Open Orphan plc

ANNUAL REPORT
FOR THE YEAR ENDED 31 DECEMBER 2021

OPEN ORPHAN PLC ANNUAL REPORT 2021

Our Vision

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

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For the year ended 31 December 2021

Introduction

I am pleased to report on trading for the year ended 31 December 2021, a period in which we continued our strong momentum. The Group reported substantial revenue growth of 76%, with total revenue (incl. other income) of £39.0m (2020: £22.2m), and more importantly a transition to positive EBITDA of £2.9m (2020: £(6.1)m). 2021 was also a year of considerable operational progress; the Group conducted a record number of human challenge trials and successfully completed the spin-off of Poolbeg Pharma plc, which listed on the London Stock Exchange in July 2021, giving our shareholders a stake in Poolbeg Pharma plc through the distribution in specie shares.

In the two years since we acquired hVIVO, we have transformed the way that it runs human challenge trials by both reducing the time taken to complete a study, from 18 months to six months, and substantially increasing the Company's capacity and capability to run more studies; increasing our total quarantine capacity to 62 beds. In addition, we have focused on expanding the Company's human challenge trials to include non-viral disease indications such as asthma, and by making new challenge models available to our clients, including COVID-19 and malaria.

Furthermore, as a result of the pandemic, hVIVO and the UK received worldwide recognition as a world centre for conducting human challenge trials. This was a direct result of successfully completing the world's first COVID-19 human challenge trial mid-pandemic. The pandemic also highlighted the significant value of human challenge trials which provide human efficacy data in a fraction of the time and cost it would take to complete a normal field trial. As a result of these initiatives, the global market for human challenge trials has increased significantly and as the world leader in the provision of these studies, we expect the business to deliver an increasing number of challenge trials year on year going forward.

Strategic delivery 2021

Below is an outline of the Group's achievements in 2021 across key business revenue streams and market trends.

Human challenge / clinical services

2021 was a record year for hVIVO's core human challenge trial business, with the Company delivering a strong and growing pipeline of challenge study contract wins across our world leading portfolio of human challenge models. The Company is benefitting from a significantly expanded market for infectious and respiratory disease products, with four of the top 10 global biopharma companies working with us in 2021.

In 2021 we successfully collaborated with a client who funded the rapid and cost-efficient conversion of the unoccupied Whitechapel Hotel located immediately beside our existing QMB facility, into the Whitechapel Clinic, a 19-bedroom quarantine clinic. Following the successful delivery of this trial to the client, we continue to operate the Whitechapel Clinic for challenge trials. This expanded our existing quarantine bedroom capacity to 43 (which was subsequently increased post-period end, providing us with access to 62 beds).

We also converted a vacant lot adjacent to the existing QMB facility into a new FluCamp volunteer recruitment screening centre. Similarly, we expanded our FluCamp screening facilities with the opening of new facilities in Manchester. These projects were completed at minimal cost and the expansion enabled us to screen 84,000 volunteers for human challenge studies in 2021.

COVID-19

2021 was a pivotal year for the UK and its attempt to emerge from the COVID-19 pandemic, and I was proud of the significant contribution that our team made to this. As a commitment to help the UK government to fight the pandemic, the team at hVIVO worked tirelessly under difficult conditions in the midst of a pandemic, to deliver a COVID-19 characterisation study to provide unique insights into COVID-19. The results of the study were published in the peer reviewed scientific journal 'Nature Medicine' in February 2022. It is a testament to the hVIVO team and their knowledge and commitment that this study was completed safely and in a timely manner. The study was conducted in partnership with the UK Government's Vaccine Taskforce and Department of Health and Social Care (DHSC), Imperial College London and the Royal Free London NHS Foundation

Trust. Additionally, we were contracted to manufacture a SARS-CoV-2 Delta variant challenge agent with Imperial College London, as part of a Wellcome Trust-funded initiative.

The extensive worldwide coverage we received as part of this work raised Open Orphan's profile as the world leader in conducting human challenge trials and highlighted the significant benefit of these studies to deliver critical human efficacy data.

While effective vaccines and antiviral treatments have lessened the impact of COVID-19 infection in human populations, the lasting legacy of the pandemic is a significantly enlarged infectious and respiratory disease market, which is expected to grow to in excess of $250bn by 2025. The Group is leveraging this significant market growth. With extensive relationships across the industry, a world class reputation, and an ability to continue enhancing and diversifying its offering, the Group is well placed to secure further work as a result of this renewed investment and focus on respiratory diseases.

Board changes

We strengthened our Board with the appointment of Yamin 'Mo' Khan, initially as Non-Executive Director on 13 October 2021 before he was subsequently appointed CEO, post-period end, on 24 February 2022. Mo brings 25 years of CRO experience to his role, and I have thoroughly enjoyed working with him since he joined the Group. Mo has had a significant impact on the business, and we were delighted that he since accepted the position of CEO. Mo brings extensive industry specific insights that we will leverage to deliver on our expanding pipeline of opportunities, and I am confident Mo will continue to drive the Group's upward trajectory.

In July 2021, Professor Brendan Buckley, Non-Executive Director, and myself collectively purchased a further 1,320,754 ordinary shares at 26.5 pence per ordinary share, which increased my shareholding to 7.0% and Brendan's shareholding to 1.2% of the Company's issued ordinary share capital. I hope this demonstrates to our shareholders the Board's commitment to the business and our desire to drive shareholder value to match our considerable financial and operational growth and momentum.

In April 2022, we appointed Liberum Capital Limited as our Nominated Adviser and Joint Broker. We are delighted to be working with Liberum which is ideally placed to introduce Open Orphan's fast growing, profitable and sustainable business to new investors.

Summary

In a pandemic-hit 2021, the Group achieved record revenues, transitioned to making an EBITDA profit, and made significant operational progress. The business conducted a record number of human challenge trials, and has established itself as the world-leading provider of human challenge trials in the rapidly expanding infectious and respiratory disease market. Our work in COVID-19 enabled us to demonstrate our unparalleled expertise to a wider audience, and the market is now clearly recognising the value that human challenge trials can offer.

The business is firmly profitable and remains well capitalised with a cash balance of £15.7m to help drive the business forward and to realise further value for our shareholders. I would like to thank all of our employees for their incredible efforts this year, and our shareholders for their continued support.

Cathal Friel
Executive Chairman

6 June 2022

CEO Statement

For the year ended 31 December 2021

Introduction

2021 has been an exceptional year for Open Orphan with our subsidiary, hVIVO, strengthening its position as the world leader in human challenge trials and our drug consultancy subsidiary, Venn Life Sciences, consolidating its position as a leading provider of integrated clinical development solutions. Since joining Open Orphan, initially as a Non-Executive Director and later transitioning into the role of CEO in Q1 2022, I am excited by the significant opportunity for the Group to capitalise on the substantial increase of investment in respiratory and infectious diseases by global pharmaceutical and biotech companies.

In this time, I have witnessed the substantial demand for hVIVO's human challenge trial models, and our ability to efficiently deliver key human efficacy data to support our clients' clinical development programmes. I am also excited by the growth prospects of Venn Life Sciences, offering a complete end-to-end service to our clients' drug development programmes, from pre-clinical to late phase clinical development.

The exceptional delivery of our services would not be possible without the commitment of the team across the Open Orphan Group. Their dedication and hard work through the challenges of the COVID-19 pandemic was exemplary and their unique knowledge and expertise sets the Group apart from our competitors. I would like to thank them for their excellent contribution to our success in 2021.

Strong financial results

The Group achieved record revenues (incl. other income) in 2021 of £39.0 million, representing a substantial increase of 76% on 2020. A large portion of this revenue is attributable to hVIVO's human challenge trials, which gained global publicity in 2021 as they continued to grow into the mainstream drug development pathway. The Company completed human challenge trials with a number of top 10 Big Pharma and smaller biotechs such as Bavarian Nordic (RSV) and SAB Therapeutics (influenza). The Company also continued to support the UK Government's Vaccine Taskforce resulting in the completion of the world's first COVID-19 challenge study and the manufacture of a SARS-CoV-2 Delta variant challenge agent with Imperial College London. In addition, Venn Life Sciences also performed strongly across its early clinical, non-clinical development, CMC, and biometry services.

The Group was EBITDA positive in 2021, with an EBITDA of £2.9m compared to a £6.1m EBITDA loss in 2020. The Group benefitted from its post-acquisition restructuring plan and a record year of revenue, while also ensuring disciplined cost management in the period. The Group remains well capitalised with cash and cash equivalents of £15.7m as at 31 December 2021. Furthermore, in June 2021, we completed a distribution in specie to the Company's shareholders, through the demerger of certain non-core assets into Poolbeg Pharma.

Customer delivery

Open Orphan has firmly established itself as the world leader in the provision of human challenge trials, offering the largest portfolio of commercial challenge models to a range of clients across Europe, North America and Asia Pacific. The Group serves a wide array of biopharma companies. We worked directly with four of the world's 10 largest biopharma companies in 2021, a number of them as repeat customers. In addition, we also worked with a variety of biotech companies, who tend to have fewer assets and thus place great importance on quickly and efficiently achieving key human efficacy data. hVIVO's challenge trials can provide a fast and cost-efficient route to efficacy data, often resulting in a key value inflection point.

Open Orphan served over 60 clients in 2021 with around 80% year-on-year repeat business. Our goal to become a long-term partner for our clients is now being realised.

The Group achieved significant contract wins in H2 2021 in influenza, RSV and asthma challenge trials. The majority of the revenue relating to these trials will be recognised in 2022, positioning the Group to deliver continued growth into 2022, and beyond.

As hVIVO's challenge studies continue to gain a foothold into the mainstream clinical pathway, a number of our clients achieved notable successes in 2021, which further validates the benefits of human challenge trials. Two of our clients obtained Breakthrough Therapy designation from the US Food and Drug Administration ("FDA") as a consequence of the successful clinical data achieved from hVIVO challenge trials:

- Our successful Phase 2a RSV challenge trial for a Big Pharma client which completed in 2021 enabled them to obtain Breakthrough Therapy designation from the FDA for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age or older
- The FDA granted Breakthrough Therapy designation for Bavarian Nordic's RSV vaccine candidate, MVA-BN® RSV. hVIVO successfully conducted a Phase 2, double-blinded, placebo controlled human challenge trial to assess MVA-BN® RSV using its RSV human challenge study model

Breakthrough Therapy designation can significantly shorten the time to market for recipients, enabling clients to gain a competitive advantage. The receipt of Breakthrough Therapy designation by these high-profile clients has directed further attention to our challenge trials across all indications, leading to numerous new inbound enquiries and enhanced growth of our pipeline.

It should be noted that one of the impacts of the COVID-19 pandemic has been to increase public and industry awareness across all viral pathogens and release R&D funding across a number of indications.

Outlook

As the new CEO of the Group, I am keen to build on the significant milestones the business has achieved in 2021 while also expanding the Group into new challenge models, adding new revenue streams and expanding our facilities. The future looks exceptionally bright across all areas, with evidence of the benefits already coming to fruition.

Challenge Models

The human challenge trial model will remain the core business for the hVIVO team and we will be aggressively marketing our challenge models to new and existing customers in 2022 and beyond. We expect the influenza and RSV models to continue to attract significant interest across the entire market; from smaller biotechs to larger Big Pharma customers. Funding in the development of vaccines and antivirals across the infectious disease space continues to increase as the life sciences industry looks to address the next potential pandemic. The indicators for hVIVO are very positive with huge interest across our portfolio of models and notable challenge trial wins already in 2022; one in influenza and the other in RSV, in addition to our largest ever commercial challenge programme win with an existing top five global pharmaceutical client. This engagement will include the manufacture of an influenza challenge agent, the characterisation study to identify a dose that causes a safe and reliable infection in healthy volunteers and the challenge trial which will help determine the efficacy of a number of different vaccine candidates for the reduction in incidence of symptomatic flu infection and disease severity in healthy volunteers. This contract win helps to re-affirm our position as a "go-to" partner for an increasing number of global biopharma companies.

The HRV-asthma model will also be active in 2022 and beyond as we look to increase our position into the respiratory field, building on the landmark HRV-asthma challenge study signed with a top 3 global pharma company in H2 2021. In addition, we will be establishing a foothold in the anti-parasitic market as we look to establish our newly launched malaria model and target our first study in malaria or a related indication in 2022. The anti-parasitic market is experiencing an increased volume of funding and we are already witnessing the influx of enquiries from potential clients about running a challenge trial.

COVID-19 Challenge Model

hVIVO has already shown its ability to deliver a COVID-19 challenge trial safely and in a timely manner. We have pride in leading the world's first COVID-19 challenge study and helping the UK government in the fight against the pandemic. We have also manufactured a challenge agent of the Delta variant and are working with world leading institutions to continue to research the SARS-CoV-2 virus. Our aim is to conduct further COVID-19 challenge trials in the near future. A COVID-19 challenge trial can quickly provide the crucial human efficacy data required to confirm early proof of concept.

Capacity Growth

To support Open Orphan's rapid growth and consolidate its world

Executive CEO Statement
Continued

leading position, we have expanded our facilities including increasing our screening capacity and our number of beds. In March 2022, our London FluCamp recruitment operation moved to a new low cost 12 bed facility. This enabled us to double the Group's previous volunteer screening capacity, while significantly boosting our ability to identify and enrol study volunteers to deliver the significant volume of trials to be completed in 2022 and beyond. We also opened a new Manchester volunteer screening facility at the same cost as the old facility to increase volunteer numbers from the North-West region.

The increased capacity will ensure the Group maintains its world leading position through its volunteer recruitment arm, FluCamp.

New Revenue Streams

The increased scale of our volunteer recruitment screening facilities will allow us to broaden our offering to deliver new revenue streams, namely using the existing FluCamp infrastructure in London as a site for Phase 2 and Phase 3 field studies. The initial target will be to recruit healthy volunteers into field-based vaccines trials. We will target a range of current and new clients, leveraging FluCamp's existing infrastructure to deliver research site services. This should act as a natural follow-on to a number of our clients who have completed Phase 2a challenge studies.

