIVO Plc (formerly Open Orphan Plc) and its subsidiary companies as set out in Note 14.

Financial period

These financial statements cover the financial year from 1 January to 31 December 2022, with comparative figures for the financial year from 1 January to 31 December 2021.

Accounting principles and policies

Going Concern

The financial statements have been prepared using the historical cost convention modified by the revaluation of certain items, as stated in the accounting policies, and on a going concern basis. The Directors consider the use of the going concern basis to be appropriate given the significant cash reserves at year end and strong contracted order book. The Directors have prepared working capital projections which show that the Group & Company will be able to continue as a going concern.

2. Summary of significant accounting policies

Consolidation

The consolidated financial statements include:

- the assets and liabilities, the results and cash flows, of the Company and its subsidiaries.
- the Group's share of the results and net assets of associates.
- the Group's share of assets, liabilities, revenue and expenses of associates.

Entities over which the Group has the power to direct the relevant activities so as to affect the returns to the Group, generally through control over the financial and operating policies, are accounted for as subsidiaries. Where the Group has the ability to exercise significant influence over entities, they are accounted for as associates. The results and assets and liabilities of associates are incorporated into the consolidated financial statements using the equity method of accounting. The assets, liabilities, revenue and expenses of associates are included in the consolidated financial statements in accordance with the Group's rights and obligations. Interests acquired in entities are consolidated from the date the Group acquires control and interests sold are de-consolidated from the date control ceases.

Transactions and balances between subsidiaries are eliminated and no profit before tax is taken on sales between subsidiaries until the products are sold to customers outside the Group. The relevant proportion of profits on transactions with associates is also deferred until the products are sold to third parties. Transactions with non-controlling interests are recorded directly in equity. Deferred tax relief on unrealised intra-Group profit is accounted for only to the extent that it is considered recoverable.

New accounting requirements

Amendments to accounting standards issued by the IASB and adopted in the year ended 31 December 2022 did not have a material impact on the results or financial position of the Group. Certain new accounting standards, amendments to accounting standards and interpretations have been published that are not mandatory for 31 December 2022 reporting periods and have not been adopted early by the Group. These standards, amendments and interpretations are not expected to have a material impact on the results or financial position of the Group in future reporting periods.

Business combinations

The Group uses the acquisition method of accounting to account for business combinations. The consideration transferred for the acquisition of a subsidiary is the fair values of the assets transferred, the liabilities incurred, and the equity interests issued by the Group. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration agreement. Acquisition related costs are expensed as incurred. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. On an acquisition by acquisition basis, the Group recognises any non-controlling interest in the acquiree either at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets.

Notes to the Financial Statements

Continued

The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the Group's share of the identifiable net assets acquired is recorded as goodwill. If this is less than the fair value of the net assets of the subsidiary acquired in the case of a bargain purchase, the difference is recognised directly in the Statement of Comprehensive Income.

Investments in subsidiaries are accounted for at cost less impairment. Cost is adjusted to reflect changes in consideration arising from contingent consideration amendments.

Associates

Associates are all entities over which the group has significant influence but not control or joint control as defined under IAS28. Investments in associates are accounted for using the equity method of accounting (see equity method below), after initially being recognised at cost less any fair value adjustment.

Equity Method:

Under the equity method of accounting, the investments are initially recognised at cost and adjusted thereafter to recognise the group's share of the post-acquisition profits or losses of the investee in profit or loss, and the group's share of movements in other comprehensive income of the investee in other comprehensive income. Dividends received or receivable from associates are recognised as a reduction in the carrying amount of the investment.

When the group's share of losses in an equity-accounted investment equals or exceeds its interest in the entity, including any other unsecured long-term receivables, the group does not recognise further losses, unless it has incurred obligations or made payments on behalf of the other entity. Unrealised gains on transactions between the group and its associates are eliminated to the extent of the group's interest in these entities. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred.

Accounting policies of equity accounted investees have been changed where necessary to ensure consistency with the policies adopted by the group. The carrying amount of equity-accounted investments is tested for impairment.

Foreign currency translation

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in GBP£, which is the functional and presentation currency of the main operating entities.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions where items are re-measured. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the Statement of Comprehensive Income within 'direct project and administrative expenses', except when deferred in other comprehensive income as qualifying cash flow hedges and qualifying net investment hedges.

The results and financial position of all the Group entities (none of which has the currency of a hyper-inflationary economy) that have a functional currency different from the presentation currency are translated into the presentational currency as follows:

- assets and liabilities presented are translated at the closing rate at the date of that reporting period;
- income and expenses are translated at average exchange rates; and
- all resulting exchange differences are recognised in other comprehensive income.

On consolidation, exchange differences arising from the translation of the net investment in foreign operations are taken to other comprehensive income. When a foreign operation is partially disposed of or sold, exchange differences that were recorded in equity are recognised in the Statement of Comprehensive Income as part of the gain or loss on sale.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the foreign entity and translated at the closing rate.

Segmental reporting

Operating segments are reported in a manner consistent with the internal monthly management reporting provided to the chief operating decision-makers. The chief operating decision-makers ("CODM"), who are responsible for allocating resources and assessing performance of the operating segments, have been identified as the Executive Directors and Non-Executive Chairman who make strategic decisions.

The first principal activity of the Group is conducting human challenge trials and related laboratory services in London though the hVIVO Services subsidiary. This work is supported by our second principal activity, which is providing a suite of consulting and early clinical trial services to pharmaceutical, biotechnology and medical device organisations, in London and also in Paris and Breda though Venn Life sciences Biometry Services, Venn Life Sciences Ltd and Venn Life Sciences ED B.V.

Previously the Group reported results under two segments, hVIVO and Venn but as the Group has become more integrated, internal management reporting provided to the CODM is on a consolidated basis. As many of our business contracts are multi-country contracts, pulling resources from many different locations, the CODM considers the group to be one business unit.

Management therefore considers both operating segments to form one reporting segment for disclosure purposes.

Revenue

Revenue from contracts

The Group enter into fixed-price and multi-service contracts with customers. Revenue from contracts with customers is recognised at an amount that reflects the consideration to which the Group expects to be entitled in exchange for the goods or services and is shown net of Value Added Tax. Revenue is recognised based on the actual service provided to the end of the reporting period as a proportion of the total services to be provided because the customer receives and uses the benefits simultaneously. This is determined by labour hours incurred to the period end as a percentage of the total estimated labour hours for the contract or as considered recoverable in respect of each individual performance obligation.

Payment terms tend to vary between 30 and 90 days.

Provisions for losses to be incurred on contracts are recognised in full in the period in which it is determined that a loss will result from the performance of the contractual arrangement.

