

## **Delivering today's healthcare** by empowering tomorrow's innovation

Annual Report & Accounts 2023





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## Responsible Business

Read about how hVIVO's Environmental, Social and Governance (ESG) is at the heart of the business

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## CEO's Statement

Hear from our Chief Executive Officer on another record year

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# **Company Overview**



Challenge Study Models

50+ Years of Combined Service

75+ Number of Studies Completed

**4,300+** Volunteers Inoculated

## Mission

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

## Vision

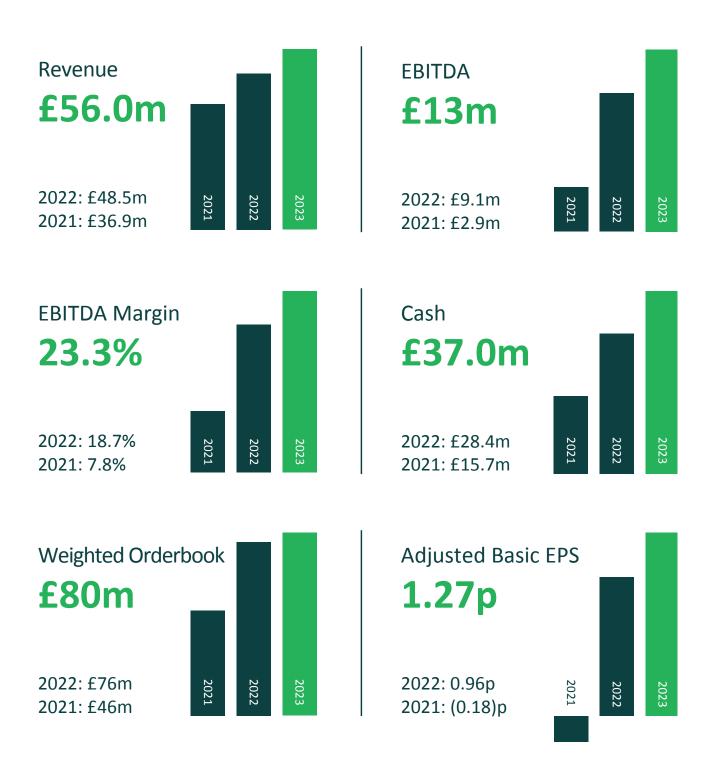
To transform global healthcare by revolutionising the drug development process through scientific ingenuity.

## Values

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

# **Financial Highlights**

## A record year for the hVIVO Group



# **Operational Highlights**

Building a long-term sustainable growth model



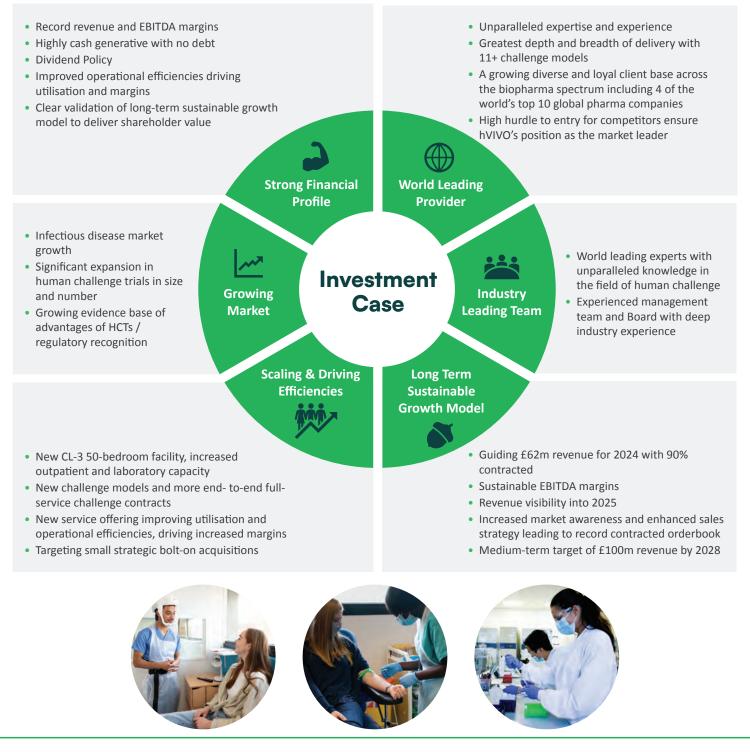


## 2023 Operational Highlights

- Construction commenced at new state of the art site in Canary Wharf
- New offices in Leiden, NL
- Contracts for new services signed
- Multiple MSAs signed in lab and challenge services
- Expanded client reach with first APAC contract in decade
- Automation improvements programme initiated and new cybersecurity system implemented

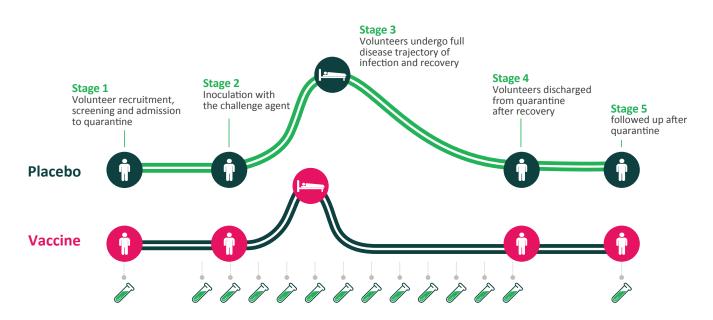
# **Investment Case**

hVIVO is the world leader in human challenge trials with a unique, long term sustainable, cash generative business model



## What is a Human Challenge Trial?

A clinical trial where healthy volunteers are exposed to a pathogen to test the effectiveness of vaccines and treatments...



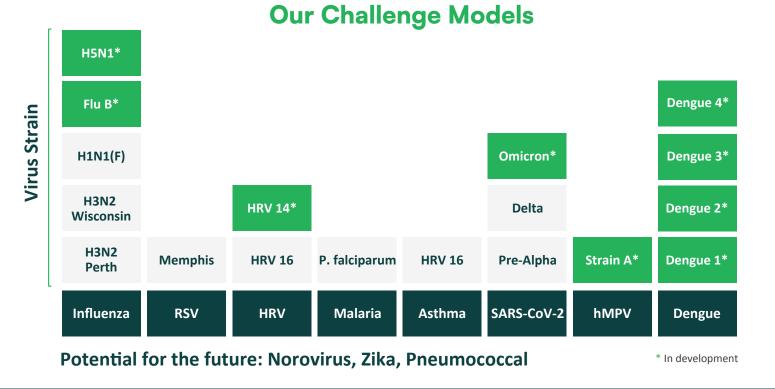
## ... in a faster and more efficient setting.



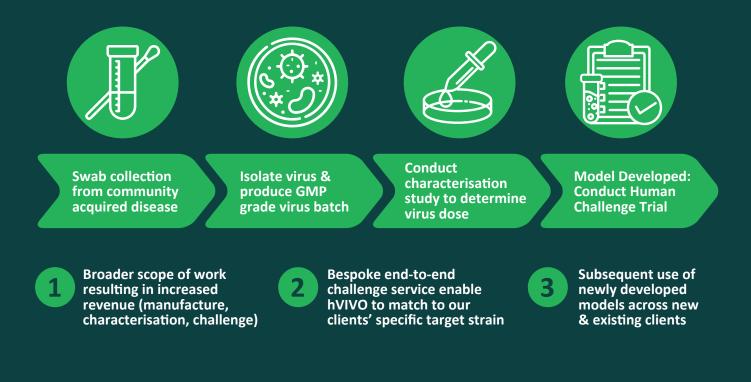
n human viral challenge studies, the first stage is to screen volunteers to ensure that they are healthy and suitable for the study, which is done at our state-of-theart volunteer screening facilities. Suitable volunteers come into our quarantine unit for the infection phase of the study where a second health check takes place before inoculation with our challenge virus. The volunteers in the placebo group of the study will then be expected to get ill and develop symptoms associated with coldcausing viruses (runny nose, sneezing, etc). The volunteers are monitored closely throughout the full duration of the disease until the virus is no longer detected, and the volunteer no longer has any symptoms. At this stage, the volunteers will be discharged from the quarantine unit and are allowed to return home.

After discharge, volunteers return for a final check-up where we test for antibodies. Those vaccinated prior to inoculation are expected to have lower infection rates and milder symptoms, recovering faster than those who received a placebo. This can often mean that infected subjects that received an efficacious vaccine will a lower severity of symptoms and will also fully recover far quicker compared to the subjects who received the placebo, instead of the active vaccine.

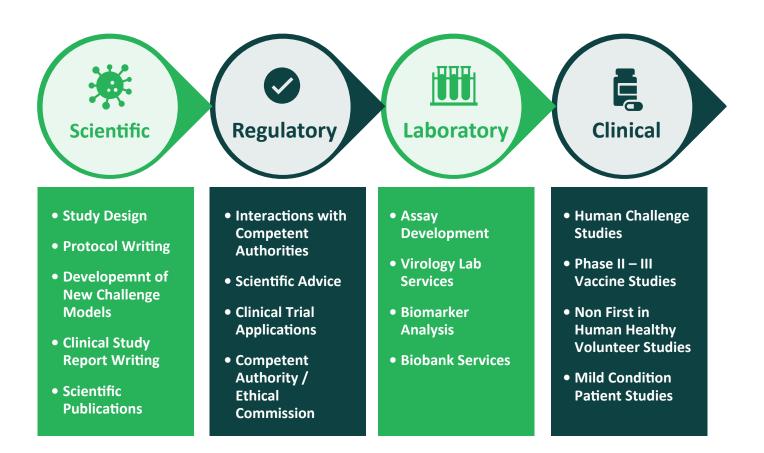
## **Unique Human Challenge Services**



## **End-to-End Human Challenge Service**



## **Full Human Challenge Service**



## **Testimonials**

A big Thank You to you and the hVIVO team for all your hard work on this study despite highly difficult conditions through the pandemic and very ambitious timelines. Global top 5 pharma client

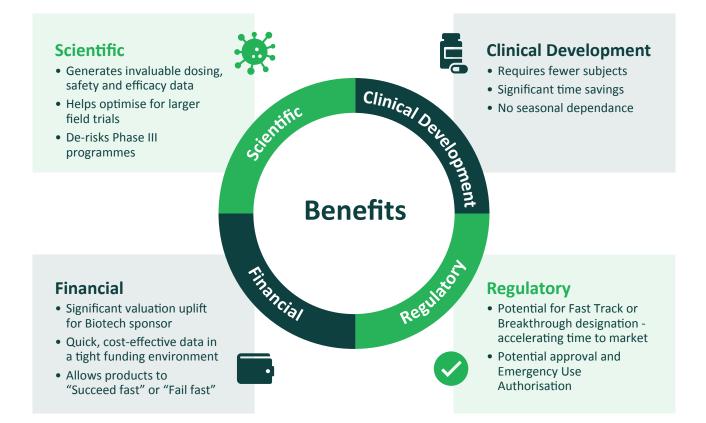
**Experienced and engaged team with expertise in human challenge studies.** Asian mid-size pharma client

## Overall fast replies and efficient feedback on questions & inquiries. European mid-size pharma client

**Fast and efficient support in review of the study documents.** 

## **The Power of Human Challenge Trials**

## The Benefits



## **Key Success Stories 2023**

## US Biopharmaceutical Company



### April 2023

Data from hVIVO Phase 2a influenza human challenge trial instrumental in FDA decisions



## May 2023

**RSV Vaccine Approved** 

### FDA Breakthrough Designation awarded March 2022

*Primarily informed by the positive results of a proof-of-concept human challenge trial conducted by hVIVO* 

US Biotechnology Company

## FDA grants Breakthrough Therapy and Fast Track designations to Drug Targeting Influenza June 2023

## New State-of-the-Art Facility in Canary Wharf



Given the state-of-the-art infrastructure and strategic location, it presents an ideal environment for cutting-edge research and innovation in the field. The emergence of Canary Wharf as a life sciences hub has attracted attention from various organisations keen to be part of this burgeoning ecosystem. With our expertise in clinical trials and infectious diseases, we see Canary Wharf as a promising setting to collaborate with potential clients, other industry players, academia, and research institutions, ultimately contributing to advancements in healthcare. This transformative shift underscores London's evolving landscape as a global centre for scientific excellence and economic growth.

Joining Canary Wharf's Growing Life Science Community



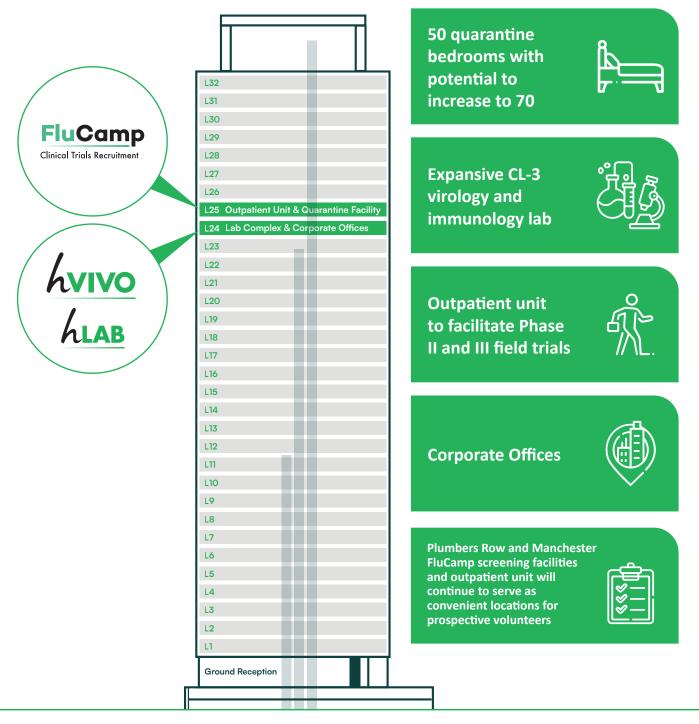
UK Health Security Agency

General Pharmaceutical Council



## World's Largest Commercial Human Challenge Trial Unit

his expansion, largely funded by clients, signifies a significant milestone for the Company. With a 10-year lease and a 5-year break clause, coupled with reduced aggregate rent per square foot and a rent cap in place, the new facility offers over 30% more usable space compared to previous quarantine and lab facilities. The Canary Wharf facility is expected to not only improve margins but also increase our revenue cap. Furthermore, the enhanced facilities for both staff and volunteers at the new site align with our commitment to environmental, social, and governance (ESG) principles, providing tangible ESG benefits to our operations.



## **Significant Progress to Date**





**Clinical Trials Recruitment** 

#### Recruitment Excellence through FluCamp

hVIVO's dedicated recruitment arm, FluCamp, stands out as a leader in the clinical trial recruitment industry. With an unparalleled database exceeding 300,000 potential volunteers, and state-of-the-art facilities located in central London and dedicated screening facilities in Manchester, FluCamp has made significant strides in patient recruitment for clinical trials.

#### **Addressing Recruitment Challenges**

Recruiting volunteers for clinical trials poses a serious challenge within the industry. With patient recruitment issues causing the cancellation of 55% of clinical trials<sup>1</sup> and the failure to meet enrolment timelines in over 80% of cases in the US alone<sup>2</sup>, FluCamp's innovative approach has proven to be highly successful.

#### Achieving 100% Recruitment Success

FluCamp's robust screening process has a 100% recruitment success rate. By screening volunteers for suitability across various challenge studies, FluCamp is able to mitigate recruitment risks and enhance trial outcome.

### **Integrated CRM and Future Potential**

FluCamp's fully integrated CRM system efficiently

captures and nurtures volunteers, facilitating seamless engagement and retention. Notably, 85% of screened volunteers remain available for future human challenge trials or non-challenge studies, underscoring FluCamp's long-term impact and sustainability.

#### **Strategic Screening Programmes**

By utilising generic screening capabilities FluCamp is able to significantly reduce study recruitment timelines. With access to screening facilities strategically located in Manchester and Central London, FluCamp minimises the travel burden for volunteers while expanding its reach and accessibility.