2022 is shaping up to be a breakthrough year for hVIVO's highly specialised virology and immunology laboratory team, expanding its portfolio of customers to help grow the Group's business. We plan to receive CAP and IOS 17025 (UKAS) accreditation for our laboratories in 2022. This should lead to further opportunities for our world class laboratory teams to deliver virology and immunology services to a range of clients.

Venn Life Sciences

Our Venn Life Science subsidiary continues to deliver specialist drug development consultancy services across non-clinical and clinical development, pharmacology, CMC and biometry services. Venn Life Sciences is a trusted partner to an extensive range of clients, and our highly skilled scientific team have helped nurture a number of long-term client relationships. We are experiencing continued demand across our comprehensive suite of services and we expect Venn Life Sciences to continue its upward trajectory in new areas, notably in advanced therapy medicinal products (ATMPs) and consulting advice for medical device companies.

Order book and pipeline

As at 31 December 2021, Open Orphan had an order book of signed contracts worth £46m (2020: £41.6m). This order book will be recognised across 2022, 2023 and 2024. Additional new project wins in 2022 have further enhanced our order book including a landmark £14.7m contract for an influenza challenge trial that includes the characterisation and completion of a challenge trial for an existing top five global pharma customer, a £7.3m influenza challenge trial and a £5m RSV challenge trial. This has seen our order book has expanded to £64.2m by 1 June 2022.

Open Orphan's pipeline of new opportunities continues to grow with a number of further challenge study opportunities at advanced negotiations across influenza, asthma, RSV, malaria and COVID-19. This growth is driven by the increased success and awareness of human challenge trials, and the development of new challenge models. A significant portion of our pipeline includes returning Big Pharma customers, in addition to a wider group of new clients who have observed the benefits of human challenge trials.

These developments reaffirm the management's expectations of revenues in the region of £50m in 2022, with the Group now delivering strong sustainable long-term profitability.

Summary

I am very satisfied with the strong performance of our business across the twelve months to 2021 as the Group became EBITDA profitable. We will build on this performance into 2022 and have set challenging and achievable growth plans across all areas of the business. We believe the operational infrastructure is in place to deliver on the exceptional contracted order book and pipeline of opportunities the business has, and we can already see the strategy coming to fruition. Our strategy is to continue to enhance and diversify our core and non-core offering, solidifying our world leading position in order to capitalise on the increased demand for human challenge trials and the growth in the infectious and respiratory disease market. We believe this will deliver growth on our revenue and EBITDA for our shareholders, continuously improve our employee satisfaction and ensure an efficient operational delivery to our customers.

As a Board, we are confident that we can deliver on our growth plans for 2022 and beyond as we continue to focus on the execution of our strategy to generate value for our shareholders.

Yamin 'Mo' Khan
CEO

6 June 2022

The Board

Cathal Friel, Executive Chairman (aged 57)

Cathal Friel is a successful entrepreneur, whom started working at the age of 16 due to his father's untimely illness. He went on to complete his education by taking night classes, receiving an MBA from the University of Ulster in 1990. Cathal then spent the following five years lecturing International Marketing and Business Planning at the University of Ulster on a part-time basis while running his own technology services business. In 2001, Cathal was part of the team who successfully established Merrion Stockbrokers in Dublin and in 2007 he founded Raglan Capital.

Cathal is the Chairman and co-founder of Open Orphan plc which successfully IPO'd on the London and Dublin stock exchanges in June 2019. He is also Chairman of Poolbeg Pharma plc which listed on the London Stock Exchange in July 2021. In 2015, he co-founded Amryt Pharma plc, along with Joe Wiley, which listed on the London Stock Exchange in 2016 and which has been listed on Nasdaq since July 2020. Prior to Amryt, Cathal founded Fastnet Oil & Gas plc in 2011 which he IPO'd on the London Stock Exchange. Cathal was a finalist in the International category of the EY Entrepreneur of the Year 2020.

Dr. Yamin 'Mo' Khan, Chief Executive Officer (aged 52)

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.

Leo Toole, Chief Financial Officer (aged 49)

Leo Toole brings over 20 years' experience in senior finance roles in Pharmaceuticals, Medical Technology and FMCG sectors. Through positions in multinational companies across Europe and in the venture capital space in the UK and Ireland, he has extensive experience in building finance teams, corporate development, equity and debt financing, public markets, and mergers and acquisitions. Leo is a Business graduate of Trinity College Dublin, Ireland and HEC Liège, Belgium. He also holds an MBA with Distinction from INSEAD in France and Singapore.

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

Professor Brendan Buckley is a medical graduate of University College Cork and a doctoral graduate in Biochemistry of Oxford University. Brendan has over 30 years' experience in clinical research. He is one of the founders of Open Orphan as well as being Adjunct Professor at University College Dublin. Brendan is the Chief Medical Officer at Teckro. He was the Chief Medical Officer of ICON plc until 2017. In 2009, Brendan co-founded Firecrest Clinical Ltd, a company which focussed on improving the performance of clinical trial sites. Brendan was a Director of the Health Products Regulatory Authority of Ireland between 2004 and 2011. He was also a member of the EMA's Committee for Orphan Medicinal Products (COMP) from 2000-2003 and the EMA's Scientific Advisory Committee on Diabetes and Metabolism until 2011.

Dr. Elaine Sullivan, Non-Executive Director (aged 61)

Elaine is a business leader and senior scientist with over 25 years' international experience in the pharmaceutical and biotech industries. Elaine is currently the CEO of Keltic Pharma Therapeutics. Elaine has an in-depth background and knowledge of virology having received a PhD from the University of Edinburgh in Molecular Virology. She has been a member of senior R&D management teams in Lilly and AstraZeneca. Elaine also has extensive start-up experience as CEO and co-founder of Curadh Pharmaceuticals and co-founder and former CEO of Carrick Therapeutics, where she helped to raise over $95m of funding. Elaine is a Non-Executive Director of IP Group plc, Active Biotech AB Nykode Therapeutics, where she is also chair of their R & D committee. She is also member of the Supervisory Board at Evotec AG.

Strategic Report

For the year ended 31 December 2021

Review of the business

A comprehensive review of the year is given in the Chairman's Statement on page 2 and CEO's Statement on page 4. The directors' duty under section 172 of the Companies Act 2006 is outlined in the Directors Report on page 14.

Principal risks and uncertainties

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

Management and employees

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

Political risk

The Group operates in politically stable jurisdictions. Nevertheless, it is possible that political or economic events in other jurisdictions could cause disruption to its operations. The Group seeks to reduce risk by carefully assessing the clients it works with and sub-contractors or suppliers that support its operations. Pricing is monitored regularly as part of the Group's bid process to ensure that inflationary pressure in the Group's cost base are reflected in its sales contracts.

Regulatory risk

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

Competition risk

The Group's current and future potential competitors include, amongst others, major international CROs and drug development consultancy companies with substantially greater resources than those of the Group. There can be no assurance that competitors will not succeed in developing services that are more effective or economic than any of those developed by the Group. The Group seeks to reduce this risk by ensuring that a professional and better standard of service is provided to its partners.

Effect of foreign currency

The Group in general does not hedge the foreign currency risk arising from sales by an operation denominated in a currency other than its functional currency. The Group has limited foreign currency exposure by contracting its sales as much as possible in the functional currency of the jurisdictions where it operates. The cost base of operations in these jurisdictions is predominantly in the functional currency of those jurisdictions. In the limited cases where the Group has foreign currency exposure on receipts in a particular currency, it seeks to match the payment of any expenses in this currency to mitigate this risk.

Covid-19 outbreak

The Group continues to closely monitor the Covid-19 outbreak. Our primary focus remains the safety of our employees and the Group implemented government policies in relation to the outbreak. These included travel restrictions for staff. These risks were mitigated using technology that allowed staff to work from home effectively. However, in light of the significant adoption rates of vaccinations in the countries where we operate, our businesses are operating in line with our pre-pandemic practices. We nevertheless are engaging with our staff and clients to assess how we alter our work and travel polices to best meet the needs of all stakeholders in a post pandemic world.

Financial risk management

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

Future outlook

The CEO's Statement on page 4 gives information on the future outlook of the Group.

Key Performance Indicators (KPIs)

The key performance indicators currently used by the Group are revenue, EBITDA (before exceptional items) and cash. (See page 2-7). The Company also uses non-financial key performance indicators such as measuring order backlog, new business win rates and staff utilisation.

Review of strategy and business model

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

As noted in the CEO's Statement, we continue to invest in new challenge models including asthma, malaria and COVID-19 as we seek to capitalise on the significant growth in funding for infectious and respiratory disease post-pandemic. Our 62-bed quarantine facilities in the UK reaffirm our position as the world leader in the delivery of human challenge trials.

The Group is focussed on delivering on its significant order backlog, continuing to grow its pipeline of new opportunities and to develop new revenue streams.

Environment

The Directors consider that the nature of the Group's activities is not inherently detrimental to the environment.

Employees

The Group places value on the involvement of its employees and they are regularly briefed on the Group's activities. The Group closely monitors staff attrition rates which it seeks to maintain at current low levels and aims to structure staff compensation levels at competitive rates in order to attract and retain high calibre personnel.

Disabled employees

Applications for employment by disabled persons are always fully considered, bearing in mind the specific aptitudes of the applicant involved. It is the policy of the Group that the training, career development and promotion of disabled persons, as far as possible, be identical with that of other employees.

Social, community, and human rights

The Board recognises that the Group has a duty to be a good corporate citizen and to respect the laws, and where appropriate the customs and culture of the territories in which it operates. It contributes as far as is practicable to the local communities in which it operates and takes a responsible and positive approach to employment practices.

The Strategic Report was approved by the Board on 6 June 2022 and signed on its behalf by:

Cathal Friel
Executive Chairman

Report of the Directors

For the year ended 31 December 2021

The Directors are pleased to submit this report together with the audited financial statements of Open Orphan Plc for the year ended 31 December 2021.

Directors

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

Prof. Brendan Buckley

Cathal Friel

Michael Meade (Resigned 12 October 2021)

Leo Toole

Dr Elaine Sullivan

Yamin 'Mo' Khan (Appointed 12 October 2021)

Principal activities

The principal activity of the Group is that of a rapidly growing specialist CRO pharmaceutical services company which is the world leader in the testing of vaccines and antivirals using human challenge clinical trials. The Group has a presence in the UK, Ireland, France and Netherlands.

Specific information, including key risks and future developments, have not been included in the Directors' Report because they are shown in the Strategic Report, Chairman's Statement and CEO Statement as permitted by section 414C (11) of the Companies Act.

Dividends

There were no cash dividends paid or proposed by the Company in either year. See note 39 for details of Distribution-in-Specie in June 2021.

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 should be able to operate within the level of its current financing position. For more detail refer to note 2.

After making enquiries, 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 2021 and as at the date of signing of these financial statements, all of which are beneficial, in the share capital of the Company Open Orphan plc were as follows:

	% Holding of Ordinary Shares of 0.1p each	On 31 December 2021 Ordinary Shares of 0.1p each	On 1 January 2021 Ordinary Shares of 0.1p each
Cathal Friel*	7%	**47,087,086**	**45,965,011**
Prof. Brendan Buckley	1%	**8,034,539**	**7,845,860**

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

Substantial shareholdings

As at 31 May 2022, the following interests of 3% or more in the issued Ordinary Share capital appear in the share register of the Company:

Share register	Number of Shares	Percentage of issued share capital
HARGREAVES LANSDOWN /NOMINEES/ LIMITED	56,256,061	8.38%
DAVYCREST NOMINEES	49,139,800	7.32%
HARGREAVES LANSDOWN /NOMINEES/ LIMITED	40,859,796	6.09%
INTERACTIVE INVESTOR SERVICES NOMINEES LIMITED	30,611,419	4.56%
INTERACTIVE INVESTOR SERVICES NOMINEES LIMITED	28,290,618	4.22%
HARGREAVES LANSDOWN /NOMINEES/ LIMITED	25,737,080	3.84%
BARCLAYS DIRECT INVESTING NOMINEES LIMITED	23,215,149	3.46%
RAGLAN ROAD CAPITAL LIMITED*	21,536,124	3.21%

*Company controlled by Director Cathal Friel – See also Director's Interests on page 12 for full shareholding of Cathal Friel

Events after the end of the reporting period

The following events have taken place since the year end:

a) Yamin 'Mo' Khan, a non-Executive Director, was appointed as Chief Executive Officer on 24 February 2022.

b) Appointment of Liberum Capital Limited as Nominated Advisor ("NOMAD") and Joint Broker on 28 April 2022.

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.

Report of the Directors

Continued

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

Auditors

Jeffreys Henry LLP have expressed their willingness to continue in office as auditors and a resolution to reappoint them will be proposed at the forthcoming Annual General Meeting.

Disclosure of information to the Auditors

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

Annual General Meeting

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

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 likely consequences of any decision in the long term. The Group's outlook is set out in the CEO's Report on page 4 with associated risks highlighted in the Strategic report on Page 10.
- the interests of the Group's employees. Our employees are fundamental to us achieving our long-term strategic objectives.
- the impact of the Group's operations on the community and the environment. The Group operates honestly and transparently. We consider the impact on the environment on our day-to-day operations and how we can minimise this.
- the desirability of the Group maintaining a reputation for high standards of business conduct. Our intention is to behave in a responsible manner, operating within the high standard of business conduct and good corporate governance, as highlighted in the Corporate Governance Statement on page 16.
- the obligation to act in the interests of all shareholders of the Group. Our intention is to behave responsibly towards our shareholders and treat them fairly and equally so that they may benefit from the successful delivery of our strategic objectives.

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 6 June 2022 and signed on its behalf by

Cathal Friel
Executive Chairman

Corporate Governance Statement

For the year ended 31 December 2021

Compliance

The Directors recognise the value of the principles of the UK Corporate Governance Code (the Code). Although, as an AIM company, compliance with the UK Corporate Governance Code is not required, the Directors acknowledge that compliance with a recognised code is mandatory under the AIM rules. In this respect, the Directors have targeted to be compliant with the Code to the greatest extent possible, given the size and nature of the Group.