The difference between the amount of revenue from contracts with customers recognised and the amount invoiced on a particular contract is included in the statement of financial position as deferred income. Amounts become billable in advance upon the achievement of certain milestones, in accordance with pre-agreed invoicing schedules included in the contract or on submission of appropriate detail. Any cash payments received as a result of this advance billing are not representative of revenue earned on the contract as revenues are recognised over the period during which the specified contractual obligations are fulfilled. Amounts included in deferred income are expected to be recognised within one year and are included within current liabilities.

In the event of contract termination, if the value of work performed and recognised as revenue from contracts with customers is greater than aggregate milestone billings at the date of termination, cancellation clauses provide for the Group to be paid for all work performed to the termination date.

Other operating income (mainly research & development tax credits/R&D tax credits)

R&D tax credits are multi-government backed tax incentive that allows companies to claim back some of the costs they have incurred on research, development and innovation. These are non taxable and involve high level of management judgement. See Note 4.

Notes to the Financial Statements

Continued

Interest income

Interest income is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable.

Exceptional items

These are items of an unusual or non-recurring nature incurred by the Group and include transactional costs and one-off items relating to business combinations, such as acquisition expenses, restructuring and redundancy costs.

Property, plant and equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation and any provision for impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the asset and bringing the asset to its working condition for its intended use.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only where it is probable that future economic benefits associated with the asset will flow to the Group and the cost of the asset can be measured reliably. The carrying amount of the replaced part is derecognised. All other repairs and maintenance are charged to the Statement of Comprehensive Income during the financial period in which they are incurred. Any borrowing costs associated with qualifying property, plant and equipment are capitalised and depreciated at the rate applicable to that asset category.

Depreciation on assets is calculated using the straight-line method or reducing balances method to allocate their cost to its residual values over their estimated economic useful lives, as follows:

Leasehold Improvements	the shorter of five years or the life of the lease
Plant & Machinery	four years
Fixtures and fittings	three to five years

The assets' residual values and useful economic lives are reviewed regularly, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying value is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on the disposal of assets are determined by comparing the proceeds with the carrying amount and are recognised in direct project administration expenses in the Statement of Comprehensive Income.

Intangible assets

(a) Goodwill

Goodwill represents the excess amount of the cost of an acquisition over the fair value of the Group's share of the net identifiable assets of the acquired underlying businesses at the date of the acquisition. Goodwill on acquisitions of businesses is included in intangible assets. In normal cases goodwill has an indefinite useful life and is tested annually for impairment and carried at cost less accumulated impairment losses. Impairment losses on goodwill are not reversed. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold.

Goodwill is allocated to cash-generating units for the purpose of impairment testing. The allocation is made to those cash-generating units or groups of cash-generating units that are expected to benefit from the business combination in which the goodwill arose.

(b) Intellectual property rights

Intellectual property rights relate to patents acquired by the Group. Amortisation is calculated using the straight-line method over the expected life of no more than 10 years and is charged to direct project and administrative expenses in the Statement of Comprehensive Income.

(c) Capitalised Software development and wearables development

Internally generated intangible assets involving research and development expenditure.

Expenditure on research activities is recognised as an expense in the period in which it is incurred. Development costs are capitalised when the related products meet the recognition criteria of an internally generated intangible asset, the key criteria being as follows:

- technical feasibility of the completed intangible asset has been established;
- it can be demonstrated that the intangible asset will generate probable future economic benefits;
- adequate technical, financial and other resources are available to complete the development;
- the expenditure attributable to the intangible asset can be reliably measured; and
- management has the ability and intention to use or sell the intangible asset.

Expenses for research and development include associated wages and salaries, material costs, depreciation on non-current assets and directly attributable overheads. Development costs recognised as assets are amortised over their expected useful life.

Impairment of non-financial assets

Assets that have an indefinite life such as Goodwill are not subject to amortisation and are tested annually for impairment. Assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the carrying amount exceeds its recoverable amount.

The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset which the estimates of future cash flows have not been adjusted.

For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows. Impairment losses recognised for cash-generating units, to which Goodwill has been allocated, are credited initially to the carrying amount of Goodwill. Any remaining impairment loss is charged pro rata to the other assets in the cash-generating unit.

Where an impairment loss subsequently reverses, the carrying amount of the asset (cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset (cash-generating unit) in the prior period. A reversal of an impairment loss is recognised in the Statement of Comprehensive Income immediately. If Goodwill is impaired however, no reversal of the impairment is recognised in the financial statements.

Investments in associates

Investments in associates are carried in the Consolidated Statement of Financial Position at the Group's share of their net assets at date of acquisition and of their post-acquisition retained profits or losses and other comprehensive income together with any goodwill arising on the acquisition. The Group recognises the assets, liabilities, revenue and expenses of joint operations in accordance with its rights and obligations.

Notes to the Financial Statements

Continued

As of 31 December 2022, in view of little progress made to move either of Imutex's portfolio towards commercialisation, management does not consider carrying value of the investment in Imutex Limited of £6.9m supported. Full impairment is therefore considered appropriate.

Right of use assets

The Group recognises right of use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right of use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right of use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognised right of use assets is depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term.

Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value (i.e., below $5,000). Lease payments on short-term leases and leases of low-value assets are recognised as expense on a straight-line basis over the lease term.

Inventories

Inventories are reported at the lower of cost (purchase price and/or production cost) and net realisable value. Net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and applicable variable selling expenses.

Financial instruments

Financial assets

The financial assets of the group consist of trade receivables, accrued income, cash and other receivables. Financial assets are measured at amortised cost, fair value through other comprehensive income or fair value through profit or loss. The measurement basis is determined by reference to both the business model for managing the financial asset and the contractual cash flow characteristics of the financial asset. A lifetime expected credit loss (ECL) allowance is recorded on initial recognition of a financial asset. If there is subsequent evidence of a significant increase in the credit risk of an asset, the allowance is increased to reflect the full lifetime ECL. If there is no realistic prospect of recovery, the asset is written off. ECLs are recognised in the Statement of Comprehensive Income.

Cash and cash equivalents

Cash and short-term deposits in the Statement of Financial Position comprise cash at bank and in hand and short-term deposits with an original maturity of less than three months, reduced by overdrafts to the extent that there is a right of offset against other cash balances.

Financial liabilities

The financial liabilities of the group consist of trade payables, accrued expenses, lease liabilities, and borrowings. Financial liabilities are classified as financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate.

Borrowings

Borrowings are recognised initially at the fair value of proceeds received, net of transaction costs incurred. Borrowings are subsequently carried at amortised cost. Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the reporting period date.

Borrowing costs are expensed in the consolidated Statement of Comprehensive Income under the heading 'finance costs'. Arrangement and facility fees together with bank charges are charged to the Statement of Comprehensive Income under the heading 'direct project and administrative costs'.

Current and deferred income tax

The tax expense comprises current and deferred tax. Tax is recognised in the Statement of Comprehensive Income, except to the extent that it relates to items recognised in other comprehensive income where the associated tax is also recognised in other comprehensive income.