#### **Expansion and Enhanced Capacity**

FluCamp continues to increase its capabilities with strategic third party partnerships enabling access to patient / volunteer data and health records across the UK, with over 30,000 patient applications received in 2023.

### **Quarantine Facilities and Future Growth**

The move to Canary Wharf in H1 2024 will increase quarantine capacity as well as offer volunteers a more modern and state-of-the-art experience, further solidifying FluCamp's leading position and reputation in volunteer recruitment and human trial management.



<sup>1</sup> Perspective in Clinical Research, <sup>2</sup> GlobalData





LAB is a highly specialised Virology and Immunology laboratory offering a suite of services to support pre-clinical & clinical respiratory drug and vaccine discovery and development.

Our work includes assay development, optimisation & validation, and Clinical Trial support services, including, clinical trial kit provision, sample processing, analytical laboratory, and BioRepository Services. We also offer extensive options in pre-clinical research and sample matrix & stability analysis. All assays are validated to FDA, EMA and ICH guidelines, in accordance with Good Clinical Practice (GCP) for Laboratories.

With specialists focusing on virology, immunology and molecular biology, our hLAB is well equipped 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 2024 hLAB will be onboarding a new state-of-the-art Biosafety Level 3 facility along with increased Biosafety Level 2 capacity.

During 2023, hLAB successfully conducted their first BioMarker Analysis commercial study, was appointed as an approved vendor for a global laboratory partner, and is currently working towards UKAS ISO 17025 Accreditation and the rollout of a customised Laboratory Information Management System.





+ 114,000 lab assays and samples in 2023



Bio-repository stores in excess of 450,000 samples



**Biosafety Level 3 (CAT 3)** along with increased Biosafety Level 2 capacity in 2024



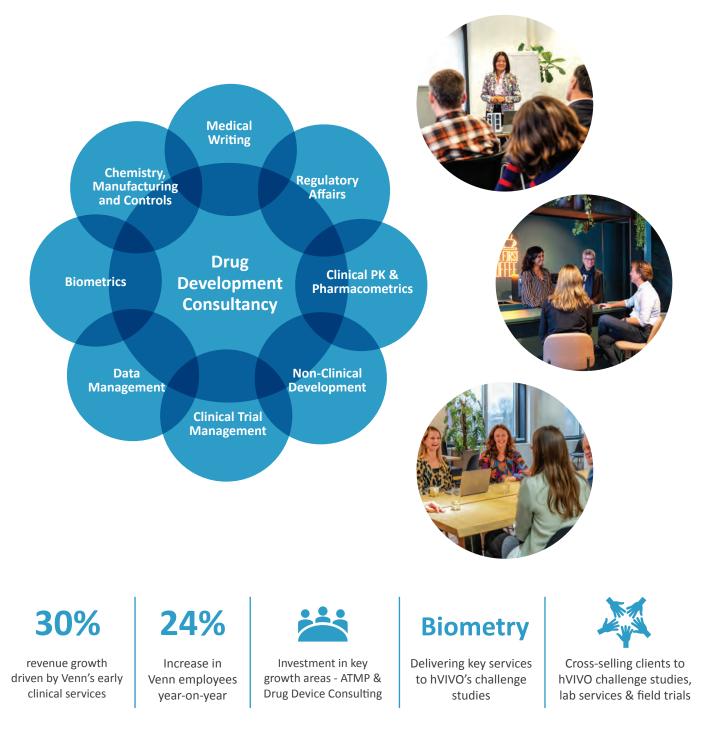
Quality Standards GCLP, CAP Accredited and external QA, HTA, FLUCOP

Venn Life Sciences

part of hVIVO

## **Integrated Drug Development Partner**

enn Life Sciences serves as an integrated partner in drug development, offering a unique blend of consultancy, clinical trial design, and execution services. This integrated approach empowers us to deliver comprehensive support across all phases of our clients' drug development journey, from initial planning to implementation. With a long-standing presence in the industry of over 25 years and a dedicated team of experts, we're committed to expedite our clients' drug development seffectively.





## **Meeting Growing Demand**

## **Testimonials**

We have been working with Venn Life Sciences for several years on two compounds requiring sophisticated formulation development work. Their deep knowledge and expertise in formulation development enabled us to initiate clinical trials of both programs. Through the collaboration with Venn, we were also able to access to the outstanding features of other services, including CMC, Non-Clinical and Early Clinical consultancy/operational services to achieve the goal. They are talented and committed individuals with great expertise in the scientific and regulatory landscape, and always willing to support us to overcome a number of challenges faced on the projects. I now consider them as a part of our clinical development team

Akinori Arimura, PhD Director Clinical Development, Carna Biosciences



I highly appreciated the flexibility of Vennlife to provide a custom PK analysis with a very short timeline.

Jonathan Back Director Translational Research of GlycoEra AG



Want to send a thanks to my friends at Venn Life Sciences. After I reached out to the Linked community asking for help to a European regulatory hurdle, they gave their time and found the solution allowing our study in a rare disease to progress. Very grateful.

**Bradley Joblin** Founder, Study Design & Clinical Development Specialist



75%

**Repeat Business** 

Trusted partner to the life science industry

**25** years

## New office at Leiden Bio Science Park

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









Workshop 1 Roadmap to Clinical Entry: Devil in the Detail

Workshop 2 Do it Right the First Time: The Value of a Drug Development Plan

## 100%

Customers surveyed would work with Venn again

## Chair's Statement

For the year ended 31 December 2023



## 2023 – A record year across all metrics

Another record year across all financial and operational metrics. hVIVO had nine active challenge studies in the quarantine clinic and inoculated our highest number of healthy volunteers during the year. Revenue continued its upward momentum delivering strong double-digit growth, with further efficiency gains resulting in record profit margins. The weighted contracted orderbook of £80 million as at 31 December 2023 provides good visibility into 2024 and beyond. The business also continues to efficiently generate cash, demonstrating the strength of our highly cash-generative business model. Venn Life Sciences (Venn), hVIVO's early drug development consultancy, also continued its impressive trajectory delivering more than 30% revenue growth, underlining the strong momentum visible across the entire Group.

We are also pleased to confirm the start of an annual dividend policy, a sign of the significant progress made to date and our confidence in the current health and future of the business. The upcoming move to our new state-of-the-art facility in Canary Wharf, largely funded by our clients, will increase our revenue capacity from current levels and further improve operational efficiencies, ultimately enhancing our profit margins.

## An established business delivering consistent growth

hVIVO is the world leader in human challenge trials (HCTs) and an established early clinical development services business. The Group continues to execute its strategy, expanding its portfolio and diversifying client services, to deliver long-term sustainable growth and profitability. To that end, post period end we have announced a new medium-term target to grow Group revenue to £100 million by 2028, which the Board is confident is achievable through continued strong organic growth complemented by small bolt-on acquisitions that meet our disciplined strategic and financial criteria.

Organic growth in the period was driven by the steady expansion of the HCT market, with our influenza and respiratory syncytial virus (RSV) challenge models being key growth drivers. In particular, there has been renewed interest in RSV vaccine and drug development from the global biopharma industry following the approval of the world's first RSV vaccines last year. hVIVO conducted the successful Phase 2 challenge trial for Pfizer's ABRYSVO<sup>™</sup> vaccine, the data from which supported the FDA Breakthrough Designation and an accelerated approval. We anticipate RSV continuing to be a key growth driver going forward.

We have continued to win larger, fullservice or bespoke human challenge contracts that include client-funded development of new challenge models, adding new indications to our world leading portfolio. Coupled with our new state-of-the-art facilities, we have built robust foundations to further scale the business and drive continued long-term organic growth. It is also worth contextualising the Group's excellent progress against the tight biopharma funding environment that has persisted for a couple of years. That said, we are starting to see positive green shoots across the market, with January 2024 the strongest month of biotech funding since November 2021, and we are confident hVIVO is well placed to benefit should this trend continue.

Whilst our existing HCT and Venn businesses are both delivering strong

organic growth, we will seek to enhance this via our inorganic growth strategy, and we are actively assessing synergistic opportunities for small bolt-on acquisitions in the areas of drug development consulting, patient recruitment and clinical trial site services that will support our growth strategy whilst also diversifying the Group's revenue streams. With a growing cash position of £37 million at 31 December 2023 and strong sector and M&A expertise on the Board, we are in a strong position to execute this strategy.

#### Annual dividend

In 2023, the Company paid its first cash dividend, a one-off special dividend of £3.1 million. From 2024, as part of the Company's annual dividend policy, we will pay an annual dividend in light of the cash generative qualities of the business and the substantial cash balances on hand. A dividend of c.£1.4 million, being 0.20p per Ordinary Share will be payable on 20 May 2024 to shareholders on the register on 19 April 2024, subject to shareholder approval at the AGM. The corresponding ex-dividend date is 18 April 2024.

## Chair's Statement

#### Outlook

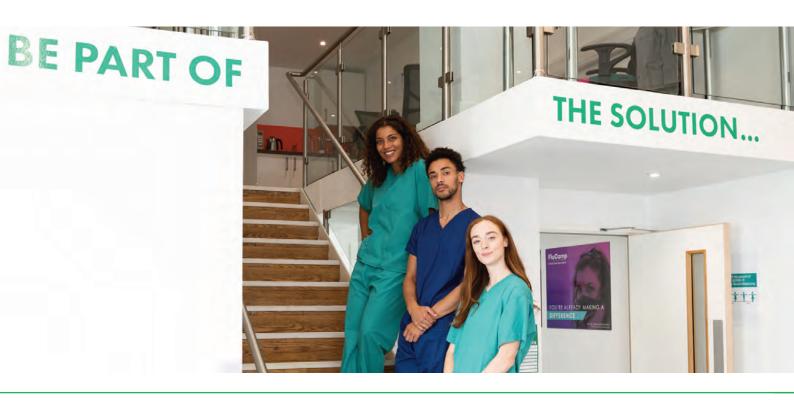
hVIVO has had a strong start to 2024, conducting multiple concurrent challenge trials and has 90% of this year's revenue guidance already contracted, with record revenue visibility into 2025. The Board is confident that the Group's consistent year-on-year growth of revenue, orderbook, sales pipeline, and contract values are a strong indicator of the long-term health and growth potential of the HCT market. The Group continues to evaluate opportunities to optimise its business model and diversify its revenue streams via organic and inorganic means to take advantage of this significant opportunity, helping both grow the HCT market and further cement hVIVO's position as the global leader.

Having received HSE approval in April 2024, the Group is on schedule to open its new state-of-the-art facility in Canary Wharf in H1 2024, enabling

hVIVO to meet the growing demand for HCTs. The new facility will allow the Group to further scale and drive revenue and margin improvements across its business and will underpin the new medium-term target of growing Group revenues to £100 million by 2028. As a result of the current strong outlook and performance of the business, the Board remains confident in achieving revenues of £62 million in 2024.

Cathal Friel Chair

8 April 2024



## **Chief Executive Officer's Statement**

For the year ended 31 December 2023



## An established long-term sustainable growth model

Another record year has underlined hVIVO's ability to further build and expand the human challenge trial market, with a growing number of evidence-based use cases having showcased the tangible benefits these trials can bring to the development of new vaccines and antivirals. Consequently, an increasing number of drug developers have incorporated HCTs into their clinical development plans resulting in an increase in both repeat and new business from our growing roster of biopharma clients. Notably, four of the top ten global biopharma firms are among our clients with contracts generally increasing in both size and scope. The heightened demand for our services is evidenced in the growing portfolio of our challenge models and the imminent move to our new state-of-the-art quarantine facility.

The fact that the majority of our new challenge models are funded by our clients, and that our key clients have largely financed the new facility, underpins our confidence in the future of the HCT market. These investments also demonstrate the industry's recognition of the value that hVIVO's HCTs can provide, and their ability to transform the development pathway for new medicines.

The record revenue and profitability achieved during the year are testament to our ongoing efforts to continually optimise the business to ensure we can service this growing market over the long-term as part of an established long term sustainable growth model.

## Another set of record results

hVIVO delivered record full year revenue of £56.0 million (2022: £48.5 million), a 16% increase on the previous year. The Group also recorded a substantial 44% increase in EBITDA to £13.0 million (2022: £9.1 million), with EBITDA margin increasing to 23.3% (2022: 18.7%). This growth was primarily driven by the simultaneous conduct of multiple clinical trials leading to improvements in the efficiency of volunteer recruitment, and enhanced facility and staff utilisation. The client funding towards our new Canary Wharf facility has also contributed to an improvement in EBITDA which benefited margins in 2023 and is expected to also benefit 2024.

The considerable growth in cash to £37.0 million as at 31 December 2023 (31 December 2022: £28.4 million) is a result of an increase in the receipt of upfront non-refundable fees, including client receipts for the new facility as

well as increased profitability in the conduct of HCTs. This offset the effect of MHRA delays which impacted all clinical trials across the UK in 2023, and also includes the £3 million one-off dividend paid in June 2023. Looking ahead, our weighted orderbook grew to £80 million as at 31 December 2023 (31 December 2022: £76 million) having delivered £56.0 million of revenues in 2023. This substantial orderbook ensured that we entered the year in a very strong position with 90% of 2024 revenue guidance already contracted. It is important to emphasise that our orderbook is comprised of clients who have signed a contractual agreement and paid the up-front non-refundable fee.

## Exceptional operational execution

In 2023, hVIVO delivered nine active HCTs and inoculated a record number of volunteers, with more than 17,000 potential volunteers undergoing in-house screening. By leveraging our strong orderbook, we have strategically managed and planned the utilisation of our guarantine clinic to optimise staff and facility usage. The team has consistently demonstrated our ability to convert the orderbook into revenue at excellent margins. In addition, our contracts include milestone payments such that we maintain a positive cashflow throughout the project lifecycle. We have also seen greater integration across the Group, between hVIVO and Venn, especially across Medical Writing, Data Management and Biostatistical service units. This synergy has created a seamless end-toend offering of early clinical development services. Volunteer and patient recruitment continues to be the main challenge for the clinical trial industry, with over 80% of clinical trials failing to meet enrolment timelines in the US alone. FluCamp, the Group's technology-enabled volunteer recruitment arm, provides industry leading volunteer recruitment for hVIVO's trials. With an unparalleled database exceeding 300,000 potential volunteers and around 1,500

## Chief Executive Officer's Statement Continued

volunteers screened each month, FluCamp has a very high success rate in meeting healthy volunteer recruitment deadlines. In 2023, we introduced a new volunteer management system which has improved engagement and retention of potential volunteers as well as improving efficiencies.

The exceptional operational delivery across the business is a testament to the outstanding team we have in place across the Group and is reflected by the year-on-year repeat business from Big Pharma and biotech clients.

## Delivering on our growth strategy: Optimise, scale and diversify

#### **Optimising our operations**

A large and diverse orderbook allows us to schedule our work in an efficient manner. The main efficiency gains in the period were driven by the concurrent conduct of challenge trials across multiple challenge agents. This has an impact on a number of facets including volunteer recruitment, staff and site utilisation. The screening of volunteers against multiple challenge trials increases the likelihood of a volunteer entering a trial. This leads to an increased throughput in the quarantine clinic, and greater utilisation of our operational resources, both staff and facilities. Going forward, we expect the new facility to be the main driver of further efficiency improvements, as it will allow the Company to conduct even more challenge trials concurrently. FluCamp has also benefitted from greater automation as it transitions from paper-based processes to fully cloud-based integrated systems. Likewise, the implementation of a lab information management system (LIMS) in 2024 will help to streamline lab processes and improve efficiency.

#### Scaling the business

The trend towards larger HCTs continues, reflecting the expanding utility of HCTs. While the use of the two-arm study design comparing placebo versus active remains prevalent, there's an evolution towards multi-arm studies, comparing different doses and/or technologies. It is important to note that the size of the trial cohort remains the primary determinant of contract value. In addition, there's an increase in data collection to provide deeper insights into the drug, including dosing strategies and endpoint selection, which informs later-stage field trials.