The following statement describes how the Group seeks to address the principles underlying the Code where practicable and appropriate for a company of this size.

Board composition and responsibility

The Board currently comprises an Executive Chairman, two Executive Directors and two Non-executive Directors. The Board notes that the UK Corporate Governance Code recommends that at least half the Board should comprise independent Non-Executive Directors. The Board has determined that Elaine Sullivan is an independent in character and judgement and that there are no relationships or circumstances which could materially affect or interfere with the exercise of her independent judgement. Prior to his appointment as CEO of the Company in February 2022, Yamin 'Mo' Khan was an independent Non-Executive Director. As such, the Board intends to include an additional Independent Non-Executive Director in the near future. The Board is satisfied with the balance between Executive and Non-Executive Directors which allows it to exercise objectivity in decision making and proper control of the Group's business. The Board considers this composition is appropriate in view of the size and requirements of the Group's business and the need to maintain a practical balance between Executives and Non-Executives.

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

The Board's primary objective is to focus on adding value to the assets of the Group by identifying and assessing business opportunities and ensuring that potential risks are identified, monitored and controlled. Matters reserved for Board decisions include strategic long-term objectives and capital structure of major transactions. The Executive Chairman is responsible for the overall strategy of the Group and oversees its implementation through the Senior Management Team (CEO, CFO, COO, Head of HR and other Senior Leaders), which is accountable for the operational performance of the Group.

Board meetings

19 Board meetings were held during the year. The Directors' attendance record (in their respective roles) during 2021 is as follows:

Cathal Friel (Executive Chairman)	19	
Leo Toole (Chief Financial Officer)	19	
Prof. Brendan Buckley (Non-Executive Director)	18	
Michael Meade (Non-Executive Director - Resigned 12 October 2021)	12	(of a possible 17)
Elaine Sullivan (Non-Executive Director)	11	
Yamin 'Mo' Khan (Chief Executive Officer - Appointed 12 October 2021)	1	(of a possible 2)

Audit and Risk Committee

The Audit and Risk Committee comprises Elaine Sullivan as Chair, with Brendan Buckley and Yamin 'Mo' Khan as the other member of the committee. The principal duties of the committee are to review the 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; and
- Ensure appropriate 'whistle-blowing' arrangements are in place.

The Chairman may seek information from any employee of the Group and obtain external professional advice at the expense of the Company if considered necessary. Due to the relatively low number of personnel employed within the Group, the nature of the business and the current control and review systems in place, the Board has decided not to establish a separate internal audit department.

Remuneration Committee

The Company 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.

This committee comprises Brendan Buckley as Chairman with Elaine Sullivan as the other member of the committee. 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 intends to meet at least twice a year.

Board appointments

The Nomination Committee comprises Elaine Sullivan as Chair with Brendan Buckley as the other member of the committee. It identifies and nominates for the approval of the Board, candidates to fill Board vacancies as and when they arise. The Nomination Committee intends to meet at least twice a year.

Internal control

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

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

Corporate Governance Statement

Continued

Internal financial reporting

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

Relations with shareholders

The Company reports to shareholders twice a year. The Company 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 Chairman of the Audit and Remuneration Committees normally attend the Annual General Meeting and will answer questions which may be relevant to their work. The Chairman advises the meeting of the details of proxy votes cast on each of the individual resolutions after they have been voted on in the meeting.

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

Corporate social responsibility

The Board recognises that it has a duty to be a good corporate citizen and is conscious that its business processes minimise harm to the environment, contributes as far as is practicable to the local communities in which it operates and takes a responsible and positive approach to employment practices.

Report of the Remuneration Committee

For the year ended 31 December 2021

Statement of compliance

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

Policy on Executive Directors' remuneration

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

Directors' remuneration

The remuneration of the Directors serving for the year ended 31 December 2021 is shown below and in note 9:

	Salary/Fee £'000	Annual Bonus £'000	Pension £'000	Total 2021 £'000	Total 2020 £'000
Executive Directors:					
Cathal Friel	138	34	–	172	178
Leo Toole	138	34	17	189	163
Former Directors (resigned in 2020)	–	–	–	–	105
Sub-Total	**276**	**68**	**17**	**361**	**446**
Non-Executive Directors:					
Brendan Buckley	45	–	–	45	45
Michael Meade	50	–	–	50	57
Elaine Sullivan	30	–	–	30	3
Yamin 'Mo' Khan[(1)]	57	–	–	57	–
Former Directors (resigned in 2020)	–	–	–	–	45
Sub-Total	**182**	**–**	**–**	**182**	**150**
Total	**458**	**68**	**17**	**543**	**596**

(1) Yamin 'Mo' Khan was a Non-Executive Director during 2021. He became an Executive Director in February 2022.

Directors' share options and warrants

As at 31 December 2021 no options had been granted to Directors.

657,285 warrants are legally held by Cathal Friel CMF Pension Fund. These warrants were issued on 11/12/2018 in connection with the 2018 Open Orphan Plc Loan Note and expire on 10/12/2023 and have an exercise price of 0.1/2.2 p.

Independent auditor’s report

to the members of Open Orphan Plc

Opinion

We have audited the financial statements of Open Orphan Plc (the ‘parent company’) and its subsidiaries (the ‘group’) for the year ended 31 December 2021 which comprise the consolidated statement of comprehensive income, the consolidated and company statements of financial position, the consolidated and company statements of cash flows, the consolidated and company statements of changes in equity and notes to the financial statements, including a summary of significant accounting policies.

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

In our opinion:

- the financial statements give a true and fair view of the state of the group’s and of the parent company’s affairs as at 31 December 2021 and of the group’s loss for the year then ended;
- the group financial statements have been properly prepared in accordance with United Kingdom adopted International Accounting Standards;
- the parent company financial statements have been properly prepared in accordance with United Kingdom adopted International Accounting Standards and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006;

Basis for opinion

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

Conclusions related to going concern

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

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the Group's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

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

These are explained in more detail below.

Key audit matter	How our audit addressed the key audit matter
Carrying value of intangibles All intangibles are being held at cost less impairment. The Group had intangible assets of £6,219,000 (2020: £6,127,000) at 31 December 2021. Of this, £5,600,000 relates to capitalised goodwill recognised on acquisitions and £618,000 relates to software, preferred right to reserve a slot and WBS Development. There have been no impairments in the year.	Our audit procedures: • we have tested items which were not capitalised as additions to intellectual property and checked that the conditions for capitalisation had not been met; • Intangibles are only assessed for impairment when indicators of impairment exist; • where an impairment test was necessary, we audited management's assumptions and sensitivities; • we considered whether management had exercised any bias in assumptions used or the outputs produced in the forecasts prepared; • we performed an analytical review to compare the profitability of components and discussed the findings with management; and The analysis work undertaken by the directors shows that the Group is expected to become cash generative. We have understood and assessed the methodology used by directors in this analysis and determined it to be reasonable.

Independent auditor's report

Continued

Key audit matter	How our audit addressed the key audit matter
Revenue recognition The amount of revenue recognised by the Group was £36,864,000 (2020: £20,602,000). The Group recognises revenue from clinical trial services provided to customers, incrementally as work is performed, using service milestones noted in the contracts and percentage of completion of contract when recognising revenue over time. The percentage of completion is determined using level of work completed to date in respect of each individual milestones assigned to the clinical services contract. The milestones are measured using metrics assigned to the individual contracts. These metrics determines how the progress of each milestone can be measured. This requires management to estimate both the allocation of revenue to milestones in the contract at contract inception date, and the percentage of completion of each milestone at each reporting date. Contract assets and liabilities have been reviewed by the board in detail including each contract with all major customers and revenue has been recognised in accordance with IFRS 15. We identified a risk of inaccurate or incomplete recognition of revenue due to the incorrect allocation of milestones to service contracts and percentages of completion in calculating revenue and cost of sales. The assumptions and judgements made in estimating the percentage of completion require a significant degree of management judgement and are susceptible to management override and represent a fraud risk. We therefore determined this to be a key audit matter.	Our audit approach: • assessed the appropriateness of the Group's revenue recognition accounting policies; • reviewed a sample of contracts with customers and tested that the Group has correctly accounted for the revenue arising from these contracts in accordance with the accounting policies and reviewed management's judgement on the contract price and the allocation to performance obligations; • performed detailed testing on individually significant contracts, including substantiating a sample of transactions with underlying documents such as contracts, progress metrics data, internal forecasts and project completion reports, as well as discussions with project managers; • we checked a sample of time sheets and supporting information which were used to calculate the postings to the revenue account; • we reviewed the calculation of revenue to be accrued and tested a sample of items for the hours and rates applied from the time sheet system and agreed contract rates to the amount posted in the nominal ledger; • where appropriate we considered the remaining amount of accrued revenue which still required to be invoiced including calculations of that revenue and considered the recoverability of a sample of balances; • we performed a walk-through of the process followed and related controls with regard to the recognition of revenue; and • evaluated whether revenue has been appropriately presented and disclosed in the financial statements. Based on the audit work performed, we are satisfied that management have appropriately accounted for revenue in line with their accounting policy and in accordance with the requirements of IFRS 15. We are also satisfied that all necessary disclosures have been made in the consolidated financial statements.

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

Independent auditor’s report

Continued

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

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

Independent auditor’s report

Continued

Key audit matter	How our audit addressed the key audit matter
Carrying value of investment in subsidiaries and carrying value of inter-company debtors (Company only risk) The Company had investments of £22,377,000 (2020: £22,334,000) at 31 December 2021 relating exclusively to the investments in subsidiary undertakings. We identified a risk that the investment of the parent company (Open Orphan plc) in its subsidiaries and amounts receivable, may be impaired. Management’s assessment of the recoverable amount of investments in subsidiaries requires estimation and judgement around assumptions used, including the cash flows to be generated from continuing operations. Changes to assumptions could lead to material changes in the estimated recoverable amount, impacting the value of investment in the subsidiary and impairment charges.	We have performed the following audit procedures: • reviewed management’s assessment of future operating cashflows and indicators of impairment; • assessed the methodology used by management to estimate the future profitability of its subsidiaries and recoverable value of the investments, in conjunction with any intra-group balances, to ensure that the method used is appropriate; • assessed the reasonableness of the key assumptions used in management’s estimates of recoverable value, in line with the economic and industry statistics relevant to the business; • challenged cash inflows from revenue generating activities and the key assumptions applied in arriving at these, including the milestones achieved in research programmes; the number and monetary value of clinical studies in the foreseeable future, and the market share of studies in key areas of disease focus; • assessed the reasonability of cash outflows, including contracted delivery costs, and research and capital spend; • assessed the appropriateness and applicability of discount rate applied to the current business performance; • confirmed that any adverse change in key assumptions would not materially increase the impairment loss; • considered the appropriateness of the Parent Company’s disclosures in relation to any impairment in the Company only financial statements; and • ensured that disclosures of the key judgements and assumptions, and sensitivity of the impairment loss recognised was appropriately disclosed. Based on the audit work performed we are satisfied that the management have accounted for the impairment loss appropriately and in accordance with accounting standards, and the impairment loss is appropriately disclosed in the Parent Company financial statements.

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	£390,000	£220,000
How we determined it	Based on 1% of revenue.	Based on 1% of revenue.
Rationale for benchmark applied	We believe that revenues are a primary measure used by shareholders in assessing the Group's performance. This is considered a standard industry benchmark.	We believe that revenues are a primary measure used by shareholders in assessing the Group's performance. 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 £20,000 and £302,000.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £4,000 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 9 reporting units, comprising the Group's operating businesses and holding companies.

We performed audits of the complete financial information of Open Orphan Plc, hVIVO 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 9 reporting units.

The Group engagement team performed all audit procedures, with the exception of the audit of Venn Life Sciences Limited, Venn Life Sciences (France) SAS, 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.

Independent auditor's report

Continued

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 13, 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:
  - making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
  - considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

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

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

Independent auditor's report

Continued

- 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.

Other matters which we are required to address

We were appointed by the shareholders of the Company on 2 October 2019 to audit the financial statements for the period ending 31 December 2019. This is the third year we are auditing the Group, however we had been engaged for the audits of the Venn Life Sciences Holdings PLC (the target of the reverse in the previous year) for 8 years, where our total uninterrupted period of engagement was 8 years, covering the periods ending 31 December 2011 to 31 December 2018.

The non-audit services prohibited by the FRC's Ethical Standard were not provided to the group or the parent company and we remain independent of the group and the parent company in conducting our audit. Further services were provided to the Group as disclosed in note 8 of the accounts.

Our audit opinion is consistent with the additional report to the audit committee.

Use of this report

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

Sudhir Rawal (Senior Statutory Auditor)

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

6 June 2022

Consolidated Statement of Comprehensive Income

For the year ended 31 December 2021

	Notes	Year to 31 December 2021 £'000	Year to 31 December 2020 Restated £'000
Operations			
Revenue, from contracts with customers	5,35	**36,864**	20,602
Other operating income	33	**2,141**	1,576
Direct project and administrative costs	6	**(36,117)**	(28,260)
EBITDA before exceptional items		**2,888**	(6,082)
Depreciation & amortisation	6,16,17,37	**(2,565)**	(2,052)
Exceptional items	7	**267**	(2,125)
Operating profit/(loss)		**590**	(10,259)
Finance expense	12	**(215)**	(374)
Share based payment charge	32	**(27)**	(240)
Share of loss of associate using equity method	18b	**(71)**	(107)
Profit/(Loss) before income tax		**277**	(10,980)
Income tax (charge)/credit	13	**(351)**	189
(Loss) for the year		**(74)**	(10,791)
(Loss) for the year is attributable to:			
Owners of the parent		**(74)**	(10,791)
Other comprehensive income			
Currency translation differences		**(111)**	318
Total comprehensive (loss) for the year		**(185)**	(10,473)
Earnings per share from operations attributable to owners of the parent during the year			
Basic and diluted (loss) per ordinary share			
From operations	14	**(0.01p)**	(1.80p)
For the year		**(0.01p)**	(1.80p)

All activities relate to continuing operations.