The current income tax charge is calculated on the basis of the tax laws enacted at the reporting period date in the countries where the Company and its subsidiaries operate and generate taxable income. Management evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation and establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred tax assets are recognised for all deductible temporary differences, carry-forward of unused tax assets and tax losses, to the extent that they are regarded as recoverable. They are regarded as recoverable where, on the basis of available evidence, there will be sufficient taxable profits against which the future reversal of the underlying temporary differences can be deducted.

The carrying value of the amount of deferred tax assets is reviewed at each reporting period date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all, or part, of the tax asset to be utilised.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realised or the liability is settled, based on the tax rates (and tax laws) that have been substantively enacted at the reporting period date.

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income tax assets and liabilities relate to income taxes levied by the same taxation authority on either the taxable entity or different taxable entities where there is an intention to settle the balances on a net basis.

Share capital

Ordinary Shares and Deferred shares are classified as equity. Proceeds in excess of the nominal value of shares issued are allocated to the share premium account and are also classified as equity. Incremental costs directly attributable to the issue of new Ordinary Shares or options are deducted from the share premium account.

Merger reserve

The reserve represents a premium on the issue of the ordinary shares for the acquisition of subsidiary undertakings. The relief is only available to the issuing company securing at least a 90% equity holding in the acquired undertaking in pursuance of an arrangement providing for the allotment of equity shares in the issuing company on terms that the consideration for the shares allotted is to be provided by the issue to the issuing company of equity shares in the other company.

Lease liabilities

At the commencement date of the lease, the Group recognises lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating a lease, if the lease term reflects the Group exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognised as expense in the period on which the event or condition that triggers the payment occurs.

Notes to the Financial Statements

Continued

In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

Employee benefits

Pension obligations

Group companies operate a pension scheme with defined contribution plans, under which the Group pays fixed contributions into a separate entity with the pension cost charged to the Statement of Comprehensive Income as incurred.

The Group has no further obligations once the contributions have been paid.

Share-based payment

Where equity settled share options and warrants are awarded to Directors and employees, the fair value of the options and warrants at the date of grant is charged to the consolidated statement of comprehensive income over the vesting period and the corresponding entry recorded in the share-based payment reserve. Non-market vesting conditions are reflected by adjusting the number of equity instruments expected to vest at each reporting date so that, the cumulative amount recognised over the vesting period is based on the number of options that eventually vest.

Leasehold provision

Provisions for dilapidations and onerous lease commitments are recognised when the Group has a present or constructive obligation as a result of past events. The recognition of a provision requires management to make best estimates of the consideration required to settle the present obligation at the end of the reporting period, reflecting the risks and uncertainties surrounding the obligation. There is reasonable uncertainty around the likelihood and timing of the exit of the lease as negotiations will involve third parties.

3. Financial risk management

Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk (foreign exchange risk and cash flow interest rate risk), credit risk, liquidity risk, capital risk and fair value risk. The Group's risk management programme focuses on the unpredictability of the financial markets and seeks to minimise the potential adverse effects on the Group's financial performance. The Group does use derivative financial instruments to hedge specific client contracted currency risk exposures.

Risk management is carried out by the head office finance team. It evaluates and mitigates financial risks in close co-operation with the Group's operating units. The Board provides principles for overall risk management whilst the head office finance team provides specific policy guidance for the operating units in terms of managing foreign exchange risk, credit risk and cash and liquidity management.

(a) Market risk

(i) Foreign exchange – cash flow risk

The Group's presentation currency is GBP£ although it operates internationally and is exposed to foreign exchange risk arising from various currency exposures, primarily between Euro, USD$ and the GBP£ such that the Group's cash flows are affected by fluctuations in the rate of exchange between GBP£ and the aforementioned foreign currencies.

The Group does not speculate in foreign currencies and no operating Company is permitted to take unmatched positions in any foreign currency.

(ii) Foreign exchange – fair value risk

Translation exposures that arise on converting the results of overseas subsidiaries are not hedged. Net assets held in foreign currencies are hedged wherever practical by matching liabilities in the same currency. The principal exchange rates used by the Group in translating overseas profits and net assets into GBP£ are set out in the table below.

	Average rate	Average rate	**Year end rate**	Year end rate
Rate compared to GBP£	**2022**	2021	**2022**	2021
Euro	**1.17**	1.16	**1.13**	1.19
USD$	**1.24**	1.37	**1.21**	1.35

As a guide to the sensitivity of the Group's results to movements in foreign currency exchange rates, a one penny movement in the GBP£ to Euro rate would impact annual earnings by approximately £24,000 due to natural hedging (2021: £19,000).

(iii) Cash flow and fair value interest rate risk

The Group has assets in the form of cash and cash equivalents and did have limited interest-bearing liabilities which relate to short-term borrowing. Where possible, the Group earns market interest rates on cash and cash equivalents on deposit whilst interest rates on borrowings were fixed and therefore did expose the Group to fair value interest rate risk. The Group does not speculate on future changes in interest rates.

The Group does not use interest rate swaps.

(b) Credit risk

Credit risk is managed at the operating business unit level and monitored at the Group level to ensure adherence to Group policies. Each local subsidiary and operating business unit is responsible for managing and analysing the credit risk for each of their new clients before standard payment and delivery terms and conditions are offered. It is the Group policy to obtain prepayment deposits from customers where possible, particularly overseas customers. If there is no independent rating, local management assesses the credit quality of the customer, taking into account its financial position, past experience and other factors. The utilisation of credit limits is regularly monitored.

Credit risk also arises from cash and cash equivalents, derivative financial instruments and deposits with banks and financial institutions, as well as credit exposures to customers.

(c) Liquidity risk

Cash flow forecasting is performed in the individual operating entities of the Group and is aggregated by the Head of Finance team. The Head of Finance team monitors cash and cash flow forecasts and it is the Group's liquidity risk management policy to maintain sufficient cash and available funding through an adequate amount of cash and cash equivalents.

The Group's policy in relation to the finance of its overseas operations requires that sufficient liquid funds be maintained in each of its territory subsidiaries to support short and medium-term operational plans. Where necessary, short-term funding is provided by the Company. Excess funds are placed as short-term deposits, to provide a balance between interest earnings and flexibility.

Notes to the Financial Statements

Continued

The table below analyses the Group's non-derivative financial liabilities into relevant maturity groupings based on the remaining period at the Statement of Financial Position date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

	Note	Less than one year £'000	Between 1 and 2 years £'000	Between 2 and 5 years £'000	Total £'000
At 31 December 2022:					
Borrowings	21	–	–	–	–
Leased liabilities	32	826	271	466	1,563
Trade and other payables	19	28,869	–	–	28,869
At 31 December 2021:					
Borrowings	21	294	–	–	294
Leased liabilities	32	1,991	477	386	2,854
Trade and other payables	19	18,397	–	–	18,397

(d) Capital risk management

The Group's objectives when managing capital are to safeguard the ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

The Group is currently un-geared, having no borrowings at 31 December 2022.