With the collaboration of our key clients, the Company is laying the groundwork to meet the growing market demands. The Canary Wharf facility will house 50 guarantine beds with dedicated HEPA air handling systems, meaning we can conduct more concurrent trials than are currently possible. Furthermore, we can also add up to 20 more beds if the demand for challenge trials continues unabated. It will also house a much larger laboratory including a CL-3 capability allowing us to conduct HCTs in CL-3 pathogens such as SAR-CoV-2. The new facility is projected to open, and be fully operational, by the end of H1 2024, and is set to be the world's largest commercial human challenge trial unit. hLAB, the Group's highly specialised virology and immunology laboratory service offering, saw a 100% increase in completed lab assays during the year.

Venn, our drug development consulting subsidiary, also achieved remarkable success, with over 30% year-on-year revenue growth. Venn saw a 24% increase in employee headcount as it successfully delivered larger contracts for its 75% repeat fast-growing biotech and Big Pharma clients. We anticipate further growth opportunities for Venn and have increased strategic investment in the key growth areas of advanced therapy medicinal products (ATMP) and drug device consulting.

## Diversifying our orderbook and services

hVIVO signed multiple bespoke, fullservice human challenge contracts to develop new challenge models, further expanding our world-leading portfolio of challenge models. These contracts are unique to hVIVO and provide a source of potential long-term revenue. We also achieved a significant milestone by signing our first HCT contract with a client based in the Asia-Pacific (APAC) region in over a decade, effectively diversifying our order book across clients, challenge models and geographies. Our current £80 million orderbook is weighted highly diversified, with work contracted across 7 challenge agents and 11 HCT clients, substantially reducing the impact to hVIVO of potential postponements or cancellations.

Our new facility will further expand our service offerings, featuring an enhanced laboratory and an on-site outpatient unit. enabling the facilitation of Phase II and Phase III field trials. Furthermore, we aim to strengthen our service portfolio through strategic small bolt-on acquisitions in existing synergistic areas of expertise. We are particularly interested in acquiring drug development consulting businesses that complement Venn, patient recruitment companies synergistic with FluCamp, and Phase I units that can utilise volunteers from our extensive database who are ineligible for HCTs. We are actively evaluating potential opportunities aligned with our growth strategy, leveraging our team's deep sector knowledge and operational expertise to ensure successful acquisitions that enhance our position as a global CRO service provider. Aligned with our M&A strategy, it is important to note that we will wait for the right opportunity rather than rush into a quick acquisition. Our growth strategy includes both organic and inorganic growth, but we will re-align our targets depending on the opportunities available.

In a recent development, we have received notice that the biopharmaceutical company funding the development of the hMPV model is now intending to proceed directly to a Phase III clinical study and no longer plans to conduct a challenge study. As a result, hVIVO will recognise a cancellation fee for the cancelled characterisation study in the current financial year. The hMPV vaccine challenge study has never been included in the Group's weighted orderbook and there is no change to 2024 financial guidance. The manufacture of the hMPV challenge agent has been completed and is the Group's IP, we will be marketing the agent for characterisation and challenge studies moving forwards.

## An evidence-based sales strategy

Our ability to expand the HCT market is driven by the continued notable successes that our HCTs have delivered on behalf of our clients. hVIVO is the world leader in HCTs, conducting on average 5-10 trials a year across multiple challenge agents, substantially more than the 1-2 conducted each year by our next closest competitor. This is a significant differentiator for the Group, as we optimise our models after every trial, ensuring they deliver robust and reliable results for our clients.

The following client case studies provide strong examples of what has been achieved following a HCT with hVIVO:

- Pfizer's ABRYSVO<sup>™</sup> became one of the first RSV vaccines to receive FDA approval in May 2023 having received FDA Breakthrough designation
- At least two biotechs received FDA Fast Track and/or Breakthrough Designation

These case studies provide the vital evidence-based foundations for our ongoing sales efforts, highlighting how hVIVO's HCTs can generate rapid efficacy data that is recognised and valued by the FDA, leading to potentially expedited pathways to market via FDA Breakthrough or Fast Track designation. Pfizer's RSV vaccine ABRYSVO<sup>™</sup> provides a strong example of what is achievable through HCTs - its pathway to market was significantly accelerated following a HCT conducted by hVIVO, saving potentially up to two years of clinical development time that would have been required as part of a traditional field trial. For biotechs with fewer resources and smaller pipelines, the tight funding environment has also increased the attractiveness of HCTs. HCTs can deliver quick efficacy data at a lower cost than field trials, substantially increasing the value of their vaccines or antivirals, which can strengthen their case for further funding and increase their attractiveness to Pharma partners as a potential acquisition/licensing candidate. This potential is evidenced by ReViral, who were acquired by Pfizer for up to \$525 million following an RSV HCT conducted by hVIVO.

We are confident that our evidencebased sales strategy will continue to grow our market given the strong market dynamics related to the development of new vaccines and antivirals. There are an increasing number of vaccines and antivirals in development every year, yet for antivirals, there remains just one approved treatment for every 20 viruses known to infect humans.

## Well placed to deliver future growth targets

In 2023, we witnessed another year of strong growth in the HCT market, as both Big Pharma and biotech companies increasingly recognised the evidence supporting the ability of HCTs to expedite the development of new vaccines and antivirals. Our record revenues, profitability and the number of volunteers inoculated not only reflect the growing market but also highlight our expertise and capability to meet this demand, establishing a longterm sustainable growth model. It is testament to the hVIVO team that in the current financially challenging life sciences market we have been able to continue our strong growth trajectory. I am confident that once the funding environment in the biotech industry improves, we will see a further increase in demand for HCTs and in the meantime we remain well placed with a significant orderbook stretching into 2025. Furthermore, we anticipate that new challenge agents being developed, as well the development of next generation of vaccines including mucosal and multi-valent vaccines will help to drive further growth going forward.

## Chief Executive Officer's Statement Continued

We have a well-defined growth strategy comprising both organic and inorganic avenues. Our primary focus remains on expanding our core HCT business, including the enhancement of the portfolio of challenge models. Additionally, we aim to grow in complementary areas such as laboratory services, patient recruitments, and clinical site services. This strategy is underpinned by the move to the new facility with a larger quarantine and laboratory capabilities. We also plan to explore opportunities for small bolt-on acquisitions in existing synergistic areas to diversify our

offerings. In the short-term, I am confident our record orderbook, visibility, and strong outlook for the business will enable us to achieve our guidance of £62 million in revenue for 2024. Looking ahead, we are committed to building the Company to achieve our medium-term target of growing Group revenues to £100 million by 2028.

Mani bhe

**Dr Yamin 'Mo' Khan** CEO 8 April 2024



## **ESG** Sustainability Statement

t hVIVO, sustainability is integral to our corporate ethos and operational framework. We recognise our responsibility to drive positive change in environmental, social, and governance (ESG) fronts while advancing our mission of delivering today's healthcare by empowering tomorrow's innovation. Our commitment to sustainability is encapsulated by our ESG Group, a dedicated team which reports to the Audit & Risk Committee, ensuring comprehensive oversight and monitoring of actions on climate change risks and social governance matters.



Our ESG values underscore our dedication to advancing health and research, fostering a culture of equality, diversity and inclusion, and prioritising ethical business practices. These values guide our initiatives across social and community investment, sustainability practices, and our support for volunteers and patients.

Aligned with the United Nations Sustainable Development Goals, we focus our efforts on key areas relevant to our industry. We actively contribute to global health challenges by supporting the development of vital medicines to tackle infectious diseases. Our commitment extends to neglected tropical diseases, where our expanded portfolio addresses critical medical needs.

We prioritise our staff's well-being and development, fostering an inclusive workplace culture supported by our policies, initiatives, and events which reflect our dedication to creating a supportive and collaborative environment.

Furthermore, our social and community investment initiatives demonstrate our commitment to giving back and creating meaningful impacts beyond our corporate borders.

Operating sustainably is fundamental to our business model. We are committed to effective environmental management, minimizing our environmental footprint, and are on a path towards implementing ISO14001 principles. ISO14001 is an internationally recognised standard for environmental management systems (EMS). It provides a framework for organizations to design and implement an EMS, and continually improve their environmental performance. Our streamlined energy and carbon reporting, waste reduction initiatives, and responsible food supply practices all form part of our commitment to environmental stewardship.

Ethical and compliant business practices are non-negotiable for us. We uphold the highest standards of corporate governance, ethical conduct, and transparency across all our operations. Our robust quality systems, adherence to regulatory standards, and commitment to participant safety underscore our dedication to ethical clinical research.

We made excellent progress in our ESG efforts in 2023 and we will continue to innovate, collaborate, and drive positive change in 2024 and beyond, ensuring that our operations remain aligned with our core values and contribute meaningfully to a more sustainable future for all.

Dr Yamin 'Mo' Khan CEO 8 April 2024



## **ESG Group**

VIVO has formed the ESG Group, a cross-business working team led by our CEO, dedicated to identifying climate change risks and other social governance matters. Reporting directly to the Audit and Risk Committee, this group comprises representatives from different sectors within our company, ensuring a comprehensive approach to ESG considerations. The Audit and Risk Committee oversees the Company's ESG reporting and subsequently recommends it to the Board for review.



### Advancing Health & Research – Social and Governance



Social & Community Investment – Social

## **Our ESG Values**



Commitment to Staff – Social



Operating Sustainably -Environmental



### Commitment to Volunteers & Patients – Social and Governance



Commitment to Ethical & Compliant Business Practices - Governance

## Our Sustainable Development Goals

NIVO strives to align with the 17 United Nations Sustainable Development Goals. However, we focus our efforts on the specific goal areas listed below, as they hold greater relevance to our business operations:



## **ESG Goal Implementation Overview**

	Company Values	The significance	Relevant SDGS	hVIVO's Implementation
Value 1	Advancing Health & Research	hVIVO has taken on the responsibility as a world leader in human challenge trials to further scientific research and advance healthcare.	3 INSTRUCTION	<ul> <li>Developing Vital Medicines</li> <li>Sharing Knowledge &amp; Tackling Infectious Disease</li> <li>Neglected Tropical Diseases</li> </ul>
Value 2	Commitment to our Staff	Our team is the key to our success, we are focussed on building a strong corporate culture that places diversity and equality at its centre.	3 montain	<ul> <li>Equality, Inclusion &amp; Diversity</li> <li>Flexible Working</li> <li>Whistleblowing</li> <li>Equal Opportunities Policy</li> <li>Performance Management</li> <li>hBenefits</li> <li>Training and Development</li> <li>hKitchen</li> </ul>
Value 3	Social and Community Investment	Social and community investment involves strategically allocating resources to initiatives that promote positive social impact and foster community development. By supporting projects focused on education, healthcare, and sustainable development, hVIVO can contribute to the well-being and resilience of communities, creating a lasting positive influence.	3 montain A and a second seco	<ul> <li>Volunteering and Charitable Donations</li> <li>Annual NL Doet</li> <li>Internal Charity Days</li> <li>Community Health Check</li> </ul>
Value 4	Commitment to Volunteers & Patients	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.	8 RECENT WORK AND RECENTIVORE GROWTH RECENTIVORE RECENTIVO RECENTIVORE RECENTIVORE RECENTIVO	<ul> <li>Post-visit online questionnaire</li> <li>Post Residential Stay Telephone Survey</li> <li>Trustpilot Reviews</li> <li>Access to Members of FluCamp during Quarantine</li> <li>Comprehensive Health Checks for Volunteers</li> <li>Referral to Volunteer Physician</li> <li>hKitchen</li> <li>Entertainment in Quarantine</li> <li>Compensation</li> </ul>
Value 5	Operating Sustainably	hVIVO is committed to effective environmental management and to minimise the impact of our businesses on the environment. We are working towards implementing the principles of ISO14001.	8 весен тикк ма ссолова: влачни	<ul> <li>Sustainable Working Practices</li> <li>Internal Engagement</li> <li>Travel &amp; Reducing Emissions</li> <li>hKitchen and Responsibly Sourced Food</li> <li>Compostable Packaging</li> <li>Menu and Food Waste</li> <li>Food App</li> <li>Waste and Recycling</li> <li>Streamlined Energy and Carbon Reporting ('SECR')</li> </ul>
Value ó	Commitment to Ethical and Compliant Business Practices	hVIVO ensures that it operates under high regulated and quality compliance standards.	8 весект жилек ми соможе сокумти С	<ul> <li>Business Ethics</li> <li>Anti-Bribery &amp; Corruption</li> <li>Human Rights</li> <li>Suppliers</li> <li>Quality &amp; Volunteer Safety</li> </ul>

## **Environmental, Social & Governance (ESG)**

Continued

## 1. Advancing Health & Research

## (Social & Governance)

### **Developing Vital Medicines**

Addressing the pressing global challenge of equitable access to essential healthcare is paramount. At hVIVO, we are aware of our pivotal role in facilitating our clients' endeavours to expedite the development of vital medicines through our comprehensive clinical development consulting and trial services. This commitment to social responsibility aligns with our vision of transforming global healthcare by revolutionising the drug development process through scientific ingenuity.

In 2023, we expanded our portfolio of human challenge agents to help further scientific research and support the development of vaccines and antivirals in new disease areas and our goal is to continue to broaden our challenge agents and test new medicines.

#### Sharing Knowledge & Tackling Infectious Disease

Our dedication to sharing knowledge and expertise is integral to our mission of combatting infectious diseases.

Through collaborations with industry organisations, academic centres such as Imperial College London, Kings College London, Emory University, and non-profit entities like The Wellcome Trust and HIC-VAC, we actively promote and expand the understanding of human challenge trials.

As a company, we participate actively in commercial and academic scientific events and conferences worldwide, presenting data and insights from human challenge trials and nurturing scientific discussion. Our findings, in collaboration with trial sponsors, are regularly published in leading scientific journals.

As part of our commitment to sharing knowledge and aiding scientific research in combating infectious diseases, our team of scientific experts authored multiple papers, articles, and blogs in 2023, as well hosting multiple public forums where the experts from hVIVO and Venn Life Sciences shared their knowledge with more than 500 attendees. By leveraging the expertise and resources of hVIVO Group, we have been able to amplify the impact of the research we do, ultimately driving innovation and progress in our field while also forging meaningful connections within the scientific community.

#### **Neglected Tropical Diseases**

hVIVO's wide portfolio of challenge models primarily focuses on respiratory infections, however as the Group expands and with the introduction of the new site in Canary Wharf, the Group will continue to assess its expansion into new human challenge models to assist in the advancement of novel drug and vaccine candidates.

The Group currently offers a malaria human challenge model, a life-threatening illness that disproportionately affects vulnerable population in tropical and subtropical regions. The impact of climate change is effecting the epidemiology of diseases like Malaria, meaning finding effective drugs against these infections is growing in importance.

#### 2024 and beyond

- Continue pursuing our mission to "Deliver today's healthcare by empowering tomorrow's innovation", which can be implemented by further assessing the opportunities presented and actively expanding our challenge models and services
- New facility in Canary Wharf the world's largest commercial quarantine unit, which will not only expand our capacity for conducting human challenge trials but also enhance our site and laboratory services
- Enhanced infrastructure, including 50 quarantine bedrooms designed for diverse human challenge trials, we aim to
  expedite the development of essential medicines
- Our new laboratories, featuring a containment level three (CL-3) certification, will empower us to engage with a broader spectrum of pathogens such as COVID-19, malaria, and dengue, among others

## 2. Commitment to our Staff

## (Social & Governance)

#### **Equality, Inclusion, Diversity**

At hVIVO, our goal is to cultivate a culture characterised by equality, inclusion, and diversity, empowering us to forge a strong team and deliver outstanding results for our clients. Aligned with our Diversity Policy, we firmly believe that a diverse, inclusive, and collaborative workplace fosters an environment where our team can flourish, and we are unwavering in our commitment to providing equal opportunities for all. We deeply appreciate and honour the unique differences that define each individual, striving to nurture a culture that champions meritocracy, transparency, fairness, and transparency.