The notes on pages 35 to 74 are an integral part of these consolidated financial statements.

Consolidated and Company's Statement of Financial Position

As at 31 December 2021

	Notes	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
Assets					
Non-current assets					
Intangible assets	17	**6,219**	6,127	**–**	–
Property, plant and equipment	16	**927**	1,068	**–**	–
Investment in associates	18b	**7,005**	7,076	**–**	–
Investments in subsidiaries	18a	**–**	–	**22,377**	22,334
Right of use asset	37	**2,788**	4,230	**–**	–
Total non-current assets		**16,939**	18,501	**22,377**	22,334
Current assets					
Inventories	20	**659**	953	**–**	–
Trade and other receivables	21	**8,944**	9,806	**9,701**	10,960
Current tax recoverable		**38**	80	**–**	–
Cash and cash equivalents	22	**15,694**	19,205	**8,663**	8,689
Total current assets		**25,335**	30,044	**18,364**	19,649
Total assets		**42,274**	48,545	**40,741**	41,983
Equity attributable to owners					
Share capital	26	**671**	731	**671**	731
Share premium account	27	**1**	44,480	**1**	44,480
Merger reserves	27	**(6,856)**	(6,856)	**(2,241)**	(2,241)
Foreign currency reserves	27	**1,331**	1,442	**2,014**	2,573
Share option reserve	27/32	**327**	493	**327**	493
Retained earnings	27	**25,206**	(17,993)	**36,767**	(4,983)
Total equity		**20,680**	22,297	**37,539**	41,053
Liabilities					
Non-current liabilities					
Trade and other payables	23	**–**	2	**–**	–
Lease liabilities	37	**863**	2,194	**–**	–
Leasehold provision		**40**	20	**–**	–
Total non-current liabilities		**903**	2,216	**–**	**–**
Current liabilities					
Trade and other payables	23	**18,396**	21,396	**3,202**	885
Deferred taxation	24	**–**	32	**–**	–
Lease liabilities	37	**1,991**	2,245	**–**	–
Leasehold provision		**10**			
Borrowings	25	**294**	359	**–**	45
Total current liabilities		**20,691**	24,032	**3,202**	930
Total liabilities		**21,594**	26,248	**3,202**	930
Total equity and liabilities		**42,274**	48,545	**40,741**	41,983

The notes on pages 35 to 74 are an integral part of these financial statements.

The financial statements were approved and authorised for issue by the Board on 6 June 2022

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the parent Company income statement account. The loss for the parent Company for the year was £1,522,000 (2020: loss of £1,891,000).

Cathal Friel - Executive Chairman

Open Orphan Plc
Registered no: 07514939

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

Group	Share capital £'000	Share premium £'000	Merger reserve £'000	Share Option reserve £'000	Foreign currency reserve £'000	Retained earnings £'000	Total £'000
At 1 January 2020	–	–	–	–	–	(1,463)	(1,463)
Changes in equity for the Year ended 31 Dec 2020							
(Loss) for the year	–	–	–	–		(10,791)	(10,791)
Currency differences	–	–	–	–	318	–	318
Total comprehensive (loss) for the year	–	–	–	–	318	(10,791)	(10,473)
Transactions with the owners							
Share based payment res.	–	–	–	240	–	–	240
Shares issued	414	29,266	–	–	–	–	29,680
Total contributions by and distributions to owners	414	29,266	–	240	–	–	29,920
At 31 December 2020	731	44,480	(6,856)	493	1,442	(17,993)	22,297
Changes in equity for the Year ended 31 Dec 2021							
(Loss) for the year	**–**	**–**	**–**	**–**		**(74)**	**(74)**
Currency differences	**–**	**–**	**–**	**–**	**(111)**	**–**	**(111)**
Total comprehensive (loss) for the year	**–**	**–**	**–**	**–**	**(111)**	**(74)**	**(185)**
Transactions with the owners							
Share based payment res.	**–**	**–**	**–**	**(166)**	**–**	**193**	**27**
Shares issued	**3**	**37**	**–**	**–**	**–**	**–**	**40**
Capital reduction	**(63)**	**(44,516)**				**44,579**	**–**
Distribution in specie (note 39)	**–**	**–**	**–**	**–**	**–**	**(1,500)**	**(1,500)**
Total contributions by and distributions to owners	**(60)**	**(44,479)**	**–**	**(166)**	**–**	**43,272**	**(1,433)**
At 31 December 2021	**671**	**1**	**(6,856)**	**327**	**1,331**	**25,206**	**20,680**

Company	Share capital £'000	Share premium £'000	Share option reserve £'000	Merger reserve £'000	Foreign currency reserve £'000	Retained earnings £'000	Total £'000
At 1 January 2020	–	–	–	–	–	(1,463)	(1,463)
Changes in equity for the year ended 31 December 2020							
Total comprehensive loss for year	–	–	–	–	–	(1,891)	(1,891)
Share based payment res.	–	–	240	–	–	–	240
Currency differences	–	–	–	–	1,488	–	1,488
Shares issued	414	29,266	–	–	–	–	29,680
Total contributions by and distributions to owners	414	29,266	240	–	1,488	(1,891)	29,517
At 31 December 2020	731	44,480	493	(2,241)	2,573	(4,983)	41,053
Changes in equity for the year ended 31 December 2021							
Total comprehensive loss for year	**–**	**–**	**–**	**–**	**–**	**(1,522)**	**(1,522)**
Share based payment res.	**–**	**–**	**(166)**	**–**	**–**	**193**	**27**
Currency differences	**–**	**–**	**–**	**–**	**(559)**	**–**	**(559)**
Shares issued	**3**	**37**	**–**	**–**	**–**	**–**	**40**
Capital reduction	**(63)**	**(44,516)**				**44,579**	**–**
Distribution in specie (note 39)	**–**	**–**	**–**	**–**	**–**	**(1,500)**	**(1,500)**
Total contributions by and distributions to owners	**(60)**	**(44,479)**	**(166)**	**–**	**(559)**	**41,750**	**(3,514)**
At 31 December 2021	**671**	**1**	**327**	**(2,241)**	**2,014**	**36,767**	**37,539**

Consolidated and Company's Statement of Cash Flows

For the year ended 31 December 2021

	Notes	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
Cash Flow from operating activities					
Continuing operations					
Cash used in operations	28	**(2,868)**	2,540	**680**	(6,568)
Income tax (R & D) received		**1,304**	1,631	**–**	–
Net cash used in operating activities		**(1,564)**	4,171	**680**	(6,568)
Cash flow from investing activities					
Cash acquired with acquisition of subsidiary		**–**	2,276	**–**	–
Investment in new subsidiary		**–**	–	**(43)**	–
Purchase of property, plant and equipment		**(329)**	(818)	**–**	–
Purchase of intangible asset		**(410)**	(274)	**–**	–
Net cash used in investing activities		**(739)**	1,184	**(43)**	–
Cash flow from financing activities					
Proceeds from issuance of ordinary shares & options	26	**40**	18,031	**40**	18,031
Costs of January and May 2020 fund raising		**–**	(1,335)	**–**	(1,335)
Exceptional Costs re RTO, Spin-out & restructuring	7	**(1,169)**	(2,108)	**(409)**	(867)
Repayment of Invoice Discounting		**–**	(156)	**–**	–
Interest (Paid)		**(21)**	(188)	**–**	(152)
Stamp Duty re capital reduction	39	**–**	–	**(7)**	
Loan Note Redemptions		**(45)**	(1,205)	**(45)**	(1,205)
Net cash generated by financing activities		**(1,195)**	13,039	**(421)**	14,472
Net increase in cash and cash equivalents		**(3,498)**	18,394	**216**	7,904
Cash and cash equivalents at beginning of year		**19,205**	1,037	**8,689**	421
FX translation		**(13)**	(226)	**(242)**	364
Cash and cash equivalents at end of year	22	**15,694**	19,205	**8,663**	8,689

Notes to the Financial Statements

For the year ended 31 December 2021

1. General information

Open Orphan Plc is a company incorporated in England and Wales. The Company is a public limited company, limited by shares, listed on the AIM market of the London Stock Exchange and on Euronext Growth in Dublin. The address of the registered office is Queen Mary Bio Enterprises, Innovation Centre, 42 New Road, London, E1 2AX, UK.

The principal activity of the Group is that of a rapidly growing specialist CRO pharmaceutical services company which is the world leader in the testing of vaccines and antivirals using human challenge clinical trials. The Group has a presence in the UK, Ireland, France and Netherlands.

The financial statements are presented in GBP£'000 (except where indicated otherwise), the currency of the primary economic environment in which the Group's trading companies operate. The Group comprises Open Orphan Plc and its subsidiary companies as set out in note 18. The Board decided to change the presentation currency of the Group from Euro (€) to pounds Sterling (£) in 2020 given the increased weighting of the UK operations on the financial statements as a result of the merger between Open Orphan plc and hVIVO plc in January 2020.

The registered number of the Company is 07514939.

2. Summary of significant accounting policies

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. The policies have been consistently applied throughout the year, unless otherwise stated.

Basis of preparation

Open Orphan Plc (formerly Venn Life Sciences Holdings Plc) completed an IPO on the London AIM Exchange and the Dublin Euronext exchange on 28 June 2019 through a reverse acquisition of Open Orphan DAC, an Irish Company, into Venn Life Sciences Holdings Plc (Venn), a UK company. Based on the accounting standards under IFRS 3 and IFRS 10, the Group has determined that the entity with control of the combined group after the combination is Open Orphan DAC. It was therefore determined that reverse acquisition accounting is to be applied for presentation of the financial statements of the Group. This means that results reported for 2019 reflected those of Open Orphan DAC for the full 12-month period and for Venn Life Sciences group Plc group from 01 July 2019 to year end 2019. The percentage of the enlarged share capital represented by the consideration shares issued to Open Orphan DAC on the reverse takeover was 40.1% which represented a fair value consideration of £5.7m.

Open Orphan Plc completed, on 17 January 2020, an acquisition of the hVIVO group. The results reported for 2020 reflected those of Open Orphan Plc and Venn Group for the full 12-month period and for hVIVO group from 17 January 2020 to year end 2020. The percentage of the enlarged share capital represented by the consideration shares issued to hVIVO group on the acquisition takeover was 33.1% which represented a fair value consideration of £12.96m.

The Balance Sheet reported for 2021 reflect those of the now fully combined group with share capital reflecting the position of the ultimate parent company Open Orphan Plc.

For information purposes, a pro forma statement of Comprehensive Income for the prior year 2020 for Open Orphan Plc on a stand-alone basis is presented in the chairman's statement to allow a comparison of a normalized presentation of Comprehensive Income for the Group during the years 2021 and 2020.

The consolidated financial statements of Open Orphan Plc have been prepared in accordance with UK adopted international accounting standards (IFRSs), IFRIC interpretations and the Companies Act 2006 applicable to companies reporting under IFRS. These are the first financial statements prepared under UK adopted international accounting standards. On 31 December 2020, IFRS as adopted by the European Union at that date was brought into UK law and became UK adopted international accounting standards, with future changes being subject to endorsement by the UK Endorsement Board. Open Orphan Plc transitioned to UK-adopted International Accounting Standards in its consolidated

Notes to the Financial Statements

Continued

and parent company financial statements on 1 January 2021. This change constitutes a change in accounting framework. However, there is no change on recognition, measurement or disclosure in the financial year reported as a result of the change in framework.

The consolidated financial statements have been prepared under the historical cost convention.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 4.

Changes in accounting policies and disclosures

The accounting policies adopted are consistent with those of the previous financial year. Standards and amendments to IFRS effective as of 1 January 2021 have been applied by the Group, where applicable.

Summary of new accounting policies

Standards, amendments and interpretations effective and adopted in 2021

Several amendments and interpretations apply for the first time in 2021.

Standard or Interpretation	Title	Effective for annual periods beginning on or after
IFRS 16	COVID-19-Related Rent Concessions (Amendment to IFRS 16)	1 June 2020
IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform – Phase 2 (Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16)	1 January 2021

Standards, amendments and interpretations issued and effective in 2021 but not relevant

There are no IFRSs or IFRIC interpretations that are effective and not relevant to the Group.

Standards, amendments and interpretations issued but not yet effective in 2021

There were a number of standards and interpretations which were in issue at 31 December 2021 but not effective for periods commencing 1 January 2021 and have not been adopted for these financial statements. The Directors have assessed the full impact of these accounting changes on the Company. To the extent that they may be applicable, the Directors have concluded that none of these pronouncements will cause material adjustments to the Group's financial statements. They may result in consequential changes to the accounting policies and other note disclosures. The new standards will not be early adopted by the Group and will be incorporated in the preparation of the Group financial statements from the effective dates noted below.

Standard or Interpretation	Title	Effective for annual periods beginning on or after
IFRS 16	COVID-19-Related Rent Concessions beyond 30 June 2021. (Amendment to IFRS 16)	1 April 2021
IAS 37	Onerous Contracts – Cost of Fulfilling a Contract. (Amendments to IAS 37)	1 January 2022
IAS 16	Property, Plant and Equipment: Proceeds before Intended Use. (Amendments to IAS 16)	1 January 2022
IFRS	Annual Improvements to IFRS Standards 2018–2020	1 January 2022

Standard or Interpretation	Title	Effective for annual periods beginning on or after
IFRS 3	Reference to the Conceptual Framework. (Amendments to IFRS 3)	1 January 2022
IAS 1	Classification of Liabilities as Current or Non-current. (Amendments to IAS 1)	1 January 2023
IFRS 17	IFRS 17 Insurance Contracts and amendments to IFRS 17 Insurance Contracts.	1 January 2023
IAS 1	Disclosure of Accounting Policies. (Amendments to IAS 1 and IFRS Practice Statement 2)	1 January 2023
IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction. (Amendments to IAS 12)	1 January 2023
IAS 8	Definition of Accounting Estimates. (Amendments to IAS 8)	1 January 2023

There are no other IFRSs or IFRIC interpretations that are not yet effective that would be expected to have a material impact on the Group.