4. Critical accounting estimates and judgements

In the process of applying the Group's accounting policies, management has made accounting judgements in the determination of the carrying value of certain assets and liabilities. Due to the inherent uncertainty involved in making assumptions and estimates, actual outcomes will differ from those assumptions and estimates. The following judgements have the most significant effect on the amounts recognised in the financial statements.

(a) Impairment of goodwill and cost of investments and associates

The Group tests annually whether goodwill has suffered any impairment, in accordance with the accounting policy stated in note 2. The recoverable amount of the cash-generating unit has been determined based on value-in-use calculations. These calculations require the use of estimates as set out in note 13. In addition, the Group has also considered the impairment of the investments in the subsidiaries undertakings as set out in note 14a and also the associates in note 14b. During 2022, an impairment has been recognised in respect of associate Company Imutex. No impairment of subsidiary undertakings have been recorded.

(b) Impairment of receivables

Trade and other receivables are carried at the contractual amount due less any estimated provision for non-recovery. Provision is made based on a number of factors including the age of the receivable, previous collection experience and the financial circumstances of the counterparty.

(c) Deferred tax assets

Deferred tax assets are only recognised to the extent that it is probable that future taxable profits will be available against which deductible temporary differences can be utilised. See note 20.

(d) Intangible assets

The Group amortises intangible assets over their estimated useful life. The useful lives of capitalised software, preferential right to reserve a slot and wearables development have been estimated by the Group as stated in note 2. The Group tests annually whether there is any indication that intangible assets have been impaired.

(e) Revenue recognition

Estimates of revenues, costs or extent of progress toward completion are revised if circumstances change. Any resulting increases or decreases in estimated revenues or costs are reflected in profit or loss in the period in which the circumstances that give rise to the revision become known by management. At each period end, management reviews each material individual contract to assess whether any anticipated losses should be recognised immediately.

(f) Virus inventory

In valuing virus inventory, management is required to make assumptions in relation to the future commercial use, being both external client revenue engagements, engagements with our equity investments and internal research and development engagements, for each virus. This includes consideration of both the current business pipeline and management's estimates of the future virus requirements, based on its significant knowledge and experience in the field of virology.

(g) Research and development tax credits

The Group's research and development tax credits claims in its various jurisdictions are complex and require management to make assumptions, with appropriate external tax advice, in building the methodology for the claim, interpreting research and development tax legislation in relation to the Group's specific circumstances, and agreeing the basis of the Group's tax computations with relevant Tax Authorities.

(h) Leasehold provision

Provisions for dilapidations and onerous lease commitments are recognised when the Group has a present or constructive obligation as a result of past events. The recognition of provision requires management to make best estimates of the consideration required to settle the present obligation at the end of the reporting period, taking into account the risks and uncertainties surrounding the obligation. There is reasonable uncertainty around the likelihood and timing of the exit of the lease as negotiations will involve third parties. The provision is discounted for the time value of money.

Notes to the Financial Statements

Continued

5. Expenses – analysis by nature

The following items have been included in operating profit:

	2022 £'000	2021 £'000
Employee benefit expense (note 7)	**18,081**	15,897
Other expenses	**23,544**	20,220
Total direct project and administrative costs	**41,625**	36,117
Also included within operating profit are the below depreciation and amortisation charges:		
PPE Depreciation (note 12) and amortisation (note 13)	**999**	523
Depreciation related to Right of use Assets (note 32)	**1,931**	2,039

Also included within operating profit are exceptional items as shown below:

	2022 £'000	2021 £'000
Exceptional items include:		
– Transaction costs relating to business combinations, acquisitions & Re-organisations	**119**	923
– Transaction gain relating to Capital Reduction and spin out (note 33)	**–**	(1,190)
Total exceptional items	**119**	(267)

Services provided by the Company's auditor and its associates. During the year the Group (including its overseas subsidiaries) obtained the following services from the Company's auditor and its associates:

	2022 £'000	2021 £'000
Fees payable to Company's auditor for the audit of the parent Company and consolidated financial statements	**52**	38
Fees payable to Company's auditor for the audit of subsidiaries and their consolidated financial statements	**37**	39
Total paid to the Company auditor	**89**	77
Fees payable to the auditors of subsidiaries for services:		
– The audit of Company's subsidiaries pursuant to legislation paid to other auditors	**55**	62
– Other services paid to other auditors	**1**	7
– Tax services paid to other auditors	**2**	11
Total paid to other auditors	**58**	80
Total auditor's remuneration	**147**	157

6. Directors' emoluments

	2022 £'000	2021 £'000
Aggregate emoluments	**995**	526
Social Security Costs	**119**	62
Contribution to defined contribution pension scheme	**42**	17
Total Directors' remuneration	**1,156**	605

See further disclosures within the Report of the Remuneration Committee.

Highest paid Director	2022 £'000	2021 £'000
Total emoluments received	**518**	172
Defined contribution pension scheme	**27**	17

A Long-Term Incentive Plan ("LTIP") was agreed with the highest paid director during the year. See note 28 for more details. No options were exercised during the year by the highest paid director.

7. Employee benefit expense

	2022 £'000	2021 £'000
Wages and salaries	**15,077**	13,179
Social security costs	**2,100**	1,846
Pension costs	**904**	872
Total employee benefit expense	**18,081**	15,897

8. Average number of people employed

	2022 No	2021 No
Average number of people (including Executive Directors) employed was:		
Administration	**43**	38
Clinical research	**161**	172
Sales and marketing	**6**	8
Total average number of people employed	**210**	218

Monthly weighted average used in above calculation.

Notes to the Financial Statements

Continued

9. Finance income and costs

	2022 £'000	2021 £'000
Interest expense:		
– Interest on Lease liabilities (note 32)	**(133)**	(227)
– Interest on other loans	**1**	7
Finance costs	**(132)**	(220)
Finance income		
– FX gain on sales & expenses	**613**	–
– Interest income on cash and short-term deposits	**136**	5
Finance income	**749**	5
Net finance income/(expense)	**617**	(215)

10. Income tax expense

Group	2022 £'000	2021 £'000
Current tax:		
Current year research and development tax charge	**352**	350
Current year other	**50**	–
Current year hVIVO Inc US tax charge	**9**	6
Total current tax charge	**411**	356
Deferred tax (note 20):		
Origination and reversal of temporary differences	**–**	(5)
Total deferred tax	**–**	(5)
Income tax charge	**411**	351

The income tax charge on the Group's results before tax differs from the theoretical amount that would arise using the standard tax rate applicable to the profits of the consolidated entities as follows:

	2022 £'000	2021 £'000
(Loss)/Profit before tax	**(365)**	277
Tax calculated at domestic tax rates applicable to UK standard rate of tax of 19.00% (2021: 19%)	**(69)**	53
Tax effects of:		
– Expenses not deductible for tax purposes	**1,488**	168
– VLS Germany tax risk on liquidation	**51**	–
– Current Year R & D Tax (credit)	**(194)**	(108)
– Temporary timing differences	**(153)**	(182)
– Adjustments in respect of prior year	**33**	37
– Additional allowances deductible for tax purposes	**125**	(79)
– Losses carried forward	**(870)**	462
Income tax charge	**411**	351

There are no tax effects on the items in the Statement of Comprehensive Income.