We uphold a steadfast principle of assessing all staff solely based on merit and capability, without any form of discrimination on the basis of age, race, gender, disability, religion, sexual orientation, or any other protected characteristic. We are committed to creating an environment where every individual is treated with respect and dignity, and where they are empowered to realise their fullest potential.

International Potluck Day stands out as a dynamic occasion in our corporate calendar, emblematic of hVIVO's commitment to embracing cultural diversity. Through the shared experience of preparing and enjoying a variety of international dishes, International Potluck Day reinforces our corporate ethos of fostering inclusivity and appreciation for the diverse backgrounds that enrich our hVIVO community.

#### **Flexible Working**

Across hVIVO group, we adopt a flexible working policy to ensure we support a positive work-life balance for our staff. It's a principle which supports our ability to hire and retain the best capable individuals and provides employment opportunities to individuals with personal commitments. With employees distributed across multiple regions and time zones, we are proud of our ability to adapt to the ever-evolving work environment.

#### Health & Safety

Our Health & Safety Policy highlights our commitment to providing a safe working environment for our staff, visitors and the general public in accordance with the Working Conditions Act. We appoint internal Health & Safety Officers and provide access to external consultants for support as required.

#### **Training and Development**

Our objective is to recruit exceptional individuals and nurture their growth through our comprehensive training and development programmes. This approach fosters a culture where employees align with our business values and future objectives. In 2024, most of our senior leaders and department heads have progressed through internal development pathways. Our training is categorised into General Training, applicable to all employees, and Specialist Training, tailored to specific roles.

#### Lunch and Learn

In 2023, hVIVO implemented a townhall-like Lunch and Learn initiative, a vibrant initiative fostering a culture of knowledge sharing and community building. Staff can showcase their expertise during a 20-minute virtual presentation and Q&A session during lunchtime. This not only enhances collaboration but also empowers our team members to contribute to each other's professional growth. It's a dynamic platform where diverse perspectives converge, promoting a sense of community and continuous learning throughout our organisation.

## Environmental, Social & Governance (ESG)

## Continued

### hBenefits

Our dedicated HR team plays a pivotal role in fostering a thriving and cohesive workplace environment. They serve as the backbone of organisational culture, ensuring effective communication, conflict resolution, and employee engagement. By recruiting, developing, and retaining top talent, HR contributes directly to hVIVO's success. Their expertise helps to create a workplace where individuals can flourish, fostering innovation and productivity, while simultaneously adhering to our Company mission and vision.

At hVIVO, we prioritise our employees' well-being and work-life balance through our competitive hBenefits package offering support such as pension, healthcare, life assurance and schemes such as Bike to Work. Our Employee Assistance Programme offer 24-hour support to our team for financial, legal or family affairs.



\* As at 31 December 2023

## hKitchen

In 2023 hVIVO opened hKitchen, our in-house culinary experience. Beyond catering for our FluCamp volunteers, hKitchen goes the extra mile by offering affordable meal options to our staff. Crafted in-house, these delicious meals not only ensure fresh and healthy food for our team, but also competes with local supermarket meal deal prices. Accessible through the user-friendly hKitchen app, our staff can now enjoy the convenience of ordering nutritious and freshly-prepared meals on demand. It's more than just a kitchen; it's a culinary experience designed to nourish our team and foster a sense of well-being throughout our workplace.

#### 2024 and beyond

- The move to Canary Wharf in 2024 will bring our clinical site teams (currently split across two locations and five floors), lab team, and corporate office into one purpose-built facility which we expect to improve in employee engagement
- The LIMS system to automate sample management will improve employee experience
- Staff will benefit from Canary Wharf community offerings, great local amenities, and improved transport links
- hVIVO will continue to foster a culture of equality, inclusion and diversity, ensuring equal opportunities, celebrating diverse perspectives, and cultivate an atmosphere that encourages collaboration

## 3. Social and Community Investment

## **Charity Donation & Volunteer Leave Policy**

hVIVO has implemented a Volunteer Leave Policy that empowers our staff to contribute to meaningful causes. At hVIVO, we believe in making a positive impact not only within our organisation but also in the communities we serve. We encourage staff to take one day per year to participate in charitable volunteering events to give back to the community and make a difference. By participating in volunteering activities, the wider hVIVO team can collectively contribute to social and community causes.

Furthermore, hVIVO actively engages in supporting charitable endeavours involving our staff, encouraging active participation in volunteer opportunities. We provide assistance and make charitable contributions to recognise and enhance the impactful initiatives of our team. Prior to selection, all charities undergo evaluation by our HR Team to ensure they resonate with our values and dedication to fostering positive change.

#### **Annual NL Doet**

The Venn Life Sciences team in Breda actively engages in the annual NL Doet volunteer day, committing their efforts to support local community projects in the vicinity. This longstanding tradition has been upheld by the Venn Life Sciences team for several years, showcasing their enduring commitment to community service.



#### **Internal Charity Days**

Our internal charity initiatives exemplify our dedication to social

responsibility, reinforcing our commitment to creating a positive impact in the communities where we operate.

We are proud to engage with our local community through the **White-chapel Mission** by setting up a non-per-ishable food collection and donations box.

Our Christmas Jumper Day supported **Action for Children and Crisis.** 

We supported 20 hVIVO team members participation in Tough Mudder 2023. The team took part in **Tough Mudder in aid of Asthma and Lung UK**,











#### **Community Health Check**

In 2023 hVIVO offered complimentary healthcare services to the Whitechapel community through its Community Health Check initiative conducted at our FluCamp volunteer screening facility in Plumber's Row. The health check included blood pressure readings, lung function assessments, and BMI measurements. Emphasising accessibility, community members were encouraged to attend the free services through walk-ins, supported by an awareness campaign facilitated by distributing flyers to enhance community engagement.

#### 2024 and Beyond

- Continue to support local charities and promote our Charity Donation & Volunteer Leave policies
- Encourage involvement in the Canary Wharf ESG community initiatives
- Partnership with local charity/community
- Continue to increase communication of the Company's ESG efforts across the Group

(Social)

## Environmental, Social & Governance (ESG)

Continued

## 4. Commitment to Volunteers & Patients

Ensuring the safety and well-being of our volunteers and patients is a priority to hVIVO and our volunteer recruitment platform, FluCamp. We hold a steadfast commitment to maintaining the highest ethical standards in clinical research, with a particular emphasis on data privacy and protection.

FluCamp has a team of dedicated staff members to help deliver our volunteer recruitment. Their primary goal is to ensure the delivery, enhancement, and monitoring of our volunteers' experiences. Our dedication to excellence in research extends beyond mere compliance; it's about fostering a culture of care, respect, and continuous advancement for all those involved.

We deeply value every individual involved in our studies and their feedback. We actively seek ways to enhance our procedures and processes, striving to create an environment where their voices are not only heard but make contributions into our ongoing efforts to improve. We conduct post screening online questionnaire's as well as post quarantine telephone surveys to ensure our volunteers to share their insights and reflections.

Trustpilot is an excellent independent tool for the volunteers to provide feedback on FluCamp and their experience at hVIVO. In 2023 we held a 4.3-star review rating on Trustpilot (highest rated clinical trial company), from 94 reviews in 2023, 84% were 5 - star ratings.

## Access to FluCamp Team during Quarantine

In addition to having access to our medical professionals during their quarantine experience, our volunteers also have access to our FluCamp team members, to provide support during their time in quarantine. This is an easy and direct route to resolve any non-medical issues that may arise as well as ensuring our volunteers feel fully supported throughout their quarantine experience.

## **Comprehensive Health Check**

All volunteers undergo a three-step health check prior to participation in any of our clinical trials to identify their suitability for a trial as well as ensuring the safety and well-being of our volunteers. A post-quarantine health-check is also conducted on volunteers, to ensure that they have returned to full health before exiting quarantine. During the volunteers stay we perform multiple in-depth tests including daily or twice daily PCR, these tests confirm that our volunteers are no longer infectious before they leave our facility.

Should our medical experts discover an existing health abnormality at any stage of our volunteer health check, the volunteers' results will be promptly relayed to their physician or GP. Please note that volunteers deemed unsuitable for trials will not be included in our studies.

#### hKitchen

hVIVO has introduced a kitchen to serve volunteers throughout their quarantine period. hKitchen strengthens our dedication to volunteers by providing freshly prepared, nutritious meals customised to their dietary requirements. Volunteers can conveniently request meals through the volunteer food app, accessible within our quarantine facility.

## **Entertainment in Quarantine**

During volunteer's quarantine stay, volunteers' bedrooms are equipped with an ensuite bathroom and an array of entertainment options such as board games, PlayStations, Wi-Fi and smart TV's, to ensure that volunteers can fill their time in a safe and entertaining environment.

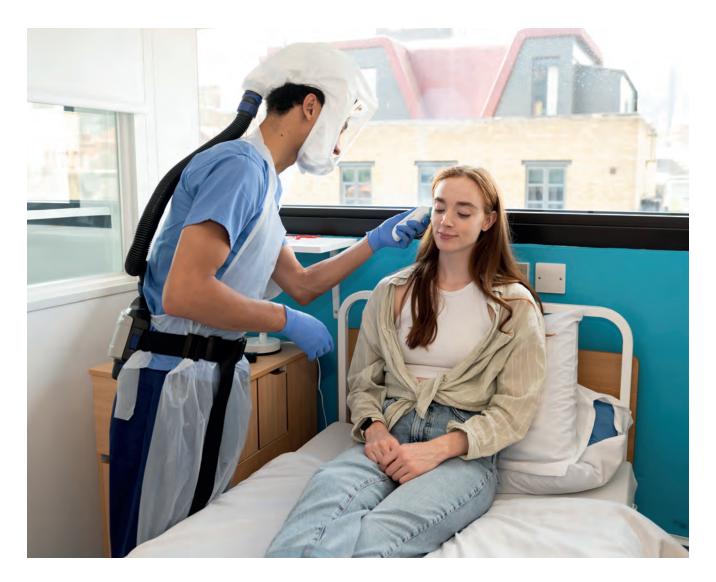
(Social & Governance)

### Compensation

Our volunteers are compensated for the time they spend in quarantine as well as screening visits. hVIVO has adopted a wage payment model using the London Living Wage as guidance to ensure standardisation of remuneration across all studies. All study-specific advertising to recruit volunteers discloses the full compensation amount and is pro-actively approved by the Ethics Committee.

#### 2024 & Beyond:

- Communicate hVIVO's ESG values and activities to our volunteers
- Continue to seek and implement feedback to improve our volunteers experience
- Canary Wharf is set to enhance our volunteer's experience with some enjoying fantastic views overlooking the city as well as additional amenities such as individual room temperature control, new food menu and upgraded entertainment options



## Environmental, Social & Governance (ESG)

Continued

## 5. Operating Sustainably

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, we implemented our Environmental Policy which was made available to all staff to ensure awareness of their roles and responsibilities in relation to environmental management. hVIVO is committed to promoting sustainable practices within our organisation by educating our team on ESG principles.

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

## **Working Practices:**

- Continued flexible work from home
- Virtual meetings encouraged across hVIVO and subsidiaries
- LIMS implementation underway to reduce paper waste

#### Travel & Reducing Emissions:

- Introduced company-wide Travel Policy, to reduced international travel
- Electric Vehicle Scheme implemented at hVIVO UK in 2023
- Cycle to work scheme available at hVIVO UK
- Electric vehicle charging available at Venn Breda
- Low carbon modes of transport encouraged (season ticket loan)

#### **Volunteer Travel**

hVIVO's principal screening and quarantine facility is located in Whitechapel, London. In 2022, the Company opened a second FluCamp volunteer screening site to facilitate better access for volunteers located across the UK and to reduce volunteer travel, in turn reducing our CO<sub>2</sub> emissions.

In 2023, over 5,000 volunteers attended screening appointments at our Manchester FluCamp site. Based on the distance between London and Manchester (211.2 miles one way) and based off all volunteers travelling on the national rail, we estimate a saving of 83.90 Tco<sub>2</sub>e in 2023.



## (Environmental)

### hKitchen & Responsible Food

In 2023, hKitchen was introduced which has vastly reduced food waste by ensuring appropriate quantities of food are ordered to fill the demand required. A number of other initiatives were introduced during the year which has positively impacted its environmental impact:

- Compostable Packaging
- Seasonal & locally sourced food, wherever possible
- FluCamp Food App introduced in 2023 reduces paper waste

2023

2022

- Partnered with Waste Not - reducing food waste

#### Waste & Recycling

In 2023, hVIVO continued its mission of reducing waste and improving recycling at its facilities through multiple initiatives as well as encouraging hVIVO team members to reduce, reuse and recycle. Continuous monitoring of waste and e-waste production is upheld, while waste contractors are thoroughly vetted and monitored. Recycling facilities at all hVIVO sites have been extended, with a continued focus on disposing of electronic waste in compliance with regulations and minimising its generation. A maintenance program has been implemented to ensure that plant and equipment are kept at optimal levels and replaced at the end of their lifecycle.

#### Streamlined Energy and Carbon Reporting ('SECR')

hVIVO 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 12 months from 1 January 2023 to 31 December 2023 compared to the first mandatory reporting year in 2022.

#### Emissions (tCO2e)

	2023	2022
Scope 1 Emissions from combustion of gas	12.6	63.8
Scope 2 Emissions from purchased electricity	78.2	12.9
Scope 3 Emissions from business travel in rental cars or employee vehicles		
where company is responsible for purchasing the fuel	57.3	27.6
Total	148.1	104.3
Other metrics		
Intensity ratio from Scope 1, 2 & 3 (tCO₂e / £10,000 turnover)	0.025	0.021
Intensity ratio: tCO <sub>2</sub> e from Scope 1, 2 and 3 / FTE	0.541	0.497
Total energy used (GWh)	683,378	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

#### 2024 and Beyond

In 2024 we will benefit from Canary Wharf's strong focus on ESG which will help us to reach our goals for improving and enhancing or corporate social responsibility

- Complete implementation of the principles of ISO14001
- Complete implementation of LIMS system to reduce paper waste & drive efficiency
- Seek renewable energy sources where possible and implement energy targets
- Implement process to switch off energy sources when not in use across all sites
- Develop new initiatives to reduce waste generation
- Ensure that any sites producing more than 200kg of hazardous waste in a 12-month period are registered
- Expansion of Cycle to Work scheme to be offered in Breda in addition to the UK

## **Environmental, Social & Governance (ESG)**

Continued

## 6. Commitment to Ethical & Compliant Business Practices

## (Governance)

## **Business Ethics**

At hVIVO, we uphold the highest standards of ethical conduct and transparency across all facets of our operations to reinforce our commitment to business integrity. As a key player in one of the world's most regulated industries, we recognise the paramount importance of adhering to rigorous ethical guidelines.

The Directors recognise the value and the importance of high standards of corporate governance and given the Group's size and constitution of the Board, the Group follows the recommendations outlined in the Corporate Governance Code published by the Quoted Companies Alliance in 2018 (QCA Code). We acknowledge the significance of maintaining a culture of robust corporate governance, reflective of our dedication to ethical business conduct. Please refer to the Corporate Governance statement on page 42.

#### Anti-bribery and corruption

In 2023 we digitised the gift reporting process detailed in our Anti-Corruption and Bribery Policy process to create a simple and effective way to comply with our obligations under anti-bribery laws.

#### Whistleblowing

At hVIVO, we support an open and collaborative working culture, which is core to our values. We are committed to identifying and eliminating all forms of corruption, malpractice or wrongdoing within the workplace and taking appropriate measures to remedy a situation. To ensure our staff can highlight any issues freely, supports our priority to create the right environment for employees and deliver the best quality for our clients.