Going concern

The Directors have prepared the financial statements on a going concern basis. During the financial year ended 31 December 2021 the Group made a loss of £0.07m and had net cash outflows of £3.5m. However the Directors consider the use of the going concern basis to be appropriate given the significant cash reserves of £15.7m at year end, the level of new contracts signed in 2021, which will generate revenue in 2022 and beyond and the level of new contracts signed in the post period end to date (See CEO's statement). The Directors have prepared working capital projections which show that the Group & Company will be able to continue as a going concern.

Basis of consolidation

The consolidated financial statements incorporate the financial statements of the Company and its subsidiary undertakings. Subsidiaries are all entities over which the Group has the power to govern their financial and operating policies generally accompanying a shareholding of more than fifty per cent of the voting rights. The existence and effect of potential voting rights that are currently exercisable or convertible are considered when assessing whether the Group controls another entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

Inter-Company transactions, balances and unrealised gains on transactions between Group companies are eliminated. Unrealised losses are also eliminated. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Associates are all entities over which the group has significant influence but not control, generally accompanying a shareholding of between 20% and 50% of the voting rights. Investments in associates are accounted for using the equity method of accounting. Under the equity method, the investment is initially recognised at cost, and the carrying amount is increased or decreased to recognise the group's share of the profit or loss of the associate after the date of acquisition.

The group's share of post-acquisition profit or loss is recognised in the income statement.

Notes to the Financial Statements

Continued

(a) Accounting for business combinations

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

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

Investments in subsidiaries are accounted for at cost less impairment. Cost is adjusted to reflect changes in consideration arising from contingent consideration amendments. The acquisition of the hVIVO group in January 2020 was accounted for using principles of acquisition accounting.

(b) Associates

Associates are all entities over which the group has significant influence but not control or joint control as defined under IAS28. This is generally the case where the group holds between 20% and 50% of the voting rights. Investments in associates are accounted for using the equity method of accounting (see equity method below), after initially being recognised at cost less any fair value adjustment.

Equity Method:

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

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

Accounting policies of equity accounted investees have been changed where necessary to ensure consistency with the policies adopted by the group. The carrying amount of equity-accounted investments is tested for impairment in accordance with the policy described in page 35.

(c) Group re-organisation

The Group re-organisation of common control transaction is scoped out under IFRS 3. The results of the Group and all of its subsidiary undertakings affected by the group re-organisation are accounted using the merger accounting method. The method of accounting for such business combination is treated to take place before the transition of IFRS. The investment is recorded at the nominal value of the shares issued, together with the fair value of any additional consideration paid.

Merged subsidiary undertakings are treated as if they had always been a member of the Group. This treatment is permitted under the exemption in IFRS 1 to not restate acquisitions before transition.

The corresponding figures for the previous period include its results for that period, the assets and liabilities at the previous balance sheet date and the shares issued by the company as consideration as if they had always been in issue. Any difference between the nominal value of the shares acquired by the Company and those issued by the company to acquire them is taken to reserves as re-organisation reserve.

(d) Reverse acquisition accounting

The acquisition of Venn Life Sciences Holdings Plc (renamed Open Orphan Plc) and its subsidiaries by Open Orphan DAC on 27 June 2019 has been accounted using the principles of reverse acquisition accounting. Although the Group financial statements have been prepared in the name of the legal parent, Open Orphan Plc, they are in substance a continuation of the consolidated financial statements of the legal subsidiary, Open Orphan DAC. The following accounting treatment has been applied in respect of the reverse accounting:

The assets and liabilities of the legal subsidiary, Open Orphan DAC, are recognised and measured in the Group financial statements at the pre-combination carrying amounts, without restatement of fair value. The retained earnings and other equity balances recognised in the Group financial statements reflect the retained earnings and other equity balances of Open Orphan DAC immediately before the business combination and the results of the period from 1 January 2019 to the date of the business combination are those of Open Orphan DAC. However, the equity structure appearing in the Group financial statements reflects the equity structure of the legal parent, Open Orphan Plc (formerly Venn Life Sciences Holdings Plc), including the equity instruments issued in order to affect the business combination.

Foreign currency translation

(a) Functional and presentation currency

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

(b) Transactions and balances

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 income statement within 'administrative expenses', except when deferred in other comprehensive income as qualifying cash flow hedges and qualifying net investment hedges.

(c) Group companies

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 for each balance sheet presented are translated at the closing rate at the date of that balance sheet;
- income and expenses for each income statement 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 income statement 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.

Notes to the Financial Statements
Continued

Segmental reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-makers (“CODM”), who are is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Executive Directors who make strategic decisions.

Property, plant and equipment

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

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

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

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

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

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

Gains and losses on the disposal of assets are determined by comparing the proceeds with the carrying amount and are recognised in administration expenses in the income statement.

Intangible assets

(a) Goodwill

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

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

(b) Trade secrets

Trade secrets, including technical know-how, operating procedures, contact network, methods and processes, acquired in a business combination are recognised at fair value at the acquisition date. Trade secrets have a finite useful life and are carried at cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the cost of trade secrets over their estimated useful lives of 10 years and is charged to administrative expenses in the income statement.

(c) Intellectual property rights

Intellectual property rights relate to patents acquired by the Group. Amortisation is calculated using the straight-line method over the expected life of 10 years and is charged to administrative expenses in the income statement.

(d) Capitalised Software development, Licences, Preferential right to reserve a slot and wearables development

Internally generated intangible assets involving research and development expenditure.

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

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

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

Impairment of non-financial assets

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

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

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

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

Financial instruments

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

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Financial assets

The financial assets of the group consist of trade receivables, accrued income, cash and other receivables.

Initial recognition and measurement

Financial assets are classified, at initial recognition, and subsequently measured at amortised cost, fair value through other comprehensive income (OCI), and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient, the Group initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15. Refer to the accounting policies in note 35 Revenue from contracts with customers.

In order for a financial asset to be classified and measured at amortised cost or fair value through OCI, it needs to give rise to cash flows that are 'solely payments of principal and interest (SPPI)' on the principal amount outstanding. This assessment is referred to as the SPPI test and is performed at an instrument level.

The Group's business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both.

Purchases or sales of financial assets that require delivery of assets within a time frame established by regulation or convention in the marketplace (regular way trades) are recognised on the trade date, i.e., the date that the Group commits to purchase or sell the asset.

Subsequent measurement

For purposes of subsequent measurement, financial assets are classified in four categories:

- Financial assets at amortised cost (debt instruments)
- Financial assets at fair value through OCI with recycling of cumulative gains and losses (debt instruments)
- Financial assets designated at fair value through OCI with no recycling of cumulative gains and losses upon derecognition (equity instruments)
- Financial assets at fair value through profit or loss

However, only financial assets at amortised cost are discussed as all the Group's financial assets are measured at amortised cost, with the exception of investments in subsidiaries and associates which are held at cost less impairment.

Financial assets at amortised cost (debt instruments)

This category is the most relevant to the Group. The Group measures financial assets at amortised cost if both of the following conditions are met:

- The financial asset is held within a business model with the objective to hold financial assets in order to collect contractual cash flows, and
- The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding

Financial assets at amortised cost are subsequently measured using the effective interest (EIR) method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired.

The Group's financial assets at amortised cost comprise of trade and other receivables and cash and cash equivalents.

Derecognition

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group's consolidated statement of financial position) when:

- The rights to receive cash flows from the asset have expired, OR
- The Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset

When the Group has transferred its rights to receive cash flows from an asset or has entered into a passthrough arrangement, it evaluates if, and to what extent, it has retained the risks and rewards of ownership. When it has neither transferred nor retained substantially all of the risks and rewards of the asset, nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of its continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

Impairment provisions for current and non-current trade receivables are recognised based on the simplified approach within IFRS 9 using a provision matrix in the determination of the lifetime expected credit losses. During this process the probability of the non-payment of the trade receivables is assessed. This probability is then multiplied by the amount of the expected loss arising from default to determine the lifetime expected credit loss for the trade receivables. For trade receivables, which are reported net, such provisions are recorded in a separate provision account with the loss being recognised in the consolidated statement of comprehensive income. On confirmation that the trade receivable will not be collectable, the gross carrying value of the asset is written off against the associated provision.

From time to time, the Group elects to renegotiate the terms of trade receivables due from customers with which it has previously had a good trading history. Such renegotiations will lead to changes in the timing of payments rather than changes to the amounts owed and, in consequence, the new expected cash flows are discounted at the original effective interest rate and any resulting difference to the carrying value is recognised in the consolidated statement of comprehensive income (operating profit).

Financial liabilities

The financial liabilities of the group consist of trade payables, accrued expenses, lease liabilities, borrowings, social security and other taxes payable.

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate.

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All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade and other payables and loans and borrowings.

Subsequent measurement

Loans and borrowings

This is the category most relevant to the Group. After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortised cost using the EIR method. Gains and losses are recognised in profit or loss when the liabilities are derecognised as well as through the EIR amortisation process. Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortisation is included as finance costs in the statement of profit or loss. This category generally applies to interest-bearing loans and borrowings. For more information, refer to note 25.

Derecognition

A financial liability is derecognised when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognised in the statement of profit or loss.

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.

Inventories comprise completed manufactured grade viruses, work in process in relation to the manufacture of viruses, and laboratory and clinical consumables. The cost of virus inventory is calculated using the weighted average cost method for each individual strain, with cost including direct materials and, where applicable, direct labour costs and an attributable portion of production overheads that have been incurred in bringing the inventories to their present location and condition. Adjustments are made for any inventories where net realisable value is lower than cost, or which are considered to be obsolete. Any inventories which management considers are not usable on future commercial engagements are provided against in the statement of comprehensive income.

Trade and other receivables

Trade receivables are initially recognised at fair value, being the original invoice amount, and subsequently measured at amortised cost less provision for impairment. A provision for impairment is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of the receivable. Trade receivables that are less than three months past due date are not considered impaired unless there are specific financial or commercial reasons that lead management to conclude that the customer will default. Older debts are considered to be impaired unless there is sufficient evidence to the contrary that they will be settled. The amount of the provision is the difference between the asset's carrying value and the present value of the estimated future cash flows. The carrying amount of the asset is reduced through the use of an allowance account, and the amount of the loss is recognised in the income statement within administrative expenses. When a trade receivable is uncollectible it is written off against the allowance account. Subsequent recoveries of amounts previously written off are credited against administrative expenses in the income statement.

Trade payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Accounts payable are classified as current liabilities if payment is due within one year or less (or in the normal operating cycle of the business if longer). If not, they are presented as non-current liabilities. Trade payables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method.

Cash and cash equivalents

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

For the purposes of the consolidated cash flow statement, cash and cash equivalents consist of cash and short-term deposits as defined above net of outstanding bank overdrafts.

Share capital

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

Merger reserve

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

Borrowings

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

Borrowing costs are expensed in the consolidated Group income statement under the heading ‘finance costs’. Arrangement and facility fees together with bank charges are charged to the income statement under the heading ‘administrative costs’.

Current and deferred income tax

The tax expense comprises current and deferred tax. Tax is recognised in the income statement, 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 or substantively enacted at the balance sheet 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 is disclosed in accordance with IAS 12 and recognised using the liability method, on all temporary differences at the balance sheet date between the tax bases of assets and liabilities and their carrying amounts for financial reporting

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purposes. Deferred tax liabilities are recognised in respect of all temporary differences except where the deferred tax liability arises from the initial recognition of goodwill in business combinations.

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 balance sheet 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 balance sheet date.

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

Right of use assets

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

Lease liabilities

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

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

Short-term leases and leases of low-value assets

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

Employee benefits

Pension obligations

Group companies operate a pension scheme with defined contribution plans. A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate entity with the pension cost charged to the income statement as incurred.

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

Share-based payment

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

Where the terms and conditions of options are modified before they vest, the increase in the fair value of the options, measured immediately before and after the modification, is also charged to the consolidated statement of comprehensive income over the remaining vesting period.

Leasehold provision

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

Revenue recognition

(a) Revenue from Contracts in the Venn Division

The Division provides clinical consulting services and drug development services. Revenue from providing services is recognised in the accounting period in which the services are rendered. For fixed-price contracts, revenue is recognised based on the actual service provided to the end of the reporting period as a proportion of the total services to be provided because the customer receives and uses the benefits simultaneously. This is determined in reference to the stage of completion which is measured by labour hours incurred to the period end as a percentage of the total estimated labour hours for the contract. Where the contract outcome cannot be measured reliably, revenue is recognised to the extent of the expenses recognised that are recoverable.

Some contracts include multiple performance obligations in the form of various service offerings. Where the contracts include multiple performance obligations, the transaction price will be allocated to each performance obligation measured by reference to labour hours incurred to the period end as a percentage of the total estimated labour hours to achieve a particular performance obligation. Where the contract outcome cannot be measured reliably, revenue is recognised to the extent of the expenses recognised that are recoverable.

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.

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In case of fixed-price contracts, the customer pays the fixed amount based on a payment schedule. If the services rendered by the Division exceed the payment, a contract asset is recognised. If the payments exceed the services rendered, a contract liability is recognised.

Terms and Conditions tend to vary from contract to contract and in general the payment terms tend to be between 30 and 90 days in The Netherlands and between 30 and 60 days in France and Ireland.

Some contracts include references to milestone events. Where no fee is payable until a milestone is achieved, revenue is recognised up to the value of the milestone event set to occur.

The Division is applying practical expedient per IFRS 15 to not disclose the aggregate amount of the transaction price allocated to the performance obligations that are unsatisfied (or partially unsatisfied) as of the end of the reporting period as the entity has a right to consideration from a customer in an amount that corresponds directly with the value to the customer of the entity's performance completed to date and recognise revenue in the amount to which the entity has a right to invoice.

(b) Revenue from contracts in the hVIVO Division

Revenue from contracts with customers is recognised at an amount that reflects the consideration to which the Division expects to be entitled in exchange for the goods or services and is shown net of Value Added Tax.