11. Earnings/(Losses) per share

(a) Basic

Basic loss per share is calculated by dividing the loss attributable to equity holders of the Company by the weighted average number of ordinary shares in issue during the year.

	2022	2021
	£'000	£'000
Losses for the year	**(776)**	(74)
Total	**(776)**	(74)
Weighted average number of Ordinary Shares in issue	**670,943,918**	670,187,313
Losses per share from operations	**(0.12p)**	(0.01p)

(b) Adjusted

Adjusted Profit/(Loss) per share is calculated by dividing the Profit/(Loss) attributable to equity holders of the Company excluding one-off large non-recurring items by the weighted average number of ordinary shares in issue during the year. In 2022 the impairment of the investment in Imutex is excluded. In 2021 the net gain on the spin out of the Pilau license asset is excluded.

	2022	2021
	£'000	£'000
Losses for the year	**(776)**	(74)
Add back Imutex impairment (2022) / Deduct net gain re Pilau (2021)	**6,957**	(1,190)
Adjusted profit/(Loss) for the year	**6,181**	(1,264)
Total	**6,181**	(1,264)
Weighted average number of Ordinary Shares in issue	**670,943,918**	670,187,313
Earnings/(loss) per share from operations	**0.92p**	(0.19p)

(c) Diluted Basic

Due to the losses in the periods the effect of the share options and warrants noted below were considered to be anti-dilutive.

Details of share options and warrants are given in note 28.

	2022	2021
Potential dilutive ordinary shares:		
Options	**15,502,029**	8,393,213
Warrants	**2,264,427**	2,264,427
Total	**17,766,456**	10,657,640

(d) Diluted Adjusted

Due to adjusted losses in the prior year the effect of the share options and warrants noted above were considered to be anti-dilutive.

	2022	2021
	£'000	£'000
Earning/(loss) per share	**0.90p**	(0.19p)

Notes to the Financial Statements

Continued

12. Property, plant and equipment

Group	Leasehold Improvements £'000	Plant & Machinery £'000	Fixtures & Fittings £'000	2022 Total £'000	2021 Total £'000
Cost					
At 1 January 2022	842	2,507	1,111	4,460	5,770
Additions	450	540	286	1,276	329
Disposals	–	(90)	–	(90)	(1,620)
Exchange differences	–	–	44	44	(19)
At 31 December 2022	**1,292**	**2,957**	**1,441**	**5,690**	4,460
Depreciation					
At 1 January 2022	706	2,141	686	3,533	4,702
Charge for the year	333	166	217	716	406
Elimination on disposal	–	(90)	–	(90)	(1,555)
Exchange differences	–	–	18	18	(20)
At 31 December 2022	1,039	2,217	921	4,177	3,533
Net book value					
At 31 December 2022	**253**	**740**	**520**	**1,513**	
At 31 December 2021	136	366	425	927	

The Company had no property, plant and equipment at 31 December 2022. (2021: Nil).

13. Intangible fixed assets

	Goodwill £'000	Software development £'000	Pref right to reserve slot £'000	WBS development £'000	2022 Total £'000	2021 Total £'000
Cost						
At 1 January 2022	7,228	2,199	274	411	10,112	9,701
Additions	–	87	–	–	87	411
At 31 December 2022	**7,228**	**2,286**	**274**	**411**	**10,199**	10,112
Amortisation						
At 1 January 2022	1,628	2,173	92	–	3,893	3,801
Charge for the year	–	19	182	82	283	92
At 31 December 2022	**1,628**	**2,192**	**274**	**82**	**4,176**	3,893
Net book value						
At 31 December 2022	**5,600**	**94**	**–**	**329**	**6,023**	
At 31 December 2021	5,600	26	182	411	6,219	

Goodwill was allocated to the Group's single cash-generating unit (CGU) identified according to a single operating segment.

	2022	2021
	£'000	£'000
hVIVO Group	**5,600**	5,600

Goodwill is tested for impairment at the Statement of Financial Position date. The recoverable amount of goodwill at 31 December 2022 was assessed at £5,600,000 (2021: £5,600,000) on the basis of value in use. An impairment loss was not recognised as a result of this review.

The key assumptions in the calculation to assess value in use are the future revenues and the ability to generate future cash flows. The most recent financial results and forecast approved by management for the next two years were used followed by an extrapolation of expected cash flows at a constant growth rate for a further seven years. The projected results were discounted at a rate which is a prudent evaluation of the pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the cash-generating units.

The key assumptions used for value in use calculations in 2022 were as follows:

Longer-term growth rate (from 2023 onwards)	7.5%
Discount rate	15%

The impairment review is prepared on the group basis rather than a single unit basis.

The Directors have performed a sensitivity analysis to assess the impact of downside risk of the key assumptions underpinning the projected results of the Group. The projections and associated headroom used for the group is sensitive to the EBITDA growth assumptions that have been applied.

The Company has no intangible assets.

14a. Investments in subsidiaries

	2022	2021
Company	**£'000**	£'000
Shares in Group undertakings		
At 1 January	**22,377**	22,334
Transfer of services, knowhow and assets from Venn Life Sciences (VLS) France S.A.S to VLS Biometry Services S.A.S	**–**	43
At 31 December	**22,377**	22,377

Investments in Group undertakings are recorded at cost, which is the fair value of the consideration paid. Following review an impairment provision of Nil (2021: Nil) has been made to the investment in subsidiaries.

VLS Biometry Services S.A.S, a new subsidiary in France, acquired from VLS France S.A.S all of their advisory services and global services to enterprises for the integration of computer, statistics, data management techniques, study design and methodology. The assets sold included the benefit and the liability of all on-going contracts and agreements in relation with the activity, and the various contracts concluded with the customers and suppliers.

VLS France S.A.S subsequently ceased trading.