#### **Human Rights**

The Group is opposed to any form of slavery and human trafficking and conducts its business in line with the UK Modern Slavery Act 2015 and has a Modern Slavery Policy in place which is available on the Group's website: www.hvivo.com

#### **Suppliers**

hVIVO has integrated a number of ESG-focused questions into its standard Quality Assurance Supplier Quality Assessment to evaluate suppliers in areas such as modern slavery, equality, health and safety anti-bribery. Moving forward, the Group aims to expand the scope of these assessments to encompass additional ESG considerations.

#### **Quality and Volunteer Safety**

Our commitment to quality and volunteer safety goes beyond regulatory requirements, as we continuously enhance our quality systems and policies. Under the guidance of our Head of Quality Assurance, we operate within a robust Quality Management System (QMS) bolstered by comprehensive Standard Operating Procedures (SOPs). This ensures the highest standards of quality, safety, regulatory compliance, and ethical conduct throughout our trials. Our 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.

Our engagement with regulatory authorities, ethics committees, and institutional review boards underscores our unwavering dedication to honesty, transparency, and quality. Upholding the principles of Good Clinical Practice (GCP) and adhering to applicable national and international regulations are fundamental tenets of our Clinical Governance Policy and Business Code of Ethics.

All our clinical trials undergo rigorous scrutiny by the Medicines and Health Products Regulatory Agency (MHRA) and/or independent Research Ethics Committees (RECs) to uphold the highest standards of safety and ethics. Prior to submission for approval, our internal experts meticulously assess available data to ensure compliance with regulatory requirements.

The safety of the participants in our clinical trials is our number one concern and our priority in all of our activities. Our trials are meticulously designed with ongoing medical oversight at every stage, as outlined in our Medical Management Policy. Regular training on GCP and data integrity principles ensures our staff's competence in maintaining quality and data integrity throughout the trials. 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.

## **Risk Management**

The Directors continually identify, monitor and manage the risks and uncertainties of the Group. Risk is inherent in all businesses.

The Board has responsibility for the effectiveness of the Group's system of risk management and internal controls. The Group operates a Group-wide Risk Register. This is reviewed by the Board on a quarterly basis. The Executive Directors are responsible for identifying, managing and monitoring risks.

The principal risks are listed on the following pages. The risks are not listed in order of priority, nor do they represent an exhaustive list of all risks affecting the business. The impact and probability ratings are assessed as the residual level taking into account the Group's controls and mitigating actions. These mitigating actions are shown next to each identified risk.

Risk	Description of risk	Probability	Impact	Mitigation
Reliance on regulatory bodies	hVIVO's human challenge trial business relies on approval from regulatory bodies such as the MHRA in the UK. During 2023, we have seen delays in study approvals. In addition, there can be no guarantee that the Group will be able to maintain the necessary regulatory approvals in the territories in which it operates.	Μ	Μ	<ul> <li>Flexible workforce and operational planning of quarantine facilities</li> <li>Further sales and business development</li> <li>Focus on services with low-risk profiles</li> <li>Use of advisers</li> </ul>
Trial quality	hVIVO must ensure high trial quality to remain the leading provider of challenge trials. Loss of trial quality may lead to a loss of competitiveness and therefore a loss of revenue. Loss of quality may also lead to regulatory sanctions.	L	H	<ul> <li>Continued investment in staff training and our Quality Assurance function</li> <li>Conduct of internal audits</li> <li>Review of Standard Operating Procedures</li> </ul>

## Risk Management Continued

Risk	Description of risk	Probability	Impact	Mitigation
Volunteer wellbeing	Volunteer complaints and screening issues could lead to a reduction in the ability to recruit volunteers, regulatory sanctions or financial penalties.	Μ	Μ	<ul> <li>New Volunteer Complaints Procedure in place</li> <li>Ensure complaints are dealt with quickly and actions are taken from complaints. Robust quality systems to manage volunteer data</li> <li>Staff training</li> <li>Maintenance of rigorous reviews of our screening activities to ensure volunteers' wellbeing throughout</li> </ul>
Key personnel loss	hVIVO relies on key personnel to deliver its services and manage the business. Key personnel have on going relationships with customers and suppliers.	М	l	<ul> <li>Market remuneration reviews</li> <li>Avoidance of single person dependencies</li> <li>Succession planning</li> <li>Key relationships are maintained by more than one individual</li> </ul>
Cyber-attacks	In common with all businesses, there is an underlying threat of sophisticated cyber-attacks. This could result in significant reputational, operational and financial damage.	L	H	<ul> <li>hVIVO employs a multi-layered defence strategy against cyber threats:</li> <li>Continuous Threat Monitoring: Vigilant systems detect and respond to potential threats.</li> <li>Advanced Prevention Software: Up-to- date tools block malicious activity.</li> <li>Penetration Testing: Rigorous tests uncover vulnerabilities.</li> <li>User Awareness Training: Employees practise security best practices.</li> <li>Encryption of IT Systems</li> <li>On top of these measures, hVIVO also holds a certificate in Cyber Essentials.</li> <li>Engagement of independent risk consultancy. Penetration testing. User awareness training.</li> </ul>

Risk	Description of risk	Probability	Impact	Mitigation
Data protection breaches	A data breach would damage our reputation and has the potential for regulatory fines.	L	H	<ul> <li>To mitigate the impact of data breaches, we focus on key measures:</li> <li>Enhanced Breach Handling and Consent Withdrawal Processes: Swift and effective response protocols minimise damage.</li> <li>Standard Operating Procedures for Data Handling: Documented procedures ensure consistency and compliance</li> <li>Staff Training: Educating our team on breach prevention and response is crucial.</li> <li>Role-Based Access Controls: Limiting privileges enhances security.</li> <li>Data Loss Prevention: Monitoring of sensitive data movement.</li> <li>Data movement: Restrictions are in</li> </ul>
Lower infectivity rates	As viruses become established in a population and the population builds immunity, the infectivity rates of our challenge agents decrease.	М	M	<ul> <li>place that limit the use of cloud repositories or USB devices attached t laptops.</li> <li>Review infectivity rates in real time</li> <li>Manufacture of newer challenge agents</li> </ul>
Quarantine capacity	Challenge agents decrease. This can impact our ability to conduct challenge studies. Challenge trial revenue is limited by the number of quarantine beds available.		М	<ul> <li>Capacity is being expanded with plans in place for further expansion within the same facility if needed</li> </ul>
				<ul> <li>Maintain relationships with current facilities in case of temporary need</li> </ul>

## Risk Management Continued

Risk	Description of risk	Probability	Impact	Mitigation
Political risk	There is always an underlying risk of political instability in any jurisdiction. Such events have the potential to lead to high rates of inflation, exchange rate volatility, and supply chain disruptions, among other implications.	М	Μ	<ul> <li>Operating in stable jurisdictions</li> <li>Supplier selection</li> <li>Customer monitoring</li> <li>Monitoring macro-economic developments</li> </ul>
Foreign currency risk	The Group has exposure to foreign currencies where supplier or customer payments are made in a currency other than the functional currency of the company using or supplying the goods or services and on balances between subsidiaries in the Group.			<ul> <li>Contracting, where possible, in the functional currency of the entity</li> <li>Use of natural hedging</li> <li>Use of forward contracts where necessary</li> <li>Supplier selection</li> <li>Minimising intercompany balances</li> </ul>
Competition Risk	hVIVO is the world leader in human challenge trails and therefore exposed to competition.	Η	Μ	<ul> <li>Maintain reputation by continuing to provide exceptional service</li> <li>Expansion of new and contemporary challenge models</li> <li>Business diversification into ancillary operations</li> </ul>

### **Financial risk management**

The Group has instigated certain financial risk management policies and procedures which are set out in Note 24 to the financial statements. The Group also reports monthly on the financial KPI listed below and uses non-financial key performance indicators such as measuring staff and quarantine utilisation, staff turnover, quality assurance metrics and pipeline tracking.

## **Key Performance Indicators (KPIs)**

	2023	2022
	£'000	£'000
Revenue	56,043	48,477
EBITDA (before exceptional items)	13,037	9,072
Contracted order book (weighted)	80,000	76,000
Cash	36,973	28,444

The Strategic Report on pages 3 to 38 was approved by the Board on 8 April 2024 and signed on its behalf by:

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**Dr Yamin 'Mo' Khan** CEO 8 April 2024

## **Statement of Directors' Responsibility**

## 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:

- 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 consider the potential long-term consequences of our decisions and take steps to mitigate any risks.
- **The interests of our employees (see page 27, 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 32, 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 44): 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.

## **The Board**



Cathal Friel Non-Executive Chair Independent: No Committees: N/A



## Dr Yamin 'Mo' Khan

#### **Chief Executive Officer** Independent: No Committees: N/A



### Stephen Pinkerton Chief Financial Officer Independent: No Committees: N/A

Cathal Friel is a seasoned serial entrepreneur with a long and successful history and to date has listed five companies on the London Stock Exchange. Cathal serves as Chair and co-founder of hVIVO plc (formerly named Open Orphan plc), where he brings extensive experience in successfully growing public companies, particularly in navigating through M&A transactions.

Cathal is also co-founder and Chairman of Poolbeg Pharma plc, a publicly-listed biopharmaceutical company which was demerged from hVIVO plc in 2021. Cathal also co-founded and sits on the Board of European Green Transition plc, which listed on London Stock Exchange in April 2024. Cathal co-founded Amryt Pharma plc which listed on the London Stock Exchange in 2016 and dual listed on Nasdaq in 2020 and was later sold to Chiesi Farmaceutici for \$1.48 billion in 2023. Prior to that, he was co-founder and Chairman of Fastnet Oil & Gas plc, which listed on the London Stock Exchange in 2011. In 2001, Cathal was part of the team that successfully established Merrion Stockbrokers in Dublin. Following Merrion's trade sale in 2006, he founded Raglan Capital which is renowned for building in-house companies that are listed on the public stock markets. Cathal was a finalist in the international category of the EY Entrepreneur of the Year 2020.

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 is a chartered accountant with over 25 years of experience in a range of leadership positions in industries covering publishing, technology, exhibitions, and clinical research. The roles have covered both small to large international listed businesses, providing strong technical and commercial experience. Prior to joining hVIVO, he worked in Thomson Reuters for eleven years in various senior roles. He did his articles with Deloitte following the completion of an Honours Degree in Bachelor of Commerce and a Bachelor's Degree in Accounting and Finance from the University of Cape Town.



### Dr Elaine Sullivan Non-Executive Director Independent: Yes Committees: Audit & Risk, Remuneration, Nominations



## Prof Brendan Buckley

Non-Executive Director Independent: No Committees: N/A



Martin Gouldstone

Non-Executive Director Independent: Yes Committees: Audit & Risk, Remuneration, Nominations Dr Elaine Sullivan is a Senior pharmaceutical and biotech industry executive with a successful track record in science, investment, business development, and start-ups with over 25 years' experience. She has extensive global leadership experience including membership of the top senior global R&D management teams at Eli Lilly (US) where she held the position of Vice President Global External Research & Development, and she was a member of Lilly Ventures and Lilly Asian Venture steering Committee. At AstraZeneca (UK) she held a number of positions including Vice President R&D, Head of New Opportunities Therapy Area and Vice President, Science & Technology. Former positions also include positions co-founder and CEO of Carrick Therapeutics. Her board appointments include Member of the Supervisory Board of Evotec AG, Non-Executive Director of the IP Group plc, hVIVO plc, Zealand Pharmaceuticals and Nykode Therapeutics ASI where she is also the Chair of the R&D committee. In addition, Elaine is a member of the Scientific Advisory board of Poolbeg Pharma. She was named Ernst Young Emerging Entrepreneur of the Year (Ireland). Elaine holds a BSc (Hons) in Molecular Biology from the University of Glasgow an a PhD in Molecular Virology from the University of Edinburgh.

Prof. Brendan Buckley is a medical graduate of University College Cork and a doctoral graduate of Oxford University . For most of his career he worked in academic clinical practice as a consultant physician. He holds professorial titles in the faculties of Medicine at Universities in Cork and Dublin. 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 became Chief Medical Officer of ICON plc, following their acquisition of Firecrest Clinical Ltd, which he had co-founded. He was a member of ICON plc's Executive Leadership Team and was actively involved in M&A targeting, assessment and diligence. Firecrest was one of a number of companies focused on clinical trial innovation which he co-founded and sold.

Brendan was a non-executive director of the Irish national medicines regulatory authority (now the Health Products Regulatory Authority) between 2004 and 2011. He was a member of the inaugural 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'.

Martin has 30 years of corporate finance and 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 CEO of Oncimmune, an AIM listed Biotech business focused on auto antibody profiling and discovery with operations across Europe and the US. 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.

## **Corporate Governance Statement**

For the year ended 31 December 2023

## Compliance

The Directors recognise the value and the importance of high standards of corporate governance and believe that it creates shareholder value by improving performance, whilst reducing or mitigating risks, as it seeks to create long-term sustainable growth. The Board has applied and strives towards compliance with the recommendations of the Corporate Governance Code, published by the Quoted Companies Alliance.

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 comprises a Non-Executive Chair, two Executive Directors and three Non-Executive Directors.

Cathal Friel, the Non-Executive Chair is responsible for the smooth running and effectiveness of the Board of Directors and for ensuring that the Company meets stakeholder expectations. The Chair is responsible for developing the overall strategy of the Group in conjunction with all Board members and ensures that the Executive Directors oversee its implementation and day-to-day activities through the Senior Management Team, which is accountable for the operational performance of the Group.

The Board has determined that Non-Executive Directors 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. Elaine Sullivan is recognised as Senior Independent Director.

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 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.

## **Board meetings**

11 Board meetings were held during the year. The Directors' attendance record (in their respective roles) during 2023 is as follows:

Cathal Friel (Non-Executive Chair)	10
Yamin 'Mo' Khan (Chief Executive Officer)	7
Stephen Pinkerton (Chief Financial Officer)	9
Elaine Sullivan (Non-Executive Director)	9
Prof. Brendan Buckley (Non-Executive Director)	9
Martin Gouldstone (Non-Executive Director)	10

## 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

In 2022, the Company introduced the ESG Group, a cross-business working team led by Yamin 'Mo' Khan and dedicated to identifying climate change risks and other social governance matters. The ESG Group reports directly into the Audit and Risk Committee half yearly. The Audit and Risk Committee is responsible for reviewing the Company's ESG reporting and recommending it to the Board. Read the full ESG Report on page 23.

The Audit and Risk Committee comprises independent directors Martin Gouldstone as Chair with Elaine Sullivan as the other member of the Committee. The Committee brings to it a wide range of experience and expertise with Martin Gouldstone bringing financial expertise from multiple previous roles including as Head of Lifesciences in the UK for BDO.

The Committee intends to meet at least twice a year, the Chief Financial Officer, and Group Financial Controller normally attend meetings of the Committee while the Chief Executive Officer attends when necessary. The external auditors attend as required and have direct access to the Committee Chair at all times. The Committee found no significant issues in 2023.

### **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, receiving advice from independent compensation and benefits consultants when necessary.

The Remuneration Committee comprises independent directors Elaine Sullivan as Chair with Martin Gouldstone as the other member of the Committee. The Committee intends to meet at least twice a year.

The Remuneration Committee's report for the 2023 financial year is set out on page 45.

### **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 independent directors Elaine Sullivan as Chair with Martin Gouldstone as the other member of the committee. The Committee intends to meet at least twice a year.

# Corporate Governance Statement

## **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.

## 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. The budget is presented to the board annually and approved. Quarterly updates on performance and updated forecast reviewed by the board on a timely 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's focus on investor relations and the growing interest from equity market participants is evidenced by the growing number of equity analysts providing research coverage on the Group. Engaging with the analyst community is a key part of how hVIVO communicates with the capital markets.

The Board views the Annual Report, as well as its Interim Results, as key communication channels through which to update shareholders as to the Group's progress and objectives. 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 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 Chair 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 2023

The Remuneration Committee is responsible for setting the remuneration policy of the Executive Directors, including terms of employment, salaries, any performance bonuses and share option awards.

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, performance related bonuses, benefits and share option incentives.