Service revenues

The Division primarily earns revenues by undertaking client clinical services engagements. A client clinical services engagement typically comprises a number of quarantine cohorts. Each quarantine cohort lasts two to three weeks, but the timeline of work involved in building up to undertaking a clinical study is in the range of three to twelve months. Whether a client clinical services engagement is for one quarantine cohort or for a number of quarantine cohorts, the overall timeline of the engagement is much the same, apart from the additional time for the quarantine cohorts themselves and the time lags in between quarantine cohorts (with some cohorts offset in parallel and some sequential), as much of the upfront work is the same whether for one or a number of quarantine cohorts.

Client clinical services revenue is recognised based on a performance over time, as the performance of the clinical services engagements do not create an asset with an alternative use to the Division and the Division has an enforceable right to payment for the performance completed to date.

The Division measures its progress towards the satisfaction of performance obligations using output measures. Depending on the contractual terms, revenue from contracts with customers is recognised based on the level of work completed to date in respect of each individual performance obligation of the client clinical services contract.

Contracts generally contain provisions for renegotiation in the event of changes in the scope, nature, duration, volume of services or conditions of the contract (contract modifications). Contract modifications are assessed based on the terms of the contract. Contract modifications which are distinct and provided at a stand-alone selling price are accounted for as a separate contract. Where modifications are not distinct or provided at a stand-alone selling price, the Division evaluates whether the remaining goods or services are distinct from those already provided. If so, the modification is accounted for as a termination of the existing contract and the creation of a new contract. If not, the transaction price and measure of progress is updated for the single performance obligation and amounts are recognised as revenue by revision to the total contract value arising as a result. 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 contract liabilities. Normally 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 contract liabilities 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 Division to be paid for all work performed to the termination date (enforceable right to payment for services provided to date).

Licensing revenues

Where licensing arrangements have a single contracted performance obligation to provide the right to use intellectual property which exists at a certain point in time, such as the delivery of a licence for study data, revenue from contracts with customers is recognised when the Company has transferred to the customer control over the intellectual property, which generally occurs at the beginning of the period for which the customer has the right to use the intellectual property. Licence revenue for such arrangements is therefore generally recognised at the point of delivery of the data when the performance obligation has been satisfied. Until this point in time, any amount invoiced in respect of the arrangement is presented in the statement of financial position as a contract liability. Costs associated with development of the study data are capitalised as a current intangible asset from the point that it is probable future economic benefits will be generated and are transferred to cost of sales upon handover of the deliverable.

Where licensing arrangements are determined to have contracted performance obligations to provide a right of access to the intellectual property, revenue is recognised over time, in line with the methods applied in recognising service revenues.

(c) Interest income

Interest income is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that asset's net carrying amount.

(d) Royalty and license income

Royalty and license income are recognised on an accruals basis in accordance with the substance of the relevant agreements.

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.

3. Financial risk management

Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk (foreign exchange risk and cash flow interest rate risk), credit risk, liquidity risk, capital risk and fair value risk. The Group's overall 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 not use derivative financial instruments to hedge risk exposures.

Risk management is carried out by the head office finance team. It evaluates and mitigates financial risks in close co-operation with the Group's operating units. The Board provides principles for overall risk management whilst the head

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office finance team provides specific policy guidance for the operating units in terms of managing foreign exchange risk, credit risk and cash and liquidity management.

(a) Market risk

(i) Foreign exchange – cash flow risk

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

Management do not use derivative financial instruments to mitigate the impact of any residual foreign currency exposure not mitigated by the natural hedge within the business model. 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 borrowings 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.

Rate compared to Euro	Average rate 2021	Average rate 2020	Year end rate 2021	Year end rate 2020
GBP£	**0.86**	0.89	**0.84**	0.90
USD$	**1.18**	1.14	**1.13**	1.23

Rate compared to GBP£	Average rate 2021	Average rate 2020	Year end rate 2021	Year end rate 2020
Euro	**1.16**	1.12	**1.19**	1.11
USD$	**1.37**	1.28	**1.35**	1.26

As a guide to the sensitivity of the Group's results to movements in foreign currency exchange rates, a one penny movement in the GBP£ to Euro rate would impact annual earnings by approximately £19,000 due to natural hedging (2020: £3,000).

(iii) Cash flow and fair value interest rate risk

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

It is the Group's policy not to trade in derivative financial instruments. The Group does not use interest rate swaps.

(b) Credit risk

Credit risk is managed on a Group basis, except for credit risk relating to accounts receivable balances. Each local subsidiary and operating business unit is responsible for managing and analysing the credit risk for each of their new clients before standard payment and delivery terms and conditions are offered. It is the Group policy to obtain prepayment deposits from customers where possible, particularly overseas customers. In addition, the Group will seek confirmed letters of credit for the balances due. Credit risk is managed at the operating business unit level and monitored at the Group level to ensure adherence to Group policies. 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. Individual risk limits are set based on internal or external ratings in accordance with limits set by the board. The utilisation of credit limits is regularly monitored.

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

(c) Liquidity risk

Cash flow forecasting is performed in the individual operating entities of the Group and is aggregated by the Head of Finance team. The Head of Finance team monitors cash and cash flow forecasts and it is the Group's liquidity risk management policy to maintain sufficient cash and available funding through an adequate amount of cash and cash equivalents and committed credit facilities from its bankers. Due to the dynamic nature of the underlying businesses, the Head of Finance team aims to maintain flexibility in funding by keeping sufficient cash and cash equivalents available to fund the requirements of the Group.

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 holding Company. In the UK, the working capital bank facility and the management of liquid funds in excess of operational needs are controlled centrally. Typically, excess funds are placed as short-term deposits, to provide a balance between interest earnings and flexibility.

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

	Note	Less than one year £'000	Between 1 and 2 years £'000	Between 2 and 5 years £'000	More than 5 years £'000	Total £'000
At 31 December 2021:						
Borrowings	25	294	–	–	–	294
Leased Liabilities	37	1,991	477	386	–	2,854
Trade and other payables	23	18,396	–	–	–	18,396
At 31 December 2020:						
Borrowings	25	359	–	–	–	359
Leased Liabilities	37	2,245	1,510	684	–	4,439
Trade and other payables	23	21,396	2	–	–	21,398

(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 monitors capital on the basis of the gearing ratio. This ratio is calculated as net debt divided by total capital. Net debt is calculated as total borrowings (including "current and non-current borrowings" as shown in the consolidated balance sheet) less cash and cash equivalents. Total capital is the sum of net debt plus equity.

The Group is currently largely un-geared, having net cash at 31 December 2021.

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4. Critical accounting estimates and judgements

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

(a) Business combinations

The recognition of business combinations requires the excess of the purchase price of acquisitions over the net book value of assets acquired to be allocated to the assets and liabilities of the acquired entity. The Group makes judgements and estimates in relation to the fair value allocation of the purchase price. If any unallocated portion is positive it is recognised as goodwill. However, in applying the reverse acquisition accounting method this has necessitated the Group to recognise the unallocated portion as deemed acquisition costs as required under IFRS 3 – Business Combinations. See also note 2 (d) regarding reverse acquisition accounting treatment for most recent transaction.

(b) Impairment of goodwill and cost of investments

The Group tests annually whether goodwill has suffered any impairment, in accordance with the accounting policy stated in note 2. The recoverable amounts of cash-generating units have been determined based on value-in-use calculations. These calculations require the use of estimates as set out in note 17. In addition, the Group has also considered the impairment of the investments in the subsidiaries undertakings as set out in note 18.

(c) 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.

(d) 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 24.

(e) Intangible assets

The Group amortises intangible assets over their estimated useful life. The useful lives of Trade Secrets, Intellectual Property Rights, software, licences and Preferential Right to Reserve a Slot have been estimated by the Group as stated in note 2. The Group tests annually whether there is any indication that intangible assets have been impaired.

(f) Revenue recognition

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

(g) Virus inventory

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

(h) Research and development tax credit

The Group's research and development tax credit claims in its various jurisdictions are complex and require management to make significant 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.

(i) Leasehold provision

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

5. Segmental reporting

Management has determined the Group's operating segments based on the monthly management reports presented to the Chief Operating Decision Maker ('CODM'). The CODM is the Executive Directors and the monthly management reports are used by the Group to make strategic decisions and allocate resources.

The first principal activity of the Group is conducting human challenge trials and related laboratory services as part of the Group's hVIVO Division.

The second principal activity is that of Venn Life Sciences' Clinical Research Division, providing a suite of consulting and clinical trial services to pharmaceutical, biotechnology and medical device organisations. Key services areas covered include: Clinical PK & Pharmacometrics, Non-Clinical Development Consultancy, Chemistry, Manufacturing and Controls (CMC) Consultancy, Medical Writing & Regulatory Affairs, Data Management, Statistics, Study Design & Methodology, and Regulatory Pathways / Data Services for Rare Diseases. As many of Venn Life Sciences business contracts are multi-country contracts, pulling resources from many different locations, the CODM considers this one business unit.

Currently the key financial performance measures used by the CODM are Revenue and EBITDA (before exceptional items).

Notes to the Financial Statements

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The segment information provided to the Board for the reportable segments for the year ended 31 December 2021 is as follows:

	2021 hVIVO £'000	2021 Venn £'000	2021 Total £'000
Income statement			
External revenue and other income	**31,932**	**7,073**	**39,005**
EBITDA before exceptional items	**3,134**	**(246)**	**2,888**
Exceptional items			267
Depreciation & amortisation			(2,565)
Operating Profit			**590**
Finance Expense			(215)
Share based payments charge			(27)
Share of loss of associate using equity method			(71)
Profit before income tax			**277**

	2020 hVIVO £'000	2020 Venn £'000	2020 Total £'000
Income statement			
External revenue and other income	14,336	7,842	22,178
EBITDA before exceptional items	(3,653)	(2,429)	(6,082)
Exceptional items			(2,125)
Depreciation & amortisation			(2,052)
Operating (loss)			(10,259)
Finance Expense			(374)
Share based payments charge			(240)
Share of loss of associate using equity method			(107)
(Loss) before income tax			(10,980)

6. Expenses – analysis by nature

	2021 £'000	2020 £'000
Employee benefit expense (note 10)	**15,897**	15,240
PPE Depreciation (note 16) and amortisation (note 17)	**523**	368
Depreciation related to Right of use Assets (note 37)	**2,039**	1,684
Exceptional items (note 7)	**(267)**	2,125
Inventories consumed	**963**	727
Professional fees	**1,632**	1,326
IT	**1,338**	1,021
Premises Costs	**1,399**	1,331
Volunteer costs	**2,943**	961
Agency, Subcontractors and freelancers	**4,305**	1,691
Other expenses	**7,643**	5,963
Total direct project and administrative costs (incl. Depreciation, Amortisation and Exceptional costs)	**38,415**	32,437

7. Exceptional items

Included within note 6 above are exceptional items as shown below:

	2021 £'000	2020 £'000
Exceptional items include:		
– Transaction costs relating to business combinations, acquisitions & Re-organisations	**923**	2,125
– Transaction (gain) relating to Capital Reduction and spin out (note 39)	**(1,190)**	–
Total exceptional (Gain)/Loss	**(267)**	2,125

8. Auditor remuneration

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:

	2021 £'000	Restated 2020 £'000
Fees payable to Company's auditor for the audit of the parent Company and consolidated financial statements	**38**	36
Fees payable to Company's auditor for the audit of subsidiaries and their consolidated financial statements	**39**	60
Total paid to the Company auditor	**77**	96
Fees payable to the auditors of subsidiaries for services:		
– The audit of Company's subsidiaries pursuant to legislation paid to other auditors	**62**	48
– Other services paid to other auditors	**7**	10
– Tax services paid to other auditors	**11**	8
Total paid to Other auditors	**80**	66
Total auditor's remuneration	**157**	162

Notes to the Financial Statements
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9. Directors' emoluments

	2021 £'000	2020 £'000
Aggregate emoluments	**526**	576
Social Security Costs	**62**	69
Contribution to defined contribution pension scheme	**17**	20
Total Directors' remuneration	**605**	665

See further disclosures within the Report of the Remuneration Committee.

Highest paid Director	2021 £'000	2020 £'000
Total emoluments received	**172**	178
Defined contribution pension scheme	**17**	–

No share options were exercised in the year by highest paid Director nor was there any shares awarded to that Director in the year.

10. Employee benefit expense

	2021 £'000	2020 £'000
Wages and salaries	**13,179**	12,461
Social security costs	**1,846**	1,944
Pension costs	**872**	835
Total employee benefit expense	**15,897**	15,240

11. Average number of people employed

	2021 No	Restated 2020 No
Average number of people (including Executive Directors) employed was:		
Administration	**38**	52
Clinical research	**172**	157
Sales and marketing	**8**	9
Total average number of people employed	**218**	219

Monthly weighted average used in above calculation. (2020 restated as simple average (of start and end of year position) used in prior year)

12. Finance income and costs

	2021 £'000	2020 £'000
Interest expense:		
– Interest on Lease liabilities (note 37)	**227**	243
– Interest on other loans	**(7)**	131
Finance costs	**220**	374
Finance income		
– Interest income on cash and short-term deposits	**(5)**	–
Finance income	**(5)**	–
Net finance expense	**215**	374

13. Income tax expense

Group	2021 £'000	Restated 2020 £'000
Current tax:		
Current year research and development tax charge/(credit)	**350**	(186)
Current year Hvivo Inc US Tax charge	**6**	6
Total current tax charge/(credit)	**356**	(180)
Deferred tax (note 24):		
Origination and reversal of temporary differences	**(5)**	(9)
Total deferred tax	**(5)**	(9)
Income tax charge/(credit)	**351**	(189)

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:

	2021 £'000	2020 £'000
Profit/(Loss) before tax	**277**	(10,980)
Tax calculated at domestic tax rates applicable to UK standard rate of tax of 19.00% (2020 – 19%)	**53**	(2,086)
Tax effects of:		
– Expenses not deductible for tax purposes	**168**	322
– Current Year R & D Tax (credit)	**(108)**	(207)
–Temporary timing differences	**(182)**	424
– Adjustments in respect of prior year	**37**	–
– Additional allowances deductible for tax purposes	**(79)**	(8)
– Losses carried forward	**462**	1,367
Income tax charge/(credit)	**351**	(189)

Notes to the Financial Statements
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There are no tax effects on the items in the Statement of Comprehensive Income.