Notes to the Financial Statements

Continued

The subsidiaries of hVIVO Plc (formerly Open Orphan Plc) are as follows:

Name of Company	Active/ Dormant	100% direct/indirect shareholding	Country of Registration	Nature of business
hVIVO Holdings Limited (formerly hVIVO Limited)	Active	Direct	England & Wales	Intermediate holding company
hVIVO Services Limited	Active	Indirect	England & Wales	Viral challenge and related laboratory services
hVIVO INC	Active	Indirect	USA	Sales & marketing services
Venn Life Sciences ED B.V	Active	Direct	Netherlands	Pre-clinical & early clinical research services
Venn Life Science Biometry Services S.A.S	Active	Direct	France	Data management & statistics services
Open Orphan DAC	Active	Direct	Ireland	Group services company
Venn Life Sciences Limited	Active	Direct	Ireland	Intermediate holding company
Venn Life Sciences (Germany) Gmbh	Dormant	Direct	Germany	Clinical research organisation
Venn Life Sciences (France) S.A.S	Dormant	Direct	France	Data management & randomisation systems

All the subsidiaries are included in the consolidation. The proportions of voting shares held by the parent Company do not differ from the proportion of Ordinary Shares held.

14b. Investments in associates

The group, via its holding in hVIVO Holdings Limited, has investments in two associated companies as follows:

Name of Company	Country of Registration	Nature of Business
Imutex Limited[1]	England & Wales	Clinical development
PrEP Biopharm Limited[2]	England & Wales	Clinical development

(1) hVIVO Holdings Limited owns 49% of the Ordinary Shares and after adjusting for share of loss in 2022 of £48,000. the investment was fully impaired and is valued at Nil at 31 December 2022 (2021: £7,005,000).

(2) hVIVO Holdings Limited owns 62.62% of Ordinary Shares. In 2018 the carrying value was fully impaired so the investment has a value of Nil at 31 December 2022.

15. Financial instruments by category

(a) Assets

	Group 2022 £'000	Group 2021 £'000	**Company 2022 £'000**	Company 2021 £'000
31 December				
Assets				
Trade and other receivables	**11,908**	8,089	**11,290**	9,357
Cash and cash equivalents	**28,444**	15,694	**2,799**	8,663
Total	**40,352**	23,783	**14,089**	18,020

Assets in the analysis above are all categorised as 'other financial assets at amortised cost' for the Group and Company.

(b) Liabilities

	Group	Group	**Company**	Company
	2022	2021	**2022**	2021
	£'000	£'000	**£'000**	£'000
31 December				
Liabilities				
Borrowings	**–**	294	**–**	–
Lease liabilities (note 32)	**1,563**	2,854	**–**	–
Trade and other payables	**8,103**	5,205	**363**	441
Total	**9,666**	8,352	**363**	441

Liabilities in the analysis above are all categorised as 'other financial liabilities at amortised cost' for the Group and Company.

(c) Credit quality of financial assets

The Group is exposed to credit risk from its operating activities (primarily for trade receivables and other receivables) and from its financing activities, including deposits with banks and financial institutions, foreign exchange transactions and other financial instruments.

The Group's maximum exposure to credit risk, due to the failure of counter parties to perform their obligations as at 31 December 2022 and 31 December 2021, in relation to each class of recognised financial assets, is the carrying amount of those assets as indicated in the accompanying Statement of Financial Position.

Trade receivables

The credit quality of trade receivables that are neither past due date nor impaired have been assessed based on historical information about the counterparty default rate. The Group does not hold any other receivable balances with customers, whose past default has resulted in the non-recovery of the receivables balances.

Cash at bank

The credit quality of cash has been assessed by reference to external credit ratings, based on reputable credit agencies' long-term issuer ratings:

	2022	2021
Rating	**£'000**	£'000
A – AAA	**28,444**	15,605
Sub-A rating	**–**	89
Total	**28,444**	15,694

The 2021 balance categorised as Sub-A rating relate to balances held at that date with Allied Irish Banks Plc and Ulster Bank DAC.

Notes to the Financial Statements

Continued

16. Inventories

	Group 2022 £'000	Group 2021 £'000	Company 2022 £'000	Company 2021 £'000
Beginning of the year	**659**	953	**–**	–
Laboratory and clinical consumables-movement	**38**	(92)	**–**	–
Virus – movement	**(198)**	(202)	**–**	–
End of the year	**499**	659	**–**	–

Inventories expensed in the consolidated Statement of Comprehensive income are shown within direct project and administrative costs. All inventories are carried at the lower of cost or net realisable value in the consolidated statement of financial position. No provision against inventories was required during 2022.

17. Trade and other receivables

	Group 2022 £'000	Group 2021 £'000	Company 2022 £'000	Company 2021 £'000
Trade receivables	**8,276**	4,774	**–**	–
Prepayments	**992**	855	**346**	335
Accrued income	**1,505**	1,008	**–**	–
Amounts owed by subsidiary undertakings	**–**	–	**11,280**	9,356
Other receivables (incl. R& D tax credits)	**2,127**	2,307	**10**	1
Total	**12,900**	8,944	**11,636**	9,692

The Directors consider that the carrying amount of trade and other receivables approximates to their fair value.

The majority of the Group's contracts are based on milestone payments and the Group seeks to ensure that contract milestones are timed to result in invoicing occurring in advance where at all possible, prior to the satisfaction of performance obligations. Therefore, projects that are in progress are typically in a deferred income position. However, some smaller contracts are on a time and materials basis and consequently work is undertaken initially and invoiced subsequently, and this gives rise to the accrued income balance noted above. The costs incurred to obtain or fulfil a contract which has been recognised as accrued income have been determined with reference to labour hours incurred to the period end as a percentage of the total estimated labour hours to complete specified performance obligations as stipulated by the relevant contracts. Accrued income is not amortised as it is of a short-term nature.

Contractual payment terms are typically 30 to 90 days from date of invoice.

The carrying amounts of the Group's trade and other receivables denominated in all currencies were as follows:

	Group 2022 £'000	Group 2021 £'000	**Company 2022 £'000**	Company 2021 £'000
GBP£	**9,553**	6,746	**632**	1,467
Euro	**2,066**	2,198	**11,004**	8,225
USD$	**1,281**	–	**–**	–
Total	**12,900**	8,944	**11,636**	9,692

18. Cash and cash equivalents

Cash and cash equivalents include the following for the purposes of the statement of cash flows:

	Group 2022 £'000	Group 2021 £'000	**Company 2022 £'000**	Company 2021 £'000
Cash at bank and on hand	**28,444**	15,694	**2,799**	8,663
Cash and cash equivalents	**28,444**	15,694	**2,799**	8,663

The Directors consider that the carrying amount of cash and cash equivalents approximates to its fair value.

19. Trade and other payables

	Group 2022 £'000	Group 2021 £'000	**Company 2022 £'000**	Company 2021 £'000
Trade payables	**2,701**	2,055	**105**	306
Amounts due to subsidiary undertakings	**–**	–	**–**	2,761
Social security and other taxes	**738**	857	**50**	13
Other payables	**718**	436	**–**	2
Accrued expenses	**3,946**	1,856	**208**	120
Deferred income	**20,766**	13,192	**–**	–
	28,869	18,396	**363**	3,202

All balances are due within 1 year.