The Group's remuneration structure has been designed to ensure the alignment of senior leadership with shareholder interests, thereby supporting future value creation. The Committee's aim is that the total remuneration package provides a competitive level of incentive and is appropriate for a company of comparable size and complexity at each level of performance. To this end, the Committee considers appropriate goals from time to time which it believes will best ensure delivery of the Group's short- and long-term objectives and ensure alignment with stakeholder interests.

## **Directors' remuneration**

The remuneration of the Directors serving for the year ended 31 December 2023 is shown below and in Note 7:

	Salary/Fee	Annual Bonus	Pension	Total 2023	Total 2022
	£'000	£'000	£'000	£'000	£'000
Executive Directors:					
Yamin 'Mo' Khan <sup>(1)</sup>	304	283	34	621	499
Stephen Pinkerton <sup>(2)</sup>	176	83	15	274	49
Cathal Friel <sup>(3)</sup>	_	_	_	_	176
Leo Toole <sup>(4)</sup>	_	_	_	_	121
Sub-Total	480	366	49	895	845
Non-Executive Directors:					
Cathal Friel <sup>(3)</sup>	139	69	8	216	28
Brendan Buckley	45	_	_	45	45
Elaine Sullivan	45	_	_	45	47
Martin Gouldstone <sup>(4)</sup>	45	_	_	45	25
Yamin 'Mo' Khan <sup>(1)</sup>	_	_	_	_	46
Sub-Total	274	69	8	351	191
Total	754	435	57	1,246	1,036

(1) Yamin 'Mo' Khan was a Non-Executive Director up to 24 February 2022 when he became the Chief Executive Officer.

(2) Stephen Pinkerton replaced Leo Toole on 18 October 2022 as CFO and Executive Director.

(3) Cathal Friel became a Non-Executive Chair of the Board on 18 October 2022.

(4) Martin Gouldstone joined the Board on 8 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

## Long-term incentives

In order to achieve the objective of aligning senior leadership with shareholder interests, the Company has awarded share options under a Long-Term Incentive Plan (LTIP) to the Executive Directors.

The awards made to Yamin 'Mo' Khan are conditional on three-year total shareholder return (TSR) performance and a service condition. 75% of the award vests based on achievement of the TSR objectives and 25% of the award vests on the service condition.

Details of awards held by Executive Directors under the LTIP schemes are shown below:

	Year of	Number of shares under option at 31 December	Number of awards granted in		Number of shares under option at 31 December	
	grant	2022	the year	Vesting date	2023	Exercise price
Yamin 'Mo' Khan	2022	7,227,273	_	23/02/2025	7,227,273	0.1p
Stephen Pinkerton	2017	67,364	_	20/12/2020	67,364	2р

In February 2024, in connection with his appointment as Chief Financial Officer, Stephen Pinkerton was awarded options of up to 2,433,824 shares under the LTIP scheme. The vesting is conditional upon a three-year total shareholder return (TSR) performance against an initial 17p reference price. The LTIP Options will vest on the third anniversary of the date of award subject to the achievement of a minimum 10% CAGR TSR performance increasing on a straight-line basis to vesting in full subject to the achievement of a 22.5% CAGR TSR performance, with a vesting date of 1 February 2026 and an exercise price of 0.1p.

## **Other transactions with Directors**

For details of other, non-remuneration related transactions with Directors, see note 29 of the financial statements.

## **Report of the Directors**

For the year ended 31 December 2023

The Directors are pleased to submit this report together with the audited financial statements of hVIVO plc for the year ended 31 December 2023.

### Directors

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

Cathal Friel Dr Yamin 'Mo' Khan Stephen Pinkerton Dr Elaine Sullivan Prof. Brendan Buckley Martin Gouldstone

## **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, financial risk management, and future developments are shown in the Strategic Report, Chair'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.

The Group has a cash balance of £37.0m, is cash generative 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.

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 2023 and as at the date of signing of these financial statements, all of which are beneficial, in the Ordinary Share Capital of the Company hVIVO plc of 0.1p each were as follows:

	% holding (8 April 2024 / 31 December	8 April	31 December	1 January
	2023)	2024	2023	2023
Cathal Friel*	3%/7%	21,159,177	47,097,086	47,097,086
Yamin 'Mo' Khan	<1%/<1%	523,730	523,730	510,204
Prof. Brendan Buckley	<1%/1%	4,017,270	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 31 March 2024:

		Percentage	
	Number	of issued	
Shareholder	of shares	share capital	
JPMorgan Asset Management (UK) Limited	47,887,547	7.03%	
Canaccord Genuity Wealth Management	24,783,250	3.64%	
Cathal Friel*	21,159,177	3.11%	
Allan Rankin	20,702,209	3.04%	

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

## Dividend

A final dividend for the year ended 31 December 2023 of £1,361,000 (0.20p per ordinary share) is recommended by the Directors and is to be paid to all ordinary shareholders on the register at the close of business on 19 April 2024 with payment being made on 20 May 2024, subject to shareholder approval at the Annual General Meeting.

## 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.

### **Auditor**

The auditor, Gravita Audit Ltd, is being proposed for reappointment at the forthcoming Annual General Meeting of the Company.

## **Disclosure of information to the Auditor**

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 auditor is unaware, and each Director has taken all the steps that they ought to have taken as Directors in order to make themselves aware of any relevant audit information and to establish that the Group and Company's auditor is 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 8 April 2024 and signed on its behalf by

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Dr Yamin 'Mo' Khan CEO

## **Independent auditor's report**

to the members of hVIVO Plc

## Opinion

We have audited the financial statements of HVIVO Plc (the 'parent company') and its subsidiaries (the 'group') for the year ended 31 December 2023 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 group financial statements is applicable law and United Kingdom adopted International Accounting Standards (IFRS). The financial reporting framework that has been applied in the preparation of the parent company financial statements is applicable law and United Kingdom adopted International Accounting Standards (IFRS), 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 2023 and of the group's profit (parent company'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 director's assessment of the entity's ability 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, 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 intangibles
- Revenue recognition
- 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	Our audit procedures:			
All intangibles are held at cost less impairment.	<ul> <li>we have tested items which were not capitalised as</li> </ul>			
The Group had intangible assets of £5,667,000 (2022: £6,024,000) at 31 December 2023.	additions to intellectual property and checked that the conditions for capitalisation had not been met;			
Of this, £5,601,000 relates to capitalised goodwill recognised on acquisitions and £66,000 relates to software.	<ul> <li>Intangibles are only assessed for impairment when indicators of impairment exist;</li> </ul>			
All the preferred right to reserve a slot and WBS Development were impaired to £Nil as they are not considered usable in existing projects.	<ul> <li>where an impairment test was necessary, we audited management's assumptions and sensitivities;</li> </ul>			
	<ul> <li>we considered whether management had exercised any bias in assumptions used or the outputs produced in the forecasts prepared; and</li> </ul>			
	<ul> <li>we performed an analytical review to compare the profitability of components and discussed the findings with management;</li> </ul>			
	The analysis work undertaken by the directors shows that the Group is expected to remain cash generative for the foreseeable future. We have understood and assessed the methodology used by directors in this analysis and determined it to be reasonable.			

## Independent auditor's report Continued

#### Key audit matter

#### **Revenue recognition**

The amount of revenue recognised by the Group was £56.0m (2022: £48.5m). 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.

#### How our audit addressed the 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.

#### 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.

#### How our audit addressed the key audit matter

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.

## Independent auditor's report Continued

#### Key audit matter

Carrying value of investment in subsidiaries and carrying value of inter-company debtors (Company only risk)

The Company had investments of £22.4m (2022: £22.4m) at 31 December 2023 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.

In the year there was an impairment recorded in respect of inter-company receivables.

#### How our audit addressed the key audit matter

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.

## 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	£587,000 (2022: £484,000)	£262,000 (2022: £92,300)
How we determined it	Based on 1% of revenue (2022: Based on 1% of revenue)	Based on 1% of gross assets (2022: Based on 5% of net profit/loss)
Rationale for benchmark applied	We believe that revenue is a primary measure used by shareholders in assessing the Group's performance. This is considered a standard industry benchmark.	We believe that Gross Assets 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 £19,000 and £504,000.

We set performance materiality at an amount less than materiality for the financial statements as a whole to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds materiality for the financial Statements as a whole. The Performance materiality was set at £440,000 for the Consolidated Group and £197,000 for the Parent company.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £12,000 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.

## Independent auditor's report Continued

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 48, 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. 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:
  - o making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
  - o 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:

## Independent auditor's report Continued

- o agreeing financial statement disclosures to underlying supporting documentation;
- o reading the minutes of meetings of those charged with governance;
- o enquiring of management as to actual and potential litigation and claims; and
- o 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.

Jan Charlesworth (Senior Statutory Auditor)

For and on behalf of Gravita Audit Limited, (Statutory Auditor) Finsgate 5-7 Cranwood Street, London EC1V 9EE

8 April 2024

## **Consolidated Statement of Comprehensive Income**

For the year ended 31 December 2023

		2023	2022
	Note	£'000	£'000
Operations			
Revenue from contracts with customers	4	56,043	48,477
Other operating income	5	2,623	2,220
Direct project and administrative costs	6	(45,629)	(41,625)
EBITDA before exceptional items		13,037	9,072
Depreciation & amortisation	13, 14, 16	(2,716)	(2,930)
Exceptional items	6	(219)	(119)
Operating profit		10,102	6,023
Net finance income	10	1,055	617
Impairment of investment in associate	15	-	(6,957)
Share of loss of associate using equity method		(10)	(48)
Profit/(loss) before income tax		11,147	(365)
Income tax credit/(charge)	11	4,968	(411)
Profit/(loss) for the year		16,115	(776)
Profit/(loss) for the year is attributable to:			
Shareholders		16,115	(776)
Other comprehensive income			
Items that will not be subsequently reclassified to income statement:			
Currency translation differences		(49)	27
Total comprehensive income/(loss) for the year		16,066	(749)
Earnings per share attributable to shareholders during the year:			
Basic earnings per share	12	2.38p	(0.12)p
Diluted earnings per share	12	2.35p	(0.12)p
Adjusted earnings per share attributable to shareholders during the year:			
Basic adjusted earnings per share	12	1.27p	0.96p
Diluted adjusted earnings per share	12	1.25p	0.96p

All activities relate to continuing operations.

The notes on pages 63 to 87 are an integral part of these financial statements.

## **Consolidated and Company Statements of Financial Position**

As at 31 December 2023

	Note	Group 2023 £'000	Group 2022 £'000	Company 2023 £'000	Company 2022 £'000
Assets					
Non-current assets					
Intangible assets	13	5,667	6,023	-	-
Property, plant and equipment	14	6,203	1,513	-	-
Investments in subsidiaries	15	-	-	22,377	22,377
Right of use assets	16	13,835	1,610	-	-
Deferred tax asset	11	5,519	-	-	-
Total non-current assets		31,224	9,146	22,377	22,377
Current assets					
Inventories	17	426	499	-	-
Trade and other receivables	18	14,605	13,291	1,527	11,651
Cash and cash equivalents	19	36,973	28,444	2,281	2,799
Total current assets		52,004	42,234	3,808	14,450
Total assets		83,228	51,380	26,185	36,827
Equity attributable to owners					
Share capital	25	680	671	680	671
Share premium account	26	516	4	516	4
Merger reserves	26	(6,856)	(6,856)	(2,241)	(2,241)
Foreign currency reserves	26	1,309	1,358	2,014	2,014
Retained earnings		38,677	25,041	21,970	36,016
Total equity		34,326	20,218	22,939	36,464
Liabilities					
Non-current liabilities					
Lease liabilities	16	12,163	737	-	-
Leasehold provision	21	1,559	660	-	-
Total non-current liabilities		13,722	1,397	-	-
Current liabilities					
Trade and other payables	20	34,228	28,869	3,246	363
Lease liabilities	16	367	826	-	-
Leasehold provision	21	585	70	-	-
Total current liabilities		35,180	29,765	3,246	363
Total liabilities		48,902	31,162	3,246	363
Total equity and liabilities		83,228	51,380	26,185	36,827

The notes on pages 63 to 87 are an integral part of these financial statements.

The financial statements were approved and authorised for issue by the Board on 8 April 2024.

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 £11,567,000 (2022: loss of £1,362,000).

Mari ble

Yamin Mo Khan – CEO

hVIVO Plc Registered no: 07514939

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

For the year ended 31 December 2023

680	516	(6,856)	1,309	38,677	34,326
9	512	-	-	(2,479)	(1,958)
-	-	-	-	(3,054)	(3,054)
9	512	-	_	-	521
_	-	-	_	575	575
-	-	-	(49)	16,115	16,066
-		-	(49)	-	(49)
-	-	-	_	16,115	16,115
671	4	(6,856)	1,358	25,041	20,218
-	3	-	-	284	287
_	3	-	-	-	3
-	-	-	-	284	284
-	-	-	27	(776)	(749)
-	-	-	27	-	27
-	_	-	_	(776)	(776)
671	1	(6,856)	1,331	25,533	20,680
£'000	£'000	£'000	£'000	£'000	£'000
capital	premium	reserve	reserve	earnings	Total
Share	Share	Merger	currency	Retained	
			Foreign		
	capital £'000 671     671  671             	capital     premium       £'000     £'000       671     1       —     — <td>capital     premium     reserve       £'000     £'000     £'000       671     1     (6,856)       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     3     -       -     3     -       -     3     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -</td> <td>Share         Share         Merger         currency           capital         premium         reserve         reserve           £'000         £'000         £'000           671         1         (6,856)         1,331           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         -           -         -         -         -           -         -         -         -         -           -         -         -         -         -           -         -         -         -         -           -         -         -         -         -</td> <td>Share         Share         Merger         currency         Retained           capital         premium         reserve         reserve         reserve         earnings           £'000         £'000         £'000         £'000         £'000         £'000           671         1         (6,856)         1,331         25,533           -         -         -         (776)           -         -         27         -           -         -         27         (776)           -         -         27         (776)           -         -         27         (776)           -         -         -         284           -         3         -         -           -         3         -         -           -         3         -         -           -         3         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -     </td>	capital     premium     reserve       £'000     £'000     £'000       671     1     (6,856)       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     3     -       -     3     -       -     3     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -     -     -       -	Share         Share         Merger         currency           capital         premium         reserve         reserve           £'000         £'000         £'000           671         1         (6,856)         1,331           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         27           -         -         -         -           -         -         -         -           -         -         -         -         -           -         -         -         -         -           -         -         -         -         -           -         -         -         -         -	Share         Share         Merger         currency         Retained           capital         premium         reserve         reserve         reserve         earnings           £'000         £'000         £'000         £'000         £'000         £'000           671         1         (6,856)         1,331         25,533           -         -         -         (776)           -         -         27         -           -         -         27         (776)           -         -         27         (776)           -         -         27         (776)           -         -         -         284           -         3         -         -           -         3         -         -           -         3         -         -           -         3         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -           -         -         -         -

				Foreign		
	Share	Share	Merger	currency	Retained	
	capital	premium	reserve	reserve	earnings	Total
Company	£'000	£'000	£'000	£'000	£'000	£'000
At 1 January 2022	671	1	(2,241)	2,014	37,094	37,539
Changes in equity for the year ended 31 December 2022						
Loss for the year	-	-	-	_	(1,362)	(1,362)
Share based payments (note 27)	-	-	-	-	284	284
Shares issued (note 25)	-	3	-	-	-	3
Total contributions by and distributions to owners	-	3	-	-	(1,078)	(1,075)
At 31 December 2022	671	4	(2,241)	2,014	36,016	36,464
Changes in equity for the year ended 31 December 2023						
Loss for the year	-	-	-	-	(11,567)	(11,567)
Share based payments (note 27)	-	-	-	-	575	575
Shares issued (note 25)	9	512	-	_	-	521
Dividends paid	-	-	-	-	(3,054)	(3,054)
Total contributions by and distributions to owners	9	512	-	-	(14,046)	(13,525)
At 31 December 2023	680	516	(2,241)	2,014	21,970	22,939
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## **Consolidated and Company's Statement of Cash Flows**