In 2020 the R & D Expenditure Credit (“RDEC”) income was recorded net of tax in other income but as hVIVO Services Limited is now profitable in 2021, RDEC is being recorded gross in other income (see note 33) and the related tax charge is shown above in the tax line. Prior year comparatives have been restated accordingly. (See note 38)

In 2020 hVIVO Services Limited was eligible for an SME tax credit (as it was loss making). In 2021 hVIVO Services Limited is no longer loss making so there is no SME tax credit repayable. However, the SME related costs will be reflected in Tax losses carried forward for hVIVO Services Limited.

14. Loss per share

(a) Basic

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

	2021 £’000	2020 £’000
(Loss) from operations	(74)	(10,791)
Total	**(74)**	(10,791)
Weighted average number of Ordinary Shares in issue	670,187,313	599,920,207
Earnings per share from operations	(0.01p)	(1.80p)

(b) Diluted

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

Details of share options and warrants are given in note 32.

	2021	2020
Potential dilutive ordinary shares:		
Options	8,393,213	9,516,111
Warrants	2,264,427	4,185,248
Total	**10,657,640**	13,701,359

15. Dividends

There were no cash dividends paid or proposed by the Company in either year. See note 39 for details of Distribution-in-Specie in June 2021.

16. Property, plant and equipment

Group	Leasehold Improvements £'000	Plant & Machinery £'000	Fixtures & Fittings £'000	Total £'000
Cost				
At 1 January 2021	686	3,039	2,045	5,770
Additions	156	76	97	329
Disposals	–	(608)	(1,012)	(1,620)
Exchange differences	–	–	(19)	(19)
At 31 December 2021	**842**	**2,507**	**1,111**	**4,460**
Depreciation				
At 1 January 2021	590	2,628	1,484	4,702
Charge for the year	116	100	190	406
Elimination on disposal	–	(587)	(968)	(1,555)
Exchange differences	–	–	(20)	(20)
At 31 December 2021	**706**	**2,141**	**686**	**3,533**
Net book value				
At 31 December 2021	**136**	**366**	**425**	**927**
At 31 December 2020	**96**	**411**	**561**	**1,068**

The Company had no property, plant and equipment at 31/12/2021. (2020: nil).

17. Intangible fixed assets

Group	Goodwill £'000	Trade secrets £'000	Intellectual property rights £'000	Software development £'000	Licences £'000	Pref right to reserve slot £'000	WBS development £'000	Total £'000
Cost								
At 1 January 2021	7,228	633	2,118	2,199	64	274	–	12,516
Additions	–	–	–	–	–	–	411	411
Disposals	–	(633)	–	–	(64)	–	–	(697)
At 31 December 2021	**7,228**	**–**	**2,118**	**2,199**	**–**	**274**	**411**	**12,230**
Amortisation								
At 1 January 2021	1,628	470	2,118	2,127	–	46	–	6,389
Charge for the year	–	25	–	46	–	46	–	117
Disposals	–	(495)	–	–	–	–	–	(495)
At 31 December 2021	**1,628**	**–**	**2,118**	**2,173**	**–**	**92**	**–**	**6,011**
Net book value								
At 31 December 2021	**5,600**	**–**	**–**	**26**	**–**	**182**	**411**	**6,219**
At 31 December 2020	**5,600**	**163**	**–**	**72**	**64**	**228**	**–**	**6,127**

Notes to the Financial Statements

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Goodwill was allocated to the Group's cash-generating units (CGUs) identified according to operating segment. An operating segment-level summary of the goodwill allocation is presented below.

	2021 £'000	2020 £'000
Venn Division	2,821	2,821
hVIVO Division	2,779	2,779
Total	**5,600**	5,600

Goodwill is tested for impairment at the balance sheet date. The recoverable amount of goodwill at 31 December 2021 was assessed at £5,600,000 (2020: £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 2021 were as follows:

Longer-term growth rate (from 2023 onwards)	5%
Discount rate	15%

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

The Directors have made significant estimates on future revenues and EBITDA growth over the next ten years based on the Group's budgeted investment in recruiting key employees and marketing the services.

The Directors have performed a sensitivity analysis to assess the impact of downside risk of the key assumptions underpinning the projected results of the Group. The projections and associated headroom used for the group is sensitive to the EBITDA growth assumptions that have been applied. The Company has no intangible assets.

18a. Investments in subsidiaries

Company	2021 £'000	2020 £'000
Shares in Group undertakings		
At 1 January	**22,334**	8,195
Investment in VLS Biometry Services S.A.S	43	–
Investment in hVIVO Plc	–	14,161
Impairment of Investment in VLS Germany GmbH	–	(22)
At 31 December	**22,377**	22,334

Investments in Group undertakings are recorded at cost, which is the fair value of the consideration paid. Following review an impairment provision of Nil (2020: £22k) has been made to the investment in subsidiaries.

The subsidiaries of Open Orphan Plc are as follows:

Name of Company	Country of Registration	Nature of Business
Active Trading Companies:		
hVIVO Services Limited**	England & Wales	Viral challenge and related laboratory services
Venn Life Sciences (EDS) B.V.*	Netherlands	Pre-clinical & Early Clinical Research services
Venn Life Science Biometry Services S.A.S.*	France	Data Management & Statistics services
Open Orphan DAC*	Ireland	Regulatory Pathways for Rare/Orphan diseases
hVIVO INC**	USA	Sales & Marketing services
Venn Life Sciences Limited*	Ireland	Intermediate holding company
hVIVO Limited*	England & Wales	Intermediate holding company
Dormant Companies - Dissolved or in the process of being dissolved:		
Venn Life Sciences (NI) Limited*(1)	England & Wales	Clinical Research Organisation
Venn Life Sciences (Germany) Gmbh *(2)	Germany	Clinical Research Organisation
Venn Life Sciences B.V.**(2)	Netherlands	Clinical Research Organisation
Venn Life Science (France) S.A.S.*(2)	France	Data Management & randomisation Systems

* 100% Direct Ordinary Shareholding;
** 100% Indirect Ordinary shareholding
(1) Company dissolved January 2022;
(2) Company in process of being dissolved post year end.

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

18b. Investments in associates

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

Name of Company	Country of Registration	Nature of Business
Imutex Ltd(1)	England & Wales	Clinical development services
PrEP Biopharm Limited(2)	England & Wales	Clinical development services

(1) hVIVO Limited owns 49% of the Ordinary Shares and the investment is valued at £7,005,000 at 31 December 2021 after adjusting for share of loss in 2021 of £71,000.
(2) hVIVO Limited owns 62.62% of Ordinary Shares. In 2018 the carrying value was fully impaired so the investment has a value of Nil at 31 December 2021.

19. Financial instruments by category

(a) Assets

	Group 2021 £'000	Restated Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
31 December				
Assets as per balance sheet				
Trade and other receivables	**8,089**	8,967	**9,357**	10,847
Cash and cash equivalents	**15,694**	19,205	**8,663**	8,689
Total	**23,783**	28,172	**18,020**	19,536

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

Notes to the Financial Statements

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(b) Liabilities

	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
31 December				
Liabilities as per balance sheet				
Borrowings	**294**	359	**–**	45
Lease Liabilities (note 37)	**2,854**	4,439	**–**	–
Trade and other payables	**5,205**	6,376	**441**	885
Total	**8,352**	11,174	**441**	930

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 2021 and 31 December 2020, in relation to each class of recognised financial assets, is the carrying amount of those assets as indicated in the accompanying balance sheets.

Trade receivables

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

Cash at bank

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

Rating	2021 £'000	2020 £'000
A – AAA	**15,605**	19,158
Sub-A rating	**89**	47
Total	**15,694**	19,205

The balance categorised as Sub-A rating relate to balances held with Allied Irish Banks p.l.c. and Ulster Bank ROI (Both Guaranteed by Irish government as key shareholder)

20. Inventories

	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
Beginning of the year	**953**	–	**–**	–
Laboratory and clinical consumables	**(92)**	168	**–**	–
Virus – finished goods	**(202)**	785		
End of the year	**659**	953	**–**	–

Inventories expensed (2021: £963,000; 2020 £727,000) in the consolidated statement of comprehensive income are shown within Direct project and administrative costs (see note 6). All inventories are carried at the lower of cost or net realisable value in the consolidated statement of financial position. No provision against inventories was required during 2021.

21. Trade and other receivables

	Group 2021 £'000	Restated Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
Trade receivables	**4,774**	5,316	**–**	–
Less: provision for impairment of trade receivables	**–**	–	**–**	–
Trade receivables – net	**4,774**	5,316	**–**	–
Prepayments and accrued income (note 35)	**1,863**	2,560	**335**	112
Amounts owed by subsidiary undertakings	**–**	–	**9,356**	10,778
Other receivables (incl. R& D credit income)	**2,307**	1,930	**1**	70
	8,944	9,806	**9,692**	10,960

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

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

	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
GBP£	**6,746**	5,481	**1,467**	2,756
Euro	**2,198**	4,325	**8,225**	8,204
	8,944	9,806	**9,692**	10,960

22. Cash and cash equivalents

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

	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
Cash at bank and on hand	**15,694**	19,205	**8,663**	8,689
Cash and cash equivalents (excluding bank overdrafts)	**15,694**	19,205	**8,663**	8,689

The Group's cash and cash equivalents are held in non-interest-bearing accounts. The Directors consider that the carrying amount of cash and cash equivalents approximates to their fair value.

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23. Trade and other payables

	Group 2021 £'000	Restated Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
Trade payables	**2,055**	2,271	**306**	72
Amounts due to subsidiary undertakings	**–**	–	**2,762**	543
Social security and other taxes	**857**	695	**13**	–
Other payables*	**438**	353	**2**	64
Accrued expenses and deferred income	**15,047**	18,079	**120**	206
	18,397	21,398	**3,203**	885

*There are no other payables due after one year after year end 2021 (2020: £2,000). All other balances are due within 1 year.

24. Deferred income tax

Deferred tax balances were as follows:

	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
Deferred tax liabilities were made up as follows:				
Accelerated tax depreciation	**–**	32	**–**	–
	–	32	**–**	–

Deferred tax assets

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

	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
At 1 January	**32**	41	**–**	–
Exceptional Item	**(27)**	–		
Income statement movement (note 13)	**(5)**	(9)	**–**	–
At 31 December	**–**	32	**–**	–

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

25. Borrowings

	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
Current – falling due within 1 year				
Loan Notes	**–**	45	**–**	45
Convertible debenture securities ("CDS")	**294**	314	**–**	–
Total borrowings	**294**	359	**–**	45

The Company and Group do not have bank borrowings. All Borrowings due within one year.

Loan Notes for £1m issued on 11 December 2018 with a two-year term and a 10% coupon rate were available for redemption in Dec 2020. All but one Loan Note for £45k was redeemed by 31 Dec 2020. The final Loan Note was redeemed in February 2021.

There are 2 remaining Convertible debenture securities holders and they are entitled to interest of 7% per annum on their securities. Neither of these CDS holders chose to convert their securities into Ordinary shares in Open Orphan DAC at the time of the reverse takeover of the Venn Group in June 2019. Consequently, these CDS holdings can be redeemed by the company at any time from June 2020 up to their redemption dates in March 2022 and September 2022 respectively. Following reverse acquisition, the holders lost their right to convert.

26. Share capital

	Group 2021 £'000	Group 2020 £'000	Company 2021 £'000	Company 2020 £'000
670,929,314 (2020 – 668,052,261) Ordinary shares of £0.001	**671**	668	**671**	668
Nil (2020 – 62,833,339) Deferred shares of £0.001	**–**	63	**–**	63
Total	**671**	731	**671**	731

The Company exercised its right in July 2021 to acquire all deferred shares for an aggregate price of £1 (see note 39).

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

During the year the Company issued 2,877,053 shares.:

621,015	£0.001/Share
1,133,140	£0.022/Share
1,122,898	£0.02/Share

27. Other reserves

Group and Company

Share Premium

Share premium is the difference between the nominal value of share capital and the actual cash received on fund-raising less any costs associated with the fund-raising. (See also note 39).

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Merger Reserves

This includes reverse acquisition reverse which resulted from the reverse acquisition of Venn Life Sciences Holdings Plc by Open Orphan DAC on 28 June 2019. See note 2 (d). Also includes a Group re-organisation reserve relating to previous re-organisation of the Old Venn Group.

Foreign Currency Reserve

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

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

Share Option Reserve

A share option reserve of £151,000 was created in June 2019, prior to the reverse takeover of Venn Life Sciences Holdings PLC by Open Orphan DAC, in relation to the share options and warrants issued in June 2019. After the reverse takeover, further provisions of £102,000 in 2019 and £240,000 in 2020 were made. In 2021 an additional provision of £27,000 was made.

Retained Earnings

For the Group and Company, earnings for the prior year reflect the earnings of Open Orphan Plc including Open Orphan DAC for the full year plus the earnings of hVIVO Group from date of acquisition 17 January 2020 to year end 2020.