The Group seeks to ensure that study contract milestones are timed to result in invoicing occurring in advance where at all possible, prior to the satisfaction of performance obligations. Therefore, projects that are in progress are typically in a contract liability position which gives rise to the deferred income balance above. Performance obligations of contracts with customers are satisfied on the delivery of study data to the customer along with a final study report. Due to the nature of the business, there are no warranties or refunds expected or provided for.

The Group is using the practical expedient not to adjust the amount of consideration for the effects of a significant financing component as the period between when the promised services are transferred and when the customer pays for the service is less than twelve months.

Notes to the Financial Statements

Continued

20. Deferred income tax

Deferred tax assets

Deferred income tax assets are recognised to the extent that the realisation of the related tax benefit through future taxable profits is probable. There is no deferred tax asset recognised for the Group or Company. The gross movement on the deferred income tax account was as follows:

	Group 2022 £'000	Group 2021 £'000	**Company 2022 £'000**	Company 2021 £'000
At 1 January	**–**	32	**–**	–
Exceptional Item	**–**	(27)	**–**	–
Statement of Comprehensive Income movement (note 10)	**–**	(5)	**–**	–
At 31 December	**–**	–	**–**	

The asset to which this deferred tax asset applied was written down to Nil on 1 July 2021 and the write off of the balance in the deferred tax asset was accelerated.

21. Borrowings

	Group 2022 £'000	Group 2021 £'000	**Company 2022 £'000**	Company 2021 £'000
Current – falling due within 1 year				
Convertible debenture securities ("CDS")	**–**	294	**–**	–
Total borrowings	**–**	294	**–**	**–**

The Company and Group do not have any borrowings.

As at 31 December 2021, there were 2 remaining CDS holders and they were entitled to interest of 7% per annum on their securities. Neither of these CDS holders chose to convert their securities into Ordinary shares in hVIVO Plc (formerly Open Orphan Plc) at the time of the reverse takeover of the Venn Group in June 2019. Consequently, these CDS holdings were redeemed by Open Orphan DAC at redemption dates in April 2022 and October 2022 respectively.

22. Share capital

	Group 2022 £'000	Group 2021 £'000	**Company 2022 £'000**	Company 2021 £'000
671,047,771 (2021 – 670,929,314) Ordinary shares of £0.001	**671**	671	**671**	671

The Company exercised its right in July 2021 to acquire all deferred shares for an aggregate price of £1 (see note 33).

Subsequently, the share capital of hVIVO Plc (formerly Open Orphan Plc) consists only of fully paid ordinary shares. All shares are equally eligible to share in declared dividends, appoint Directors, receive notice of, attend, speak and vote at any general meeting of the Company.

During the year the Company issued 118,457 shares @ £0.02/Share as a result of share options being exercised by former employees.

23. Other reserves

Group and Company

Share premium

Share premium is the difference between the nominal value of share capital and the actual cash received on fund-raising less any costs associated with the fund-raising (see Note 33).

Merger reserve

This includes reverse acquisition reserve which resulted from the reverse takeover of Venn Life Sciences Holdings Plc by Open Orphan DAC on 28 June 2019. Also included is a Group re-organisation reserve relating to previous re-organisation of the Venn Group.

Foreign currency reserve

The presentation currency of the Group became GBP£ in 2020. Previously the presentation currency was Euro. This reserve arises from the translation of the opening balances from Euro to GBP£ and also from the translation of the subsidiaries which are denominated in Euro into GBP£ on consolidation.

The Euro denominated subsidiaries are Venn Life Sciences Limited, Venn Life Sciences Germany GmbH, Venn Life Sciences France S.A.S, Venn Life Sciences E.D. B.V., Venn Life Sciences Biometry Services and Open Orphan DAC.

Share based payments reserve

A share option reserve of £151,000 was created in June 2019, prior to the reverse takeover of Venn Life Sciences Holdings PLC by Open Orphan DAC, in relation to the share options and warrants issued in June 2019. After the reverse takeover, further provisions of £102,000 (2019), £240,000 (2020), £27,000 (2021) were made and an additional provision of £284,000 was made in 2022 and expensed to direct project and administration expenses. To date £226,000 has been released from the share based payments reserve back to retained earnings in respect of share options that have since been exercised.

Retained earnings

For the Group and Company, earnings reflect the earnings of hVIVO Plc (formerly Open Orphan Plc).

Notes to the Financial Statements

Continued

24. Cash used in operations

	Group 2022 £'000	Group 2021 £'000	Company 2022 £'000	Company 2021 £'000
(Loss)/Profit before income tax	**(365)**	277	**(1,311)**	(1,522)
Adjustments for:				
– Depreciation and amortisation (note 5)	**2,930**	2,565	**–**	–
– Exceptional Items (note 5)	**119**	(267)	**–**	409
– Impairment of associate (note 14b)	**6,957**	–	**–**	–
– Net (gain)/loss on disposals of PPE	**(12)**	189	**–**	–
– Net finance (Income)/costs (note 9)	**(617)**	215	**(834)**	(768)
– Share based payment charge (note 28)	**284**	27	**–**	–
– R & D Credit incl. in other income	**(1,851)**	(1,842)	**–**	–
– Share of Imutex loss (note 14.b)	**48**	71	**–**	–
Changes in working capital				
Impairments on intercompany balances (note 14a)	**–**	–	**282**	485
– (Increase)/Decrease trade and other receivables	**(4,309)**	904	**(1,135)**	(241)
– Decrease inventories	**172**	294	**–**	–
– Increase/(Decrease) trade and other payables	**11,152**	(2,972)	**(2,890)**	2,317
Net cash generated/(used) in operations	**14,508**	(539)	**(5,888)**	680

25. Related Party Disclosures

Directors

Directors' emoluments are set out in the Report of the Remuneration Committee Report.

Key management compensation for the year was as follows:

	2022 €'000	2021 €'000
Aggregate emoluments	**994**	526
Employer contribution to pension scheme	**42**	17
	1,036	543

Report of the Key management includes the Directors only.

Group

Non-Executive Group Chairman, Cathal Friel, is a Director of Raglan Road Capital group companies which has provided advisory and office related services to Open Orphan DAC (2022 charge €9,798; 2021 charge €23,175). The balance owed by Open Orphan DAC to Raglan Road Capital group companies at year end 2022 was €2,000 (2021: €16,901).

There were no other related party transactions during the year.

The Company

During the year the Company absorbed net management charges of £141,598 (2021 – £109,547) from its subsidiaries. At 31 December 2022 the Company was owed £11,280,000 (2021 – £6,594,000) by its subsidiaries.

26. Capital commitments

The Group had no capital commitments at 31 December 2022 or at 31 December 2021.