For the year ended 31 December 2023

		Group	Group	Company	Company
		2023	2022	2023	2022
	Note	£'000	£'000	£'000	£'000
Cash generated from/(used in) operations					
Profit/(loss) before income tax		11,147	(365)	(11,565)	(1,311)
Adjustments for:					
<ul> <li>Depreciation &amp; amortisation</li> </ul>	6	2,716	2,930	-	_
<ul> <li>Impairment of intangible assets</li> </ul>	13	254	-	-	-
- Exceptional items		219	119	-	-
<ul> <li>Impairment of associate</li> </ul>		-	6,957	-	_
<ul> <li>Net gain on disposals of PPE</li> </ul>		-	(12)	-	-
– Net finance income	10	(1,055)	(617)	(182)	(834)
<ul> <li>Share based payment charge</li> </ul>	27	575	284	-	-
<ul> <li>– R&amp;D tax credit Included in other income</li> </ul>	5	(2,432)	(1,851)	-	-
<ul> <li>Share of associate loss</li> </ul>		10	48	-	-
<ul> <li>Impairment of intercompany balances</li> </ul>		-	_	10,428	282
<ul> <li>Movement in provisions through P&amp;L</li> </ul>		155	-	-	-
Changes in working capital:					
- (Increase)/decrease in trade and other receivables	5	(1,158)	(4,309)	3,325	(1,135)
- Decrease in inventories		73	172	-	-
<ul> <li>Increase/(decrease) in trade and other payables</li> </ul>		5,187	11,152	15	(2,890)
Net cash generated from/(used in) operations		15,691	14,508	2,021	(5,888)
Income tax (R&D tax credit) received/(paid)		1,548	1,473	(24)	-
Net cash generated from/(used in) operating activi	ties	17,239	15,981	1,997	(5,888)
Cash flow from investing activities					
Purchase of property, plant and equipment		(5,177)	(1,275)	-	_
Purchase of intangible assets		-	(87)	-	_
Net cash used in investing activities		(5,177)	(1,362)	-	-
Cash flow from financing activities					
Lease payments	16	(2,044)	(2,178)	-	_
Dividends paid	28	(3,054)	_	(3,054)	_
Proceeds from issue of shares	25	521	3	521	3
Interest & FX gains received		1,054	635	21	19
Repayment of convertible debenture security		-	(294)	-	_
Net cash (used in)/generated from financing activit	ties	(3,523)	(1,834)	(2,512)	22
Net increase in cash and cash equivalents		8,539	12,785	(515)	(5,866)
Cash and cash equivalents at beginning of year		28,444	15,694	2,799	8,663
FX translation		(10)	(35)	(3)	2
Cash and cash equivalents at end of year	19	36,973	28,444	2,281	2,799

## **Notes to the Financial Statements**

For the year ended 31 December 2023

## 1. Presentation of the financial statements

### **Description of business**

The hVIVO plc Group is a rapidly growing specialist CRO pharmaceutical services group which is the world leader in the testing of vaccines and antivirals using human challenge clinical trials.

hVIVO plc (the "Company") 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 3, 'Critical accounting estimates and judgements'. The preparation of the financial statements in conformity with generally accepted accounting principles requires management to make estimates that affect the reported amounts of assets and liabilities, 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 thousands of pounds sterling ( $\pounds$ '000), unless otherwise indicated.

These financial statements comprise the accounts of hVIVO plc and its subsidiaries (the "Group") for the year ended 31 December 2023. A list of subsidiaries is set out in note 15.

#### Parent company financial statement

The financial statements of the parent company, hVIVO plc, 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. The Company's Statement of Financial Position is presented on page 60 with accompanying notes where applicable on pages 63 to 87.

#### 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 and Company will be able to continue as a going concern for the foreseeable future.

## 2. Summary of significant accounting policies

#### Consolidation

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. 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.

# Notes to the Financial Statements

#### Associates

Investments in associates are accounted for using the equity method of accounting, after initially being recognised at cost less any fair value adjustment.

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.

#### New accounting requirements

Amendments to accounting standards issued by the IASB and adopted in the year ended 31 December 2023 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 2023 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.

#### 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 pounds sterling, 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 (CODM). The CODM have been identified as the Executive Directors and Non-Executive Chair.

Internal management reporting provided to the CODM is on a consolidated basis. Management therefore considers the Group to be one business unit and therefore one reporting segment for disclosure in these financial statements.

#### **Revenue from contracts with customers**

The Group enters into fixed-price and multi-service contracts with customers. Revenue 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.

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 either deferred income or accrued 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 are multi-government backed tax incentives that allows companies to claim back some of the costs they have incurred on research, development and innovation. These are non taxable and involve a high level of management judgement.

#### 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.

All other repairs and maintenance are charged to the Statement of Comprehensive Income during the financial period in which they are incurred.

Depreciation on assets is calculated using the straight-line method to allocate asset cost to its residual value over its estimated economic useful life, as follows:

Leasehold improvements	the expected life of the lease, three to ten years
Plant & machinery	four years
Fixtures & fittings	three to ten years

# Notes to the Financial Statements

The assets' residual values and useful economic lives are reviewed annually, 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 sale proceeds with the carrying amount and are recognised in direct project and administrative costs in the Statement of Comprehensive Income.

#### Intangible assets

#### Goodwill

Goodwill is stated at cost less impairments. Goodwill is deemed to have an indefinite useful life and is tested for impairment annually.

#### Other intangible assets

Intangible assets are stated at cost less provisions for amortisation and impairments.

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.

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 for which the estimates of future cash flows have not been adjusted.

Impairment of goodwill is not reversed. For other intangible assets, where an impairment loss subsequently reverses, the carrying amount of the asset 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.

#### Leases

The Group recognises right of use assets under lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets, which are charged to the Statement of Comprehensive Income as incurred. Right of use assets owned by third parties under lease agreements are capitalised at the inception of the lease and recognised in the Statement of Financial Position. The corresponding liability to the lessor is recognised as a lease liability. The carrying amount is subsequently increased to reflect interest on the lease liability and reduced by lease payments made.

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.

Finance costs are charged to the Statement of Comprehensive Income so as to produce a constant periodic rate of charge on the remaining balance of the lease liabilities for each accounting period.

If modifications or reassessments of lease obligations occur, the lease liability and right of use asset are remeasured.

#### 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, other receivables, accrued income and cash and cash equivalents. The Group's financial assets are measured at amortised cost. 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.

#### **Financial liabilities**

The financial liabilities of the Group consist of trade payables, other payables, , accrued expenses and lease liabilities. The Group's financial liabilities are measured at amortised cost.

#### Fair value hierarchy

Inputs used in determining fair value measurements are categorised into different levels based on how observable the inputs used in the valuation technique utilised are (the 'fair value hierarchy'):

- Level 1: Quoted prices in active markets for identical items.
- Level 2: Observable direct or indirect inputs other than Level 1 inputs.
- Level 3: Unobservable inputs (i.e. not derived from market data).

## Notes to the Financial Statements Continued

The level of fair value hierarchy for the Group's financial assets and liabilities is shown below:

Financial assets:		
Trade receivables	Level 3	
Other receivables	Level 3	
Accrued income	Level 3	
Cash and cash equivalents	Level 1	
Financial liabilities:		
Trade payables	Level 3	
Other payables	Level 3	
Accrued expenses	Level 3	
Lease liabilities	Level 3	

#### 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.

#### 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. Merger reserve is non-distributable.

#### **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 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.

## 3. 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 may 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 subsidiary undertakings and associates as set out in note 15. During 2022, an impairment was recognised in respect of associate company lmutex. No impairments of subsidiaries or associates were recognised in the current year.

#### (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. In the current year, an impairment was recognised in the Company accounts for receivables from subsidiaries that are no longer trading. The impairment will only be reversed if the amounts are later paid.

#### (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 11.

#### (d) Revenue

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.

#### (e) Virus inventory

In valuing virus inventory, management is required to make assumptions in relation to the future commercial use of the inventory, which is primarily for external client revenue engagements. 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.

## Notes to the Financial Statements Continued

#### (f) 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.

#### (g) Leasehold provisions

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. The provision is discounted for the time value of money.

## 4. Segmental analysis

The Directors are responsible for resource allocation and the assessment of performance. In the performance of this role, the Directors review the Group's activities, in the aggregate. The Group has therefore determined that it has only one reportable segment under IFRS 8 Operating Segments, which is 'medical and scientific research services'.

During the year ended 31 December 2023, the Group had two customers who each generated revenue greater than 10% of total revenue (2022: three customers) across multiple projects. These customers generated 34% and 21% of revenue (2022: 12%, 12% and 11% of revenue).

## 5. Other operating income

Other operating income mainly represents research and development tax credits (R&D tax credits) received to fund research and development activities around the Group.

		2023	2022
		£'000	£'000
hVIVO	Gross RDEC Credits	2,267	1,851
Venn	R&D Related Credits	165	213
hVIVO	Recharge of staff to third parties	191	156
		2,623	2,220

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.

# 6. Expenses – analysis by nature

The following items have been included in operating profit:

	2023	2022
	£'000	£'000
Employment Benefit expense (note 8)	20,884	18,081
Share based payments (note 27)	575	284
Other expenses	24,170	23,260
Total direct project and administrative costs	45,629	41,625
Also included within operating profit are the below depreciation and amortisation charges:		
PPE depreciation (note 14) and amortisation (note 13)	827	999
Depreciation related to right of use assets (note 16)	1,889	1,931
Also included within operating profit are exceptional items as shown below:		
	2023	2022
	£'000	£'000
Exceptional items include:		
- Transaction costs relating to business combinations, acquisitions & re-organisations	-	119
- Write off of receivables from associates	219	-
Total exceptional items	219	119

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:

	2023	2022
	£'000	£'000
Fees payable to Company's auditor for the audit of the parent Company and consolidated		
financial statements	53	52
Fees payable to Company's auditor for the audit of subsidiaries and their consolidated		
financial statements	42	37
Total paid to the Company auditor	95	89
Fees payable to the auditors of subsidiaries for services:		
<ul> <li>The audit of Company's subsidiaries pursuant to legislation paid to other auditors</li> </ul>	55	55
- Other services paid to other auditors	-	1
- Tax services paid to other auditors	2	2
Total paid to other auditors	57	58
Total auditors' remuneration	152	147

Continued

# 7. Directors' emoluments

	Group	Group
	2023	2022
	£'000	£'000
Aggregate emoluments	1,189	995
Social security costs	154	119
Contribution to defined contribution pension scheme	57	42
Total directors' remuneration	1,400	1,156

See further disclosures within the Report of the Remuneration Committee.

	Group	Group
	2023	2022
Highest paid director	£'000	£'000
Total emoluments received	587	518
Defined contribution pension scheme	34	27
	621	545

# 8. Staff costs

	Group	Group
	2023	2022
	£'000	£'000
Wages and salaries	17,447	15,077
Social security costs	2,520	2,100
Pension costs	917	904
Employee Benefit expense	20,884	18,081
Share based payments	575	284
	21,459	18,365
	Group	Group
	2023	2022
	£'000	£'000
Average number of people (including Executive Directors) employed was:		
Administration	48	43
Clinical operations	218	161
Sales and marketing	8	6
Total average number of people employed	274	210

# 9. Pensions

The Group operates a number of defined contribution pension schemes whose assets are independently administered. The charge for the year in respect of these defined contribution schemes was £917,000 (2022: £904,000). Contributions of £100,000 were payable to the funds at the year end and are included within trade and other payables (2022: £98,000).

# **10.** Finance income and costs

	2023	2022
	£'000	£'000
Interest expense:		
Interest on lease liabilities	(155)	(133)
Other finance costs	(21)	1
Finance costs	(176)	(132)
Finance income:		
FX gain on sales & expenses	50	613
Interest income on cash and short-term deposits	1,181	136
Finance income	1,231	749
Net finance income	1,055	617

# 11. Taxation

	2023	2022
Group	£'000	£'000
Current tax:		
Research and development tax charge	537	352
Tax in foreign jurisdictions	14	9
Other	-	50
Current tax charge	551	411
Deferred tax:		
Current year	2,588	-
Adjustment in respect of prior years	(8,107)	-
Deferred tax credit	(5,519)	-
Income tax (credit)/charge	(4,968)	411

Continued

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:

	2023	2022
Group	£'000	£'000
Profit/(Loss) before tax	11,147	(365)
Tax calculated at domestic tax rates applicable to UK standard rate of tax of 23.5% (2022: 19%)	2,620	(69)
Tax effects of:		
<ul> <li>Expenses not deductible for tax purposes</li> </ul>	236	1,488
- VLS Germany tax risk on liquidation	-	51
– Current Year R & D Tax (credit)	(190)	(194)
- Temporary timing differences	565	(153)
<ul> <li>Adjustments in respect of prior year</li> </ul>	(8,107)	33
<ul> <li>Additional allowances deductible for tax purposes</li> </ul>	-	125
- Losses carried forward	(92)	(870)
Income tax (credit)/charge	(4,968)	411

The Group has recognised a deferred tax asset for losses carried forward for the first time relating to losses in hVIVO Services Limited. Management only recognises a deferred tax asset when there is evidence that recoverability of the asset is probable, taking into account business forecasts and tax regulations. The Group, and entity in which losses are recognised, has seen underlying profitability for both the current and prior year, and expects to continue to be profit making. Therefore, management considers it appropriate to recognise a deferred tax asset.

Deferred tax assets and liabilities are only offset where there is a legally enforceable right of offset and there is an intention to settle the balances on a net basis.

The reconciliation of the deferred tax asset is shown below:

Group	Tax losses £'000	Right of use assets £'000	Lease liabilities and provisions £'000	Accelerated capital allowances £'000	Total £'000
At 1 January 2022	_	_	-	-	_
Statement of Comprehensive					
Income movement	_	_	-	-	-
At 31 December 2022	_	_	_	-	-
Adjustment in respect of prior years	8,251	_	_	(144)	8,107
Statement of Comprehensive					
Income movement	(2,213)	(2,944)	2,944	(375)	(2,588)
At 31 December 2023	6,038	(2,944)	2,944	(519)	5,519

The current portion of the deferred tax asset cannot be reliably estimated.

# 12. Earnings per share

Basic earnings per share has been calculated by dividing the profit attributable to shareholders by the weighted average number of shares in issue during the year.

	2023	2022
Basic earnings/(loss) per share (p)	2.38p	(0.12)p
Basic adjusted earnings per share (p)	1.27p	0.96p
Diluted earnings/(loss) per share (p)	2.35p	(0.12)p
Diluted adjusted earnings per share (p)	1.25p	0.96p

Diluted earnings per share has been calculated after adjusting the weighted average number of shares used in the basic calculation to assume the conversion of all potentially dilutive shares. A potentially dilutive share is a warrant or option where its exercise price is below the average market price of hVIVO shares during the year and any performance conditions attaching to the scheme have been met at the Statement of Financial Position date. The adjusted profit is used in the calculation of adjusted earnings per share as reconciled below:

Adjusted profit for the year	8,583	6,465
Impairment of investment in associate	-	6,957
Share based payments	575	284
Initial recognition of deferred tax assets	(8,107)	-
Profit/(loss) for the year	16,115	(776)
	£'000	£'000
	2023	2022

The numbers of shares used in calculating basic and diluted earnings per share are reconciled below. Where there is a loss in the year, the share options are deemed to be antidilutive and therefore not included in the calculation.