28. Cash used in operations

	Group 2021 £'000	Restated Group 2020 £'000	**Company 2021 £'000**	Company 2020 £'000
Profit/(Loss) before income tax	**277**	(10,980)	**(1,522)**	(1,891)
Adjustments for:				
– Depreciation and amortisation (note 6)	**2,565**	2,052	**–**	–
– Exceptional Items (note 7)	**(267)**	2,125	**409**	867
– Net loss on disposals of PPE, Intangible Assets & leases	**189**	–	**–**	–
– Net finance costs/(Income) (note 12)	**215**	374	**(768)**	(651)
– Share Based Payment charge (note 32)	**27**	240	**–**	50
– R & D Credit incl. in other Income	**(1,842)**	(961)	**–**	–
– Share of Imutex loss (note 18.b)	**71**	107	**–**	–
Changes in working capital				
– Impairments on Investments/Loans (note 18a)	**–**	–	**485**	22
– Lease Payments (note 37)	**(2,329)**	(1,999)	**–**	–
– (Increase)/Decrease Trade and other receivables	**904**	(2,800)	**(241)**	(4,491)
– (Increase)/Decrease Inventories	**294**	(28)	**–**	–
– (Decrease)/Increase Trade and other payables	**(2,972)**	14,410	**2,317**	(474)
Net cash used in operations	**(2,868)**	2,540	**680**	(6,568)

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:

	2021 €'000	2020 €'000
Aggregate emoluments	526	576
Employer contribution to pension scheme	17	20
	543	596

Key management includes the Directors only.

Group

On 10 November 2016 the Group signed a contract worth €2.5m with Sedana Medical AB ("Sedana Medical").

The then CEO of Sedana Medical, Michael Ryan, was also a Director of Venn Life Sciences at that time. Accordingly, Michael Ryan was a related party of Venn Life Sciences as defined in the AIM Rules and ESM Rules. As a result, the contract was treated as a "related party transaction" under the AIM Rules and the ESM Rules.

The Independent Directors, at that date, being Allan Wood, Anthony Richardson, Jonathan Hartshorn, Gracielle Schutjens, Cornelius Groen, Paul Kennedy and Mary Sheahan, who are not related parties under the AIM Rules and ESM Rules for the purpose of the contract, consulted with Davy, the Company's NOMAD and ESM adviser at the time of consultation. For the purpose of the AIM Rules and ESM Rules, Davy considered the contract to be fair and reasonable insofar as the shareholders of the Company are concerned. Michael Ryan did not take part in the Board's consideration of these matters. Michael Ryan resigned as a Director on 17 January 2020. The contract with Sedana Medical concluded in early 2021.

Executive Group Chairman, Cathal Friel, held a share of £108,642 of the £1m Loan Note issued in December 2018 through his pension vehicle. This Loan Note was redeemed in full in December 2020. Cathal Friel also held all of the £250,000 Loan Note issued in April 2019. This Loan Note was redeemed in full in April 2020. Gross Loan Note interest of Nil (2020: £15,000) was due in 2021. Cathal Friel is also a Director of Raglan Road Capital Limited and Raglan Professional Services Limited which has rented office space and provided advisory and office related services to Open Orphan DAC (2021 charge €23,175; 2020 charge €108,000). The balance owed by the Group to Raglan Road Capital Limited and Raglan Professional Services Limited at year end 2021 was €16,901 (2020: €3,780). Cathal Friel is also a Director of Poolbeg Pharma (Ireland) Limited which is now renting office space and providing advisory and office related services to Open Orphan DAC (2021 charge €96,049; 2020 charge Nil). The balance owed by the Group to Poolbeg Pharma (Ireland) Limited at year end 2021 was €14,651 (2020: Nil). As part of reciprocal agreement, Open Orphan DAC also provides advisory and office related services to Poolbeg Pharma (Ireland) Limited (2021 revenue € 158,085;2021 revenue Nil). The balance owed to the Group by Poolbeg Pharma (Ireland) Limited at year end 2021 was €13,805 (2020: Nil).

Elaine Sullivan, Non-Executive Director, through the company Dargle Therapeutics Limited, provided specialist consultancy advice specifically in relation to a development asset, at a cost to the Group of £38,125 (excl. V.A.T).

There were no other related party transactions during the year.

The Company

During the year the Company absorbed net management charges of £109,547 (2020 – £324,475) from its subsidiaries. At 31 December 2021 the Company was owed £6,594,000 (2020 – £10,234,000) by its subsidiaries.

Notes to the Financial Statements
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30. Capital commitments

The Group had no capital commitments at 31 December 2021 or at 31 December 2020.

31. Discontinued Operations

A decision to close the clinical operations division across Europe was made during 2020 and Venn Life Sciences (NI) Ltd, Venn Life Sciences B.V. and Venn Life Sciences Germany GmbH consequently ceased to trade from 1 January 2021 onwards. Venn Life Sciences (NI) Ltd, as well as dormant companies Venn Life Sciences UK Ltd and Venn Life Sciences (Ireland) Ltd, were dissolved consequently in 2021. Venn Life Sciences Germany GmbH is currently undergoing a liquidation process in 2022 and arrangements to dissolve Venn Life Sciences B.V. will be undertaken later in 2022. There were no new discontinued operations during 2021.

32. Share options and warrants

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

Some share options have vested. Some share options have been forfeited as a result of the Director or employee leaving the Group before options vested.

Number of outstanding share options remaining at 31 December 2021:

Date of Grant	# Options at 01/01/2021	# of Options Exercised	# of Options Forfeited	# Options at 31/12/2021
28/01/2015	280,000	–	–	280,000
28/06/2019	7,716,964	–	–	7,716,964
17/01/2020	1,519,147	1,122,898	–	396,249
Total	**9,516,111**	**1,122,898**	**–**	**8,393,213**

The weighted-average exercise price of all options outstanding at year end is 5.7p and the weighted-average remaining contractual life is 1 year.

The pricing and vesting criteria of the share options in existence at 31 December 2021 are as follows:

In relation to the Options granted in 2015:

Options in issue 31/12/2021	280,000
Exercise price (in equal thirds when price 25p/35p/45p)	13p
Expected volatility	28%
Expected dividend	0%
Contractual life	1.5 years
Risk free rate	95%
Estimated fair value of each option	£0.00

In relation to the Options granted in 2019:

Options in issue 31/12/2021	7,716,964
Exercise price	5.6p
Expected volatility	60%
Expected dividend	0%
Contractual life	0.5 years
Risk free interest rate	1.84%
Estimated fair value of each option	£0.02

In relation to the Options granted in 2020:

Options in issue 31/12/2021	396,249
Exercise price	2p
Expected volatility	72.8%
Expected dividend	0%
Contractual life	1 years
Risk free interest rate	0.57%
Estimated fair value of each option	£0.04

Share based payment charge for the year was £27,000 (2020 – £240,000). No new share options were granted in 2021. However, due to share options being exercised £193,000 (2020: Nil) of the share-based payment reserve was released back to retained earnings.

The share option reserve (£151,000) was initially created before the reverse takeover by Open Orphan DAC in 2019 in relation to the shares and warrants granted in June 2019. Further reserves were made of £102,000 (year end 2019) and £240,000 (year end 2020) bringing total opening 2021 reserve to £493,000.

The share options granted in 2015 have no value given the vesting conditions when issued.

The Company has used the Black Scholes model to value the options at 31 December 2021. This method simulates a range of possible future share price scenarios and calculates the average of net present value of the option across those scenarios and which captures the effect of the market-based performance conditions applying to such awards. The expected volatility was calculated with reference to historic share price movements.

Warrants

2,264,427 warrants existed at 31 December 2021 (2020: 4,185,248).

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

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

Notes to the Financial Statements

Continued

33. Other operating income

Other operating income represents government grants received to fund Research and Development activities around the group. (In 2020 it also included specific COVID-19 related government support grants)

		2021 £'000	2020 £'000
hVIVO	Gross RDEC credit	**1,842**	960
hVIVO	COVID-19 supports	**–**	224
Venn	R & D Related credits	**299**	380
Venn	COVID-19 supports	**–**	12
Total		**2,141**	1,576

Note: The subsidiary, hVIVO Services Limited, can claim UK R&D incentives under both RDEC scheme (noted above) and the SME scheme (when company is loss making). The SME scheme (when claimed) appears on the tax line as a tax credit. Venn Division can claim Credit Tax Research ('CIR') payments in France and can claim R & D credits against payroll taxes in the Netherlands.

34. Post balance sheet events

The following events have taken place since the year end:

1. Yamin 'Mo' Khan, then a non-Executive Director, was appointed as Chief Executive Officer on 24 February 2022.

2. Appointment of Liberum Capital Limited as Nominated Advisor ("NOMAD") and Joint Broker on 28 April 2022.

35. Revenue, Assets and Liabilities related to contracts with customers

(a) hVIVO Division

The Group carries out its activities through hVIVO Services Limited in the United Kingdom. All revenue from contracts with customers is derived from activities undertaken in the United Kingdom.

During the period ended 31 December 2021, the Company had four customers, out of more than 30 customers, who each generated revenue greater than 10% of total revenue which was £30m. These customers generated 34%, 14%, 13% and 11% of revenue respectively.

The value of contract liabilities has decreased by £1.7 million to £12.8m at 31 December 2021 from £14.5 million at 31 December 2020. Contract assets have decreased by £0.5 million to £0.3m at 31 December 2021 from £0.8 million at 31 December 2020.

Net accrued income, related to contracts with customers in hVIVO Division

	2021 Total £'000	2020 Total £'000
Net Accrued Income brought forward	**(13,703)**	–
Net Accrued Income acquired on acquisition of hVIVO group	**–**	(1,689)
Movement in the period:		
– arising from a change in the measure of progress	**1,206**	(12,014)
Net Accrued Income as at 31 December 2020	**(12,497)**	(13,703)
Split:		
Accrued Income	**275**	821
Deferred Income	**(12,772)**	(14,524)
Net Accrued Income carried forward	**(12,497)**	(13,703)

The majority of the contract liabilities balance is expected to be recognised within six months, as follows:

Analysis of expected realisation of revenue within contract liabilities

	31 December 2021 £'000	31 December 2020 £'000
Within six months	**10,248**	14,469
Between six months and one year	**2,524**	55
After one year	**–**	–
	12,772	14,524

The Division seeks to ensure that contract milestones are timed so as to result in invoicing occurring in advance, prior to the satisfaction of performance obligations. Therefore, projects that are in progress are typically in a contract liability position. 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. Contractual payment terms are typically 30 to 45 days from date of invoice.

The Division considers whether there are other obligations in the contract that are separate performance obligations to which a portion of the transaction price needs to be allocated. The Division's data and intellectual property may be made available to the client but solely to the extent that this is necessary to the satisfaction of the client contract. This is not considered a distinct performance obligation but an obligation in conjunction with the client study. Therefore, the full transaction price is allocated to performing the client study.

The Division is using the practical expedient not to adjust the amount of consideration for the effects of a significant financing component due to the fact that the period between when the promised services are transferred and when the customer pays for the service is less than twelve months. The entity does not, in the normal course of business, incur incremental costs to obtain a contract and has therefore not recognised any assets in this regard.

Notes to the Financial Statements
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(b) Venn Division

The Division derives revenues from external customers from the provision of clinical consulting services and drug development services split into various service offerings across various geographical regions.

Venn Life Sciences E.D B. V, based in Breda in the Netherlands, provides Early clinical, Non-Clinical and CMC services to a wide variety of customers. Venn Life Sciences France S.A.S. and Venn Life Sciences Biometry Services S.A.S both based in Paris, France and Venn Life Sciences Ltd, based in Ireland, provide Data management, Bio Statistics, Medical Methodology and Randomisation services. Revenue in 2021 for Venn Division was £6.8m.

Net accrued income, related to contracts with customers in Venn Division

	2021 Total £'000	2020 Total £'000
Net Accrued Income brought forward	**382**	601
Movement in the period:		
– arising from a change in the measure of progress	**(68)**	(219)
Net Accrued Income carried forward	**314**	382
Split:		
Accrued Income	**733**	900
Deferred Income	**(419)**	(518)
Net Accrued Income	**314**	382

The costs incurred to obtain or fulfil a contract which has been recognised as contract assets 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. Contract assets are not amortised as they are of a short- term nature.

36. Pensions

The Group operates a number of defined contribution pension schemes whose assets are held separately from those of the Group in independently administered funds. The pension charge represents contributions payable by the Group and amounted to £872,000 for the year (year ended 31 December 2020: £861,000). Contributions totalling £79,000 were payable to the funds at the year end and are included within trade and other payables (31 December 2020: £77,000 - restated).

37. Leases

Amounts recognised in the Statement of Financial Position

	Right of use assets £'000	Lease liabilities £'000
As at 1 January 2021	4,230	4,439
New Leases Acquired	1,399	1,399
Leases Exited	(738)	(816)
Depreciation expense (note 6)	(2,039)	–
Interest expense (note 12)	–	227
Payments (note 28)	–	(2,329)
Exchange differences	(64)	(66)
As at 31 December 2021	2,788	2,854
Current	–	1,991
Non-current	2,788	863

Maturity of leases

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

Short-term Lease payments expensed in year ended 31/12/21: £8,000 (2020 £25,000).

38. Prior period re-statement

In 2020, and prior years when hVIVO Services Limited was loss-making, the Research and Development Expenditure Credit ('RDEC') was recorded net of tax in the Other operating income line in the published Statement of Comprehensive Income. In 2021, it was decided that this RDEC should be shown gross of tax, now that Hvivo Services Limited is profitable, in Other operating income and the tax impact should appear on the Taxation line in the Statement of Comprehensive Income. Consequently, the 2020 Other operating income and Tax figures have been restated to reflect this new treatment. This change also impacts the 2020 comparatives in note 28.

Notes to the Financial Statements

Continued

	Note	Restated 2020 £'000	2020 As originally Published £'000
Statement of Comprehensive Income:			
Other operating income	33	**1,576**	1,393
Taxation	13	**189**	372
Cash Used in Operations:			
Loss before tax	28	**(10,980)**	(11,163)
R & D credit incl. in Other Income	28	**(961)**	(778)

39. Capital Reduction and Distribution-in-Specie

On 19 May 2021, the Company received Court approval for a reduction in its share capital. Consequently, the deferred share capital balance of £62,833 (see note 26) was bought back by the Company and the then balance in the Share Premium account of £44,516,591 of the Company was transferred in full to retained earnings.

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

Company Information

Directors

Cathal Friel (Executive Chairman)
Yamin 'Mo' Khan (Chief Executive Officer)
Leo Toole (Chief Financial Officer)
Prof. Brendan Buckley (Non-Executive Director)
Dr. Elaine Sullivan (Non-Executive Director)

Company Secretary

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