27. Discontinued operations

Venn Life Sciences (NI) Ltd, Venn Life Sciences B.V. and Venn Life Sciences Germany GmbH ceased to trade from 1 January 2021 onwards. Venn Life Sciences (NI) Ltd and Venn Life Sciences B.V. were dissolved in 2022. Venn Life Sciences Germany GmbH commenced a liquidation process in early 2022 and that is expected to conclude in early 2023. There were no new discontinued operations during 2022.

28. Share options and warrants

Share options

The Group has various share option plans under which it has granted share options to certain Directors and senior management of the Group.

The number of outstanding share options remaining at 31 December 2022 are as follows:

Date of Issue	Exercise Price	Date of Expiry	# Options at 01/01/2022	# of Options Exercised	# of Options Granted	# Options at 31/12/2022
2015	13p	2025	280,000	–	–	280,000
2019	5.6p	2024	7,716,964	–	–	7,716,964
2020	2p	2024	396,249	(118,457)	–	277,792
2022	0.1p	2025	–	–	7,227,273	7,227,273
			8,393,213	**(118,457)**	**7,227,273**	**15,502,029**

The weighted-average exercise price of all options outstanding at year end is 3.1p and the weighted-average remaining contractual life is 1.8 years.

Share based payment charge for the year was £284,000 included in direct project and administration costs (2021 – £27,000). The only new share options granted during the year relate to the implementation of a Long-Term Incentive Plan ("LTIP") (outlined in Note 6). A reserve of £250,000 has been created in 2022 in respect of this award. The following key assumptions were factored into the model when valuing these options at the date of grant:

- expected volatility of 74%
- option life of 3 years
- expected dividends yield of 0%
- risk-free interest rate of 0.72%

An additional £33,000 charge has been created in relation to the vesting of shares under the existing SIP scheme.

Due to share options being exercised during the year £33,000 (2021: £193,000) of the existing share-based payment reserve was released back to retained earnings.

The Company has used the Black Scholes model to value the options at 31 December 2022 and 31 December 2021.

Warrants

2,264,427 warrants existed at 31 December 2022 (2021: 2,264,427).

Notes to the Financial Statements

Continued

232,696 warrants were granted on 11 December 2018 and are exercisable from the date of grant to 10 December 2023. The exercise price is 0.1p per ordinary share under warrant. 424,589 warrants were granted on 11 December 2018 and are exercisable from the date of grant to 10 December 2023. The exercise price is 2.2p per ordinary share under warrant.

1,607,142 warrants were granted on 28 June 2019 and are exercisable from the date of grant to 27 June 2024. The exercise price is 5.6p per ordinary share under warrant.

29. Other operating income

Other operating income represents government grants received to fund research and development activities around the group.

		2022	2021
		£'000	£'000
hVIVO	Gross RDEC credit	**1,851**	1,842
Venn	R & D related credits	**369**	299
Total		**2,220**	2,141

The subsidiary, hVIVO Services Limited, can claim UK R&D incentives under both the RDEC scheme (noted above) and the SME scheme (when the Company is loss making). Venn Life Sciences Biometry services S.A.S. can claim Credit Tax Research ('CIR') payments in France and Venn Life Sciences ED B.V. can claim R & D credits against payroll taxes in the Netherlands.

30. Post reporting period date events

The following events have taken place since the year end:

a) The Directors propose a special, one off dividend of 0.45 pence per share. The payment is subject to approval by shareholders at the Company's Annual General Meeting on 23 May 2023.

b) On 28 March 2023 the Company issued 7,716,964 shares @ £0.056/Share as a result of share options being exercised by a former employee.

c) hVIVO Holdings Limited owns 62.62% of PrEP Biopharm Limited. In 2018 the carrying value was fully impaired so the investment has a value of Nil at 31 December 2022. The Directors of PrEP Biopharm have made a decision to commence the process of a solvent liquidation. The liquidation is expected to complete in 2023.

31. Pensions

The Group operates a number of defined contribution pension schemes whose assets are held in independently administered funds. The pension charge represents contributions payable by the Group and amounted to £904,000 for the year (2021: £872,000). Contributions of £98,000 were payable to the funds at the year end and are included within trade and other payables (2021: £79,000).

32. Leases

Amounts recognised in the Statement of Financial Position

	Right of use assets		Lease liabilities	
	2022	2021	**2022**	2021
	£'000	£'000	**£'000**	£'000
As at 1 January	**2,788**	4,230	**2,854**	4,439
New leases acquired	**740**	1,399	**739**	1,399
Leases exited	**(8)**	(738)	**(20)**	(816)
Depreciation expense (note 5)	**(1,931)**	(2,039)	**–**	–
Interest expense (note 9)	**–**	–	**133**	227
Payments	**–**	–	**(2,178)**	(2,329)
Exchange differences	**21**	(64)	**35**	(66)
As at 31 December	**1,610**	2,788	**1,563**	2,854
Current	**–**	–	**826**	1,991
Non-current	**1,610**	2,788	**737**	863

Maturity of lease liabilities

	31 December 2022	31 December 2021
	£'000	£'000
Current – Within one year	**826**	1,991
Non-current – Between one to two years	**271**	477
Non-current – Between two to five years	**466**	386
	1,563	2,854

Short-term lease payments expensed during year ended 31 December 2022: £47,000 (2021: £32,000 (re-stated)).

33. Prior-Year Capital Reduction and Distribution-in-Specie

On 19 May 2021, the Company received court approval for a reduction in its share capital. Consequently, the deferred share capital balance of £62,833 (see note 22) was bought back by the Company and the then balance in the share premium account of £44,516,591 of the Company was transferred in full to retained earnings.

On 18 June 2021, hVIVO Plc (formerly Open Orphan Plc) made a distribution-in-specie to all shareholders on the share register at close of business on 17 June 2021. Shareholders received shares in Poolbeg Pharma Ltd. These shares were held in trust by Croft Nominees Limited for a period of 9 months following Poolbeg Pharma Ltd.'s admission to the AIM market of the London Stock Exchange. Poolbeg Pharma Ltd changed its name to Poolbeg Pharma Plc on 23 June 2021. Following a successful period of fund-raising, Poolbeg Pharma Plc was admitted to AIM on 19 July 2021.

Notes to the Financial Statements

Continued

34. Leasehold provision

Leasehold provision relates to dilapidation.

	Leasehold provision £'000
As at 1 January 2022	–
Addition	730
As at 31 December 2022	**730**
Current	70
Non-current	670

Company Information

Directors

Cathal Friel (Non-Executive Chairman)
Yamin 'Mo' Khan (Chief Executive Officer)
Stephen Pinkerton (Chief Financial Officer)
Prof. Brendan Buckley (Non-Executive Director)
Dr. Elaine Sullivan (Non-Executive Director)
Martin Gouldstone (Non-Executive Director)

Company Secretary

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