	2023	2022
Weighted average number of shares in issue	No.	No.
Basic	677,444,133	670,943,918
Dilution for share options and warrants	8,403,182	-
Diluted	685,847,315	670,943,918

Continued

# 13. Intangible assets

Goodwill £'000 7,228 –	Development £'000 2,199	Assets £'000 685	Total £'000
7,228	2,199		
		685	10.112
		685	10 112
_	~ -		10,112
	87	-	87
7,228	2,286	685	10,199
-	-	-	-
7,228	2,286	685	10,199
1,628	2,173	92	3,893
-	19	264	283
1,628	2,192	356	4,176
_	27	75	102
-	-	254	254
1,628	2,219	685	4,532
5,600	26	593	6,219
5,600	94	329	6,023
5,600	67	-	5,667
	7,228 - 7,228 1,628 - 1,628 - 1,628 5,600 5,600	7,228       2,286         -       -         7,228       2,286         1,628       2,173         -       19         1,628       2,192         -       27         -       -         1,628       2,2192         5,600       26         5,600       94	7,228     2,286     685       -     -     -       7,228     2,286     685       1,628     2,173     92       -     19     264       1,628     2,192     356       -     27     75       -     -     254       1,628     2,219     685       5,600     26     593       5,600     94     329

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

	2023	2022
	£'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 2023 was assessed at £5,600,000 (2022: £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 2023 were as follows:

Longer-term growth rate (from 2024 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 had no intangible assets at 31 December 2023 (2022: nil).

# 14. Property plant and equipment

	Leasehold improvements £'000	Plant &	Fixtures &	Total
		improvements Machinery	Fittings	
		£'000	£'000	£'000
Cost				
At 1 January 2022	842	2,507	1,111	4,460
Additions	450	540	286	1,276
Disposals	-	(90)	_	(90)
Exchange differences	-	_	44	44
At 31 December 2022	1,292	2,957	1,441	5,690
Additions	4,808	414	194	5,416
Disposals	-	_	(58)	(58)
Exchange differences	-	(1)	(10)	(11)
At 31 December 2023	6,100	3,370	1,567	11,037
Depreciation				
At 1 January 2022	706	2,141	686	3,533
Charge for the year	333	166	217	716
Elimination on disposal	-	(90)	_	(90)
Exchange differences	-	_	18	18
At 31 December 2022	1,039	2,217	921	4,177
Charge for the year	189	292	244	725
Elimination on disposal	-	_	(58)	(58)
Exchange differences	-	-	(10)	(10)
At 31 December 2023	1,228	2,509	1,097	4,834
Net book value				
At 1 January 2022	136	366	425	927
At 31 December 2022	253	740	520	1,513
At 31 December 2023	4,872	861	470	6,203

The Company had no property plant and equipment at 31 December 2023 (2022: nil).

Continued

# 15. Investments in subsidiaries and associates

	2023	2022
Company	£'000	£'000
Shares in Group undertakings		
At 1 January and 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 (2022: nil) has been made to the investment in subsidiaries.

The subsidiaries of hVIVO plc are as follows:

		Propo	ortion of ordinary
	Country of	S	shares and voting
Name of Company	Registration	Principal activities	rights held (%)
hVIVO Holdings Limited*^	England & Wales	Intermediate holding company	100
hVIVO Services Limited*	England & Wales	Viral challenge and related laboratory services	100
hVIVO Inc.	USA	Sales & marketing services	100
Venn Life Sciences ED B.V^	Netherlands	Pre-clinical & early clinical research services	100
Venn Life Science Biometry Services S.A.S^	France	Data management & statistics services	100
Open Orphan DAC <sup>^</sup>	Ireland	Group services company	100
Venn Life Sciences Limited <sup>^</sup>	Ireland	Dormant	100
Venn Life Sciences (Germany) GmbH^	Germany	In liquidation	100
Venn Life Sciences (France) S.A.S^	France	Dormant	100

\*Registered address Queen Mary Bioenterprises Innovation Centre, 42 New Road, London, E1 2AX ^Directly owned by hVIVO plc

These consolidated financial statements incorporate the financial statements of all entities controlled by the Company at 31 December 2023.

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

			Proportion of ordinary shares held/voting
Name of Company	Country of Registration	Principal activities	rights held (%)
Imutex Limited <sup>(1)</sup>	England & Wales	Clinical development	49/49
PrEP Biopharm Limited <sup>(2)</sup>	England & Wales	In liquidation	62.62/49.98

(1) Carrying value of nil at 31 December 2023 (2022: nil). The registered office address is The Walbrook Building, 25 Walbrook, London, England, EC4N 8AF. The investment was fully impaired in the year ended 31 December 2022.

(2) Carrying value of nil at 31 December 2023 (2022: nil). The registered office address is Unit 2 Spinnaker Court 1c Becketts Place, Hampton Wick, Kingston Upon Thames, KT1 4EQ

# 16. Leases

	Right of use assets		Lease Liabilities	
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
As at 1 January	1,610	2,788	1,563	2,854
New leases acquired	14,149	740	12,890	739
Leases exited	(22)	(8)	(24)	(20)
Depreciation expense	(1,889)	(1,931)	-	_
Interest expense	-	-	155	133
Payments	-	_	(2,044)	(2,178)
Exchange differences	(13)	21	(10)	35
As at 31 December	13,835	1,610	12,530	1,563
Current			367	826
Non-current			12,163	737

# Maturity of lease liabilities:

	31 December	31 December
	2023	2022
	£'000	£'000
Current – Within one year	367	826
Non-current – Between one to two years	2,457	271
Non-current – Between two to five years	9,706	466
	12,530	1,563

Short-term lease payments expensed during the year ended 31 December 2023 were £19,000 (2022: £47,000).

# **17. Inventories**

	Group	Group
	2023	2022
	£'000	£'000
Virus inventory	286	385
Consumables	140	114
Total inventories	426	499

Inventories expensed in the Consolidated Statement of Comprehensive Income are £685,000 (2022: 697,000) and are shown within direct project and administrative costs. No provision against inventories was required during 2023.

Continued

# 18. Trade and other receivables

	Group 2023	Group	Company	Company
		2022	2023	2022
	£'000	£'000	£'000	£'000
Trade receivables	9,117	8,276	-	_
Prepayments	1,405	992	72	346
Accrued income	760	1,505	-	-
Amounts owed by subsidiary undertakings	-	_	1,445	11,280
Other receivables (incl. R&D tax credits)	3,323	2,518	10	25
	14,605	13,291	1,527	11,651

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	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
GBP£	13,167	9,944	90	647
Euro	1,438	2,066	1,437	11,004
USD\$	-	1,281	-	_
Total	14,605	13,291	1,527	11,651

# 19. Cash and cash equivalents

	Group	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
Cash at bank and cash equivalents	36,973	28,444	2,281	2,799

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

# 20. Trade and other payables

	Group	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
Trade payables	2,088	2,701	51	105
Amounts due to subsidiary undertakings	-	_	2,890	_
Social security and other taxes	814	738	28	50
Other payables	525	718	_	_
Accrued expenses	5,857	3,946	277	208
Deferred income	24,944	20,766	-	_
	34,228	28,869	3,246	363

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 any 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.

# 21. Leasehold provision

	2023	2022
	£'000	£'000
As at 1 January	730	_
Additional provisions	1,484	730
Utilisation of provisions	(70)	_
As at 31 December	2,144	730
Current	585	70
Non-Current	1,559	660
	2,144	730

Leasehold provisions relate to dilapidation provisions for the Group's various property leases.

Continued

# 22. Capital commitments

# Group

The Group has net capital commitments of £1,248,000 at 31 December 2023 relating to the new facility build in Canary Wharf (2022: nil).

# Company

The Company has agreed to act as surety to a lease agreement for its subsidiary, hVIVO Services Ltd, No liability has been recognised in the Company Statement of Financial Position.

# 23. Financial instruments

a) Assets

	Group	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
31 December				
Assets				
Trade and other receivables	13,200	11,908	1,455	11,290
Cash and cash equivalents	36,973	28,444	2,281	2,799
Total	50,173	40,352	3,736	14,089

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
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
31 December				
Liabilities				
Lease liabilities (note 16)	12,530	1,563	-	_
Trade and other payables	8,470	7,365	3,218	313
Total	21,000	8,928	3,218	313

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 2023 and 31 December 2022, 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 Company gives careful consideration to which organisations it uses for its banking services in order to minimise credit risk. The Company seeks to limit the level of credit risk on cash and cash equivalents by only depositing surplus liquid funds with counterparty banks that have high credit ratings.

# 24. Financial risk management

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 and capital 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 cooperation 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 pounds sterling (GBP) although it operates internationally and is exposed to foreign exchange risk arising from various currency exposures, primarily between euro, US dollars and 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£	2023	2022	2023	2022
Euro	1.15	1.17	1.15	1.13
USD\$	1.25	1.24	1.27	1.21

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 profit for the year by approximately £21,000 (2022: £24,000).

#### (iii) Cash flow and fair value interest rate risk

The Group has assets in the form of cash and cash equivalents. Where possible, the Group earns market interest rates on cash and cash equivalents on deposit. The Group does not speculate on future changes in interest rates.

The Group does not use interest rate swaps.

# Notes to the Financial Statements Continued

#### (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. 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. The Group manages this credit risk by holding deposits across multiple institutions.

### (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.

The maturity groupings of the Group's non-derivative financial liabilities, namely trade and other payables and lease liabilities, are disclosed in notes 20 and 16 respectively.

#### (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 has no borrowings at 31 December 2023.

# 25. Share capital

	Group	Group	Company	Company
	2023	2022	2023	2022
	£'000	£'000	£'000	£'000
680,371,877 (2022: 671,047,771) Ordinary Shares of £0.001	680	671	680	671

During the year the Company issued 9,324,106 @ £0.056/Share resulting in an increase of £9,000 (2022: nil) to share capital and £512,000 (2022: £3,000) to share premium as a result of share options and warrants being exercised (see note 27).

# 26. Other reserves

# **Group and Company**

# Share premium

Share premium is the difference between the nominal value of shares issued and the actual cash received for the issued shares.

#### 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 foreign currency reserve arises from a one off transition of the Group from a presentational currency of euro to pounds sterling, and from the translation of subsidiaries' results on consolidation which have a functional currency other than pounds sterling.

# 27. 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 under its Long-Term Incentive Plan.

The number of outstanding share options remaining at 31 December 2023, along with the comparative period are as follows:

#### 2023:

Date of issue	Exercise price	Vesting date	# of options at 01/01/2023	# of options exercised	# of options granted	# of options at 31/12/2023
2015	13p	2025	280,000	-	_	280,000
2019	5.6p	2024	7,716,964	(7,716,964)	-	-
2017	2р	2024	277,792	_	-	277,792
2022	0.1p	2025	7,227,273	_	-	7,227,273
			15,502,029	(7,716,964)	_	7,785,065

#### 2022:

Date of issue	Exercise price	Vesting date	# of options at 01/01/2022	# of options exercised	# of options granted	# of options at 31/12/2022
2015	13p	2025	280,000	-	_	280,000
2019	5.6p	2024	7,716,964	-	_	7,716,964
2017	2р	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 0.63p (2022: 3.1p) and the weighted-average remaining contractual life is 1.0 year (2022: 1.8 years).

Share based payment charge for the year was £575,000 included in direct project and administration costs (2022: £284,000). There were no new share options granted during the year. An estimated charge of £148,000, included in the total charge, has been recognised for share options that were granted post-year end where the obligation to issue them existed at the year end.

In the prior year, new share options granted during the year relate to the implementation of a Long-Term Incentive Plan (LTIP). The weighted average fair value of the options at measurement date was 14.74p per option. The Company used the Black Scholes model to value the options. The following key assumptions were factored into the model when valuing these options at the date of grant:

- expected volatility of 74%, based on observable market inputs
- option life of 3 years
- expected dividends yield of 0%
- risk-free interest rate of 3.11%
- a 25% deduction was taken to the fair value to reflect market conditions in the option agreement

### Warrants

The number of outstanding warrants remaining at 31 December 2023, along with the comparative period are as follows:

#### 2023:

			# of warrants at	# of warrants	# of warrants	# of warrants at
Date of issue	Exercise price	Expiry date	01/01/2023	expired	exercised	31/12/2023
11/12/2018	0.1p	10/12/2023	232,696	(232,696)	-	_
11/12/2018	2.2p	10/12/2023	424,589	(424,589)	-	-
28/06/2019	0.1p	27/06/2024	1,607,142	-	(1,607,142)	_
			2,264,427	(657,285)	(1,607,142)	_

20	77	٠
ZU	~~	-

			# of warrants at	# of warrants	# of warrants	# of warrants at
Date of issue	Exercise price	Expiry date	01/01/2022	expired	exercised	31/12/2022
11/12/2018	0.1p	10/12/2023	232,696	_	-	232,696
11/12/2018	2.2p	10/12/2023	424,589	-	-	424,589
28/06/2019	0.1p	27/06/2024	1,607,142	-	-	1,607,142
			2,264,427	_	-	2,264,427

# 28. Dividends

	2023	2022
Equity dividends	£'000	£'000
Special dividend for 2022: 0.45p per ordinary share	3,054	-

A final dividend for the year ended 31 December 2023 of £1,361,000 (0.20p per ordinary share) is recommended by the Directors and is to be paid to all ordinary shareholders on the register at the close of business on 19 April 2024 with payment being made on 20 May 2024, subject to shareholder approval at the Annual General Meeting.

# 29. 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:

	2023	2022
	€′000	€′000
Aggregate emoluments	1,189	994
Employer contribution to pension scheme	57	42
	1,246	1,036

Key management includes the Directors only.

#### **Other transactions with Directors**

In December 2018, Venn Life Sciences Holdings plc completed a £1 million financing from private individuals, including Cathal Friel who participated via his pension fund, the CMF Pension Fund. The financing was completed via the issue of a two-year loan note and as part of their investment, the holders of the loan notes received warrants to purchase shares in the Group with an expiry date in December 2023. Cathal Friel was unable to exercise these warrants prior to their expiry due to his knowledge of insider information for extended periods of time. As such, the Board agreed that the Group would pay 19.95p per warrant share (being the closing price on 8 December 2023, the last trading day prior to the Final Date of the Warrant Instrument) minus the subscription price of £9,573.65 to the CMF Pension Fund for a total of £121,554 in lieu of the unexercised warrants.

#### Group

Non-Executive Group Chair, Cathal Friel, is a Director of Raglan Professional Services Ltd which has provided office related services, charged at cost, to Open Orphan DAC (2023 charge £4,000; 2022 charge £9,000). The balance owed by Open Orphan DAC to Raglan Professional Services Ltd at year end 2023 was £1,000 (2022: £2,000).

There were no other related party transactions during the year.

#### Company

During the year the Company absorbed net management charges of £344,000 (2022: £142,000) from its subsidiaries. At 31 December 2023 the Company was owed £11,874,000 (2022: £11,280,000) by its subsidiaries, and the Company owed £2,890,000 (2022: nil) to its subsidiaries. The Company holds a provision of £10,428,000 against the receivable.

# **Company Information**

#### Directors

Cathal Friel (Non-Executive Chair) Dr 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**

**Beach Secretaries Limited** 

#### **Registered office**

Queen Mary BioEnterprises Innovation Centre 42 New Road London, E1 2AX, UK

# **Head office**

21 Plumbers Row London, E1 1EQ, UK

# **Place of incorporation**

England and Wales (Company number - 07514939)

# Auditor

Gravita Audit Limited Finsgate, 5 - 7 Cranwood Street London, UK

#### Nominated Advisor and Joint Broker

Cavendish Capital Markets Ltd 1 Bartholomew Close London, EC1A 7BL, UK

# Joint Broker

Peel Hunt LLP 100 Liverpool Street London, EC2M 2AT, UK

### **Euronext Growth Advisor and Broker**

Davy Davy House 49 Dawson Street Dublin 2, Ireland

#### Solicitors to the Company

DAC Beachcroft 25 Walbrook London EC4N 8AF, UK

# Registrars

Equiniti Limited Aspect House, Spencer Road, Lancing, West Sussex, BN99 6DA

### Bankers

Natwest 1000 Cathedral Square Cathedral Hill Guildford Surrey, GU2 7YL, UK

# **Public relations**

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#### Website

www.hvivo.com

#### **Ticker: HVO**

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